#### STATUTORY INSTRUMENTS

# 2016 No. 1152

The Non-automatic Weighing Instruments Regulations 2016

### PART 5

## NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

#### Introductory

- **47.**—(1) This Part applies to the notification to the Commission and other EEA states of the bodies authorised to carry out conformity assessment procedures in the United Kingdom in relation to regulated non-automatic weighing instruments.
  - (2) For the purposes of this Part, a notified body is a conformity assessment body—
    - (a) which has been notified to the Commission and to other EEA states in accordance with the Directive; and
    - (b) in respect of which no objections are raised by the Commission or other EEA states—
      - (i) within 2 weeks of a notification, where an accreditation certificate is used; or
      - (ii) within 2 months of a notification, where accreditation is not used.
  - (3) Paragraph (2) has effect subject to regulation 54 (changes to notifications).

## The notifying authority

- **48.**—(1) The notifying authority for the purposes of these Regulations is the Secretary of State.
- (2) The functions of the notifying authority are—
  - (a) to assess whether applicants for recognition as conformity assessment bodies meet the requirements for recognition as such;
  - (b) where an assessment that a body is qualified to act as a conformity assessment body is made, to notify the Commission of that fact; and
  - (c) to carry out such monitoring of bodies notified to the Commission to ensure continuing compliance with the requirements of these Regulations.
- (3) The notifying authority may delegate the performance of its functions to a body that meets the requirements of Articles 20(3) and 21 of the Directive but in the event of such a delegation the notifying authority remains fully responsible for the performance of those functions.
- (4) The notifying authority must supply such information as the Commission may request in relation to a body notified by it.

## Notification

- **49.**—(1) The Secretary of State may notify to the Commission and the other EEA states only those conformity assessment bodies that qualify for notification.
- (2) A conformity assessment body qualifies for notification if the first and the 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 regulated non-automatic weighing instrument in respect of which the conformity assessment body claims to be competent; and
  - (b) an accreditation certificate or 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 requirements of Schedule 3 ("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 meets the notified body requirements.
- (6) When deciding whether to notify a conformity assessment body that qualifies for notification to the 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.
- (7) The Secretary of State must inform the Commission of the United Kingdom's procedures for the assessment and notification of conformity assessment bodies, and any changes to those procedures.

#### Presumption of conformity of notified bodies

- **50.**—(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 of the European Union, 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.

#### **Contents of notification**

- **51.** A notification under regulation 49 (notification) 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 module in respect of which the conformity assessment body has made its application for notification;
    - (iii) the regulated non-automatic weighing instrument in respect of which the conformity assessment body has made its application for notification; and
  - (b) either or both of the following—
    - (i) an accreditation certificate; or
    - (ii) documentary evidence which attests to—

- (aa) the conformity assessment body's competence; and
- (bb) 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**

- **52.**—(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 49(6)(b); and
  - (c) carries out its functions in accordance with these Regulations.
- (2) The Secretary of State must inform the Commission of the United Kingdom's procedures for the monitoring of notified bodies, and any changes to those procedures.

### **Delegation to the United Kingdom Accreditation Service**

- **53.**—(1) 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 notified body requirements;
    and
  - (b) monitoring notified bodies.
- (2) Where the Secretary of State authorises the United Kingdom Accreditation Service pursuant to paragraph (1), the Secretary of State remains fully responsible for anything done pursuant to that authorisation.

## **Changes to notifications**

- **54.**—(1) Where the Secretary of State determines that a notified body no longer meets a notified body requirement, or that it is failing to fulfil any of its obligations under these Regulations other than conditions set in accordance with regulation 49(6)(b), the Secretary of State must restrict, suspend or withdraw the body's status as a notified body under regulation 49 (notification).
- (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 49(6)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a notified body under regulation 49 (notification).
- (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 notified body 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 EEA states.
- (6) 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 body must—

- (a) on the request of the Secretary of State, transfer its files to another notified body or to the Secretary of State; or
- (b) in the absence of a request under sub-paragraph (a), ensure that its files are kept available for the Secretary of State and each enforcing authority for such period as the Secretary of State may specify.
- (7) The Secretary of State may impose a monetary penalty on a United Kingdom notified body that fails to comply with any requirement imposed by or under paragraph (6).
  - (8) Schedule 5 has effect in relation to monetary penalties imposed under paragraph (7).