



# The Electromagnetic Compatibility Regulations 2006

Guidelines for the  
designation of Notified  
Bodies

April 2007

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## 1. INTRODUCTION

### 1.1 The purpose of these guidelines

These guidelines set out the requirements that a person will need to meet in order to be designated as a United Kingdom notified body pursuant to the Electromagnetic Compatibility Regulations 2006 (SI No. 2006/3418) ("the Regulations"). 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 designated.

### 1.2 The Directive and the Regulations

The Regulations implement in the United Kingdom Council Directive 2004/108/EC of the European Parliament and of the Council on the approximation of the laws of the member States relating to Electromagnetic Compatibility ("the Directive"). The Regulations are made under the European Communities Act 1972. Unless otherwise stated references to regulations in these guidelines are to the Regulations.

### 1.3 The Regulations and notified bodies

In the United Kingdom, the Secretary of State for Trade and Industry has responsibility for designating notified bodies to carry out the functions described in Part IV of the Regulations and for notifying the European Commission of such designations.

Regulation 1(2) empowers the Secretary of State to designate notified bodies *from 20 January 2007*, when regulations 24, 25 and Schedule 5 relating to the designation of notified bodies came into force. However, notified bodies designated by the Secretary of State will not be able to issue a statement **until 20 July 2007**, when the remaining regulations come into force. Having completed the internal production control procedure set out in regulation 19, the manufacturer (or his authorised representative) may **choose**, under regulation 20, to involve a notified body to demonstrate compliance with some or all of the essential requirements (see regulation 4 and 5).

## **2. APPLICATION AND DESIGNATION**

### **2.1 Eligibility and legal identity**

To be eligible for designation as a United Kingdom notified body for the purposes of the Regulations, the applicant must be a person resident, incorporated or carrying on business 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.

### **2.2 Application to be designated as a notified body**

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 of Trade and Industry and this will be taken to be the formal application to the Secretary of State. (Please see Annex II for the addresses of UKAS and the Department and Annex III for references to downloadable documents.)

### **2.3 Overall process of assessment by UKAS**

UKAS will carry out an assessment of the applicant 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 to the use of subcontracted UKAS assessors**

UKAS will use suitably qualified assessors or assessment teams to undertake the assessment and make clear to applicants when sub-contracted assessors or technical experts are to be used. Applicants 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 applicants against its own standard scale of charges for its assessment activities carried out under these guidelines.

### **2.6 Insurance**

The applicant shall provide evidence of its insurance cover to UKAS before any designation is made. After any designation, the notified body shall provide evidence of continued appropriate insurance cover to UKAS at each annual inspection. (Further details can be found in Section 5.4.)

## **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 designation is at the discretion of the Secretary of State and it should not be assumed that, if an applicant meets all the criteria, then a designation will automatically follow. If the Secretary of State is minded not to designate an applicant as a notified body, then the applicant 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 is suitable, and should be designated, a letter of designation will be issued to the applicant.

## **2.8 The letter of designation (see also Annex IV)**

The precise terms and conditions of designation will be set out in the individual letters of designation, but there will be standard conditions that the notified body agrees:

- to surveillance annually or at whatever intervals are thought appropriate by the Secretary of State (a newly designated person 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 6.5); 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 designation.

## **2.9 Designation by the Secretary of State and notification to the European Commission and other Member States**

The applicant shall sign and return the letter of designation to the Department and when it is received, the designation as a notified body shall take effect. The Department will notify the designation to the Commission and other Member States. The Commission will verify that all the required information is present and transfer the details to the NANDO on-line database<sup>1</sup>. If the notified body has not previously been assigned an identification number according to another EC Directive, the Commission will assign such a number as part of the first notification process. This number will apply for any subsequent notifications in respect of other

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

Directives. The notified body may begin working when the designation has taken place, but it shall not issue any certificates until the notification appears on the NANDO website. (See also section 1.3.)

## **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 the body's letter of designation 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 designation. 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 designation, including compliance with the requirements in these guidelines.

## **2.11 Co-ordination of action between the Department and UKAS on suspension or termination of accreditation**

If the designation 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 designation. If the applicant body appeals against a decision by UKAS, UKAS will advise the Department of the outcome of the appeal if it can no longer support its recommendation for designation. UKAS will inform the Department when an accreditation that supports designation 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 a designation has been varied or terminated.

### **3. THE SCOPE OF DESIGNATION**

#### **3.1 The overall scope of designation.**

The scope of designation of a notified body for the directive, sets out the entitlement to carry out certain tasks in relation to the product scope.

#### **3.2 Product scope**

The Regulations apply to any apparatus or fixed installation as defined in regulation 3.

#### **3.3 Conformity assessment procedure**

There is only one conformity assessment procedure in the Regulations, but it is in two parts. The first part is in regulation 19 and is carried out by the manufacturer. The second part is in regulation 20 and is carried out (after the first) by a notified body. Regulation 18 states that the second part of the procedure (i.e. regulation 20) and hence the involvement of a notified body, is voluntary and at the discretion of the manufacturer or his authorised representative.

#### **3.4 Involvement of a notified body**

1. The manufacturer or his authorised representative may involve a notified body in order to demonstrate compliance with all or some of the essential requirements.
2. The manufacturer or his authorised representative shall specify to the notified body which aspects of the essential requirements are to be assessed by the notified body.
3. Having completed the internal production control procedure in respect of those aspects to be assessed by the notified body, the manufacturer or his authorised representative shall present the technical documentation to the notified body and request the notified body for an assessment of such documentation.
4. The notified body shall review the technical documentation and assess whether the technical documentation properly demonstrates that the requirements of these Regulations that it has to assess are met.
5. The notified body shall, if satisfied with the technical documentation demonstrating that the apparatus is compliant with those aspects of the essential requirements it has been asked to assess, issue a statement to the manufacturer or his authorised representative confirming the compliance of the apparatus.
6. That statement shall be limited to those aspects of the essential requirements which have been assessed by the notified body.
7. The manufacturer or his authorised representative shall add the statement of the notified body to the technical documentation.



## **4 GENERAL GUIDANCE ON 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/EEC<sup>2</sup> 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 a notified body.* (However please refer to Section 4.5 which makes it clear that accreditation to the relevant standard, whilst recommended, is not mandatory. In such a case, assessment by UKAS will be based on the relevant standard.) It should be noted that the 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’.

### **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 a body. The assessment of a notified body for New Approach EC Directives in general 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 designation.

- **BS EN ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories***
- **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 contents are identical.)
- **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 International Accreditation Forum (IAF) and therefore, from 15 September 2008, accreditation to BS EN 45012:1998 (or the equivalent ISO/IEC Guide 62:1996) will no longer be valid.)

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<sup>2</sup> 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”).

### 4.3 The conformity assessment procedure in the Directive and the conformity assessment body standards

Regulation 24(3) States that "A person who meets the assessment criteria fixed by a standard which is a relevant harmonised standard within the meaning of Article 12.2 of the EMC Directive shall be presumed to meet the minimum criteria covered by such harmonised standard." Until such time as the harmonised standards have been specified, the standards referred to in the table below are considered to be applicable.

|                        | <b>Conformity assessment body standards applicable</b>   |
|------------------------|--|
| Annex III of Directive | BS EN ISO/IEC 17020 (General criteria for the operation of various types of bodies performing inspection)<br><br>BS EN 45011 (General requirements for bodies operating product certification systems) |

### 4.4 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. 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 designation 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.***

### 4.5 Policy on accreditation

The Department recommends that notified bodies are accredited to one of the conformity assessment body standards listed in section 4.3 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 designation 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**

Regulation 24(2) provides that the Secretary of State shall not make a designation of a person to be a notified body under the Regulations unless he is satisfied that the applicant satisfies the minimum criteria set out in Schedule 5. These are listed below and will be referred in these guidelines as 'the minimum criteria'.

1. availability of personnel and of the necessary means and equipment;
2. technical competence and professional integrity of personnel;
3. independence in preparing the reports and performing the verification function provided for in the EMC Directive;
4. independence of staff and technical personnel in relation to all interested parties, groups or persons directly or indirectly concerned with the equipment in question;
5. maintenance of professional secrecy by personnel; and
6. possession of civil liability insurance unless such liability is covered by the Member State under national law.

### **5.2 Guidance on minimum criterion (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 designation. 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 minimum criterion (2) (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 designation 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 as defined in regulation 3 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.

#### **5.4 Guidance on minimum criterion (6) (civil liability insurance)**

A notified body's activities under the Regulations shall be covered by public liability insurance and professional indemnity insurance policies. 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 shall send summary written evidence of its public liability and professional indemnity insurance policies provided by its insurance broker to UKAS, prior to any designation 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 notified 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 designation. Thereafter, as one of the conditions of designation, 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. 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 notified body to explain the basis on which the amount of insurance has been determined. The Department reserves the right to refuse or terminate the designation if the issue cannot be resolved to the Department's satisfaction.

## **5.5 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 designation. 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 shall 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, as specified in its scope of designation, according to the conformity assessment procedure in its scope of designation.

### **6.3 Procedures to ensure consistency**

Where judgements or interpretation of a standard or requirement are implicit or explicit in a decision to issue, vary or refuse a statement of compliance pursuant to the Regulations, the notified body is required to have procedures for achieving consistency in such matters.

### **6.4 Documentation to be retained by the notified body**

The notified body is required to maintain an up to date record of all statements it has issued, to whom they have been issued and to what they apply. These records shall be retained by the notified body and shall be made available on request to the Secretary of State, or such other person as may be authorised by the Secretary of State. A list of the relevant technical documentation (construed in accordance with Schedule 3 of the Regulations) must be annexed to the statement and a copy kept by the notified body. As the EMC 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 for agreement between the notified body and its client. It is suggested however, that the technical documentation relating to the statement issued should be retained until the statement is no longer valid or required either as a matter of contract or to comply with requests from the enforcement authorities.

## **6.5 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.

## **6.6 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 examination statement 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 designation;
- 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.

## **6.7 Confidentiality/Data Protection**

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 activities as a notified body. The notified body shall also comply with the provisions of the Data Protection Act 1998.

## **6.8 Policy and procedures for the control of its identification number**

The notified body's quality manual documentation shall state its policy and procedure for controlling the use of statements it has issued and its identification number.

## **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. An applicant should inform the Department if it wishes to be considered for designation 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

### 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.

| <b>EU MEMBER STATES</b>       |         |               |                |
|-------------------------------|---------|---------------|----------------|
| 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      |                |
| <b>EEA EFTA MEMBER STATES</b> |         |               |                |
| Iceland                       | Norway  | Liechtenstein |                |

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

[http://ec.europa.eu/enlargement/index\\_en.htm](http://ec.europa.eu/enlargement/index_en.htm)



## **ANNEX II**

### **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 can be downloaded from the publications section of the UKAS website given below.

#### **The applications for appointment should be sent to:**

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

Tel: 020 8917 8400

Fax: 020 8917 8500

<mailto:apps@ukas.com>

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

#### **And be copied to:**

Kevin Lane  
Department of Trade and Industry  
151 Buckingham Palace Road  
London SW1W 9SS

Tel: 020 7215 1774

<mailto:Kevin.Lane@dti.gsi.gov.uk>

## **ANNEX III**

### **RELEVANT DOCUMENTS AND SOURCES OF INFORMATION**

#### **The Regulations**

A copy of the EMC Regulations 2006 SI No. 3418 can be found at:

<http://www.opsi.gov.uk/si/si2006/20063418.htm>

#### **The Directive**

The Eur-lex website <http://europa.eu.int/eur-lex/en/index.html> has the Official Journal from 1998 onwards on-line.

A copy the EMC Directive can be found at:

[http://europa.eu.int/eur-lex/lex/LexUrServ/site/en/oj/2004/l\\_390/l\\_3902004231en00240037.pdf](http://europa.eu.int/eur-lex/lex/LexUrServ/site/en/oj/2004/l_390/l_3902004231en00240037.pdf)

#### **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: <http://www.bsi-global.com/en>

#### **Guidelines on the Regulations and a list of UK notified bodies**

DTI <http://www.dti.gsi.gov.uk/innovation/strd/ecdirect/page12469.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.

UKAS <http://www.ukas.com>

### **NANDO**

The Commission's on-line database of notified bodies notified by the UK and other Member States

<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)

### **New Approach Guide**

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

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

### **European Accreditation (EA)**

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

## ANNEX IV

### MODEL LETTER OF DESIGNATION

Dear

#### **DESIGNATION OF [NAME ] AS A NOTIFIED BODY PURSUANT TO REGULATION 24 OF THE ELECTROMAGNETIC COMPATIBILITY REGULATIONS 2006**

I am writing to inform you that the Secretary of State hereby designates **[name]** (the Company) as a Notified Body under regulation 24 of the Electromagnetic Compatibility Regulations 2006 (the "Regulations") which implement the provisions of Council Directive 2004/108/EC (the "Directive") on electromagnetic compatibility, subject to the conditions set out in this letter. Words and expressions used in this letter shall have the same meaning as in the Regulations.

However, you should note that you will not be able to issue a statement pursuant to the Regulations until 20 July 2007.

1. The Company is designated for the purposes of issuing statements pursuant to regulation 27 of the Regulations, in relation to the following:

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

2. This designation shall remain in force until such time as it is terminated by the Secretary of State pursuant to regulation 25 of the Regulations.
3. This designation is subject to the following specific conditions:
  - A. The Company shall at all times carry out the duties and functions of a Notified Body under regulations 27 and 28 of the Regulations to the satisfaction of the Secretary of State;
  - B. That 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 this regard the Company shall, in some circumstances and at the Secretary of State's request, submit to immediate reassessment of its suitability for designation;
  - C. 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 designation, complies with the Regulations and meets the minimum criteria; in this regard, the first surveillance shall take place no later than six months after the date of acceptance of this designation provided always that the Secretary of State may require more frequent surveillances..

- D. 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 designation;
- E. 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;
- F. The Company shall fulfil and comply at all times with the minimum criteria specified in Schedule 5 of the Regulations (which is set out in Appendix 1 to this letter);
- G. It is the responsibility of the Company to provide to the satisfaction of the Secretary of State annual evidence of insurance cover taking into account all relevant circumstances in relation to the scope of the Company's activities;
- H. The Company shall follow the relevant conformity assessment procedures as stated in regulation 20 of the Regulations;
- I. Where the Company, in accordance with regulation 33(1) of the Regulations, is minded to refuse to issue a statement of compliance, vary a statement (other than at the request of the person to whom it was given) or withdraw a statement of compliance it shall give to the applicant, or the person to whom the statement was given, a notice in writing:
- (i) giving reasons for the refusal, variation or withdrawal;
  - (ii) specifying the date on which the refusal, variation or withdrawal is to take effect; and
  - (iii) giving the applicant, or the person to whom the statement was given the opportunity to make representations within 21 days from the date of such notice and stating that the Company shall consider any representations that are made to it within that period by that applicant or person.
- Where the Company, having considered the representations made to it under paragraph (iii) above remains of the opinion that an application for a statement should be refused or a statement should be varied or withdrawn it shall inform the applicant, or the person to whom the statement was given, of that decision in writing.
- J the sub-contracting of work by the Notified Body as permitted by regulation 29 of the Regulations, shall be subject to appropriate conditions guaranteeing:-

- (i) the competence of the establishment operating as sub-contractor by meeting the relevant requirements of the EN 17000 series of standards; and
- (ii) its ability to exercise effective responsibility for the work carried out under sub-contract; and
- (iii) any other matter required in guidelines issued by the Secretary of State in respect of the sub-contracting of work.

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

- K the Company shall authorise, at any reasonable time, access by or on behalf of the Secretary of State to:
  - (i) all documentation arising out of its duties and functions under this designation 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;
  - (ii) any of its premises for the purpose of verifying its compliance with the conditions in this letter of designation and with the minimum criteria.
- L. the Company shall take part in Notified Body co-ordination activities at national and European levels;
- M. 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;
- N. The Company shall inform the Secretary of State of any changes that 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;
- O. 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:
  - (i) 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;
  - (ii) 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).

- P. The Secretary of State may, by notice in writing, add conditions or vary or delete any conditions, to this designation; such additions, variations or deletions shall have effect thirty days after the date of that notice unless a different period is agreed in writing between the Secretary of State and the Company;
  - Q. The Company shall comply with the Regulations in so far as they apply to notified bodies.
  - R. The Company shall comply with the provisions of any relevant guidelines for the designation of notified bodies issued by the Secretary of State.
4. This designation is subject to the following additional conditions in the event of it being varied or terminated:
- (a) The Company shall prepare and submit to the Secretary of State within three calendar months of the date on which the termination of the designation 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;
  - (b) 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.
  - (c) The Company shall comply with any directions given by the Secretary of State for the purposes of making arrangements for the determination of outstanding applications as he considers appropriate.
5. 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.
6. You should note that Notified Bodies are to be encouraged to apply the modules without unnecessary burdens for applicants.

7. The Secretary of State will notify the European Commission and other EEA States of this designation to act for the purposes stated above and it will be made public.
8. If the above terms and conditions of designation 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 designation shall take effect upon receipt of your Company's consent and you will receive formal confirmation of this.

For and on behalf of the Secretary of State

On behalf of **[name of Company]** I hereby accept the designation 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.....