SCHEDULE 27

Regulation 30

Amendment of the Measuring Instruments Regulations 2016

Introduction

1. The Measuring Instruments Regulations 2016 are amended in accordance with paragraphs 2 to 53.

Commencement Information

I1 Sch. 27 para. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 2

2.—(1) Regulation 2 (interpretation) is amended as follows.

(2) In paragraph (1)—

(a) omit the definition of "accreditation";

(b) omit the definition of "accreditation certificate";

(c) after the definition of "active electrical energy meter", insert—

""approved body" has the meaning given to it in regulation 53 (approved bodies);";

F1(d) . . . . . .

(e) omit the definition of "CE marking";

(f) omit the definition of "Commission";

(g) in the definition of "conformity assessment" before "measuring" insert " regulated ";

(h) after the definition of "conformity assessment body", insert—

""declaration of conformity" means a declaration of conformity required to be drawn up in accordance with chapter 3 of Part 4;

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

"design examination certificate" means a design certificate issued by an approved body in accordance with Module H1 in Schedule 1B";

(i) omit the definition of "dimensional measuring instrument";

(j) in the definition of "distributor" before "measuring" insert " regulated ";

(k) in the definition of "essential requirements"—

(i) before "measuring" insert " regulated ";

(ii) for "1", substitute " 1A and 1C to 1J ";

(l) omit the definition of "EU declaration of conformity";

(m) omit the definition of "EU-design examination certificate";

(n) omit the definition of "EU-type examination certificate";

(o) in the definition of "exhaust gas analyser" before "measuring" insert " regulated ";

(p) omit the definition of "harmonised standard";

(q) for the definition of "importer" substitute—

[F2""importer" means a person who—

(a) is established in the United Kingdom and places a regulated measuring instrument from a country outside of the United Kingdom on the market; or

(b) is established in Northern Ireland and places a regulated measuring 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;"**]**;

(r) in the definition of "M marking"—

(i) before "measuring" insert " regulated ";

(ii) for "CE", substitute " UK ";

(s) omit the definition of "measuring instrument";

(t) in the definition of "make available on the market"—

(i) before "measuring" insert " regulated ";

[[F3](ii) for "the European Economic Area market" substitute "market of Great Britain";**]**

(u) in the definition of "manufacturer" insert " regulated " before "measuring" in each place it occurs;

(v) in the definition of "market surveillance authority", omit from "and" to "EEA state";

(w) omit the definition of "national accreditation body";

(x) omit the definition of "non-prescribed measuring instrument";

(y) omit the definition of "notified body";

(z) omit the definition of "notified body requirements";

(aa) omit the definition of "notifying authority";

(bb) in the definition of "place on the market"—

(i) before "measuring" insert " regulated ";

[[F4](ii) for ", in the European Economic Area" substitute "of Great Britain";**]**

(cc) in the definition of "putting into use" insert " regulated " before "measuring";

(dd) in the definition of "relevant conformity assessment procedure"—

(i) before "measuring" insert " regulated ";

(ii) for "Schedule 1", substitute " Schedules 1C to 1J ";

(ee) in the definition of "relevant economic operator" insert " regulated " before "measuring" in both places it occurs;

(ff) omit the definition of "sub-assembly";

(gg) in the definition of "taximeter" insert " regulated " before "measuring";

(hh) in the definition of "technical specification" insert " regulated " before "measuring";

(ii) after the definition of "technical specification" insert—

""type examination certificate" means a type examination certificate issued by an approved body in accordance with Module B in Schedule 1B;

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

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

(jj) omit the definition of "thermal energy meter";

(kk) omit the definition of "Union harmonisation legislation";

(ll) omit the definition of "United Kingdom Accreditation Service";

(mm) omit the definition of "volume conversion device";

(nn) in the definition of "withdraw" insert " regulated " before "measuring" in both places it occurs.

(3) After paragraph (1) insert—

"(1A) Schedules 1A to 1J reproduce the provisions of Annexes I to V, VII to X and XII to the Directive (respectively) with amendments to correct deficiencies in retained EU law.

(1B) A reference to a provision of Schedules 1A to 1J is a reference to the equivalent provision of the relevant Annex to the Directive as set out in the relevant Schedule.".

(4) Omit paragraph (2).

F1 Sch. 27 para. 2(2)(d) omitted (31.12.2020 immediately before IP completion day) by virtue of 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. 3(k)**

F2 Words in Sch. 27 para. 2(2)(q) substituted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 19(2)**

F3 Sch. 27 para. 2(2)(t)(ii) substituted (31.12.2020 immediately before IP completion day) 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(15)(a)**

F4 Sch. 27 para. 2(2)(bb)(ii) substituted (31.12.2020 immediately before IP completion day) 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(15)(b)**

Commencement Information

I2 Sch. 27 para. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 2A

3. After regulation 2 insert—

"**Designated 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, 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 regulated measuring instrument, process, service or system and which lays down one or more of the following—

(a) the characteristics required of a regulated measuring instrument, including—

(i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and

(ii) the requirements applicable to the regulated measuring instrument as regards the name under which the regulated 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 regulated measuring instrument, where these have an effect on the characteristics of the regulated measuring 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).

(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 person 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 technical specifications adopted by the other recognised standardisation bodies.

(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 (9) is subject to annulment in pursuance of a resolution of either House of Parliament.".

Commencement Information

I3 Sch. 27 para. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 3

4.—(1) In regulation 3 (meaning of "measuring instrument" and related expressions and application of these Regulations) in the heading—

(a) before "measuring" insert " regulated ";

(b) omit "and related expressions"; and

(2) omit paragraphs (1) and (3).

Commencement Information

I4 Sch. 27 para. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 7

[[F5]**5.** In regulation 7 (manufacturer's responsibilities - design, conformity assessment and marking of regulated measuring instruments)—

(a) the existing paragraph is renumbered paragraph (1);

(b) in paragraph (1)(d) (as so renumbered) for "an EU" substitute " a ";

(c) in paragraph (1)(e) (as so renumbered)—

(i) after "instrument" insert " 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 ";

(ii) for "CE" substitute " UK ";

(d) after the renumbered paragraph (1) insert—

"(2) For a period of 24 months 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.".**]**

F5 Sch. 27 para. 5 substituted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 19(3)**

Commencement Information

I5 Sch. 27 para. 5 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 8

6. In regulation 8 (manufacturers - obligations in respect of records) omit "EU".

Commencement Information

I6 Sch. 27 para. 6 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 9

7. In regulation 9 (manufacturers' obligations to ensure continuing conformity with essential requirements), in paragraph (2)(b), for "harmonised", substitute " designated ".

Commencement Information

I7 Sch. 27 para. 7 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 11

8. In regulation 11 (manufacturers to mark contact details on regulated measuring instruments where possible), for paragraph (4) substitute—

"(4) The contact details required by this regulation must be clear, legible and in easily understandable English."

Commencement Information

I8 Sch. 27 para. 8 in force on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

I9 Sch. 27 para. 8 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 12

9. In regulation 12 (documentation to accompany regulated measuring instruments)—

(a) in paragraph (1)(a), omit "EU";

(b) omit paragraph (3); and

(c) in paragraph (4), for "understandable and intelligible" substitute " legible and in easily understandable English ".

Commencement Information

I10 Sch. 27 para. 9 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 13

10. In regulation 13 (action to be taken where regulated measuring instruments placed on the market are not in conformity with the essential requirements), in paragraph (3), for "national" to "market", substitute " authority ".

Commencement Information

I11 Sch. 27 para. 10 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 15

11. In regulation 15 (use of authorised representatives by manufacturers)—

(a) in paragraph (1) for "an" substitute " a person established in the United Kingdom as their ";

(b) in paragraph (3)(a), omit "EU".

Commencement Information

I12 Sch. 27 para. 11 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 16

12. In regulation 16 (introductory), omit "European Economic Area that is imported into the".

Commencement Information

I13 Sch. 27 para. 12 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 17

13. In regulation 17 (ensuring compliance of regulated measuring instruments), in paragraph (2) —

(a) in sub-paragraph (c), for "CE", substitute " UK "; and

(b) in sub-paragraph (d), omit "EU".

Commencement Information

I14 Sch. 27 para. 13 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 19

14. In regulation 19 (requirements to mark importers' details on regulated measuring instruments) —

(a) for paragraph (2) substitute—

"(2) Paragraph (1) does not apply where—

(a) either—

(i) the regulated measuring instrument it too small or too sensitive a composition to allow it to bear the information required by paragraph (1); or

(ii) the importer has imported the regulated measuring instrument from an EEA state **[**F6or Switzerland**]** and places it on the market within the period of **[**F724 months**]** beginning with **[**F8 IP completion day**]**, and

(b) before placing the regulated measuring instrument on the market, the importer sets out the information referred to in paragraph (1)—

(i) where sub-paragraph (a)(i) applies, on any packaging in which the instrument is supplied and in any accompanying documents;

(ii) where sub-paragraph (a)(ii) applies, in a document accompanying the instrument.";

(b) for paragraph (3) substitute—

"(3) Any contact details required by this regulation must be clear, legible and in easily understandable English.".

F6 Words in Sch. 27 para. 14(a) inserted (31.12.2020 immediately before IP completion day) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(3), **5**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in Sch. 27 para. 14(a) substituted (31.12.2020 immediately before IP completion day) 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. 2(1)(k)**

F8 Words in Sch. 27 para. 14(a) substituted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/852), regs. 2(2), 4(2), **Sch. 1 para. 1(p)(ii)**

Commencement Information

I15 Sch. 27 para. 14 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 20

15. In regulation 20 (importers' duty to ensure that regulated measuring instruments are accompanied by relevant documentation)—

(a) in paragraph (1), omit "in a language easily understood by end-users"; and

(b) for paragraph (2), substitute—

"(2) The instructions and information referred to in paragraph (1) must be clear, legible and in easily understandable English.".

Commencement Information

I16 Sch. 27 para. 15 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 24

16. In regulation 24 (requirement for importer to keep copy of EU declaration of conformity), and in the heading to that regulation, omit "EU".

Commencement Information

I17 Sch. 27 para. 16 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 28

17. In regulation 28 (distributors - verification obligations)—

(a) in paragraph (1), for "CE", substitute " UK ";

(b) in paragraph (2)(a), omit "EU"; and

(c) for paragraph (4), substitute—

"(4) Instructions and information supplied in accordance with this regulation must be clear, legible and in easily understandable English.".

Commencement Information

I18 Sch. 27 para. 17 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 33A [F9 33B and 33C]

18. After regulation 33 insert—

"**Obligations which are met by complying with obligations in the Directive**

33A.—(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 4(22);

(c) "Module B" means the conformity assessment procedure set out under the heading "MODULE B: EU-TYPE EXAMINATION" in Annex II;

(d) "Module H1" means the conformity assessment procedure set out under the heading "MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION" in Annex II;

(e) "EU-design examination certificate" means an EU design certificate issued in accordance with Module H1;

(f) "EU-type examination certificate" means an EU-type examination certificate issued in accordance with Module B;

(g) "harmonised standard" has the meaning given to it in Article 4(14);

(h) "instrument-specific Annexes" means Annexes III to XII.

(2) Paragraph (3) applies where, before placing a regulated measuring instrument on the market, the manufacturer—

(a) ensures that the regulated measuring instrument has been designed and manufactured in accordance with the essential requirements set out in Annex I and in the relevant instrument-specific Annex which applies to the regulated measuring instrument;

(b) ensures that the one of the relevant conformity assessment procedures listed in the relevant instrument-specific Annex that apply to that regulated measuring instrument in accordance with Article 17 have been carried out;

(c) draws up the technical documentation referred to in Article 18;

(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 a CE marking and the supplementary metrology marking, in accordance with Articles 21 and 22(1) to (6);

(f) draws up an EU declaration of conformity, in accordance with Article 19; and

(g) ensures that the EU declaration of conformity is prepared in or translated into English.

(3) Where this paragraph applies—

(a) the requirements of regulations 7(a) to (e), 48 and 52(2) are to be treated as being satisfied;

(b) regulations 8, 9(2), 51, 68(1)(a) to (e), 72, 73 and 75 apply subject to the modifications in paragraph (8); and

(c) regulations 36 to 39 do not apply.

(4) Paragraph (5) applies where, before placing a regulated measuring instrument on the market, the importer ensures that—

(a) the relevant conformity assessment procedures that apply to that measuring instrument in accordance with Article 17 have been carried out;

(b) the manufacturer has drawn up the technical documentation referred to in Article 18; and

(c) the measuring instrument bears the CE marking, and the supplementary metrology marking referred to in Article 21(2).

(5) Where this paragraph applies—

(a) the requirements of regulation 17(2)(a) to (c) are to be treated as being satisfied; and

(b) regulations 18, 21, 23, 51, 68(1)(a) to (e), 72, 73 and 75 apply subject to the modifications in paragraph (8).

(6) Paragraph (7) applies where, before making a regulated measuring instrument available on the market, a distributor ensures that the regulated measuring instrument bears the CE marking, and the supplementary metrology marking referred to in Article 21(2).

(7) Where this paragraph applies—

(a) regulation 28(1) is to be treated as being satisfied; and

(b) regulations 29(1),30, 68(1)(a), 68(1)(b), 72 and 73 apply subject to the modifications in paragraph (8).

(8) The modifications referred to in 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 "essential requirements" is to be read as a reference to the essential requirements referred to in Annex I and in the relevant instrument-specific Annex which applies to the regulated measuring instrument;

(d) any reference to "designated standard" is to be read as a reference to a harmonised standard;

(e) any reference to "relevant conformity assessment procedure" is to be read as a reference to the relevant conformity assessment procedures that apply to the regulated measuring instrument in accordance with Article 17;

(f) any reference to "technical documentation" is a reference to the technical documentation referred to in Article 18;

(g) any reference to "type examination certificate" is to be read as a reference to an EU-type examination certificate; and

(h) any reference to "design examination certificate" is to be read as a reference to an EU-design examination certificate;

(i) any reference to "M marking" is to be read as a reference to the supplementary metrology marking; and

(j) 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;

(k) any reference to "authorised mark" includes the CE marking and the supplementary metrology marking.

Conformity assessment procedure obligation which is met by complying with the Directive

33B.—(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) "Module B" means the conformity assessment procedure set out under the heading "MODULE B: EU-TYPE EXAMINATION" in Annex II;

(c) "EU-type examination certificate" means an EU-type examination certificate issued in accordance with Module B;

(d) "harmonised standard" has the meaning given to it in Article 4(14);

(e) "instrument-specific Annexes" means Annexes III to XII.

(2) Paragraph (3) applies where—

(a) in accordance with Article 17, one of the conformity assessment procedures listed in the instrument-specific Annex that applies to the regulated measuring instrument is Module B; and

(b) before placing a regulated measuring instrument on the market, the manufacturer ensures that—

(i) the regulated measuring instrument has been designed in accordance with the essential requirements set out in Annex I and in the relevant instrument-specific Annex which applies to the regulated measuring instrument; and

(ii) Module B has been complied with in respect of that regulated measuring instrument.

(3) Where this paragraph applies—

(a) any reference in regulation 7(c) to "relevant conformity assessment procedure" includes Module B;

(b) any reference to "type examination certificate" in regulations 45(1)(j), 72(3)(b) and 73(3)(b) is to be read as a reference to "EU-type examination certificate"; and

(c) any reference to "designated standard" in regulation 45(1)(f) is to be read as a reference to "harmonised standard.

[F10Expiry of regulations 33A and 33B

33C.—(1) Subject to paragraph (2), regulation 33A ceases to have effect at the end of the period of 12 months beginning with IP completion day.

(2) Notwithstanding the expiry of regulation 33A—

(a) any regulated measuring instrument which was placed on the market pursuant to regulation 33A may continue to be made available on the market on or after the expiry of regulation 33A;

(b) any obligation to which a person was subject under regulation 33A in respect of any regulated measuring instrument placed on the market pursuant to regulation 33A continues to have effect after the expiry of regulation 33A, in respect of that instrument.

(3) Subject to paragraph (4), regulation 33B ceases to have effect at the end of the period of 12 months beginning with IP completion day.

(4) Where a conformity assessment procedure has been completed pursuant to regulation 33B in relation to a regulated measuring instrument prior to the expiry of regulation 33B, regulation 33B 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 33B(1)(c).

Qualifying Northern Ireland Goods

33D.—(1) Where paragraph (2) applies—

(a) a regulated measuring 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 regulated measuring 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; and

(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 19;

(b) ensures that—

(i) the relevant conformity assessment procedure has been carried out.

(ii) the manufacturer has drawn up the technical documentation; and

(iii) the regulated measuring instrument bears the CE marking.

(4) In this regulation—

"CE marking" has the meaning given it in 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;

"relevant conformity assessment procedure" has the meaning given to it in regulation 2(1), as it applies in Northern Ireland;

"technical documentation" has the meaning given to it in regulation 2(1), as it applies in Northern Ireland."**]**.

F9 Words in Sch. 27 para. 18 heading substituted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 19(4)(a)**

F10 Words in Sch. 27 para. 18 inserted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 19(4)(b)**

Commencement Information

I19 Sch. 27 para. 18 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to Part 3

19. Omit Part 3 (non-prescribed measuring instruments).

Commencement Information

I20 Sch. 27 para. 19 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 36

20. For regulation 36 (introductory), substitute—

"**36.** This chapter applies for the purposes of establishing whether a regulated measuring instrument complies with the essential requirements.".

Commencement Information

I21 Sch. 27 para. 20 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 37

21. In regulation 37 (methods of establishing conformity with the essential requirements)—

(a) in the opening words insert " regulated " before "measuring";

(b) in paragraph (a)—

(i) for "harmonised", the first time it appears, substitute " designated "; and

(ii) omit from "where" to "Union";

(c) in paragraph (b), for "in the Official Journal of the European Union", substitute " by the Secretary of State ".

Commencement Information

I22 Sch. 27 para. 21 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 38

22. In regulation 38 (presumptions of conformity of measuring instruments)—

(a) in paragraphs (1) and (2) and in the heading, before "measuring" insert " regulated ";

(b) in paragraphs (1) and (3), for "harmonised", substitute " designated ".

Commencement Information

I23 Sch. 27 para. 22 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 39

23. In regulation 39 (conformity assessment procedures)—

(a) in paragraph (1)—

(i) before "measuring" insert " regulated " in both places it occurs;

(ii) for "1" substitute " 1C to 1J "; and

(b) in paragraph (2), for "A notified" substitute " An approved ".

Commencement Information

I24 Sch. 27 para. 23 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insert of regulation 39A

24. After regulation 39, insert—

"**Power to amend Schedules 1C to 1J**

39A.—(1) Where the one or more of the conditions in paragraph (2) are met, the Secretary of State may by regulations make provision to amend Schedules 1C to 1J in relation to any of the following matters—

(a) maximum permissible errors (MPEs) and accuracy classes;

(b) rated operating conditions;

(c) critical change values; and

(d) disturbances.

(2) The conditions referred to in paragraph (1) are that the Secretary of State considers that the purpose of the provision is to—

(a) take into account scientific or technical progress; or

(b) provide adequate protection of consumers or other end users.

(3) The power to make regulations under this regulation includes the power—

(a) to make different provision for different cases; and

(b) to make such supplemental, consequential and transitional provision as the Secretary of State considers appropriate

(4) Regulations made under paragraph (1) are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.".

Commencement Information

I25 Sch. 27 para. 24 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 40

25. In regulation 40 (capacity serving measures – accredited in house bodies)—

(a) in paragraph (2) for "of Annex II to the Directive" substitute " in Schedule 1B ";

(b) in paragraphs (3) and (4)(c), before "measuring" insert " regulated "; and

(c) for paragraph (5) substitute—

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

Commencement Information

I26 Sch. 27 para. 25 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 41

26. For regulation 41 (subsidiaries and contractors) substitute—

"**Subsidiaries and contractors**

41.—(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 [M1].".

Commencement Information

I27 Sch. 27 para. 26 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 2006 c.46.

Amendment to regulation 42

27. In regulation 42 (fees)—

(a) for "a United Kingdom notified" substitute " an approved " in both places in which it occurs;

(b) in paragraph (2)(a) for "United Kingdom notified" substitute " approved ".

Commencement Information

I28 Sch. 27 para. 27 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 44

28. In regulation 44 (general requirements to be met by technical documentation)—

(a) in paragraphs (1)(a), (2)(b) and (2)(c) before "measuring" insert " regulated ";

(b) in paragraph (1)(b) for "the Directive" substitute " these Regulations ".

Commencement Information

I29 Sch. 27 para. 28 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 45

29. In regulation 45 (specific information to be included in technical documentation), in paragraph (1)—

(a) before "measuring" insert " regulated " in each place it occurs;

(b) in sub-paragraph (f)—

(i) for "harmonised", substitute " designated "; and

(ii) omit ", the references of which have been published in the Official Journal of the European Union";

(c) in sub-paragraph (g) for "harmonised" substitute " designated ";

(d) in sub-paragraph (i)(i) for "the Directive" substitute " these Regulations ";

(e) in sub-paragraph (i)(ii) for ", water and thermal-energy" substitute " and water ";

(f) in sub-paragraph (j)—

(i) for "EU-type" substitute " type ";

(ii) omit "EU" in the second place it occurs.

Commencement Information

I30 Sch. 27 para. 29 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to the heading of Chapter 3

30. In the heading to Chapter 3 omit "EU".

Commencement Information

I31 Sch. 27 para. 30 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 46

31. In regulation 46 (application of Chapter)—

(a) omit "EU"; and

(b) before "measuring" insert " regulated ".

Commencement Information

I32 Sch. 27 para. 31 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 47

32. In regulation 47 (form and contents of EU declaration of conformity etc)—

(a) in paragraphs (1) and (2) and in the heading, omit "EU";

(b) in paragraph (1)(b) for "Annex II to the Directive" substitute " Schedule 1B "; and

(c) in paragraph (1)(c) for "Annex XIII to the Directive" substitute " Schedule 1K ".

Commencement Information

I33 Sch. 27 para. 32 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 48

33. For regulation 48 (measuring instruments that require more than one declaration of conformity) substitute—

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

Commencement Information

I34 Sch. 27 para. 33 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 49

34. In regulation 49 (responsibility of manufacturer that draws up declaration of conformity)—

(a) for "an EU" substitute " a "; and

(b) before "measuring" insert " regulated " in both places it occurs.

Commencement Information

I35 Sch. 27 para. 34 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 50

35. In regulation 50 (conformity with Directive requirements to be indicated by the CE marking)—

(a) in the heading omit "Directive"; and

(b) in the regulation and in the heading, for "CE", substitute " UK ".

Commencement Information

I36 Sch. 27 para. 35 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 51

36. For regulation 51 (general principles relating to the M marking), substitute—

> "**Prohibition on improper use of the UK marking and the M marking**
>
> **51.**—(1) An economic operator must not affix the UK marking or the M marking to a regulated measuring instrument unless—
>
> (a) that economic operator is the manufacturer of the regulated measuring instrument; and

(b) the conformity of the regulated measuring instrument with the essential requirements has been demonstrated by a relevant conformity assessment procedure.

(2) An economic operator must not affix a marking to a regulated measuring instrument which is not the UK marking or the M marking but which purports to attest that the regulated measuring instrument satisfies the essential requirements.

(3) An economic operator must not affix to a regulated measuring instrument a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the marking.

(4) An economic operator must not affix to a regulated measuring instrument any other marking if the visibility, legibility and meaning of the UK marking or the M marking would be impaired as a result.".

Commencement Information

I37 Sch. 27 para. 36 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 52

37. In regulation 52 (rules and conditions for affixing the CE marking and the M marking)—

(a) in paragraphs (1) to (6) before "measuring" insert " regulated " in each place it occurs;

(b) in paragraphs (1) and (7) and in the heading, for "CE", substitute " UK ";

[[F11](bb) in paragraph (2) for "or its data plate" substitute " , its data plate, or where regulation 7(2) applies, to a label affixed to the measuring instrument or to a document accompanying the measuring instrument; "**]**

(c) in paragraph (4) omit ", not being sub-assemblies";

(d) in paragraph (8) for "Annex II to the Directive" substitute " Schedule 1B "; and

(e) in paragraphs (8), (9) and (10) for "notified" substitute " approved ".

F11 Sch. 27 para. 37(bb) inserted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 19(5)**

Commencement Information

I38 Sch. 27 para. 37 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to Part 5

38. For Part 5 substitute—

"PART 5

Approval of Conformity Assessment Bodies

Approved bodies

53.—(1) An approved body is a conformity assessment body which—

(a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 54 (approval of conformity assessment bodies); or

(b) immediately before **[**F12IP completion day**]** was a notified body in respect of which the Secretary of State had taken no action under regulation 60(1) or (2) as they had effect immediately before **[**F12IP completion day**]** to suspend or withdraw the body's status as a notified body.

(2) Paragraph (1) has effect subject to regulation 57 (restriction, suspension or withdrawal of approval).

(3) In this Part—

"notified body" means a body—

(a) which the Secretary of State had before **[**F12IP completion day**]** notified to the European Commission and the member States of the European Union, in accordance with Article 23 of the Directive; and

(b) in respect of which no objections had been raised, as referred to in regulation 53(2)(b), as it had effect immediately before **[**F12IP completion day**]**;

"approved body requirements" means the requirements set out in Schedule 5.

Approval of conformity assessment bodies

54.—(1) The Secretary of State may approve only those conformity assessment bodies that qualify for approval.

(2) A conformity assessment body qualifies for approval if the first and second conditions below are met.

(3) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent; and

(iii) the regulated measuring instrument for which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate; or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

(4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b)(i), as sufficient evidence that the conformity assessment body meets the approved body requirements.

(6) When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may–

(a) have regard to any other matter which appears to the Secretary of State to be relevant; and

(b) set conditions that the conformity assessment body must meet.

(7) For the purposes of this regulation "accreditation certificate" means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.

Presumption of conformity of approved bodies

55.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements covered by that standard (or that part of that standard).

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

Monitoring

56. The Secretary of State must monitor each approved body with a view to verifying that the body—

(a) continues to meet the approved body requirements;

(b) meets any conditions set—

(i) in accordance with regulation 54(6)(b); or

(ii) in the case of an approved body which was a notified body immediately before **[**[F13]IP completion day**]**, in accordance with regulation 54(6)(b) as it applied immediately before **[**[F13]IP completion day**]**; and

(c) carries out its functions in accordance with these Regulations.

Restriction, suspension or withdrawal of approval

57.—(1) Where the Secretary of State determines that an approved body—

(a) no longer meets an approved body requirement, or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 54(6)(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 54 (approval of conformity assessment bodies).

(2) With the consent of an approved body, or where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 56(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 54 (approval of conformity assessment bodies).

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

(a) give notice in writing to the approved body of the proposed action and the reasons for it;

(b) give the approved body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and

(c) consider any such representations made by the approved body.

(5) Where the Secretary of State has taken action in respect of an approved body under paragraph (1) or (2), or where an approved body has ceased its activity, the approved body must—

(a) on the request of the Secretary of State, transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State; or

(b) in the absence of a request under sub-paragraph (a), ensure that its files relating to the activities it has undertaken as an approved body are kept available for the Secretary of State and competent authorities for a period of 10 years from the date they were created.

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

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

(8) Schedule 7 has effect in relation to a monetary penalty imposed under paragraph (7).

Register of approved bodies

58.—(1) The Secretary of State must—

(a) assign an approved body identification number to each approved body; and

(b) compile and maintain a register of—

(i) approved bodies;

(ii) their approved body identification numbers;

(iii) the activities for which they have been approved; and

(iv) any restrictions on those activities.

(2) The register referred to in paragraph (1) must be made publicly available.

UK national accreditation body

59.—(1) The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

(a) assessing whether a conformity assessment body meets the approved body requirements; and

(b) monitoring approved bodies in accordance with regulation 56;

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

F12 Words in Sch. 27 para. 38 substituted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/852), regs. 2(2), 4(2), **Sch. 1 para. 1(p)(iii)**

F13 Words in Sch. 27 para. 38 substituted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/852), regs. 2(2), 4(2), **Sch. 1 para. 1(p)(iv)**

Commencement Information

I39 Sch. 27 para. 38 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 63

39. In regulation 63 (regulated measuring instruments presenting a risk)—

(a) in paragraph (5) for "notified", substitute " approved ";

(b) omit paragraph (6);

(c) in paragraph (7) for "on the market throughout the European Economic Area", substitute " in the United Kingdom ";

[[F14](d) omit paragraph (9);**]**

[[F15](e) omit paragraph (10).**]**

F14 Sch. 27 para. 39(d) substituted (31.12.2020) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(4), **15(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F15 Sch. 27 para. 39(e) substituted (31.12.2020) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(4), **15(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I40 Sch. 27 para. 39 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 64

40. Omit regulation 64 (EU safeguard procedure).

Commencement Information

I41 Sch. 27 para. 40 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 65

41. In regulation 65 (compliant regulated measuring instruments which present a risk) omit paragraph (3).

Commencement Information

I42 Sch. 27 para. 41 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 68

42. In regulation 68 (compliance notice procedure), in paragraph (1)—

(a) in sub-paragraphs (a) and (b) for "CE" substitute " UK " in each place in which it occurs;

(b) in sub-paragraph (a) for "Article 30 of the RAMS regulation or the requirements of these Regulations" substitute " regulation 51 or regulation 52 ";

(c) in sub-paragraph (c) for "notified" substitute " approved " in each place in which it occurs; and

(d) in sub-paragraph (d) omit "EU".

Commencement Information

I43 Sch. 27 para. 42 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 69

43. In regulation 69 (enforcement notices)—

(a) in paragraph (5)—

(i) for "a United Kingdom notified" substitute " an approved ";

(ii) for "that notified" substitute " that approved "; and

(b) omit paragraph (6).

Commencement Information

I44 Sch. 27 para. 43 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 72

44. In regulation 72 (disqualification)—

(a) in paragraph (2)—

(i) in sub-paragraph (a) for "CE", substitute " UK ";

(ii) in sub-paragraph (c) for "notified", substitute " approved "; and

(b) in paragraph 3(b) omit "EU-" in each place it occurs.

Commencement Information

I45 Sch. 27 para. 44 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 73

45. In regulation 73 (requalification) in paragraph 3(b), omit "EU-" in each place it occurs.

Commencement Information

I46 Sch. 27 para. 45 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 75

46. In regulation 75 (unauthorised application of authorised marks), paragraph (5)—

(a) in sub-paragraph (a) for "CE" substitute " UK "; and

(b) in sub-paragraph (c) for "notified" substitute " approved ".

Commencement Information

I47 Sch. 27 para. 46 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 81

47. In regulation 81 (review) omit paragraph (2).

Commencement Information

I48 Sch. 27 para. 47 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to Schedule 1

48. Omit Schedule 1 (essential requirements and applicable conformity assessment procedures).

Commencement Information

I49 Sch. 27 para. 48 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of Schedules

49. Before Schedule 2 insert—

"SCHEDULE 1A Regulation 2

ESSENTIAL REQUIREMENTS (Annex I to the Directive)

A regulated measuring instrument shall provide a high level of metrological protection in order that any party affected can have confidence in the result of measurement, and shall be designed and manufactured to a high level of quality in respect of the measurement technology and security of the measurement data.

The essential requirements that shall be met by regulated measuring instruments are set out below and are supplemented, where appropriate, by instrument-specific requirements in Schedules 1C to 1J that provide more detail on certain aspects of the general requirements.

The solutions adopted in the pursuit of the essential requirements shall take account of the intended use of the instrument and any foreseeable misuse thereof.

DEFINITIONS

Measurand	The measurand is the particular quantity subject to measurement
Influence quantity	An influence quantity is a quantity that is not the measurand but that affects the result of measurement.
Rated Operating Conditions	The rated operating conditions are the values for the measurand and influence quantities making up the normal working conditions of an instrument.
Disturbance	An influence quantity having a value within the limits specified in the appropriate requirement but outside the specified rated operating conditions of the regulated measuring instrument. An influence quantity is a disturbance if for that influence quantity the rated operating conditions are not specified.
Critical change value	The critical change value is the value at which the change in the measurement result is considered undesirable.
Material Measure	A material measure is a device intended to reproduce or supply in a permanent manner during its use one or more known values of a given quantity.
Direct sales	A trading transaction is direct sales if: — the measurement result serves as the basis for the price to pay; and — at least one of the parties involved in the transaction related to measurement is a consumer or any other party requiring a similar level of protection; and — all the parties in the transaction accept the measurement result at that time and place.
Climatic environments	Climatic environments are the conditions in which regulated measuring instruments may be used. To cope with climatic differences, a range of temperature limits has been defined.
Utility	A utility is regarded as a supplier of electricity, gas or water.

ESSENTIAL REQUIREMENTS

Allowable Errors

1

1.1. Under rated operating conditions and in the absence of a disturbance, the error of measurement shall not exceed the maximum permissible error (MPE) value as laid down in the appropriate instrument-specific requirements.

Unless stated otherwise in the instrument-specific Schedules, MPE is expressed as a bilateral value of the deviation from the true measurement value.

1.2. Under rated operating conditions and in the presence of a disturbance, the performance requirement shall be as laid down in the appropriate instrument-specific requirements.

Where the instrument is intended to be used in a specified permanent continuous electromagnetic field the permitted performance during the radiated electromagnetic field-amplitude modulated test shall be within MPE.

1.3. The manufacturer shall specify the climatic, mechanical and electromagnetic environments in which the instrument is intended to be used, power supply and other influence quantities likely to affect its accuracy, taking account of the requirements laid down in the appropriate instrument-specific Schedules.

1.3.1 Climatic environments

The manufacturer shall specify the upper temperature limit and the lower temperature limit from any of the values in Table 1 unless otherwise specified in Schedules 1C to 1J and indicate whether the instrument is designed for condensing or non-condensing humidity as well as the intended location for the instrument, i.e. open or closed.

Table 1

	Temperature Limits			
Upper temperature limit	30 °C	40 °C	55 °C	70 °C
Lower temperature limit	5 °C	-10 °C	-25 °C	-40 °C

1.3.2 (a) Mechanical environments are classified into classes M1 to M3 as described below.

M1	This class applies to instruments used in locations with vibration and shocks of low significance, e.g. for instruments fastened to light supporting structures subject to negligible vibrations and shocks transmitted from local blasting or pile-driving activities, slamming doors, etc.
M2	This class applies to instruments used in locations with significant or high levels of vibration and shock, e.g. transmitted from machines and passing vehicles in the vicinity or adjacent to heavy machines, conveyor belts, etc.
M3	This class applies to instruments used in locations where the level of vibration and shock is high and very high, e.g. for instruments mounted directly on machines, conveyor belts, etc.

(b) The following influence quantities shall be considered in relation with mechanical environments:

— vibration

— mechanical shock

1.3.3. (a) Electromagnetic environments are classified into classes E1, E2 or E3 as described below, unless otherwise laid down in the appropriate instrument-specific Schedules.

E1	This class applies to instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in residential, commercial and light industrial buildings.
E2	This class applies to instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in other industrial buildings.
E3	This class applies to instruments supplied by the battery of a vehicle. Such instruments shall comply with the requirements of E2 and the following additional requirements: — voltage reductions caused by energising the starter-motor circuits of internal combustion engines, — load dump transients occurring in the event of a discharged battery being disconnected while the engine is running.

(b) The following influence quantities shall be considered in relation with electromagnetic environments:

— voltage interruptions;

— short voltage reductions;

— voltage transients on supply lines and/or signal lines;

— electrostatic discharges;

— radio frequency electromagnetic fields;

— conducted radio frequency electromagnetic fields on supply lines and/or signal lines;

— surges on supply lines and/or signal lines.

1.3.4. Other influence quantities to be considered, where appropriate, are:

— voltage variation;

— mains frequency variation;

— power frequency magnetic fields;

— any other quantity likely to influence in a significant way the accuracy of the instrument.

1.4. When carrying out the tests as envisaged in these Regulations, the following points shall apply:

1.4.1 Basic rules for testing and the determination of errors

Essential requirements specified in paragraphs 1.1 and 1.2 shall be verified for each relevant influence quantity. Unless otherwise specified in the appropriate instrument-specific Schedule, these essential requirements apply when each influence quantity is applied and its effect evaluated separately, all other influence quantities being kept relatively constant at their reference value.

Metrological tests shall be carried out during or after the application of the influence quantity, whichever condition corresponds to the normal operational status of the instrument when that influence quantity is likely to occur.

1.4.2 Ambient humidity

(a) According to the climatic operating environment in which the instrument is intended to be used either the damp heat-steady state (non-condensing) or damp heat cyclic (condensing) test may be appropriate.

(b) The damp heat cyclic test is appropriate where condensation is important or when penetration of vapour will be accelerated by the effect of breathing. In conditions where non-condensing humidity is a factor the damp-heat steady state is appropriate.

Reproducibility

2. The application of the same measurand in a different location or by a different user, all other conditions being the same, shall result in the close agreement of successive measurements. The difference between the measurement results shall be small when compared with the MPE.

Repeatability

3. The application of the same measurand under the same conditions of measurement shall result in the close agreement of successive measurements. The difference between the measurement results shall be small when compared with the MPE.

Discrimination and Sensitivity

4. A regulated measuring instrument shall be sufficiently sensitive and the discrimination threshold shall be sufficiently low for the intended measurement task.

Durability

5. A regulated measuring instrument shall be designed to maintain an adequate stability of its metrological characteristics over a period of time estimated by the manufacturer, provided that it is properly installed, maintained and used according to the manufacturer's instruction when in the environmental conditions for which it is intended.

Reliability

6. A regulated measuring instrument shall be designed to reduce as far as possible the effect of a defect that would lead to an inaccurate measurement result, unless the presence of such a defect is obvious.

Suitability

7

7.1. A regulated measuring instrument shall have no feature likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal.

7.2. A regulated measuring instrument shall be suitable for its intended use taking account of the practical working conditions and shall not require unreasonable demands of the user in order to obtain a correct measurement result.

7.3. The errors of a utility measuring instrument at flows or currents outside the controlled range shall not be unduly biased.

7.4. Where a regulated measuring instrument is designed for the measurement of values of the measurand that are constant over time, the regulated measuring instrument shall be insensitive to small fluctuations of the value of the measurand, or shall take appropriate action.

7.5. A regulated measuring instrument shall be robust and its materials of construction shall be suitable for the conditions in which it is intended to be used.

7.6. A regulated measuring instrument shall be designed so as to allow the control of the measuring tasks after the instrument has been placed on the market and put into use. If necessary, special equipment or software for this control shall be part of the instrument. The test procedure shall be described in the operation manual.

When a regulated measuring instrument has associated software which provides other functions besides the measuring function, the software that is critical for the metrological characteristics shall be identifiable and shall not be inadmissibly influenced by the associated software.

Protection against corruption

8

8.1. The metrological characteristics of a regulated measuring instrument shall not be influenced in any inadmissible way by the connection to it of another device, by any feature of the connected device itself or by any remote device that communicates with the regulated measuring instrument.

8.2. A hardware component that is critical for metrological characteristics shall be designed so that it can be secured. Security measures foreseen shall provide for evidence of an intervention.

8.3. Software that is critical for metrological characteristics shall be identified as such and shall be secured.

Software identification shall be easily provided by the regulated measuring instrument.

Evidence of an intervention shall be available for a reasonable period of time.

8.4. Measurement data, software that is critical for measurement characteristics and metrologically important parameters stored or transmitted shall be adequately protected against accidental or intentional corruption.

8.5. For utility measuring instruments the display of the total quantity supplied or the displays from which the total quantity supplied can be derived, whole or partial reference to which is the basis for payment, shall not be able to be reset during use.

Information to be borne by and to accompany the instrument

9

9.1. A regulated measuring instrument shall bear the following inscriptions:

(a) manufacturer's name, registered trade name or registered trade mark;

(b) information in respect of its accuracy; and, where applicable:

(c) information in respect of the conditions of use;

(d) measuring capacity;

(e) measuring range;

(f) identity marking;

(g) number of the type examination certificate or the design examination certificate;

(h) information whether or not additional devices providing metrological results comply with the provisions of these Regulations on legal metrological control.

9.2. An instrument of dimensions too small or of too sensitive a composition to allow it to bear the relevant information shall have its packaging, if any, and the accompanying documents required by the provisions of these Regulations suitably marked.

9.3. The instrument shall be accompanied by information on its operation, unless the simplicity of the regulated measuring instrument makes this unnecessary. Information shall be easily understandable and shall include where relevant:

(a) rated operating conditions;

(b) mechanical and electromagnetic environment classes;

(c) the upper and lower temperature limit, whether condensation is possible or not, open or closed location;

(d) instructions for installation, maintenance, repairs, permissible adjustments;

(e) instructions for correct operation and any special conditions of use;

(f) conditions for compatibility with interfaces or regulated measuring instruments.

9.4. Groups of identical regulated measuring instruments used in the same location or used for utility measurements do not necessarily require individual instruction manuals.

9.5. Unless specified otherwise in an instrument-specific Schedule, the scale interval for a measured value shall be in the form 1×10^n, 2×10^n, or 5×10^n, where n is any integer or zero. The unit of measurement or its symbol shall be shown close to the numerical value.

9.6. A material measure shall be marked with a nominal value or a scale, accompanied by the unit of measurement used.

9.7. The units of measurement used and their symbols shall be in accordance with the relevant enactments on units of measurement and their symbols.

9.8. All marks and inscriptions required under any requirement shall be clear, non-erasable, unambiguous and non-transferable.

Indication of result

10

10.1. Indication of the result shall be by means of a display or hard copy.

10.2. The indication of any result shall be clear and unambiguous and accompanied by such marks and inscriptions necessary to inform the user of the significance of the result. Easy reading of the presented result shall be permitted under normal conditions of use. Additional indications may be shown provided they cannot be confused with the metrologically controlled indications.

10.3. In the case of hard copy the print or record shall also be easily legible and non-erasable.

10.4. A regulated measuring instrument for direct sales trading transactions shall be designed to present the measurement result to both parties in the transaction when installed as intended. When critical in case of direct sales, any ticket provided to the consumer by an ancillary device not complying with the appropriate requirements of these Regulations shall bear appropriate restrictive information.

10.5. Whether or not a regulated measuring instrument intended for utility measurement purposes can be remotely read it shall in any case be fitted with a metrologically controlled display accessible without tools to the consumer. The reading of this display is the measurement result that serves as the basis for the price to pay.

Further processing of data to conclude the trading transaction

11

11.1. A regulated measuring instrument other than a utility measuring instrument shall record by a durable means the measurement result accompanied by information to identify the particular transaction, when:

(a) the measurement is non-repeatable; and

(b) the regulated measuring instrument is normally intended for use in the absence of one of the trading parties.

11.2. Additionally, a durable proof of the measurement result and the information to identify the transaction shall be available on request at the time the measurement is concluded.

Conformity evaluation

12. A regulated measuring instrument shall be designed so as to allow ready evaluation of its conformity with the appropriate requirements of these Regulations.

SCHEDULE 1B Regulations 2, 40(2),47(1)(b) and 52(8)

CONFORMITY ASSESSMENT PROCEDURES (Annex II to the Directive)

MODULE A2:

INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS

1. Internal production control plus supervised instrument checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3, 4, and 5, and ensures and declares on his sole responsibility that the regulated measuring instruments concerned satisfy the requirements of these Regulations that apply to them.

Technical documentation

2. The manufacturer shall establish the technical documentation set out in regulations 44 and 45. 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.

Manufacturing

3. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured instruments with the technical documentation referred to in paragraph 2 and with the requirements of these Regulations that apply to them.

Instrument checks

4. At the choice of the manufacturer, either an accredited in-house body or an approved body, chosen by the manufacturer, shall carry out instrument checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the instrument, taking into account, inter alia, the technological complexity of the instruments and the quantity of production. An adequate sample of the final regulated measuring instruments, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the designated standard, and/or normative document, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instruments with the relevant requirements of these Regulations. In the absence of a relevant designated standard or normative document, the accredited in-house body or approved body concerned shall decide on the appropriate tests to be carried out.

In those cases where a relevant number of instruments in the sample do not conform to an acceptable quality level, the accredited in-house body or approved body shall take appropriate measures.

Where the tests are carried out by an approved body, the manufacturer shall, under the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.

Conformity marking and declaration of conformity

5

5.1. The manufacturer shall affix the UK marking and the M marking set out in these Regulations to each individual instrument that satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity for an instrument model and keep it 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. The declaration of conformity shall identify the instrument for which it was drawn up.

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

A copy of the declaration of conformity shall be supplied with each regulated measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

Authorised representative

6. The manufacturer's obligations set out in paragraph 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility provided that they are specified in the mandate.

MODULE B

TYPE EXAMINATION

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.

2. Type examination may be carried out in either of the following manners:

(a) examination of a specimen, representative of the production envisaged, of the complete regulated measuring instrument (production type),

(b) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in paragraph 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);

(c) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in paragraph 3, without examination of a specimen (design type).

The approved body decides on the appropriate manner and the specimens required.

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 set out in regulations 44 and 45. 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 application shall in addition contain, wherever applicable:

(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, and/or normative documents 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.

4. The approved body shall:

For the instrument:

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

For the specimen(s):

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 and/or normative documents, as well as the elements which have been designed in accordance with other relevant technical specifications;

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 and normative documents, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards, and/or normative documents have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of these Regulations;

4.5. agree with the manufacturer on the location where the examinations and tests will be carried out.

For the other parts of the regulated measuring instrument:

4.6. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the other parts of the regulated measuring instrument.

5. The approved body shall draw up an evaluation report that records the activities undertaken in accordance with paragraph 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.

6. Where the type meets the requirements of these Regulations, 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 regulated measuring instruments with the examined type to be evaluated and to allow for in-service control. In particular, to allow the conformity of manufactured instruments to be evaluated with the examined type regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, content shall include:

— the metrological characteristics of the type of instrument;

— measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);

— information on other elements necessary for the identification of the instruments and to check their visual external conformity to type;

— if appropriate, any specific information necessary to verify the characteristics of manufactured instruments.

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

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.

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.

8. 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.

9. 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.

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.

10. 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.

11. The manufacturer's authorised representative may lodge the application referred to in paragraph 3 and fulfil the obligations set out in paragraphs 8 and 10, provided that they are specified in the mandate.

MODULE D:

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

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 paragraphs 2 and 5, and ensures and declares on his sole responsibility that the regulated measuring 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.

Manufacturing

2. The manufacturer shall operate an approved quality system for production, final product inspection and testing of the regulated measuring instruments concerned as specified in paragraph 3 and shall be subject to surveillance as specified in paragraph 4.

Quality system

3

3.1. The manufacturer shall lodge an application for assessment of his quality system with an approved body of his choice, for the regulated measuring 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 of the approved type and a copy of the type examination certificate.

3.2. The quality system shall ensure that the regulated measuring 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. This 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;

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 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 paragraph 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.

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.

3.5. The manufacturer shall keep the approved body that has approved the quality system informed of any intended change of 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 paragraph 3.2 or whether a re-assessment is necessary.

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

Surveillance under the responsibility of the approved body

4

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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.

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.

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.

Conformity marking and declaration of conformity

5

5.1. The manufacturer shall affix the UK marking and the M marking set out in these Regulations and, under the responsibility of the approved body referred to in paragraph 3.1, the latter's identification number to each individual regulated measuring instrument that is in conformity with the type described in the type examination certificate and satisfies the applicable requirements of these Regulations.

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.

A copy of the declaration of conformity shall be supplied with each regulated measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

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 paragraph 3.1,

(b) the information relating to the change referred to in paragraph 3.5, as approved;

(c) the decisions and reports from the approved body referred to in paragraphs 3.5, 4.3 and 4.4.

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.

Authorised representative

8. The manufacturer's obligations set out in paragraphs 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE D1:

QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 4 and 7, and ensures and declares on his sole responsibility that the regulated measuring instruments concerned satisfy the requirements of these Regulations that apply to them.

Technical documentation

2. The manufacturer shall establish the technical documentation set out in regulations 44 and 45. 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.

3. 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.

Manufacturing

4. The manufacturer shall operate an approved quality system for production, final product inspection and testing of the regulated measuring instruments concerned as specified in paragraph 5 and shall be subject to surveillance as specified in paragraph 6.

Quality system

5

5.1. The manufacturer shall lodge an application for assessment of his quality system with an approved body of his choice, for the measuring 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 paragraph 2.

5.2. The quality system shall ensure compliance of the regulated measuring 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. This 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;

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

5.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 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 paragraph 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.

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.

5.5. The manufacturer shall keep the approved body that has approved the quality system informed of any intended change of 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 paragraph 5.2 or whether a re-assessment is necessary.

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

Surveillance under the responsibility of the approved body

6

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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 paragraph 2;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

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.

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 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.

Conformity marking and declaration of conformity

7

7.1. The manufacturer shall affix the UK marking, the M marking set out in these Regulations, and, under the responsibility of the approved body referred to in paragraph 5.1, the latter's identification number to each individual regulated measuring instrument that satisfies the applicable requirements of these Regulations.

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.

A copy of the declaration of conformity shall be supplied with each regulated measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

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 paragraph 5.1;

(b) the information relating to the change referred to in paragraph 5.5, as approved;

(c) the decisions and reports of the approved body referred to in paragraphs 5.5, 6.3 and 6.4.

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.

Authorised representative

10. The manufacturer's obligations set out in paragraphs 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE E:

CONFORMITY TO TYPE BASED ON INSTRUMENT QUALITY ASSURANCE

1. Conformity to type based on instrument quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 and 5, and ensures and declares on his sole responsibility that the regulated measuring 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.

Manufacturing

2. The manufacturer shall operate an approved quality system for final product inspection and testing of the regulated measuring instruments concerned as specified in paragraph 3 and shall be subject to surveillance, as specified in paragraph 4.

Quality system

3

3.1. The manufacturer shall lodge an application for assessment of his quality system with an approved body of his choice, for the regulated measuring 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 of the approved type and a copy of the type examination certificate.

3.2. The quality system shall ensure compliance of the regulated measuring instruments with the type described in the type examination certificate and with the applicable requirements of these Regulations.

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. This 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 examinations and tests that will be carried out after manufacture;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(d) the means of monitoring the effective operation of the quality system.

3.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 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 paragraph 3.1(e), 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 audit and the reasoned assessment decision.

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.

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 paragraph 3.2 or whether a re-assessment is necessary.

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

Surveillance under the responsibility of the approved body

4

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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.

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.

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.

Conformity marking and declaration of conformity

5

5.1. The manufacturer shall affix the UK marking, the M marking set out in these Regulations, and, under the responsibility of the approved body referred to in paragraph 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.

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.

A copy of the declaration of conformity shall be supplied with each regulated measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

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 paragraph 3.1;

(c) the information relating to the change referred to in paragraph 3.5, as approved;

(c) the decisions and reports of the approved body referred to in paragraphs 3.5, 4.3 and 4.4.

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.

Authorised representative

8. The manufacturer's obligations set out in paragraphs 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE E1:

QUALITY ASSURANCE OF FINAL INSTRUMENT INSPECTION AND TESTING

1. Quality assurance of final instrument inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 4 and 7, and ensures and declares on his sole responsibility that the regulated measuring instruments concerned satisfy the requirements of these Regulations that apply to them.

Technical documentation

2. The manufacturer shall establish the technical documentation set out in regulations 44 and 45. 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.

3. 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.

Manufacturing

4. The manufacturer shall operate an approved quality system for final product inspection and testing of the regulated measuring instruments concerned as specified in paragraph 5 and shall be subject to surveillance as specified in paragraph 6.

Quality system

5

5.1. The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice, for the regulated measuring 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 paragraph 2.

5.2. The quality system shall ensure compliance of the regulated measuring 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 examinations and tests that will be carried out after manufacture;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(d) the means of monitoring the effective operation of the quality system.

5.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 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 paragraph 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.

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.

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 paragraph 5.2 or whether a re-assessment is necessary.

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

Surveillance under the responsibility of the approved body

6

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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 paragraph 2;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

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.

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 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.

Conformity marking and declaration of conformity

7

7.1. The manufacturer shall affix the UK marking, the M marking set out in these Regulations, and, under the responsibility of the approved body referred to in paragraph 5.1, the latter's identification number to each individual regulated measuring instrument that satisfies the applicable requirements of these Regulations.

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.

A copy of the declaration of conformity shall be supplied with each regulated measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

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 paragraph 5.1,

(b) the information relating to the change referred to in paragraph 5.5, as approved;

(c) the decisions and reports from the approved body referred to in paragraphs 5.5, 6.3 and 6.4.

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.

Authorised representative

10. The manufacturer's obligations set out in paragraphs 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE F:

CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

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 paragraphs 2, 5.1 and 6, and ensures and declares on his sole responsibility that the regulated measuring instruments concerned, which have been subject to the provisions of paragraph 3, are in conformity with the type described in the type examination certificate and satisfy the requirements of these Regulations that apply to them.

Manufacturing

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

Verification

3. An approved body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to verify the conformity of the instruments with the type as described in the type examination certificate and the appropriate requirements of these Regulations.

The examinations and tests to verify the conformity of the regulated measuring instruments with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in paragraph 4, or by examination and testing of the regulated measuring instruments on a statistical basis as specified in paragraph 5.

4. Verification of conformity by examination and testing of every instrument

4.1. All regulated measuring instruments shall be individually examined and appropriate tests set out in the relevant designated standard(s) and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the type examination certificate and with the appropriate requirements of these Regulations.

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

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.

Statistical verification of conformity

5

5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his regulated measuring instruments for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot according to the requirements of paragraph 5.3. All regulated measuring instruments in a sample shall be individually examined and appropriate tests set out in the relevant designated standard(s) and/or normative document(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the type described in the type examination certificate and with the applicable requirements of these Regulations, and to determine whether the lot is accepted or rejected. In the absence of such designated standard or normative document, the approved body concerned shall decide on the appropriate tests to be carried out.

5.3. The statistical procedure shall meet the following requirements:

The statistical control will be based on attributes. The sampling system shall ensure:

(a) a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;

(b) a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity of less than 7 %.

5.4. If a lot is accepted, all regulated measuring instruments of the lot shall be considered approved, except for those regulated measuring instruments from the sample that have been found not to satisfy the tests.

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.

5.5. If a lot is rejected, the approved body shall take appropriate measures to prevent the placing on the market of that lot. In the event of frequent rejection of lots the approved body may suspend the statistical verification and take appropriate measures.

Conformity marking and declaration of conformity

6

6.1. The manufacturer shall affix the UK marking and the M marking set out in these Regulations, and, under the responsibility of the approved body referred to in paragraph 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.

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 market surveillance authorities upon request.

A copy of the declaration of conformity shall be supplied with each regulated measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

If the approved body referred to in paragraph 3 agrees and under its responsibility, the manufacturer may also affix the approved body's identification number to the regulated measuring instruments.

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

Authorised representative

8. 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 paragraphs 2 and 5.1.

MODULE F1:

CONFORMITY BASED ON PRODUCT VERIFICATION

1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3, 6.1 and 7 and ensures and declares on his sole responsibility that the regulated measuring instruments concerned which have been subject to the provisions of paragraph 4, are in conformity with the requirements of these Regulations that apply to them.

Technical documentation

2. The manufacturer shall establish the technical documentation set out in regulations 44 and 45. 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 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.

Manufacturing

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

Verification

4. An approved body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to verify the conformity of the regulated measuring instruments with the applicable requirements of these Regulations.

The examinations and tests to verify the conformity with the requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in paragraph 5, or by examination and testing of the regulated measuring instruments on a statistical basis as specified in paragraph 6.

Verification of conformity by examination and testing of every instrument

5

5.1. All regulated measuring instruments shall be individually examined and appropriate tests, set out in the relevant designated standards and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify their conformity with the requirements that apply to them. In the absence of such a designated standard, or normative document, the approved body concerned shall decide on the appropriate tests to be carried out.

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.

Statistical verification of conformity

6

6.1. The manufacturer shall take all measures necessary so that the manufacturing process ensures the homogeneity of each lot produced, and shall present his regulated measuring instruments for verification in the form of homogeneous lots.

6.2. A random sample shall be taken from each lot according to the requirements of paragraph 6.4.

6.3. All regulated measuring instruments in the sample shall be individually examined and appropriate tests set out in the relevant designated standards and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of these Regulations and to determine whether the lot is accepted or rejected. In the absence of such designated standard, or normative document, the approved body concerned shall decide on the appropriate tests to be carried out.

6.4. The statistical procedure shall meet the following requirements:

The statistical control will be based on attributes. The sampling system shall ensure:

(a) a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;

(b) a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity of less than 7 %.

6.5. If a lot is accepted, all regulated measuring instruments of the lot shall be considered approved, except for those regulated measuring instruments from the sample that have been found not to satisfy the tests.

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.

If a lot is rejected, the approved body shall take appropriate measures to prevent that lot from being placed on the market. In the event of frequent rejection of lots the approved body may suspend the statistical verification and take appropriate measures.

Conformity marking and declaration of conformity

7

7.1. The manufacturer shall affix the UK marking and the M marking set out in these Regulations, and under the responsibility of the approved body referred to in paragraph 4, the latter's identification number to each individual regulated measuring instrument that satisfies the applicable requirements of these Regulations.

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.

A copy of the declaration of conformity shall be supplied with each regulated measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual regulated measuring instruments in those cases where a large number of instruments is delivered to a single user.

If the approved body referred to in paragraph 5 agrees and under its responsibility, the manufacturer may also affix the approved body's identification number to the regulated measuring instruments.

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

9. 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 the first paragraph of paragraph 2, paragraph 3 and paragraph 6.1.

MODULE G

CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3 and 5 and ensures and declares on his sole responsibility that the instrument concerned, which has been subject to the provisions of paragraph 4, is in conformity with the requirements of these Regulations that apply to it.

Technical documentation

2. The manufacturer shall establish the technical documentation and make it available to the approved body referred to in paragraph 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 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.

Manufacturing

3. 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.

Verification

4. An approved body chosen by the manufacturer shall carry out the appropriate examinations and tests set out in the relevant designated standards, and/or normative documents, or equivalent tests set out in other relevant technical specifications, to verify 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, or normative document, 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 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.

Conformity marking and declaration of conformity

5

5.1. The manufacturer shall affix the UK marking and the M marking set out in these Regulations and, under the responsibility of the approved body referred to in paragraph 4, the latter's identification number to each instrument that satisfies the applicable requirements of these Regulations.

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.

A copy of the declaration of conformity shall be supplied with the regulated measuring instrument.

Authorised representative

6. The manufacturer's obligations set out in paragraphs 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE H:

CONFORMITY BASED ON FULL QUALITY ASSURANCE

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 and 5, and ensures and declares on his sole responsibility that the regulated measuring instruments concerned satisfy the requirements of these Regulations that apply to them.

Manufacturing

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the regulated measuring instruments concerned as specified in paragraph 3, and shall be subject to surveillance as specified in paragraph 4.

Quality system

3

3.1. The manufacturer shall lodge an application for assessment of his quality system with the approved body of his choice, for the regulated measuring 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) the technical documentation for one model of each category of regulated measuring instruments intended to be manufactured. 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,

(c) the documentation concerning the quality system, and

(d) a written declaration that the same application has not been lodged with any other approved body.

3.2. The quality system shall ensure compliance of the regulated measuring 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. This 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 design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant designated standards, and/or normative documents will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations that apply to the regulated measuring instruments will be met applying other relevant technical specifications;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the regulated measuring instruments pertaining to the instrument category covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 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 experienced as an assessor 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 paragraph 3.1(b) to verify the manufacturer's ability to identify the applicable requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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.

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 paragraph 3.2 or whether a re-assessment is necessary.

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

Surveillance under the responsibility of the approved body

4

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the approved body access to the design, 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 as provided for by the design part of the quality system, such as results of analyses, calculations, tests.;

(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

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.

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 check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Conformity marking and declaration of conformity

5

5.1. The manufacturer shall affix the UK marking, the M marking set out in these Regulations and, under the responsibility of the approved body referred to in paragraph 3.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of these Regulations.

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.

A copy of the declaration of conformity shall be supplied with each regulated measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

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 technical documentation referred to in paragraph 3.1,

(b) the documentation concerning the quality system referred to in paragraph 3.1,

(c) the information relating to the change referred to in paragraph 3.5, as approved;

(d) the decisions and reports of the approved body referred to in paragraphs 3.5, 4.3 and 4.4.

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.

Authorised representative

8. The manufacturer's obligations set out in paragraphs 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE H1:

CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION

1. Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 and 6, and ensures and declares on his sole responsibility that the regulated measuring instruments concerned satisfy the requirements of these Regulations that apply to them.

Manufacturing

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the regulated measuring instruments concerned as specified in paragraph 3, and shall be subject to surveillance as specified in paragraph 5.

The adequacy of the technical design of the regulated measuring instruments shall have been examined in accordance with paragraph 4.

Quality system

3

3.1. The manufacturer shall lodge an application for assessment of the quality system with the approved body of his choice for the regulated measuring 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) all relevant information for the instrument category envisaged;

(c) the documentation concerning the quality system;

(d) a written declaration that the same application has not been lodged with any other approved body.

3.2. The quality system shall ensure compliance of the regulated measuring 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. This 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 design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant designated standards and/or normative documents will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations that apply to the regulated measuring instruments will be met, applying other relevant technical specifications;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the regulated measuring instruments pertaining to the instrument category covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 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 experienced as an assessor 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 manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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.

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 paragraph 3.2 or whether a re-assessment is necessary.

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

3.6. 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.

Design examination

4

4.1. The manufacturer shall lodge an application for examination of the design with the approved body referred to in paragraph 3.1.

4.2. The application shall make it possible to understand the design, manufacture and operation of the instrument, and to assess the conformity with the requirements of these Regulations that apply to it.

It shall include:

(a) the name and address of the manufacturer;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) 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). It shall, as far as relevant for such assessment, cover the design and operation of the instrument;

(d) the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant designated standards and/or normative documents have not been applied in full, and 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.

4.3. The approved body shall examine the application, and where the design meets the requirements of these Regulations that apply to the instrument it shall issue a design examination certificate to the manufacturer. That certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. That certificate may have one or more annexes attached.

That certificate and its annexes shall contain all relevant information to allow the conformity of manufactured regulated measuring instruments with the examined design to be evaluated and to allow for in-service control. It shall allow the evaluation of conformity of the manufactured instruments with the examined design regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, including:

(a) the metrological characteristics of the design of the instrument;

(b) measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);

(c) information on other elements necessary for the identification of the instrument and to check its visual external conformity to the design;

(d) if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;

(e) in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or regulated measuring instruments.

The approved body shall establish an evaluation report in this regard and keep it at the disposal of the Secretary of State. Without prejudice to paragraph 9 of Schedule 5, the approved body shall release the content of this report, in full or in part, only with the agreement of the manufacturer.

The certificate shall have a validity of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

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

4.4. The approved body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design 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 keep the approved body that has issued the design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of these Regulations or the conditions for validity of the certificate. Such modifications shall require additional approval – from the approved body that issued the design examination certificate – in the form of an addition to the original design examination certificate.

4.5. Each approved body shall inform the Secretary of State of the design 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 certificates and/or any additions thereto refused, suspended or otherwise restricted.

The other approved bodies and the Secretary of State may, on request, obtain a copy of the design examination certificates and/or additions thereto. On request, the Secretary of State may obtain a copy of the technical documentation and of the results of the examinations carried out by the approved body.

The approved body shall keep a copy of the design 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 the certificate.

4.6. The manufacturer shall keep a copy of the design examination certificate, its annexes and additions with the technical documentation at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market.

Surveillance under the responsibility of the approved body

5

5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

5.2. The manufacturer shall, for assessment purposes, allow the approved body access to the design, 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 as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;

(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

5.3. 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.

5.4. 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 check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Conformity marking and declaration of conformity

6

6.1. The manufacturer shall affix the UK marking and the M marking set out in these Regulations, and, under the responsibility of the approved body referred to in paragraph 3.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of these Regulations.

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 and shall mention the number of the design examination certificate.

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

A copy of the declaration of conformity shall be supplied with each regulated measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

7. 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 concerning the quality system referred to in paragraph 3.1,

(b) the information relating to the change referred to in paragraph 3.5, as approved;

(c) the decisions and reports of the approved body referred to in paragraphs 3.5, 5.3 and 5.4.

Authorised representative

8. The manufacturer's authorised representative may lodge the application referred to in paragraphs 4.1 and 4.2 and fulfil the obligations set out in paragraphs 3.1, 3.5, 4.4, 4.6, 6 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.

SCHEDULE 1C

Regulations 2 and 39(1)

WATER METERS (MI-001) (Annex III to the Directive)

The relevant requirements of Schedule 1A, the specific requirements of this Schedule and the conformity assessment procedures listed in this Schedule, apply to water meters intended for the measurement of volumes of clean, cold or heated water in residential, commercial and light industrial use.

DEFINITIONS

Minimum Flowrate (Q_1)	The lowest flowrate at which the water meter provides indications that satisfy the requirements concerning the maximum permissible errors (MPEs.)
Transitional Flowrate (Q_2)	The transitional flowrate is the flowrate value occurring between the permanent and minimum flowrates, at which the flowrate range is divided into two zones, the ‘upper zone’ and the ‘lower zone’. Each zone has a characteristic MPE.
Permanent Flowrate (Q_3)	The highest flowrate at which the water meter operates in a satisfactory manner under normal conditions of use, i.e. under steady or intermittent flow conditions.
Overload Flowrate (Q_4)	The overload flowrate is the highest flowrate at which the meter operates in a satisfactory manner for a short period of time without deteriorating.

SPECIFIC REQUIREMENTS

Rated Operating Conditions

The manufacturer shall specify the rated operating conditions for the instrument, in particular:

1. The flowrate range of the water.

The values for the flowrate range shall fulfil the following conditions:

$Q_3/Q_1 \geq 40$

$Q_2/Q_1 = 1.6$

$Q_4/Q_3 = 1.25$

2. The temperature range of the water.

The values for the temperature range shall fulfil the following conditions:
0.1 °C to at least 30 °C

3. The relative pressure range of the water, the range being 0.3 bar to at least 10 bar at Q_3.

4. For the power supply: the nominal value of the AC voltage supply and/or the limits of DC supply.

MPE

5. The MPE, positive or negative, on volumes delivered at flowrates between the transitional flowrate (Q_2) (included) and the overload flowrate (Q_4) is:
2 % for water having a temperature ≤ 30 °C,

The meter shall not exploit the MPE or systematically favour any party.

6. The MPE, positive or negative, on volumes delivered at flowrates between the minimum flowrate (Q_1) and the transitional flowrate (Q_2) (excluded) is 5 % for water having any temperature.

The meter shall not exploit the MPE or systematically favour any party.

Permissible Effect of Disturbances

Electromagnetic immunity

7

7.1.1. The effect of an electromagnetic disturbance on a water meter shall be such that:

— the change in the measurement result is no greater than the critical change value as defined in paragraph 7.1.3, or

— the indication of the measurement result is such that it cannot be interpreted as a valid result, such as a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result.

7.1.2. After undergoing an electromagnetic disturbance the water meter shall:

— recover to operate within MPE, and

— have all measurement functions safeguarded, and

— allow recovery of all measurement data present just before the disturbance.

7.1.3. The critical change value is the smaller of the two following values:

— the volume corresponding to half of the magnitude of the MPE in the upper zone on the measured volume;

— the volume corresponding to the MPE on the volume corresponding to one minute at flowrate Q_3.

Durability

7.2. After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:

7.2.1. The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed:

— 3 % of the metered volume between Q_1 included and Q_2 excluded;

— 1.5 % of the metered volume between Q_2 included and Q_4 included.

7.2.2. The error of indication for the volume metered after the durability test shall not exceed:

— ± 6 % of the metered volume between Q_1 included and Q_2 excluded;

— ± 2.5 % of the metered volume between Q_2 included and Q_4 included for water meters intended to meter water with a temperature between 0.1 °C and 30 °C,

Suitability

8.1. The meter shall be able to be installed to operate in any position unless clearly marked otherwise.

8.2. The manufacturer shall specify whether the meter is designed to measure reverse flow. In such a case, the reverse flow volume shall either be subtracted from the cumulated volume or shall be separately recorded. The same MPE shall apply to both forward and reverse flow.

Water meters not designed to measure reverse flow shall either prevent reverse flow or shall withstand an accidental reverse flow without any deterioration or change in metrological properties.

Units of Measurement

9. Metered volume shall be displayed in cubic metres.

Putting into Use

10. The requirements under paragraphs 1, 2 and 3 are determined by the utility or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

CONFORMITY ASSESSMENT The conformity assessment procedures specified in the modules in Schedule 1B applicable to water meters that the manufacturer can choose between are:

(a) B and F;

(b) B and D; or

(c) H1.

SCHEDULE 1D

Regulations 2 and 39(1)

GAS METERS (MI-002) (Annex IV to the Directive)

The relevant requirements of Schedule 1A, the specific requirements of this Schedule and the conformity assessment procedures listed in this Schedule, apply to gas meters.

DEFINITIONS

Minimum flowrate (Q_{min})	The lowest flowrate at which the gas meter provides indications that satisfy the requirements regarding maximum permissible error (MPE).
Maximum flowrate (Q_{max})	The highest flowrate at which the gas meter provides indications that satisfy the requirements regarding MPE.
Transitional flowrate (Q_t)	The transitional flowrate is the flowrate occurring between the maximum and minimum flowrates at which the flowrate range is divided into two zones, the 'upper zone' and the 'lower zone'. Each zone has a characteristic MPE.
Overload Flowrate (Q_r)	The overload flowrate is the highest flowrate at which the meter operates for a short period of time without deteriorating.
Base conditions	The specified conditions to which the measured quantity of fluid is converted.

PART I

SPECIFIC REQUIREMENTS

GAS METERS

1. Rated operating conditions

The manufacturer shall specify the rated operating conditions of the gas meter, taking into account:

1.1. The flowrate range of the gas shall fulfil at least the following conditions:

Class	*Qmax/Qmin*	*Qmax/Qt*	*Qr/Qmax*
1.5	≥ 150	≥ 10	1.2
1.0	≥ 20	≥ 5	1.2

1.2. The temperature range of the gas, with a minimum range of 40 °C.

The fuel/gas related conditions

1.3. The gas meter shall be designed for the range of gases and supply pressures of the United Kingdom. In particular the manufacturer shall indicate:

— the gas family or group;

— the maximum operating pressure.

1.4. A minimum temperature range of 50 °C for the climatic environment.

1.5. The nominal value of the AC voltage supply and/or the limits of DC supply.

Maximum permissible error (MPEs)

2

Gas meter indicating the volume at metering conditions or mass

Table 1

Class	1.5	1.0
$Q_{min} \leq Q < Q_t$	3 %	2 %
$Q_t \leq Q \leq Q_{max}$	1.5 %	1 %

The gas meter shall not exploit the MPEs or systematically favour any party.

2.2. For a gas meter with temperature conversion, which only indicates the converted volume, the MPE of the meter is increased by 0.5 % in a range of 30 °C extending symmetrically around the temperature specified by the manufacturer that lies between 15 °C and 25 °C. Outside this range, an additional increase of 0.5 % is permitted in each interval of 10 °C.

Permissible effect of disturbances

3

Electromagnetic immunity

3

3.1.1. The effect of an electromagnetic disturbance on a gas meter shall be such that:

— the change in the measurement result is no greater than the critical change value as defined in paragraph 3.1.3, or

— the indication of the measurement result is such that it cannot be interpreted as a valid result, such as a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result.

3.1.2. After undergoing a disturbance, the gas meter shall:

— recover to operate within MPE, and

— have all measurement functions safeguarded, and

— allow recovery of all measurement data present just before the disturbance.

3.1.3. The critical change value is the smaller of the two following values:

— the quantity corresponding to half of the magnitude of the MPE in the upper zone on the measured volume;

— the quantity corresponding to the MPE on the quantity corresponding to one minute at maximum flowrate.

Effect of upstream-downstream flow disturbances

3.2. Under installation conditions specified by the manufacturer, the effect of the flow disturbances shall not exceed one third of the MPE.

Durability

4. After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:

Class 1.5 Gas Meters

4

4.1.1. The variation of the measurement result after the durability test when compared with the initial measurement result for the flow rates in the range Q_t to Q_{max} shall not exceed the measurement result by more than 2 %.

4.1.2. The error of indication after the durability test shall not exceed twice the MPE in paragraph 2.

Class 1.0 Gas Meters

4

4.2.1. The variation of the measurement result after the durability test when compared with the initial measurement result shall not exceed one-third of the MPE in paragraph 2.

4.2.2. The error of indication after the durability test shall not exceed the MPE in paragraph 2.

Suitability

5

5.1. A gas meter powered from the mains (AC or DC) shall be provided with an emergency power supply device or other means to ensure, during a failure of the principal power source, that all measuring functions are safeguarded.

5.2. A dedicated power source shall have a lifetime of at least five years. After 90 % of its lifetime an appropriate warning shall be shown.

5.3. An indicating device shall have a sufficient number of digits to ensure that the quantity passed during 8,000 hours at Q_{max} does not return the digits to their initial values.

5.4. The gas meter shall be able to be installed to operate in any position declared by the manufacturer in its installation instruction.

5.5. The gas meter shall have a test element, which shall enable tests to be carried out in a reasonable time.

5.6. The gas meter shall respect the MPE in any flow direction or only in one flow direction clearly marked.

Units

6. Metered quantity shall be displayed in cubic metre, or in kilogram.

PART II

PUTTING INTO USE AND CONFORMITY ASSESSMENT

7. Putting into use

(a) The measurement of residential use must be performed by means of any Class 1.5 gas meter, or by Class 1.0 gas meters which have a Q_{max}/Q_{min} ratio equal to or greater than 150.

(b) Measurement of commercial and/or light industrial use must be performed by any Class 1.0 or Class 1.5 gas meter.

(c) The person responsible for installing a gas meter must have regard to the requirements under paragraphs 1.2 and 1.3 of Part I of this Schedule and must ensure that the gas meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

CONFORMITY ASSESSMENT The conformity assessment procedures specified in the modules in Schedule 1B applicable to gas meters that the manufacturer can choose between are:

(a) B and F;

(b) B and D; or

(c) H1.

SCHEDULE 1E

Regulations 2 and 39(1)

ACTIVE ELECTRICAL ENERGY METERS (MI-003) (Annex V to the Directive)

The relevant requirements of Schedule 1A, the specific requirements of this Schedule and the conformity assessment procedures listed in this Schedule, apply to active electrical energy meters.

Note:

Electrical energy meters may be used in combination with external instrument transformers, depending upon the measurement technique applied. However, this Schedule covers only electrical energy meters but not instrument transformers.

DEFINITIONS

An active electrical energy meter is a device which measures the active electrical energy consumed in a circuit.

I	=	the electrical current flowing through the meter;
I_n	=	the specified reference current for which the transformer operated meter has been designed;
I_{st}	=	the lowest declared value of I at which the meter registers active electrical energy at unity power factor (polyphase meters with balanced load);
I_{min}	=	the value of I above which the error lies within maximum permissible errors (MPEs) (polyphase meters with balanced load);
I_{tr}	=	the value of I above which the error lies within the smallest MPE corresponding to the class index of the meter;
I_{max}	=	the maximum value of I for which the error lies within the MPEs;

U	=	the voltage of the electricity supplied to the meter;
U_n	=	the specified reference voltage;
f	=	the frequency of the voltage supplied to the meter;
f_n	=	the specified reference frequency;
PF	=	power factor = cosφ = the cosine of the phase difference φ between I and U.

SPECIFIC REQUIREMENTS

Accuracy

1. The manufacturer shall specify the class index of the meter. The class indices are defined as: Class A, B and C.

Rated operating conditions

2. The manufacturer shall specify the rated operating conditions of the meter; in particular:

The values of f_n, U_n, I_n, I_{st}, I_{min}, I_{tr} and I_{max} that apply to the meter. For the current values specified, the meter shall satisfy the conditions given in Table 1;

Table 1

	Class A	***Class B***	***Class C***
For direct-connected meters			
$\mathbf{I_{st}}$	$\leq 0.05 \cdot I_{tr}$	$\leq 0.04 \cdot I_{tr}$	$\leq 0.04 \cdot I_{tr}$
$\mathbf{I_{min}}$	$\leq 0.5 \cdot I_{tr}$	$\leq 0.5 \cdot I_{tr}$	$\leq 0.3 \cdot I_{tr}$
$\mathbf{I_{max}}$	$\geq 50 \cdot I_{tr}$	$\geq 50 \cdot I_{tr}$	$\geq 50 \cdot I_{tr}$
For transformer-operated meters			
$\mathbf{I_{st}}$	$\leq 0.06 \cdot I_{tr}$	$\leq 0.04 \cdot I_{tr}$	$\leq 0.02 \cdot I_{tr}$
$\mathbf{I_{min}}$	$\leq 0.4 \cdot I_{tr}$	$\leq 0.2 \cdot I_{tr}$ [1]	$\leq 0.2 \cdot I_{tr}$
$\mathbf{I_n}$	$= 20 \cdot I_{tr}$	$= 20 \cdot I_{tr}$	$= 20 \cdot I_{tr}$
$\mathbf{I_{max}}$	$\geq 1.2 \cdot I_n$	$\geq 1.2 \cdot I_n$	$\geq 1.2 \cdot I_n$

[1] For Class B electromechanical meters $I_{min} \leq 0.4 \cdot I_{tr}$ shall apply.

The voltage, frequency and power factor ranges within which the meter shall satisfy the MPE requirements are specified in Table 2. These ranges shall recognise the typical characteristics of electricity supplied by public distribution systems.

The voltage and frequency ranges shall be at least:

$0.9 \cdot U_n \leq U \leq 1.1 \cdot U_n$

$0.98 \cdot f_n \leq f \leq 1.02 \cdot f_n$

power factor range at least from cosφ = 0.5 inductive to cosφ = 0.8 capacitive.

MPEs

3. The effects of the various measurands and influence quantities (a, b, c,…) are evaluated separately, all other measurands and influence quantities being kept relatively constant at their reference values. The error of measurement, that shall not exceed the MPE stated in Table 2, is calculated as:

$$\text{Error of measurement} = \sqrt{(a^2 + b^2 + c^2 \ldots)}$$

When the meter is operating under varying-load current, the percentage errors shall not exceed the limits given in Table 2.

Table 2

	Operating temperatures			***Operating temperatures***			***Operating temperatures***			***Operating temperatures***		
MPEs in percent at rated operating conditions and defined load current levels and operating temperature												
	Operating temperatures + 5 °C … + 30 °C			Operating temperatures – 10 °C … + 5 °C or + 30 °C … + 40 °C			Operating temperatures – 25 °C … – 10 °C or + 40 °C … + 55 °C			Operating temperatures – 40 °C … – 25 °C or + 55 °C … + 70 °C		
Meter class	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
Single phase meter; polyphase meter if operating with balanced loads												
$I_{min} \leq I < I_{tr}$	3.5	2	1	5	2.5	1.3	7	3.5	1.7	9	4	2
$I_{tr} \leq I < I_{max}$	3.5	2	0	4.5	2.5	1	7	3.5	1.3	9	4	1.5
Polyphase meter if operating with single phase load												
$I_{tr} \leq I < I_{max}$, see exception below	4	2.5	1	5	3	1.3	7	4	1.7	9	4.5	2
For electromechanical polyphase meters the current range for single-phase load is limited to $5I_{tr} \leq I \leq I_{max}$												

When a meter operates in different temperature ranges the relevant MPE values shall apply.

The meter shall not exploit the MPEs or systematically favour any party.

4. Permissible effect of disturbances

4.1. General

As electrical energy meters are directly connected to the mains supply and as mains current is also one of the measurands, a special electromagnetic environment is used for electricity meters.

The meter shall comply with the electromagnetic environment E2 and the additional requirements in paragraphs 4.2 and 4.3.

The electromagnetic environment and permissible effects reflect the situation that there are disturbances of long duration which shall not affect the accuracy beyond the critical change values and transient disturbances, which may cause a temporary degradation or loss of function or performance but from which the meter shall recover and shall not affect the accuracy beyond the critical change values.

When there is a foreseeable high risk due to lightning or where overhead supply networks are predominant, the metrological characteristics of the meter shall be protected.

Effect of disturbances of long duration

Table 3

Critical change values for disturbances of long duration ***Disturbance***	***Critical change values in percent for meters of class***		
	A	***B***	***C***
Reversed phase sequence	1.5	1.5	0.3
Voltage unbalance (only applicable to polyphase meters)	4	2	1
Harmonic contents in the current circuits	1	0.8	0.5
DC and harmonics in the current circuit	6	3	1.5
Fast transient bursts	6	4	2
Magnetic fields; HF (radiated RF) electromagnetic field; Conducted disturbances introduced by radio-frequency fields; and Oscillatory waves immunity	3	2	1

In the case of electromechanical electricity meters, no critical change values are defined for harmonic contents in the current circuits and for DC and harmonics in the current circuit.

Permissible effect of transient electromagnetic phenomena

4

4.3.1 The effect of an electromagnetic disturbance on an electrical energy meter shall be such that during and immediately after a disturbance:
— any output intended for testing the accuracy of the meter does not produce pulses or signals corresponding to an energy of more than the critical change value,

and in reasonable time after the disturbance the meter shall:

— recover to operate within the MPE limits, and

— have all measurement functions safeguarded, and

— allow recovery of all measurement data present prior to the disturbance, and

— not indicate a change in the registered energy of more than the critical change value.
$m \cdot U_n \cdot I_{max} \cdot 10^{-6}$

(m being the number of measuring elements of the meter, Un in Volts and Imax in Amps).

4.3.2. For overcurrent the critical change value is 1.5 %.

Suitability

5

5.1. Below the rated operating voltage the positive error of the meter shall not exceed 10 %.

5.2. The display of the total energy shall have a sufficient number of digits to ensure that when the meter is operated for 4,000 hours at full load ($I = I_{max}$, $U = U_n$ and PF = 1) the indication does not return to its initial value and shall not be able to be reset during use.

5.3. In the event of loss of electricity in the circuit, the amounts of electrical energy measured shall remain available for reading during a period of at least 4 months.

Running with no load

5.4. When the voltage is applied with no current flowing in the current circuit (current circuit shall be open circuit), the meter shall not register energy at any voltage between $0.8 \cdot U_n$ and $1.1\ U_n$.

Starting

5.5. The meter shall start and continue to register at U_n, PF = 1 (polyphase meter with balanced loads) and a current which is equal to I_{st}.

Units

6. The electrical energy measured shall be displayed in kilowatt-hours or in megawatt-hours.

Putting into use

(a) Subject to sub-paragraph (b), measurement may be performed by means of any active electrical energy meter provided that the temperature range to which an active electrical energy meter is exposed is not wider than the range specified by the manufacturer in relation to that active electrical energy meter in accordance with paragraph 1.3.1 and Table 1 in Schedule 1A to these Regulations.

(b) Class A active electrical energy meters may not be used when operating outside the temperature range of an upper temperature limit of 30°C to a lower temperature limit of 5°C.

(c) The person responsible for installing the active electrical energy meter must determine the correct current range and assess the climatic environment.

CONFORMITY ASSESSMENT The conformity assessment procedures specified in the modules in Schedule 1B applicable to active electrical energy meters that the manufacturer can choose between are:

(a) B and F;

(b) B and D; or

(c) H1.

SCHEDULE 1F

Regulations 2 and 39(1)

MEASURING SYSTEMS FOR THE CONTINUOUS AND DYNAMIC MEASUREMENT OF QUANTITIES OF LIQUIDS OTHER THAN WATER (MI-005) (Annex VII to the Directive)

The relevant essential requirements of Schedule 1A, the specific requirements of this Schedule and the conformity assessment procedures listed in this Schedule, apply to measuring systems intended for the continuous and dynamic measurement of quantities (volumes or masses) of liquids other than water. If appropriate, the terms ‘volume, and L’ in this Schedule can be read as: ‘mass and kg’.

DEFINITIONS

Meter	An instrument designed to measure continuously, memorise and display the quantity at metering conditions of liquid flowing through the measurement transducer in a closed, fully charged conduit.
Calculator	A part of a meter that receives the output signals from the measurement transducer(s) and possibly, from associated regulated measuring instruments and displays the measurement results.
Associated Measuring Instrument	An instrument connected to the calculator for measuring certain quantities which are characteristic of the liquid, with a view to make a correction and/or conversion.
Conversion Device	A part of the calculator which by taking account of the characteristics of the liquid (temperature, density, etc.) measured using associated regulated measuring instruments, or stored in a memory, automatically converts: — the volume of the liquid measured at metering conditions into a volume at base conditions and/or into mass, or — the mass of the liquid measured at metering conditions into a volume at metering conditions and/or into a volume at base conditions *Note:* A conversion device includes the relevant associated measuring instruments.
Base conditions	The specified conditions to which the measured quantity of liquid at metering conditions is converted.
Measuring System	A system that comprises the meter itself and all devices required to ensure correct measurement or intended to facilitate the measuring operations.
Fuel dispenser	A measuring system intended for the refuelling of motor vehicles, small boats and small aircraft.
Self-service arrangement	An arrangement that allows the customer to use a measuring system for the purpose of obtaining liquid for his own use.
Self-service device	A specific device that is part of a self-service arrangement and which allows one of more measuring systems to perform in this self-service arrangement.

Minimum measured quantity (MMQ)	The smallest quantity of liquid for which the measurement is metrologically acceptable for the measuring system.
Direct indication	The indication, either volume or mass, corresponding to the measure and that the meter is physically capable of measuring. *Note:* The direct indication may be converted into another quantity using a conversion device.
Interruptible/non-interruptible	A measuring system is considered as interruptible/non-interruptible when the liquid flow can/cannot be stopped easily and rapidly.
Flowrate range	The range between the minimum flowrate (Q_{min}) and maximum flowrate (Q_{max}).

SPECIFIC REQUIREMENTS

Rated operating conditions

1. The manufacturer shall specify the rated operating conditions for the instrument, in particular;

The flowrate range

1.1. The flowrate ran ge is subject to the following conditions:

(i) the flowrate range of a measuring system shall be within the flowrate range of each of its elements, in particular the meter.

(ii) meter and measuring system:

Table 1

Specific measuring system	***Characteristic of liquid***	***Minimum ratio of Q_{max}: Q_{min}***
Fuel dispensers	Not Liquefied gases	10: 1
	Liquefied gases	5: 1
Measuring system	Cryogenic liquids	5: 1
Measuring systems on pipeline and systems for loading ships	All liquids	Suitable for use
All other measuring systems	All liquids	4: 1

1.2. The properties of the liquid to be measured by the instrument by specifying the name or type of the liquid or its relevant characteristics, for example:

— Temperature range;

— Pressure range;

— Density range;

— Viscosity range.

1.3. The nominal value of the AC voltage supply and/or limits of the DC voltage supply.

1.4. The base conditions for converted values.

This is without prejudice to the Secretary of State's obligations to require use of a temperature of 15 °C in accordance with section 12(1) of the Finance Act 1993 [M2].

Accuracy classification and maximum permissible errors (MPEs)

2

2.1. For quantities equal to or greater than 2 litres the MPE on indications is:

Table 2

	Accuracy Class				
	Accuracy Class				
	0.3	0.5	1.0	1.5	2.5
Measuring systems (A)	0.3 %	0.5 %	1.0 %	1.5 %	2.5 %
Meters (B)	0.2 %	0.3 %	0.6 %	1.0 %	1.5 %

2.2. For quantities less than two litres the MPE on indications is:

Table 3

Measured volume V	***MPE***
V < 0.1 L	4 × value in Table 2, applied to 0.1 L
0.1 L ≤ V < 0.2 L	4 × value in Table 2
0.2 L ≤ V < 0.4 L	2 × value in Table 2, applied to 0.4 L
0.4 L ≤ V < 1 L	2 × value in Table 2
1 L ≤ V < 2 L	Value in Table 2, applied to 2 L

2.3. However, no matter what the measured quantity may be, the magnitude of the MPE is given by the greater of the following two values:

— the absolute value of the MPE given in Table 2 or Table 3,

— the absolute value of the MPE for the minimum measured quantity (E_{min}).

2.4.1 For minimum measured quantities greater than or equal to 2 litres the following conditions apply:

Condition 1

E_{min} shall fulfil the condition: $E_{min} \geq 2$ R, where R is the smallest scale interval of the indication device.

Condition 2

E_{min} is given by the formula: $E_{min} = (2MMQ)x\ (A/100)$ where:

— MMQ is the minimum measured quantity,

— A is the numerical value specified in line A of Table 2.

2.4.2. For minimum measured quantities of less than two litres, the above mentioned condition 1 applies and E_{min} is twice the value specified in Table 3, and related to line A of Table 2.

Converted indication

2.5. In the case of a converted indication the MPEs are as in line A of Table 2.

Conversion devices

2.6. MPEs on converted indications due to a conversion device are equal to ± (A — B), A and B being the values specified in Table 2.

Parts of conversion devices that can be tested separately

(a) **Calculator**

MPEs on quantities of liquid indications applicable to calculation, positive or negative, are equal to one-tenth of the MPEs as defined in line A of Table 2.

(b) **Associated regulated measuring instruments**

Associated regulated measuring instruments shall have an accuracy at least as good as the values in Table 4:

Table 4

MPE on Measurements	***Accuracy classes of the measuring system***				
	0.3	**0.5**	**1.0**	**1.5**	**2.5**
Temperature	± 0.3 °C	± 0.5 °C			± 1.0 °C
Pressure	Less than 1 MPa: ± 50 kPa From 1 to 4 MPa: ± 5 % Over 4 MPa: ± 200 kPa				
Density	± 1 kg/m^3		± 2 kg/m^3		± 5 kg/m^3

These values apply to the indication of the characteristic quantities of the liquid displayed by the conversion device.

(c) **Accuracy for calculating function**

The MPE for the calculation of each characteristic quantity of the liquid, positive or negative, is equal to two fifths of the value fixed in (b).

2.7. The requirement (a) in paragraph 2.6 applies to any calculation, not only conversion.

2.8. The measuring system shall not exploit the MPEs or systematically favour any party.

Maximum permissible effect of disturbances

3

3.1. The effect of an electromagnetic disturbance on a measuring system shall be one of the following:

— the change in the measurement result is not greater than the critical change value as defined in paragraph 3.2, or

— the indication of the measurement result shows a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result. Furthermore, in the case of an interruptible system, this can also mean the impossibility to perform any measurement, or

— the change in the measurement result is greater than the critical change value, in which case the measuring system shall permit the retrieval of the measuring result just before the critical change value occurred and cut off the flow.

3.2. The critical change value is the greater of MPE/5 for a particular measured quantity or E_{min}.

Durability

4. After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criterion shall be satisfied:

The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed the value for meters specified in line B of table 2.

Suitability

5

5.1. For any measured quantity relating to the same measurement, the indications provided by various devices shall not deviate one from another by more than one scale interval where devices have the same scale interval. In the case where the devices have different scale intervals, the deviation shall not be more than that of the greatest scale interval.

However, in the case of a self-service arrangement the scale intervals of the main indicating device on the measuring system and the scale intervals of the self-service device shall be the same and results of measurement shall not deviate one from another.

5.2. It shall not be possible to divert the measured quantity in normal conditions of use unless it is readily apparent.

5.3. Any percentage of air or gas not easily detectable in the liquid shall not lead to a variation of error greater than:

— 0.5 % for liquids other than potable liquids and for liquids of a viscosity not exceeding 1 mPa.s, or

— 1 % for potable liquids and for liquids of a viscosity exceeding 1 mPa.s.

However, the allowed variation shall never be smaller than 1 % of MMQ. This value applies in the case of air or gas pockets.

Instruments for direct sales

5

5.4.1. A measuring system for direct sales shall be provided with means for resetting the display to zero.

It shall not be possible to divert the measured quantity.

5.4.2. The display of the quantity on which the transaction is based shall be permanent until all parties in the transaction have accepted the measurement result.

5.4.3. Measuring systems for direct sales shall be interruptible.

5.4.4. Any percentage of air or gas in the liquid shall not lead to a variation of error greater than the values specified in paragraph 5.3.

Fuel Dispensers

5

5.5.1. Displays on fuel dispensers shall not be capable of being reset to zero during a measurement.

5.5.2. The start of a new measurement shall be inhibited until the display has been reset to zero.

5.5.3. Where a measuring system is fitted with a price display, the difference between the indicated price and the price calculated from the unit price and the indicated quantity shall not exceed the price corresponding to E_{min}However this difference need not be less than the smallest monetary value.

Power supply failure

6. A measuring system shall either be provided with an emergency power supply device that will safeguard all measuring functions during the failure of the main power supply device or be equipped with means to save and display the data present in order to permit the conclusion of the transaction in progress and with means to stop the flow at the moment of the failure of the main power supply device.

Putting into use

Table 5

Accuracy class	***Types of Measuring system***
0.3	Measuring systems on pipeline
0.5	All measuring systems if not differently stated elsewhere in this Table, in particular: fuel dispensers (not for liquefied gases), measuring systems on road tankers for liquids of low viscosity (< 20 mPa.s)
1.0	Measuring systems for liquefied gases under pressure measured at a temperature equal to or above – 10 °C Measuring systems normally in class 0.3 or 0.5 but used for liquids whose temperature is less than – 10 °C or greater than 50 °C whose dynamic viscosity is higher than 1,000 mPa.s whose maximum volumetric flowrate is not higher than 20 L/h
1.5	Measuring systems for liquefied gases under pressure measured at a temperature below – 10 °C (other than cryogenic liquids)
2.5	Measuring systems for cryogenic liquids (temperature below – 153 °C)

Units of measurement

8. The metered quantity shall be displayed in millilitres, cubic centimetres, litres, cubic metres, grams, kilograms or tonnes.

CONFORMITY ASSESSMENT The conformity assessment procedures specified in the modules in Schedule 1B applicable to measuring systems for the continuous and dynamic measurement of quantities of liquids other than water that the manufacturer can choose between are:

(a) B and F;

(b) B and D;

(c) H1; or

(d) G.

SCHEDULE 1G

Regulations 2 and 39(1)

AUTOMATIC WEIGHING INSTRUMENTS (MI-006) (Annex VIII to the Directive)

The relevant essential requirements of Schedule 1A, the specific requirements of this Schedule and the conformity assessment procedures listed in Chapter I of this Schedule, apply to automatic weighing instruments defined below, intended to determine the mass of a body by using the action of gravity on that body.

DEFINITIONS

Automatic weighing instrument	An instrument that determines the mass of a product without the intervention of an operator and follows a predetermined programme of automatic processes characteristic of the instrument.
Automatic catchweigher	An automatic weighing instrument that determines the mass of pre-assembled discrete loads (for example prepackages) or single loads of loose material.
Weight labeller	An automatic catchweigher that labels individual articles with the weight value.
Weight/price labeller	An automatic catchweigher that labels individual articles with the weight value, and price information.
Automatic gravimetric filling instrument	An automatic weighing instrument that fills containers with a predetermined and virtually constant mass of product from bulk.
Discontinuous totaliser (totalising hopper weigher)	An automatic weighing instrument that determines the mass of a bulk product by dividing it into discrete loads. The mass of each discrete load is determined in sequence and summed. Each discrete load is then delivered to bulk.
Continuous totaliser	An automatic weighing instrument that continuously determines the mass of a bulk product on a conveyor belt, without systematic subdivision of the product and without interrupting the movement of the conveyor belt.

Rail-weighbridge	An automatic weighing instrument having a load receptor inclusive of rails for conveying railway vehicles.

SPECIFIC REQUIREMENTS

CHAPTER I

Requirements common to all types of automatic weighing instruments

Rated Operating Conditions

1. The manufacturer shall specify the rated operating conditions for the instrument as follows:

1.1. For the measurand:

The measuring range in terms of its maximum and minimum capacity.

1.2. For the electrical supply influence quantities:

In case of AC voltage supply :	the nominal AC voltage supply, or the AC voltage limits.
In case of DC voltage supply :	the nominal and minimum DC voltage supply, or the DC voltage limits.

1.3. For the mechanical and climatic influence quantities:

The minimum temperature range is 30 °C unless specified otherwise in the following chapters of this Schedule.

The mechanical environment classes according to Schedule 1A, paragraph 1.3.2 are not applicable. For instruments which are used under special mechanical strain, e.g. instruments incorporated into vehicles, the manufacturer shall define the mechanical conditions of use.

1.4 For other influence quantities (if applicable):

The rate(s) of operation.

The characteristics of the product(s) to be weighed.

2. Permissible effect of disturbances — Electromagnetic environment

The required performance and the critical change value are given in the relevant Chapter of this Schedule for each type of instrument.

Suitability

3

3.1. Means shall be provided to limit the effects of tilt, loading and rate of operation such that maximum permissible errors (MPEs) are not exceeded in normal operation.

3.2. Adequate material handling facilities shall be provided to enable the instrument to respect the MPEs during normal operation.

3.3. Any operator control interface shall be clear and effective.

3.4. The integrity of the display (where present) shall be verifiable by the operator.

3.5. Adequate zero setting capability shall be provided to enable the instrument to respect the MPEs during normal operation.

3.6. Any result outside the measurement range shall be identified as such, where a printout is possible.

Conformity assessment

4. The conformity assessment procedures specified in the modules in Schedule 1B applicable to automatic weighing instruments that the manufacturer can choose between are:

(a) For mechanical systems:

(i) B and D;

(ii) B and E;

(iii) B and F;

(iv) D1;

(v) F1;

(vi) G; or

(vii) H1.

(b) For electromechanical instruments:

(i) B and D;

(ii) B and E;

(iii) B and F;

(iv) G; or

(v) H1.

(c) For electronic systems or systems containing software:

(i) B and D;

(ii) B and F;

(iii) G; or

(iv) H1.

CHAPTER II

Automatic Catchweighers

1. These categories are divided into four accuracy classes:
Y(I), Y(II), Y(a) & Y(b)

which shall be specified by the manufacturer.

MPE

2

2.1. MPE Category Y instruments

Table 1

Net Load (m) in verification scale intervals (e)	***Maximum permissible mean error***	***Maximum permissible error***

Y(I)	***Y(II)***	***Y(a)***	***Y(b)***	***Static***	***Automatic***
0 < m ≤ 50,000	0 < m ≤ 5,000	0 < m ≤ 500	0 < m ≤ 50	± 0.5 e	± 1 e
50,000 < m ≤ 200,000	5,000 < m ≤ 20,000	500 < m ≤ 2,000	50 < m ≤ 200	± 1.0 e	± 1.5 e
200,000 < m	20,000 < m ≤ 100,000	2,000 < m ≤ 10,000	200 < m ≤ 1,000	± 1.5	± 2 e

Verification scale interval — single interval instruments

Table 2

Accuracy classes		***Verification scale interval***	Number of verification scale intervalsn = Max/e	
			Minimum	***Maximum***
			Minimum	Maximum
XI	Y(I)	0.001 g ≤ e	50,000	
XII	Y(II)	0.001 g ≤ e ≤ 0.05 g	100	100,000
		0.1 g ≤ e	5,000	100,000
XIII	Y(a)	0.1 g ≤ e ≤ 2 g	100	10,000
		5 g ≤ e	500	10,000
XIIII	Y(b)	5 g ≤ e	100	1,000

Verification scale interval — multi-interval instruments

Table 3

Verification scale interval		Number of verification scale intervalsn = Max/e	
		Minimum value[1] **$n = Max_i / e_{(i+1)}$** For i = r the corresponding column of Table 2 applies with e replaced by e_r.	**Maximum value $n = Max_i / e_i$**
Y(I)	0.001 g ≤ e_i	50,000	
Y(II)	0.001 g ≤ e_i ≤ 0.05 g	5,000	100,000
	0.1 g ≤ e_i	5,000	100,000
Y(a)	0.1 g ≤ e_i	500	10,000
Y(b)	5 g ≤ e_i	50	1 000

[1] For i = r the corresponding column of Table 2 applies with e replaced by e_r.

Where:

i = 1, 2, … r

i = partial weighing range

r = total number of partial ranges

Measurement Range

3. In specifying the measurement range for class Y instruments the manufacturer shall take account that the minimum capacity shall not be less than:

class Y(I)	:	100 e
class Y(II)	:	20 e for 0.001 g ≤ e ≤ 0.05 g, and 50 e for 0.1 g ≤ e
class Y(a)	:	20 e
class Y(b)	:	10 e
Scales used for grading, e.g. postal scales and garbage weighers	:	5 e

Dynamic Setting

4

4.1. The dynamic setting facility shall operate within a load range specified by the manufacturer.

4.2. When fitted, a dynamic setting facility that compensates for the dynamic effects of the load in motion shall be inhibited from operating outside the load range, and shall be capable of being secured.

Performance Under Influence Factors And Electromagnetic Disturbances

5

5.1. The MPEs due to influence factors are:

5.1.1. For category Y instruments

— For each load in automatic operation; as specified in Table 1,

— For static weighing in non-automatic operation; as specified in Table 1.

5.1.2. The critical change value due to a disturbance is one verification scale interval.

5.2. Temperature range:

— For class Y(I) the minimum range is 5 °C,

— For class Y(II) the minimum range is 15 °C.

CHAPTER III

Automatic Gravimetric Filling Instruments

Accuracy classes

1

1.1. The manufacturer shall specify both the reference accuracy class Ref(x) and the operational accuracy class(es) X(x).

1.2. An instrument type is designated a reference accuracy class, Ref(x), corresponding to the best possible accuracy for instruments of the type. After installation, individual instruments are designated for one or more operational accuracy classes, X(x), having taken account of the specific products to be weighed. The class designation factor (x) shall be ≤ 2, and in the form 1×10^k, 2×10^k or 5×10^k where k is a negative whole number or zero.

1.3. The reference accuracy class, Ref(x) is applicable for static loads.

1.4. For the operational accuracy class X(x), X is a regime relating accuracy to load weight and (x) is a multiplier for the limits of error specified for class X(1) in paragraph 2.2.

MPE

2

Static weighing error

2

2.1.1. For static loads under rated operating conditions, the MPE for reference accuracy class Ref(x), shall be 0.312 of the maximum permissible deviation of each fill from the average; as specified in Table 5; multiplied by the class designation factor (x).

2.1.2. For instruments where the fill may be made up from more than one load (e.g. cumulative or selective combination weighers) the MPE for static loads shall be the accuracy required for the fill as specified in paragraph 2.2 (i.e. not the sum of the maximum permissible deviation for the individual loads).

Deviation from average fill

Table 4

Value of the mass, m (g), of the fills	*Maximum permissible deviation of each fill from the average for class X(1)*
m ≤ 50	7.2 %
50 < m ≤ 100	3.6 g
100 < m ≤ 200	3.6 %
200 < m ≤ 300	7.2 g
300 < m ≤ 500	2.4 %
500 < m ≤ 1,000	12 g
1,000 < m ≤ 10,000	1.2 %
10,000 < m ≤ 15,000	120 g
15,000 < m	0.8 %

Note:

The calculated deviation of each fill from the average may be adjusted to take account for the effect of material particle size.

Error relative to pre-set value (setting error)

2.3. For instruments where it is possible to pre-set a fill weight; the maximum difference between the pre-set value and the average mass of the fills shall not exceed 0.312 of the maximum permissible deviation of each fill from the average, as specified in Table 4.

Performance Under Influence Factor And Electromagnetic Disturbance

3

3.1. The MPE due to influence factors shall be as specified in paragraph 2.1.

3.2. The critical change value due to a disturbance is a change of the static weight indication equal to the MPE as specified in paragraph 2.1 calculated for the rated minimum fill, or a change that would give equivalent effect on the fill in the case of instruments where the fill consists of multiple loads. The calculated critical change value shall be rounded to the next higher scale interval (d).

3.3. The manufacturer shall specify the value of the rated minimum fill.

CHAPTER IV

Discontinuous Totalisers

1. Accuracy Classes

Instruments are divided into four accuracy classes as follows: 0.2; 0.5; 1; 2.

2. MPEs

Table 5

Accuracy class	*MPE of totalised load*
0.2	± 0.10 %
0.5	± 0.25 %
1	± 0.50 %
2	± 1.00 %

Totalisation scale interval

3. The totalisation scale interval (dt) shall be in the range: 0.01 % Max ≤ d_t ≤ 0.2 % Max

Minimum Totalised Load ($^{\Sigma}_{min}$)

4. The minimum totalised load ($^{\Sigma}_{min}$) shall be not less than the load at which the MPE is equal to the totalisation scale interval (dt) and not less than the minimum load as specified by the manufacturer.

Zero Setting

5. Instruments that do not tare weigh after each discharge shall have a zero setting device. Automatic operation shall be inhibited if zero indication varies by:

— 1 d_t on instruments with automatic zero setting device;

— 0.5 d_t on instruments with a semi-automatic, or non-automatic, zero setting device

Operator Interface

6. Operator adjustments and reset function shall be inhibited during automatic operation.

Printout

7. On instruments equipped with a printing device, the reset of the total shall be inhibited until the total is printed. The printout of the total shall occur if automatic operation is interrupted.

Performance under influence factors and electromagnetic disturbances

8

8.1. The MPEs due to influence factors shall be as specified in Table 6.

Table 6

Load (m) in totalisation scale intervals (d_t)	*MPE*
$0 < m \leq 500$	$\pm 0.5\ d_t$
$500 < m \leq 2{,}000$	$\pm 1.0\ d_t$
$2{,}000 < m \leq 10{,}000$	$\pm 1.5\ d_t$

8.2. The critical change value due to a disturbance is one totalisation scale interval for any weight indication and any stored total.

CHAPTER V

Accuracy classes

1. Instruments are divided into three accuracy classes as follows: 0.5; 1; 2.

Measurement Range

2

2.1. The manufacturer shall specify the measurement range, the ratio between the minimum net load on the weighing unit and the maximum capacity, and the minimum totalised load.

2.2. The minimum totalised load $^{\Sigma}_{min}$ shall not be less than

800 d for class 0.5,

400 d for class 1,

200 d for class 2.

Where d is the totalisation scale interval of the general totalisation device.

MPE

Table 7

Accuracy class	*MPE for totalised load*

0.5	± 0.25 %
1	± 0.5 %
2	± 1.0 %

Speed of the belt

4. The speed of the belt shall be specified by the manufacturer. For single-speed beltweighers, and variable-speed beltweighers having a manual speed setting control, the speed shall not vary by more than 5 % of the nominal value. The product shall not have a different speed than the speed of the belt.

General Totalisation Device

5. It shall not be possible to reset the general totalisation device to zero.

Performance under influence factors and electromagnetic disturbances

6

6.1. The MPE due to influence factor, for a load not less than the $^{\Sigma}_{min}$, shall be 0.7 times the appropriate value specified in Table 7, rounded to the nearest totalisation scale interval (d).

6.2. The critical change value due to a disturbance shall be 0.7 times the appropriate value specified in Table 7, for a load equal to $^{\Sigma}_{min}$, for the designated class of the beltweigher; rounded up to the next higher totalisation scale interval (d).

CHAPTER VI

Automatic Rail Weighbridges

Accuracy classes

1. Instruments are divided into four accuracy classes as follows: 0.2; 0.5; 1; 2.

MPE

2

2.1. The MPEs for weighing-in-motion of a single wagon or a total train are shown in Table 8.

Table 8

Accuracy class	*MPE*
0.2	± 0.1 %
0.5	± 0.25 %
1	± 0.5 %
2	± 1.0 %

2.2. The MPEs for the weight of coupled or uncoupled wagons weighing-in-motion shall be one of the following values, whichever is the greatest:

— the value calculated according to Table 8, rounded to the nearest scale interval;

— the value calculated according to Table 8, rounded to the nearest scale interval for a weight equal to 35 % of the maximum wagon weight (as inscribed on the descriptive markings);

— one scale interval (d).

2.3. The MPEs for the weight of train weighing-in-motion shall be one of the following values, whichever is the greatest:

— the value calculated according to Table 9, rounded to the nearest scale interval;

— the value calculated according to Table 9, for the weight of a single wagon equal to 35 % of the maximum wagon weight (as inscribed on the descriptive markings) multiplied by the number of reference wagons (not exceeding 10) in the train, and rounded to the nearest scale interval;

— one scale interval (d) for each wagon in the train, but not exceeding 10 d.

2.4. When weighing coupled wagons; the errors of not more than 10 % of the weighing results taken from one or more passes of the train may exceed the appropriate MPE given in paragraph 2.2, but shall not exceed twice the MPE.

Scale interval (d)

3. The relationship between the accuracy class and the scale interval shall be as specified in Table 9.

Table 9

Accuracy class	*Scale interval (d)*
0.2	$d \leq 50$ kg
0.5	$d \leq 100$ kg
1	$d \leq 200$ kg
2	$d \leq 500$ kg

Measurement range

4

4.1. The minimum capacity shall not be less than 1 t, and not greater than the value of the result of the minimum wagon weight divided by the number of partial weighings.

4.2. The minimum wagon weight shall not be less than 50 d.

Performance under influence factor and electromagnetic disturbance

5

5.1. The MPE due to an influence factor shall be as specified in Table 10.

Table 10

Load (m) in verification scale intervals (d)	**MPE**
$0 < m \leq 500$	± 0.5 d

500 < m ≤ 2,000	± 1.0 d
2,000 < m ≤ 10,000	± 1.5 d

5.2. The critical change value due to a disturbance is one scale interval.

SCHEDULE 1H

Regulations 2 and 39(1)

TAXIMETERS (MI-007) (Annex IX to the Directive)

The relevant requirements of Schedule 1A, the specific requirements of this Schedule and the conformity assessment procedures listed in this Schedule apply to taximeters.

DEFINITIONS

Appropriate Licensing Authority

Within this Schedule, "appropriate licensing authority" means –

(a) in relation to the area to which the Metropolitan Public Carriage Act 1869 [M3] applies, Transport for London;

(b) in relation to any other area in England and Wales, the authority responsible for licensing taxis in that area;

(c) in relation to Scotland, the district or islands council responsible for licensing taxis in that area;

(d) and in relation to Northern Ireland, the Department of the Environment for Northern Ireland.

Taximeter

A device that works together with a signal generator [M4] to make a regulated measuring instrument.

This device measures duration, calculates distance on the basis of a signal delivered by the distance signal generator. Additionally, it calculates and displays the fare to be paid for a trip on the basis of the calculated distance and/or the measured duration of the trip.

Fare

The total amount of money due for a trip based on a fixed initial hire fee and/or the length and/or the duration of the trip. The fare does not include a supplement charged for extra services.

Cross-over speed

The speed value found by division of a time tariff value by a distance tariff value.

Normal calculation mode S (single application of tariff)

Fare calculation based on application of the time tariff below the cross-over speed and application of the distance tariff above the cross-over speed.

Normal calculation mode D (double application of tariff)

Fare calculation based on simultaneous application of time tariff and distance tariff over the whole trip.

Operating position

The different modes in which a taximeter fulfils the different parts of its functioning. The operating positions are distinguished by the following indications:

'For Hire'	:	The operating position in which the fare calculation is disabled
'Hired'	:	The operating position in which the fare calculation takes place on the basis of a possible initial charge and a tariff for distance travelled and/or time of the trip
'Stopped'	:	The operating position in which the fare due for the trip is indicated and at least the fare calculation based on time is disabled.

DESIGN REQUIREMENTS

1. The taximeter shall be designed to calculate the distance and to measure the duration of a trip.

2. The taximeter shall be designed to calculate and display the fare, incrementing in steps equal to the resolution fixed by the appropriate licensing authority in the operation position 'Hired'. The taximeter shall also be designed to display the final value for the trip in the operating position 'Stopped'.

3. A taximeter shall be able to apply the normal calculation modes S and D. It shall be possible to choose between these calculation modes by a secured setting.

4. A taximeter shall be able to supply the following data through an appropriate secured interface(s):

— operation position: 'For Hire', 'Hired' or 'Stopped';

— totaliser data according to paragraph 15.1;

— general information: constant of the distance signal generator, date of securing, taxi identifier, real time, identification of the tariff;

— fare information for a trip: total charged, fare, calculation of the fare, supplement charge, date, start time, finish time, distance travelled;

— tariff(s) information: parameters of tariff(s).

Where a device is required to be connected to the interface(s) of a taximeter, it shall be possible, by way of a secured setting, to inhibit automatically the operation of the taximeter for reasons of the non-presence or improper functioning of the required device.

5. If relevant, it shall be possible to adjust a taximeter for the constant of the distance signal generator to which it is to be connected and to secure the adjustment.

RATED OPERATING CONDITIONS

6.1. The mechanical environment class that applies is M3.

6.2. The manufacturer shall specify the rated operating conditions for the instrument, in particular:

— a minimum temperature range of 80 °C for the climatic environment;

— the limits of the DC power supply for which the instrument has been designed.

MAXIMUM PERMISSIBLE ERRORS (MPEs)

7. The MPE, excluding any errors due to application of the taximeter in a taxi, are:

— For the time elapsed: ± 0.1 %

minimum value of mpe: 0.2 s;

minimum value of mpe: 4 m;

minimum, including rounding: corresponding to the least significant digit of the fare indication.

PERMISSIBLE EFFECT OF DISTURBANCES

8. Electromagnetic immunity

8.1. The electromagnetic class that applies is E3.

8.2. The MPE laid down in paragraph 7 shall also be respected in the presence of an electromagnetic disturbance. **POWER SUPPLY FAILURE**

9. In case of a reduction of the voltage supply to a value below the lower operating limit as specified by the manufacturer, the taximeter shall:

— continue to work correctly or resume its correct functioning without loss of data available before the voltage drop if the voltage drop is temporary, i.e. due to restarting the engine;

— abort an existing measurement and return to the position ‘For Hire’ if the voltage drop is for a longer period.

OTHER REQUIREMENTS

10. The conditions for the compatibility between the taximeter and the distance signal generator shall be specified by the manufacturer of the taximeter.

11. If there is a supplement charge for an extra service, entered by the driver on manual command, this shall be excluded from the fare displayed. However, in that case a taximeter may display temporarily the value of the fare including the supplementary charge.

12. If the fare is calculated according to calculation mode D a taximeter may have an additional display mode in which only the total distance and duration of the trip are displayed in real time.

13. All values displayed for the passenger shall be suitably identified. These values as well as their identification shall be clearly readable under daylight and night conditions.

14.1. If the fare to be paid or the measures to be taken against fraudulent use can be affected by the choice of functionality from a pre-programmed setting or by free data setting, it shall be possible to secure the instrument settings and data entered.

14.2. The securing possibilities available in a taximeter shall be such that separate securing of the settings is possible.

14.3. The provisions in paragraph 8.3 of Schedule 1A apply also to the tariffs.

15.1. A taximeter shall be fitted with non-resettable totalisers for all of the following values:

— The total distance travelled by the taxi;

— The total distance travelled when hired;

— The total number of hirings;

— The total amount of money charged as supplements;

— The total amount of money charged as fare.

The totalised values shall include the values saved according to paragraph 9 under conditions of loss of power supply.

15.2. If disconnected from power, a taximeter shall allow the totalised values to be stored for one year for the purpose of reading out the values from the taximeter to another medium.

15.3. Adequate measures shall be taken to prevent the display of totalised values from being used to deceive passengers.

16. Automatic change of tariffs is allowed due to the:

— distance of the trip;

— duration of the trip;

— time of the day;

— date;

— day of the week.

17. If properties of the taxi are important for the correctness of the taximeter, the taximeter shall provide means to secure the connection of the taximeter to the taxi in which it is installed.

18. For the purpose of testing after installation, the taximeter shall be equipped with the possibility to test separately the accuracy of time and distance measurement and the accuracy of the calculation.

19. A taximeter and its installation instructions specified by the manufacturer shall be such that, if installed according to the manufacturer's instructions, fraudulent alterations of the measurement signal representing the distance travelled are sufficiently excluded.

20. The general essential requirement dealing with fraudulent use shall be fulfilled in such a way that the interests of the customer, the driver, the driver's employer and the fiscal authorities are protected.

21. A taximeter shall be designed so that it can respect the MPEs without adjustment during a period of one year of normal use.

22. The taximeter shall be equipped with a real-time clock by means of which the time of the day and the date are kept, one or both can be used for automatic change of tariffs. The requirements for the real-time clock are:

— the timekeeping shall have an accuracy of 0.02 %;

— the correction possibility of the clock shall be not more than 2 minutes per week. Correction for summer and wintertime shall be performed automatically;

— correction, automatic or manually, during a trip shall be prevented.

23. The values of distance travelled and time elapsed, when displayed or printed in accordance with these Regulations, shall use the following units:

Distance travelled:

— kilometres;

— miles.

Time elapsed:
— seconds, minutes or hours, as may be suitable; keeping in mind the necessary resolution and the need to prevent misunderstandings.

CONFORMITY ASSESSMENT The conformity assessment procedures specified in the modules in Schedule 1B applicable to taximeters that the manufacturer can choose between are:

(a) B and F;

(b) B and D; or

(c) H1.

SCHEDULE 1I

Regulations 2 and 39(1)

MATERIAL MEASURES (MI-008) (Annex X to the Directive)

CHAPTER 1

Material measures of length

The relevant essential requirements of Schedule 1A, the specific requirements of this Schedule and the conformity assessment procedures listed in this chapter, apply to material measures of length defined below. However, the requirement for the supply of a copy of declarations of conformity may be interpreted as applying to a batch or consignment rather than each individual instrument.

SPECIFIC REQUIREMENTS

Reference Conditions

1.1. For tapes of length equal to or greater than 5 metres, the maximum permissible errors (MPEs) are to be met when a tractive force of fifty newtons or other force values as specified by the manufacturer and marked on the tape accordingly, or in the case of rigid or semi-rigid measures no tractive force is needed, is applied.

1.2. The reference temperature is 20 °C unless otherwise specified by the manufacturer and marked on the measure accordingly.

MPEs

2. The MPE, positive or negative in mm, between two non-consecutive scale marks is (a + bL), where:

— L is the value of the length rounded up to the next whole metre; and

— a and b are given in Table 1 below.

When a terminal interval is bounded by a surface, the MPE for any distance beginning at this point is increased by the value c given in Table 1.

Table 1

Accuracy Class	a(mm)	***b***	c(mm)
I	0.1	0.1	0.1
II	0.3	0.2	0.2
III	0.6	0.4	0.3

The MPE for the length between consecutive scale marks, and the maximum permissible difference between two consecutive intervals, are given in Table 2 below.

Table 2

Length i of the interval	***MPE or difference in millimetres according to accuracy class***		
	I	II	III
i ≤ 1 mm	0.1	0.2	0.3
1 mm < i ≤ 1 cm	0.2	0.4	0.6

Where a rule is of the folding type, the jointing shall be such as not to cause any errors, supplementary to those above, exceeding: 0.3 mm for Class II, and 0.5 mm for Class III.

Materials

3.1. Materials used for material measures shall be such that length variations due to temperature excursions up to ± 8 °C about the reference temperature do not exceed the MPE.

3.2. Measures made from material whose dimensions may alter materially when subjected to a wide range of relative humidity, may only be included in Classes II or III.

Markings

4. The nominal value shall be marked on the measure. Millimetre scales shall be numbered every centimetre and measures with a scale interval greater than 2 cm shall have all scale marks numbered.

CONFORMITY ASSESSMENT The conformity assessment procedures specified in the modules in Schedule 1B applicable to material measures of length that the manufacturer can choose between are:

(a) F1;

(b) D1;

(c) B and D;

(d) H; or

(e) G.

CHAPTER II

Capacity serving measures

The relevant essential requirements of Schedule 1A, and the specific requirements and the conformity assessment procedures listed in this chapter, apply to capacity serving measures defined below. However, the requirement for the supply of a copy of declarations of conformity may be interpreted as applying to a batch or consignment rather than each individual instrument. Also, the requirement for the instrument to bear information in respect of its accuracy shall not apply.

DEFINITIONS

Line measure	A capacity serving measure marked with a line to indicate nominal capacity.
Brim measure	A capacity serving measure for which the internal volume is equal to the nominal capacity.
Transfer measure	A capacity serving measure from which it is intended that the liquid is decanted prior to consumption.
Capacity	The capacity is the internal volume for brim measures or internal volume to a filling mark for line measures.

SPECIFIC REQUIREMENTS

Reference Conditions

1

1.1. Temperature: the reference temperature for measurement of capacity is 20 °C.

1.2. Position for correct indication: free standing on a level surface.

MPEs

Table 1

	Line	***Brim***
Transfer measures		
Transfer measures		
< 100 ml	± 2 ml	– 0 + 4 ml
≥ 100 ml	± 3 %	– 0 + 6 %

Serving measures		
< 200 ml	± 5 %	– 0 + 10 %
≥ 200 ml	± (5 ml + 2.5 %)	– 0 + 10 ml + 5 %

Materials

3. Capacity serving measures shall be made of material which is sufficiently rigid and dimensionally stable to maintain capacity within the MPE.

Shape

4

4.1. Transfer measures shall be designed so that a change of contents equal to the MPE causes a change in level of at least 2 mm at the brim or filling mark.

4.2. Transfer measures shall be designed so that the complete discharge of the liquid being measured will not be impeded.

Marking

5

5.1. The nominal capacity declared shall be clearly and indelibly marked on the measure.

5.2. Capacity serving measures may also be marked with up to three clearly distinguishable capacities, none of which shall lead to confusion one to the other.

5.3. All filling marks shall be sufficiently clear and durable to ensure that MPEs are not exceeded in use.

CONFORMITY ASSESSMENT The conformity assessment procedures specified in the modules in Schedule 1B applicable to capacity serving measures that the manufacturer can choose between are:

(a) A2;

(b) F1;

(c) D1;

(d) E1;

(e) B and E;

(f) B and D; or

(g) H.

SCHEDULE 1J

Regulations 2 and 39(1)

EXHAUST GAS ANALYSERS (MI-010) (Annex XII to the Directive)

The relevant requirements of Schedule 1A, the specific requirements of this Schedule and the conformity assessment procedures listed in this Schedule, apply to exhaust gas analysers to the extent that they are also regulated measuring instruments.

The volume fractions of the exhaust gas components are expressed as a percentage (% vol) for carbon monoxide (CO), carbon dioxide (CO_2) and oxygen (O_2) and in parts per million (ppm vol) for hydrocarbons (HC).

The content of HC has to be expressed as concentration of n-hexane (C_6H_{14}), measured with near-infrared absorption techniques.

DEFINITIONS

Lambda	Lambda is a dimensionless value representative of the burning efficiency of an engine in terms of air/fuel ratio in the exhaust gases.

SPECIFIC REQUIREMENTS

Instrument Classes

1. Two classes (0 and I) are being defined for exhaust gas analysers. The relevant minimum measuring ranges for these classes are shown in Table 1.

Table 1

Classes and measuring ranges	
Parameter	***Classes 0 and I***
CO fraction	from 0 to 5 % vol
CO_2 fraction	from 0 to 16 % vol
HC fraction	from 0 to 2,000 ppm vol
O_2 fraction	from 0 to 21 % vol
λ	from 0.8 to 1.2

Rated operating conditions

2. The values of the operating conditions shall be specified by the manufacturer as follows:

2.1. For the climatic and mechanical influence quantities:

— a minimum temperature range of 35 °C for the climatic environment;

— the mechanical environment class that applies is M1.

2.2. For the electrical power influence quantities:

— the voltage and frequency range for the AC voltage supply

— the limits of the DC voltage supply.

2.3. For the ambient pressure:

— the minimum and the maximum values of the ambient pressure are for both classes: $p_{min} \leq 860$ hPa, $p_{max} \geq 1{,}060$ hPa.

Maximum permissible errors (MPEs)

3. The MPEs are defined as follows:

3.1. For each of the fractions measured, the maximum error value permitted under rated operating conditions according to paragraph 1.1 of Schedule 1A is the greater of the two values shown in Table 2. Absolute values are expressed in % vol or ppm vol, percentage values are percent of the true value.

Table 2

Parameter MPEs	***Class 0***	***Class I***
CO fraction	± 0.03 % vol ± 5 %	± 0.06 % vol ± 5 %
CO_2 fraction	± 0.5 % vol ±5 %	± 0.5 % vol ± 5 %
HC fraction	± 10 ppm vol ± 5 %	± 12 ppm vol ± 5 %
O_2 fraction	± 0.1 % vol ± 5 %	± 0.1 % vol ± 5 %

3.2. The MPE on lambda calculation is 0.3 %. The conventional true value is calculated according to the formula set out in point 5.3.7.3 of Regulation No 83 of the Economic Commission for Europe of the United Nations (UN/ECE).

For this purpose, the values displayed by the instrument are used for calculation.

Permissible effect of disturbances

4. For each of the volume fractions measured by the instrument, the critical change value is equal to the MPE for the parameter concerned.

5. The effect of an electromagnetic disturbance shall be such that:

— either the change in the measurement result is not greater than the critical change value laid down in paragraph 4; or

— the presentation of the measurement result is such that it cannot be taken for a valid result.

Other requirements

6. The resolution shall be equal to or of one order of magnitude higher than the values shown in Table 3.

Table 3

Resolution	**CO**	**CO_2**	**O_2**	**HC**
Class O and class I	0.01 % vol	0.1 % vol	0.01 % vol for measurand values below or equal to 4 % vol, otherwise 0.1 % vol.	1 ppm vol

The lambda value shall be displayed with a resolution of 0.001.

The standard deviation of 20 measurements shall not be greater than one third of the modulus of the MPE for each applicable gas volume fraction.

8. For measuring CO, CO_2 and HC, the instrument, including the specified gas handling system, must indicate 95 % of the final value as determined with calibration gases within 15 seconds after changing from a gas with zero content, e.g. fresh air. For measuring O_2, the instrument under similar conditions must indicate a value differing less than 0.1 % vol from zero within 60 seconds after changing from fresh air to an oxygen-free gas.

9. The components in the exhaust gas, other than the components whose values are subject to the measurement, shall not affect the measurement results by more than the half of the modulus of the MPEs when those components are present in the following maximum volume fractions:

6 % vol CO,

16 % vol CO_2,

10 % vol O_2,

5 % vol H_2,

0.3 % vol NO,

2,000 ppm vol HC (as n-hexane),

water vapour up to saturation.

10. An exhaust gas analyser shall have an adjustment facility that provides operations for zero-setting, gas calibration and internal adjustment. The adjustment facility for zero-setting and internal adjustment shall be automatic.

11. For automatic or semi-automatic adjustment facilities, the instrument shall be unable to make a measurement as long as the adjustments have not been made.

12. An exhaust gas analyser shall detect hydrocarbon residues in the gas handling system. It shall not be possible to carry out a measurement if the hydrocarbon residues, present before any measurement, exceed 20 ppm vol.

13. An exhaust gas analyser shall have a device for automatically recognising any malfunctioning of the sensor of the oxygen channel due to wear or a break in the connecting line.

14. If the exhaust gas analyser is capable to operate with different fuels (e.g. petrol or liquefied gas), there shall be the possibility to select the suitable coefficients for the Lambda calculation without ambiguity concerning the appropriate formula.

CONFORMITY ASSESSMENT The conformity assessment procedures specified in the modules in Schedule 1B applicable to exhaust gas analysers that the manufacturer can choose between are:

(a) B and F;

(b) B and D; o

(c) H1.

SCHEDULE 1K

Regulation 47(1)(c)

Declaration of Conformity

Declaration of Conformity (No. XXXX) [M5]

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 the 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 statutory requirements:

6. References to the relevant designated standards or normative documents 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):".

Commencement Information

I50 Sch. 27 para. 49 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M2 1973 c. 43.

M3 1869 c.115.

M4 A signal generator is outside the scope of these Regulations.

M5 It is optional for the manufacturer to assign a number to the declaration of conformity.

Amendment to Schedule 3

50. In Schedule 3 (revocations and transitional and consequential provisions)—

(a) after paragraph 2, insert—

"**Transitional provisions relating to UK withdrawal from the EU**

2A.—(1) In this regulation—

"pre-exit period" means the period beginning with the commencement date and ending immediately before **[**[F16]IP completion day**]**;

(2) Subject to paragraph (3), where a regulated measuring instrument was made available on the market during the pre-exit period, despite the amendments made by Schedule 27 of the Product Safety and Metrology (Amendment etc.) (EU Exit) Regulations 2019 [M6], any obligation to which a person was subject under these Regulations as they had effect immediately before **[**[F16]IP completion day**]**, continues to have effect as it did immediately before **[**[F16]IP completion day**]**, in relation to that regulated measuring 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 regulated measuring instrument.

(4) Where during the pre-exit period—

(a) a regulated measuring instrument has not been placed on the market; and

(b) a manufacturer has taken any action under regulation 39 as it had effect immediately before **[**[F16]IP completion day**]** in relation to that regulated measuring instrument,

that action has effect as if it had been done under regulation 39 as it had effect on and after **[**[F16]IP completion day**]**."

(b) in paragraph 4—

(i) in sub-paragraphs (4)(a), (4)(b), (6)(c)(i) and (6)(c)(ii), for "Annex IV to the Directive", substitute " Schedule 1D to the Measuring Instruments Regulations 2016 [M7] " in each place it occurs;

(ii) in sub-paragraphs (4)(b), (6)(c)(i) and (6)(c)(ii), for "Annex IV", substitute " Schedule 1D to the Measuring Instruments Regulations 2016 ";

(c) in paragraph 5—

(i) in sub-paragraphs (4)(a) and (4)(b) for "Annex IV to the Directive", substitute " Schedule 1D to the Measuring Instruments Regulations 2016 " in each place it occurs;

(ii) in sub-paragraphs (4)(a) and (4)(b), for "Annex IV", substitute " Schedule 1D to the Measuring Instruments Regulations 2016 " in each place it occurs;

(d) in paragraphs 6 and 7, for "Annex V to the Directive", substitute " Schedule 1E of the Measuring Instruments Regulations 2016 " in each place it occurs.

F16 Words in Sch. 27 para. 50(a) substituted (31.12.2020 immediately before IP completion day) by The Product Safety and Metrology (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/852), regs. 2(2), 4(2), **Sch. 1 para. 1(p)(v)**

Commencement Information

I51 Sch. 27 para. 50 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M6 S.I. 2019/696.

M7 S.I. 2016/1153.

Amendment to Schedule 4

51. In Schedule 4 (operational obligations of notified bodies)—

(a) in paragraphs 3, 4 and 6 for "a notified" substitute " an approved ";

(b) in all places in which it occurs (other than the paragraphs referred to in paragraph 51(a)) including in the heading, for "notified" substitute " approved ";

(c) in paragraph 7—

(i) for "notifying authority" substitute " Secretary of State "; and

(ii) in subparagraphs (b) and (d) for "notification" substitute " approval " in both places in which it occurs;

(d) in paragraph 8—

(i) after "bodies", the second time it occurs, insert " approved ";

(ii) for "this Directive" substitute " these Regulations "; and

(e) in paragraph 9 omit from "convened" to "Directive".

Commencement Information

I52 Sch. 27 para. 51 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to Schedule 5

52. In Schedule 5 (requirements related to notified bodies)—

(a) in paragraph 1 for "under the national law of an EEA state" substitute " in the United Kingdom ";

(b) in paragraph 5(1) for "1" substitute " 1B ";

(c) in paragraph 6(c)(ii) for "harmonised" substitute " designated ";

(d) in paragraph 6(c)(iii)—

(i) omit "of Union harmonisation legislation and";

(ii) for "national" substitute " applicable ";

(e) in paragraph 9(1) omit from "except" to "carried out";

(f) in paragraph 10 for "under the relevant Union harmonisation legislation" substitute " by the Secretary of State "; and

(g) in paragraph 5(2)(c) for "a notified" substitute " an approved ";

(h) in all places in which it occurs, including in the heading, for "notified" substitute " approved ".

Commencement Information

I53 Sch. 27 para. 52 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to Schedule 6

53. In Schedule 6 (in service requirements for certain regulated measuring instruments in Great Britain), Part 5, paragraph 14 for "the Directive" substitute " Schedule 1G ".

Commencement Information

I54 Sch. 27 para. 53 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Changes to legislation:
There are currently no known outstanding effects for the The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, SCHEDULE 27.