
STATUTORY INSTRUMENTS

2016 No. 1107

**The Equipment and Protective Systems Intended for Use
in Potentially Explosive Atmospheres Regulations 2016**

PART 4

Notification of conformity assessment bodies

Notified Bodies

- 42.**—(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, the other Member States and Northern Ireland—
 - (i) under regulation 44 (notification), or
 - (ii) before the commencement date, in accordance with Article 17 of the ATEX Directive, and
 - (b) in respect of which no objections are raised by the European Commission or other Member States—
 - (i) within two weeks of the date of notification, where the notification is accompanied by an accreditation certificate, or
 - (ii) within two months of the date of notification, where the notification is not accompanied by an accreditation certificate.
- (2) Paragraph (1) has effect subject to regulation 48 (changes to notifications).

Presumption of conformity of notified bodies

43.—(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.

Notification

44.—(1) The Secretary of State may notify to the European Commission, the other Member States and Northern Ireland only those conformity assessment bodies established within Great Britain 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 makes an application to the Secretary of State for notification 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 module for which the conformity assessment body claims to be competent, and
 - (iii) the product 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 fulfils the notified body requirements.
- (6) When deciding whether to notify a conformity assessment body that qualifies for notification to the European Commission, the other Member States and Northern Ireland, 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 Great Britain's procedures for the assessment and notification of conformity assessment bodies and of 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, and
 - (iii) the product 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 meet the notified body requirements.

Monitoring

- 46.—**(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 of any changes to those procedures.

United Kingdom Accreditation Service

47. 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 46 (monitoring).

Changes to notifications

48.—(1) Where the Secretary of State determines that a notified body no longer meets a notified body requirement, or is failing to fulfil its obligations under these Regulations other than conditions 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 42.

(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 42.

(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) Where the Secretary of State takes action under paragraph (1) or (2), the Secretary of State must immediately inform the European Commission, the other Member States and Northern Ireland.

(5) 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—

- (a) at the request of 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) in the absence of a request under sub-paragraph (a), keep its files relating to the activities it has undertaken as a notified body available for inspection by the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.

Operational obligations of notified bodies

49. When a notified body carries out a relevant conformity assessment procedure, Schedule 3 (operational obligations of notified bodies) has effect.

Subsidiaries and contractors

50.—(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 39 (conformity assessment procedures) where the conditions in paragraphs (2) and (3) are satisfied.

(2) The notified body must—

- (a) ensure that the subcontractor or subsidiary meets 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 the 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.

(5) When monitoring a notified body in accordance with regulation 46, the Secretary of State must treat the notified body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.