



Department of Trade and Industry

ELECTROMAGNETIC COMPATIBILITY (EMC) REGULATIONS 1992

Guidelines on the appointment of Competent Bodies

August 1999

URN 99/627

1. INTRODUCTION

- 1.1 The European Community Directive 89/336/EEC¹ on the approximation of the laws of the member States relating to electromagnetic compatibility (“the Directive”), as amended by Council Directive 92/31/EEC², and Council Directive 93/68/EEC³ has been implemented in the United Kingdom by means of the Electromagnetic Compatibility Regulations 1992 (SI 1992/2372) as amended by SI 1994/3080 and SI 1995/3180 (“the EMC Regulations”). The EMC Regulations are made under the European Communities Act 1972.
- 1.2 The EMC Regulations provide, among other things, for the appointment of Competent Bodies to carry out assessments of technical construction files and compile reports or issue certificates as described under its Part V (The Technical Construction File “TCF” Route to compliance detailed at Appendix A).
- 1.3 In the United Kingdom, the Secretary of State for Trade and Industry has responsibility for appointing Competent Bodies to carry out the functions described in clause 1.2 above and for informing the European Commission of such appointments (see reg. 46 of the EMC Regulations). For information purposes only the Secretary of State will from time to time publish a list of Competent Bodies indicating the descriptions of relevant apparatus in respect of which the body is appointed.

2. APPLICATION FOR APPOINTMENT AS A COMPETENT BODY

- 2.1 Application for assessment for the purposes of appointment should be made in the first instance to the United Kingdom Accreditation Service (UKAS) and copied to the Department of Trade and Industry at the addresses indicated in clause 2.6. The copy application to the Department will form the application for appointment as a competent body. Application to UKAS should be made using the forms obtainable from the UKAS contact (see clause 2.6). UKAS, will then carry out an assessment of the undertaking on behalf of the Secretary of State for Trade and Industry against the criteria set out in these guidelines which will be updated from time to time. UKAS will quote and charge applicants against its standard scales of charges for its surveillance activities under the scope of these guidelines. UKAS has established procedures to handle complaints or appeals associated with its assessment activities.
- 2.2 The Department will require details of the applicant’s insurance cover which should be forwarded to UKAS with the application and copied to the Department. The cover must include both public liability and professional indemnity insurance, and should extend to the whole of the European Economic Area or, if the applicant intends to carry out work outside the EEA, worldwide. The Secretary of State will not, in any cases, cover the applicant’s liability.

¹ OJ No. L139 of 23 May 1989

² OJ No. L 126 of 12 May 1992

³ OJ No. L220 of 30 August 1993.

- 2.3 Following appointment by the Secretary of State, the Competent Body will be required under its conditions of appointment to make available to UKAS evidence of liability insurance at each annual surveillance visit undertaken by UKAS.
- 2.4 The Secretary of State will, after the applicant has been assessed and a report has been made to him, consider whether the applicant is suitable for appointment and whether it should be appointed. If the Secretary of State is satisfied that the applicant should be appointed a letter of appointment will be issued. The applicant is then required to return to the Department a copy of the letter, duly signed by an authorised representative of the applicant. The Department will then inform the EC Commission of the applicant's appointment as a Competent Body.
- 2.5 The precise terms and conditions of appointment will be set out in the letter of appointment a copy of a model of which is attached at Appendix C, but it will be a condition that the applicant agrees:
- a. to play a full part in Competent Body co-ordination activities at both UK and European level;
 - b. to surveillance by UKAS, on behalf of the Secretary of State, annually or whatever intervals are thought appropriate by the Secretary of State (in addition the Secretary of State will reserve the right for surveillance to be undertaken by the Department or a third party acting on behalf of the Secretary of State) (new applicants will undergo an initial surveillance after 6 months); and
 - c. to a full reassessment by UKAS on behalf of the Secretary of State, every four years or whatever intervals are thought appropriate by the Secretary of State.
- 2.6 Contact address details for the DTI and UKAS are:

For the Department/Secretary of State:

Peter Howick
Standards and Technical Regulations Directorate 4
Bay 323
Department of Trade and Industry
151 Buckingham Palace Road
London
SW1W 9SS

Telephone: 0171 215 1595
Facsimile: 0171 215 1529

For UKAS:

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

Telephone: 0181 917 8436

Facsimile: 0181 917 8500

3. CRITERIA FOR APPOINTMENT AS A COMPETENT BODY

- 3.1 Accreditation, to an appropriate scope, to the relevant EN45000 standards specified in clause 3.2 below (which contain specifications for bodies issuing certificates, performing inspections or conducting tests) may be used as the basis for demonstrating conformity with the criteria in Appendix B. However, accreditation is not mandatory and the relevant criteria may be met in other ways. All applicants, whether accredited to the relevant standard(s) or not, will need to meet the additional requirements set out in these guidelines, which may change from time to time. Meeting the criteria does not lead to automatic appointment; appointment is at the discretion of the Secretary of State.
- 3.2 Applicants who are able to provide current proof of their conformity with the appropriate harmonised standards EN45004 (General criteria for the operation of various types of bodies performing inspection) or EN45011 (General criteria for certification bodies operating product certification) by presenting a certificate of accreditation which has been issued by UKAS, are presumed to be competent and in this respect to conform with the requirements of the Directive and Regulations, subject to the provisions of clause 3.4 below.
- 3.3 Applicants which are not accredited to the relevant EN45000 standard(s) specified in clause 3.2 above, will be required to undergo an assessment carried out on behalf of the Secretary of State by UKAS. That assessment will be based on the relevant requirements of the relevant EN45000 standard(s) and the additional requirements set out in these guidelines.
- 3.4 In addition to accreditation or assessment to the relevant EN45000 standard(s) or to an equivalent standard, the applicant is also required to demonstrate to the Department's satisfaction compliance with Schedule 5 of the EMC Regulations (see Appendix B) and to the requirements in the following paragraphs of this clause which will be updated from time to time. These will include details of qualifications and experience of personnel who will carry out any testing functions and those who are capable of demonstrating their ability to make the necessary analytical technical judgements, and a thorough knowledge of the EMC Directive and the Regulations. Elements such as knowledge of the products and the TCF Route to compliance, technology involved, and the voluntary nature of standards must be considered.

- 3.5 A Competent Body shall have a Quality System, usually specified in a Quality Manual, and associated documented operational procedures. The Quality System shall ensure that all the relevant requirements of the appropriate standards and protection requirements of the Regulations are met.
- 3.6 A Competent Body shall pay due regard to any test reports included in the manufacturer's TCF. Although the Directive does not require testing as a mandatory requirement for Competent Body status, there may be occasions where test evidence is required in support of TCFs. Where a Competent Body operates its own testing facilities to undertake any additional testing requested by the manufacturer, these, and their associated activities, shall conform, or be equivalent, to the relevant requirements of EN45001 (General criteria for the operation of testing laboratories).
- 3.7 Where a Competent Body wishes to subcontract any additional testing requested by the manufacturer, the Quality Manual of the Competent Body shall describe the procedures to be followed by the Competent Body to ensure compliance by the subcontractors with the requirements and to demonstrate that the subcontractor is competent to carry out the task for which it has been engaged. Such competence will include, but is not limited to, the ability to conform fully to the requirements that are placed on the Competent Body itself in respect of the task contained within the subcontract. The Competent Body shall maintain documented procedures for the assessment and monitoring of subcontractors and the facilities used by them to carry out work packages on behalf of the Competent Body. The list shall form part of the Register specified in clause 3.8.
- 3.8 A Competent Body shall have fully documented agreements with its subcontractors. A Register of all subcontractors, which may be used by the Competent Body, shall be maintained; the Quality Manual will either contain the Register or shall state where the Register is to be found. The agreements and the Register shall be available for scrutiny at any reasonable time on request by the Secretary of State or such other person as may be appointed by the Secretary of State for that purpose.
- 3.9 A Competent Body shall at all times be responsible for ensuring the conformity assessment and the activities for which it is appointed are carried out in accordance with the requirements of the Regulations whether or not the competent body sub-contracts any testing.
- 3.10 A Competent Body will be required to inform both the Secretary of State and UKAS immediately of any changes within itself which, in any way, affect its ability to carry out the duties within the authorised scope to the declared procedures. This includes any changes in its status.
- 3.11 All manufacturers and importers of apparatus to which the EMC Regulations apply must have access to the services of a Competent Body. Competent Bodies shall not place undue financial or other conditions upon them. The procedures under which a Competent Body operates shall be administered in a non-discriminatory manner.

4. INTERNAL AUDIT AND PERIODIC REVIEW

- 4.1 The Competent Body shall undertake internal audits and management reviews as required by the particular EN45000 standard to which it is working or in accordance with the conditions of its appointment. Audits and reviews shall include checking compliance with the criteria for appointment as a Competent Body and checking that the certification process is correctly and effectively implemented.

5. MISUSE OF REPORTS AND OPINIONS

- 5.1 The Quality Manual shall state a Competent Body's policy and procedure for controlling the use of its reports and opinions.

6. MUTUAL RECOGNITION AGREEMENTS

- 6.1 Applicants should note that the European Community aims to reach Mutual Recognition Agreements (MRAs) with key trading partners. Under these agreements, European Community (EC) Competent Bodies may be eligible to perform conformity assessments as required by these key trading partners' laws and, similarly, those trading partners' equivalents to EC Competent Bodies may be eligible to perform conformity assessments under EC Directives. A Competent Body should inform the Department if it wishes to be considered for appointment under the MRAs.

7. SOURCES OF RELEVANT DOCUMENTS

- 7.1 Copies of the UK EMC Regulations may be obtained from:

The Stationery Office
Publications Centre
PO Box 276
London
SW8 5DT

Telephone Orders: 0870 600 5522
Fax Orders: 0171 873 8200

by ordering Statutory Instrument SI 1992/2372 "The Electromagnetic Compatibility Regulations".

- 7.2 Copies of the EMC Directive may be obtained from:

European Information Centres

by ordering Council Directive 89/336/EEC (Official Journal L139, 23.5.89) on the approximation of the laws of the Member States relating to electromagnetic compatibility.

7.3 Standards may be obtained from:

BSI Standards
389 Chiswick High Road
London
W4 4AL
Tel: 0181 996 7000
Fax 0181 996 7001

**CONFORMITY ASSESSMENT PROCEDURE
TECHNICAL CONSTRUCTION FILE ROUTE**

Part V of the UK EMC Regulations implementing Article 10(2) of the EMC Directive makes provision for a Technical Construction File “TCF” Route to compliance and for the appointment of Competent Bodies. The manufacturer compiles a TCF for the product(s) and submits it to a Competent Body to obtain a technical report or certificate.

The TCF route can be used to cover many instances, but is more often used in the following circumstances:

- For apparatus where there is no applicable European harmonised EMC standard.
- For apparatus where European harmonised standards exist but the manufacturer applied that standard in part only.
- For installations where testing to European harmonised standards is not practicable due to the physical properties (e.g. size, location) of the installations.
- For products where the testing of each individual product to European harmonised standards is not practicable due to the large number of similar product variants.
- For products having existing certification to EMC standards not recognised by the EC, but which are nevertheless regarded as indicating compliance with the protection requirements of the Directive.

BASIC REQUIREMENTS OF A TCF

Part I: Description of the apparatus

- i) identification of apparatus;
- ii) a technical description.

Part II: Procedures used to ensure conformity of the apparatus to the protection requirements:

- i) a technical rationale;
- ii) details of significant design elements;
- iii) test evidence where appropriate.

Part III A report or certificate from a Competent Body

It is envisaged that Parts I and II of the TCF will be written by the manufacturer in co-operation or consultation with the Competent Body. The report from the Competent Body should therefore not need to repeat much of the information contained in Parts I and II.

At the end of the report a detachable certificate will be supplied. This can be used by the manufacturer as an indicator of compliance where it is felt it would be inappropriate to submit the entire report. It is possible that where Parts I and II of the report are prepared by the manufacturer largely 'speak for themselves', the Competent Body might prepare a certificate only.

It should be emphasised that the manufacturer is ultimately responsible for the declaration of conformity of products certified via the TCF route. The role of the Competent Body is to certify by way of a technical report or technical certificate that apparatus conforms to the requirements of the EMC Directive (as implemented). In performing this role, the Competent Body must be presented, among other things, with the manufacturers draft TCF. It is the manufacturer's responsibility to ensure that the information provided in support of a report or certificate is correct and that subsequent production units are consistent with it.

**MINIMUM CRITERIA FOR THE ASSESSMENT OF UNITED KINGDOM
COMPETENT BODIES**

The criteria (being the criteria for the assessment of the bodies to be notified listed in Annex II of the EMC Directive and the criteria which competent bodies are required by Article 1.5 of that Directive to meet) which a person is required to meet to be eligible for appointment as a United Kingdom competent body are as follows⁴:

1. availability of personnel and of the necessary means and equipment;
2. technical competence and professional integrity of personnel;
3. independence, in carrying out the tests, preparing the reports, issuing the certificates and performing the verification function provided for in the EMC Directive, of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with the product in question;
4. maintenance of professional secrecy by personnel; and
5. possession of civil liability insurance unless such liability is covered by the government of the United Kingdom.

⁴ Schedule 5 of the UK EMC Regulations SI 1992/2372

COMPETENT BODY APPOINTMENT LETTER

Dear

**APPOINTMENT OF {NAME OF COMPANY} AS A COMPETENT BODY
UNDER REGULATION 46 OF THE ELECTROMAGNETIC
COMPATIBILITY REGULATIONS 1992 (S.I. 1992/2372)**

I am writing to inform you that the Secretary of State hereby appoints [**name of company**] (the Company) as a Competent Body under regulation 46 of the Electromagnetic Compatibility Regulations 1992 (S.I. 1992/2372) (the Regulations) which implement the provisions of Council Directive 89/336/EEC (the Directive) on electromagnetic compatibility subject to the conditions set out in this letter.

- I. The Company is appointed for the purposes of issuing technical reports and technical certificates, in relation to the following:

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

- II. This appointment shall remain in force until such time as it is withdrawn by the Secretary of State pursuant to clause 4 below or after the elapse of a period of 30 days after the Company has notified the Secretary of State in writing that it wishes the appointment to be terminated pursuant to clause 5 below.

- III. This appointment is subject to the following specific conditions:

- A. the Company shall at all times carry out the duties and functions of a Competent Body under regulations 45 and 50 of the Regulations to the satisfaction of the Secretary of State;
- B. the Secretary of State continues to be satisfied as to the Company's suitability - including its status and competence - to be a Competent 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;
- 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 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.

- 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 appointment;
- 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 being the criteria listed in Annex II of the Directive (which is set out in Appendix 1 to this letter);
- G. 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;
- H. the Company shall follow the relevant conformity assessment procedures as stated in regulation 45 of the Regulations (these are the procedures mentioned or referred to in Article 10(2) of the Directive);
- I. where the Company, in accordance with regulation 50(4) of the Regulations, is minded to refuse to issue a technical report or technical certificate it shall:
 - 1 give notice in writing to the applicant of the reasons why it is minded to do so; and
 - 2 give the applicant the opportunity of making representations within 28 days of the notice being given as to why it should not be refused and consider any representations which are made by that person within that period;
- J. the sub-contracting of work by the Competent Body, shall be subject to certain conditions guaranteeing:-
 - 1 the competence of the establishment operating as sub-contractor by meeting the relevant requirements of the [EN 45000 series] of standards; and
 - 2 its ability to exercise effective responsibility for the work carried out under sub-contract; and
 - 3 any other matter required in guidelines issued by the Secretary of State in respect of the sub-contracting of work.

In any case the Competent 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 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;
 - ii its premises for the purpose of verifying its compliance with the conditions with the minimum criteria.
- L. the Company shall take part in Competent 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 which have a bearing upon its status as a Competent Body or its ability to perform the duties and functions of a Competent 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:
1. 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;
 2. 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 appointment; 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;

- IV. This appointment shall be withdrawn forthwith in accordance with regulation 48 of the Regulations if it appears to the Secretary of State that the Company no longer meets the minimum criteria for appointment.
- V. This appointment shall be terminated in accordance with regulation 48 of the Regulations at the request of the Company upon 30 days' notice in writing to the Secretary of State.
- VI. This appointment is subject to the following additional conditions in the event of it being withdrawn 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 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;
 - 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.
- VII. 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.
- VIII. You should note that Competent Bodies are to be encouraged to apply the modules without unnecessary burdens for applicants.
- IX. 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.
- X. 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.

David Reed
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 Competent Body on the terms and conditions set out in this letter.

Signed.....
(duly authorised to sign in that behalf)

Name in Capitals.....

Position.....

Dated.....