

## SCHEDULE 26

### Amendment of the Non-automatic Weighing Instruments Regulations 2016

#### **Amendment to Part 5**

**32.** For Part 5, substitute—

### “PART 5

#### APPROVAL OF CONFORMITY ASSESSMENT BODIES

##### **Approved bodies**

**47.**—(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 48 (approval of conformity assessment bodies); or
- (b) immediately before exit day was a notified body in respect of which the Secretary of State had taken no action under regulation 54(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 51 (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 State of the European Union, in accordance with Article 27 of the Directive; and
- (b) in respect of which no objections had been raised, as referred to in regulation 47(2)(b), as it had effect immediately before exit day;

“approved body requirements” means the requirements set out in Schedule 3.

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

**48.**—(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 class of regulated non-automatic weighing instruments in respect of which the conformity assessment body claims to be competent; and

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(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)(i), as sufficient evidence that the conformity assessment body meets the approved body requirements.

(6) 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.

(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**

**49.**—(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 that part of that standard).

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

### **Monitoring**

**50.** 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 48(6)(b); or

(ii) in the case of an approved body which was a notified body immediately before exit day, in accordance with regulation 48(6)(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**

**51.**—(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 50(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 48 (approval of conformity assessment bodies).

(2) With the consent of an approved body, or where the Secretary of State determines that an approved body no longer meets a condition in accordance with regulation 50(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 48 (approval of conformity assessment bodies).

(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 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 that 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—

- (a) on the request of the Secretary of State, transfer its files to another approved body 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 an approved body are kept available for the Secretary of State and competent authorities for a period of 10 years from the date they were created.

(6) The activities undertaken as an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.

(7) The Secretary of State may impose a monetary penalty on an approved body that fails to comply with any requirement imposed by or under paragraph (5).

(8) Schedule 5 has effect in relation to monetary penalties imposed under paragraph (7).

### **Subsidiaries and contractors**

**52.—**(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 meets the approved 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 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 documentation 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.

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(4) In this regulation “subsidiary” has the meaning given to it in section 1159 of the Companies Act 2006(1).

**Register of approved bodies**

**53.**—(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 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.

**UK national accreditation body**

**54.**—(1) 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; and
- (b) monitoring approved bodies in accordance with regulation 50.

(2) Where the Secretary of State authorises the UK national accreditation body pursuant to paragraph (1), the Secretary of State remains fully responsible for anything done pursuant to that authorisation.”.

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(1) 2006 c.46.