

STATUTORY INSTRUMENTS

2016 No. 1091

The Electromagnetic Compatibility Regulations 2016

PART 4

[^{F1}Notification of conformity assessment bodies]

[^{F1}Approval of Conformity Assessment Bodies]

Textual Amendments

- F1** Pt. 4 substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/696), reg. 1, **Sch. 20 para. 28** (with Sch. 20 para. 33) (as amended by S.I. 2020/676, regs. 1(1), 2, and [The Product Safety and Metrology \(Amendment\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/852), regs. 2(2), 4(2), Sch. 1 para. 1(i), (**iv**)); 2020 c. 1, **Sch. 5 para. 1(1)**)

[^{F1}Approved bodies **E+W+S**]

- 43.**—(1) An approved body is a conformity assessment body which—
- (a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 44 (approval of conformity assessment bodies); or
 - (b) immediately before IP completion day was a notified body in respect of which the Secretary of State had taken no action under regulation 49(1) or (2) as they had effect immediately before IP completion day to suspend or withdraw the body's status as a notified body.
- (2) Paragraph (1) has effect subject to regulation 47 (restriction, suspension or withdrawal of approval).
- (3) In this Part—
- “notified body” means a body—
- (a) which the Secretary of State had before IP completion day notified to the European Commission and the member State of the European Union, in accordance with Article 20 of the Directive; and
 - (b) in respect of which no objections had been raised, as referred to in regulation 43(1)(b), as it had effect immediately before IP completion day;
- “approved body requirements” means the requirements set out in Schedule 5.]

Extent Information

- E1** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

Status: Point in time view as at 31/12/2020.

Changes to legislation: The Electromagnetic Compatibility Regulations 2016, PART 4 is up to date with all changes known to be in force on or before 22 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Notified bodies **N.I.**

- 43.**—(1) For the purposes of this Part, a notified body is a conformity assessment body—
- (a) which has been notified by the Secretary of State to the European Commission and to the other ^[F2]relevant states] —
 - (i) under regulation 44 (notification); or
 - (ii) before the date these Regulations come into force, in accordance with Article 20 of the Directive; and
 - (b) in respect of which no objections ^[F3], other than an immaterial objection,] were raised by the European Commission or other ^[F2]relevant states]—
 - (i) within 2 weeks of the date of notification, where the notification is accompanied by an accreditation certificate; or
 - (ii) within 2 months of the date of notification, where the notification is not accompanied by an accreditation ^[F4]certificate;]
 - ^[F5](c) in sub-paragraph (b), an “immaterial objection” is an objection on the grounds that—
 - (i) the conformity assessment body is established in the United Kingdom; or
 - (ii) the accreditation certificate was issued by the United Kingdom Accreditation Service.]
- (2) Paragraph (1) has effect subject to regulation 49 (changes to notifications).

Textual Amendments

- F2** Words in [reg. 43\(1\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1112), [reg. 1\(b\)](#), [Sch. 8 para. 4\(1\)\(a\)](#)
- F3** Words in [reg. 43\(1\)\(b\)](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1112), [reg. 1\(b\)](#), [Sch. 8 para. 4\(1\)\(b\)\(i\)](#)
- F4** Word in [reg. 43\(1\)\(b\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1112), [reg. 1\(b\)](#), [Sch. 8 para. 4\(1\)\(b\)\(ii\)](#)
- F5** [Reg. 43\(1\)\(c\)](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1112), [reg. 1\(b\)](#), [Sch. 8 para. 4\(1\)\(c\)](#)

^[F1]Approval of conformity assessment bodies **E+W+S**

44.—(1) The Secretary of State may approve only those conformity assessment bodies that qualify for approval.

(2) A conformity assessment body qualifies for approval if the first and second conditions below are met.

(3) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—

- (a) a description of—
 - (i) the conformity assessment activities that the conformity assessment body intends to carry out;
 - (ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

- (iii) the category of apparatus in respect of which the conformity assessment body claims to be competent; and
- (b) either—
 - (i) an accreditation certificate; or
 - (ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.
- (4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.
- (5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.
- (6) When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may—
 - (a) have regard to any other matter which appears to the Secretary of State to be relevant; and
 - (b) set conditions that the conformity assessment body must meet.
- (7) For the purposes of this regulation “accreditation certificate” means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.]

Extent Information

E2 This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

Notification **N.I.**

- 44.**—(1) The Secretary of State may notify to the European Commission and the other [^{F6}relevant states] only those conformity assessment bodies that qualify for notification.
- (2) A conformity assessment body qualifies for notification if the first and second conditions below are met.
- (3) The first condition is that the conformity assessment body has applied to the Secretary of State to become a notified body and the application is accompanied by—
- (a) a description of—
 - (i) the conformity assessment activities that the conformity assessment body intends to carry out;
 - (ii) the conformity assessment module or modules in respect of which the conformity assessment body claims to be competent; and
 - (iii) the apparatus for which the conformity assessment body claims to be competent; and either
 - (b) an accreditation certificate; or
 - (c) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the notified body requirements.
- (4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the notified body requirements.

Status: Point in time view as at 31/12/2020.

Changes to legislation: The Electromagnetic Compatibility Regulations 2016, PART 4 is up to date with all changes known to be in force on or before 22 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body meets the notified body requirements.

(6) When deciding whether to notify a conformity assessment body that qualifies for notification to the European Commission and the other [^{F6}relevant states], the Secretary of State may—

- (a) have regard to any other matter which appears to the Secretary of State to be relevant; and
- (b) set conditions that the conformity assessment body must meet.

(7) The Secretary of State must inform the European Commission of the United Kingdom's procedures for the assessment and notifications of conformity assessment bodies, and any changes to those procedures.

Textual Amendments

- F6** Words in [reg. 44](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 8 para. 4\(2\)](#)

[^{F1}Presumption of conformity of approved bodies **E+W+S**]

45.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.]

Extent Information

- E3** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

Contents of notification **N.I.**

45. A notification under regulation 44 (notification) must include—

- (a) the details of—
 - (i) the conformity assessment activities in respect of which the conformity assessment body has made its application for notification;
 - (ii) the conformity assessment module or modules in respect of which the conformity assessment body has made its application for notification;
 - (iii) the apparatus in respect of which the conformity assessment body has made its application for notification; and either
- (b) an accreditation certificate; or
- (c) documentary evidence which attests to—
 - (i) the conformity assessment body's competence; and
 - (ii) the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to satisfy the notified body requirements.

[F1] Monitoring E+W+S

46. The Secretary of State must monitor each approved body with a view to verifying that the body—

- (a) continues to meet the approved body requirements;
- (b) meets any conditions set—
 - (i) in accordance with regulation 44(6)(b); or
 - (ii) in the case of an approved body which was a notified body immediately before IP completion day, in accordance with regulation 44(6)(b) as it applied immediately before IP completion day; and
- (c) carries out its functions in accordance with these Regulations.]

Extent Information

E4 This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

Presumption of conformity of notified bodies N.I.

46.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a harmonised standard (or part of such a standard), the reference of which has been published in the Official Journal, the Secretary of State is to presume that the conformity assessment body meets the notified body requirements covered by that standard (or part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

[F1] Restriction, suspension or withdrawal of approval E+W+S

47.—(1) Where the Secretary of State determines that an approved body—

- (a) no longer meets an approved body requirement, or
- (b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 46(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 43 (approved bodies).

(2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 46(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 43.

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

- (a) give notice in writing to the approved body of the proposed action and the reasons for it;
- (b) give the approved body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and
- (c) consider any such representations made by the approved body.

(5) Where the Secretary of State has taken action in respect of an approved body under paragraph (1) or (2), or where an approved body has ceased its activity, the approved body must, at the request of the Secretary of State—

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- (a) transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State; or
 - (b) keep its files relating to the activities it has undertaken as an approved body available for the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.
- (6) The activities undertaken as an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.]

Extent Information

E5 This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

Monitoring of notified bodies **N.I.**

47.—(1) The Secretary of State must monitor each notified body with a view to verifying that the notified body—

- (a) continues to meet the notified body requirements;
- (b) meets any conditions set in accordance with regulation 44(6)(b); and
- (c) carries out its functions in accordance with these Regulations.

(2) The Secretary of State must inform the European Commission of the United Kingdom's procedures for the monitoring of notified bodies, and any changes to those procedures.

[^{F1}Operational matters in relation to approved bodies **E+W+S**

48.—(1) Subject to the terms of its appointment, an approved body must carry out the conformity assessment activities and procedures—

- (a) in respect of which the body's approval was given under regulation 44; or
- (b) in respect of which the body's notification as a notified body was made.

(2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 6.

(3) An approved body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body to issue a Type-examination certificate referred to in Schedule 3.]

Extent Information

E6 This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

United Kingdom Accreditation Service **N.I.**

48. The Secretary of State may authorise the United Kingdom Accreditation Service (a company limited by guarantee incorporated in England and Wales under number 03076190) to carry out the following activities on behalf of the Secretary of State—

- (a) assessing whether a conformity assessment body meets the notified body requirements; and

- (b) monitoring notified bodies as required by regulation 47 (monitoring of notified bodies).

[^{F1}Subsidiaries and contractors **E+W+S**

49.—(1) An approved body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

- (a) the body is satisfied that the subcontractor or subsidiary meets the approved body requirements;
- (b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements; and
- (c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

(2) The approved body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

(3) Where an approved body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the approved body must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documentation concerning—

- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
- (b) the conformity assessment activity carried out by the subcontractor or subsidiary.

(4) In this regulation “subsidiary” has the meaning given to it in section 1159 of the Companies Act 2006.]

Extent Information

E7 This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

Changes to notifications **N.I.**

49.—(1) Where the Secretary of State determines that a notified body no longer meets a notified body requirement, or that it is failing to fulfil its obligations under these Regulations other than a condition set in accordance with regulation 44(6)(b), the Secretary of State must restrict, suspend or withdraw the body's status as a notified body under regulation 43.

(2) With the consent of a notified body, or where the Secretary of State determines that a notified body no longer meets a condition set in accordance with regulation 44(6)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a notified body under regulation 43.

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

- (a) give notice in writing to the notified body that the Secretary of State intends to take such action and the reasons for it; and
- (b) give the notified body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice and consider any such representations.

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(5) Where the Secretary of State takes action under paragraph (1) or (2), the Secretary of State must immediately inform the Commission and the other ^[F7]relevant states].

(6) Where the Secretary of State has taken action in respect of a notified body under paragraph (1) or (2), or where a notified body has ceased its activity, the notified body must, at the request of the Secretary of State—

- (a) transfer its files relating to the activities it has undertaken as a notified body to another notified body or to the Secretary of State; or
- (b) keep its files relating to the activities it has undertaken as a notified body available for the Secretary of State and market surveillance authorities for a period of 10 years from the date on which the relevant document was created.

Textual Amendments

F7 Words in [reg. 49\(5\)](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 8 para. 4\(3\)](#)

^[F1]Register of approved bodies **E+W+S**

50.—(1) The Secretary of State must—

- (a) assign an approved body identification number to each approved body; and
- (b) compile and maintain a register of—
 - (i) approved bodies;
 - (ii) their approved body notification numbers;
 - (iii) the activities for which they have been approved; and
 - (iv) any restrictions on those activities.

(2) The register referred to in paragraph (1) must be made publicly available.]

Extent Information

E8 This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

Operational obligations of notified bodies **N.I.**

50. When a notified body carries out a relevant conformity assessment procedure, Schedule 6 has effect (operational obligations of notified bodies).

^[F1]UK national accreditation body **E+W+S**

51. The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

- (a) assessing whether a conformity assessment body meets the approved body requirements;
- (b) monitoring approved bodies in accordance with regulation 46; and
- (c) compiling and maintaining the register of approved bodies, in accordance with regulation 50.]

Extent Information

- E9** This version of this provision extends to England, Wales and Scotland only; a separate version has been created for Northern Ireland only

Subsidiaries and contractors **N.I.**

51.—(1) A notified body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

- (a) the body is satisfied that the subcontractor or subsidiary meets the notified body requirements;
- (b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements; and
- (c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

(2) The notified body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

(3) Where a notified body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the notified body must, for a period of at least 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all the relevant documentation concerning—

- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
- (b) the conformity assessment activities carried out by the subcontractor or subsidiary.

Status:

Point in time view as at 31/12/2020.

Changes to legislation:

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