STATUTORY INSTRUMENTS

2016 No. 1153

The Measuring Instruments Regulations 2016

PART 4

CONFORMITY OF MEASURING INSTRUMENTS CHAPTER 1

ESTABLISHING COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

Introductory E+W+S

[F136. This chapter applies for the purposes of establishing whether a regulated measuring instrument complies with the essential requirements.]

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

Textual Amendments

F1 Reg. 36 substituted (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. 20 (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)

Introductory N.I.

36. This chapter applies for the purposes of establishing whether a measuring instrument (whether it is a regulated measuring instrument or a non-prescribed measuring instrument) complies with the essential requirements.

Extent Information

E17 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Methods of establishing conformity with the essential requirements E+W+S

- **37.** Conformity with the essential requirements may be established in relation to a [F²regulated] measuring instrument—
 - (a) through conformity with [F3designated] standards (or parts of those standards) covering the essential requirements F4...;

- (b) through conformity with parts of normative documents which cover the essential requirements where the parts of the normative documents have been included in a list published [F5by the Secretary of State]; or
- (c) through the use by the manufacturer of any other technical solution that complies with the essential requirements.

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

Textual Amendments

- F2 Word in reg. 37 inserted (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. 21(a) (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)
- F3 Word in reg. 37(a) substituted (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. 21(b)(i) (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)
- **F4** Words in reg. 37(a) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 27 para. 21(b)(ii)** (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)
- F5 Words in reg. 37(b) substituted (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. 21(c) (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)

Methods of establishing conformity with the essential requirements N.I.

- **37.** Conformity with the essential requirements may be established in relation to a measuring instrument—
 - (a) through conformity with harmonised standards (or parts of those standards) covering the essential requirements where the harmonised standards have been published in the Official Journal of the European Union;
 - (b) through conformity with parts of normative documents which cover the essential requirements where the parts of the normative documents have been included in a list published in the Official Journal of the European Union; or
 - (c) through the use by the manufacturer of any other technical solution that complies with the essential requirements.

Extent Information

E18 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Presumptions of conformity of [F6regulated] measuring instruments E+W+S

38.—(1) [FRegulated] measuring instruments which are in conformity with [F8designated] standards (or parts of those standards) of a kind mentioned in regulation 37(a), are to be presumed to be in conformity with the essential requirements covered by those standards (or parts of those standards).

- (2) [F9Regulated] measuring instruments which are in conformity with parts of normative documents of a kind mentioned in regulation 37(b), are to be presumed to be in conformity with the essential requirements covered by those parts of normative documents.
- (3) To benefit from a presumption of conformity under paragraphs (1) or (2), the manufacturer must correctly apply solutions mentioned in the relevant [F10 designated] standards or in the normative documents.
- (4) Compliance with the appropriate tests mentioned in regulation 45(1)(i) is to be presumed if the corresponding test programme has been performed in accordance with the documents mentioned in paragraphs (1) and (2) and if the test results ensure compliance with the essential requirements.

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

Textual Amendments

- **F6** Word in reg. 38 heading inserted (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. 22(a)** (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)
- F7 Word in reg. 38(1) inserted (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. 22(a) (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)
- **F8** Word in reg. 38(1) substituted (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. 22(b)** (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)
- F9 Word in reg. 38(2) inserted (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. 22(a) (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)
- **F10** Word in reg. 38(3) substituted (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. 22(b)** (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)

Presumptions of conformity of measuring instruments N.I.

- **38.**—(1) Measuring instruments which are in conformity with harmonised standards (or parts of those standards) of a kind mentioned in regulation 37(a), are to be presumed to be in conformity with the essential requirements covered by those standards (or parts of those standards).
- (2) Measuring instruments which are in conformity with parts of normative documents of a kind mentioned in regulation 37(b), are to be presumed to be in conformity with the essential requirements covered by those parts of normative documents.
- (3) To benefit from a presumption of conformity under paragraphs (1) or (2), the manufacturer must correctly apply solutions mentioned in the relevant harmonised standards or in the normative documents.
- (4) Compliance with the appropriate tests mentioned in regulation 45(1)(i) is to be presumed if the corresponding test programme has been performed in accordance with the documents mentioned in paragraphs (1) and (2) and if the test results ensure compliance with the essential requirements.

E19 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Conformity assessment procedures E+W+S

- **39.**—(1) Conformity assessment of a [FII regulated] measuring instrument with the essential requirements must be established by the application at the choice of the manufacturer, of one of the conformity assessment procedures listed as applicable in relation to the [FII regulated] measuring instrument in Schedule [FII] C to 1JI.
- (2) [F13An approved] body must carry out the conformity assessment procedure selected by the manufacturer in accordance with the requirements of Schedule 4.
- (3) The documents and correspondence relating to the conformity assessment procedures referred to in this regulation which are carried out in the United Kingdom must be drawn up in English.

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

Textual Amendments

- **F11** Word in reg. 39(1) inserted (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. 23(a)(i)** (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)
- F12 Words in reg. 39(1) substituted (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. 23(a)(ii) (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)
- **F13** Words in reg. 39(2) substituted (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. 23(b)** (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)

Conformity assessment procedures N.I.

- **39.**—(1) Conformity assessment of a measuring instrument with the essential requirements must be established by the application at the choice of the manufacturer, of one of the conformity assessment procedures listed as applicable in relation to the measuring instrument in Schedule 1.
- (2) A notified body must carry out the conformity assessment procedure selected by the manufacturer in accordance with the requirements of Schedule 4.
- (3) The documents and correspondence relating to the conformity assessment procedures referred to in this regulation which are carried out in the United Kingdom must be drawn up in English.

Extent Information

E20 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F14Power to amend Schedules 1C to 1J

- **39A.**—(1) Where the one or more of the conditions in paragraph (2) are met, the Secretary of State may by regulations make provision to amend Schedules 1C to 1J in relation to any of the following matters—
 - (a) maximum permissible errors (MPEs) and accuracy classes;
 - (b) rated operating conditions;
 - (c) critical change values; and
 - (d) disturbances.
- (2) The conditions referred to in paragraph (1) are that the Secretary of State considers that the purpose of the provision is to—
 - (a) take into account scientific or technical progress; or
 - (b) provide adequate protection of consumers or other end users.
 - (3) The power to make regulations under this regulation includes the power—
 - (a) to make different provision for different cases; and
 - (b) to make such supplemental, consequential and transitional provision as the Secretary of State considers appropriate
- (4) Regulations made under paragraph (1) are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.]

Textual Amendments

F14 Reg. 39A inserted (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. 24 (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)

Capacity serving measures - accredited in house bodies E+W+S

- **40.**—(1) This regulation applies to the conformity assessment of capacity serving measures.
- (2) An accredited in-house body may be used to carry out conformity assessment activities for the undertaking of which it forms part for the purposes of implementing the procedures set out in Module A2 [F15 in Schedule 1B].
- (3) The body must constitute a separate and distinct part of the undertaking and must not participate in the design, production, supply, installation, use or maintenance of the [F16 regulated] measuring instrument it assesses.
 - (4) An accredited in-house body must meet the following requirements—
 - (a) it must be accredited in accordance with RAMS;
 - (b) the body and its personnel must be organisationally identifiable and have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate it to the relevant national accreditation body;
 - (c) neither the body, nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the [F17 regulated] measuring instruments they assess nor shall they engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities; and
 - (d) it must supply its services exclusively to the undertaking of which it forms a part.

[F18(5)] An accredited in-house body need not be approved by the Secretary of State, but information concerning its accreditation must be given by the undertaking of which it forms part to the Secretary of State at the request of the Secretary of State.]

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

Textual Amendments

- F15 Words in reg. 40(2) substituted (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. 25(a) (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)
- **F16** Word in reg. 40(3) inserted (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. 25(b)** (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)
- **F17** Word in reg. 40(4)(c) inserted (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. 25(b)** (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)
- F18 Reg. 40(5) substituted (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. 25(c) (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)

Capacity serving measures - accredited in house bodies N.I.

- **40.**—(1) This regulation applies to the conformity assessment of capacity serving measures.
- (2) An accredited in-house body may be used to carry out conformity assessment activities for the undertaking of which it forms part for the purposes of implementing the procedures set out in Module A2 of Annex II to the Directive.
- (3) The body must constitute a separate and distinct part of the undertaking and must not participate in the design, production, supply, installation, use or maintenance of the measuring instrument it assesses.
 - (4) An accredited in-house body must meet the following requirements—
 - (a) it must be accredited in accordance with RAMS;
 - (b) the body and its personnel must be organisationally identifiable and have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate it to the relevant national accreditation body;
 - (c) neither the body, nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the measuring instruments they assess nor shall they engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities; and
 - (d) it must supply its services exclusively to the undertaking of which it forms a part.
- (5) An accredited in-house body need not be notified to the notifying authority or the Commission, but information concerning its accreditation must be given by the undertaking of which it forms part to the notifying authority at the request of that authority.

E21 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Subsidiaries and contractors E+W+S

- [F1941.—(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.
- (4) In this regulation "subsidiary" has the meaning given to it in section 1159 of the Companies Act 2006.]

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

Textual Amendments

F19 Reg. 41 substituted (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. 26 (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)

Subsidiaries and contractors N.I.

- **41.**—(1) Where a notified body 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 for the purposes of regulation 39 (conformity assessment procedures) where the conditions in paragraphs (2) and (3) are met.
 - (2) The notified body must—
 - (a) ensure that the subcontractor or subsidiary meets the notified body requirements; and
 - (b) inform the Secretary of State accordingly.

- (3) The notified body must have obtained the agreement of the client to the use of a subcontractor or subsidiary.
- (4) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the notified body must for a period of at least 10 years beginning on the day on which the activities are carried out, keep at the disposal of 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 in accordance with regulation 58 (monitoring), the Secretary of State must treat the notified body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.

E22 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Fees E+W+S

- **42.**—(1) [F²⁰An approved] body may charge fees in connection with, or incidental to, the carrying out of conformity assessment procedures or specific tasks as it may determine.
 - (2) The fees referred to in paragraph (1) must not exceed the following—
 - (a) the costs incurred or to be incurred by the [F21 approved] body in performing the relevant function; and
 - (b) an amount on account of profit which is reasonable in the circumstances having regard to—
 - (i) the character and extent of the work done or to be done by that notified body on behalf of the applicant; and
 - (ii) the commercial rate normally charged on account of profit for that work or similar work
- (3) The power in paragraph (1) includes the power to require payment of fees or a reasonable estimate of such fees in advance of carrying out the work requested by the applicant.
- (4) Where any fees payable to I^{F20} an approved] body pursuant to this regulation remain unpaid 28 days after either the work has been requested or payment of the fees has been requested in writing, whichever is the later, the notified body may by 14 days' notice in writing provide that, unless the fees are paid before the expiry of the notice, the certificate or notification appropriate to the relevant conformity assessment procedure may be suspended until payment of the fees has been received.
 - (5) This regulation does not apply to the Secretary of State.

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

Textual Amendments

- **F20** Words in reg. 42 substituted (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. 27(a)** (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)
- **F21** Word in reg. 42(2)(a) substituted (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. 27(b)** (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)

Fees N.I.

- **42.**—(1) A United Kingdom notified body may charge fees in connection with, or incidental to, the carrying out of conformity assessment procedures or specific tasks as it may determine.
 - (2) The fees referred to in paragraph (1) must not exceed the following—
 - (a) the costs incurred or to be incurred by the United Kingdom notified body in performing the relevant function; and
 - (b) an amount on account of profit which is reasonable in the circumstances having regard to—
 - (i) the character and extent of the work done or to be done by that notified body on behalf of the applicant; and
 - (ii) the commercial rate normally charged on account of profit for that work or similar work.
- (3) The power in paragraph (1) includes the power to require payment of fees or a reasonable estimate of such fees in advance of carrying out the work requested by the applicant.
- (4) Where any fees payable to a United Kingdom notified body pursuant to this regulation remain unpaid 28 days after either the work has been requested or payment of the fees has been requested in writing, whichever is the later, the notified body may by 14 days' notice in writing provide that, unless the fees are paid before the expiry of the notice, the certificate or notification appropriate to the relevant conformity assessment procedure may be suspended until payment of the fees has been received.
 - (5) This regulation does not apply to the Secretary of State.

Extent Information

E23 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

CHAPTER 2

REQUIREMENTS AS TO THE TECHNICAL DOCUMENTATION REQUIRED FOR THE PURPOSES OF CONFORMITY ASSESSMENT

Application of this Chapter

43. The technical documentation required for the purposes of conformity assessment under these Regulations must satisfy the requirements of this Chapter.

General requirements to be met by technical documentation E+W+S

44.—(1) The technical documentation must—

- (a) render the design, manufacture and operation of the [F22 regulated] measuring instrument intelligible; and
- (b) permit an assessment of its conformity with the applicable requirements of [F23these Regulations].
- (2) The technical documentation must be sufficiently detailed to ensure compliance with the following requirements—
 - (a) the definition of the metrological characteristics;
 - (b) the reproducibility of the metrological performances of produced [F24 regulated] measuring instruments when properly adjusted using appropriate intended means; and
 - (c) the integrity of the [F25 regulated] measuring instrument.

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

Textual Amendments

- **F22** Word in reg. 44(1)(a) inserted (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. 28(a)** (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)
- **F23** Words in reg. 44(1)(b) substituted (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. 28(b)** (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)
- **F24** Word in reg. 44(2)(b) inserted (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. 28(a)** (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)
- **F25** Word in reg. 44(2)(c) inserted (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. 28(a)** (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)

General requirements to be met by technical documentation N.I.

- **44.**—(1) The technical documentation must—
 - (a) render the design, manufacture and operation of the measuring instrument intelligible; and
 - (b) permit an assessment of its conformity with the applicable requirements of the Directive.
- (2) The technical documentation must be sufficiently detailed to ensure compliance with the following requirements—
 - (a) the definition of the metrological characteristics;
 - (b) the reproducibility of the metrological performances of produced measuring instruments when properly adjusted using appropriate intended means; and
 - (c) the integrity of the measuring instrument.

Extent Information

E24 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Specific information to be included in technical documentation E+W+S

- **45.**—(1) The technical documentation must, insofar as relevant for assessment and identification of either the [F26 regulated] measuring instrument or its type (or both), include the following information—
 - (a) a general description of the [F26 regulated] measuring instrument;
 - (b) the conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits etc.;
 - (c) manufacturing procedures to ensure consistent production;
 - (d) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;
 - (e) descriptions and explanations necessary for the understanding of the information referred to in sub-paragraphs (b) to (d);
 - (f) a list of any [F27designated] standards and normative documents which have been applied in full or in partF28...;
 - (g) descriptions of the solutions adopted to meet the essential requirements where [F29] designated] standards or normative documents have not been applied, including a list of other relevant technical specifications applied;
 - (h) results of design calculations, examinations etc.;
 - (i) the appropriate test results, where necessary to demonstrate that the type or [F26 regulated] measuring instruments or both comply with the following—
 - (i) the requirements of [F30 these Regulations] under declared rated operating conditions and under specified environmental disturbances; and
 - (ii) the durability specifications for gas [F31 and water] meters as well as for liquids other than water; and
 - (j) the [F32type] examination certificates or F33... design examinations certificates in respect of [F26regulated] measuring instruments containing parts identical to those in the design.
 - (2) The manufacturer must specify where seals and markings have been applied.
- (3) The manufacturer must indicate the conditions for compatibility with interfaces and sub-assemblies where relevant.

Extent Information

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

Textual Amendments

- **F26** Word in reg. 45(1) inserted (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. 29(a)** (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)
- **F27** Word in reg. 45(1)(f) substituted (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. 29(b)(i)** (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)
- **F28** Words in reg. 45(1)(f) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 27 para. 29(b)(ii)** (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)

- **F29** Word in reg. 45(1)(g) substituted (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. 29(c)** (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)
- **F30** Words in reg. 45(1)(i)(i) substituted (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. 29(d) (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)
- **F31** Words in reg. 45(1)(i)(ii) substituted (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. 29(e)** (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)
- **F32** Word in reg. 45(1)(j) substituted (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. 29(f)(i)** (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)
- **F33** Word in reg. 45(1)(j) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 27 para. 29(f)(ii) (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)

Specific information to be included in technical documentation N.I.

- **45.**—(1) The technical documentation must, insofar as relevant for assessment and identification of either the measuring instrument or its type (or both), include the following information—
 - (a) a general description of the measuring instrument;
 - (b) the conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits etc.;
 - (c) manufacturing procedures to ensure consistent production;
 - (d) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;
 - (e) descriptions and explanations necessary for the understanding of the information referred to in sub-paragraphs (b) to (d);
 - (f) a list of any harmonised standards and normative documents which have been applied in full or in part, the references of which have been published in the Official Journal of the European Union;
 - (g) descriptions of the solutions adopted to meet the essential requirements where harmonised standards or normative documents have not been applied, including a list of other relevant technical specifications applied;
 - (h) results of design calculations, examinations etc.;
 - (i) the appropriate test results, where necessary to demonstrate that the type or measuring instruments or both comply with the following—
 - (i) the requirements of the Directive under declared rated operating conditions and under specified environmental disturbances; and
 - (ii) the durability specifications for gas, water and thermal-energy meters as well as for liquids other than water; and
 - (j) the EU-type examination certificates or EU design examinations certificates in respect of measuring instruments containing parts identical to those in the design.
 - (2) The manufacturer must specify where seals and markings have been applied.
- (3) The manufacturer must indicate the conditions for compatibility with interfaces and sub-assemblies where relevant.

E25 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

CHAPTER 3

REQUIREMENTS RELATING TO [F34EU] DECLARATIONS OF CONFORMITY

Textual Amendments

F34 Word in Pt. 4 Ch. 3 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 27 para. 30** (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)

Application of Chapter E+W+S

46. This Chapter applies in relation to ^{F35}... declarations of conformity made in relation to a [F36 regulated] measuring instrument for the purposes of these Regulations.

Extent Information

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

Textual Amendments

- F35 Word in reg. 46 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 27 para. 31(a) (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)
- **F36** Word in reg. 46 inserted (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. 31(b)** (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)

Application of Chapter N.I.

46. This Chapter applies in relation to EU declarations of conformity made in relation to a measuring instrument for the purposes of these Regulations.

Extent Information

E26 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Form and contents of F37... declaration of conformity etc. E+W+S

- 47.—(1) The F38... declaration of conformity must—
 - (a) state that the fulfilment of the essential requirements has been demonstrated in relation to the measuring instrument;

- (b) contain the elements specified in the relevant conformity assessment modules set out in [F39Schedule 1B] and be updated when appropriate;
- (c) have the model structure set out in [F40Schedule 1K].
- (2) Where a regulated measuring instrument is placed or made available on the market in the United Kingdom, the ^{F41}... declaration of conformity in relation to the instrument must be in English.

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

Textual Amendments

- F37 Word in reg. 47 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 27 para. 32(a) (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)
- **F38** Word in reg. 47(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 27 para. 32(a) (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)
- **F39** Words in reg. 47(1)(b) substituted (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. 32(b)** (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)
- **F40** Words in reg. 47(1)(c) substituted (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. 32(c) (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)
- **F41** Word in reg. 47(2) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 27 para. 32(a)** (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)

Form and contents of EU declaration of conformity etc. N.I.

- **47.**—(1) The EU declaration of conformity must—
 - (a) state that the fulfilment of the essential requirements has been demonstrated in relation to the measuring instrument;
 - (b) contain the elements specified in the relevant conformity assessment modules set out in Annex II to the Directive and be updated when appropriate;
 - (c) have the model structure set out in Annex XIII to the Directive.
- (2) Where a regulated measuring instrument is placed or made available on the market in [F60]Northern Ireland], the EU declaration of conformity in relation to the instrument must be in English.

Extent Information

E27 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

F60 Words in reg. 47(2) 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. 4(1)

$[^{F42}$ Regulated measuring instruments that require more than one declaration of conformity E+W+S

48. Where a regulated measuring instrument is subject to more than one enactment requiring the drawing up of a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment by its title.]

Extent Information

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

Textual Amendments

F42 Reg. 48 substituted (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. 33 (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)

Measuring instruments that require more than one declaration of conformity N.I.

- **48.**—(1) This regulation applies where a measuring instrument is subject to [^{F61}an NI Protocol obligation] for an EU declaration of conformity otherwise than by virtue of these Regulations.
- (2) Where this regulation applies, a single EU declaration of conformity must be drawn up covering all applicable requirements which identifies the [F62 relevant] Union acts concerned including their publication references.

Extent Information

E28 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

- **F61** Words in reg. 48(1) 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. 4(2)(a)
- **F62** Word in reg. 48(2) 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. 4(2)(b)

Responsibility of manufacturer that draws up declaration of conformity E+W+S

49. A manufacturer, who draws up [^{F43}a] declaration of conformity in relation to a [^{F44}regulated] measuring instrument, is responsible for compliance of the measuring instrument with the requirements of these Regulations.

Extent Information

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

Textual Amendments

- **F43** Word in reg. 49 substituted (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. 34(a)** (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)
- **F44** Word in reg. 49 inserted (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. 34(b)** (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)

Responsibility of manufacturer that draws up declaration of conformity N.I.

49. A manufacturer, who draws up an EU declaration of conformity in relation to a measuring instrument, is responsible for compliance of the measuring instrument with the requirements of these Regulations.

Extent Information

E29 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

CHAPTER 4

CONFORMITY MARKING

Conformity with F45... requirements to be indicated by the F46UK marking E+W+S

50. The conformity of a measuring instrument with the requirements of these Regulations must be indicated by the presence on it of the [F47UK] marking and the M marking.

Extent Information

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

Textual Amendments

- **F45** Word in reg. 50 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 27 para. 35(a)** (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)
- **F46** Word in reg. 50 heading substituted (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. 35(b)** (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)
- **F47** Word in reg. 50 substituted (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. 35(b)** (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)

Conformity with Directive requirements to be indicated by the CE marking N.I.

50. The conformity of a measuring instrument with the requirements of these Regulations must be indicated by the presence on it of the CE marking and the M marking.

E30 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F48Prohibition on improper use of the UK marking and the M marking E+W+S

- **51.**—(1) An economic operator must not affix the UK marking or the M marking to a regulated measuring instrument unless—
 - (a) that economic operator is the manufacturer of the regulated measuring instrument; and
 - (b) the conformity of the regulated measuring instrument with the essential requirements has been demonstrated by a relevant conformity assessment procedure.
- (2) An economic operator must not affix a marking to a regulated measuring instrument which is not the UK marking or the M marking but which purports to attest that the regulated measuring instrument satisfies the essential requirements.
- (3) An economic operator must not affix to a regulated measuring instrument a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the marking.
- (4) An economic operator must not affix to a regulated measuring instrument any other marking if the visibility, legibility and meaning of the UK marking or the M marking would be impaired as a result.]

Extent Information

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

Textual Amendments

F48 Reg. 51 substituted (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. 36** (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)**

General principles relating to the M marking N.I.

51. The general principles set out in article 30 of RAMS apply to the M marking with such modifications as are necessary in the circumstances.

Extent Information

E31 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Rules and conditions for affixing the [F49UK] marking and the M marking E+W+S

52.—(1) The [F50UK] marking and the M marking ("the markings") must be affixed to a [F51 regulated] measuring instrument in accordance with the provisions of this regulation.

- (2) The markings must be affixed visibly, legibly and indelibly to the [F51 regulated] measuring instrument [F52, its data plate, or where regulation 7(2) applies, to a label affixed to the [F51 regulated] measuring instrument or to a document accompanying the [F51 regulated] measuring instrument].
- (3) Paragraph (2) does not apply where it is not possible or not warranted on account of the nature of the [F51] regulated] measuring instrument, in which case the markings must be affixed to the documents which accompany the [F51] regulated] measuring instrument and any packaging.
- (4) When a [F51 regulated] measuring instrument consists of a series of devices F53..., operating together, the markings must be affixed on the instrument's main device.
- (5) The markings must be affixed before the [F51 regulated] measuring instrument is placed on the market
- (6) The markings may be affixed to the [F51 regulated] measuring instrument during the fabrication process, if justified.
 - (7) The M marking must immediately follow the [F54UK] marking.
- (8) The markings must immediately be followed by the identification number of the [F55 approved] body where that body is involved in the production control phase as set out in [F56 Schedule 1B].
 - (9) The identification number of the [F57approved] body referred to in paragraph (8) must—
 - (a) be affixed by the body itself, or under its instructions by the manufacturer or his authorised representative; and
 - (b) be indelible or self-destructive upon removal.
- (10) The markings and (where applicable) the identification number of the [F58 approved] body may be followed by any other mark indicating a special risk or use.

E16 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F49 Word in reg. 52 heading substituted (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. 37(b) (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)
- F50 Word in reg. 52(1) substituted (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. 37(b) (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)
- **F51** Word in reg. 52(1)-(6) inserted (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. 37(a)** (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)
- F52 Words in reg. 52(2) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 27 para. 37(bb) (as inserted by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), Sch. 3 para. 19(5))
- **F53** Words in reg. 52(4) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 27 para. 37(c)** (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)
- **F54** Word in reg. 52(7) substituted (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. 37(b)** (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)

- **F55** Word in reg. 52(8) substituted (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. 37(e)** (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)
- **F56** Words in reg. 52(8) substituted (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. 37(d)** (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)
- F57 Word in reg. 52(9) substituted (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. 37(e) (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)
- **F58** Word in reg. 52(10) substituted (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. 37(e)** (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)

Rules and conditions for affixing the CE marking and the M marking N.I.

- **52.**—(1) The CE marking and the M marking ("the markings") must be affixed to a measuring instrument in accordance with the provisions of this regulation.
- (2) The markings must be affixed visibly, legibly and indelibly to the measuring instrument or its data plate.
- (3) Paragraph (2) does not apply where it is not possible or not warranted on account of the nature of the measuring instrument, in which case the markings must be affixed to the documents which accompany the measuring instrument and any packaging.
- (4) When a measuring instrument consists of a series of devices, not being sub-assemblies, operating together, the markings must be affixed on the instrument's main device.
 - (5) The markings must be affixed before the measuring instrument is placed on the market.
- (6) The markings may be affixed to the measuring instrument during the fabrication process, if justified.
 - (7) The M marking must immediately follow the CE marking.
- (8) The markings must immediately be followed by the identification number of the notified body where that body is involved in the production control phase as set out in Annex II to the Directive.
 - (9) The identification number of the notified body referred to in paragraph (8) must—
 - (a) be affixed by the body itself, or under its instructions by the manufacturer or his authorised representative; and
 - (b) be indelible or self-destructive upon removal.
- (10) The markings and (where applicable) the identification number of the notified body may be followed by any other mark indicating a special risk or use.

Extent Information

E32 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F59UK(NI) indication

- **52A.**—(1) Where the CE marking is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the regulated measuring instrument, in accordance with this regulation.
 - (2) The UK(NI) indication must be affixed—

- (a) visibly, legibly and indelibly; and
- (b) before the regulated measuring instrument is placed on the market in Northern Ireland.
- (3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 52.
 - (4) The UK(NI) indication must be affixed by—
 - (a) the manufacturer; or
 - (b) the manufacturer's authorised representative.
- (5) When placing a regulated measuring instrument on the market in Northern Ireland, an importer must ensure that the manufacturer has complied with their obligations under this regulation.

Textual Amendments

F59 Regs. 52A, 52B inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), **Sch. 2 para. 12(3)**

Register of notified bodies established in the United Kingdom

- **52B.**—(1) The Secretary of State must ensure that—
 - (a) each notified body established in the United Kingdom is assigned an identification number; and
 - (b) there is a register of—
 - (i) notified bodies established in the United Kingdom;
 - (ii) their notified body identification number;
 - (iii) the activities for which they have been notified;
 - (iv) any restrictions on those activities.
- (2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.
- (3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).]

Textual Amendments

F59 Regs. 52A, 52B inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), Sch. 2 para. 12(3)

Changes to legislation:There are currently no known outstanding effects for the The Measuring Instruments Regulations 2016, PART 4.