

STATUTORY INSTRUMENTS

2016 No. 1107

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

[^{F1}PART 4

Approval of Conformity Assessment Bodies

Textual Amendments

- F1** Pt. 4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 25 para. 27** (with [Sch. 25 para. 34](#)) (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(n)(iv)(v)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Approved bodies

- 42.**—(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 43 (approval of conformity assessment bodies); or
 - (b) immediately before IP completion day was a notified body in respect of which the Secretary of State has taken no action under regulation 48(1) or (2) as it had effect immediately before IP completion day to restrict, suspend or withdraw the body's status as a notified body.
- (2) Paragraph (1) has effect subject to regulation 46 (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 17 of the ATEX Directive; and
 - (b) in respect of which no objections had been raised as referred to in regulation 42(1)(b) as it had effect immediately before IP completion day.
- “approved body requirements” means the requirements set out in Schedule 2.

Approval of conformity assessment bodies

- 43.**—(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 products 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 applies 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.

Presumption of conformity of approved bodies

44.—(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 part of that standard).

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

Monitoring

45. 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 43(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 43(6)(b) as it applied immediately before IP completion day; and
- (c) carries out its functions in accordance with these Regulations.

Restriction, suspension or withdrawal of approval

46.—(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 45(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 42 (approved bodies).

(2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 45(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved 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) 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 by an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.

Operational matters in relation to approved bodies

47.—(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 43, 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 3.

(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 Part 1 of Schedule 3B;
- (b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 41 (UK marking).

Subsidiaries and contractors

48.—(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 meet the approved body requirements;
 - (b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meet 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 documents 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;

Register of approved bodies

- 49.**—(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.

UK national accreditation body

- 50.** 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 45; and
 - (c) compiling and maintaining the register of approved bodies, in accordance with regulation 49.]

Changes to legislation:

There are currently no known outstanding effects for the The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016, PART 4.