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STATUTORY INSTRUMENTS

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**2016 No. 1105**

**The Pressure Equipment (Safety) Regulations 2016**

**PART 4**

**Notification of conformity assessment bodies**

**Notified bodies**

**51.**—(1) For the purposes of these Regulations, a notified body is a conformity assessment body—

- (a) which has been notified by the Secretary of State to the Commission and to other Member States as a notified body—
  - (i) under regulation 55 (notification); or
  - (ii) before the date these Regulations come into force, in accordance with Article 21 of the Directive; and
- (b) in respect of which no objection has been raised by the 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 notification, where the notification is not accompanied by an accreditation certificate.

(2) Paragraph (1) has effect subject to regulation 62 (changes to notifications).

**Recognised third party organisations**

**52.**—(1) For the purposes of these Regulations, a recognised third party organisation is a conformity assessment body—

- (a) which has been notified to the Commission and the other Member States by the Secretary of State as a recognised third party organisation—
  - (i) under regulation 55 (notification); or
  - (ii) before the date these Regulations come into force, in accordance with Article 21 of the Directive; and
- (b) in respect of which no objection has been raised by the Commission or other Member States—
  - (i) within two weeks of a notification, where the notification is accompanied by an accreditation certificate; or
  - (ii) within two months of a notification, where the notification is not accompanied by an accreditation certificate.

(2) Paragraph (1) has effect subject to regulation 62 (changes to notifications).

### **User inspectorates**

**53.**—(1) For the purposes of these regulations, a user inspectorate is a conformity assessment body—

- (a) which has been notified by the Secretary of State to the Commission and the other Member States as a user inspectorate—
  - (i) under regulation 55 (notification); or
  - (ii) before the date these Regulations come into force, in accordance with Article 21 of the Directive (as amended from time to time); and
- (b) in respect of which no objection has been raised by the European Commission or other Member States—
  - (i) within two weeks of a notification, where the notification is accompanied by an accreditation certificate; or
  - (ii) within two months of a notification, where the notification is not accompanied by an accreditation certificate.

(2) Paragraph (1) has effect subject to regulation 62 (changes to notifications).

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

**54.**—(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 or 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.

### **Notification**

**55.**—(1) The Secretary of State may notify to the European Commission and the other member States only those conformity assessment bodies which—

- (a) qualify for notification as a notified body in accordance with regulation 56;
- (b) qualify for notification as a recognised third party organisation in accordance with regulation 57; or
- (c) qualify for notification as a user inspectorate in accordance with regulation 58.

(2) When deciding whether to notify a conformity assessment body 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.

(3) 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.

**56.**—(1) A conformity assessment body qualifies for notification as a notified body if the conditions in paragraphs (2) and (3) below are met.

(2) The first condition is the conformity assessment body has made an application to the Secretary of State for notification as 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 modules for which the conformity assessment body claims to be competent; and
  - (iii) the pressure equipment or assemblies 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.

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

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

(2) The first condition is that the conformity assessment body has made an application to the Secretary of State for notification as 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 modules for which the conformity assessment body claims to be competent; and
  - (iii) the pressure equipment or assemblies 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.

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

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

(2) The conformity assessment body must make an application to the Secretary of State for notification as 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 modules for which the conformity assessment body claims to be competent; and
  - (iii) the pressure equipment or assemblies for which the conformity assessment body claims to be competent;
  - (iv) a list of the establishments satisfying the requirement in paragraph (7); and either—
- (b) an accreditation certificate; or
- (c) 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 referred to in Annex III to the Directive (as amended from time to time).
- (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 pressure equipment and assemblies.
- (6) The user inspectorate must act exclusively for the group of which it is part.
- (7) Pressure equipment or assemblies, the conformity of which has been assessed by a user inspectorate, may be used only 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.

### **Contents of notification**

**59.** A notification under regulation 55 must include—

- (a) 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 modules in respect of which the conformity assessment body has made its application for notification;
  - (iii) the pressure equipment in respect of which the conformity assessment body has made its application for notification; and
  - (iv) where the notification relates to a user inspectorate, a list of the establishments satisfying the requirement in regulation 58(7) in relation to that user inspectorate; 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 or the user inspectorate requirements, as the case may be.

## **Monitoring**

**60.**—(1) The Secretary of State must monitor each notified body, recognised third party organisation and user inspectorate with a view to verifying that the notified body, recognised third party organisation or user inspectorate—

- (a) continues to meet the notified body requirements or user inspectorate requirements, as applicable;
- (b) meets any conditions set in accordance with regulation 55(2)(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, recognised third party organisations and user inspectorates, and any changes to those procedures.

## **United Kingdom Accreditation Service**

**61.** 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 or the user inspectorate requirements, as applicable; and
- (b) monitoring notified bodies, recognised third party organisations and user inspectorates in accordance with regulation 60 (monitoring).

## **Changes to notifications**

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

- (a) no longer meets a notified body requirement, or
- (b) is failing to fulfil any of its obligations under these Regulations other than conditions set in accordance with regulation 55(2)(b),

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

(2) With the consent of the notified body or recognised third party organisation, or where the Secretary of State determines that a notified body or recognised third party organisation no longer meets a condition set in accordance with regulation 55(2)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a notified body or recognised third party organisation under regulation 51 or 52, as the case may be.

(3) In deciding what action is required under paragraph (1), 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 that the Secretary of State intends to take such action and the reasons for taking such action; and
- (b) give the notified body or recognised third party organisation 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 Commission and the other member States.

(6) Where the Secretary of State has taken action in respect of a notified body or recognised third party organisation under paragraph (1) or (2), or where a notified body or recognised third party organisation has ceased its activity, the body must—

- (a) on the request of the Secretary of State, transfer its files relating to the activities it has undertaken as a notified body or recognised third party organisation to another notified body or recognised third party organisation or to the Secretary of State; or
- (b) in the absence of a request under sub-paragraph (a), ensure that its files relating to the activities it has undertaken as a notified body or recognised third party organisation are kept available for inspection by the Secretary of State and enforcing authorities for a period of 10 years from the date they were created.

**63.**—(1) Where the Secretary of State determines that a user inspectorate no longer meets the user inspectorate requirements, or that it is failing to fulfil its obligations under these Regulations, the Secretary of State must restrict, suspend or withdraw that body's status as a user inspectorate under regulation 53.

(2) Where the Secretary of State determines that a user inspectorate no longer meets any conditions set in accordance with regulation 55(2)(b), the Secretary of State may restrict, suspend or withdraw that 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 failure.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

- (a) give notice in writing that the Secretary of State intends to take such action and the reasons for taking such action; and
- (b) give the user inspectorate 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 Commission and the other member States.

(6) Where the Secretary of State has taken action under paragraph (1) or (2), or where the user inspectorate has ceased its activity, the body must—

- (a) on the request of the Secretary of State, transfer its files relating to the activities it has undertaken as a user inspectorate to another notified body or recognised third party organisation or to the Secretary of State; or
- (b) in the absence of a request under sub-paragraph (a), ensure that its files relating to the activities it has undertaken as a user inspectorate are kept available for the Secretary of State and enforcing authorities for a period of 10 years from the date they were created.

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

**64.**—(1) When a conformity assessment body carries out a relevant conformity assessment procedure, it must do so in accordance with Schedule 6 (operational obligations of notified bodies, recognised third parties and user inspectorates).

(2) A notified body must make provision for a manufacturer to be able to appeal against a refusal by the body—

- (a) to issue an EU-type examination certificate in relation to a conformity assessment procedure; or
- (b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 49 (CE marking).

### **Subsidiaries and contractors**

65.—(1) Where a notified body, recognised third party organisation or user inspectorate 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, recognised third party organisation or user inspectorate for the purposes of regulation 41 (conformity assessment procedures) where the conditions in paragraphs (2) and (3) are met.

(2) The notified body, recognised third party organisation or user inspectorate must—

- (a) ensure that the subcontractor or subsidiary meets the notified body requirements or user inspectorate requirements, as applicable; and
- (b) inform the Secretary of State accordingly.

(3) The notified body, recognised third party organisation or user inspectorate must have obtained the agreement of the client to the use of a subcontractor or subsidiary.

(4) Where a notified body, recognised third party organisation or user inspectorate subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the notified body, recognised third party organisation or user inspectorate must for a period of 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, recognised third party organisation or user inspectorate in accordance with regulation 60, the Secretary of State must treat the notified body, recognised third party organisation or user inspectorate as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.