STATUTORY INSTRUMENTS

2016 No. 1152

WEIGHTS AND MEASURES

The Non-automatic Weighing Instruments Regulations 2016

Made - - - - 29th November 2016
Laid before Parliament 6th December 2016
Coming into force - - 28th December 2016

The Secretary of State is a Minister designated M1 for the purposes of section 2(2) of the European Communities Act 1972 M2 in relation to, and for purposes ancillary to, the regulation of specifications, construction, placing on the market and use of articles, instruments, containers or other equipment intended for weighing, measuring or testing.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for certain references to provisions of EU instruments to be construed as references to those provisions as amended from time to time.

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A M3 of Schedule 2 to, that Act and, in relation to Part 7 of the Regulations (and any other provisions of these Regulations to the extent that they apply to, or give effect to, Part 7), under powers conferred by sections 15(1) and 86(1) of the Weights and Measures Act 1985 M4.

Marginal Citations

- M1 S.I. 1975/427.
- M2 1972 c.68. Section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), section 27(1) and the European Union (Amendment) Act 2008 (c.7), Schedule, Part 1.
- M3 Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 and amended by the European Union (Amendment) Act 2008, Schedule, Part 1.
- **M4** 1985 c.72.

PART 1

INTRODUCTORY

Citation commencement and extent

- **1.**—(1) These Regulations may be cited as the Non-automatic Weighing Instruments Regulations 2016.
 - (2) These Regulations come into force on 28th December 2016.
 - (3) These Regulations extend to Northern Ireland except for Part 7.

Interpretation E+W+S

2.—(1) In these Regulations—

F1...

F2...

[F3."approved body" has the meaning given to it in regulation 47 (approved bodies);]

"authorised representative" means any person established [F4 in the United Kingdom] who has received a written mandate from a manufacturer to act on the manufacturer's behalf in relation to specified tasks;

F5...

"commencement date" means the date referred to in regulation 1(2);

"competent authority" means a person who is, pursuant to regulation 62 (competent authorities and enforcement proceedings), authorised to enforce these Regulations;

"compliance notice" means a notice served in accordance with regulation 63(2);

"conformity assessment" means the process demonstrating whether the essential requirements relating to a regulated non-automatic weighing instrument have been met;

"conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

[F7" conformity assessment procedure" means a procedure referred to in regulation 36;]

 $[^{F7}$ " declaration of conformity" means a declaration of conformity required to be drawn up in accordance with Chapter 2 of Part 3;]

[F7" designated standard" has the meaning given to it in regulation 2A;]

"the Directive" means Directive 2014/31/EU of the European Parliament and of the Council of 26th February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments ^{M5} and references to the Directive (or a specific provision of it) are references to the Directive (or that provision) [F8(as it has effect immediately before IP completion day)];

[F9" disqualification mark" means a marking in the form set out in paragraph 1 of Schedule A1;] "distributor" means any person in the supply chain, other than a manufacturer or an importer, who makes a non-automatic weighing instrument available on the market;

"economic operator" means a manufacturer, authorised representative, importer or distributor;

"enforcement notice" means a notice served in accordance with regulation 64(2);

"enforcement officer" means—

- (a) an inspector; or
- (b) a person appointed by the Secretary of State to act on the Secretary of State's behalf to enforce these Regulations;

"essential requirements" means, in relation to a regulated non-automatic weighing instrument (or a class of that instrument), the requirements specified as being applicable in relation to that regulated non-automatic weighing instrument (or that class of instrument) in [F10]Schedule 6];

F11 ... F12 ... F13

I^{F14}"importer" means a person who—

- (a) is established in the United Kingdom and places a non-automatic weighing instrument from a country outside of the United Kingdom on the market; or
- (b) is established in Northern Ireland and places a non-automatic weighing instrument on the market that has been supplied to them for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge, from an EEA state;]

"in writing" includes text that is—

- (a) transmitted by electronic means;
- (b) received in legible form; and
- (c) capable of being used for subsequent reference.

"M marking" means a marking applied to a regulated non-automatic weighing instrument which consists of the capital letter 'M' and the last two digits of the year of its affixing surrounded by a rectangle, the height of which is equal to that of the [F15UK] marking applied to that instrument;

"make available on the market" means any supply of a non-automatic weighing instrument for distribution or use on the [F16market of Great Britain] in the course of a commercial activity, whether in return for payment or free of charge and related expressions are to be construed accordingly;

"manufacturer" means any person who—

- (a) manufactures a non-automatic weighing instrument or has a non-automatic weighing instrument designed or manufactured and markets that instrument under their name or trademark; or
- (b) is to be treated as a manufacturer by virtue of regulation 5(2);

"market surveillance authority" means the Secretary of State acting in the capacity of market surveillance authority pursuant to the designation made by regulation 57 (the market surveillance authority), and, where the context requires, a market surveillance authority in another EEA state;

F17

"non-automatic weighing instrument" means a weighing instrument that—

- (a) serves to determine the mass of a body by using the action of gravity on that body and which may also serve to determine other mass-related magnitudes, quantities, parameters and characteristics; and
- (b) requires the intervention of an operator during weighing;

"notified body" means a conformity assessment body that has been notified to the Commission in accordance with Part 5 and includes, where the context so requires, a notified body designated as such in another EEA state in accordance with the Directive;

F18 ... F19

"place on the market" means the first making available of a non-automatic weighing instrument on the market [F20] of Great Britain] and related expressions are to be construed accordingly;

"RAMS" means Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93^{M6} (as amended from time to time);

"recall" means any measure aimed at achieving the return of a regulated non-automatic weighing instrument that has already been made available to the end-user and related expressions are to be construed accordingly;

"regulated non-automatic weighing instrument" means a non-automatic weighing instrument which is intended to be used to perform one of the functions referred to in regulation 3(2);

"relevant economic operator" means, in relation to a non-automatic weighing instrument, an economic operator with obligations in respect of that non-automatic weighing instrument under Part 2;

[F21" re-qualification mark" means a marking in the form set out in paragraph 2 of Schedule A1;] "technical documentation" means the documentation which meets the requirements of [F22 Schedule 7]:

"technical specification" means a document that prescribes technical requirements to be fulfilled by a regulated non-automatic weighing instrument;

[F23···Type-examination certificate" means a type-examination certificate issued by an approved body in accordance with Module B of Schedule 7;]

[F23"UK marking" means the marking in the form set out in Annex 2 of RAMS;]

[F23"UK national accreditation body" means the body appointed by the Secretary of State in accordance with Article 4 of RAMS;]

F24

"United Kingdom Accreditation Service" means the company limited by guarantee incorporated in England and Wales under number 3076190;

"weights and measures authority" means a local weights and measures authority within the meaning set out in section 69 of the Weights and Measures Act 1985;

"withdraw" when used in relation to a regulated non-automatic weighing instrument means taking any measure aimed at preventing an instrument in the supply chain from being made available on the market and related expressions are to be construed accordingly.

- [F25(1A) Schedules 6 to 8 reproduce the provisions of Annexes I to III to the Directive (respectively) with amendments to correct deficiencies in retained EU law.
- (1B) A reference to any provision of Schedules 6 to 8 is a reference to the equivalent provision of the relevant Annex to the Directive as set out in the relevant Schedule.]

$^{\mathbf{r}_{26}}(2)$

- (3) Other expressions used in these Regulations have in relation to the application of these Regulations to—
 - (a) Great Britain, the same meanings as in the Weights and Measures Act 1985 M7; and

(b) Northern Ireland, the same meanings as in the Weights and Measures (Northern Ireland) Order 1981 M8.

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 Words in reg. 2(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. 26 para. 2(2)(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F2 Words in reg. 2(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. 26 para. 2(2)(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F3 Words in reg. 2(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. 26 para. 2(2)(c) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F4 Words in reg. 2(1) substituted (E.W.S.) (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. 5 para. 1(4)(a)
- F5 Words in reg. 2(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. 26 para. 2(2)(e) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F6** Words in reg. 2(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. 26 para. 2(2)(f)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F7 Words in reg. 2(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. 26 para. 2(2)(g) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F8 Words in reg. 2(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. 26 para. 2(2)(h) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/852, regs. 2(2), 4(2), Sch. 1 para. 1(o)(ii)); 2020 c. 1, Sch. 5 para. 1(1)
- F9 Words in reg. 2(1) substituted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, 5(2)(a)
- F10 Words in reg. 2(1) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 26 para. 2(ha) (as inserted by The Product Safety and Metrology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/852), regs. 2(2), 4(3)(b))
- F11 Words in reg. 2(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. 26 para. 2(2)(i) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F12 Words in reg. 2(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. 26 para. 2(2)(j) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F13 Words in reg. 2(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. 26 para. 2(2)(k) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F14 Words in reg. 2(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. 26 para. 2(2)(1) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 18(2)); 2020 c. 1, Sch. 5 para. 1(1)

- F15 Word in reg. 2(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. 26 para. 2(2)(m) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F16 Words in reg. 2(1) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 26 para. 2(2)(n) (as substituted by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), 4(14)(a))
- F17 Words in reg. 2(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. 26 para. 2(2)(o) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F18** Words in reg. 2(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. 26 para. 2(2)(p) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F19 Words in reg. 2(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. 26 para. 2(2)(q) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F20** Words in reg. 2(1) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, **Sch. 26 para. 2(2)(r)** (as substituted by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), **4(14)(b)**)
- **F21** Words in reg. 2(1) substituted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **5(2)(b)**
- F22 Words in reg. 2(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. 26 para. 2(2)(s) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F23 Words in reg. 2(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. 26 para. 2(2)(t) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- Words in reg. 2(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. 26 para. 2(2)(u) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F25 Reg. 2(1A)(1B) 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. 26 para. 2(3) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F26 Reg. 2(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. 26 para. 2(4) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Marginal Citations

- **M5** OJ L 96, 29.3.2014 p. 107.
- **M6** OJ L 218, 13.8.2008, p. 30.
- **M7** 1985 c.72.
- **M8** S.I. 1981/231 (N.I. 10).

Interpretation N.I.

2.—(1) In these Regulations—

"accreditation" means accreditation as defined in point 10 of Article 2 of RAMS;

"accreditation certificate" means a certificate, issued by the United Kingdom Accreditation Service or a national accreditation body as defined in point 11 of Article 2 of RAMS in another [F171] relevant] state, attesting that a conformity assessment body meets the notified body requirements;

"authorised representative" means any person established within the [F172 relevant market] who has received a written mandate from a manufacturer to act on the manufacturer's behalf in relation to specified tasks;

"CE marking" means a marking which takes the form set out in Annex II of RAMS;

"commencement date" means the date referred to in regulation 1(2);

"Commission" means the Commission of the European Union:

"competent authority" means a person who is, pursuant to regulation 62 (competent authorities and enforcement proceedings), authorised to enforce these Regulations;

"compliance notice" means a notice served in accordance with regulation 63(2);

"conformity assessment" means the process demonstrating whether the essential requirements relating to a regulated non-automatic weighing instrument have been met;

"conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

"the Directive" means Directive 2014/31/EU of the European Parliament and of the Council of 26th February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments F173 and references to the Directive (or a specific provision of it) are references to the Directive (or that provision) as from time to time amended;

[F966 disqualification mark" means a marking in the form set out in paragraph 1 of Schedule A1;]

"distributor" means any person in the supply chain, other than a manufacturer or an importer, who makes a non-automatic weighing instrument available on the market;

"economic operator" means a manufacturer, authorised representative, importer or distributor;

"enforcement notice" means a notice served in accordance with regulation 64(2);

"enforcement officer" means—

- (a) an inspector; or
- (b) a person appointed by the Secretary of State to act on the Secretary of State's behalf to enforce these Regulations;

"essential requirements" means, in relation to a regulated non-automatic weighing instrument (or a class of that instrument), the requirements specified as being applicable in relation to that regulated non-automatic weighing instrument (or that class of instrument) in Annex I to the Directive;

"EU declaration of conformity" means a declaration of conformity required to be drawn up in accordance with Chapter 2 of Part 3;

"EU-type examination certificate" means an EU-type examination certificate issued by a notified body in accordance with Module B of Annex II to the Directive;

"harmonised standard" has the meaning set out in point 1(c) of Article 2 of Regulation (EU) No. 1025/2012 of the European Parliament and of the Council on European standardisation ^{F174} (as amended from time to time);

"importer" means any person who-

- (a) is established within the [F175] relevant market]; and
- (b) places a non-automatic weighing instrument from a [F176market outside of the relevant market on the relevant] market;

"in writing" includes text that is—

(a) transmitted by electronic means;

- (b) received in legible form; and
- (c) capable of being used for subsequent reference.

"M marking" means a marking applied to a regulated non-automatic weighing instrument which consists of the capital letter 'M' and the last two digits of the year of its affixing surrounded by a rectangle, the height of which is equal to that of the CE marking applied to that instrument;

"make available on the market" means any supply of a non-automatic weighing instrument for distribution or use on the [F177 relevant market] in the course of a commercial activity, whether in return for payment or free of charge and related expressions are to be construed accordingly;

"manufacturer" means any person who-

- (a) manufactures a non-automatic weighing instrument or has a non-automatic weighing instrument designed or manufactured and markets that instrument under their name or trademark; or
- (b) is to be treated as a manufacturer by virtue of regulation 5(2);

"market surveillance authority" means the Secretary of State acting in the capacity of market surveillance authority pursuant to the designation made by regulation 57 (the market surveillance authority), and, where the context requires, a market surveillance authority in another [F178 relevant] state;

"national accreditation body" means the national accreditation body as defined in point 11 of Article 2 of RAMS;

[F179c NI Protocol obligation" means any obligation created or arising by or under the Protocol on Ireland/ Northern Ireland in the EU withdrawal agreement, whether or not an obligation to which section 7A(2) of the European Union (Withdrawal) Act 2018 applies;]

"non-automatic weighing instrument" means a weighing instrument that—

- (a) serves to determine the mass of a body by using the action of gravity on that body and which may also serve to determine other mass-related magnitudes, quantities, parameters and characteristics; and
- (b) requires the intervention of an operator during weighing;

"notified body" means a conformity assessment body that has been notified to the Commission in accordance with Part 5 and includes, where the context so requires, a notified body designated as such in another [F180] relevant] state in accordance with the Directive;

"notified body requirements" means the requirements set out in Schedule 3 (requirements related to notified bodies)

"notifying authority" means the notifying authority within the meaning of regulation 48 (the notifying authority);

"place on the market" means the first making available of a non-automatic weighing instrument on the [F181 relevant market] and related expressions are to be construed accordingly;

"RAMS" means Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93^{F182} (as amended from time to time);

"recall" means any measure aimed at achieving the return of a regulated non-automatic weighing instrument that has already been made available to the end-user and related expressions are to be construed accordingly;

"regulated non-automatic weighing instrument" means a non-automatic weighing instrument which is intended to be used to perform one of the functions referred to in regulation 3(2);

"relevant economic operator" means, in relation to a non-automatic weighing instrument, an economic operator with obligations in respect of that non-automatic weighing instrument under Part 2;

[F183" relevant market" means—

- (a) the market in Northern Ireland; and
- (b) the market of the EEA states;]

[F183"relevant state" means—

- (a) Northern Ireland; or
- (b) any EEA state;]

[F21" re-qualification mark" means a marking in the form set out in paragraph 2 of Schedule A1;] "technical documentation" means the documentation which meets the requirements of Annex II to the Directive;

"technical specification" means a document that prescribes technical requirements to be fulfilled by a regulated non-automatic weighing instrument;

[F184c'UK(NI) indication" means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020;]

"Union harmonisation legislation" means any European Union legislation harmonising the conditions for the marketing of products;

"United Kingdom Accreditation Service" means the company limited by guarantee incorporated in England and Wales under number 3076190;

"weights and measures authority" means a local weights and measures authority within the meaning set out in section 69 of the Weights and Measures Act 1985;

"withdraw" when used in relation to a regulated non-automatic weighing instrument means taking any measure aimed at preventing an instrument in the supply chain from being made available on the market and related expressions are to be construed accordingly.

- (2) A non-automatic weighing instrument that meets the requirements of the Directive by virtue of the laws of another [F185] relevant] state is to be treated as meeting the requirements of these Regulations (except any requirement of these Regulations for anything to be written in English) and references to a non-automatic weighing instruments being in conformity with these Regulations are to be construed accordingly.
- (3) Other expressions used in these Regulations have in relation to the application of these Regulations to—
 - (a) Great Britain, the same meanings as in the Weights and Measures Act 1985 F186; and
 - (b) Northern Ireland, the same meanings as in the Weights and Measures (Northern Ireland) Order 1981 F187.

Extent Information

E51 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

F9 Words in reg. 2(1) substituted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **5(2)(a)**

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Words in reg. 2(1) substituted (9.12.2021) by The Product Safety and Metrology etc. (Amendment)
      Regulations 2021 (S.I. 2021/1273), regs. 1, 5(2)(b)
F171 Word in reg. 2(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. 13
      para. 2(1)(a)(i)
F172 Words in reg. 2(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. 13
      para. 2(1)(b)
F173 OJ L 96, 29.3.2014 p. 107.
F174 OJ L 316, 14.11.2012, p. 12.
F175 Words in reg. 2(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. 13
      para. 2(1)(c)(i)
F176 Words in reg. 2(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. 13
      para. 2(1)(c)(ii)
F177 Words in reg. 2(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. 13
F178 Word in reg. 2(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. 13
      para. 2(1)(a)(ii)
F179 Words in reg. 2(1) 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. 13
F180 Word in reg. 2(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. 13
      para. 2(1)(a)(iii)
F181 Words in reg. 2(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. 13
      para. 2(1)(f)
F182 OJ L 218, 13.8.2008, p. 30.
F183 Words in reg. 2(1) 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. 13
      para. 2(1)(g)
F184 Words in reg. 2(1) 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. 11(2)
F185 Word in reg. 2(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. 13
      para. 2(2)
F186 1985 c.72.
F187 S.I. 1981/231 (N.I. 10).
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[F27Designated standard

- **2A.**—(1) Subject to paragraphs (6) and (7), in these Regulations a "designated standard" means a technical specification which is—
 - (a) adopted by a recognised standardisation body [F28 or an international standardising body], for repeated or continuous application, with which compliance is not compulsory; and
 - (b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

- (2) For the purposes of paragraph (1), a "technical specification" means a document that prescribes technical requirements to be fulfilled by a non-automatic weighing instrument, process, service or system and which lays down one or more of the following—
 - (a) the characteristics required of a non-automatic weighing instrument, including—
 - (i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and
 - (ii) the requirements applicable to the non-automatic weighing instrument as regards the name under which the measuring instrument is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
 - (b) production methods and processes relating to the non-automatic weighing instrument, where these have an effect on the characteristics of the non-automatic weighing instrument.
- (3) For the purposes of this regulation a "recognised standardisation body" means any one of the following organisations—
 - (a) the European Committee for Standardisation (CEN);
 - (b) the European Committee for Electrotechnical Standardisation (Cenelec);
 - (c) the European Telecommunications Standards Institute (ETSI);
 - (d) the British Standards Institution (BSI).
- F²⁹(3A) In this regulation "international standardising body" has the same meaning as it has for the purposes of the Agreement on Technical Barriers to Trade, part of Annex 1A to the agreement establishing the World Trade Organisation signed at Marrakesh on 15 April 1994 (as modified from time to time).]
- (4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any persons who may have an interest in the standard.
- (5) Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with [F30 such] technical specifications adopted by the other recognised standardisation bodies [F31 or by international standardising bodies as the Secretary of State considers to be relevant.]
- (6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).
- (7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.
- (8) The Secretary of State may by regulations amend paragraph (3) to reflect any changes in the name or structure of the recognised standardisation bodies.
 - (9) Regulations made under paragraph (8) are to be made by statutory instrument.
- (10) A statutory instrument containing regulations made under paragraph (8) is subject to annulment in pursuance of a resolution of either House of Parliament.]

Textual Amendments

F27 Reg. 2A 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. 26 para. 3 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- **F28** Words in reg. 2A(1)(a) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 15(a)**; S.I. 2020/1662, reg. 2(ee)
- F29 Reg. 2A(3A) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), Sch. 4 para. 15(b); S.I. 2020/1662, reg. 2(ee)
- **F30** Word in reg. 2A(5) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), Sch. 4 para. 15(c)(i); S.I. 2020/1662, reg. 2(ee)
- **F31** Words in reg. 2A(5) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 15(c)(ii)**; S.I. 2020/1662, reg. 2(ee)

Application of these Regulations

- **3.**—(1) Subject to regulation 4 (revocations and transitional and consequential provisions), these Regulations apply to non-automatic weighing instruments.
- (2) These Regulations, except Part 4, apply to an instrument (referred to in these Regulations as a "regulated non-automatic weighing instrument") for use for any of the following purposes—
 - (a) the determination of mass for commercial transactions;
 - (b) the determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;
 - (c) the determination of mass for the application of laws or regulations or for an expert opinion given in court proceedings;
 - (d) the determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;
 - (e) the determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories; and
 - (f) the determination of price on the basis of mass for the purposes of direct sales to the public and the making up of prepackages.
 - (3) Part 4 applies to a non-automatic weighing instrument that is not a regulated instrument.

Revocations and transitional and consequential provisions

- **4.**—(1) The Non-automatic Weighing Instruments Regulations 2000 ^{M9} and the Non-automatic Weighing Instruments (Amendment) Regulations 2008 ^{M10} are revoked.
- (2) In this regulation, "the former law" means the Regulations referred to in paragraph (1) I^{F32} subject to the modifications made in paragraph (3A)].
- (3) This paragraph applies to a regulated non-automatic weighing instrument placed on the market before the commencement date which was required by any provision of the former law to meet the essential requirements.
 - [F33(3A) The modifications referred to in paragraph (2) are as follows—
 - (a) in the Non-automatic Weighing Instruments Regulations 2000 and the Non-automatic Weighing Instruments (Amendment) Regulations 2008—
 - (i) any reference to "the Community" is to be read as including the United Kingdom;
 - (ii) references to "member State" is to be read as including the United Kingdom;
 - (b) in the Non-automatic Weighing Instruments Regulations 2000—
 - (i) omit regulation 10(14);
 - (ii) in regulations 25(6)(a)(i) and 25(7)(a) for "; and" substitute "."; and

- (iii) omit regulations 25(6)(a)(ii), 25(6)(b) and 25(7)(b).]
- (4) A regulated non-automatic weighing instrument to which paragraph (3) applies which meets the requirements of the former law applicable to it is to be treated as meeting the requirements of these Regulations.
- (5) Where a regulated non-automatic weighing instrument to which paragraph (3) applies does not meet the requirements of the former law, these Regulations apply to that instrument as they apply to a regulated instrument placed on the market or put into service after the commencement date which does not comply with the requirements of these Regulations.
- (6) Part 7 (use for trade of regulated non-automatic weighing instruments for the purposes listed in regulation 3(2)) applies to regulated non-automatic weighing instruments to which paragraph (3) applies as it applies to a regulated instrument placed on the market or put into service after the commencement date.
- (7) A certificate granted under any provision of the former law has effect as if granted under the corresponding provision of these Regulations.
- (8) In the list in paragraph 10 in Schedule 5 to the Consumer Rights Act 2015 M11, insert at the appropriate place the following entry—
- "regulation 62 of the Non-automatic Weighing Instruments Regulations 2016 (S.I. 2016/1152)".
- (9) In the table in paragraph 11 of Schedule 5 to the Consumer Rights Act 2015, omit the entry relating to the Non-automatic Weighing Instruments Regulations 2000.
- (10) An application to be a recognised as a notified body which is made before the commencement date is to be treated as having been made under these Regulations if it meets the requirements of these Regulations.
- (11) Except in a case where paragraph (10) applies, a requirement of these Regulations ("the relevant requirement") is to be treated as having been satisfied by anything done on or after 20th April 2016 but before the commencement date where that thing—
 - (a) was done for the purposes of complying with a requirement of the Directive; and
 - (b) if it had been done on or after the commencement date it would have met the relevant requirement.

Textual Amendments

- **F32** Words in reg. 4(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. 26 para. 4(a)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**
- F33 Reg. 4(3A) 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. 26 para. 4(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Marginal Citations

M9 S.I. 2000/3236.M10 S.I. 2008/738.M11 2015 c.15.

[F34 Transitional provision in relation to EU Exit

4A.—(1) In this regulation—

"pre-exit period" means the period beginning with the commencement date and ending immediately before IP completion day.

- (2) Subject to paragraph (3), where a non-automatic weighing instrument was made available on the market during the pre-exit period, despite the amendments made by Schedule 26 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 F35, any obligation to which a person was subject under these Regulations as they had effect immediately before IP completion day, continues to have effect as it did immediately before IP completion day, in relation to that non-automatic weighing instrument.
 - (3) Paragraph (2) does not apply to—
 - (a) any obligation of any competent authority to inform the European Commission or Member States of any matter; or
 - (b) any obligation to take action outside of the United Kingdom in respect of that non-automatic weighing instrument.
 - (4) Where during the pre-exit period—
 - (a) a non-automatic weighing instrument has not been placed on the market; and
 - (b) a manufacturer has taken any action under regulation 36 as it had effect immediately before IP completion day in relation to that non-automatic weighing instrument,

that action has effect as if it had been done under regulation 36 as it had effect on and after IP completion day.]

- [F36(5)] Where paragraph (6) applies to a regulated non-automatic weighing instrument, regulations 67 and 68 have effect subject to the modifications in paragraph (7).
- (6) This paragraph applies to a regulated non-automatic weighing instrument that has been placed on the market—
 - (a) during the pre-exit period; or
 - (b) pursuant to Article 41 of the EU withdrawal agreement.
 - (7) The modifications referred to in paragraph (5) are that—
 - (a) the reference in regulation 67(1)(a) to "UK marking" is to be read as a reference to the CE marking within the meaning of Article 2(19) of the Directive;
 - (b) the reference in regulation 67(1)(b) to "M marking" is to be read as a reference to the supplementary metrology marking as described in Article 16(2) of the Directive;
 - (c) the reference in regulation 67(1)(c) to "approved body" is to be read as a reference to the body that undertook any conformity assessment procedure in accordance with Article 13 of the Directive;
 - (d) the references in regulations 67(2)(b) and 68(4)(b) to "type examination certificate" are to be read as references to an EU-type examination certificate, issued in accordance with the conformity assessment procedure set out in point 1 of Annex II to the Directive, known as "Module B".
- F37(8) Subject to paragraph (9), where before 11pm on 31st December 2024—
 - (a) a non-automatic weighing instrument has not been placed on the market or put into service; and
 - (b) a manufacturer has taken any action under the conformity assessment procedure that applies to that product in accordance with Article 13 of the Directive

that action has effect as if it had been done under the applicable conformity assessment procedure referred to in regulation 36.

(9) Paragraph (8) does not apply—

- (a) after the expiry of the validity of any certificate issued pursuant to the applicable conformity assessment procedure; and
- (b) in any event, after 31st December 2027.

Textual Amendments

- F34 Reg. 4A 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. 26 para. 5 (as amended by S.I. 2020/676, regs. 1(1), 2 and further amended by S.I. 2020/852, regs. 2(2), 4(2), Sch. 1 para. 1(o)(iii)); 2020 c. 1, Sch. 5 para. 1(1)
- **F35** S.I. 2019/696.
- **F36** Reg. 4A(5)-(7) inserted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, 11(2)
- F37 Reg. 4A(8)(9) inserted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 17(2)

PART 2

REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS - OBLIGATIONS OF ECONOMIC OPERATORS

CHAPTER 1

OBLIGATIONS OF MANUFACTURERS AND PERSONS TO BE TREATED AS MANUFACTURERS

Introductory

- **5.**—(1) This Chapter applies in relation to the placing on the market of a regulated non-automatic weighing instrument by a manufacturer.
 - (2) The obligations in this Chapter also apply to an importer or distributor who—
 - (a) places a regulated non-automatic weighing instrument on the market under the name or trade mark of that importer or distributor; or
 - (b) modifies a regulated non-automatic weighing instrument already placed on the market in such a way that compliance with these Regulations may be affected,

and the expression "manufacturer" is to be construed accordingly.

Manufacturers' responsibilities – design, conformity assessment and marking of regulated non-automatic weighing instruments E+W+S

- **6.**—[F38(1)] A manufacturer must not place on the market a regulated non-automatic weighing instrument unless the manufacturer has—
 - (a) designed and manufactured the instrument in accordance with the essential requirements;
 - (b) drawn up technical documentation in relation to the instrument;
 - (c) carried out (or procured the carrying out of) the relevant conformity assessment procedure which has demonstrated compliance of the instrument with the applicable requirements;
 - (d) drawn up [F39a] declaration of conformity; and

- (e) affixed to the instrument [F40] or where paragraph (2) applies, in respect of the UK marking, to a label affixed to a product or to a document accompanying the product]
 - (i) the [F41UK] marking; and
 - (ii) the M marking.
- [F42(2)] For a period of [F43seven years] beginning with IP completion day, the UK marking may be affixed to—
 - (a) a label affixed to the instrument; or
 - (b) to a document accompanying the instrument.]

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

Textual Amendments

- F38 Reg. 6 renumbered as reg. 6(1) (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 26 para. 6(a) (as substituted 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. 18(3))
- Word in reg. 6(1)(d) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 26 para. 6(b) (as substituted 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. 18(3))
- F40 Words in reg. 6(1)(e) inserted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 26 para. 6(c)(i) (as substituted 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. 18(3))
- F41 Word in reg. 6(1)(e) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 26 para. 6(c)(ii) (as substituted 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. 18(3))
- F42 Reg. 6(2) inserted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 26 para. 6(d) (as substituted 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. 18(3))
- F43 Words in reg. 6(2) substituted (E.W.S) (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 3, Sch. 2 para. (o)

Manufacturers' responsibilities – design, conformity assessment and marking of regulated non-automatic weighing instruments N.I.

- **6.** A manufacturer must not place on the market a regulated non-automatic weighing instrument unless the manufacturer has—
 - (a) designed and manufactured the instrument in accordance with the essential requirements;
 - (b) drawn up technical documentation in relation to the instrument;
 - (c) carried out (or procured the carrying out of) the relevant conformity assessment procedure which has demonstrated compliance of the instrument with the applicable requirements;
 - (d) drawn up an EU declaration of conformity; and
 - (e) affixed to the instrument—
 - (i) the CE marking; and
 - (ii) the M marking.

Extent Information

E52 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Manufacturers' obligations in respect of records

7. A manufacturer must keep the technical documentation and the [F44EU] declaration of conformity for a period of 10 years beginning with the day after the day on which the regulated non-automatic weighing instrument to which it relates has been placed on the market.

Textual Amendments

F44 Word in reg. 7 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. 26 para. 7** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), **2**); 2020 c. 1, **Sch. 5 para. 1(1)**

Manufacturers' obligations to ensure continuing conformity with the essential requirements E+W+S

- **8.**—(1) Manufacturers must have procedures in place for series production of regulated non-automatic weighing instruments by them to ensure that instruments so manufactured continue to meet the essential requirements.
 - (2) These procedures must adequately take into account changes in-
 - (a) regulated non-automatic weighing instrument design or characteristics; and
 - (b) changes in the [F45] designated] standards or in other technical specifications by reference to which the conformity of the regulated non-automatic weighing instrument is declared.
- (3) When deemed appropriate with regard to the risks presented by the use of a regulated non-automatic weighing instrument, a manufacturer must—
 - (a) carry out sample testing of regulated non-automatic weighing instruments made available by the manufacturer on the market;
 - (b) investigate complaints about regulated non-automatic weighing instruments made available by the manufacturer on the market;
 - (c) if necessary, keep a register of—
 - (i) such complaints;
 - (ii) non-conforming regulated non-automatic weighing instruments; and
 - (iii) regulated non-automatic weighing instrument recalls; and
 - (d) keep distributors informed of any monitoring action the manufacturer has undertaken.

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

Textual Amendments

F45 Word in reg. 8(2)(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. 26 para. 8** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), **2**); 2020 c. 1, **Sch. 5 para. 1(1)**

Manufacturers' obligations to ensure continuing conformity with the essential requirements N.I.

- **8.**—(1) Manufacturers must have procedures in place for series production of regulated non-automatic weighing instruments by them to ensure that instruments so manufactured continue to meet the essential requirements.
 - (2) These procedures must adequately take into account changes in—
 - (a) regulated non-automatic weighing instrument design or characteristics; and
 - (b) changes in the harmonised standards or in other technical specifications by reference to which the conformity of the regulated non-automatic weighing instrument is declared.
- (3) When deemed appropriate with regard to the risks presented by the use of a regulated non-automatic weighing instrument, a manufacturer must—
 - (a) carry out sample testing of regulated non-automatic weighing instruments made available by the manufacturer on the market;
 - (b) investigate complaints about regulated non-automatic weighing instruments made available by the manufacturer on the market;
 - (c) if necessary, keep a register of—
 - (i) such complaints;
 - (ii) non-conforming regulated non-automatic weighing instruments; and
 - (iii) regulated non-automatic weighing instrument recalls; and
 - (d) keep distributors informed of any monitoring action the manufacturer has undertaken.

Extent Information

E53 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Manufacturers' obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.

- **9.**—(1) A manufacturer must ensure that a regulated non-automatic weighing instrument, which that manufacturer has placed on the market, bears a type, batch, serial number or other element allowing identification of the instrument.
- (2) A manufacturer must ensure that a regulated non-automatic weighing instrument is marked with the information specified in Schedule 1 (information to be marked on regulated non-automatic weighing instruments) and in the manner required by that Schedule.
- (3) Where a regulated non-automatic measuring instruments includes or is attached to devices which are not used or intended to be used for any of the purposes listed in regulation 3(2), the manufacturer must affix to those devices a symbol constituted by a capital letter (M) printed in black on a red background at least 25mm x 25mm square with two intersecting diagonals forming a cross.
 - (4) The symbol referred to in paragraph (3) must be affixed in a clearly visible and indelible form.

Manufacturers to mark contact details on regulated non-automatic weighing instruments **E** +W+S



- 10.—(1) A manufacturer must indicate on every regulated non-automatic weighing instruments manufactured by that manufacturer, the manufacturer's name, registered trade name or registered trade mark and the postal address at which the manufacturer can be contacted.
- (2) The address required by these Regulations must indicate a single point at which the manufacturer can be contacted.
- (3) The contact details required by this regulation must be [F46clear, legible and in easily understandable | English.

Extent Information

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

F46 Words in reg. 10(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. 26 para. 9 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Manufacturers to mark contact details on regulated non-automatic weighing instruments N.I.

- 10.—(1) A manufacturer must indicate on every regulated non-automatic weighing instruments manufactured by that manufacturer, the manufacturer's name, registered trade name or registered trade mark and the postal address at which the manufacturer can be contacted.
- (2) The address required by these Regulations must indicate a single point at which the manufacturer can be contacted.
- (3) The contact details required by this regulation must be in a language that is easily understood by end-users and market surveillance authorities and in the case of regulated non-automatic weighing instruments made available in [F188] Northern Ireland], they must be in English.

Extent Information

E54 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

F188 Words in reg. 10(3) 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. 13 para. 3(1)

Documentation to accompany regulated non-automatic weighing instruments E+W+S

11. —(1)	A m	nanufa	cturer	must	ensur	e that	regulat	ed	non-automati	c we	eighing ii	nstru	ments
manufactured	l by	that	manuf	acturer	are	accom	panied	by	instructions	and	informat	ion	easily
understood by	y end	l-users	S.										

F47	2)																																
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(3) Such instructions and information and any labelling relating to a regulated non-automatic weighing instrument must be [F48clear, legible and in easily understandable English].

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

- F47 Reg. 11(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. 26 para. 10(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F48** Words in reg. 11(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. 26 para. 10(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Documentation to accompany regulated non-automatic weighing instruments N.I.

- 11.—(1) A manufacturer must ensure that regulated non-automatic weighing instruments manufactured by that manufacturer are accompanied by instructions and information easily understood by end-users.
- (2) Where end-users are in [F189]Northern Ireland], those instructions and information must be in English.
- (3) Such instructions and information and any labelling relating to a regulated non-automatic weighing instrument must be clear, understandable and intelligible.

Extent Information

E55 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

F189 Words in reg. 11(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. 13 para. 3(1)

Action to be taken where regulated non-automatic weighing instruments placed on the market are not in conformity with the essential requirements E+W+S

- **12.**—(1) This regulation applies where a manufacturer considers or has reason to believe that a regulated non-automatic weighing instrument placed on the market by that manufacturer is not in conformity with the requirements of these Regulations.
- (2) The manufacturer must immediately take the corrective measures necessary to bring the regulated non-automatic weighing instrument into conformity, or withdraw or recall it, if appropriate.
- (3) Where the regulated non-automatic weighing instrument presents a risk, the manufacturer must immediately inform the competent [F49 authority] to that effect giving details, in particular, of the non-compliance and of any corrective measures taken.

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

F49 Word in reg. 12(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. 26 para. 11** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**

Action to be taken where regulated non-automatic weighing instruments placed on the market are not in conformity with the essential requirements N.I.

- 12.—(1) This regulation applies where a manufacturer considers or has reason to believe that a regulated non-automatic weighing instrument placed on the market by that manufacturer is not in conformity with the requirements of these Regulations.
- (2) The manufacturer must immediately take the corrective measures necessary to bring the regulated non-automatic weighing instrument into conformity, or withdraw or recall it, if appropriate.
- (3) Where the regulated non-automatic weighing instrument presents a risk, the manufacturer must immediately inform the competent national authorities of the [F¹⁹⁰relevant] states in which the instrument has been made available on the market to that effect giving details, in particular, of the non-compliance and of any corrective measures taken.

Extent Information

E56 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

F190 Word in reg. 12(3) 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. 13 para. 3(2)

Provision of information to the competent authority

- 13.—(1) A manufacturer must, further to a reasoned request from a competent authority, provide that authority, with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a regulated non-automatic weighing instrument manufactured by that manufacturer with the requirements of these Regulations.
- (2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.
- (3) A manufacturer must co-operate with a competent authority, at the request of that authority, on any action to eliminate the risks posed by regulated non-automatic weighing instruments that the manufacturer has placed on the market.

Use of authorised representatives by manufacturers

14.—(1) A manufacturer may, by written mandate, appoint an authorised representative to discharge the responsibilities of that manufacturer under these Regulations in relation to the placing on the market of a regulated non-automatic weighing instrument.

- (2) The authorised representative does not have the power to discharge the manufacturer's obligations under regulations 6(a) and 6(b).
 - (3) The authorised representative must be treated as authorised to—
 - (a) keep the [F50] declaration of conformity and the technical documentation at the disposal of the market surveillance authority for 10 years beginning with the day after the day on which a regulated non-automatic weighing instrument has been placed on the market;
 - (b) provide a competent authority further to a reasoned request from that authority with all the information and documentation necessary to demonstrate the conformity of a regulated non-automatic weighing instrument; and
 - (c) co-operate with a competent authority, at its request, on any action taken to eliminate the risks posed by regulated non-automatic weighing instruments covered by its mandate.

Textual Amendments

F50 Word in reg. 14(3)(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. 26 para. 12** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER 2

OBLIGATIONS OF IMPORTERS

Introductory E+W+S

15. This Chapter applies to the placing on the market of a regulated non-automatic weighing instrument that is imported into the United Kingdom from a country outside the [F51United Kingdom].

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

F51 Words in reg. 15 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. 26 para. 13** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**

Introductory N.I.

15. This Chapter applies to the placing on the market of a regulated non-automatic weighing instrument that is imported into [F191]Northern Ireland] from a country outside the [F192]relevant market].

Extent Information

E57 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

- F191 Words in reg. 15 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. 13 para, 3(1)
- F192 Words in reg. 15 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. 13 para. 3(3)

Ensuring compliance of regulated non-automatic weighing instruments E+W+S

- **16.**—(1) An importer must only place compliant regulated non-automatic weighing instruments on the market.
 - (2) An importer must ensure that—
 - (a) the appropriate conformity assessment procedure has been carried out by the manufacturer of the regulated non-automatic weighing instrument (or by the importer where the importer is to be regarded as the manufacturer by virtue of regulation 5(2);
 - (b) the manufacturer has drawn up the technical documentation (or that the importer has done so where the importer is treated as the manufacturer by virtue of regulation 5(2);
 - (c) the regulated non-automatic weighing instrument bears the [F52UK] marking and the M marking;
 - (d) the manufacturer (or the importer where he is treated as the manufacturer under regulation 5(2)) has complied with the requirements of regulations 9 (manufacturers' obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.) and 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments).

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

Textual Amendments

F52 Word in reg. 16(2)(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. 26 para. 14** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**

Ensuring compliance of regulated non-automatic weighing instruments N.I.

- **16.**—(1) An importer must only place compliant regulated non-automatic weighing instruments on the market.
 - (2) An importer must ensure that—
 - (a) the appropriate conformity assessment procedure has been carried out by the manufacturer of the regulated non-automatic weighing instrument (or by the importer where the importer is to be regarded as the manufacturer by virtue of regulation 5(2);
 - (b) the manufacturer has drawn up the technical documentation (or that the importer has done so where the importer is treated as the manufacturer by virtue of regulation 5(2);
 - (c) the regulated non-automatic weighing instrument bears the CE marking and the M marking;

(d) the manufacturer (or the importer where he is treated as the manufacturer under regulation 5(2)) has complied with the requirements of regulations 9 (manufacturers' obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.) and 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments).

Extent Information

E58 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Importers duty to notify manufacturer and market surveillance authorities of non-compliant regulated non-automatic weighing instruments that present a risk

17. Where an importer considers, or has reason to believe, that the regulated non-automatic weighing instrument is not in conformity with the essential requirements and presents a risk, the importer must inform the manufacturer and the market surveillance authority.

Requirements to mark importers' details on regulated non-automatic weighing instruments E+W+S

- **18.**—(1) An importer must indicate on any regulated non-automatic weighing instrument imported by that importer, the importer's name, registered trade name or trademark, and the postal address at which the importer can be contacted.
 - [F53(2) Paragraph (1) does not apply where—
 - (a) either—
 - (i) the importer would have to open the packaging in order to indicate the information on the instrument; or
 - (ii) the importer has imported the instrument from an EEA state or Switzerland and places it on the market within the period of [F54seven years] beginning with IP completion day, and
 - (b) before placing the instrument on the market, the importer sets out the information referred to in paragraph (1)—
 - (i) where sub-paragraph (a)(i) applies, on the packaging and in a document accompanying the instrument;
 - (ii) where sub-paragraph (a)(ii) applies, in a document accompanying the instrument.]
- (3) The contact details required by this regulation must be [F55clear, legible and in easily understandable] English.

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

F53 Reg. 18(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. 26 para. 15(a) (with Sch. 26 para. 5) (as amended by S.I. 2019/1246, regs. 1(3), 5; S.I. 2020/676, regs. 1(1), 2; S.I. 2020/852, regs. 2(2), 4(2), Sch. 1 para. 1(o)(iv) and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 2(1)(j)); 2020 c. 1, Sch. 5 para. 1(1)

- F54 Words in reg. 18(2)(a)(ii) substituted (E.W.S) (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 4, Sch. 3 para. (m)
- **F55** Words in reg. 18(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. 26 para. 15(b)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Modifications etc. (not altering text)

C1 Reg. 18 modified by The Conformity Assessment (Mutual Recognition Agreements) Regulations 2019 (S.I. 2019/392), reg. 6 (as inserted (temp.) (10.9.2019) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(2)(4), 2(3) (with reg. 18))

Requirements to mark importers' details on regulated non-automatic weighing instruments N.I.

- **18.**—(1) An importer must indicate on any regulated non-automatic weighing instrument imported by that importer, the importer's name, registered trade name or trademark, and the postal address at which the importer can be contacted.
- (2) Where this would require the packaging to be opened, those indications may be given on the packaging and in a document accompanying the instrument.
- (3) The contact details required by this regulation must be in a language that is easily understood by end-users and market surveillance authorities, and in the case of regulated non-automatic weighing instruments made available in [F193]Northern Ireland], they must be in English.

Extent Information

E59 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

F193 Words in reg. 18(3) 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. 13 para. 3(1)

Modifications etc. (not altering text)

Reg. 18 modified by The Conformity Assessment (Mutual Recognition Agreements) Regulations 2019 (S.I. 2019/392), reg. 6 (as inserted (temp.) (10.9.2019) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(2)(4), 2(3) (with reg. 18))

Importers' duty to ensure that regulated non-automatic weighing instruments are accompanied by relevant documentation. E+W+S

19.—(1) An importer must ensure that regulated non-automatic weighing	instruments imp	orted
by the importer are accompanied by instructions and information [F56which are	re clear, legible a	ınd in
easily understandable English].		

F57(2)																

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

- **F56** Words in reg. 19(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. 26 para. 16(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F57 Reg. 19(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. 26 para. 16(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Importers' duty to ensure that regulated non-automatic weighing instruments are accompanied by relevant documentation. N.I.

- 19.—(1) An importer must ensure that regulated non-automatic weighing instruments imported by the importer are accompanied by instructions and information in a language easily understood by end users
- (2) Where end users are in [F194]Northern Ireland], the instructions and information referred to in paragraph (1) must be in English.

Extent Information

E60 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

F194 Words in reg. 19(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. 13 para. 3(1)**

Duty of importers to ensure proper conditions of storage and transport

20. An importer must, in respect of regulated non-automatic weighing instruments under the importer's responsibility, ensure that the conditions of their storage or transport are not such as to jeopardise their continuing compliance with the essential requirements.

Duties of importers with regard to monitoring etc.

- **21.**—(1) When deemed appropriate with regard to the performance of a regulated non-automatic weighing instrument imported by an importer, the importer must—
 - (a) carry out a sample testing of regulated non-automatic weighing instruments made available on the market by the importer;
 - (b) investigate complaints about regulated non-automatic weighing instruments imported by them; and
 - (c) if necessary, keep a register of—
 - (i) such complaints;
 - (ii) non-conforming regulated non-automatic weighing instruments;

- (iii) regulated non-automatic weighing instrument recalls; and
- (d) where the importer is not also the distributor of the regulated non-automatic weighing instrument, keep distributors, to whom he has supplied an instrument, informed of any monitoring undertaken by that importer.

Action to be taken by importers where regulated non-automatic weighing instruments placed on the market by them are not in conformity with essential requirements

- **22.**—(1) This regulation applies where an importer considers, or has reason to believe, that a regulated non-automatic weighing instrument placed on the market by the importer is not in conformity with the requirements of these Regulations.
- (2) Where this regulation applies, the importer must immediately take the corrective measures necessary to bring the regulated non-automatic weighing instrument into conformity, or withdraw or recall it, if appropriate.
- (3) Where the non-automatic weighing instrument presents a risk, the importer must immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that importer.

Requirement for importer to keep copy of [F58EU] declaration of conformity

23. The importer must, for a period of 10 years beginning with the day after the day on which the regulated non-automatic weighing instrument is placed on the market, keep a copy of the [F59EU] declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request.

Textual Amendments

- F58 Word in reg. 23 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. 26 para. 17 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F59** Word in reg. 23 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. 26 para. 17** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Provision of information to a competent authority

- **24.**—(1) The importer must, further to a reasoned request from a competent authority, provide the competent authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the regulated non-automatic weighing instrument with the requirements of these Regulations.
- (2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.
- (3) An importer must co-operate with a competent authority, at its request, as regards any action to eliminate the risks posed by any regulated non-automatic weighing instrument that the importer has placed on the market.

CHAPTER 3

OBLIGATIONS OF DISTRIBUTORS

Introductory

25. This Chapter applies in relation to the making available on the market of a regulated non-automatic weighing instrument by a distributor.

Distributors - duty to act with due care

26. Before making the regulated non-automatic instrument available on the market, the distributor must act with due care in relation to the requirements of these Regulations.

Distributors – verification obligations E+W+S

- **27.**—(1) The distributor must verify that the regulated non-automatic weighing instrument bears the $[^{F60}UK]$ marking and the M marking.
- (2) The distributor must verify that the regulated non-automatic weighing instrument, it is accompanied by instructions and information [F61which are clear, legible and in easily understandable English].
- (4) The distributor must verify that the manufacturer and the importer have complied with the requirements set out in regulation 9 (manufacturers' obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.), regulation 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments) and regulation 18 (requirements to mark importers' details on regulated non-automatic weighing instruments).

Extent Information

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

- **F60** Word in reg. 27(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. 26 para. 18(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F61** Words in reg. 27(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. 26 para. 18(b)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**
- **F62** Reg. 27(3) 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. 26 para. 18(c)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), **2**); 2020 c. 1, **Sch. 5 para. 1(1)**

Distributors – verification obligations N.I.

- **27.**—(1) The distributor must verify that the regulated non-automatic weighing instrument bears the CE marking and the M marking.
- (2) The distributor must verify that the regulated non-automatic weighing instrument, it is accompanied by instructions and information easily understood by end users.

- (3) Instructions and information supplied in accordance with this regulation must be in a language that is easily understood by end users and where those users are in [F195]Northern Ireland] must be in English.
- (4) The distributor must verify that the manufacturer and the importer have complied with the requirements set out in regulation 9 (manufacturers' obligations in relation to the marking of regulated non-automatic weighing instruments with serial numbers etc.), regulation 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments) and regulation 18 (requirements to mark importers' details on regulated non-automatic weighing instruments).

Extent Information

E61 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

F195 Words in reg. 27(3) 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. 13 para. 3(1)

Distributors not to make non-conforming non-automatic weighing instruments available on the market etc.

- **28.**—(1) This regulation applies where a distributor considers, or has reason to believe, that a regulated non-automatic weighing instrument is not in conformity with the essential requirements.
- (2) Where this regulation applies, the distributor must not make the regulated non-automatic weighing instrument available on the market until it has been brought into conformity.
- (3) Where the regulated non-automatic weighing instrument presents a risk, the distributor must immediately inform—
 - (a) the manufacturer;
 - (b) the importer (where the distributor is not also the manufacturer or importer); and
 - (c) the market surveillance authority,

to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that distributor.

Duty of distributors to ensure proper conditions of storage and transport

29. A distributor must, in respect of regulated non-automatic weighing instruments under that distributor's responsibility, ensure that the conditions of their storage or transport are not such as to jeopardise their continuing compliance with the essential requirements.

Action to be taken by distributors where regulated non-automatic weighing instruments placed on the market by them are not in conformity with essential requirements

30.—(1) This regulation applies where a distributor considers, or has reason to believe, that a regulated non-automatic weighing instrument [^{F63}made available] on the market by that distributor is not in conformity with the requirements of these Regulations.

- (2) Where this regulation applies, the distributor must immediately take the corrective measures necessary to bring the regulated non-automatic weighing instrument into conformity, or withdraw or recall it, if appropriate.
- (3) Where the regulated non-automatic weighing instrument presents a risk, the distributor must immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that distributor.

Textual Amendments

F63 Words in reg. 30(1) substituted (1.2.2019) by The Weights and Measures etc. (Miscellaneous) (Amendment) Regulations 2019 (S.I. 2019/5), regs. 1, **7(2)**

Provision of information to the competent authority

- **31.**—(1) The distributor must, further to a reasoned request from a competent authority, provide that authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the regulated non-automatic weighing instrument with the requirements of these Regulations.
- (2) Information and documentation supplied to a competent authority pursuant to this regulation must be supplied in English.
- (3) A distributor must co-operate with a competent authority, at its request, as regards any action to eliminate the risks posed by any regulated non-automatic weighing instrument that the distributor has placed on the market.

CHAPTER 4

IDENTIFICATION OF ECONOMIC OPERATORS

- **32.**—(1) Economic operators must, on request, identify to the market surveillance authorities—
 - (a) any economic operator who has supplied them with a regulated non-automatic weighing instrument; and
 - (b) any economic operator to whom they have supplied a regulated non-automatic weighing instrument
- (2) Economic operators must be able to present the information referred to in paragraph (1) for 10 years beginning with the day on which they have been supplied with the regulated non-automatic weighing instrument and for 10 years beginning with the day after the day on which they have supplied the instrument.
- (3) The Secretary of State may impose a monetary penalty on an economic operator who fails to comply with an obligation imposed by this regulation.
 - (4) Schedule 5 has effect in relation to the imposition of a monetary penalty under paragraph (3).

[F64Obligations which are met by complying with obligations in the Directive

- **32A.**—(1) In this regulation—
 - (a) any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive;
 - (b) "CE marking" has the meaning given to it in Article 2(19);
 - (c) "Module B" means the conformity assessment procedure set out in point 1 of Annex II;

- (d) "EU-type examination certificate" means an EU-type examination certificate issued in accordance with Module B;
- (e) "harmonised standard" has the meaning given to it in Article 2(11).
- (2) Paragraph (3) applies where, before placing a non-automatic weighing instrument on the market, the manufacturer—
 - (a) ensures that the non-automatic weighing instrument has been designed and manufactured in accordance with the essential requirements set out in Annex I;
 - (b) ensures that the relevant conformity assessment procedures that apply to that non-automatic weighing instrument in accordance with Article 13 have been carried out;
 - (c) draws up the technical documentation referred to in Annex II;
 - (d) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;
 - (e) affixes the CE marking and the supplementary metrology marking, in accordance with Articles 16 and 17(1) to (5);
 - (f) affixes the inscriptions provided for in points 1 or 2 of Annex III in accordance with Article 6(5);
 - (g) affixes where required in accordance with Article 6(5) the restrictive use symbol as provided for in Article 18 and in point 3 of Annex III;
 - (h) draws up an EU declaration of conformity, in accordance with Article 14; and
 - (i) ensures that the EU declaration of conformity is prepared in or translated into English.
 - (3) Where this paragraph applies—
 - (a) the requirements of regulations 6, 9(3) and (4), 41 and 45(2) are to be treated as being satisfied;
 - (b) regulations 7, 8(2), 44, 63(1)(a) to (e), 67, 68 and 71 apply subject to the modifications in paragraph (8); and
 - (c) Regulations 34 to 36 do not apply.
- (4) Paragraph (5) applies where, before placing a regulated non-automatic weighing instrument on the market, the importer ensures that—
 - (a) the relevant conformity assessment procedure referred to in Article 13 has been carried out;
 - (b) the manufacturer has drawn up the technical documentation referred to in Annex II; and
 - (c) the non-automatic weighing instrument bears the CE marking and supplementary metrology marking in accordance with Articles 16 and 17(1) to (5).
 - (5) Where this paragraph applies—
 - (a) the requirements of regulation 16(2)(a) to (c) are to be treated as being satisfied; and
 - (b) regulations 23, 63(1)(a) to (e), 67 and 68 apply subject to the modifications in paragraph (8).
- (6) Paragraph (7) applies where, before making a regulated non-automatic weighing instrument available on the market, a distributor ensures that the non-automatic weighing instrument bears the CE marking and the inscriptions referred to in point 1 of Annex III.
 - (7) Where this paragraph applies—
 - (a) regulation 27(1) is to be treated as being satisfied; and
 - (b) regulations 28(1), 28(2), 29, 63(1)(a), 63(1)(b), 67, 68 and 71 apply subject to the modifications in paragraph (8).
 - (8) The modifications referred to in sub-paragraphs (3)(b), (5)(b) and (7)(b) are that—

- (a) any reference to "declaration of conformity" is to be read as a reference to the EU declaration of conformity;
- (b) any reference to "UK marking" is to be read as a reference to the CE marking;
- (c) any reference to "designated standard" is to be read as a reference to a harmonised standard;
- (d) any reference to "relevant conformity assessment procedure" is to be read as a reference to the relevant conformity assessment procedures referred to in Article 13;
- (e) any reference to "technical documentation" is to be read as a reference to the technical documentation referred to in Annex II;
- (f) any reference to "type examination certificate" is to be read as a reference to an EU-type examination certificate:
- (g) any reference to "M marking" is to be read as a reference to the supplementary metrology marking;
- (h) [F65 except in relation to regulation 68,] any reference to "approved body" is to be read as a reference to the body that undertook any conformity assessment procedure in accordance with Article 13;
- (i) any reference to "authorised mark" includes the CE marking and the supplementary metrology marking.]

Textual Amendments

F64 Regs. 32A-32D 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. 26 para. 19 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 18(4)); 2020 c. 1, Sch. 5 para. 1(1)

F65 Words in reg. 32A(8)(h) inserted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **11(3)**

[F64Conformity assessment procedure obligations that are met by complying with the Directive

32B.—(1) In this regulation—

- (a) any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive;
- (b) "EU-type examination certificate" means an EU-type examination certificate issued in accordance with the conformity assessment procedure set out in point 1 of Annex II (Module B);
- (c) any reference to "the first stage of the conformity assessment procedure" is a reference to one or both of the following—
 - (i) all examinations and tests which are not gravity dependent and which are included in the conformity assessment procedures set out in points 2 to 5 of Annex II;
 - (ii) the examinations and tests included in the conformity assessment procedures set out in points 2 to 5 of Annex II that may be carried out at the manufacturer's works or any other location where—
 - (aa) the transport of the instrument to its place of use requires dismantling of the instrument; or

- (bb) the putting into service of the instrument in its place of use requires assembly of the instrument or other technical installation work that is likely to affect the instrument's performance.
- (2) Paragraph (3) applies where, prior to the manufacture of a non-automatic weighing instrument the manufacturer has ensured that the conformity assessment procedure as set out in point 1 of Annex II (Module B) has been carried out.
 - (3) Where this paragraph applies—
 - (a) the reference in regulation 36(a) to "Module B as set out in point 1 of Schedule 7" is to be read as a reference to the conformity assessment procedure as set out in point 1 of Annex II (Module B); and
 - (b) regulations 6(b) and (c), 7, 16(2)(a) and (b), 63(1)(e), 67(2)(b), 68(4)(b) and paragraph 1 of Schedule 1 apply subject to the modifications in paragraph (6).
 - (4) Paragraph (5) applies where—
 - (a) in accordance with point 7.1 of Annex II, the procedures set out in points 2 to 5 of that Annex may be carried out in two stages; and
 - (b) the first stage of the conformity assessment procedure is carried out in accordance with any of the following points of Annex II—
 - (i) point 2 (Module D);
 - (ii) point 3 (Module D1);
 - (iii) point 4 (Module F); or
 - (iv) point 5 (Module F1).
 - (5) Where this paragraph applies—
 - (a) the reference in regulation 36(1)(a)(i) to "Module D as set out in point of Schedule 7" is to be read as including the first stage of the conformity assessment procedure as set out in point 2 of Annex II (Module D);
 - (b) the reference in regulation 36(1)(a)(ii) to "Module F as set out in point 4 of Schedule 7" is to be read as including the first stage of the conformity assessment procedure as set out in point 4 of Annex II (Module F);
 - (c) the reference in regulation 36(3)(a) to "Module D1 as set out in point 3 of Schedule 7" is to be read as including the first stage of the conformity assessment procedure as set out in point 3 of Annex II (Module D1);
 - (d) the reference in regulation 36(3)(b) to "Module F1 as set out in point 5 of Schedule 7" is to be read as including the first stage of the conformity assessment procedure as set out in point 5 of Annex II (Module F1);
 - (e) regulations 6(b) and (c), 7, 16(2)(a) and (b), 45(6) and (7), 63(1)(c) and (e) and 67(1)(c) apply subject to the modifications in paragraph (6).
 - (6) The modifications referred to in paragraphs (3)(b) and (5)(e) are that—
 - (a) any reference to "relevant conformity assessment procedure" is to be read as including—
 - (i) where paragraph (3) applies, the conformity assessment procedure set out in point 1 of Annex II;
 - (ii) where paragraph (5) applies, the relevant first stage conformity assessment procedure;
 - (b) any reference to "type examination" is to be read as a reference to the EU-Type examination certificate;

- (c) any reference to "technical documentation" is to be read as including the technical documentation required by points 1 to 5 of Annex II (as applicable);
- (d) any reference to "approved body" is to be read as including the body which undertook the first stage conformity assessment procedure.]

Textual Amendments

F64 Regs. 32A-32D 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. 26 para. 19** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 18(4)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F64Expiry of regulations 32A and 32B

- **32C.**—(1) Subject to [^{F66}paragraphs (2) and (6)], regulation 32A ceases to have effect at the end of the period of [^{F67}four years] beginning with IP completion day.
 - (2) Notwithstanding the expiry of regulation 32A—
 - (a) any non-automatic weighing instrument which was placed on the market pursuant to regulation 32A may continue to be made available on the market on or after the expiry of regulation 32A;
 - (b) any obligation to which a person was subject under regulation 32A in respect of any non-automatic weighing instrument placed on the market pursuant to regulation 32A continues to have effect after the expiry of regulation 32A, in respect of that instrument.
- (3) Subject to [^{F68}paragraphs (4) and (6)], regulation 32B ceases to have effect at the end of the period of [^{F69}four years] beginning with IP completion day.
- (4) Where a conformity assessment procedure has been completed pursuant to regulation 32B in relation to a non-automatic weighing instrument prior to the expiry of regulation 32B, regulation 32B continues to apply in respect of that instrument where—
 - (a) the manufacturer arranges for the EU-Type examination certificate and any annexes to be transferred to an approved body;
 - (b) the approved body referred to in sub-paragraph (a) accepts responsibility for the EU-Type examination certificate; and
 - (c) the approved body issues a Type-examination certificate relying, or relying in part, on any examinations or tests undertaken prior to the issue of the EU-Type examination certificate.
- (5) In paragraph (4) "EU-Type examination certificate" has the meaning given to it in regulation 32B(1)(b).
- F⁷⁰(6) regulations 67 and 68 continue to have effect in relation to any non-automatic weighing instrument—
 - (a) placed on the market pursuant to 32A; or
 - (b) in relation to which a manufacturer has undertaken a conformity assessment procedure in accordance with regulation 32B,

as if regulations 32A or 32B had not expired.]

Textual Amendments

- F64 Regs. 32A-32D 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. 26 para. 19 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 18(4)); 2020 c. 1, Sch. 5 para. 1(1)
- **F66** Words in reg. 32C(1) substituted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, 11(4)(a)
- Words in reg. 32C(1) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, Sch. 1 para. (p)
- **F68** Words in reg. 32C(3) substituted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, 11(4)(b)
- Words in reg. 32C(3) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, Sch. 1 para. (p)
- F70 Reg. 32C(6) inserted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, 11(4)(c)

Qualifying Northern Ireland Goods

- **32D.**—(1) Where paragraph (2) applies—
 - (a) a non-automatic weighing instrument is to be treated as being in conformity with the essential requirements; and
 - (b) each relevant economic operator is to be treated as having complied or as complying with the obligations imposed on them under Part 2.
- (2) This paragraph applies where—
 - (a) a non-automatic weighing instrument is—
 - (i) in conformity with the essential requirements, within the meaning of that term in regulation 2, as it applies in Northern Ireland; and
 - (ii) qualifying Northern Ireland goods;
 - (b) each relevant economic operator has complied or is complying with the obligations imposed on them under Part 2, as that Part applies in Northern Ireland; and
 - (c) an importer has complied with the obligations set out in paragraph (3).
- (3) The obligations referred to in paragraph (2)(c) are that, before placing the non-automatic weighing instrument on the market, the importer—
 - (a) complies with regulation 18;
 - (b) ensures that—
 - (i) the relevant conformity assessment procedure has been carried out in accordance with Part 3, as that Part applies in Northern Ireland;
 - (ii) the manufacturer has drawn up the technical documentation; and
 - (iii) the non-automatic weighing instrument bears the CE marking.
- F71(3A) After a non-automatic weighing instrument has been placed on the market pursuant to this regulation, regulations 67 and 68 are to be read in relation to that instrument subject to the following modifications—
 - (a) the reference in regulation 67(1)(a) to "UK marking" is to be read as a reference to the CE marking, within the meaning of regulation 2(1) as it applies in Northern Ireland;

- (b) the reference in regulation 67(1)(b) to "M marking", is to be read as a reference to the M Marking as defined in regulation 2(1), as it applies in Northern Ireland;
- (c) the reference in regulation 67(1)(c) to "approved body" is to be read as a reference to a "notified body" as defined in regulation 2(1), as it applies in Northern Ireland;
- (d) the references in regulations 67(2)(a) and 68(4)(a) to "essential requirements" are to be read as the essential requirements within the meaning of that term in regulation 2(1), as it applies in Northern Ireland; and
- (e) the references in regulations 67(2)(b) and 68(4)(b) to "type examination certificate" is to be read as a reference to an EU-type examination certificate as defined in regulation 2(1), as it applies in Northern Ireland.]
- (4) In this regulation—
 - "CE marking" has the meaning given to it in regulation 2(1), as it applies in Northern Ireland; "qualifying Northern Ireland goods" has the meaning given to it in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;
 - "technical documentation" has the meaning given to it in regulation 2(1), as it applies in Northern Ireland.]

Textual Amendments

- F64 Regs. 32A-32D 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. 26 para. 19 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/1460, reg. 1(4), Sch. 3 para. 18(4)); 2020 c. 1, Sch. 5 para. 1(1)
- F71 Reg. 32D(3A) inserted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, 11(5)

PART 3

CONFORMITY OF REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS

CHAPTER 1

ESTABLISHING COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

Introductory

33. This Chapter applies for the purposes of establishing whether a regulated non-automatic weighing instrument complies with the essential requirements.

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

- **34.** Conformity with the essential requirements may be established in relation to a regulated non-automatic weighing instrument—
 - (a) through conformity with [F72 designated] standards (or parts of those standards) covering the essential requirements F73 ...; or
 - (b) through the use by the manufacturer of any other technical solution that complies with the essential requirements.

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

- F72 Word in reg. 34(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. 26 para. 20(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F73 Words in reg. 34(a) omitted (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. 26 para. 20(b) (with Sch. 26 para. 5) (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.

- **34.** Conformity with the essential requirements may be established in relation to a regulated non-automatic weighing 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; or
 - (b) through the use by the manufacturer of any other technical solution that complies with the essential requirements.

Extent Information

E62 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 regulated non-automatic weighing instruments E+W+S

35. Regulated non-automatic weighing instruments which are in conformity with [F74] designated] standards (or parts of those standards) shall be presumed to be in conformity with the essential requirements covered by those standards (or parts of those standards).

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

F74 Word in reg. 35 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. 26 para. 21 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Presumptions of conformity of regulated non-automatic weighing instruments N.I.

35. Regulated non-automatic weighing instruments which are in conformity with harmonised standards (or parts of those standards) shall be presumed to be in conformity with the essential requirements covered by those standards (or parts of those standards).

Extent Information

E63 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

- **36.**—(1) The conformity of regulated non-automatic weighing instruments to the essential requirements may, subject to paragraph (2), be established by either of the following conformity assessment procedures as selected by the manufacturer—
 - (a) Module B as set out in point 1 of [F75Schedule 7] followed by either—
 - (i) Module D as set out in point 2 of [F76Schedule 7]; or
 - (ii) Module F as set out in point 4 of [F77Schedule 7]; or
 - (b) Module G as set out in point 6 of [F78Schedule 7].
 - (2) Module B is compulsory for instruments—
 - (a) which use electronic devices; and
 - (b) the load measuring device of which uses a spring to balance the load.
- (3) Where an instrument is not submitted to Module B, either of the following modules must be applied—
 - (a) Module D1 as set out in point 3 of [F79Schedule 7]; or
 - (b) Module F1 as set out in point 5 of [F80Schedule 7].
- (4) [F81An approved] body must carry out the conformity assessment procedure selected by the manufacturer in accordance with the requirements of Schedule 2.
- (5) The documents and correspondence relating to the conformity assessment procedures referred to in this regulation, and which are carried out in the United Kingdom, must be drawn up in English.
- (6) In this regulation a reference to a module other than Module B includes the common provisions as set out in point 7 of [F82Schedule 7].

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

- F75 Words in reg. 36(1)(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. 26 para. 22(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F76** Words in reg. 36(1)(a)(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. 26 para. 22(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F77 Words in reg. 36(1)(a)(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. 26 para. 22(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F78** Words in reg. 36(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. 26 para. 22(b)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, **Sch. 5 para. 1(1)**

- F79 Words in reg. 36(3)(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. 26 para. 22(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F80** Words in reg. 36(3)(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. 26 para. 22(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F81** Words in reg. 36(4) 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. 26 para. 22(c) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F82** Words in reg. 36(6) 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. 26 para. 22(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Conformity assessment procedures N.I.

- **36.**—(1) The conformity of regulated non-automatic weighing instruments to the essential requirements may, subject to paragraph (2), be established by either of the following conformity assessment procedures as selected by the manufacturer—
 - (a) Module B as set out in point 1 of Annex II to the Directive followed by either—
 - (i) Module D as set out in point 2 of Annex II; or
 - (ii) Module F as set out in point 4 of Annex II; or
 - (b) Module G as set out in point 6 of Annex II.
 - (2) Module B is compulsory for instruments—
 - (a) which use electronic devices; and
 - (b) the load measuring device of which uses a spring to balance the load.
- (3) Where an instrument is not submitted to Module B, either of the following modules must be applied—
 - (a) Module D1 as set out in point 3 of Annex II; or
 - (b) Module F1 as set out in point 5 of Annex II.
- (4) A notified body must carry out the conformity assessment procedure selected by the manufacturer in accordance with the requirements of Schedule 2.
- (5) The documents and correspondence relating to the conformity assessment procedures referred to in this regulation, and which are carried out in the United Kingdom, must be drawn up in English.
- (6) In this regulation a reference to a module other than Module B includes the common provisions as set out in point 7 of Annex II to the Directive.

Extent Information

E64 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F83Subsidiaries and contractors

- **37.**—(1) This regulation applies where—
 - (a) a notified body subcontracts specific conformity assessment activities, or
 - (b) has such activities carried out by a subsidiary.

- (2) The activities are only to be treated as having been carried out by a notified body for the purposes of regulation 36 (conformity assessment procedures) where the conditions in paragraphs (3) and (4) are met.
 - (3) The notified body must—
 - (a) ensure that the subcontractor or subsidiary meets the notified body requirements; and
 - (b) inform the Secretary of State accordingly.
- (4) The notified body must have obtained the agreement of the client to the use of a subcontractor or subsidiary.
- (5) 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 after 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.
- (6) When monitoring a notified body in accordance with regulation 52 (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.]

Textual Amendments

F83 Reg. 37 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. 26 para. 23 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Fees E+W+S

- **38.**—(1) [F84 An 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 [F85 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 [F84 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

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

- **F84** Words in reg. 38 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. 26 para. 24(a)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F85 Word in reg. 38(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. 26 para. 24(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Fees N.I.

- **38.**—(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

E65 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 RELATING TO [F86EU] DECLARATIONS OF CONFORMITY

Textual Amendments

F86 Word in Pt. 3 Ch. 2 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. 26 para. 25 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Application of Chapter

39. This Chapter applies in relation to [F87EU] declarations of conformity made in relation to a regulated non-automatic weighing instrument for the purposes of these Regulations.

Textual Amendments

F87 Word in reg. 39 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. 26 para. 25** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Form and contents of F88... declaration of conformity etc. E+W+S

- **40.**—(1) The ^{F89}... declaration of conformity must—
 - (a) state that the fulfilment of the essential requirements has been demonstrated in relation to the regulated non-automatic weighing instrument;
 - (b) have the model structure set out in [F90Schedule 9]; and
 - (c) contain the elements specified in the relevant modules set out in [F91Schedule 7] and must be updated when appropriate.
- (2) Where a regulated non-automatic weighing instrument is placed or made available on the market in the United Kingdom, the ^{F92}... declaration of conformity in relation to the instrument must be in English.

Extent Information

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

- F88 Word in reg. 40 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. 26 para. 26(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F89** Word in reg. 40(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. 26 para. 26(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F90** Words in reg. 40(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. 26 para. 26(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- F91 Words in reg. 40(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. 26 para. 26(c) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F92** Word in reg. 40(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. 26 para. 26(d) (with Sch. 26 para. 5) (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.

- **40.**—(1) The EU declaration of conformity must—
 - (a) state that the fulfilment of the essential requirements has been demonstrated in relation to the regulated non-automatic weighing instrument;
 - (b) have the model structure set out in Annex IV to the Directive; and
 - (c) contain the elements specified in the relevant modules set out in Annex II to the Directive and must be updated when appropriate.
- (2) Where a regulated non-automatic weighing instrument is placed or made available on the market in [F196]Northern Ireland], the EU declaration of conformity in relation to the instrument must be in English.

Extent Information

E66 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

F196 Words in reg. 40(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. 13 para. 4(1)

Regulated instruments that require more than one declaration of conformity E+W+S

[^{F93}41. Where a non-automatic weighing 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

E17 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

F93 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. 26 para. 27 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

- **41.**—(1) This regulation applies where a regulated non-automatic weighing instrument is subject to [F197 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 [F198] relevant] Union acts concerned including their publication references.

Extent Information

E67 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

F197 Words in reg. 41(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. 13 para. 4(2)(a)

F198 Word in reg. 41(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. 13 para. 4(2)(b)

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

42. A manufacturer, who draws up [^{F94}a] declaration of conformity in relation to a regulated non-automatic weighing instrument, is responsible for compliance of that instrument with the requirements of these Regulations.

Extent Information

E18 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

F94 Word 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. 26 para. 28** (with Sch. 26 para. 5) (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.

42. A manufacturer, who draws up an EU declaration of conformity in relation to a regulated non-automatic weighing instrument, is responsible for compliance of that instrument with the requirements of these Regulations.

Extent Information

E68 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

CONFORMITY MARKING

Conformity with ^{F95}... requirements to be indicated by the [F96UK] marking E+W+S

43. The conformity of a regulated non-automatic weighing instrument with the requirements of these Regulations must be indicated by the presence on it of the [F97UK] marking and the M marking.

Extent Information

E19 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

- F95 Word in reg. 43 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. 26 para. 29(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F96 Word in reg. 43 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. 26 para. 29(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F97 Word in reg. 43 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. 26 para. 29(b) (with Sch. 26 para. 5) (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.

43. The conformity of a regulated non-automatic weighing instrument with the requirements of these Regulations must be indicated by the presence on it of the CE marking and the M marking.

Extent Information

E69 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

|F98Prohibition on improper use of UK marking and the M marking E+W+S

- **44.**—(1) An economic operator must not affix the UK marking or the M marking to a regulated non-automatic weighing instrument unless—
 - (a) that economic operator is the manufacturer of the non-automatic weighing instrument; and
 - (b) the conformity of the non-automatic weighing instrument with the essential requirements has been demonstrated by a conformity assessment procedure.
- (2) An economic operator must not affix a marking to a regulated non-automatic weighing instrument which is not the UK marking or the M marking but which purports to attest that the non-automatic weighing instrument satisfies the essential requirements.
- (3) An economic operator must not affix to a regulated non-automatic weighing 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

E20 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

F98 Reg. 44 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. 26 para. 30 (with Sch. 26 para. 5) (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.

44. 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

E70 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 [F99UK] marking and the M marking etc. E+W+S

- **45.**—(1) The [F100UK] marking and M marking ("the markings") must be affixed to a regulated non-automatic weighing instrument in accordance with the provisions of this regulation.
- (2) The markings must be affixed visibly, legibly and indelibly to the regulated non-automatic weighing instrument [F101], its data plate, or where regulation 6(2) applies in respect of the UK marking, to a label affixed to the regulated non-automatic weighing instrument, or to a document accompanying the regulated non-automatic weighing instrument].
- (3) The markings must be affixed before the regulated non-automatic weighing instrument is placed on the market.
 - (4) The M marking must immediately follow the [F102UK] marking.
- (5) The markings must immediately be followed by the identification of the [F103 approved] body where that body is involved in the production control phase as set out in [F104 Schedule 7].
- (6) The identification number of the [F105 approved] body which carried out the conformity assessment procedure must be affixed by the body itself, or under its instructions by the manufacturer or the manufacturer's authorised representative.
- (7) The markings and the identification number of the [F106 approved] body may be followed by any other mark indicating a special risk or use.

Extent Information

E21 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

F99 Word in reg. 45 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. 26 para. 31(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- **F100** Word in reg. 45(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. 26 para. 31(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F101 Words in reg. 45(2) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 26 para. 31(ab) (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. 18(5))
- **F102** Word in reg. 45(4) 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. 26 para. 31(a)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F103** Word in reg. 45(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. 26 para. 31(c)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F104** Words in reg. 45(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. 26 para. 31(b)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F105** Word in reg. 45(6) 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. 26 para. 31(c)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F106** Word in reg. 45(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. 26 para. 31(c)** (with Sch. 26 para. 5) (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 etc. N.I.

- **45.**—(1) The CE marking and M marking ("the markings") must be affixed to a regulated non-automatic weighing instrument in accordance with the provisions of this regulation.
- (2) The markings must be affixed visibly, legibly and indelibly to the regulated non-automatic weighing instrument or its data plate.
- (3) The markings must be affixed before the regulated non-automatic weighing instrument is placed on the market.
 - (4) The M marking must immediately follow the CE marking.
- (5) The markings must immediately be followed by the identification of the notified body where that body is involved in the production control phase as set out in Annex II to the Directive.
- (6) The identification number of the notified body which carried out the conformity assessment procedure must be affixed by the body itself, or under its instructions by the manufacturer or the manufacturer's authorised representative.
- (7) The markings and the identification number of the notified body may be followed by any other mark indicating a special risk or use.

Extent Information

E71 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F107UK(NI) indication

45A.—(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 non-automatic weighing instrument, in accordance with this regulation.

- (2) The UK(NI) indication must be affixed—
 - (a) visibly, legibly and indelibly; and
 - (b) before the regulated non-automatic weighing 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 45.
 - (4) The UK(NI) indication must be affixed by—
 - (a) the manufacturer; or
 - (b) the manufacturer's authorised representative.
- (5) When placing a regulated non-automatic weighing instrument on the market in Northern Ireland, an importer must ensure that the manufacturer has complied with their obligations under this regulation.]

Textual Amendments

F107 Regs. 45A, 45B 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. 11(3)

[F107]Register of notified bodies established in the United Kingdom

- **45B.**—(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

F107 Regs. 45A, 45B 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. 11(3)

PART 4

REQUIREMENTS FOR NON-REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS

- **46.**—(1) This regulation applies to a non-automatic weighing instrument which is not a regulated non-automatic weighing instrument.
- (2) A manufacturer must not place on the market a non-automatic weighing instrument to which this regulation applies unless it is marked legibly and indelibly with the following information—
 - (a) the manufacturer's name, registered trade name or registered trade mark; and
 - (b) the maximum capacity of the instrument, in the form "Max....".
 - (c) the postal address at which they can be contacted, indicating a single point of contact.
- (3) Before placing on the market a non-automatic weighing instrument to which this regulation applies, an importer must ensure that—
 - (a) the manufacturer has marked the instrument in the manner referred to in paragraph (2) with the information referred to in that paragraph;
 - (b) the importer has indicated on the instrument their name or registered trade mark and the postal address at which they can be contacted.
- (4) Where compliance with paragraph (3)(b) would require the packaging to be opened, the information required by that paragraph may be given on the packaging and in a document accompanying the non-automatic weighing instrument.
- (5) Before making available on the market a non-automatic weighing instrument to which this regulation applies, a distributor must verify that—
 - (a) the manufacturer has marked the instrument in the manner referred to in paragraph (2) with the information referred to in that paragraph;
 - (b) the importer of the instrument has complied with paragraph (3).

PART 5

$[^{F108}$ NOTIFICATION OF CONFORMITY ASSESSMENT BODIES] $[^{F108}$ APPROVAL OF CONFORMITY ASSESSMENT BODIES]

Textual Amendments

F108 Pt. 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. 26 para. 32** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), **2**; S.I. 2020/852, reg. 4(2), **Sch. 1 paras. 1(o)(v)**, (vi)); 2020 c. 1, **Sch. 5 para. 1(1)**

[F108Approved bodies E+W+S

- **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 IP completion 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 IP completion 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 IP completion 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 IP completion day;
 - "approved body requirements" means the requirements set out in Schedule 3.]

Extent Information

E22 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.

- **47.**—(1) This Part applies to the notification to the Commission and other [F199] relevant] 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 [F199 relevant] states in accordance with the Directive; and
 - (b) in respect of which no objections [F200, other than an immaterial objection,] are raised by the Commission or other [F199 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 [F201 used;]
 - [F202(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 54 (changes to notifications).

Extent Information

E72 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

- F199 Word in reg. 47 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. 13 para. 5(1)(a)
- F200 Words in reg. 47(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. 13 para. 5(1)(b)(i)
- F201 Word in reg. 47(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. 13 para, 5(1)(b)(ii)
- F202 Reg. 47(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. 13 para. 5(1)(c)

[F108] Approval of conformity assessment bodies E+W+S

- **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
 - (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

E23 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.

- **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.

Extent Information

E73 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F108Presumption of conformity of approved bodies E+W+S

- **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.

Extent Information

E24 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.

- **49.**—(1) The Secretary of State may notify to the Commission and the other [F203 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 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 [F204 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

E74 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

F203 Word in reg. 49(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. 13** para. 5(2)(a)

F204 Words in reg. 49(6) 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. 13** para. 5(2)(b)

[F108] Monitoring E+W+S

- **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 IP completion day, in accordance with regulation 48(6)(b), as it applied immediately before IP completion day; and
 - (c) carries out its functions in accordance with these Regulations.]

Extent Information

E25 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.

- **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.

Extent Information

E75 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F108] Restriction, suspension or withdrawal of approval E+W+S

- **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).]

Extent Information

E26 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.

- **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.

Extent Information

E76 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F108 Subsidiaries and contractors E+W+S

- **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.
- (4) In this regulation "subsidiary" has the meaning given to it in section 1159 of the Companies Act 2006^{F109} .]

Extent Information

E27 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

F109 2006 c.46.

Monitoring N.I.

- **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.

Extent Information

E77 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F108 Register of approved bodies E+W+S

- **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.]

Extent Information

E28 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.

- **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.

Extent Information

E78 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F108UK national accreditation body E+W+S

- **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.]

Extent Information

E29 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.

- **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 $[^{F205}$ 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 5 has effect in relation to monetary penalties imposed under paragraph (7).

Extent Information

E79 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

F205 Word in reg. 54(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. 13 para. 5(3)**

PART 6

PUTTING INTO SERVICE OF REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS FOR THE PURPOSES LISTED IN REGULATION 3(2)

55. No person shall put into service a regulated non-automatic weighing instrument for any of the uses listed in regulation 3(2) or have such an instrument in his possession for such use unless prior to placing the instrument on the market it has been established by the application of the appropriate conformity assessment procedure that the essential requirements are met in relation to the instrument.

PART 7

USE FOR TRADE OF REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS IN GREAT BRITAIN

56. Schedule 4 applies to the use for trade of regulated non-automatic weighing instruments in Great Britain.

PART 8

MARKET SURVEILLANCE AND ENFORCEMENT CHAPTER 1

MARKET SURVEILLANCE

The market surveillance authority

57. The Secretary of State is the market surveillance authority for the purposes of these Regulations and RAMS.

Regulated non-automatic weighing instruments presenting a risk E+W+S

- **58.**—(1) This regulation applies where the market surveillance authority has sufficient reason to believe that a regulated non-automatic weighing instrument presents a risk in relation to any of the purposes set out in regulation 3(2).
- (2) Where this regulation applies the market surveillance authority must carry out an evaluation of the regulated non-automatic weighing instrument covering all relevant requirements of these Regulations which apply to that instrument.
- (3) The relevant economic operators in relation to the non-automatic weighing instrument must co-operate as necessary with the market surveillance authority for that purpose.
- (4) Where, in the course of the evaluation referred to in paragraph (2), the market surveillance authority finds that that the regulated non-automatic weighing instrument does not comply with the essential requirements applicable to it, it must without delay issue a direction which requires the relevant economic operator to—
 - (a) take all appropriate corrective actions;
 - (b) withdraw the regulated non-automatic weighing instrument from the market; or
 - (c) recall it within a reasonable period commensurate with the nature of the risk.
- (5) Where the market surveillance authority acts under paragraph (4) it must without delay inform the [F110 approved] body that carried out the conformity assessment procedure in respect of the regulated non-automatic weighing instrument of—
 - (a) the respect in which the regulated non-automatic weighing instrument is not in conformity with the requirements of these Regulations; and
 - (b) the actions that the authority is requiring the relevant economic operator to take.
- (7) The economic operator must ensure that all appropriate corrective action is taken in respect of all the regulated non-automatic weighing instruments concerned that it has made available [F112] in the United Kingdom].

- (8) Where the relevant economic operator does not take adequate corrective action within a reasonable period, the market surveillance authority must take all provisional measures to prohibit or restrict the regulated non-automatic weighing instrument being made available on the market, to withdraw the instrument from that market or to recall it.
- (9) Where the market surveillance authority takes measures under paragraph (8), the market surveillance authority must notify the [F113] Secretary of State] of those measures without delay.
 - (10) A notification under paragraph (9) must include all available details, in particular—
 - (a) the data necessary for the identification of the non-compliant regulated measuring instrument;
 - (b) the origin of the instrument;
 - (c) the nature of the non-compliance alleged and the risk involved;
 - (d) the nature and duration of the measures taken;
 - (e) the arguments put forward by the relevant economic operator; and
 - (f) whether the non-compliance is due to either of the following—
 - (i) failure of the regulated measuring instrument to meet the requirements relating to a risk; or
 - (ii) shortcomings in the [F114 designated] standards referred to in regulation 34(a).

Extent Information

E30 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

- **F110** Word in reg. 58(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. 26 para. 33(a)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F111 Reg. 58(6) 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. 26 para. 33(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F112** Words in reg. 58(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. 26 para. 33(c)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F113** Words in reg. 58(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. 26 para. 33(d)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F114** Word in reg. 58(10)(f)(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. 26 para. 33(e)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Regulated non-automatic weighing instruments presenting a risk N.I.

- **58.**—(1) This regulation applies where the market surveillance authority has sufficient reason to believe that a regulated non-automatic weighing instrument presents a risk in relation to any of the purposes set out in regulation 3(2).
- (2) Where this regulation applies the market surveillance authority must carry out an evaluation of the regulated non-automatic weighing instrument covering all relevant requirements of these Regulations which apply to that instrument.

- (3) The relevant economic operators in relation to the non-automatic weighing instrument must co-operate as necessary with the market surveillance authority for that purpose.
- (4) Where, in the course of the evaluation referred to in paragraph (2), the market surveillance authority finds that that the regulated non-automatic weighing instrument does not comply with the essential requirements applicable to it, it must without delay issue a direction which requires the relevant economic operator to—
 - (a) take all appropriate corrective actions;
 - (b) withdraw the regulated non-automatic weighing instrument from the market [F206in Northern Ireland]; or
 - (c) recall it within a reasonable period commensurate with the nature of the risk.
- (5) Where the market surveillance authority acts under paragraph (4) it must without delay inform the notified body that carried out the conformity assessment procedure in respect of the regulated non-automatic weighing instrument of—
 - (a) the respect in which the regulated non-automatic weighing instrument is not in conformity with the requirements of these Regulations; and
 - (b) the actions that the authority is requiring the relevant economic operator to take.
- (6) [F207 Subject to paragraph (6A),] where the market surveillance authority considers that non-compliance is not restricted to [F208 Northern Ireland], it must inform the Commission and the other [F209 relevant] states of the results of the evaluation and of the actions which they have required the economic operator to take.
- [F210(6A) Paragraph (6) does not require the Secretary of State to inform the Commission or the other relevant states where the non-compliance extends only to any of England or Wales or Scotland.]
- (7) The economic operator must ensure that all appropriate corrective action is taken in respect of all the regulated non-automatic weighing instruments concerned that it has made available on the market throughout [F211] Northern Ireland].
- (8) Where the relevant economic operator does not take adequate corrective action within a reasonable period, the market surveillance authority must take all provisional measures to prohibit or restrict the regulated non-automatic weighing instrument being made available on the market [F212 in Northern Ireland], to withdraw the instrument from that market or to recall it.
- (9) Where the market surveillance authority takes measures under paragraph (8), the market surveillance authority must notify the Commission and the other [F213 relevant] states of those measures without delay.
 - (10) A notification under paragraph (9) must include all available details, in particular—
 - (a) the data necessary for the identification of the non-compliant regulated measuring instrument;
 - (b) the origin of the instrument;
 - (c) the nature of the non-compliance alleged and the risk involved;
 - (d) the nature and duration of the measures taken;
 - (e) the arguments put forward by the relevant economic operator; and
 - (f) whether the non-compliance is due to either of the following—
 - (i) failure of the regulated measuring instrument to meet the requirements relating to a risk; or
 - (ii) shortcomings in the harmonised standards referred to in regulation 34(a).

Extent Information

E80 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

- F206 Words in reg. 58(4)(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. 13 para. 6(1)(a)
- F207 Words in reg. 58(6) 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. 13 para. 6(1)(b)(i)
- F208 Words in reg. 58(6) 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. 13 para. 6(1)(b)(ii)
- F209 Word in reg. 58(6) 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. 13 para. 6(1)(b)(iii)
- F210 Reg. 58(6A) 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. 13 para. 6(1)(c)
- F211 Words in reg. 58(7) 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. 13 para. 6(1)(d)
- F212 Words in reg. 58(8) 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. 13 para. 6(1)(e)
- F213 Word in reg. 58(9) 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. 13 para. 6(1)(f)

[F115EU safeguard procedure

- **59.**—(1) Where another [FII6] relevant] state has initiated the procedure under Article 37 of the Directive, the market surveillance authority must without delay, inform the Commission and the other [FII6] relevant] states of—
 - (a) any measures taken by competent authority in respect of the regulated non-automatic weighing instrument;
 - (b) any additional information which the market surveillance authority has at its disposal relating to the lack of conformity of the regulated non-automatic weighing [F117] instrument.]

F118(c)																

- (2) Where a measure taken by another [F119relevant] state in respect of a regulated non-automatic weighing instrument is considered justified under Article 37(7) of the Directive, the market surveillance authority must ensure that appropriate measures to withdraw the instrument are taken in respect of the regulated non-automatic weighing instrument without delay.
- (3) If, pursuant to Article 38 of the Directive, the Commission considers a direction given pursuant to regulation 58(4) is unjustified, the market surveillance authority must forthwith withdraw it and notify other competent authorities and economic operators affected accordingly.]

Textual Amendments

- F115 Reg. 59 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. 26 para. 34 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F116 Word in reg. 59(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. 13 para. 6(2)(a)(i)
- F117 Word in reg. 59(1)(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. 13 para. 6(2)(a)(ii)
- F118 Reg. 59(1)(c) omitted (N.I.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), Sch. 13 para. 6(2)(a)(iii)
- F119 Word in reg. 59(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. 13 para. 6(2)(b)

Compliant regulated non-automatic weighing instruments which present a risk E+W+S

- **60.**—(1) This regulation applies where, having carried out an evaluation under regulation 58 (regulated non-automatic weighing instruments presenting a risk), the market surveillance authority finds that although a regulated non-automatic weighing instrument is in compliance with the requirements of these Regulations, it presents a risk in relation to its use in relation to any activity referred to in regulation 3(2).
- (2) Where this regulation applies, the market surveillance authority must issue a direction requiring the economic operator to—
 - (a) take all appropriate measures to ensure that the non-automatic weighing instrument concerned, when placed on the market, no longer presents that risk;
 - (b) withdraw the non-automatic weighing instrument from the market; or
 - (c) recall it within a reasonable period, commensurate with the nature of the risk as it may prescribe.
- (3) Where this regulation applies, the market surveillance authority must immediately inform the [F120]Secretary of State] of all available details including—
 - (a) the data necessary for the identification of the regulated non-automatic weighing instrument concerned;
 - (b) the origin and supply chain of the regulated non-automatic weighing instrument;
 - (c) the nature of the risk involved; and
 - (d) the nature and duration of the national measures taken.

Extent Information

E31 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

F120 Words in reg. 60(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. 26 para. 35** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Compliant regulated non-automatic weighing instruments which present a risk N.I.

- **60.**—(1) This regulation applies where, having carried out an evaluation under regulation 58 (regulated non-automatic weighing instruments presenting a risk), the market surveillance authority finds that although a regulated non-automatic weighing instrument is in compliance with the requirements of these Regulations, it presents a risk in relation to its use in relation to any activity referred to in regulation 3(2).
- (2) Where this regulation applies, the market surveillance authority must issue a direction requiring the economic operator to—
 - (a) take all appropriate measures to ensure that the non-automatic weighing instrument concerned, when placed on the market [F214 in Northern Ireland], no longer presents that risk;
 - (b) withdraw the non-automatic weighing instrument from the market [F215 in Northern Ireland]; or
 - (c) recall it within a reasonable period, commensurate with the nature of the risk as it may prescribe.
- (3) Where this regulation applies, the market surveillance authority must immediately inform the Commission and the other [F216 relevant] states of all available details including—
 - (a) the data necessary for the identification of the regulated non-automatic weighing instrument concerned;
 - (b) the origin and supply chain of the regulated non-automatic weighing instrument;
 - (c) the nature of the risk involved; and
 - (d) the nature and duration of the national measures taken.

Extent Information

E81 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

- F214 Words in reg. 60(2)(a) 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. 13 para. 6(3)(a)(i)
- F215 Words in reg. 60(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. 13 para. 6(3)(a)(ii)
- F216 Word in reg. 60(3) 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. 13 para. 6(3)(b)

Provisions as to directions under regulations 58 and 60

- **61.**—(1) This regulation applies in relation to directions given under regulations 58 (regulated non-automatic weighing instruments presenting a risk) and 60 (compliant regulated non-automatic weighing instruments which present a risk).
 - (2) A direction must—
 - (a) be in writing;
 - (b) describe the regulated non-automatic weighing instrument to which it relates in a manner sufficient to identify that instrument;
 - (c) specify the risk identified by the market surveillance authority; and
 - (d) specify the steps that the economic operator must take (including the time period within which they must be taken).
- (3) The Secretary of State may impose a monetary penalty on an economic operator who fails to comply with a direction given under regulation 58 or 60.
 - (4) Schedule 5 has effect in relation to monetary penalties imposed under paragraph (3).

CHAPTER 2

ENFORCEMENT PROCEDURES

Competent authorities and enforcement proceedings

- **62.**—(1) In Great Britain, it is the duty of every local weights and measures authority to enforce these Regulations within its area.
- (2) In Northern Ireland, it is the duty of the Department for the Economy to enforce these Regulations (other than Part 7).
 - (3) The Secretary of State—
 - (a) must enforce these Regulations when required to do so in the capacity of the market surveillance authority; and
 - (b) may otherwise than in the capacity of market surveillance authority enforce these Regulations and for that purpose may appoint any person to act on his behalf.
- (4) No proceedings for an offence under these Regulations may be instituted in England and Wales except by or on behalf of a competent authority.
- (5) Nothing in these Regulations authorises a competent authority to bring proceedings in Scotland for an offence.
- (6) No proceedings shall be instituted in Northern Ireland for an offence under these Regulations in respect of a regulated non-automatic weighing instrument except—
 - (a) by or on behalf of a competent authority which has responsibility for enforcing these Regulations in respect of that regulated non-automatic weighing instrument; or
 - (b) the Director of Public Prosecutions for Northern Ireland.

Compliance notice procedure E+W+S

- **63.**—(1) This regulation applies where a competent authority has reasonable grounds for considering that one or more of the following breaches applies in relation to a regulated non-automatic weighing instrument that has been placed on the market—
 - (a) the [F121UK] marking or the M marking has been affixed in violation of [F122 regulation 44 or regulation 45];

- (b) the [F123UK] marking or the M marking has not been affixed;
- (c) the identification number of the [F124approved] body, where the body is involved in the production control phase has—
 - (i) been affixed otherwise than in accordance with the requirements of these Regulations; or
 - (ii) not been affixed;
- (d) the F125... declaration of conformity has not been drawn up correctly;
- (e) the technical documentation is either not available or is not complete;
- (f) the information referred to in regulation 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments) or regulation 18 (requirements to mark importers' details on regulated non-automatic weighing instruments) is absent, false or incomplete; or
- (g) any other failure—
 - (i) by a manufacturer to comply with the requirements of Chapter 1 of Part 2; or
 - (ii) by an importer to comply with the requirements of Chapter 2 of Part 2.
- (2) The competent authority may serve a notice in writing ("a compliance notice") on the economic operator it considers is responsible for the breach which must—
 - (a) describe the regulated non-automatic weighing instrument to which it relates in a manner sufficient to identify that instrument;
 - (b) specify which of the circumstances in paragraph (1) applies in relation to the regulated non-automatic weighing instrument;
 - (c) require the economic operator on whom the notice is served to take steps specified in the notice to remedy the matters referred to in sub-paragraph (b);
 - (d) specify the date, being not less than 21 days from the date of the notice, by which the steps specified in it must be taken; and
 - (e) warn that person that, where the non-conformity continues beyond the date specified in sub-paragraph (d), the competent authority may take further action under regulation 64 (enforcement notice procedure) in respect of that regulated non-automatic weighing instrument.
- (3) Where a compliance notice is served by a competent authority other than the Secretary of State, it must, at the same time as it serves that notice, send a copy to the Secretary of State.

Extent Information

E32 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

- **F121** Word in reg. 63(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. 26 para. 36(a)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F122** Words in reg. 63(1)(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. 26 para. 36(b)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F123** Word in reg. 63(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. 26 para. 36(a)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- **F124** Word in reg. 63(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. 26 para. 36(c)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F125** Word in reg. 63(1)(d) 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. 26 para. 36(d)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Compliance notice procedure N.I.

- **63.**—(1) This regulation applies where a competent authority has reasonable grounds for considering that one or more of the following breaches applies in relation to a regulated non-automatic weighing instrument that has been placed on the market—
 - (a) the CE marking or the M marking has been affixed in violation of Article 30 of the RAMS Regulation or the requirements of these Regulations;
 - (b) the CE marking or the M marking has not been affixed;
 - (c) the identification number of the notified body, where the body is involved in the production control phase has—
 - (i) been affixed otherwise than in accordance with the requirements of these Regulations; or
 - (ii) not been affixed;

[F217(ca) the UK(NI) indication—

- (i) has not been affixed, in contravention of regulation 45A; or
- (ii) has been affixed other than in accordance with regulation 45A;
- (d) the EU declaration of conformity has not been drawn up correctly;
- (e) the technical documentation is either not available or is not complete;
- (f) the information referred to in regulation 10 (manufacturers to mark contact details on regulated non-automatic weighing instruments) or regulation 18 (requirements to mark importers' details on regulated non-automatic weighing instruments) is absent, false or incomplete; or
- (g) any other failure—
 - (i) by a manufacturer to comply with the requirements of Chapter 1 of Part 2; or
 - (ii) by an importer to comply with the requirements of Chapter 2 of Part 2.
- (2) The competent authority may serve a notice in writing ("a compliance notice") on the economic operator it considers is responsible for the breach which must—
 - (a) describe the regulated non-automatic weighing instrument to which it relates in a manner sufficient to identify that instrument;
 - (b) specify which of the circumstances in paragraph (1) applies in relation to the regulated non-automatic weighing instrument;
 - (c) require the economic operator on whom the notice is served to take steps specified in the notice to remedy the matters referred to in sub-paragraph (b);
 - (d) specify the date, being not less than 21 days from the date of the notice, by which the steps specified in it must be taken; and
 - (e) warn that person that, where the non-conformity continues beyond the date specified in sub-paragraph (d), the competent authority may take further action under regulation 64 (enforcement notice procedure) in respect of that regulated non-automatic weighing instrument.

(3) Where a compliance notice is served by a competent authority other than the Secretary of State, it must, at the same time as it serves that notice, send a copy to the Secretary of State.

Extent Information

E82 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

F217 Reg. 63(1)(ca) 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. 11(4)**

Enforcement notice procedure E+W+S

- **64.**—(1) This regulation applies where a competent authority has reasonable grounds for considering that an economic operator on whom a compliance notice has been served by the competent authority has failed to comply with that notice.
- (2) The competent authority may serve a notice ("an enforcement notice") on the economic operator which must—
 - (a) be in writing;
 - (b) describe the regulated non-automatic weighing instrument to which it relates in a manner sufficient to identify that instrument;
 - (c) specify, with reasons, the respects in which, in the opinion of the competent authority, the compliance notice has not been complied with;
 - (d) specify the steps that the economic operator must take to comply with the compliance notice; and
 - (e) specify the date, being not less than 21 days from the date of the notice, by which the economic operator is required to take the steps specified in it.
- (3) An enforcement notice may impose either or both of the following requirements where appropriate—
 - (a) that the regulated non-automatic weighing instrument is to be withdrawn from the market unless the steps referred to in paragraph (2)(d) are taken; or
 - (b) that the placing on the market or making available on the market of the regulated non-automatic weighing instrument is to be prohibited or restricted unless the steps referred to in paragraph (2)(d) are taken.
- (4) Where an enforcement notice is served by an competent authority other than the Secretary of State, it must at the same time as it serves that notice send a copy of the notice to the Secretary of State.
- (5) If the Secretary of State is of the opinion that consideration ought to be given as to whether a certificate or notification which is granted by [F126] an approved] body should be withdrawn, the Secretary of State must inform [F127] that approved] body of that fact.

F128(6)					_				_	_	_	_		_	_	_			_	

Extent Information

E33 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

- **F126** Words in reg. 64(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. 26 para. 37(a)(i) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F127** Words in reg. 64(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. 26 para. 37(a)(ii)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F128** Reg. 64(6) 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. 26 para. 37(b)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Enforcement notice procedure N.I.

- **64.**—(1) This regulation applies where a competent authority has reasonable grounds for considering that an economic operator on whom a compliance notice has been served by the competent authority has failed to comply with that notice.
- (2) The competent authority may serve a notice ("an enforcement notice") on the economic operator which must—
 - (a) be in writing;
 - (b) describe the regulated non-automatic weighing instrument to which it relates in a manner sufficient to identify that instrument;
 - (c) specify, with reasons, the respects in which, in the opinion of the competent authority, the compliance notice has not been complied with;
 - (d) specify the steps that the economic operator must take to comply with the compliance notice; and
 - (e) specify the date, being not less than 21 days from the date of the notice, by which the economic operator is required to take the steps specified in it.
- (3) An enforcement notice may impose either or both of the following requirements where appropriate—
 - (a) that the regulated non-automatic weighing instrument is to be withdrawn from the market [F218 in Northern Ireland] unless the steps referred to in paragraph (2)(d) are taken; or
 - (b) that the placing on the market or making available on the market of the regulated non-automatic weighing instrument is to be prohibited or restricted unless the steps referred to in paragraph (2)(d) are taken.
- (4) Where an enforcement notice is served by an competent authority other than the Secretary of State, it must at the same time as it serves that notice send a copy of the notice to the Secretary of State.
- (5) If the Secretary of State is of the opinion that consideration ought to be given as to whether a certificate or notification which is granted by a United Kingdom notified body should be withdrawn, the Secretary of State must inform that notified body of that fact.

F219(6)																																
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Extent Information

E83 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

F218 Words in reg. 64(3)(a) 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. 13 para. 6(4)(a)

F219 Reg. 64(6) omitted (N.I.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), Sch. 13 para. 6(4)(b)

Review of decisions of a competent authorities

- **65.**—(1) Where a notice is served under regulation 63 (compliance notice procedure) or 64 (enforcement notice procedure) by a competent authority other than the Secretary of State, an economic operator who is aggrieved by the decision to serve that notice may, in accordance with paragraphs (2) and (3) apply to the Secretary of State to review the decision and on such application the Secretary of State may—
 - (a) hold an inquiry in connection with the decision; and
 - (b) appoint an assessor for the purposes of assisting him with his review or any such inquiry.
- (2) An application for a review of a decision under paragraph (1) must be made by notice in writing to the Secretary of State before the end of the period of 21 days beginning with the day on which the notice is served on the economic operator by the competent authority under regulation 63 or 64
- (3) A notice of application for review under this regulation must state the grounds on which the application is made.
- (4) The Secretary of State must, within a reasonable time, inform the economic operator and the authority referred to in paragraph (1) in writing of the Secretary of State's decision whether to uphold the decision of that authority and—
 - (a) in a case where the Secretary of State upholds that decision, must also state the grounds for the Secretary of State's decision; and
 - (b) in a case where the Secretary of State does not uphold that decision, may—
 - (i) where the review relates to regulation 63, give instructions for the withdrawal of the notice given under paragraph (2) of that regulation; or
 - (ii) where the review relates to regulation 64, give instructions for the withdrawal of the notice given under paragraph (2) of that regulation.

Offence of failing to comply with an enforcement notice

- **66.**—(1) This paragraph applies where an enforcement notice has been served pursuant to regulation 64 (enforcement notice procedure) on an economic operator by a competent authority other than the Secretary of State and either—
 - (a) the time for making an application for a review pursuant to regulation 65 (review of decisions of competent authorities) has expired without such an application having been made; or
 - (b) an application has been made by the economic operator and determined without an instruction for the withdrawal of the notice being given and a period of 21 days has elapsed beginning with the day after notice of the outcome of the review has been served on the economic operator.

- (2) Where this paragraph (1) applies, if the economic operator on whom the [F129] enforcement notice] has been served, fails to comply with the requirements of that notice, that economic operator is guilty of an offence.
- (3) An economic operator that fails to comply with an enforcement notice served on the economic operator by the Secretary of State is guilty of an offence.

Textual Amendments

F129 Words in reg. 66(2) substituted (1.2.2019) by The Weights and Measures etc. (Miscellaneous) (Amendment) Regulations 2019 (S.I. 2019/5), regs. 1, **7(3)**

Disqualification E+W+S

- **67.**—(1) Where the circumstances in paragraph (2) apply, an inspector may affix a disqualification mark to a regulated non-automatic weighing instrument which bears the—
 - (a) [F130UK] marking;
 - (b) M marking; and
 - (c) identification number of the [F131approved] body which carried out the conformity assessment procedure in respect of the instrument
- (2) The circumstances referred to in paragraph (1) are that the instrument is used for any of the purposes listed in regulation 3(2) in circumstances where—
 - (a) the instrument does not conform to the essential requirements;
 - (b) the instrument does not conform to any F132...type examination certificate issued in relation to it;
 - (c) by reason of any adjustment, alteration, addition, repair or replacement it is likely that the instrument has ceased to be compliant with the essential requirements; or
 - (d) any requirements applicable to the instrument by virtue of Part 7 are not met.
- (3) Where one or more of the markings and identification requirements referred to in paragraph (1) is not affixed to a regulated non-automatic weighing instrument, the inspector may affix a disqualification mark to the instrument.
- (4) Where it appears to the inspector that the nature or degree of non-compliance of the regulated non-automatic weighing instrument under paragraph (1) is not such that a disqualification mark should be immediately affixed to it, the inspector may give to any person in possession of the instrument a notice requiring the person to ensure that the instrument is made to comply with the essential requirements before the expiry of 21 days from the date of the notice or such longer period as may be specified in the notice.
- (5) If a notice given under paragraph (4) is not complied with, the inspector must affix a disqualification mark to the regulated non-automatic weighing instrument.
- (6) Any disqualification mark which is affixed to a regulated non-automatic weighing instrument under this regulation must be affixed in such a position that it is clearly visible when the instrument is in its regular operating position.
- [F133(6A) A disqualification mark may be affixed to a regulated non-automatic weighing instrument by affixing to the instrument a label which clearly, legibly and indelibly bears the disqualification mark.]
- (7) A person is guilty of an offence if that person uses for any of the purposes mentioned in regulation 3(2) a regulated non-automatic weighing instrument to which there is affixed a

disqualification mark, unless a re-qualification mark has been affixed to it in accordance with regulation 68 (re-qualification).

Extent Information

E34 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

- **F130** Word in reg. 67(1)(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. 26 para. 38(a)(i)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F131** Word in reg. 67(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. 26 para. 38(a)(ii)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F132** Word in reg. 67(2)(b) 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. 26 para. 38(b)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F133** Reg. 67(6A) inserted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **5(3)**

Disqualification N.I.

- **67.**—(1) Where the circumstances in paragraph (2) apply, an inspector may affix a disqualification mark to a regulated non-automatic weighing instrument which bears the—
 - (a) CE marking;
 - (b) M marking; and
 - (c) identification number of the notified body which carried out the conformity assessment procedure in respect of the instrument
- (2) The circumstances referred to in paragraph (1) are that the instrument is used for any of the purposes listed in regulation 3(2) in circumstances where—
 - (a) the instrument does not conform to the essential requirements;
 - (b) the instrument does not conform to any EU-type examination certificate issued in relation to it;
 - (c) by reason of any adjustment, alteration, addition, repair or replacement it is likely that the instrument has ceased to be compliant with the essential requirements; or
 - (d) any requirements applicable to the instrument by virtue of Part 7 are not met.
- (3) Where one or more of the markings and identification requirements referred to in paragraph (1) is not affixed to a regulated non-automatic weighing instrument, the inspector may affix a disqualification mark to the instrument.
- (4) Where it appears to the inspector that the nature or degree of non-compliance of the regulated non-automatic weighing instrument under paragraph (1) is not such that a disqualification mark should be immediately affixed to it, the inspector may give to any person in possession of the instrument a notice requiring the person to ensure that the instrument is made to comply with the essential requirements before the expiry of 21 days from the date of the notice or such longer period as may be specified in the notice.
- (5) If a notice given under paragraph (4) is not complied with, the inspector must affix a disqualification mark to the regulated non-automatic weighing instrument.

- (6) Any disqualification mark which is affixed to a regulated non-automatic weighing instrument under this regulation must be affixed in such a position that it is clearly visible when the instrument is in its regular operating position.
- [F133(6A) A disqualification mark may be affixed to a regulated non-automatic weighing instrument by affixing to the instrument a label which clearly, legibly and indelibly bears the disqualification mark.]
- (7) A person is guilty of an offence if that person uses for any of the purposes mentioned in regulation 3(2) a regulated non-automatic weighing instrument to which there is affixed a disqualification mark, unless a re-qualification mark has been affixed to it in accordance with regulation 68 (re-qualification).

Extent Information

E84 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

F133 Reg. 67(6A) inserted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **5(3)**

Re-qualification E+W+S

- **68.**—(1) This regulation applies where—
 - (a) a disqualification mark has been affixed to a regulated non-automatic weighing instrument in accordance with regulation 67 (disqualification);
 - (b) a notice has been served under regulation 67(4); or
 - (c) a regulated non-automatic weighing instrument intended to be used for any of the purposes mentioned in regulation 3(2) in the circumstances referred to in [F134 regulation 67(2) or 67(3)] but a disqualification mark has not been affixed to the instrument.
- (2) A person requiring a re-qualification mark to be affixed to the regulated non-automatic weighing instrument must submit it, in such manner as may be directed, to a re-qualification authority and provide such assistance as the requalification authority may reasonably require.
 - (3) For the purposes of this regulation, a requalification authority is—
 - (a) an inspector;
 - (b) an approved verifier;
 - (c) [F135an] approved F136... body for module F or F1 in [F137Schedule 7]; or
 - (d) a manufacturer whose quality system has been approved by a UK [F138 approved] body under module D or D1 of [F139 Schedule 7] for the purposes of re-qualification.
- (4) A requalification authority may affix a re-qualification mark to that regulated non-automatic weighing instrument if satisfied that the instrument is compliant with—
 - (a) the essential requirements:
 - (b) any F140...type examination certificate which applies to it; and
 - (c) where it is intended that the instrument is to be used for trade any requirements applicable to that instrument by virtue of Schedule 4.
- (5) For the purposes of being satisfied that a re-qualification mark may be affixed to a regulated non-automatic weighing instrument, a requalification authority may take such steps as the

requalification authority considers appropriate, including testing the instrument by means of such test equipment as the requalification authority considers appropriate and suitable for the purpose.

- (6) There may be charged in respect of any steps taken under paragraph (5) such fees as are reasonable in the circumstances.
 - (7) The requalification authority must keep a record of any test carried out under paragraph (5).
- (8) Where a re-qualification mark is affixed to a regulated non-automatic weighing instrument pursuant to paragraph (4), it must be affixed in such a position that it obliterates as far as possible any disqualification mark.
- [F141(9)] Where a re-qualification mark is affixed to a regulated non-automatic weighing instrument pursuant to paragraph (4), it must be accompanied by—
 - (a) the letters indicating the status of the requalification authority, as follows—
 - (i) "INS" if the requalification authority is an inspector;
 - (ii) "AV" if the requalification authority is an approved verifier;
 - (iii) "AB" if the requalification authority is an approved body for module F or F1 in Schedule 7; or
 - (iv) "AM" if the requalification authority is a manufacturer whose quality system has been approved by an approved body under module D or D1 of Schedule 7 for the purposes of re-qualification;
 - (b) the identification number of the requalification authority;
 - (c) the year of re-qualification in numerical form; and
 - (d) the letters "GB" or, where the instrument was placed on the market pursuant to regulation 32D (Qualifying Northern Ireland Goods), the letters "QNIG".
 - (10) In this regulation—
 - (a) "identification number of the requalification authority" means—
 - (i) where the requalification authority is an inspector or approved verifier, the number used to identify them in connection with their approval by or under section 11 of the Weights and Measures Act 1985 (certain equipment to be passed and stamped by inspector);
 - (ii) where the requalification authority is an approved body, the identification number assigned to it pursuant to regulation 53(1)(a);
 - (iii) where the requalification authority is a manufacturer whose quality system has been approved by an approved body under module D or D1 of Schedule 7 for the purposes of re-qualification, the requalification authority identification number assigned to it by the Secretary of State;
 - (b) the re-qualification mark and the information accompanying it required by paragraph (9) may be affixed to a regulated non-automatic weighing instrument by affixing to the instrument a label which clearly, legibly and indelibly bears the re-qualification mark and that accompanying information.]

Extent Information

E35 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

- F134 Words in reg. 68(1)(c) substituted (1.2.2019) by The Weights and Measures etc. (Miscellaneous) (Amendment) Regulations 2019 (S.I. 2019/5), regs. 1, 7(4)
- F135 Word in reg. 68(3)(c) substituted (E.W.S.) (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, 11(6)(a)
- **F136** Word in reg. 68(3)(c) 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. 26 para. 39(a)(i)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F137** Words in reg. 68(3)(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. 26 para. 39(a)(ii)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F138** Word in reg. 68(3)(d) 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. 26 para. 39(b)(i) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F139** Words in reg. 68(3)(d) 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. 26 para. 39(b)(ii)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F140** Word in reg. 68(4)(b) 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. 26 para. 39(c)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F141** Reg. 68(9)(10) inserted (E.W.S.) (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, 11(6)(b)

Re-qualification N.I.

- **68.**—(1) This regulation applies where—
 - (a) a disqualification mark has been affixed to a regulated non-automatic weighing instrument in accordance with regulation 67 (disqualification);
 - (b) a notice has been served under regulation 67(4); or
 - (c) a regulated non-automatic weighing instrument intended to be used for any of the purposes mentioned in regulation 3(2) in the circumstances referred to in [F220] regulation 67(2) or 67(3)] but a disqualification mark has not been affixed to the instrument.
- (2) A person requiring a re-qualification mark to be affixed to the regulated non-automatic weighing instrument must submit it, in such manner as may be directed, to a re-qualification authority and provide such assistance as the requalification authority may reasonably require.
 - (3) For the purposes of this regulation, a requalification authority is—
 - (a) an inspector;
 - (b) an approved verifier;
 - (c) a UK approved notified body for module F or F1 in Annex II to the Directive; or
 - (d) a manufacturer whose quality system has been approved by a UK notified body under module D or D1 of Annex II to the Directive for the purposes of re-qualification.
- (4) A requalification authority may affix a re-qualification mark to that regulated non-automatic weighing instrument if satisfied that the instrument is compliant with—
 - (a) the essential requirements;
 - (b) any EU-type examination certificate which applies to it; and
 - (c) where it is intended that the instrument is to be used for trade any requirements applicable to that instrument by virtue of Schedule 4.

- (5) For the purposes of being satisfied that a re-qualification mark may be affixed to a regulated non-automatic weighing instrument, a requalification authority may take such steps as the requalification authority considers appropriate, including testing the instrument by means of such test equipment as the requalification authority considers appropriate and suitable for the purpose.
- (6) There may be charged in respect of any steps taken under paragraph (5) such fees as are reasonable in the circumstances.
 - (7) The requalification authority must keep a record of any test carried out under paragraph (5).
- (8) Where a re-qualification mark is affixed to a regulated non-automatic weighing instrument pursuant to paragraph (4), it must be affixed in such a position that it obliterates as far as possible any disqualification mark.
- [F221(9)] Where a re-qualification mark is affixed to a regulated non-automatic weighing instrument pursuant to paragraph (4), it must be accompanied by—
 - (a) the letters indicating the status of the requalification authority, as follows—
 - (i) "INS" if the requalification authority is an inspector;
 - (ii) "AV" if the requalification authority is an approved verifier;
 - (iii) "NB" if the requalification authority is a UK approved notified body for module F or F1 in Annex II to the Directive; or
 - (iv) "AM" if the requalification authority is a manufacturer whose quality system has been approved by a UK notified body under module D or D1 of Annex II to the Directive for the purposes of re-qualification;
 - (b) the identification number of the requalification authority;
 - (c) the year of re-qualification in numerical form; and
 - (d) the letters "NI".
 - (10) In this regulation—
 - (a) "identification number of the requalification authority" means—
 - (i) where the requalification authority is an inspector or approved verifier, the number used to identify them in connection with their approval by or under article 9 of the Weights and Measures (Northern Ireland) Order 1981 (weighing or measuring equipment for use for trade);
 - (ii) where the requalification authority is a UK approved notified body, the identification number referred to in regulation 45B(1)(a);
 - (iii) where the requalification authority is a manufacturer whose quality system has been approved by a UK notified body under module D or D1 of Annex II to the Directive for the purposes of re-qualification, the requalification authority identification number assigned to it by the Secretary of State;
 - (b) the re-qualification mark and the information accompanying it required by paragraph (9), may be affixed to a regulated non-automatic weighing instrument by affixing to the instrument a label which clearly, legibly and indelibly bears the re-qualification mark and that accompanying information.]

Extent Information

E85 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

F220 Words in reg. 68(1)(c) substituted (1.2.2019) by The Weights and Measures etc. (Miscellaneous) (Amendment) Regulations 2019 (S.I. 2019/5), regs. 1, 7(4)

F221 Reg. 68(9)(10) inserted (N.I.) (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, 14

Testing of regulated non-automatic weighing instruments

- **69.**—(1) Where an inspector considers that a test of a regulated non-automatic weighing instrument is necessary, otherwise than for the purposes of regulation 68 (re-qualification), the inspector may require the person who has control of the instrument, or whom the inspector has reasonable cause to believe has control of the instrument, to provide to the inspector such equipment, test liquid, materials, qualified personnel or other assistance as the inspector may reasonably require.
 - (2) Every instrument submitted for testing must be in a clean condition.

Unsuitable use of regulated non-automatic weighing instruments

- **70.**—(1) This regulation applies to a regulated non-automatic weighing instrument.
- (2) If it appears to an inspector that a regulated non-automatic weighing instrument used for a purpose mentioned in regulation 3(2)—
 - (a) for a purpose for which it is unsuitable; or
 - (b) in circumstances where it is subject to any extraordinary environmental or operating conditions which—
 - (i) may prevent it operating consistently or accurately; or
 - (ii) are likely prematurely to degrade its metrological characteristics,

the inspector may affix a disqualification mark to the instrument; and any such mark must be affixed in such a position that it is clearly visible when the instrument is in its regular operating position.

PART 9

OFFENCES

Unauthorised application of authorised marks E+W+S

- 71.—(1) Subject to paragraph (2), a person is guilty of an offence if, that person—
 - (a) affixes an authorised mark to a regulated non-automatic weighing instrument otherwise than in accordance with these Regulations;
 - (b) alters or defaces an authorised mark affixed to a regulated non-automatic weighing instrument (otherwise than as authorised by any provision of these Regulations);
 - (c) removes an authorised mark affixed to a regulated non-automatic weighing instrument; or
 - (d) affixes any other marking to a regulated non-automatic weighing instrument which is likely to deceive any person as to the meaning or form, or both, of an authorised mark.
- (2) Where the alteration, defacement or removal of an authorised mark is occasioned solely—
 - (a) in the course of the adjustment or repair of a regulated non-automatic weighing instrument by a person regularly engaged in the business of repair of such instruments, or by that person's authorised agent; or

(b) by an enforcement officer or approved verifier in the carrying out of any of their functions under these Regulations,

that person or that person's authorised agent, enforcement officer or approved verifier is not guilty of an offence under paragraph (1)(b) or (1)(c).

- (3) A person is guilty of an offence if that person places on the market, puts into service or uses for a purpose mentioned in regulation 3(2) a regulated non-automatic weighing instrument—
 - (a) from which, to that person's knowledge, an authorised mark has been removed; or
 - (b) which to that person's knowledge, bears—
 - (i) an authorised mark affixed otherwise than in accordance with these Regulations;
 - (ii) an authorised mark that has been altered or defaced otherwise than in the circumstances referred to in paragraph (2); or
 - (iii) any marking which is likely to deceive any person as to the meaning or form, or both, of an authorised mark.
- (4) A regulated non-automatic weighing instrument in respect of which an offence under this regulation has been committed and any implement used in the commissioning of the offence shall be liable to be forfeited.
 - (5) In this regulation, "authorised mark" means
 - (a) the [F142UK] marking,
 - (b) the M marking,
 - (c) the identification number of the [F143 approved] body which carried out the conformity assessment procedure in respect of the regulated non-automatic weighing instrument,
 - (d) a disqualification mark or
 - (e) a re-qualification mark.

Extent Information

E36 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

- **F142** Word in reg. 71(5)(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. 26 para. 40(a)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **F143** Word in reg. 71(5)(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. 26 para. 40(b)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Unauthorised application of authorised marks N.I.

- 71.—(1) Subject to paragraph (2), a person is guilty of an offence if, that person—
 - (a) affixes an authorised mark to a regulated non-automatic weighing instrument otherwise than in accordance with these Regulations;
 - (b) alters or defaces an authorised mark affixed to a regulated non-automatic weighing instrument (otherwise than as authorised by any provision of these Regulations);
 - (c) removes an authorised mark affixed to a regulated non-automatic weighing instrument; or

- (d) affixes any other marking to a regulated non-automatic weighing instrument which is likely to deceive any person as to the meaning or form, or both, of an authorised mark.
- (2) Where the alteration, defacement or removal of an authorised mark is occasioned solely—
 - (a) in the course of the adjustment or repair of a regulated non-automatic weighing instrument by a person regularly engaged in the business of repair of such instruments, or by that person's authorised agent; or
 - (b) by an enforcement officer or approved verifier in the carrying out of any of their functions under these Regulations,

that person or that person's authorised agent, enforcement officer or approved verifier is not guilty of an offence under paragraph (1)(b) or (1)(c).

- (3) A person is guilty of an offence if that person places on the market, puts into service or uses for a purpose mentioned in regulation 3(2) a regulated non-automatic weighing instrument—
 - (a) from which, to that person's knowledge, an authorised mark has been removed; or
 - (b) which to that person's knowledge, bears—
 - (i) an authorised mark affixed otherwise than in accordance with these Regulations;
 - (ii) an authorised mark that has been altered or defaced otherwise than in the circumstances referred to in paragraph (2); or
 - (iii) any marking which is likely to deceive any person as to the meaning or form, or both, of an authorised mark.
- (4) A regulated non-automatic weighing instrument in respect of which an offence under this regulation has been committed and any implement used in the commissioning of the offence shall be liable to be forfeited.
 - (5) In this regulation, "authorised mark" means
 - (a) the CE marking,
 - (b) the M marking,
 - (c) the identification number of the notified body which carried out the conformity assessment procedure in respect of the regulated non-automatic weighing instrument,

[F222(ca) the UK(NI) indication;]

- (d) a disqualification mark or
- (e) a re-qualification mark.

Extent Information

E86 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

F222 Reg. 71(5)(ca) 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. 11(5)**

Offences by economic operators etc.

- 72.—(1) In this regulation, "event of default" means—
 - (a) The placing on the market of a regulated non-automatic weighing instrument which—
 - (i) does not meet the essential requirements applicable to it;

- (ii) has not been the subject of an applicable conformity assessment procedure;
- (iii) does not bear the markings or inscriptions required by these Regulations; or
- (iv) is not accompanied by the documents and information required by these Regulations;
- (b) any failure to—
 - (i) create or maintain any records required to be created or maintained under these Regulations;
 - (ii) provide to a competent authority documents or information pursuant to a requirement imposed by or under these Regulations; or
 - (iii) co-operate with the market surveillance authority under regulation 58(3);
- (c) any failure to comply with regulation 46 (requirements for non-regulated non-automatic weighing instruments);
- (d) any failure to comply with regulation 55 (putting into service of regulated non-automatic weighing instruments for the purposes listed in regulation 3(2)); or
- (e) any failure to comply with obligations arising under regulation 69 (testing of regulated non-automatic weighing instruments).
- (2) Where an event of default of a kind mentioned in paragraph (1)(a), (1)(b) or (1)(c) occurs as a result of the failure of an economic operator to comply with an obligation imposed on that economic operator by any provision of these Regulations, that economic operator is guilty of an offence.
- (3) Where an event of default of a kind mentioned in paragraph (1)(d) or (1)(e) occurs, the person responsible for that event of default is guilty of an offence.

Penalties for offences

- **73.** A person guilty of an offence under any provision of these Regulations is liable, on summary conviction—
 - (a) in England and Wales to a fine; and
 - (b) in Scotland or Northern Ireland to a fine not exceeding level 5 on the standard scale.

Defence of due diligence

- 74.—(1) In proceedings against a person for an offence under these Regulations (other than regulation 71(3)), it shall be a defence for that person to show that that person took all reasonable steps and exercised all due diligence to avoid committing the offence.
- (2) Where, in proceedings against a person for such an offence, the defence provided by paragraph (1) involves an allegation that the commission of the offence was due to—
 - (a) the act or default of another; or
 - (b) reliance on information given by another,

that person shall not, without the leave of the court, be entitled to rely on the defence, unless, not less than seven clear days before the hearing of the proceedings (or, in Scotland, the trial diet), that person has served a notice in accordance with paragraph (3) on the person bringing the proceedings.

- (3) A notice under this regulation must give such information identifying or assisting in the identification of the person who committed the act or default or gave the information as is in the possession of the person serving the notice at the time that person serves it.
- (4) A person shall not be entitled to rely on the defence provided by paragraph (1) by reason of reliance on information supplied by another, unless that person shows it was reasonable in all the circumstances for that person to have relied on the information, having regard in particular to—

- (a) the steps which that person took, and those which might reasonably have been taken, for the purpose of verifying the information; and
- (b) whether that person had any reason to disbelieve the information.

Liability of persons other than the principal offender

- 75.—(1) Where the commission by a person ("A") of an offence under these Regulations is due to the act or default of another person ("B") in the course of any business of A, B is guilty of the offence and may be proceeded against and punished, whether or not proceedings are taken against A.
 - (2) Where a body corporate commits an offence and it is proved that the offence was committed—
 - (a) with the consent or connivance of an officer of the body corporate; or
- (b) as a result of the negligence of an officer of the body corporate, the officer, as well as the body corporate, is guilty of the offence.
 - (3) In paragraph (2), a reference to an officer of a body corporate includes a reference to—
 - (a) a director, manager, secretary or other similar officer of the body corporate;
 - (b) a person purporting to act as a director, manager, secretary or other similar officer; and
 - (c) if the affairs of the body corporate are managed by its members, a member.
- (4) In this regulation, references to a "body corporate" include references to a partnership in Scotland, and in relation to such partnership, any reference to a director, manager, secretary or other similar officer of a body corporate is a reference to a partner.

PART 10

MISCELLANEOUS AND SUPPLEMENTAL

Service of documents etc.

- **76.**—(1) Any document required or authorised by these Regulations to be served on a person may be so served—
 - (a) by delivering it to that person or by leaving it at that person's proper address or by sending it by post to that person at that address;
 - (b) if the person is a body corporate, by serving it in accordance with sub-paragraph (a) on the secretary or clerk of that body corporate; or
 - (c) if the person is a partnership, by serving it in accordance with sub-paragraph (a) on a partner or on a person having control or management of the partnership business.
- (2) For the purposes of paragraph (1), and for the purposes of section 7 of the Interpretation Act 1978 M12 (which relates to the service of documents by post) in its application to that paragraph, the proper address of any person on whom a document is to be served in accordance with these Regulations shall be that person's last known address except that—
 - (a) in the case of service on a body corporate or its secretary or clerk, it shall be the address of the registered or principal office of the body corporate; and
 - (b) in the case of service on a partnership or a partner or a person having the control or management of a partnership business, it shall be the principal office of the partnership,

and for the purposes of this paragraph the principal office of a company registered outside the United Kingdom or of a partnership carrying on business outside the United Kingdom is its principal office within the United Kingdom.

Marginal Citations

M12 1978 c.30.

Review E+W+S

- 77.—(1) The Secretary of State must from time to time—
 - (a) carry out a review of these Regulations;
 - (b) set out the conclusions of the review in a report; and
 - (c) publish the report.
- (2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other EEA states.
 - (3) The report must, in particular—
 - (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
 - (b) assess the extent to which those objectives are achieved; and
 - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved by a system that imposes less regulation.
- (4) The first report under this regulation must be published no later than 5 years after the date of the coming into force of these Regulations.
 - (5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

Extent Information

E37 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Review N.I.

- 77.—(1) The Secretary of State must from time to time—
 - (a) carry out a review of these Regulations;
 - (b) set out the conclusions of the review in a report; and
 - (c) publish the report.
- (2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other [F223 relevant] states.
 - (3) The report must, in particular—
 - (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
 - (b) assess the extent to which those objectives are achieved; and
 - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved by a system that imposes less regulation.
- (4) The first report under this regulation must be published no later than 5 years after the date of the coming into force of these Regulations.
 - (5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

Extent Information

E87 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

F223 Word in reg. 77(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. 13** para. 7

Department for Business, Energy and Industrial f Strategy

Margot James
Parliamentary Under Secretary of State Minister
for Small Business, Consumers and Corporate
Responsibility

[F144SCHEDULE A1

Regulation 2(1)

Disqualification and re-qualification marks

Textual Amendments

F144 Sch. A1 inserted (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **5(4)**

Disqualification mark

1. A disqualification mark must have the following form—



Re-qualification mark

2. A re-qualification mark must have the following form—]



SCHEDULE 1

Regulation 9(2)

INFORMATION TO BE MARKED ON REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS

1. The number of the [F145EU-]type examination certificate, where appropriate.

Textual Amendments

F145 Word in Sch. 1 para. 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. 26 para. 41(a)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- 2. The manufacturer's name, registered trade name or registered trade mark.
- 3. The accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles.
- **4.** Maximum capacity, in the form "Max".
- **5.** Minimum capacity, in the form "Min".
- **6.** Verification scale interval in the form "e ="
- 7. Type, batch and serial number
- **8.** When applicable the following:
 - (a) for instruments consisting of separate but associated units, the identification mark on each unit;
 - (b) scale interval if different from e, in the form "d =";
 - (c) maximum additive tare effect, in the form "T = +...";
 - (d) maximum subtractive tare effect if it is different from Max, in the form "T = -...";
 - (e) tare interval if it is different from d, in the form " $d_T = \dots$ ";
 - (f) maximum safe load if it is different from "Max...", in the form "Lim...";
 - (g) the special temperature limits, in the form "...°C/...°C"; and
 - (h) ratio between load receptor and load.
- 9. The requirements of points 1.2 to 1.5 of [F146Schedule 8] must be complied with.

SCHEDULE 2

Regulation 36(4)

OPERATIONAL OBLIGATIONS OF [F147NOTIFIED][F147APPROVED] BODIES

Textual Amendments

F147 Words in Sch. 2 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. 26 para. 42(b) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. Conformity assessment must be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

- 2. Conformity assessment bodies must perform their activities taking due account of—
 - (a) the size of an undertaking;
 - (b) the sector in which it operates and its structure;
 - (c) the degree of complexity of the of the regulated non-automatic weighing instrument technology in question; and
 - (d) the mass or serial nature of the production process,

but respecting the degree of rigour and the level of protection required for compliance of the regulated non-automatic weighing instrument with these Regulations.

- **3.** Where [F148 an approved] body finds that the essential requirements have not been met by a manufacturer, it—
 - (a) must require that manufacturer to take appropriate corrective measures; and
 - (b) must not issue a certificate of conformity.
- **4.** Where in the course of the monitoring of conformity following the issue of a certificate, [F149 an approved] body finds that a regulated non-automatic weighing instrument no longer complies, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the certificate if necessary.
- 5. Where corrective measured are not taken or do not have the required effect, the [F150 approved] body must restrict, suspend or withdraw any certificates, as appropriate.
- **6.** Where a person is aggrieved at a decision taken by [F151] an approved] body in relation to the conformity assessment of a regulated non-automatic weighing instrument, the [F150] approved] body must have appropriate arrangements for the review of that decision by a person who was not involved in the taking of that decision.
 - 7. [F150 Approved] bodies must inform the [F152 Secretary of State] of the following—
 - (a) any refusal, restriction, suspension or withdrawal of a certificate;
 - (b) any circumstances affecting the scope of or conditions for [F153 approval];
 - (c) any request for information which they have received from market surveillance authorities regarding conformity assessment; and
 - (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
- **8.** [F150 Approved] bodies must provide other bodies [F150 approved] under [F154 these Regulations] carrying out similar conformity assessment activities covering the same regulated non-automatic weighing instruments with relevant information on issues relating to negative and, on request positive conformity assessment results.
 - I^{F155}9. Notified bodies must—
 - (a) when requested by the Secretary of State, nominate a representative to attend a group convened by the Commission pursuant to Article 35 of the Directive; and
 - (b) ensure attendance of that representative at meetings of the group.]

Textual Amendments

F155 Sch. 2 para. 9 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. 26 para. 42(f)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

SCHEDULE 3

Regulation 49(4)

[F156REQUIREMENTS RELATING TO NOTIFIED BODIES][F156APPROVED BODY REQUIREMENTS]

Textual Amendments

F156 Sch. 3 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. 26 para. 43(a) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

- **1.** A conformity assessment body must be established [F157in the United Kingdom] and have legal personality.
- **2.** A conformity assessment body must be a third party body independent of the organisation or the regulated non-automatic weighing instrument it assesses.
- **3.** A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of regulated non-automatic weighing instruments which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body of a kind referred to in paragraph 2.
- **4.** A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the regulated non-automatic weighing instruments that they assess, nor the representative of any of those parties. This provision shall not preclude the use of assessed regulated non-automatic weighing instruments that are necessary for the operations of the conformity assessment body or the use of such regulated non-automatic weighing instruments for personal purposes.
- **5.** A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks—
 - (a) must not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those regulated non-automatic weighing instruments, or represent the parties engaged in those activities.
 - (b) must not engage in any activity (including consultancy services) that may conflict with their independent of judgement or integrity in relation to the conformity assessment activities for which they are [F158 approved].
- **6.** Conformity assessment bodies must ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

- 7. Conformity assessment bodies and their personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
- **8.** A conformity assessment body must be capable of carrying out all the conformity assessment tasks assigned to it by [F159Schedule 7] and in relation to which it has been [F158approved], whether those tasks are carried out by the conformity assessment body itself or on its behalf under its responsibility.

Extent Information

E47 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

- **F158** Word in Sch. 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. 26 para. 43(e)** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- F159 Words in Sch. 3 para. 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. 26 para. 43(c) (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
- **9.** At all times and for each conformity assessment procedure and each kind or category of regulated non-automatic weighing instruments in relation to which it has been [F158 approved], a conformity assessment body must have at its disposal the necessary—
 - (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment task;
 - (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;
 - (c) appropriate policies and procedures in place that distinguish between tasks it carries out as I^{F160} an approved] body and other activities; and
 - (d) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question, and the mass or serial nature of the production process.
- **10.** A conformity assessment body must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to all necessary equipment or facilities.
- 11. The personnel responsible for carrying out conformity assessment tasks must have the following—
 - (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been [F158 approved];
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
 - (c) appropriate knowledge and understanding of the requirements set out in [F161] Schedule 6], of the applicable [F162] designated] standards, and of the relevant provisions of [F163] these Regulations];

- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
- **12.** Conformity assessment bodies, their top-level management and the personal responsible for carrying out conformity assessment tasks must be impartial in the execution of their functions.
- 13. The remuneration of the top-level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body must not depend on the number of assessments carried out or on the results of those assessments.
- **14.** A conformity assessment body must satisfy the Secretary of State that it has adequate civil liability insurance.
- 15. The personnel of a conformity assessment body must observe professional secrecy with regard to all information obtained in carry out their tasks under Annex II, except as regards the Secretary of State. Proprietary rights must be protected.
- **16.** Conformity assessment bodies must participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the [F158 approved] body coordination group established [F164 by the Secretary of State] and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

SCHEDULE 4

Regulation 56

USE FOR TRADE OF REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS IN GREAT BRITAIN

Restrictions on use of instruments for trade

- 1.—(1) An instrument marked with a weighing range may be used for trade for determining the weight of any item by ascertaining the difference between two weights (both of which fall within the weighing range).
- (2) Save in accordance with paragraph (1) above, a person must not use for trade regulated non-automatic weighing instrument marked with a weighing range for determining a weight outside that range in relation to—
 - (a) articles made from, gold, silver, platinum or palladium;
 - (b) precious stones or pearls; or
 - (c) drugs or other pharmaceutical products.
- (3) A person must not use for trade any regulated non-automatic weighing instrument other than an instrument of accuracy classification Class I or Class II within the meaning of paragraph 2 of I^{F165}Schedule 61 in any transaction relating—
 - (a) to, or to articles made from, gold, silver, platinum or palladium;
 - (b) to precious stones or pearls.
- (4) Where a regulated non-automatic weighing instrument bears a mark which signifies the manner and purpose of use, it must not be used for trade in a manner or for a purpose which does not accord with that marking.
- (5) A person must not use a Class IIII regulated non-automatic weighing instrument (within the meaning of paragraph 2 of [F166] Schedule 6]) for trade for any purpose other than for weighing—

- (a) any of the materials to which the expression "ballast" applies in Schedule 4 to the Weights and Measures 1985 Act;
- (b) any material the disposal of which constitutes a landfill disposal as defined in paragraph (2) of section 70 of the Finance Act 1996 M13, whether or not the disposal amounts to a taxable disposal as defined in section 40 of that Act; or
- (c) waste not falling within paragraph (b).
- (6) A person must not use for trade any regulated non-automatic weighing instrument for the purpose of multiple weighing, that is to say, determining the mass of a load by totalling the results of more than one static weighing operation during each of which the load is only partially supported by the load receptor.
- (7) For the purposes of this paragraph, "waste" means any substance that its holder, discards, or intends or is required to discard, including any waste disposed of for reprocessing or recycling purposes.

Textual Amendments

F165 Words in Sch. 4 para. 1(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. 26 para. 44** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F166 Words in Sch. 4 para. 1(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. 26 para. 44** (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Marginal Citations

M13 1996 c.8.

Manner of erection of regulated non-automatic weighing instruments

2. Where a regulated non-automatic weighing instrument is fitted with one or more level-indicating devices, a person must not use the instrument for trade unless each such device indicates that it has been set to its reference position.

Regulated non-automatic weighing instruments marked with temperature range

3. Where a regulated non-automatic weighing instrument is marked with a temperature range, a person must not use the instrument for trade at temperatures outside that range.

Regulated non-automatic weighing instruments marked with manner of use

4. Where a regulated non-automatic weighing instrument is marked with the manner of use, a person must not use the instrument for trade in a manner which does not accord with the marking.

Regulated non-automatic weighing instruments fitted with printing devices

5. Where a regulated non-automatic weighing instrument is fitted with a printing device, a person must not use the instrument for trade unless the printing device produces a legible and durable printout.

Load receptors

- **6.**—(1) A person must not use a regulated non-automatic weighing instrument for trade unless it is erected and used in such a manner that, during a weighing operation, the load being weighed is stationary relative to the load receptor and supported only by the load receptor.
- (2) A person must not use for trade a regulated non-automatic weighing instrument for the purpose of sales by retail—
 - (a) unless—
 - (i) the load receptor is not less than 10 mm above any adjacent surface; or
 - (ii) where the load receptor is less than 10 mm above any adjacent surface, the boundary of the top surface of all adjacent surfaces is durably marked in a distinctive and contrasting manner with a band at least 15 mm in width; or
 - (b) if the load receptor is below the level of any adjacent surface.

Operation of regulated non-automatic weighing instrument

- 7. A person must not use a regulated non-automatic weighing instrument for trade unless it is erected in such a manner that the operator can, readily take up a single position from which he can—
 - (a) see directly or with the aid of mirrors, closed-circuit television or other permanently installed facilities, the whole of the unladen load receptor;
 - (b) operate the instrument's controls; and
 - (c) obtain a weight reading from the instrument.

Regulated non-automatic weighing instruments to be set to zero or to be balanced before use

- **8.**—(1) A person must not use a regulated non-automatic weighing instrument for trade unless it is properly balanced or set to zero immediately prior to use.
- (2) Paragraph (1) does not apply in the case of a regulated non-automatic weighing instrument if it is designed so as not to balance when unloaded.

SCHEDULE 5

Regulations 32(4), 54(8) and 61(4)

MONETARY PENALTIES

Introduction

1. This Schedule applies in relation to the imposition by the Secretary of State of a monetary penalty under these Regulations.

Procedure

- **2.**—(1) Before imposing a monetary penalty under these Regulations, the Secretary of State must notify the person on whom the penalty is to be imposed of the Secretary of State's intention to do so.
 - (2) The notice must—
 - (a) specify the proposed amount of the penalty (which must not exceed £50,000),
 - (b) specify the Secretary of State's reasons for proposing to impose the penalty,
 - (c) specify the period during which the person on whom the penalty is to be imposed may make representations about the proposal ("the specified period"), and

- (d) specify the way in which those representatives may be made.
- (3) The specified period must not be less than 28 days beginning with the date on which the notice is received.
- (4) The Secretary of State must have regard to any representations made by the person during the specified period in deciding whether to impose a monetary penalty on it.
- (5) Having decided whether or not to impose a monetary penalty, the Secretary of State must notify the person of the Secretary of State's decision.
 - (6) Where the decision is to impose a monetary penalty, the notice must specify—
 - (a) the amount of the penalty, and
 - (b) the period within which the penalty must be paid or the periods within which different portions of the penalty must be paid.
 - (7) The notice must also contain information as to—
 - (a) the grounds for imposing the penalty,
 - (b) how payment may be made,
 - (c) rights of appeal,
 - (d) the period within which an appeal may be made, and
 - (e) the consequences of non-payment.
- (8) The requirement to pay the penalty is suspended at any time when an appeal could be brought in respect of the penalty or such an appeal is pending.
- (9) But sub-paragraph (8) does not prevent the requirement to pay taking effect if the person notifies the Secretary of State that it does not intend to appeal.

Appeals

- **3.**—(1) A person on whom a monetary penalty is imposed, may appeal to the First-tier Tribunal against—
 - (a) a decision under these Regulations to impose a monetary penalty on the pern;
 - (b) a decision as to the amount of the penalty.
 - (2) An appeal under this paragraph may be made on the grounds—
 - (a) that the decision was based on an error of fact;
 - (b) that the decision was wrong in law;
 - (c) that the decision was unreasonable.
 - (3) On an appeal under this paragraph the Tribunal may—
 - (a) withdraw the requirement to pay the penalty;
 - (b) confirm that requirement;
 - (c) vary that requirement;
 - (d) remit the decision whether to confirm the requirement to pay the penalty, or any matter relating to that decision, to the Secretary of State.

Interest and recovery

- **4.**—(1) This paragraph applies if all or part of a monetary penalty imposed under these Regulations is unpaid by the time when it is required to be paid.
 - (2) The unpaid amount of the penalty for the time being—

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Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Non-automatic Weighing Instruments Regulations 2016. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- (a) carries interest at the rate for the time being specified in section 17 of the Judgments Act 1838 M14, and
- (b) does not also carry interest as a judgment debt under that section.
- (3) The total amount of interest imposed under sub-paragraph (2) must not exceed the amount of the penalty.
- (4) The Secretary of State may recover from the person on whom it is imposed, as a civil debt, the unpaid amount of the penalty and any unpaid interest.
- (5) Any sums received by the Secretary of State by way of a penalty imposed under these Regulations or interest under this paragraph must be paid into the Consolidated Fund.

Marginal Citations M14 1838 c.110.

[F167SCHEDULE 6

Regulation 2

(Annex I to the Directive)

Textual Amendments

F167 Schs. 6-9 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. 26 para. 45 (with Sch. 26 para. 5) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

ESSENTIAL REQUIREMENTS

The terminology used is that of the International Organisation of Legal Metrology

Preliminary observation

Where an instrument includes, or is connected to, more than one indicating or printing device used for the applications listed in sub-paragraphs (a) to (f) of regulation 3(2), those devices which repeat the results of the weighing operation and which cannot influence the correct functioning of the instrument shall not be subject to the essential requirements if the weighing results are printed or recorded correctly and indelibly by a part of the instrument which meets the essential requirements and the results are accessible to both parties concerned by the measurement. However, in the case of instruments used for direct sales to the public, display and printing devices for the vendor and the customer must fulfil the essential requirements.

Metrological requirements

1. Units of mass

The units of mass used shall be the legal units within the meaning of the Weights and Measures Act 1985 relating to units of measurement ^{F168}.

Subject to compliance with this condition, the following units are permitted—

- (a) SI units: kilogram, microgram, milligram, gram, tonne;
- (b) imperial unit: troy ounce, if weighing precious metals;

(c) other non-SI unit: metric carat, if weighing precious stones.

For instruments that make use of the imperial unit of mass referred to above, the relevant essential requirements specified below shall be converted to that unit, using simple interpolation.

Textual Amendments

F168 1985 c.72.

- 2. Accuracy classes
- **2.1.** The following accuracy classes have been defined—
 - (a) I special
 - (b) II high
 - (c) III medium
 - (d) IIII ordinary

The specifications of these classes are given in Table 1.

Table 1

Accuracy classes					
9		Minimum capacity (Min)		per of verification scale vals n = ((Max)/(e))	
		minimum value	minimum value	maximum value	
I	$0,001 \text{ g} \leq \text{e}$	100 e	50 000		
II	$0,001 \text{ g} \le e \le 0,05 \text{ g}$	20 e	100	100 000	
	$0,1 g \leq e$	50 e	5 000	100 000	
III	$0,1 g \le e \le 2 g$	20 e	100	10 000	
	5 g ≤ e	20 e	500	10 000	
IIII	5 g ≤ e	10 e	100	1 000	

The minimum capacity is reduced to 5 e for instruments in classes II and III for determining a conveying tariff.

- 2.2. Scale intervals
- 2.2.1. The actual scale interval (d) and the verification scale interval (e) shall be in the form—

$$1 \times 10^{k}$$
, 2×10^{k} , or 5×10^{k} mass units,

k being any integer or zero.

- **2.2.2.** For all instruments other than those with auxiliary indicating devices—d = e.
 - **2.2.3.** For instruments with auxiliary indicating devices the following conditions apply—

$$e = 1 \times 10^{k} g;$$

$$d \le e \le 10 d$$
.

Those conditions do not apply for instruments of class I with $d < 10^{-4}$ g, for which $e = 10^{-3}$ g.

3. Classification

3.1. Instruments with one weighing range

Instruments equipped with an auxiliary indicating device shall belong to class I or class II. For these instruments the minimum capacity lower limits for these two classes are obtained from Table 1 by replacement in column 3 of the verification scale interval (e) by the actual scale interval (d).

If $d < 10^{-4}$ g, the maximum capacity of class I may be less than 50 000 e.

3.2. Instruments with multiple weighing ranges

Multiple weighing ranges are permitted, provided they are clearly indicated on the instrument. Each individual weighing range is classified according to point 3.1. If the weighing ranges fall into different accuracy classes the instrument shall comply with the severest of the requirements that apply for the accuracy classes in which the weighing ranges fall.

- **3.3.** Multi-interval instruments
- **3.3.1.** Instruments with one weighing range may have several partial weighing ranges (multi-interval instruments).

Multi-interval instruments shall not be equipped with an auxiliary indicating device.

3.3.2. Each partial weighing range i of multi-interval instruments is defined by—

— its verification scale interval ^e i	with $e_{(i+1)} > e_i$
— its maximum capacity Maxi	with $Max_r = Max$
— its minimum capacity Min _i	with $Min_i = Max_{(i-1)}$
	and $Min_1 = Min$

Where:

i = 1, 2, ...r,

i = partial weighing range number,

r = the total number of partial weighing ranges

All capacities are capacities of net load, irrespective of the value of any tare used.

3.3.3. The partial weighing ranges are classified according to Table 2. All partial weighing ranges shall fall into the same accuracy class, that class being the instrument's accuracy class.

Table 2

Multi-level instruments				
i =	1, 2,r, partial weighing range number, the total number of partial weighing ranges			
Class	Verification scale interval (e)	Minimum capacity (Min)	Number of verification scale intervals	
		Minimum value	Minimum value F169 $n = ((Max_i) / (e_{(i+1)}))$	Maximum value $n = ((Max_i) / (e_i))$
I	$0,\!001~g \leq e_i$	100 e1	50 000	

II	$\begin{array}{c} 0,\!001\ g \leq e_i \leq 0,\!05 \\ g \end{array}$	20 e1	5 000	100 000
	$0,1 g \leq e_i$	50 e1	5 000	100 000
III	$0,1 g \leq e_i$	20 e1	500	10 000
IIII	$5g \leq e_i$	10 e1	50	1 000

Textual Amendments

F169 For I = r, the corresponding column of Table 1 applies, with e replaced by er.

- 4. Accuracy
- **4.1.** On implementation of the procedures laid down in regulation 36, the error of indication shall not exceed the maximum permissible error of indication as shown in Table 3. In the case of digital indication the error of indication shall be corrected for the rounding error.

The maximum permissible errors apply to the net value and tare value for all possible loads, excluding preset tare values.

Table 3

Maximum permissible errors					
Load	Maximum				
Class I	Class II	Class III	Class IIII	permissible error	
$0 \le m \le 50\ 000\ e$	$0 \le m \le 5~000~e$	$0 \le m \le 500 e$	$0 \le m \le 50 e$	± 0,5 e	
50 000 e < m ≤ 200 000 e	$\begin{array}{c} 5 \ 000 \ e \leq m \leq 20 \\ 000 \ e \end{array}$	500 e < m ≤ 2 000 e	$50 \text{ e} < \text{m} \le 200 \text{ e}$	± 1,0 e	
200 000 e < m	$20000e < m \le 100\\000e$	$\begin{array}{c} 2 \ 000 \ e < m \leq 10 \\ 000 \ e \end{array}$	$200 \text{ e} < \text{m} \le 1000 \text{ e}$	± 1,5 e	

- **4.2.** The maximum permissible errors in service are twice the maximum permissible errors fixed in Section 4.1.
- **5.** Weighing results of an instrument shall be repeatable, and shall be reproducible by the other indicating devices used and in accordance with other methods of balancing used.

The weighing results shall be sufficiently insensitive to changes in the position of the load on the load receptor.

- **6.** The instrument shall react to small variations in the load.
- 7. Influence quantities and time
- **7.1.** Instruments of classes II, III and IIII, liable to be used in a tilted position, shall be sufficiently insensitive to the degree of tilting that can occur in normal use.
- **7.2.** The instruments shall meet the metrological requirements within the temperature range specified by the manufacturer. The value of this range shall be at least equal to—
 - (a) 5 °C for an instrument in class I;
 - (b) 15 °C for an instrument in class II;

(c) 30 °C for an instrument in class III or IIII.

In the absence of a manufacturer's specification, the temperature range of -10 °C to +40 °C applies.

7.3. Instruments operated from a mains power supply shall meet the metrological requirements under conditions of power supply within the limits of normal fluctuation.

Instruments operated from battery power shall indicate whenever the voltage drops below the minimum required value and shall under those circumstances either continue to function correctly or be automatically put out of service.

- **7.4.** Electronic instruments, except those in class I and in class II if e is less than 1 g, shall meet the metrological requirements under conditions of high relative humidity at the upper limit of their temperature range.
- **7.5.** Loading an instrument in class II, III or IIII for a prolonged period of time shall have a negligible influence on the indication at load or on the zero indication immediately after removal of the load.
- **7.6.** Under other conditions the instruments shall either continue to function correctly or be automatically put out of service.

Design and construction

- 8. General requirements
- **8.1.** Design and construction of the instruments shall be such that the instruments will preserve their metrological qualities when properly used and installed and when used in an environment for which they are intended. The value of the mass must be indicated.
- **8.2.** When exposed to disturbances, electronic instruments shall not display the effects of significant faults, or shall automatically detect and indicate them.

Upon automatic detection of a significant fault, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the fault disappears.

8.3. The requirements of points 8.1 and 8.2 shall be met on a lasting basis during a period of time that is normal in view of the intended use of such instruments.

Digital electronic devices shall always exercise adequate control of the correct operation of the measuring process, of the indicating device, and of all data storage and data transfer.

Upon automatic detection of a significant durability error, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the error disappears.

- **8.4.** When external equipment is connected to an electronic instrument through an appropriate interface the metrological qualities of the instrument shall not be adversely influenced.
- **8.5.** The instruments shall have no characteristics likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal. Components that may not be dismantled or adjusted by the user shall be secured against such actions.
- **8.6.** Instruments shall be designed to permit ready execution of the statutory controls laid down by these Regulations.
 - 9. Indication of weighing results and other weight values

The indication of the weighing results and other weight values shall be accurate, unambiguous and non-misleading and the indicating device shall permit easy reading of the indication under normal conditions of use.

The names and symbols of the units referred to in point 1 of this Schedule shall comply with the provisions of the Weights and Measures Act 1985 with the addition of the symbol for the metric carat which shall be the symbol 'ct'.

Indication shall be impossible above the maximum capacity (Max), increased by 9 e.

An auxiliary indicating device is permitted only to the right of the decimal mark. An extended indicating device may be used only temporarily, and printing shall be inhibited during its functioning.

Secondary indications may be shown, provided that they cannot be mistaken for primary indications.

10. Printing of weighing results and other weight values

Printed results shall be correct, suitably identified and unambiguous. The printing shall be clear, legible, non-erasable and durable.

11. Levelling

When appropriate, instruments shall be fitted with a levelling device and a level indicator, sufficiently sensitive to allow proper installation.

12. Zeroing

Instruments may be equipped with zeroing devices. The operation of these devices shall result in accurate zeroing and shall not cause incorrect measuring results.

13. Tare devices and preset tare devices

The instruments may have one or more tare devices and a preset tare device. The operation of the tare devices shall result in accurate zeroing and shall ensure correct net weighing. The operation of the preset tare device shall ensure correct determination of the calculated net value.

14. Instruments for direct sales to the public, with a maximum capacity not greater than 100 kg: additional requirements

Instruments for direct sale to the public shall show all essential information about the weighing operation and, in the case of price-indicating instruments, shall clearly show the customer the price calculation of the product to be purchased.

The price to pay, if indicated, shall be accurate.

Price-computing instruments shall display the essential indications long enough for the customer to read them properly.

Price-computing instruments may perform functions other than per-article weighing and price computation only if all indications related to all transactions are printed clearly and unambiguously and are conveniently arranged on a ticket or label for the customer.

Instruments shall bear no characteristics that can cause, directly or indirectly, indications the interpretation of which is not easy or straightforward.

Instruments shall safeguard customers against incorrect sales transactions due to their malfunctioning.

Auxiliary indicating devices and extended indicating devices are not permitted.

Supplementary devices are permitted only if they cannot lead to fraudulent use.

Instruments similar to those normally used for direct sales to the public which do not satisfy the requirements of this Section must carry near to the display the indelible marking 'Not to be used for direct sale to the public'.

15. Price labelling instruments

Price labelling instruments shall meet the requirements of price indicating instruments for direct sale to the public, as far as applicable to the instrument in question. The printing of a price label shall be impossible below a minimum capacity.]

[F167SCHEDULE 7

Regulations 2, 36(1), (3) and(6), 40(1)(c), 45(5), 68(3)(c) and (d)

(Annex II to the Directive)

CONFORMITY ASSESSMENT PROCEDURES

- 1. Module B: type examination
- 1.1. type examination is the part of a conformity assessment procedure in which an approved body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of these Regulations that apply to it.
 - 1.2. type examination may be carried out in any of the following manners—
 - examination of a specimen, representative of the production envisaged, of the complete instrument (production type);
 - assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the instrument (combination of production type and design type);
 - assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, without examination of a specimen (design type).
- **1.3.** The manufacturer shall lodge an application for type examination with a single approved body of his choice.

The application shall include—

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other approved body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of these Regulations and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall contain, wherever applicable, at least the following elements—
 - (i) a general description of the instrument;
 - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;
 - (iv) a list of the designated standards applied in full or in part, and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant

technical specifications applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied;

- (v) results of design calculations made, examinations carried out, etc.;
- (vi) test reports;
- (d) the specimens representative of the production envisaged. The approved body may request further specimens if needed for carrying out the test programme;
- (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant designated standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.
- **1.4.** The approved body shall—

For the instrument—

1.4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;

For the specimen(s)—

- **1.4.2.** verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant designated standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
- **1.4.3.** carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant designated standards, these have been applied correctly;
- **1.4.4.** carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of these Regulations;
- **1.4.5.** agree with the manufacturer on a location where the examinations and tests will be carried out.
- **1.5.** The approved body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes. Without prejudice to its obligations vis-à-vis the Secretary of State, the approved body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
- **1.6.** Where the type meets the requirements of these Regulations, that apply to the instrument concerned, the approved body shall issue a type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The type examination certificate may have one or more annexes attached.

The type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured instruments with the examined type to be evaluated and to allow for in-service control.

The type examination certificate shall have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each. In the event of fundamental changes

to the design of the instrument, e.g. as a result of the application of new techniques, the validity of type examination certificate may be limited to two years and extended by three years.

Where the type does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

- 1.7. The approved body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations, and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly. The manufacturer shall inform the approved body that holds the technical documentation relating to the type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of these Regulations or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original type examination certificate.
- **1.8.** Each approved body shall inform the Secretary of State concerning the type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each approved body shall inform the other approved bodies concerning the type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The other approved bodies and the Secretary of State may, on request, obtain a copy of the type examination certificates and/or additions thereto. On request, the Secretary of State may obtain a copy of the technical documentation and the results of the examinations carried out by the approved body. The approved body shall keep a copy of the type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

- **1.9.** The manufacturer shall keep a copy of the type examination certificate, its annexes and additions together with the technical documentation at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market.
- **1.10.** The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.
 - 2. Module D: Conformity to type based on quality assurance of the production process
- **2.1.** Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2 and 2.5, and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the type examination certificate and satisfy the requirements of these Regulations that apply to them.

2.2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 2.3, and shall be subject to surveillance as specified in point 2.4.

2.3. Quality system

2.3.1. The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice, for the instruments concerned.

The application shall include—

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other approved body;
- (c) all relevant information for the instrument category envisaged;
- (d) the documentation concerning the quality system; and
- (e) the technical documentation of the approved type and a copy of the type examination certificate.
- **2.3.2.** The quality system shall ensure that the instruments are in conformity with the type described in the type examination certificate and comply with the requirements of these Regulations that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of—

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
- **2.3.3.** The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in point 2.3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2.3.1(e) to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

2.3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

2.3.5. The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 2.3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- **2.4.** Surveillance under the responsibility of the approved body
- **2.4.1.** The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- **2.4.2.** The manufacturer shall, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular—
 - (a) the quality system documentation;
 - (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- **2.4.3.** The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- **2.4.4.** In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the approved body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The approved body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
 - 2.5. Conformity marking and declaration of conformity
- **2.5.1** The manufacturer shall affix the UK marking and the M metrology marking set out in these Regulations, and, under the responsibility of the approved body referred to in point 2.3.1, the latter's identification number to each individual instrument that is in conformity with the type described in the type examination certificate and satisfies the applicable requirements of these Regulations.
- **2.5.2.** The manufacturer shall draw up a written declaration of conformity for each instrument model and keep it at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

- **2.6.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the market surveillance authorities—
 - (a) the documentation referred to in point 2.3.1;
 - (b) the information relating to the change referred to in point 2.3.5, as approved;
 - (c) the decisions and reports of the approved body referred to in points 2.3.5, 2.4.3 and 2.4.4.
- **2.7.** Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.
 - **2.8.** Authorised representative

The manufacturer's obligations set out in points 2.3.1, 2.3.5, 2.5 and 2.6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

- 3. Module D1: Quality assurance of the production process
- **3.1.** Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.4 and 3.7, and ensures and declares on his sole responsibility that the instruments concerned satisfy the requirements of these Regulations that apply to them.

3.2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements—

- (a) a general description of the instrument;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;
- (d) a list of the designated standards applied in full or in part, and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied;
- (e) results of design calculations made, examinations carried out, etc.;
- (f) test reports.
- **3.3.** The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

3.4. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 3.5, and shall be subject to surveillance as specified in point 3.6.

3.5. Quality system

3.5.1. The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice, for the instruments concerned.

The application shall include—

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other approved body;
- (c) all relevant information for the instrument category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation referred to in point 3.2.

3.5.2. The quality system shall ensure compliance of the instruments with the requirements of these Regulations that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of—

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
- **3.5.3.** The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.2 in order to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- **3.5.4.** The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- **3.5.5.** The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.5.2 or whether reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- **3.6.** Surveillance under the responsibility of the approved body
- **3.6.1.** The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- **3.6.2.** The manufacturer shall, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular—

- (a) the quality system documentation;
- (b) the technical documentation referred to in point 3.2;
- (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- **3.6.3.** The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- **3.6.4.** In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the approved body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The approved body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
 - 3.7. Conformity marking and declaration of conformity
- **3.7.1.** The manufacturer shall affix the UK marking and the M metrology marking, set out in these Regulations, and, under the responsibility of the approved body referred to in point 3.5.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of these Regulations.
- **3.7.2.** The manufacturer shall draw up a written declaration of conformity for each instrument model and keep it at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the market surveillance authorities upon request.

- **3.8.** The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the market surveillance authorities—
 - (a) the documentation referred to in point 3.5.1;
 - (b) the information relating to the change referred to in point 3.5.5, as approved;
 - (c) the decisions and reports of the approved body referred to in points 3.5.5, 3.6.3 and 3.6.4.
- **3.9.** Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

3.10. Authorised representative

The manufacturer's obligations set out in points 3.3, 3.5.1, 3.5.5, 3.7 and 3.8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

- 4. Module F: Conformity to type based on product verification
- **4.1.** Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 4.2 and 4.5 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 4.3, are in conformity with the type described in the type examination certificate and satisfy the requirements of these Regulations that apply to them.

4.2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instruments with the approved type described in the type examination certificate and with the requirements of these Regulations that apply to them.

4.3. Verification

An approved body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the instruments with the approved type described in the type examination certificate and with the appropriate requirements of these Regulations.

The examinations and tests to check the conformity of the instruments with the appropriate requirements shall be carried out by examination and testing of every instrument as specified in point 4.4.

- **4.4.** Verification of conformity by examination and testing of every instrument
- **4.4.1** All instruments shall be individually examined and appropriate tests set out in the relevant designated standard(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the type examination certificate and with the appropriate requirements of these Regulations.

In the absence of such a designated standard, the approved body concerned shall decide on the appropriate tests to be carried out.

4.4.2. The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the market surveillance authorities for 10 years after the instrument has been placed on the market.

- **4.5.** Conformity marking and declaration of conformity
- **4.5.1.** The manufacturer shall affix the UK marking and the M metrology marking, set out in these Regulations, and, under the responsibility of the approved body referred to in point 4.3, the latter's identification number to each individual instrument that is in conformity with the approved type described in the type examination certificate and satisfies the applicable requirements of these Regulations.
- **4.5.2.** The manufacturer shall draw up a written declaration of conformity for each instrument model and keep it at the disposal of the market surveillance authorities, for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the market surveillance authorities upon request.

If the approved body referred to in point 4.3 agrees and under its responsibility, the manufacturer may also affix the approved body's identification number to the instruments.

4.6. If the approved body agrees and under its responsibility, the manufacturer may affix the approved body's identification number to the instruments during the manufacturing process.

4.7. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 4.2.

- **5.** Module F1: Conformity based on product verification
- **5.1.** Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 5.2, 5.3 and 5.6 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 5.4, are in conformity with the requirements of these Regulations that apply to them.

5.2. Technical documentation

- **5.2.1.** The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:
 - (a) a general description of the instrument;
 - (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;
 - (d) a list of the designated standards applied in full or in part, and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied;
 - (e) results of design calculations made, examinations carried out, etc.;
 - (f) test reports.
- **5.2.2.** The manufacturer shall keep the technical documentation at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market.

5.3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instruments with the applicable requirements of these Regulations.

5.4. Verification

An approved body chosen by the manufacturer shall carry out appropriate examinations and tests to check the conformity of the instruments with the applicable requirements of these Regulations.

The examinations and tests to check the conformity with those requirements shall be carried out by examination and testing of every instrument as specified in point 5.5.

- **5.5.** Verification of conformity by examination and testing of every instrument
- **5.5.1.** All instruments shall be individually examined and appropriate tests, set out in the relevant designated standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a designated standard the approved body concerned shall decide on the appropriate tests to be carried out
- **5.5.2.** The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market.

- **5.6.** Conformity marking and declaration of conformity
- **5.6.1.** The manufacturer shall affix the UK marking and the M metrology marking, set out in these Regulations, and, under the responsibility of the approved body referred to in point 5.4, the latter's identification number to each individual instrument that satisfies the applicable requirements of these Regulations.

5.6.2. The manufacturer shall draw up a written declaration of conformity for each instrument model and keep it at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

If the approved body referred to in point 5.5 agrees and under its responsibility, the manufacturer may also affix the approved body's identification number to the instruments.

5.7. If the approved body agrees and under its responsibility, the manufacturer may affix the approved body's identification number to the instruments during the manufacturing process.

5.8. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 5.2.1 and 5.3.

- **6.** Module G: Conformity based on unit verification
- **6.1.** Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 6.2, 6.3 and 6.5, and ensures and declares on his sole responsibility that the instrument concerned, which has been subject to the provisions of point 6.4, is in conformity with the requirements of these Regulations that apply to it.
 - **6.2.** Technical documentation
- **6.2.1.** The manufacturer shall establish the technical documentation and make it available to the approved body referred to in point 6.4. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements—
 - (a) a general description of the instrument;
 - (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;
 - (d) a list of the designated standards applied in full or in part, and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these Regulations, including a list of other relevant technical specifications applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied;
 - (e) results of design calculations made, examinations carried out, etc.;
 - (f) test reports.
- **6.2.2.** The manufacturer shall keep the technical documentation at the disposal of the relevant market surveillance authorities for 10 years after the instrument has been placed on the market.

6.3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instrument with the applicable requirements of these Regulations.

6.4. Verification

An approved body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant designated standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the instrument with the applicable requirements of these Regulations, or have them carried out. In the absence of such a designated standard the approved body concerned shall decide on the appropriate tests to be carried out.

The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved instrument, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market.

- **6.5.** Conformity marking and declaration of conformity
- **6.5.1.** The manufacturer shall affix the UK marking and the M metrology marking, set out in these Regulations, and, under the responsibility of the approved body referred to in point 6.4, the latter's identification number to each instrument that satisfies the applicable requirements of these Regulations.
- **6.5.2.** The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the market surveillance authorities upon request.

6.6. Authorised representative

The manufacturer's obligations set out in points 6.2.2 and 6.5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

7. Common provisions

- **7.1.** The conformity assessment according to Module D, D1, F, F1 or G may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, it shall be carried out at the place of use of the instrument.
- **7.2.** If the instrument's performance is sensitive to gravity variations the procedures referred to in point 7.1 may be carried out in two stages, with the second stage comprising all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument.
- **7.2.1.** Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in point 7.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure shall bear the identification number of the approved body involved in that stage.
- **7.2.2.** The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate containing the data necessary for identification of the instrument and specifying the examinations and tests that have been carried out.

The party which carries out the second stage of the procedure shall carry out those examinations and tests that have not yet been carried out.

The manufacturer or his authorised representative shall ensure that he is able to supply the approved body's certificates of conformity on request.

- **7.2.3.** A manufacturer who has opted for Module D or D1 in the first stage may either use this same procedure in the second stage or decide to continue in the second stage with Module F or F1 as appropriate.
- **7.2.4.** The UK marking and the M metrology marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the approved body which took part in the second stage.]

[F167SCHEDULE 8

Regulations 2, 44 and 72

(Annex III to the Directive)

INSCRIPTIONS

- 1. Instruments intended to be used for the applications listed in sub-paragraphs (a) to (f) of regulation 3(2).
 - 1.1. Those instruments shall bear visibly, legibly and indelibly the following inscriptions—
 - (i) the number of the type examination certificate, where appropriate;
 - (ii) the manufacturer's name, registered trade name or registered trade mark;
 - (iii) the accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles;
 - (iv) maximum capacity, in the form Max ...;
 - (v) minimum capacity, in the form Min ...;
 - (vi) verification scale interval, in the form e = ...;
 - (vii) type, batch or serial number and when applicable;
 - (viii) for instruments consisting of separate but associated units: identification mark on each unit;
 - (ix) scale interval if it is different from e, in the form d = ...;
 - (x) maximum additive tare effect, in the form T = + ...;
 - (xi) maximum subtractive tare effect if it is different from Max, in the form T = -...;
 - (xii) tare interval if it is different from d, in the form dT = ...;
 - (xiii) maximum safe load if it is different from Max, in the form Lim ...;
 - (xiv) the special temperature limits, in the form ... °C/... °C;
 - (xv) ratio between load receptor and load.
- **1.2.** Those instruments shall have adequate facilities for the affixing of the conformity marking and inscriptions. These shall be such that it shall be impossible to remove the conformity marking and inscriptions without damaging them, and that the conformity marking and inscriptions shall be visible when the instrument is in its regular operating position.
- **1.3.** Where a data plate is used it shall be possible to seal the plate unless it cannot be removed without being destroyed. If the data plate is sealable it shall be possible to apply a control mark to it.

- **1.4.** The inscriptions Max, Min, e, and d, shall also be shown near the display of the result if they are not already located there.
- **1.5.** Each load measuring device which is connected or can be connected to one or more load receptors shall bear the relevant inscriptions relating to the said load receptors.
- **2.** Instruments not intended to be used for the applications listed in points (a) to (f) of regulation 3(2) shall bear visibly, legibly and indelibly—
 - the manufacturer's name, registered trade name or registered trade mark;
 - maximum capacity, in the form Max

Those instruments shall not bear the conformity marking as set out in these Regulations.

3. Restrictive use symbol referred to in regulation 9(3).

The restrictive use symbol shall be constituted by a capital letter 'M' printed in black on a red background at least $25 \text{ mm} \times 25 \text{ mm}$ square with two intersecting diagonals forming a cross.]

[F167SCHEDULE 9

Regulations 2 and 40(1)(b)

DECLARATION OF CONFORMITY (No XXXX) F170

Textual Amendments

F170 It is optional for the manufacturer to assign a number to the declaration of conformity.

- 1. Instrument model/Instrument (product, type, batch or serial number):
- 2. Name and address of the manufacturer and, where applicable, his authorised representative:
- 3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
- **4.** Object of the declaration (identification of instrument allowing traceability; it may, where necessary for the identification of the instrument, include an image):
 - **5.** The object of the declaration described above is in conformity with the relevant UK legislation:
- **6.** References to the relevant designated standards used or references to the other technical specifications in relation to which conformity is declared:
- 7. The approved body ... (name, number) performed ... (description of intervention) and issued the certificate:
 - **8.** Additional information:
 - Signed for and on behalf of:
 - (place and date of issue):
 - (name, function) (signature):]

EXPLANATORY NOTE

(This note is not part of these Regulations)

These Regulations implement Directive 2014/31/EU of the European Parliament and of the Council of 26th February 2014 on the harmonisation of the laws of Member States relating to the making available on the market of non-automatic weighing instruments. These Regulations replace and revoke the Non-automatic Weighing Instruments Regulations 2000 and the Non-automatic Weighing Instruments (Amendment) Regulations 2008. Non-automatic weighing instruments are defined as instruments which require the intervention of an operator to determine mass and other things related to mass by the use of gravity. The Regulations impose requirements in relation to the manufacture of non-automatic weighing instruments which are used for determining mass for:

- (a) commercial transactions;
- (b) the determination of the amount of certain payments such as tolls or taxes;
- (c) the purposes of court proceedings and legal requirements;
- (d) the weighing of patients for medical purposes;
- (e) making up medicines and other medical and pharmaceutical laboratory purposes;
- (f) direct sales to the public and the making up of pre-packages. and the determination of price on the basis of mass.

These instruments are referred to in the Regulations as "regulated non-automatic weighing instruments".

The Regulations set out what are referred to as "the essential requirements" which must be met by regulated non-automatic weighing instruments. The essential requirements are defined in regulation 2(1) as the requirements relating to non-automatic weighing instruments set out in Annex I to the Directive.

Part 1 of the Regulation contains definitions, revocations and transitional provisions.

Part 2 of the Regulations sets out the obligations of economic operators (manufacturers (and their authorised representatives), importers and distributors) in connection with ensuring that instruments placed on the market meet the essential requirements and the other requirements of the Regulations.

Part 3 of the Regulations makes provision for establishing conformity with the essential requirements. Regulation 40 sets out the conformity assessment procedures that must be used to ensure conformity with the essential requirements and the requirements to be followed and the use of notified bodies.

Part 4 contains requirements as to markings to be placed on instruments that are not required to meet the essential requirements. Part 5 contains the requirements relating to the notification by the United Kingdom of conformity assessment bodies.

Part 6 contains provisions prohibiting the use of non-automatic weighing instruments for the purposes listed in regulation 3(2) unless they have been subject to the appropriate conformity assessment procedures. Part 7 imposes certain requirements for the use for trade of regulated non-automatic weighing instruments.

Part 8 makes provision in relation to market surveillance and enforcement of the Regulations; Part 9 makes provision about the unauthorised application of marks to regulated non-automatic weighing instruments and also makes provision in relation to penalties for offences and defences. Part 10 contains miscellaneous and supplemental provisions. A draft of these Regulations was notified to the European Commission in accordance with Directive 98/34/EC of the European Parliament and of the Council laying down a procedure for the provision of information in the

field of technical standards and regulations (OJ L 204, 21.7.1998, p.37) as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p.18).

A transposition note and an impact assessment of the effect that this instrument will have on the costs of business, the public sector and voluntary sector is available from the Regulatory Delivery Directorate, 1 Victoria Street, London SW1 0ET. They are also available with the explanatory memorandum alongside this instrument on www.legislation.gov.uk.

Changes to legislation:

There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Non-automatic Weighing Instruments Regulations 2016. Any changes that have already been made by the team appear in the content and are referenced with annotations.

View outstanding changes

Changes and effects yet to be applied to:

- Sch. 3 para. 1 substituted by S.I. 2024/504 reg. 12
- Sch. 3 heading word substituted by S.I. 2019/696 Sch. 26 para. 43(e)
- reg. 2(1) words omitted by S.I. 2020/1112 Sch. 13 para. 2(1)(h) (This amendment not applied to legislation.gov.uk. Sch. 13 para. 2(1)(h) omitted immediately before IP completion day by virtue of S.I. 2020/1486, regs. 1(3), 3(b))
- reg. 2(1) words substituted by S.I. 2019/696 Sch. 26 para. 2(2)(d) (This amendment not applied to legislation.gov.uk. Sch. 26 para. 2(2)(d) omitted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 3)
- reg. 2(1) words substituted by S.I. 2019/696 Sch. 26 para. 2(2)(n) (This amendment not applied to legislation.gov.uk. Sch. 26 para. 2(2)(n) substituted immediately before IP completion day by S.I. 2020/676, regs. 1(1), 4(14)(a))
- reg. 2(1) words substituted by S.I. 2019/696 Sch. 26 para. 2(2)(r) (This amendment not applied to legislation.gov.uk. Sch. 26 para. 2(2)(r) substituted immediately before IP completion day by S.I. 2020/676, regs. 1(1), 4(14)(b))
- reg. 2(1) words substituted in earlier amending provision S.I. 2019/696, Sch. 26 para. 2(2)(d) by S.I. 2020/852 reg. 4(2)Sch. 1 para. 1(o)(i) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 1(o)(i) omitted immediately before it comes into force by virtue of S.I. 2020/1460, regs. 1(3), Sch. 4 para. 1(3))
- reg. 6(d) word substituted by S.I. 2019/696 Sch. 26 para. 6(a) (This amendment not applied to legislation.gov.uk. Sch. 26 para. 6 substituted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 18(3))
- reg. 6(e)(i) word substituted by S.I. 2019/696 Sch. 26 para. 6(b) (This amendment not applied to legislation.gov.uk. Sch. 26 para. 6 substituted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 18(3))