
STATUTORY INSTRUMENTS

2017 No. 1206

The Radio Equipment Regulations 2017

PART 4

Notification of conformity assessment bodies

Notified bodies

- 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 Member 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 are raised by the European Commission or other Member 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 certificate.
- (2) Paragraph (1) has effect subject to regulation 52 (changes to notifications).

Notification

- 47.**—(1) The Secretary of State may notify to the European Commission and the other Member 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 Member 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.

Presumption of conformity of notified bodies

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.

Contents of notification

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.

Monitoring

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.

United Kingdom Accreditation Service

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).

Changes to notifications

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 Member 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.

Operational obligations of notified bodies

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

Subsidiaries and contractors

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.