
STATUTORY INSTRUMENTS

2005 No. 281

The Electromagnetic Compatibility Regulations 2005

PART V

THE TECHNICAL CONSTRUCTION FILE ROUTE TO COMPLIANCE

General

Application of Part V

- 43.** This Part shall have effect for the purposes of providing for—
- (a) the circumstances and manner in which the conformity assessment requirements may be complied with pursuant to the technical construction file route to compliance; and
 - (b) the appointment of United Kingdom competent bodies to exercise functions in relation thereto, and matters incidental to such appointment and exercise.

Applicability of the technical construction file route to compliance

44.—(1) Subject to paragraph (2) below, the conformity assessment requirements may be complied with pursuant to the technical construction file route to compliance where—

- (a) there are applicable EMC standards which make complete provision in respect of the apparatus, but the manufacturer has chosen not to apply all or any of those standards either as regards the whole or part thereof;
- (b) there is no applicable EMC standard; or
- (c) there are applicable EMC standards and the manufacturer has applied all or any of them as regards the whole or part thereof, but they do not make complete provision in respect of the apparatus.

(2) The technical construction file route to compliance shall not apply in respect of radiocommunication transmission apparatus.

Technical construction files

- 45.—(1)** A technical construction file is a file which—
- (a) describes the apparatus to which it relates;
 - (b) contains information about the design, manufacture and operation thereof;
 - (c) sets out the procedures used to ensure the conformity of the apparatus with the protection requirements in respect of the applicable EM characteristics of the apparatus in respect of which the manufacturer has not applied an applicable EMC standard; and
 - (d) includes a technical report or technical certificate.
- (2) A technical construction file may be composed in relation to—

- (a) a single item of apparatus;
 - (b) where a number of items are to be produced, a specimen representative of the production envisaged (a “representative”); or
 - (c) a number of items of apparatus or representatives of each such item or representative being variants of the same basic design (each such item or representative being referred to as a “variant”).
- (3) Without prejudice to the generality of paragraph (1) above, a technical construction file composed in the United Kingdom shall—
- (a) be in material form;
 - (b) be in—
 - (i) English where application for the technical report or technical certificate is made to a United Kingdom competent body; or
 - (ii) any official Community language acceptable to the competent body where such application is made to a competent body of another member State;
 - (c) give the name and address—
 - (i) of the responsible person;
 - (ii) where that person is not the manufacturer, of the manufacturer;
 - (d) contain such information as is sufficient, in all the circumstances of the case, to enable the enforcement authority to—
 - (i) identify the apparatus to which it relates; and
 - (ii) ascertain whether the apparatus to which it relates conforms with the protection requirements;
 - (e) state the numbers and titles of the applicable EMC standards, and any other standards, specifications or codes of practice, applied by the manufacturer; and
 - (f) contain particulars of the electromagnetic environment for which the apparatus is suitable.

The technical construction file route to compliance

46. The conformity assessment requirements are complied with in relation to relevant apparatus pursuant to the technical construction file route to compliance if the manufacturer or his authorised representative has composed a technical construction file in respect of the apparatus.

Competent bodies

47. For the purposes of these Regulations, a competent body is a body responsible for issuing technical reports and technical certificates pursuant to Article 10.2 of the EMC Directive either for all descriptions of relevant apparatus (other than radiocommunication transmission apparatus) or for specific descriptions thereof, and which is for the time being—

- (a) a United Kingdom competent body pursuant to appointment under regulation 48 below;
- (b) a competent body of a member State other than the United Kingdom; or
- (c) recognised for the purpose of carrying out those functions by inclusion in a mutual recognition agreement relating to the EMC Directive or a similar agreement (including a Protocol to the Europe Agreement, or other Agreement, on Conformity Assessment and Acceptance of Industrial Products) which has been concluded between the Community and a State other than an EEA State.

United Kingdom competent bodies

Appointment

48.—(1) Subject to regulation 49 below, the Secretary of State may appoint a person as a United Kingdom competent body in accordance with the following provisions of this regulation.

(2) An appointment under this regulation shall be in writing and shall, subject to regulations 50(5) and 51(3) below, be subject to such conditions as the Secretary of State may impose for the time being, and such conditions may include conditions which are to apply on or following the termination or expiry of the appointment.

(3) Subject to regulation 49(2) below, an appointment under this regulation shall have effect in respect of such descriptions of relevant apparatus as the Secretary of State may for the time being authorise, and in this Part, “authorised” shall be construed accordingly.

(4) In exercising the power conferred by paragraph (1) above, the Secretary of State may (in addition to the matters of which she is required to satisfy herself pursuant to regulation 49(2) below) have regard to any matter appearing to her to be relevant, and, without prejudice to the generality of the foregoing, she may have regard to any standards relating to the accreditation of laboratories or certification bodies appearing to her to be appropriate.

(5) Subject to regulation 50 below, an appointment under this regulation may be for—

- (a) the time being; or
- (b) such period as may be specified in the appointment.

(6) The Secretary of State shall from time to time publish lists of United Kingdom competent bodies indicating the descriptions of relevant apparatus in respect of which each body is authorised; and such lists may include information concerning any condition to which the appointment of any competent body is for the time being subject.

Eligibility and verification

49.—(1) Subject to paragraph (2) below, the following persons shall be eligible for appointment as United Kingdom competent bodies—

- (a) the Secretary of State; and
- (b) any person resident, incorporated, or carrying on a business in the United Kingdom.

(2) The criteria listed in Schedule 5 hereto (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) (“the minimum criteria”) must be satisfied in relation to any person if that person is to be appointed or remain a United Kingdom competent body, and accordingly the Secretary of State shall not—

- (a) make an appointment under regulation 48(1) above unless she is satisfied that the person concerned meets the minimum criteria; or
- (b) authorise under regulation 48(3) above the appointment to have effect in relation to any description of relevant apparatus unless she is satisfied that the body meets the minimum criteria in respect of that description of apparatus.

(3) The Secretary of State shall from time to time verify that each United Kingdom competent body meets the minimum criteria listed in paragraphs 1 and 2 of Schedule 5 hereto.

(4) A person who complies with the assessment criteria fixed by a standard which is a relevant harmonised standard within the meaning of Article 10.6 of the EMC Directive shall be presumed to meet the minimum criteria.

(5) An appointment under regulation 48 above may be subject to the condition that only a defined part of the undertaking of the appointed person may exercise the functions of a competent body, and where an appointment is, or is to be, subject to such a condition—

- (a) a reference in these Regulations to a person's meeting the minimum criteria shall be construed in relation to that person as a reference to the part of that person's undertaking so defined meeting those criteria; and
- (b) the conditions of the appointment shall include provision for ensuring that the confidentiality of confidential information held by the part of the undertaking so defined in pursuance of its function as a United Kingdom competent body is protected from disclosure to other parts of the undertaking.

(6) Upon the expiry of an appointment under regulation 48 above, the United Kingdom competent body shall be eligible for re-appointment.

Termination of appointment and transfer of functions

50.—(1) The Secretary of State, by notice in writing (a "notice of termination")—

- (a) shall terminate the appointment of a United Kingdom competent body where—
 - (i) the body so requests; or
 - (ii) it appears to the Secretary of State that—
 - (aa) the body no longer satisfies the minimum criteria; or
 - (bb) it is necessary in the interests of manufacturers, suppliers or end users of relevant apparatus to terminate the body's appointment; and
- (b) may terminate such appointment if the body is in breach of a condition of appointment.

(2) Where the Secretary of State exercises the power conferred by paragraph (1) above—

- (a) the notice of termination shall take effect on such date as shall be specified therein; and
- (b) the Secretary of State shall inform the appropriate authorities of the other member States and the Commission.

(3) Where the Secretary of State—

- (a) withdraws the authorisation of a United Kingdom competent body to exercise functions in relation to any description of apparatus pursuant to regulation 48(3) above; or
- (b) terminates the appointment of such a body pursuant to paragraph (1) of this regulation,

she may give such directions (either to the body the subject of the withdrawal or termination, as the case may be, or to another authorised United Kingdom competent body) for the purposes of making such arrangements for the determination of outstanding applications as she considers appropriate.

(4) Without prejudice to the generality of the power conferred by paragraph (3) above, such directions may include the manner in which fees already received pursuant to regulation 51 below in respect of outstanding applications by the body the subject of the withdrawal or termination, as the case may be, are to be disposed of, having regard to the work already done on such applications by that body.

(5) The Secretary of State shall, where she takes an action referred to in paragraph (3)(a) or (b) above in relation to a United Kingdom competent body, give such directions as she considers appropriate to provide for the exercise by another United Kingdom competent body or herself of the powers conferred by regulations 56(3) and 57 below exercisable by the first mentioned United Kingdom competent body, and where such directions have been given, a reference in those provisions to the United Kingdom competent body which issued a technical certificate or technical report shall be construed as a reference to that other United Kingdom competent body or to the Secretary of State, as the case may be.

Power of competent body other than the Secretary of State to charge fees

51.—(1) Without prejudice to the power of the Secretary of State, where she is a United Kingdom competent body, to charge fees pursuant to regulations made under section 56 of the Finance Act 1973 (1) and subject to paragraphs (2) and (3) below, a United Kingdom competent body other than the Secretary of State may charge applicants for technical reports or technical certificates such fees in connection with or incidental to the consideration of applications therefor as the body may determine; and such fees may include an amount on account of profit which is reasonable in the circumstances having regard to—

- (a) the character and extent of the work done or to be done by the body in the determination of such applications; and
- (b) the commercial rate normally charged on account of profit for that work or similar work.

(2) The power in paragraph (1) above includes power to require the payment of fees or a reasonable estimate thereof with the application.

(3) Without prejudice to the generality of regulation 48(2) above, the conditions to which an appointment under regulation 48(1) may be subject may include a requirement to publish from time to time the scale of fees which the United Kingdom competent body charges pursuant to this regulation, or such information about the basis of calculation thereof as may be specified in the condition.

Applications for technical reports and technical certificates

52.—(1) Subject to regulation 53 below, a United Kingdom competent body shall determine applications made thereto for the issue of technical reports and technical certificates in respect of relevant apparatus of authorised descriptions.

- (2) In determining such applications, the United Kingdom competent body—
- (a) shall have regard to the actual or usual electromagnetic environment of the apparatus; and
 - (b) may have regard to any standards (whether applicable EMC standards or otherwise) or other technical criteria appearing to it to be relevant.

(3) Where in the opinion of the United Kingdom competent body the apparatus to which an application relates conforms with the protection requirements, it shall issue a technical report or technical certificate, as the case may be, which complies with the requirements of regulation 55 below.

(4) Subject to regulation 58 below, where in the opinion of the United Kingdom competent body the apparatus to which the application relates does not conform with the protection requirements, it shall refuse to issue a technical report or technical certificate, as the case may be, giving written reasons for the refusal.

Limitations on duty to exercise functions

53.—(1) A United Kingdom competent body shall not accept any application for a technical report or technical certificate in respect of any apparatus unless the application—

- (a) is in writing;
- (b) is accompanied by a draft technical construction file, that is to say, a file containing such information as will, when the technical report or technical certificate as the case may be is added thereto, be sufficient to constitute the file as a technical construction file;

- (c) includes particulars of which applicable EMC standards the manufacturer has applied or proposes to apply in respect of the apparatus, and in respect of which applicable EM characteristics; and
 - (d) contains a declaration by the applicant that no application to another competent body for a technical report or technical certificate in respect of that apparatus is outstanding.
- (2) A United Kingdom competent body shall not be required to—
- (a) accept an application for a technical report or technical certificate where—
 - (i) the application, and the draft technical construction file, are not in English or another language acceptable to that body;
 - (ii) the applicant has not submitted with the application the amount of the fee which the competent body (not being the Secretary of State) requires to be submitted with the application pursuant to regulation 51(2) above; or
 - (iii) the body reasonably believes that, having regard to the number of applications for technical reports or technical certificates made to it which are outstanding, it will be unable to determine the application within three months of receiving the application;
 - (b) determine an application for a technical report or technical certificate where the manufacturer has not—
 - (i) granted the body access to the apparatus to which the application relates or the production facilities for the apparatus (including where applicable the production envisaged in relation to a representative) to the extent that the body reasonably requests; and
 - (ii) made available to the body such information as it may reasonably require to determine the application; or
 - (c) having determined the application, inform the applicant of the result thereof or, in the case of a successful application, issue the technical report or technical certificate, unless the applicant has paid any fees chargeable pursuant to regulation 51 above or in accordance with regulations made under section 56 of the Finance Act 1973, as the case may be.

Contractors etc.

54.—(1) Subject to paragraphs (2) and (3) below, a United Kingdom competent body may, in exercising its functions—

- (a) arrange for some other person to carry out any test, assessment or inspection on its behalf; or
- (b) require the applicant to satisfy another person with respect to any matter at the applicant's expense.

(2) Nothing in paragraph (1) above authorises a United Kingdom competent body to rely on the opinion of another person with regard to whether any relevant apparatus conforms with the protection requirements.

(3) Nothing in these Regulations shall preclude a person referred to in paragraph (1)(a) or (b) above from charging any fee in respect of any work undertaken by him in pursuance of those subparagraphs.

Form of technical reports and technical certificates

55. A technical report or technical certificate issued by a United Kingdom competent body shall be in writing and shall—

- (a) be in English;

- (b) give the name and address—
 - (i) of the applicant;
 - (ii) where that person is not the manufacturer, of the manufacturer;
- (c) be signed on behalf of the body and identify the signatory;
- (d) bear—
 - (i) the date of issue; and
 - (ii) the number of the report or certificate;
- (e) give particulars of the relevant apparatus (where applicable, in relation to each variant) to which it relates sufficient to identify it, and shall state whether the apparatus to which it relates is a single item or a representative, or a number of variants thereof, as the case may be;
- (f) certify that the apparatus to which it relates conforms with the protection requirements of the EMC Directive.

Conditions of technical reports or technical certificates

56.—(1) Subject to regulation 58 below and paragraphs (2) and (3) of this regulation, a technical report or technical certificate issued by a United Kingdom competent body may be unconditional or subject to such conditions, which must be complied with if the report or certificate as the case may be is to apply, as the body considers appropriate.

(2) Without prejudice to the generality of paragraph (1) above, such conditions may include—

- (a) a limitation on the electromagnetic environment for which the apparatus may be stated to be suitable; or
- (b) a limitation that the apparatus is only to be installed at a specific site.

(3) The conditions imposed pursuant to paragraph (1) above may be varied by the United Kingdom competent body which issued the technical report or technical certificate, and a variation under this paragraph may include the imposition of new conditions or the removal of conditions.

Withdrawal of technical reports or technical certificates

57.—(1) Subject to regulation 58 below and paragraph (2) of this regulation, the United Kingdom competent body which issued a technical report or technical certificate shall withdraw that report or certificate as the case may be if it appears that the apparatus to which it relates does not conform with the protection requirements.

(2) A withdrawal of a technical report or technical certificate shall be by notice in writing stating the reasons for the withdrawal.

Procedure where United Kingdom competent body is minded to make an unfavourable decision

58. Before making an unfavourable decision in respect of an applicant, that is to say—

- (a) refusing to grant a technical report or technical certificate pursuant to regulation 52(4) above;
- (b) the imposition of a condition of a technical report or technical certificate or the making of a restrictive variation of a condition thereof pursuant to regulation 56 above in circumstances where the applicant has not indicated in writing that the apparatus concerned is suitable for use subject to that condition;
- (c) the withdrawal of a technical report or technical certificate pursuant to regulation 57 above,

the United Kingdom competent body shall—

- (i) give notice in writing to the applicant, or holder of the technical report or technical certificate concerned, as the case may be (“the person concerned”), of the reasons why it proposes to make the unfavourable decision; and
- (ii) give the person concerned the opportunity of making representations within a period of 28 days of the notice being given as to why that body should make a favourable decision, and consider any representations which are made by that person within that period.

EC declaration of conformity

EC declaration of conformity where conformity assessment requirements are complied with by reference to a technical construction file

59.—(1) This regulation shall have effect for prescribing the form of an EC declaration of conformity issued in the United Kingdom in respect of relevant apparatus in relation to which the conformity assessment requirements have been complied with pursuant to the technical construction file route to compliance.

(2) An EC declaration of conformity to which this regulation applies shall—

- (a) be in English;
- (b) give the name and address—
 - (i) of the responsible person;
 - (ii) where that person is not the manufacturer, of the manufacturer;
- (c) be signed by or on behalf of the manufacturer or his authorised representative and identify that signatory;
- (d) bear the date of issue;
- (e) give particulars of the relevant apparatus to which it relates sufficient to identify it;
- (f) identify the technical construction file relating thereto, and give the name and address of the competent body which issued the technical report or technical certificate, and the date and any number thereof;
- (g) state the numbers and titles of the applicable EMC standards, if any, applied by the manufacturer; and
- (h) certify that the apparatus to which it relates conforms with the protection requirements of the EMC Directive.

Final provisions

Interpretation of Part V

60.—(1) In this Part—

- “authorised” in relation to any description of apparatus shall be construed in accordance with regulation 48(3);
- “minimum criteria” shall be construed in accordance with regulation 49(2);
- “representative” shall be construed in accordance with regulation 45(2)(b); and
- “variant” shall be construed in accordance with regulation 45(2)(c).

