

STATUTORY INSTRUMENTS

2016 No. 1153

The Measuring Instruments Regulations 2016

PART 5

[^{F1}APPROVAL OF CONFORMITY ASSESSMENT BODIES]

[^{F1}NOTIFICATION OF CONFORMITY ASSESSMENT BODIES]

Textual Amendments

- F1** Pt. 5 (regs. 53-59) substituted for Pt. 5 (regs. 53-60) (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 27 para. 38** (with **Sch. 27 para. 50(a)**) (as amended by [S.I. 2020/676](#), regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**

[^{F1}Approved bodies **E+W+S**]

- 53.**—(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 IP completion day was a notified body in respect of which the Secretary of State had taken no action under regulation 60(1) or (2) as they had effect immediately before IP completion day to suspend or withdraw the body's status as a notified body.
- (2) Paragraph (1) has effect subject to regulation 57 (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 23 of the Directive; and
 - (b) in respect of which no objections had been raised, as referred to in regulation 53(2)(b), as it had effect immediately before IP completion day;
- “approved body requirements” means the requirements set out in Schedule 5.]

Extent Information

- E1** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Introductory **N.I.**

53.—(1) This Part applies to the notification to the Commission and other [^{F2}relevant] states of the bodies authorised to carry out conformity assessment procedures in the United Kingdom in relation to measuring 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 [^{F2}relevant] states under regulation 55 (notification); and
 - (b) in respect of which no objections [^{F3}, other than an immaterial objection,] are raised by the Commission or other [^{F2}relevant] 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 [^{F4}used;]
- [^{F5}(c) in sub-paragraph (b), an “immaterial objection” is an objection on the grounds that—
- (i) the conformity assessment body is established in the United Kingdom; or
 - (ii) the accreditation certificate was issued by the United Kingdom Accreditation Service.]
- (3) Paragraph (2) has effect subject to regulation 60 (changes to notifications).

Extent Information

- E9** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F2** Word in reg. 53 substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 14 para. 5(1)(a)**
- F3** Words in reg. 53(2)(b) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 14 para. 5(1)(b)(i)**
- F4** Word in reg. 53(2)(b) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 14 para. 5(1)(b)(ii)**
- F5** Reg. 53(2)(c) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 14 para. 5(1)(c)**

[^{F1}Approval of conformity assessment bodies **E+W+S**

54.—(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; and
 - (iii) the regulated measuring instrument for 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)(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.]

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

The notifying authority **N.I.**

- 54.**—(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 24(3) and 25 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.

Extent Information

E10 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F1}Presumption of conformity of approved bodies E+W+S

55.—(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.]

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Notification N.I.

55.—(1) The Secretary of State may notify to the Commission and the other [^{F6}relevant] 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 measuring instrument 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.

(4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the requirements of Schedule 5 (“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 [^{F6}relevant] 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.

Extent Information

E11 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F6 Word in [reg. 55](#) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 14 para. 5\(2\)](#)

[^{F1}**Monitoring** **E+W+S**]

56. 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 54(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 54(6)(b) as it applied immediately before IP completion day; and
- (c) carries out its functions in accordance with these Regulations.]

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Presumption of conformity of notified bodies **N.I.**

56.—(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.

Extent Information

E12 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F1}**Restriction, suspension or withdrawal of approval** **E+W+S**]

57.—(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 54(6)(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 54 (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 referred to in regulation 56(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 54 (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 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—

- (a) on the request of the Secretary of State, 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) 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 7 has effect in relation to a monetary penalty imposed under paragraph (7).]

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Contents of notification **N.I.**

57. A notification under regulation 55 (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 measuring instrument in respect of which the conformity assessment body has made its application for notification; 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.

Extent Information

E13 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F1}Register of approved bodies E+W+S]

- 58.**—(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.]

Extent Information

E6 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Monitoring N.I.

- 58.**—(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 55(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.

Extent Information

E14 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[^{F1}UK national accreditation body E+W+S]

- 59.**—(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 56;

(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.]

Extent Information

E7 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Delegation to the United Kingdom Accreditation Service **N.I.**

59. 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.

Extent Information

E15 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Changes to notifications **E+W+S**

^{F1}**60.**

Extent Information

E8 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Changes to notifications **N.I.**

60.—(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 55(6)(b), the Secretary of State must restrict, suspend or withdraw the body's status as a notified body under regulation 55 (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 55(6)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a notified body under regulation 55.

(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 [^{F7}relevant] 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 7 has effect in relation to a monetary penalty imposed under paragraph (7)

Textual Amendments

- F7** Word in reg. 60(5) substituted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), reg. 1(b), **Sch. 14 para. 5(3)**

Changes to legislation:

There are currently no known outstanding effects for the The Measuring Instruments Regulations 2016, PART 5.