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**The Gas Appliances
(Safety) Regulations 1995**

**Guidelines for Organisations
seeking Notified Body status
to undertake inspection
and certification of
Gas Appliances and Fittings**

April 2007

URN 07/898

Contents

Chapter 1 Introduction

- 1.1 The purpose of these guidelines
- 1.2 The Directive and the Regulations
- 1.3 The Directive and notified bodies

Chapter 2 Application and appointment

- 2.1 Eligibility and legal identity
- 2.2 Application to become a notified body
- 2.3 Overall process of assessment by UKAS
- 2.4 Agreement on the use of subcontracted UKAS assessors
- 2.5 UKAS scale of charges
- 2.6 Insurance
- 2.7 Secretary of State's decision
- 2.8 The letter of appointment
- 2.9 Notification of the appointment to the European Commission and other Member States
- 2.10 Commission verification and formal public announcement
- 2.11 Surveillance and reassessment of notified bodies by UKAS
- 2.12 Co-ordination of action between the Department and UKAS on suspension or withdrawal of accreditation or appointment.

Chapter 3 The scope of appointment

- 3.1 Overall Scope of appointment
- 3.2 Product scope
- 3.3 Conformity assessment procedures

Chapter 4 The conformity assessment body standards

- 4.1 The BS EN ISO/IEC 17000 series and the BS EN 45000 series of standards
- 4.2 References to the conformity assessment body standards
- 4.3 The conformity assessment procedures in the Directive and the conformity assessment body standards.
- 4.4 Managing the assessment if more than one conformity assessment standard is used.
- 4.5 The presumption of conformity
- 4.6 Policy on accreditation

Chapter 5 Minimum criteria in the Directive

- 5.1 Minimum Criteria
- 5.2 Guidance on the 1st indent in section 5.1 (availability of personnel)
- 5.3 Guidance on the 2nd indent in section 5.1 (technical competence)
- 5.4 Guidance on the 3rd indent in section 5.1 (independence)
- 5.5 Guidance on the 5th indent in section 5.1 (civil liability insurance)
- 5.6 Quality management system of the notified body.

Chapter 6 Duties of a notified body

- 6.1 Access to the services of a notified body and equal treatment
- 6.2 Conformity assessment
- 6.3 Procedures to ensure consistency
- 6.4 Assessment of a manufacturer's quality management system
- 6.5 Documentation to be retained by the notified body
- 6.6 Participation in co-ordination activities
- 6.7 Circumstances in which the notified body shall contact the Department
- 6.8 Confidentiality
- 6.9 Policy and procedures for the control of its identification number

Chapter 7 Mutual recognition agreements

Annexes

- I Competence of individual staff involved in conformity assessment
- II Contracting parties to the European Economic Area Agreement
- III Contact information for applications
- IV Sources of information and relevant documents
- V Model letter of appointment

1. INTRODUCTION

1.1 The purpose of these guidelines

These guidelines set out the requirements that an organisation will need to meet in order to become a United Kingdom notified body for the purposes of Directive 90/396/EEC as amended (commonly referred to as the Gas Appliances Directive, GAD). Information is also provided on how to make an application, how the requirements will be assessed and the duties of a notified body after it has been appointed.

1.2 The Directive and the Regulations

Council Directive 90/396/EEC on the approximation of the laws of the member States relating to appliances burning gaseous fuels (as amended by Council Directive 93/68/EEC) (the Directive) is implemented in the United Kingdom by the Gas Appliances (Safety) Regulations 1995 (S.I. 1995/1629) (the Regulations), which are made under the Consumer Protection Act 1987 and the European Communities Act 1972.

1.3 The Directive and notified bodies

The Directive sets out the requirements that gas appliances and certain related fittings have to meet before they can be placed on the market and put into service in the Community. All of the conformity assessment procedures that are used to demonstrate compliance with the requirements in the Directive involve third party certification organisations known as notified bodies. In the United Kingdom, the Secretary of State for Trade and Industry (the Secretary of State) is responsible for appointing notified bodies and notifying them to the European Commission and other Member States.

2. APPLICATION AND APPOINTMENT

2.1 Eligibility and legal identity

To be eligible for appointment as a United Kingdom notified body for the purposes of the Regulations, the applicant body shall be a legal entity¹ and be established in the United Kingdom. It must carry out its conformity assessment functions within the jurisdiction of the UK and only issue certificates from an establishment in the UK. 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 it does not have to be formed according to UK law. However, it must be established in the UK and thus come under its jurisdiction.

2.2 Application to become a notified body

An application should be made in the first instance to the United Kingdom Accreditation Service (UKAS) using the general UKAS Application Form and Form AC 6. Further information on the UKAS application and assessment processes for approved and notified bodies is given in UKAS document P16: "Assessment of approved and notified bodies". 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 III for the addresses of UKAS and the Department and Annex IV for references to downloadable documents.)

2.3 Overall process of assessment by UKAS

UKAS will 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

The applicant body shall provide evidence of its insurance cover to UKAS 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 or reassessment visit.

Further information can be found in section 5.5.

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 a notified body, then the applicant body will be informed in writing of his reasons for being so minded and given the opportunity of making further representations within a period of 28 days of notice of this initial decision. 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 notified 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 national and European level (please also see Section 6.6); 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 within its scope of appointment.

For information a draft model letter of appointment may be viewed at Annex V to these guidelines.

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

When the notified 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 (or designation) is said to have taken place when the signed letter is received by the Department.

2.10 Commission verification and formal public announcement

The Commission Services verify that all the required information is present and transfer the details to the NANDO on-line database¹. If the notified body has not previously been assigned an identification number according to another EC Directive, the Commission will assign a number. This number will apply for any subsequent notifications in respect of other Directives. The appointed/designated body may begin working when the appointment has taken place, but it shall not issue any certificates until the notification appears on the NANDO website.

Note 1: <http://ec.europa.eu/enterprise/newapproach/nando/>

2.11 Surveillance and reassessment of notified bodies by UKAS

UKAS will carry out surveillance and reassessment of the notified body according to the conditions in the body's letter of appointment and send a report to the Secretary of State. UKAS shall pay particular attention to evaluating the performance of the notified body, on the basis of evaluations carried out by the notified body. 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. Surveillance and reassessment 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.

2.12 Co-ordination of action between the Department and UKAS on suspension or withdrawal of accreditation or 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 and UKAS can no longer support a 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 decided to suspend its activities, or when an appointment and notification has been withdrawn or terminated.

3. THE SCOPE OF APPOINTMENT

3.1 Overall scope of appointment

The scope of appointment of a notified body for the Directive sets out the entitlement to carry out certain tasks in relation to the product scope and includes the conformity assessment procedures for which it has been appointed.

3.2 Product scope.

Article 1.1 of the Directive states that it shall apply to:

- appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing and having where applicable, a water temperature not exceeding 105 deg C, referred in this guidance as appliances. Forced draught burners and heating bodies to be equipped with such burners will also be considered as appliances,
- safety devices, controlling devices or regulating devices and subassemblies other than forced draught burners and heating bodies to be equipped with such burners separately marked for trade use and designed to be incorporated into an appliance burning a gaseous fuel or assembled to constitute such an appliance, referred to in this guidance as fittings.

3.3 Conformity assessment procedures

Article 8 describes the options available to manufacturers to decide which conformity assessment procedure to use, within certain limits and depending on the type of production. A notified body, in discussion with UKAS, shall specify which products and conformity assessment procedures it wants to have included in its scope of appointment.

The conformity assessment procedures are detailed in Annex II of the Directive and detailed requirements for assessment are given in section 4.3 of this document.

4 THE CONFORMITY ASSESSMENT BODY STANDARDS

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

Council Decision 93/465/EEC¹ set out the general framework for the assessment of notified bodies and the policy that *Member States should use standards in the BS EN 45000 series as the basis for the assessment of a notified body*. These standards are being replaced progressively by standards in the ISO/IEC17000 series and the standards that are relevant for these guidelines are listed in the next section. They are referred to collectively as the ‘conformity assessment body standards’.

Note 1: Official Journal L220 30 August 1993. 93/465EEC 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).

4.2 References to the conformity assessment body standards

The conformity assessment body 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. The assessment of a notified body will be based on one or more of these standards where 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 General requirements for the competence of testing and calibration laboratories**

The standard refers to ‘recognition as a third party body’ in a note to clause 4.1.4. However, it does not include any requirements on independence and the assessment of this aspect shall therefore be based on the relevant requirements in one of the three standards referred to below.

- **BS EN ISO/IEC 17020 General criteria for the operation of various types of bodies performing inspection** (This standard superseded BS EN 45004:1995 but the criteria contained in the standard are the same.)

The notified body shall meet the independence criteria for a Type A inspection body in the standard and the IAF/ILAC guidance¹ on the standard shall be applied.

Note 1: http://www.ilac.org/documents/pub_ilac-a4.pdf

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

- **BS EN ISO/IEC 17021 Conformity assessment - Requirements for bodies providing audit and certification of management systems.** This standard was published on 14 September 2006. UKAS will be applying the transition period of two years, as agreed by the IAF and therefore, from 15 September 2008, accreditation to BS EN45012 (or the equivalent ISO/IEC Guide 62) will no longer be valid.

4.3 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. If a notified body includes for example the QMS procedures (i.e. those in the Directive, Annex II, sections 3 and 4) in its scope of appointment, then its assessment will be based on BS EN ISO/IEC 17021. If the notified body includes any of the other conformity assessment procedures in its scope of appointment, it will be assessed on the basis of one of the other three standards.

Conformity assessment procedures in Annex II of the Directive

- Section 1 EC Type examination
- Section 2 EC Declaration of conformity to type
- Section 3 EC Declaration of conformity to type (Guarantee of production quality)
- Section 4 EC Declaration of type conformity (Guarantee of product quality)
- Section 5 EC Verification
- Section 6 EC Unit Verification.

Procedure	Conformity assessment body standards applicable
Section 1	BS EN ISO/IEC 17025 (including the ability to evaluate and decide on conformity), or BS EN ISO/IEC 17020 (BS EN ISO/IEC 17025 to be observed for testing required), or BS EN 45011 (BS EN ISO/IEC 17025 to be observed for testing required)
Section 2	BS EN ISO/IEC 17025 (including the ability to evaluate and decide on conformity), or BS EN ISO/IEC 17020 (BS EN ISO/IEC 17025 to be observed for testing required), or BS EN 45011 (BS EN ISO/IEC 17025 to be observed for testing required)
Section 3	BS EN ISO/IEC 17021 (+ product related knowledge), or BS EN 45012 (+ product related knowledge)

Section 4	BS EN ISO/IEC 17021 (+ product related knowledge), or BS EN 45012 (+ product related knowledge)
Section 5	BS EN ISO/IEC 17025 (including the ability to evaluate and decide on conformity), or BS EN ISO/IEC 17020 (BS EN ISO/IEC 17025 to be observed for testing required), or BS EN 45011 (BS EN ISO/IEC 17025 to be observed for testing required)
Section 6	BS EN ISO/IEC 17025 (including the ability to evaluate and decide on conformity), or BS EN ISO/IEC 17020 (BS EN ISO/IEC 17025 to be observed for testing required), or BS EN 45011 (BS EN ISO/IEC 17025 to be observed for testing required)

4.4 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 body 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.

4.5 The presumption of conformity

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. (See also Article 9.2 of the Directive.) However, it should be noted that each conformity assessment body standard is intended to be applicable to a wider range of activities than the scope of appointment of a notified body.

Therefore, for the presumption to be valid - the requirements in the standard must be related to the specific tasks to be performed according to the directive.

The requirements on independence in the standards as referred to in section 4.2 are also relevant

4.6 Policy on accreditation

The Department recommends that notified bodies are accredited to one of the conformity assessment body standards listed in section 4.2 for a relevant scope but it has not made accreditation mandatory. However, if a notified 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. If a notified 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.

5.0 THE MINIMUM CRITERIA IN THE DIRECTIVE

5.1 Minimum criteria

The following text has been reproduced from Annex V of the directive. It is referred to in these guidelines as 'the minimum criteria'.

"The notified bodies designated by the Member States must fulfil the following minimum conditions:

- availability of personnel and of the necessary means and equipment,
- technical competence and professional integrity of personnel,
- independence in carrying out tests, preparing reports, issuing certificates and performing the surveillance provided for in this Directive, of management and technical staff in relation to all circles, groups or persons directly or indirectly involved in the field of the appliances,
- maintenance of professional secrecy by staff,
- possession of civil liability insurance unless that liability is covered by the State under national law.

Fulfilment of the conditions in the first two indents must be periodically verified by the competent authorities of the Member States or by bodies designated by the Member States."

5.2 Guidance on the 1st indent in section 5.1(availability of personnel)

The notified 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 notified body may employ experts in particular fields through various forms of service contract, but the experts shall operate under the notified body's quality management system in the same way as a member of its staff. There shall be a sufficient number of permanent staff to enable effective selection, management and review of expert staff under contract. 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.

5.3 Guidance on the 2nd indent in section 5.1(technical competence and professional integrity of personnel)

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 notified body shall demonstrate with respect to the scope of appointment for which it has applied:

- a thorough technical understanding of the products concerned;
- knowledge and experience of the methodology of risk analysis and risk management;
- capability to assess design documentation and the intended function and performance of the product;
- capability to assess manufacturing techniques;
- 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 knowledge of the essential requirements and the related harmonised standards;
- it has the capability to establish the appropriate test and evaluation programmes to determine compliance with the essential requirements without reference to any standards.

Annex I sets out the procedures a notified body shall be required to have in place to demonstrate the above competencies and UKAS assessment of those procedures.

5.4 Guidance on the 3rd indent in section 5.1 (independence)

The notified body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer or maintainer of the products which they inspect, nor the authorized representative of any of those parties. Further, a notified body shall not be the purchaser or owner of any proprietary interest in such products, or use them, to such an extent that the notified body's independence might be called into question: in the event of any dispute, in that respect, the Secretary of State's decision shall be final.

A notified body shall not engage in any activities that may conflict with their independence of judgment and integrity in relation to their conformity activities. In particular they shall not become directly involved in the design, manufacture, supply, installation, use or maintenance of the products for which they draw up reports on conformity or similar competitive items to such an extent that the notified body's independence might be called into question. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body. The body shall ensure that activities of its related bodies do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.

5.5 Guidance on the 5th indent of section 5.1 (civil liability insurance)

A notified body's activities under the Regulations shall be covered by public liability insurance and professional indemnity insurance. It is the responsibility of the notified body to ensure that these two types of insurance policy are properly integrated, to avoid disputes in the event of borderline claims and that the arrangements are adequate for its requirements.

Provision of information on insurance to UKAS

The applicant body shall supply summary written evidence of its public liability and professional indemnity insurance policies provided by its insurance broker to UKAS. 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 but at the latest, when requested by UKAS prior to any recommendation. 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 applicant body shall provide UKAS with a summary of current insurance cover at each annual surveillance visit.

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 UKAS should not be construed as confirmation by UKAS or the Secretary of State of the adequacy of such insurance, as this is the responsibility of the notified body. UKAS may however ask the notified body to explain the basis on which the amount of insurance has been determined.

5.6 Quality management system of the notified body

The notified body shall operate a quality management system as described in the relevant conformity assessment body 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 notified body by its management and staff.

6. DUTIES OF A NOTIFIED BODY

6.1 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 the notified body operates must be administered in a non-discriminatory manner.

6.2 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 Directive.

6.3 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.

6.4 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 procedure (Directive, Annex II, sections 3 or 4). Compliance to BS EN ISO 9001:2000, as the relevant harmonized standard, gives a presumption of conformity to the procedures, provided the quality management system is implemented to ensure that the product meets the essential requirements referred to in the module. It is permissible to exclude certain specific requirements from BS EN ISO 9001 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. 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 then it would not be possible to claim compliance with the standard.

6.5 Documentation to be retained by the notified body

The 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 made available by the notified body on request of 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. The records shall be sufficient to ensure duplicates of the original certificates can be generated, along with duplicates of any supporting documentation which were annexed to the certificate to meet the requirement of the Directive. The Regulations are silent as to how long these records should be retained. The length of period of retention is therefore 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. For guidance the Electrical Equipment (Safety) Regulations 1994, require records to be kept for 10 years after the supply of the last manufactured product to which those records relate.

6.6 Participation in co-ordination activities

The notified body shall participate in the notified body co-ordination activities at the national and European level and show that it has an effective means of providing input and making itself 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.

6.7 Circumstances in which the 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 that 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 requirements of the Regulations.)

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

6.8 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.

6.9 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 shall 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. 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 assessment 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.

The following link will provide information on the current situation for MRAs

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

ANNEX I

Competence of individual staff involved in conformity assessment

The notified body shall have procedures in place to record the knowledge and experience of staff and other key personnel. These records will provide the justification that those staff involved in notified body activities have suitable knowledge and experience for the tasks they are required to undertake.

During assessments UKAS will carry out an assessment that these procedures are being used effectively.

The Department would expect as a minimum that these procedures will provide an assessment that each individual member of staff possesses all the knowledge (technical, legal and procedural) to carry out the tasks they are required to undertake. That individuals have appropriate and relevant experience.

ANNEX II

CONTRACTING PARTIES TO THE EUROPEAN ECONOMIC AREA AGREEMENT

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

EU MEMBER STATES

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

EEA EFTA MEMBER STATES

Iceland	Norway	Liechtenstein
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(Please note: Switzerland is a member of EFTA but it is not an EEA EFTA Member State. Please see section 7 for information on EU Swiss MRAs.)

The information above was correct when these guidelines were published, the current situation can be checked via the following link:

http://ec.europa.eu/enlargement/index_en.htm

Note: A Customs agreement has been agreed to set up a free trade agreement between the EU and Turkey. For further information please see the following link, in particular Articles 8, 9 and 10:

http://europa.eu.int/comm/enlargement/turkey/pdf/ec_tk_ass_council_1_95_en.pdf

ANNEX III

CONTACT INFORMATION FOR APPLICATIONS

Applications to UKAS for assessment as a notified body will require two forms (i) a general application form and (ii) AC6 Approved or notified body form. Both forms can be downloaded from:

<http://www.ukas.com/Library/downloads/forms/UKAS%20Application%20Form.pdf>

The applications should be sent to:

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

<mailto:apps@ukas.com>

Tel: 0208 917 8400

Fax: 0208 917 8500

More information may be obtained from:

Will McGivern, <mailto:will.mcgivern@ukas.com>

Lorraine Turner, <mailto:lorraine.turner@ukas.com>

General Enquiries <mailto:info@ukas.com>

Web site: <http://www.ukas.com>

And be copied to:

Gigi Pardesi
Department of Trade and Industry
Office of Science and Innovation
Sustainable Development and Regulation Directorate
Bay 280
151 Buckingham Palace Road
London SW1W 9SS

Tel: 020 7215 1323

Fax: 020 7215 1340

<mailto:gigi.pardesi@dti.gsi.gov.uk>

ANNEX IV

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. L196 26.7.1990. Copies of this text may be obtained from:

The Stationery Office
Norwich
NR3 1GN

Tel: 0870 600 5522
Fax: 0870 600 5533

The Directive as amended by 93/68/EC can be downloaded via the link below. It has the same layout as the printed Official Journal and includes graphics.

http://europa.eu.int/eur-lex/en/consleg/pdf/1990/en_1990L0396_do_001.pdf

The Directive can also be downloaded from the Eur-lex website below using the Official Journal reference No. L196 26.7.1990 but as it is produced on html format it does not include any graphics.

<http://europa.eu.int/eur-lex/en/search/>

- **The UK Regulations**

The Regulations S.I.1995 No.1629 may be obtained from The Stationery Office (please see above.)

Or by direct download from:

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

- **European and national standards**

Copies and information on the relevant standards (see section 4.3) are available from:

BSI
389 Chiswick Road
London
W4 4AL

Tel: +44(0)20 8996 9001
Fax: +44(0)20 8996 7048
Web: <http://www.bsi-global.com>

- **Guidelines on the Regulations**
- **List of UK notified bodies for the Regulations**

These documents can be obtained from the DTI website

<http://www.dti.gov.uk/innovation/strd/ecdirect/page12491.html>

The following UKAS 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.**

These can be obtained from:

<http://www.ukas.com>

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>

(A user guide is available by clicking on 'Help' at the foot of the home page of the document.)

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>

ANNEX V

MODEL LETTER OF APPOINTMENT

[*APPOINTMENT* OF {NAME OF COMPANY} AS A *NOTIFIED BODY* UNDER REGULATION xxxx OF THE xxxx REGULATIONS]

I am writing to inform you that the Secretary of State hereby *appoints* [name of company] (the *Company*) as a *Notified Body* under regulation xxxx of [The xxxx Regulations] (the Regulations) which implement the provisions of Council Directive [number of Directive] (the Directive) on [title of Directive] subject to the conditions set out in this letter.

The *Company* is *appointed* for the purposes of [conformity assessment procedures/modules], in relation to the following:

[list product(s)/range of products for which company is appointed]

This *appointment* shall remain in force until [such time as it is withdrawn by the Secretary of State pursuant to clause 5 below] or after the elapse of a period of [xx days] after the *Company* has notified the Secretary of State in writing that it wishes the *appointment* to be terminated pursuant to clause 6 below.

This *appointment* is subject to the following specific conditions:

the *Company* shall at all times carry out the duties and functions of a *Notified Body* under regulation xxxx of the Regulations to the satisfaction of the Secretary of State;

the Secretary of State continues to be satisfied as to the *Company's* suitability - including its status and competence - to be a *Notified Body*; in connection with this, the *Company* shall, in some circumstances and at the Secretary of State's request, submit to immediate reassessment of its suitability for *appointment*;

the *Company* shall submit itself annually for surveillance for the purposes of ascertaining that the *Company* is performing its duties and functions in accordance with its appointment; [in connection with this, the first surveillance shall take place no later than six months after the date of acceptance of this *appointment*;) provided always that the Secretary of State may require more frequent surveillance.

the *Company* shall submit itself every 4 years for a full reassessment for the purposes of the Secretary of State satisfying himself that the *Company* remains suitable for appointment;

for the purposes of reassessment and surveillance an assessment shall

normally be carried out on behalf of the Secretary of State by the United Kingdom Accreditation Service (UKAS), which will submit a report to the Secretary of State; Provided always otherwise or in addition, such assessment may be carried out by or on behalf of the Secretary of State as he in his absolute discretion thinks fit;

the *Company* shall fulfil and comply at all times with the “minimum criteria” specified in Schedule [xx]/Annex [xx] of the Directive (which is set out in Appendix 1 to this letter);

It is the responsibility of the *Company* to provide annual evidence of adequate insurance cover taking into account all relevant circumstances in relation to the scope of the *Company*'s activities;

the *Company* shall follow the relevant conformity assessment procedures as stated in regulation xxxx of the Regulations (these are the procedures mentioned or referred to in Article [x] of the Directive);

[where the *Company*, in accordance with regulation [xxxx] of the Regulations, is minded to refuse to issue an *EC type-examination certificate* it shall:

give notice in writing to the applicant of the reasons why it is minded to do so; and

give the applicant the opportunity of making representations within a reasonable period of the notice being given as to why it should not be refused;]

the sub-contracting of work by the *Notified Body*, shall be subject to certain conditions guaranteeing:-

the competence of the establishment operating as sub-contractor by meeting the relevant requirements of the [EN 45000 series] of standards; and

its ability to exercise effective responsibility for the work carried out under sub-contract; and

any other matter required in guidelines issued by the Secretary of State in respect of the sub-contracting of work [(these appear at Appendix ? to the current issue of the guidelines)].

In any case the *Notified Body* remains entirely responsible for the work carried out under the sub-contract.

the *Company* shall authorise, at any reasonable time, access by or on behalf of the Secretary of State to:

all documentation arising out of its duties and functions under this *appointment* and shall comply with any reasonable request made

by or on behalf of the Secretary of State for information regarding the exercise of those duties and functions;

its premises for the purpose of verifying its compliance with the conditions with the minimum criteria

the *Company* shall take part in *Notified Body* co-ordination activities at national and European levels;

the *Company* must maintain its impartiality and independence from all applicants and in no circumstances should it take on the role of authorised representative for any applicant;

the *Company* shall inform the Secretary of State of any changes, which have a bearing upon its status as a *Notified Body* or its ability to perform the duties and functions of a *Notified Body* under the Regulations;

the *Company* shall inform the Secretary of State, forthwith on becoming the subject of a petition for an Administration Order or a petition for a Winding-up Order brought against it; and in addition the *Company* shall inform the Secretary of State within four weeks if:

the *Company* becomes the subject of a proposal for a voluntary arrangement or presents a petition for an Administration Order or a petition for a Winding-up Order or passes a resolution for a Winding-up Order or makes any composition, arrangement, conveyance or assignment for the benefit of its creditors or purports to do so, or has a receiver or any person appointed in respect of its undertaking or of any or of all of its property;

the *Company* becomes a subsidiary of any company of which it is not a subsidiary at the date of this letter; or ceases to be a subsidiary of any company of which it is a subsidiary at the date of this letter. The word “subsidiary” shall be interpreted in accordance with the definitions in Section 736 of the Companies Act 1985 (as substituted by Section 144 (1) of the Companies Act 1989).

the Secretary of State may, by notice in writing, add conditions or vary or delete any conditions, to this *appointment*; such additions, variations or deletions shall have effect thirty days after the date of [x] that notice unless a different period is agreed in writing between the Secretary of State and the *Company*;

This *appointment* shall be withdrawn forthwith [in accordance with regulation xxxx of the Regulations] if it appears to the Secretary of State that the *Company* no longer meets the minimum criteria for *appointment*.

This *appointment* shall be terminated in accordance with regulation [xxxx] of the Regulations at the request of the *Company* upon [xx] days’ notice in writing to the Secretary of State.

This *appointment* is subject to the following additional conditions in the event of it being withdrawn or terminated:

the *Company* shall prepare and submit to the Secretary of State within three calendar months of the date on which the termination of the *appointment* takes effect or, if appropriate, of the date of withdrawal, a report in writing on the exercise of its duties and functions under the Regulations; this report shall contain such information as may have been agreed in writing between the Secretary of State and the *Company*;

the *Company* shall transfer to the Secretary of State or to such person or company as the Secretary of State shall direct, without charge, all records, information and other things, whether stored manually by computer or by any other means whatsoever, arising out of the performance of its duties and functions under the Regulations as the Secretary of State may specify.

Your attention is drawn to Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of 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 harmonisation Directives.

You should note that *Notified Bodies* are to be encouraged to apply the modules without unnecessary burdens for applicants.

The Secretary of State will notify the European Commission and other *EEA* States of this *appointment* to act for the purposes stated above and it will be made public.

If the above terms and conditions of *appointment* are acceptable to you, you should signify your *Company's* consent by signing, or arranging for the signature of, the attached copy of this letter, dating and returning it to: [name and address of DTI contact]. The appointment shall take effect upon receipt of your *Company's* consent and you will receive formal confirmation of this.

Tony Pedrotti
for and on behalf of the Secretary of State

On behalf of [name of Company] I hereby accept the *appointment* of [name of Company] as a *Notified Body* on the terms and conditions set out in this letter.

Signed.....

(duly authorised to sign in that behalf)

Name in Capitals.....

Position.....

Dated.....

END OF TEXT