

## STATUTORY INSTRUMENTS

# 2017 No. 1206

## The Radio Equipment Regulations 2017

### PART 4

#### [<sup>F1</sup>Notification of conformity assessment bodies][<sup>F1</sup>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. 29 para. 36** (with Sch. 29 para. 44) (as amended by [S.I. 2020/676](#), regs. 1(1), 2 and [S.I. 2020/852](#), regs. 2(2), 4(2), Sch. 1 para. 1(r)(iv)(v)); 2020 c. 1, Sch. 5 para. 1(1)

##### [<sup>F1</sup>Approved bodies **E+W+S**]

- 46.**—(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 47 (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 regulations 52(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 50 (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 States of the European Union, in accordance with Article 22 of the Directive; and
  - (b) in respect of which no objections had been raised, as referred to in regulation 46(1)(b) as it had effect immediately before IP completion day;
- “approved body requirements” means the requirements set out in Schedule 8.]

##### Extent Information

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

## Notified bodies **N.I.**

- 46.—(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 [<sup>F2</sup>relevant states]—
    - (i) under regulation 47 (notification), or
    - (ii) before the commencement date, in accordance with Article 22 of the Directive, and
  - (b) in respect of which no objections [<sup>F3</sup>, other than an immaterial objection,] are raised by the European Commission or other [<sup>F4</sup>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 [<sup>F5</sup>certificate;]
- [<sup>F6</sup>(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 52 (changes to notifications).

### Extent Information

- E10** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

### Textual Amendments

- F2** Words in reg. 46(1)(a) 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. 16 para. 5(1)(a)**
- F3** Words in reg. 46(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. 16 para. 5(1)(b)(i)**
- F4** Words in reg. 46(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. 16 para. 5(1)(b)(ii)**
- F5** Word in reg. 46(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. 16 para. 5(1)(b)(iii)**
- F6** Reg. 46(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. 16 para. 5(1)(c)**

## [<sup>F1</sup>Approval of conformity assessment bodies **E+W+S**

47.—(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 radio equipment 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 and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### **Notification** **N.I.**

**47.**—(1) The Secretary of State may notify to the European Commission and the other [F7 relevant states] only those conformity assessment bodies that qualify for notification.

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

(3) The first condition is that the conformity assessment body applied to the Secretary of State to become a notified body and that application was accompanied by—

- (a) a description of—
  - (i) the conformity assessment activities that the body intends to carry out,
  - (ii) the conformity assessment module or modules for which the body claims to be competent, and
  - (iii) the radio equipment for which the 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 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.

(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 [F7relevant 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 notification of conformity assessment bodies, and any changes to those procedures.

#### Extent Information

**E11** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### Textual Amendments

**F7** Words in reg. 47 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. 16 para. 5\(2\)](#)

### [F1Presumption of conformity of approved bodies **E+W+S**]

**48.**—(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 and Wales and Scotland only; a separate version has been created for Northern Ireland only

### Presumption of conformity of notified bodies **N.I.**

**48.**—(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 must 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.

**Extent Information**

**E12** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**[<sup>F1</sup>Monitoring E+W+S**

**49.** 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 47(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 47(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 and Wales and Scotland only; a separate version has been created for Northern Ireland only

**Contents of notification N.I.**

**49.** A notification under regulation 47 (notification) must include—

- (a) details of—
  - (i) the conformity assessment activities,
  - (ii) the conformity assessment module,
  - (iii) the radio equipment,

in respect of which the conformity assessment body has been approved by the Secretary of State for notification, and

- (b) either—
  - (i) an accreditation certificate, where the notification is based on the accreditation, or
  - (ii) documentary evidence which attests to the conformity assessment body's competence, and to the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to meet the notified body requirements.

**Extent Information**

**E13** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**[<sup>F1</sup>Restriction, suspension or withdrawal of approval E+W+S**

**50.—(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 49(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 46 (approved bodies).

(2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 49(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 46.

(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—

- (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.]

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#### **Extent Information**

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

#### **Monitoring** **N.I.**

**50.**—(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 47(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.

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#### **Extent Information**

- E14** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**[<sup>F1</sup>Operational matters in relation to approved bodies E+W+S**

**51.**—(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 47; or
- (b) in respect of which 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 9.

(3) An approved body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body—

- (a) to issue a Type-examination certificate referred to in Schedule 3; or
- (b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 44(5) (UK marking).]

**Extent Information**

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

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

**51.** 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,
- (b) monitoring notified bodies in accordance with regulation 50 (monitoring).

**Extent Information**

**E15** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**[<sup>F1</sup>Subsidiaries and contractors E+W+S**

**52.**—(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 and Wales and Scotland only; a separate version has been created for Northern Ireland only

#### Changes to notifications **N.I.**

**52.**—(1) The Secretary of State must restrict, suspend or withdraw a notified body's status as a notified body under regulation 46 where the Secretary of State determines that the body—

- (a) no longer meets a notified body requirement, or
- (b) is failing to fulfil its obligations under these Regulations, other than a condition set in accordance with regulation 47(6)(b).

(2) The Secretary of State may restrict, suspend or withdraw the notified body's status as a notified body under regulation 46—

- (a) with the consent of a notified body, or
- (b) where the Secretary of State determines that a notified body no longer meets a condition set in accordance with regulation 47(6)(b).

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

(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 taking such action, and
- (b) give the notified body an opportunity to make representations within a reasonable period from the date of that notice and consider any such representations.

(5) Where the Secretary of State takes action under paragraph (1) or (2), the Secretary of State must immediately inform the European Commission and the other [<sup>F8</sup>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 body must—

- (a) as directed by the Secretary of State, 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 the documents relating to the activities it has undertaken as a notified body available for the Secretary of State and the enforcing authority for a period of 10 years from the date on which the product to which the document relates was placed on the market.

#### Extent Information

- E16** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only



#### Textual Amendments

- F8** Words in reg. 52(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. 16 para. 5\(3\)](#)

#### [<sup>F1</sup>Register of approved bodies **E+W+S**

- 53.**—(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 identification 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 and Wales and Scotland only; a separate version has been created for Northern Ireland only

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

**53.** When a notified body carries out a relevant conformity assessment procedure, Schedule 9 (operational obligations of notified bodies) has effect.

#### Extent Information

- E17** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

#### [<sup>F1</sup>UK national accreditation body **E+W+S**

**54.** 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 49; and
- (c) compiling and maintaining the register of approved bodies, in accordance with regulation 53.]

#### Extent Information

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

## Subsidiaries and contractors **N.I.**

**54.**—(1) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the activities are only to be treated as having been carried out by a notified body for the purposes of regulation 41 (conformity assessment procedures) where the conditions in paragraphs (2) and (3) are met.

(2) The notified body must—

- (a) ensure that the subcontractor or subsidiary satisfies the notified body requirements, and
- (b) inform the Secretary of State accordingly.

(3) The notified body must have obtained the agreement of the client to the use of a subcontractor or subsidiary.

(4) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the notified body must for a period of at least 10 years beginning on the day on which the activities are 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 under Schedule 3 (conformity assessment modules B and C) or Schedule 4 (conformity assessment module H).

(5) When monitoring a notified body in accordance with regulation 50, the Secretary of State must treat the notified body as responsible for the activities performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.

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### **Extent Information**

**E18** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**Changes to legislation:**

There are currently no known outstanding effects for the The Radio Equipment Regulations 2017, PART 4.