

## SCHEDULE 24

### Amendment of the Pressure Equipment (Safety) Regulations 2016

#### **Substitution of Part 4**

35. For Part 4 substitute—

### “PART 4

#### Approval of Conformity Assessment Bodies

##### **Approved bodies**

51.—(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 54 (approval of conformity assessment bodies); or
- (b) immediately before exit day was a notified body in respect of which the Secretary of State has taken no action under regulation 62(1) or (2) as they had effect immediately before exit day to suspend or withdraw the body’s status as a notified body.

(2) Paragraph (1) has effect subject to regulation 60 (restriction, suspension or withdrawal of approval).

(3) In this Part—

“notified body” means a body—

- (a) which the Secretary of State had before exit day notified to the European Commission and the member States of the European Union as a notified body, in accordance with Article 20 of the Directive; and
- (b) in respect of which no objections had been raised, as referred to in regulation 51(1)(b), as it had effect immediately before exit day;

“approved body requirements” means the requirements set out in Schedule 4;

“product” means pressure equipment or assemblies;

“accreditation certificate” means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.

##### **Recognised third party organisations**

52.—(1) A recognised third party organisation is a conformity assessment body which—

- (a) has been approved by the Secretary of State to be a recognised third party organisation, under regulation 54 (approval of conformity assessment bodies); or
- (b) immediately before exit day—
  - (i) was a conformity assessment body which the Secretary of State had before exit day notified to the European Commission and the member States of the European Union as a recognised third party organisation, in accordance with Article 20 of the Directive;
  - (ii) in respect of which no objections had been raised, as referred to in regulation 52(1)(b), as it had effect immediately before exit day; and

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(iii) in respect of which the Secretary of State had taken no action under regulation 62(1) or (2), as they had effect immediately before exit day to suspend or withdraw the body's status as a recognised third party organisation.

(2) Paragraph (1) has effect subject to regulation 60 (restriction, suspension or withdrawal of approval).

### **User inspectorates**

**53.**—(1) A user inspectorate is a conformity assessment body which—

(a) has been approved as a user inspectorate by the Secretary of State under regulation 54 (approval of conformity assessment bodies); or

(b) immediately before exit day—

(i) was a conformity assessment body which the Secretary of State had before exit day notified to the European Commission and the member States of the European Union as a user inspectorate, in accordance with Article 20 of the Directive;

(ii) in respect of which no objections had been raised, as referred to in regulation 53(1)(b), as it had effect immediately before exit day; and

(iii) in respect of which the Secretary of State had taken no action under regulation 62(1) or (2), as they had effect immediately before exit day, to suspend or withdraw the body's status as a recognised third party organisation.

(2) Paragraph (1) has effect subject to regulation 61 (restriction, suspension or withdrawal of approval (user inspectorates)).

### **Approval of conformity assessment bodies**

**54.**—(1) The Secretary of State may approve only those conformity assessment bodies which—

(a) qualify for approval as an approved body in accordance with regulation 55;

(b) qualify for approval as a recognised third party organisation in accordance with regulation 56; or

(c) qualify for approval as a user inspectorate in accordance with regulation 57.

(2) 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.

### **Approval of approved bodies**

**55.**—(1) A conformity assessment body qualifies for approval as an approved body if the first and second conditions below are met.

(2) 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.

(3) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(4) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

#### **Approval of recognised third party organisations**

**56.**—(1) A conformity assessment body qualifies for approval as a recognised third party organisation if the conditions in paragraphs (2), (3) and (4) are met.

(2) The first condition is that the conformity assessment body has applied to the Secretary of State to become a recognised third party organisation 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.

(3) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(4) The third condition is that the conformity assessment body must carry out approvals of only those activities referred to in paragraphs 21 and 22 of Schedule 2 (permanent joining and non-destructive tests).

(5) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

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### **Approval of user inspectorates**

**57.**—(1) A conformity assessment body qualifies for approval as a user inspectorate if the conditions in paragraphs (2) to (7) are met.

(2) The conformity assessment body must apply to the Secretary of State to become a user inspectorate and that application must be 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 user inspectorate requirements.

(3) The Secretary of State must be satisfied that the conformity assessment body meets the user inspectorate requirements.

(4) The conformity assessment procedures which a user inspectorate may carry out are modules A2, C2, F and G, set out in Part 2, Part 4, Part 9 and Part 10 of Schedule 1A respectively.

(5) The group of which the user inspectorate is part must apply a common safety policy as regards the technical specifications for the design, manufacture, inspection, maintenance and use of products.

(6) The user inspectorate must act exclusively for the group of which it is part.

(7) Where the conformity of a product has been assessed by a user inspectorate, that product may only be used in establishments operated by the group of which the user inspectorate is part.

(8) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the user inspectorate requirements.

### **Presumption of conformity of conformity assessment bodies**

**58.**—(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 or the user inspectorate requirements (as the case may be) covered by that standard (or part of that standard).

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

### **Monitoring**

**59.** The Secretary of State must monitor each approved body, recognised third party organisation and user inspectorate with a view to verifying that the body—

- (a) continues to meet the approved body requirements or user inspectorate requirements, as applicable;
- (b) meets any conditions set—
  - (i) in accordance with regulation 54(2)(b), or
  - (ii) in the case of—
    - (aa) an approved body which was a notified body immediately before exit day;
    - (bb) a recognised third party organisation falling within regulation 52(1)(b); or
    - (cc) a user inspectorate falling within regulations 53(1)(b);in accordance with regulation 55(2)(b) as it applied immediately before exit day; and
- (c) carries out its functions in accordance with these Regulations.

**Restriction, suspension or withdrawal of approval (approved bodies and recognised third party organisations)**

**60.**—(1) Where the Secretary of State determines that an approved body or a recognised third party organisation—

- (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 59(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body or a recognised third party organisation under regulation 51 or 52 (as the case may be).

(2) Where the Secretary of State determines that an approved body or a recognised third party organisation no longer meets a condition referred to in regulation 59(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body or a recognised third party organisation under regulation 51 or 52 (as the case may be).

(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 or recognised third party organisation of the proposed action and the reasons for it;
- (b) give the approved body or recognised third party organisation 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 or recognised third party organisation.

(5) Where the Secretary of State has taken action in respect of an approved body or recognised third party organisation under paragraph (1) or (2), or where an approved body or recognised third party organisation has ceased its activity, the approved body or recognised third party organisation must, at the request of the Secretary of State—

- (a) transfer its files relating to the activities it has undertaken as an approved body or recognised third party organisation to another approved body or recognised third party organisation or to the Secretary of State, or

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- (b) keep its files relating to the activities it has undertaken as an approved body or recognised third party organisation 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.

#### **Restriction, suspension or withdrawal of approval (user inspectorates)**

**61.**—(1) Where the Secretary of State determines that a user inspectorate—

- (a) no longer meets a user inspectorate requirement, or
- (b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 59(b),

the Secretary of State must restrict, suspend or withdraw the body's status as a user inspectorate under regulation 53.

(2) Where the Secretary of State determines that a user inspectorate no longer meets a condition referred to in regulation 59(b), the Secretary of State may restrict, suspend or withdraw the body's status as a user inspectorate under regulation 53.

(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 user inspectorate of the proposed action and the reasons for it;
- (b) give the user inspectorate 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 user inspectorate.

(5) Where the Secretary of State has taken action in respect of a user inspectorate under paragraph (1) or (2), or where a user inspectorate has ceased its activity, the user inspectorate must at the request of the Secretary of State—

- (a) transfer its files relating to the activities it has undertaken as a user inspectorate to an approved body, a recognised third party organisation or to the Secretary of State, or
- (b) keep its files relating to the activities it has undertaken as a user inspectorate available for the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.

#### **Operational matters in relation to approved bodies, recognised third party organisations and user inspectorates**

**62.**—(1) Subject to the terms of its appointment, an approved body, recognised third party organisation or user inspectorate must carry out the conformity assessment activities and procedures—

- (a) in respect of which the body's approval was given under regulation 55, 56 or 57 (as the case may be); or
- (b) in respect of which the body's notification to the European Commission was made as a notified body, a recognised third party organisation or a user inspectorate (as the case may be).

(2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 6.

(3) An approved conformity assessment 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 1A, or
- (b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 49 (UK marking), where applicable.

### **Subsidiaries and contractors**

**63.**—(1) An approved body, recognised third party organisation or user inspectorate may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

- (a) the body, organisation or inspectorate is satisfied that the subcontractor or subsidiary meets the approved body requirements or user inspectorate requirements, as applicable;
- (b) the body, organisation or inspectorate 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, recognised third party organisation or user inspectorate 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, recognised third party organisation or user inspectorate subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the body, organisation or inspectorate 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<sup>(1)</sup>.

### **Register of approved bodies**

**64.**—(1) The Secretary of State must—

- (a) assign—
  - (i) an approved body identification number to each approved body;
  - (ii) a recognised third party organisation identification number to each third party organisation;
  - (iii) a user inspectorate identification number to each user inspectorate; and
- (b) compile and maintain a register of—
  - (i) approved bodies, recognised third party organisations and user inspectorates;

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- (ii) their 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.

**United Kingdom Accreditation Service**

**65.** The Secretary of State may authorise the United Kingdom Accreditation Service 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 or user inspectorate requirements (as applicable);
- (b) monitoring approved bodies, recognised third party organisations and user inspectorates in accordance with regulation 59; and
- (c) compiling and maintaining the register of approved bodies, recognised third party organisations and user inspectorates, in accordance with regulation 64.”.