
STATUTORY INSTRUMENTS

2016 No. 1091

The Electromagnetic Compatibility Regulations 2016

PART 4

Notification of conformity assessment bodies

Notified bodies

- 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 member 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 were 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 49 (changes to notifications).

Notification

- 44.**—(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 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.
- (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 notifications of conformity assessment bodies, and any changes to those procedures.

Contents of notification

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.

Presumption of conformity of notified bodies

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.

Monitoring of notified bodies

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.

United Kingdom Accreditation Service

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).

Changes to notifications

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.

(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 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 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.

Operational obligations of notified bodies

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

Subsidiaries and contractors

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.