STATUTORY INSTRUMENTS

2016 No. XXXX

WEIGHTS AND MEASURES

The Non-automatic Weighing Instruments Regulations 2016

Made - - - -	***
Laid before Parliament	***
Coming into force - -	***

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

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

The Secretary of State makes the following Regulations under powers conferred on him by section 2(2) of that Act and, in relation to Part 6 of the Regulations, under powers conferred on him by sections 15(1) and 86(1) of the Weights and Measures Act 1985(**c**).

PART 1

INTRODUCTORY

Citation and commencement

1.—(1) These Regulations may be cited as the Non-automatic Weighing Instruments Regulations 2016.

(2) These Regulations come into force on 20th April 2016.

(3) These Regulations extend to Northern Ireland except for Part 6.

Interpretation

2.—(1) In these Regulations—

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

(**a**) S.I. 1975/427.
(**b**) 1972 c.68.
(**c**) 1985 c.72.

"accreditation certificate" means a certificate, issued by the United Kingdom Accreditation Service or a national accreditation body in another member State, attesting that a conformity assessment body meets the notified body requirements;

"authorised representative" means any person established within the European Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

"CE marking" means a marking which takes the form set out in Annex II of RAMS (as from time to time amended);

"competent authority" means the market surveillance authority or an enforcement authority;

"compliance notice" means a notice served in accordance with regulation 66(2);

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

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

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

"disqualification mark" means a mark or sticker the design of which is published by the Secretary of State and which may be affixed to a regulated instrument in accordance with regulation 69;

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

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

"enforcement authority" means any person who is, pursuant to regulation 65, authorised to enforce these Regulations;

"enforcement notice" means a notice served in accordance with regulation 67(2);

"enforcement officer" means—

(a) means an inspector; or

(b) a person appointed by the Secretary of State to act on his behalf to enforce these Regulations;

"essential requirements" means in relation to a regulated instrument (or a class of that instrument) the requirements specified as being applicable in relation to that regulated instrument (or that class of instrument) in Annex I to the Directive (as amended from time to time);

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

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

"European Commission" means the Commission of the European Union;

"harmonised standard" has the meaning set out in point 1(c) of Article 2 of Regulation (EU) No. 1025/2012 (as amended from time to time);

"importer" means any person who—

(a) is established within the European Union; and

(b) places an instrument from a third country on the EU market;

(**a**) OJ L 96, 29.3.2014 p. 107.

"instrument" means a non-automatic weighing instrument;

"in writing" includes text that is—

(a) transmitted by electronic means;

(b) received in legible form; and

(c) capable of being used for subsequent reference.

"M marking" means the supplementary metrology marking that meets the requirements of regulation 48;

"make available on the market" means any supply of an instrument for distribution or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge and related expressions are to be construed accordingly;

"manufacturer" means any person who—

(a) manufactures an instrument or has an instrument designed or manufactured and markets that instrument under his name or trademark; or

(b) is to be treated as the manufacturer by virtue of regulation 6(2);

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

"non-automatic weighing instrument" means a regulated instrument that requires the intervention of an operator during weighing;

"notified body" includes, where the context so requires, a notified body designated as such in another member State in accordance with the Directive;

"place on the market" means the first making available of an instrument on the EU market and related expressions are to be construed accordingly;

"put into use" means the first use of an instrument intended for the end user for the purposes for which it was intended and related expressions are to be construed accordingly;

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

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

"regulated instrument" has the meaning given in regulation 3(2);

"re-qualification mark" means a mark or sticker the design of which is published by the Secretary of State and which is affixed to an instrument in accordance with regulation 70;

"restrictive use symbol" means a symbol constituted by a capital letter (M) printed in black on a red background at least 25mm x 25mm square with two intersecting diagonals forming a cross;

"technical documentation" means the documentation which meets the requirements of Annex II to the Directive (from time to time amended);

"technical specification" means a document that prescribes technical requirements to be fulfilled by an instrument;

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

"weighing instrument" means a regulated instrument serving to determine the mass of a body by using the action of gravity on that body and which may also serve to determine other mass-related magnitudes, quantities, parameters and characteristics;

(**a**) OJ L 218, 13.8.2008, p. 30.

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

(2) Other expressions used in these Regulations have in relation to the application of these Regulations to—

(a) Great Britain, the same meanings as in the Weights and Measures Act 1985; and

(b) Northern Ireland, the Northern Ireland Weights and Measures Order 1981.

Application

3.—(1) Subject to regulation 4, these Regulations apply to non-automatic weighing instruments.

(2) These Regulations, except Part 4, apply to an instrument (referred to in these Regulations as a "regulated instrument") for use for any of the following purposes—

(a) the determination of mass for commercial transactions;

(b) the determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;

(c) the determination of mass for the application of laws or regulations or for an expert opinion given in court proceedings;

(d) the determination of mass in the practice of medicine for weighing patients for the purposes of monitoring diagnosis and medical treatment;

(e) the determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories; and

(f) the determination of price on the basis of mass for the purposes of direct sales to the public and the making up of prepackages.

(3) Part 4 applies to a non-automatic weighing instrument that is not a regulated instrument.

Revocations and consequential provisions

4.—(1) The Non-automatic Weighing Instruments Regulations 2000 and the Non-automatic Weighing Instruments (Amendment) Regulations 2008 are revoked.

(2) In this regulation, "the former law" means the Regulations referred to in paragraph (1).

(3) This paragraph applies to a non-automatic weighing instrument placed on the market before the commencement date which—

(a) was required by any provision of the former law to meet the essential requirements; and

(b) would be a regulated instrument if it were placed on the market on or after the commencement date.

(4) An instrument to which paragraph (2) applies which meets the requirements of the former law applicable to it is to be treated as meeting the requirements of these Regulations.

(5) Where an instrument to which paragraph (2) applies does not meet the requirements of the former law it shall be treated as not meeting the requirements of these Regulations and these Regulations apply to that instrument as they apply to a regulated instrument placed on the market or put into use after the commencement date which does not comply with the requirements of these Regulations.

(6) Part 6 (Use for trade of regulated instruments) applies to instruments to which paragraph (2) applies as it applies to a regulated instrument placed on the market or put into use after the commencement date.

(7) A certificate granted under any provision of the former law has effect as if granted under the corresponding provision of these Regulations.

(8) In the list in paragraph 10 in Schedule 5 to the Consumer Rights Act 2015(**a**) insert the following entry—

"regulation 65 of the Non-automatic Weighing Instruments Regulations 2016".

(9) In the Electromagnetic Compatibility Regulations 2006, in Schedule 4, add the following entry—

"Directive 2014/31/EU of the European Parliament and of the Council of 26th February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments"

Exception for trade fairs, exhibitions and demonstration

5. Nothing in these Regulations prevents the showing and use of a regulated instrument which is not in conformity with Part 2, at a trade fair, exhibition or demonstration for the marketing of regulated instruments, provided that a visible sign clearly indicates—

(a) the name and date of the trade fair or exhibition;

(b) that the instrument is not in conformity with Part 2; and

(c) that the instrument is not available for sale until brought into conformity with Part 2.

PART 2

NON-AUTOMATIC WEIGHING INSTRUMENTS – OBLIGATIONS OF ECONOMIC OPERATORS

CHAPTER 1

OBLIGATIONS OF MANUFACTURERS AND PERSONS TO BE TREATED AS MANUFACTURERS

Introductory

6.—(1) This Chapter applies in relation to the placing on the market or the putting into use of a regulated instrument by a manufacturer.

(2) The obligations in this Chapter also apply to an importer or distributor who—

(a) places a regulated instrument on the market under the name or trade mark of that importer or distributor; or

(b) modifies a regulated instrument already placed on the market in such a way that compliance with these Regulations may be affected,

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

Manufacturers' responsibilities – design, conformity assessment and marking of instruments

7. A manufacturer must not place on the market or put into use a regulated instrument unless the manufacturer has—

(a) designed and manufactured the instrument in accordance with the essential requirements;

(b) drawn up technical documentation in relation to the instrument;

(c) carried out (or procured the carrying out of) the relevant conformity assessment procedure which has demonstrated compliance of the instrument with the applicable requirements;

(d) drawn up an EU declaration of conformity; and

(**a**) 2015 c.15.

(e) affixed to the instrument—

(i) the CE marking;

(ii) the M marking; and

(iii) the number of the notified body which carried out the conformity assessment procedure in respect of the instrument.

Manufacturers' obligations in respect of records

8. A manufacturer must keep the technical documentation and the EU declaration of conformity for a period of 10 years beginning with the day after the day on which the instrument to which it relates has been placed on the market.

Manufacturers' obligations to ensure continuing conformity with the essential requirements

9.—(1) Manufacturers must have procedures in place for series production of instruments by them to ensure that instruments so manufactured continue to meet the essential requirements.

(2) These procedures must be sufficient adequately to take account of changes in—

(a) instrument design or characteristics; and

(b) changes in the harmonised standards or in other technical specifications by reference to which the conformity of the instrument is declared.

(3) When deemed appropriate with regard to the risks presented by the use of a regulated instrument for any of the purposes mentioned in regulation 3(2), a manufacturer must—

(a) carry out sample testing of instruments made available by him on the market;

(b) investigate complaints about instruments made available by him on the market;

(c) if necessary, keep a register of—

(i) such complaints;

(ii) non-conforming instruments; and

(iii) regulated instrument recalls; and

(d) keep distributors informed of any monitoring action the manufacturer has undertaken.

Manufacturers' obligations in relation to the marking of instruments with serial numbers etc.

10.—(1) A manufacturer must ensure that a regulated instrument, which that manufacturer has placed on the market, bears a type, batch, serial number or other element allowing identification of the instrument.

(2) A manufacturer must ensure that a regulated instrument is marked with the information specified in Schedule 1.

Manufacturers to mark contact details on instruments

11.—(1) A manufacturer must indicate on instruments manufactured by that manufacturer, the manufacturer's name, registered trade name or registered trade mark and the postal address at which the manufacturer can be contacted.

(2) The address required by these Regulations must indicate a single point at which the manufacturer can be contacted.

(3) The contact details required by these Regulations must be in a language easily understood by end-users and market surveillance authorities.

Documentation to accompany regulated instruments

12.—(1) A manufacturer must ensure that instruments manufactured by that manufacturer are accompanied by instructions and information easily understood by end-users.

(2) For instruments placed on the market, made available or put into use in the United Kingdom those instructions and information must be in English.

(3) Such instructions, information and any labelling relating to an instrument must be clear, understandable and intelligible.

Action to be taken where regulated instrument placed on the market not in conformity with essential requirements

13.—(1) This regulation applies where a manufacturer considers or has reason to believe that a regulated instrument placed on the market by that manufacturer is not in conformity with the requirements of these Regulations.

(2) The manufacturer must immediately take the corrective measures necessary to bring the instrument into conformity, or withdraw or recall it, if appropriate.

(3) Where the instrument presents a risk, the manufacturer must immediately inform the competent national authorities of the Member States in which the instrument has been made available on the market to that effect giving details, in particular, of the non-compliance and of any corrective measures taken.

Provision of information to the competent authority

14.—(1) A manufacturer must, further to a reasoned request from a competent authority, provide that authority, within such period as the authority may require, with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the instrument with the requirements of the Directive.

(2) Information supplied pursuant to this regulation must be supplied in English.

(3) A manufacturer must co-operate with a competent authority, at the request of that authority, on any action to eliminate the risks posed by instruments that the manufacturer has placed on the market.

Use of authorised representatives by manufacturers

15.—(1) A manufacturer may, by written mandate, appoint an authorised representative to discharge the responsibilities of that manufacturer under these Regulations.

(2) The authorised representative does not have the power to discharge the manufacturer's obligations under regulations 7(a) and 7(b).

(3) The authorised representative must be treated as authorised to—

(a) keep the EU declaration of conformity and the technical documentation at the disposal of the competent surveillance authority for 10 years after the regulated instrument has been placed on the market;

(b) further to a reasoned request from a competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an instrument; and

(c) co-operate with a competent authority, at its request, on any action taken to eliminate the risks posed by regulated instruments covered by the mandate of appointment given to the authorised representative by the manufacturer.

Offences by manufacturers

16. A manufacturer is guilty of an offence if the manufacturer contravenes—

(a) regulation 7 (manufacturers' responsibilities – design, conformity assessment and marking of instruments);

(b) regulation 8 (manufacturers' obligations in respect of records);

(c) regulation 9 (manufacturers' obligations to ensure continuing conformity with the essential requirements);

(d) regulation 10 (manufacturers' obligations in relation to the marking of instruments with serial numbers etc.);

(e) regulation 11 (manufacturers to mark contact details on instruments);

(f) regulation 12 (documentation to accompany regulated instruments);

(g) regulation 13 (action to be taken where regulated instrument placed on the market not in conformity with essential requirements); or

(h) regulation 14 (provision of information to the competent authority).

CHAPTER 2

OBLIGATIONS OF IMPORTERS

Introductory

17. This chapter applies to the placing on the market or the putting into use of a regulated instrument from a country outside the European Union that is imported into the United Kingdom.

Ensuring compliance of instruments

18.—(1) An importer must only place compliant measuring instruments on the market.

(2) An importer must ensure that—

(a) the appropriate conformity assessment procedure has been carried out by the manufacturer of the instrument (or by the importer where the importer is to be regarded as the manufacturer by virtue of Chapter 1);

(b) the manufacturer has drawn up the technical documentation (or that the importer has done so where the importer is treated as the manufacturer by virtue of Chapter 1) ;

(c) the regulated instrument bears the CE marking and the M marking;

(d) the regulated instrument is accompanied by a copy of the EU declaration of conformity and the documents referred to in regulation 12; and

(e) the manufacturer (or the importer where he is treated as the manufacturer) has complied with the requirements of regulations 10 (manufacturers' obligations in relation to the marking of instruments with serial numbers) and 11 (manufacturers to mark contact details on instruments where possible).

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

19. Where an importer considers, or has reason to believe, that the instrument is not in conformity with the essential requirements and presents a risk, the importer must inform the manufacturer and the market surveillance authorities.

Requirements to mark importers' details on instruments

20.—(1) An importer must indicate on any instrument imported by that importer, the importer's name, registered trade name or trademark, and the postal address at which the importer can be contacted.

(2) Where this would require the packaging to be opened, those indications may be given on the packaging and in a document accompanying the instrument.

(3) Any contact details must be written in a language that is easily understood by end-users of the regulated instrument and market surveillance authorities.

Importers' duty to ensure that regulated instruments are accompanied by relevant documentation

21. Importers must ensure that instruments imported by them are accompanied by instructions and information in accordance with point 9.3 of Annex 1 in a language that is easily understood by end-users of the instrument.

Duty of importers to ensure proper conditions of storage and transport

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

Duties of importers with regard to monitoring etc.

23.—(1) When deemed appropriate with regard to the performance of an instrument imported by an importer, the importer must—

(a) carry out a sample testing of regulated instruments made available on the market by the importer;

(b) investigate complaints about instruments imported by them; and

(c) if necessary, keep a register of—

(i) complaints;

(ii) any instrument that does not conform to the requirements of these Regulations; and

(iii) any recall of an instrument; and

(d) where the importer is not also the distributor of the instrument, keep distributors, to whom he has supplied an instrument, informed of any monitoring undertaken by that importer.

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

24.—(1) This regulation applies where an importer considers, or has reason to believe, that an instrument placed on the market by him is not in conformity with the requirements of these Regulations.

(2) Where this regulation applies, the importer must immediately take the corrective measures necessary to bring the instrument into conformity, or withdraw or recall it, if appropriate.

(3) Where the instrument presents a risk, the importer must immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that importer.

Requirement for importer to keep copy of EU declaration of conformity

25. The importer must, for a period of 10 years beginning with the day after the day on which the instrument is placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities upon request.

Provision of information to the competent authority

26.—(1) The importer must, further to a reasoned opinion from a competent authority, provide that authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the instrument with the requirements of these Regulations.

(2) Information and documentation supplied to a United Kingdom competent authority pursuant to this regulation must be supplied English.

(3) An importer must co-operate with a competent authority, at the request of that authority, as regards any action to eliminate the risks posed by any instrument that the importer has placed on the market.

Offences by importers

27. An importer is guilty of an offence if the importer contravenes—

(a) regulation 18 (ensuring compliance of instruments);

(b) regulation 19 (importers duty to notify manufacturer and market surveillance authorities of non-compliant instruments that present a risk);

(c) regulation 20 (requirements to mark importers' details on instruments);

(d) regulation 21 (importers' duty to ensure that regulated instruments are accompanied by relevant documentation);

(e) regulation 22 (duty of importers to ensure proper conditions of storage and transport);

(f) regulation 23 (duties of importers with regard to monitoring etc);

(g) regulation 24 (action to be taken by importers where regulated instruments placed on the market by them are not in conformity with essential requirements);

(h) regulation 25 (requirement for importer to keep copy of EU declaration of conformity); or

(i) regulation 26 (provision of information to the competent authority).

CHAPTER 3

OBLIGATIONS OF DISTRIBUTORS

Introductory

28. This chapter applies in relation to the making available on the market of an instrument by a distributor.

Distributors – duty to act with due care

29. Before making the instrument available on the market , the distributor must act with due care in relation to the requirements of these Regulations.

Distributors – verification obligations

30.—(1) The distributor must verify in the case of a regulated instrument that the instrument bears the CE marking and the M marking.

(2) The distributor must verify that in the case of a regulated the instrument is accompanied by—

(a) a copy of the EU declaration of conformity relating to it;

(b) a copy of the technical documentation relating to it; and

(c) instructions for use relating to it.

(3) Information supplied in accordance with this regulation must be in a language that can be easily understood by end-users.

(4) The distributor must verify that the manufacturer and the importer have complied with the requirements set out in regulation 10 (manufacturers' obligations in relation to the marking of instruments with serial numbers etc.), 11(manufacturers to mark contact details on instruments) and 20 (requirements to mark importers' details on instruments).

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

31.—(1) This regulation applies where a distributors considers, or has reason to believe, that a regulated instrument is not in conformity with the essential requirements.

(2) Where this regulation applies, the distributor must not make the instrument available on the market until it has been brought into conformity.

(3) Where the instrument presents a risk, the distributor must immediately inform—

(a) the manufacturer;

(b) importer (where the distributor is not also the manufacturer or importer); and

(c) the market surveillance authorities,

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

Duty of distributors to ensure proper conditions of storage and transport

32. A distributor must, in respect of instruments under his responsibility, ensure that the conditions of their storage or transport are not such as to jeopardise their continuing compliance with the essential requirements.

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

33.—(1) This regulation applies where a distributor considers, or has reason to believe, that an instrument placed on the market by him is not in conformity with the requirements of these Regulations.

(2) Where this regulation applies, the distributor must immediately take the corrective measures necessary to bring the instrument into conformity or withdraw or recall it, if appropriate.

(3) Where the instrument presents a risk, the distributor must immediately inform the competent authority to that effect, giving details, in particular, of the non-compliance of the instrument and of the corrective measures taken by that importer.

Provision of information to the competent authority

34.—(1) The distributor must, further to a reasoned opinion from a competent authority, provide that authority with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the instrument with the requirements of these Regulations.

(2) Information and documentation supplied to a competent authority in the United Kingdom pursuant to this regulation must be supplied English.

(3) An importer must co-operate with a competent authority, at the request of that authority, as regards any action to eliminate the risks posed by any instrument that the importer has placed on the market.

Offences by distributors

35. A distributor is guilty of an offence if he contravenes any of the requirements of—

(a) Regulation 29 (distributors – duty to act with due care)

(b) regulation 30 (distributors – verification obligations);

(c) regulation 31 (distributors not to make non-conforming instruments available on the market etc.);

(d) regulation 32 (duty of distributors to ensure proper conditions of storage and transport);

(e) regulation 33 (action to be taken by distributors where regulated instruments placed on the market by them are not in conformity with essential requirements);

(f) regulation 34 (provision of information to the competent authority).

CHAPTER 4

IDENTIFICATION OF ECONOMIC OPERATORS

36.—(1) Economic operators must, on request, identify to the market surveillance authorities—

(a) any economic operator who has supplied them with an instrument; and

(b) any economic operator to whom they have supplied an instrument.

(2) Economic operators must be able to present such information for 10 years after they have been supplied with the instrument and for 10 years after they have supplied the instrument.

(3) An economic operator who contravenes this regulation is guilty of an offence.

PART 3

CONFORMITY OF INSTRUMENTS

CHAPTER 1

ESTABLISHING COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

Introductory

37. This chapter applies for the purposes of establishing whether an instrument complies with the essential requirements.

Methods of establishing conformity with the essential requirements

38. Conformity with the essential requirements may be established in relation to an instrument—

(a) through conformity with harmonised standards or parts of those standards covering the essential requirements where the harmonised standards have been published in the Official Journal of the European Union; or

(b) the use by the manufacturer of any other technical solution that complies with the essential requirements.

Presumptions of conformity of regulated instruments

39. Instruments which are in conformity with harmonised standards (or parts of those standards) shall be presumed to be in conformity with the essential requirements covered by those standards (or parts of those standards).

Conformity assessment procedures

40.—(1) The conformity of instruments to the essential requirements set out in Annex I to the Directive may, subject to paragraph (2), be established by either of the following conformity assessment procedures as selected by the manufacturer:

(a) Module B as set out in point 1 of Annex II to the Directive followed by either—

(i) Module D as set out in point 2 of Annex II; or

(ii) Module F as set out in point 4 of Annex II; or

(b) Module G as set out in point 6 of Annex II.

(2) Module B is not compulsory for instruments which—

(a) do not use electronic devices; and

(b) the load measuring device of which does not use a spring to balance the load.

(3) Where under paragraph (2) an instrument is not submitted to Module B, either of the following modules must be applied—

(a) Module D1 as set out in point 3 of Annex II; or

(b) Module F1 as set out in point 5 of Annex II.

(4) A notified body must in relation to the conformity assessment procedure selected by the manufacturer act in accordance with the requirements of Schedule 2.

(5) The documents and correspondence relating to the conformity assessment procedures referred to in this regulation, and which are carried out in the United Kingdom, must be drawn up in English.

Fees

41.—(1) A United Kingdom notified body may charge fees in connection with, or incidental to, the carrying out of conformity assessment procedures or specific tasks as it may determine.

(2) Those fees must not exceed the following—

(a) the costs incurred or to be incurred by the United Kingdom notified body in performing the relevant function; and

(b) an amount on account of profit which is reasonable in the circumstances having regard to—

(i) the character and extent of the work done or to be done by that notified body on behalf of the applicant; and

(ii) the commercial rate normally charged on account of profit for that work or similar work.

(3) The power in paragraph (1) includes the power to require payment of fees or a reasonable estimate of such fees in advance of carrying out the work requested by the applicant.

(4) Where any fees payable to a United Kingdom notified body pursuant to this regulation remain unpaid 28 days after either the work has been requested or payment o

(5) f the fees has been requested in writing, whichever is the later, the notified body may by 14 days' notice in writing provide that, unless the fees are paid before the expiry of the notice, the certificate or notification appropriate to the relevant conformity assessment procedure may be suspended until payment of the fees has been received.

(6) This regulation does not apply to the Secretary of State

CHAPTER 2

REQUIREMENTS RELATING TO EU DECLARATIONS OF CONFORMITY

Application of chapter

42. This chapter applies in relation to EU declarations of conformity made in relation to an instrument for the purposes of these Regulations.

Requirement to state fulfilment of essential requirements

43. The EU declaration of conformity must state that the essential requirements have been met in relation to the instrument.

Form of EU declaration of conformity etc.

44.—(1) The EU declaration of conformity must be in the format set out in Annex IV to the Directive.

(2) The EU declaration of conformity must contain the elements specified in the relevant modules set out in Annex II to the Directive and must be updated when appropriate.

(3) The EU declaration of conformity must be in the language or languages required by the Member State in which the instrument is placed or made available on the market.

Regulated instruments that require more than one declaration of conformity

45.—(1) This regulation applies where an instrument is subject to a requirement of European Union Legislation for an EU declaration of conformity otherwise than by virtue of these Regulations.

(2) Where this regulation applies, a single EU declaration of conformity must be drawn up covering all applicable requirements which identifies the Union acts concerned including their publication references.

Responsibility of manufacturer that draws up declaration of conformity

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

CHAPTER 3

CONFORMITY MARKING

Conformity with Directive requirements to be indicated by the CE marking

47. The conformity of a regulated instrument with the requirements of these Regulations (and the provisions of the Directive applied by these Regulations) must be indicated by the presence on it of the CE marking and the M marking.

General principles relating to the M marking

48.—(1) The M marking must consist of the capital letter 'M' and the last two digits of the year of its affixing surrounded by a rectangle, the height of which is equal to that of the CE marking applied to that instrument.

(2) The general principles set out in article 30 of Regulation (EC) No 265 apply to the M marking with such modifications as are necessary in the circumstances.

Rules and conditions for affixing the CE marking and the M marking etc.

49.—(1) The CE marking and M marking ("the markings") must be affixed to an instrument in accordance with the provisions of this regulation.

(2) The markings must be affixed visibly, legibly and indelibly to the instrument or its data plate.

(3) The markings must be affixed before the instrument is placed on the market.

(4) The markings may be affixed to the instrument during the fabrication process, if justified.

(5) The M marking must immediately follow the CE marking.

(6) The markings must immediately be followed by the identification of the notified body where that body is involved in the production control phase as set out in Annex II to the Directive

(7) The identification number of the notified body which carried out the conformity assessment procedure must be affixed by the body itself, or under its instructions by the manufacturer or his authorised representative.

PART 4

REQUIREMENTS FOR NON-REGULATED NON-AUTOMATIC WEIGHING INSTRUMENTS

50.—(1) A non-regulated instrument must be marked legibly and indelibly with the following information—

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

(b) the maximum capacity of the instrument, in the form "Max…..".

(2) A non-regulated instrument must not bear the conformity assessment marking for a regulated instrument.

PART 5

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Introductory

51.—(1) This Part applies to the notification of conformity assessment bodies in relation to regulated instruments in the United Kingdom to the Commission and other Member States.

(2) For the purposes of this Part, a notified body is a conformity assessment body—

(a) which has been notified to the Commission and to other member States in accordance with the Directive; and

(b) in respect of which no objections are raised by the Commission or other member States—

(i) within 2 weeks of a notification, where an accreditation certificate is used; or

(ii) within 2 months of a notification, where accreditation is not used.

(3) Paragraph (2) has effect subject to regulation 58 (changes to notifications).

The notifying authority

52.—(1) The notifying authority for the purposes of these Regulations is the Secretary of State.

(2) The functions of the notifying authority are—

(a) to assess whether applicants for recognition as conformity assessment bodies meet the requirements for recognition as such;

(b) where an assessment that a body is qualified to act as a conformity assessment body is made, to notify the Commission of the European Union of that fact; and

(c) to carry out such monitoring of bodies notified to the Commission to ensure continuing compliance with the requirements of these Regulations.

(3) The notifying authority may delegate the performance of its functions to a body that meets the requirements of Articles 24(3) and 25 of the Directive but in the event of such a delegation the notifying authority remains fully responsible for the performance of those functions.

Notification

53.—(1) The Secretary of State may notify to the Commission and the other member States only those conformity assessment bodies that qualify for notification.

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

(3) The first condition is that the conformity assessment body makes an application to the Secretary of State for notification and that application is accompanied by—

(a) a description of—

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

(ii) the conformity assessment module for which the conformity assessment body claims to be competent; and

(iii) the regulated instrument in respect of which the conformity assessment body claims to be competent; and either

(b) an accreditation certificate; or

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

(4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the requirements of Schedule 3 ("the notified body requirements").

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

(6) When deciding whether to notify a conformity assessment body that qualifies for notification to the Commission and the other member States, the Secretary of State may—

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

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

(7) The Secretary of State must inform the Commission of the United Kingdom's procedures for the assessment and notification of conformity assessment bodies, and any changes to those procedures.

Presumption of conformity of notified bodies

54.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a harmonised standard (or part of such a standard), the reference of which has been published in the Official Journal of the European Union, the Secretary of State is to presume that the conformity assessment body meets the notified body requirements covered by that standard (or part of that standard).

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

Contents of notification

55. A notification under regulation 44 must include—

(a) details of—

(i) the conformity assessment activities in respect of which the conformity assessment body has made its application for notification;

(ii) the conformity assessment module in respect of which the conformity assessment body has made its application for notification;

(iii) the regulated instrument in respect of which the conformity assessment body has made its application for notification; and either

(b) an accreditation certificate; or

(c) documentary evidence which attests to—

(i) the conformity assessment body's competence; and

(ii) the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to meet the notified body requirements.

Monitoring

56.—(1) The Secretary of State must monitor each notified body with a view to verifying that the notified body—

(a) continues to meet the notified body requirements;

(b) meets any conditions set in accordance with regulation 53(6)(b); and

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

(2) The Secretary of State must inform the Commission of the United Kingdom's procedures for the monitoring of notified bodies, and any changes to those procedures.

Delegation to the United Kingdom Accreditation Service

57. The Secretary of State may authorise the United Kingdom Accreditation Service to carry out the following activities on behalf of the Secretary of State—

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

(b) monitoring notified bodies.

Changes to notifications

58.—(1) Where the Secretary of State determines that a notified body no longer meets a notified body requirement, or that it is failing to fulfil any of its obligations under these Regulations other than conditions set in accordance with regulation 53(6)(b), the Secretary of State must restrict, suspend or withdraw the body's status as a notified body under regulation 51.

(2) With the consent of a notified body, or where the Secretary of State determines that a notified body no longer meets a condition set in accordance with regulation 53(6)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a notified body under regulation 43.

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

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

(a) give notice in writing that the Secretary of State intends to take such action and the reasons for taking such action; and

(b) give the notified body an opportunity to make representations within a reasonable period from the date of that notice and consider any such representations.

(5) Where the Secretary of State takes action under paragraph (1) or (2), the Secretary of State must immediately inform the Commission and the other member States.

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

(a) on the request of the Secretary of State, transfer its files (including the register which it maintains under paragraph 5 of Schedule 6 (operational obligations of notified bodies)) to another notified body or to the Secretary of State; or

(b) in the absence of a request under sub-paragraph (a), ensure that its files are kept available for the Secretary of State and each enforcing authority for a period equal to that specified in paragraphs 5 and 6 of Schedule 6.

PART 6

USE FOR TRADE OF REGULATED INSTRUMENTS

59. Schedule 4 applies to the use for trade of regulated instruments.

PART 7

UNAUTHORISED APPLICATION OF AUTHORISED MARKS

Unauthorised application of authorised marks

60.—(1) A person is guilty of an offence if, in the case of an instrument, he—

(a) affixes an authorised mark to the instrument otherwise than in accordance with these Regulations;

(b) alters or defaces an authorised mark affixed to the instrument;

(c) removes an authorised mark affixed to the instrument; or

(d) affixes any other marking to the instrument which is likely to deceive any person as to the meaning or form, or both, of an authorised mark.

(2) Where the alteration or defacement of an authorised mark is occasioned solely—

(a) in the course of the adjustment or repair of an instrument by a person regularly engaged in the business of repair of such instruments, or by his authorised agent; or

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

that person or his authorised agent, enforcement officer or approved verifier shall not be guilty of an offence under paragraph (1)(b).

(3) A person shall be guilty of an offence if he places on the market, puts into use or uses for trade an instrument—

(a) which, to his knowledge, bears—

(i) an authorised mark affixed otherwise than in accordance with these Regulations;

(ii) an authorised mark that has been altered or defaced otherwise than in the circumstances referred to in paragraph (2);

(iii) any marking which is likely to deceive any person as to the meaning or form, or both, of an authorised mark; or

(b) from which, to his knowledge, an authorised mark has been removed.

(4) An instrument in respect of which an offence under this regulation has been committed and any implement used in the commissioning of the offence shall be liable to be forfeited.

(5) A reference in this regulation to other provisions of these Regulations includes a reference to corresponding provisions under the laws of other member States.

(6) In this regulation, "authorised mark" means the CE marking, the M marking, the identification number of the notified body which carried out the conformity assessment procedure in respect of the instrument, disqualification mark or re-qualification mark.

PART 8

MARKET SURVEILLANCE AND ENFORCEMENT

CHAPTER 1

MARKET SURVEILLANCE

The market surveillance authority

61. The Secretary of State is the market surveillance authority for the purposes of these Regulations and RAMS and, where the context so requires, market surveillance authority includes a body designated as such in another member State in accordance with the Directive.

Instruments presenting a risk

62.—(1) This regulation applies where the market surveillance authority has sufficient reason to believe that a regulated instrument presents a risk in relation to any of the purposes set out in regulation 3(2).

(2) Where this regulation applies the market surveillance authority must carry out an evaluation of the regulated instrument covering all relevant requirements of these Regulations which apply to that instrument.

(3) The relevant market operators in relation to the instrument must co-operate as necessary with the market surveillance authority for that purpose.

(4) Where, in the course of the evaluation referred to in paragraph (2), the market surveillance authority finds that that the regulated instrument does not comply with the essential requirements applicable to it, it must without delay issue a direction which requires the relevant economic operator to—

(a) take all appropriate corrective actions;

(b) withdraw the regulated instrument from the market; or

(c) recall it within a reasonable period commensurate with the nature of the risk.

(5) Where the market surveillance authority acts under paragraph (4) it must without delay inform the notified body that carried out the conformity assessment procedure in respect of the regulated instrument of—

(a) the respect in which the regulated instrument is not in conformity with the requirements of these Regulations; and

(b) the actions that the authority is requiring the relevant economic operator to take.

(6) Where the market surveillance authority considers that non-compliance is not restricted to the United Kingdom, it must inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

(7) The economic operator must ensure that all appropriate corrective action is taken in respect of all the regulated instruments concerned that it has made available on the market throughout the European Union.

(8) Where the relevant economic operator does not take adequate corrective action within a reasonable period, the market surveillance authority must take all provisional measures to prohibit or restrict the regulated instrument being made available on their national market, to withdraw the regulated instrument from that market or to recall it.

Compliant regulated instruments which present a risk

63.—(1) This regulation applies where, having carried out an evaluation under regulation 62, the market surveillance authority finds that although a regulated instrument is in compliance with the requirements of these Regulations, it presents a risk on grounds of public interest, public health,

public safety, public order, protection of the environment, protection of consumers, the levying of taxes and duties or fair trading.

(2) Where this regulation applies, the market surveillance authority must issue a direction requiring the economic operator to—

(a) take all appropriate measures to ensure that the instrument concerned, when placed on the market, no longer presents that risk;

(b) withdraw the instrument from the market; or

(c) recall it within a reasonable period, commensurate with the nature of the risk as it may prescribe.

(3) Where this regulation applies, the market surveillance authority must immediately inform the Commission and the other Member states of all available details including—

(a) the data necessary for the identification of the regulated instrument concerned;

(b) the origin and supply chain of the regulated instrument;

(c) the nature of the risk involved; and

(d) the nature and duration of the national measures taken.

Provisions as to directions under regulations 62 and 63

64.—(1) This regulation applies in relation to directions given under regulations 62 and 63.

(2) A direction must—

(a) be in writing;

(b) describe the instrument to which it relates in a manner sufficient to identify that instrument;

(c) specify the risk identified by the market surveillance authority; and

(d) specify the steps that the economic operator must take (including the time period within which they must be taken).

(3) An economic operator who fails to comply with a direction given under regulation 62 or 63 is guilty of an offence.

CHAPTER 2

ENFORCEMENT OTHER THAN MARKET SURVEILLANCE

Enforcement authority

65.—(1) In Great Britain, it is the duty of every local weights and measures authority to enforce these Regulations within its area.

(2) In Northern Ireland, it is the duty of the Department of Enterprise, Trade and Investment to enforce these Regulations except for Part 6.

(3) The Secretary of State may otherwise than in the capacity of market surveillance authority enforce these Regulations and for that purpose may appoint any person to act on his behalf.

(4) No proceedings for an offence under these Regulations may be instituted in England and Wales except by or on behalf of an enforcement authority.

(5) Nothing in these Regulations shall authorise an enforcement authority to bring proceedings in Scotland for an offence.

(6) No proceedings shall be instituted in Northern Ireland for an offence under these Regulations in respect of a regulated measuring instrument except—

(a) by or on behalf of an enforcement authority which has responsibility for enforcing these Regulations in respect of that regulated measuring instrument; or

(b) the Director of Public Prosecutions for Northern Ireland.

Compliance notice procedure

66.—(1) This regulation applies where an enforcement authority has reasonable grounds for considering that any of the following applies to a regulated instrument—

(a) the CE marking or the M marking has been affixed in violation of Article 30 of the RAMS Regulation of the requirements of these Regulations;

(b) the CE marking or the supplementary metrology marking has not been affixed;

(c) the identification number of the notified body, where the body is involved in the production control phase has—

(i) been affixed otherwise than in accordance with the requirements of these Regulations; or

(ii) not been affixed;

(d) the EU declaration of conformity does not accompany the regulated instrument;

(e) the EU declaration of conformity has not been drawn up correctly;

(f) the technical documentation is either not available or is not complete;

(g) the information referred to in Article 8(6) or Article 10(3) is absent false or incomplete; or

(h) there is any other breach of the requirements of Article 8 or Article 10 of the Directive.

(2) The enforcement authority shall serve a compliance notice on the manufacturer or his authorised representative which must—

(a) be in writing;

(b) describe the instrument to which it relates in a manner sufficient to identify that instrument;

(c) specify which of the circumstances in paragraph (1) applies in relation to the regulated instrument;

(d) require the person on whom the notice is served to take steps to remedy the matters referred to in paragraph (c);

(e) specify the date, being not less than 21 days from the date of the notice, by which the infringement must be ended; and

(f) warn that person that, where the non-conformity continues beyond the date specified in sub-paragraph (e), the enforcement authority may take further action under regulation 19 in respect of that instrument.

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

Immediate enforcement action

67.—(1) This regulation applies where an enforcement authority has reasonable grounds for considering that any of the following applies to a regulated measuring instrument—

(a) the manufacturer or his authorised representative has failed to comply with a compliance notice;

(b) the CE marking or the supplementary metrology marking has been affixed in violation of Article 30 of RAMS or of the requirements of these Regulations;

(c) the CE marking or the supplementary metrology marking has not been affixed;

(d) the identification number of the notified body, where the body is involved in the production control phase has—

(i) been affixed otherwise than in accordance with the requirements of these Regulations; or

(ii) not been affixed;

(e) the EU declaration of conformity does not accompany the measuring instrument;

(f) the EU declaration of conformity has not been drawn up correctly;

(g) the technical documentation is either not available or is not complete;

(h) the information referred to in regulation 11 or 20 is absent false or incomplete

(i) there is any other breach of the requirements of Chapters 1 and 2 of Part 2.

(2) The enforcement authority may serve a notice ("an enforcement notice") on the manufacturer or the manufacturer's authorised representative which must—

(a) be in writing;

(b) describe the measuring instrument to which it relates in a manner sufficient to identify that instrument;

(c) specify, with reasons, the respects in which, in the opinion of the enforcement authority the requirements of these Regulations have not been complied with; and

(d) specify the date, being not less than 21 days from the date of the notice, by which the person on which the person to whom the notice is required to comply with it.

(3) A notice under paragraph (2) may—

(a) require the instrument to be withdrawn from the market; or

(b) prohibit or restrict the placing on the market or putting into use of the measuring instrument; and

(c) specify that unless steps are taken which ensure—

(i) that the measuring instrument is compliant with the requirements of these Regulations; or

(ii) that the manufacturer or his authorised representative acts as required under sub-paragraph (a) or (b),

any certificate or notification, issued by a notified body in accordance with the relevant conformity assessment procedure applicable to the measuring instrument that the instrument satisfies the essential requirements, may be withdrawn by that notified body.

(4) Where an enforcement notice is served by an enforcement authority other than the Secretary of State, it shall at the same time as it serves that notice send a copy of the notice to the Secretary of State.

(5) In the case of a certificate or notification referred to in paragraph (3)—

(a) which is granted by a United Kingdom notified body, if the Secretary of State is of the opinion that consideration ought to be given to whether the certificate or notification should be withdrawn, the Secretary of State shall inform that notified body of that fact; and

(b) which is granted under the law of another member State if the Secretary of State is of the opinion that consideration ought to be given to whether the certificate or notification should be withdrawn, the Secretary of State shall inform the relevant competent authority of that fact.

Review of decisions of enforcement authority

68.—(1) Where a decision under regulation 66 or 67 or is given by an enforcement authority other than the Secretary of State, a person who is aggrieved by that decision may, in accordance with paragraphs (2) and (3) apply to the Secretary of State to review the decision; and on such application the Secretary of State may—

(a) hold an inquiry in connection with the decision; and

(b) appoint an assessor for the purposes of assisting him with his review or any such inquiry.

(2) An application under paragraph (1) shall be made by notice in writing to the Secretary of State, and shall be sent to him not later than 21 days after the date of the notice of the decision in respect of which the application for review is sent to the aggrieved person.

(3) A notice of application for review under this regulation shall state the grounds on which the application is made.

(4) The Secretary of State shall, within a reasonable time, inform the aggrieved person and the authority referred to in paragraph (1) in writing of his decision whether to uphold the decision of that authority and—

(a) in a case where he upholds that decision, shall also state the grounds for his decision; and

(b) in a case where he does not uphold that decision, may—

(i) where the review relates to regulation 66 give instructions for the withdrawal of the notice given under paragraph (2) of that regulation; or

(ii) where the review relates to regulation 67, give instructions for the withdrawal of the notice given under paragraph (1) of that regulation.

Disqualification

69.—(1) If it appears to an inspector that a regulated instrument which bears—

(a) the CE marking;

(b) the M marking; and

(c) the identification number of the notified body which carried out the conformity assessment procedure in respect of the instrument is used for any of the purposes listed in regulation 3(2) in circumstances where—

(i) the instrument is no longer conforms to the essential requirements; or

(ii) by reason of any adjustment, alteration, addition, repair or replacement it is likely that the instrument has ceased to be compliant with the essential requirements, or

(iii) the requirements of regulation 59 and Schedule 4 are not met

the inspector may affix a disqualification mark to the instrument.

(2) Where one or more of the markings and identification requirements referred to in paragraph (1) is not affixed to a regulated instrument, the inspector may affix a disqualification mark to the instrument.

(3) Where it appears to the inspector that the nature or degree of non-compliance of the instrument under paragraph (1) is not such that a disqualification mark should be immediately affixed to it, he may give to any person in possession of the instrument a notice requiring the person ensure that the instrument is made to comply with the essential requirements before the expiry of 21 days from the date of the notice or such longer period as may be specified in the notice.

(4) If a notice given under paragraph (3) is not complied with, the inspector shall affix a disqualification mark to the instrument.

(5) Any disqualification mark which is affixed to an instrument under this regulation must be affixed in such a position that it is clearly visible when the instrument is in its regular operating position.

(6) A person is guilty of an offence if he uses for any of the purposes mentioned in regulation 3(2) an instrument to which there is affixed a disqualification mark , unless a re-qualification mark has been affixed to it in accordance with regulation 70.

Re-qualification

70.—(1) This regulation applies where—

(a) a disqualification mark has been affixed to an instrument in accordance with regulation 69;

(b) a notice has been served under regulation 69(3); or

(c) an instrument intended to be used for any of the purposes mentioned in regulation 3(2) in the circumstances referred to in regulation 69(1)(i) to (iii) or (2) but a disqualification mark has not been affixed to the instrument.

(2) A person requiring a re-qualification mark to be affixed to the instrument shall submit it, in such manner as may be directed, to a requalifying authority and provide such assistance as the requalification authority may reasonably require.

(3) For the purposes of this regulation, a requalification authority is

(a) an inspector,

(b) an approved verifier,

(c) a UK approved notified body for module F or F1 or

(d) a manufacturer whose quality system has been approved by a UK notified body under module D or D1 for the purposes of re-qualification.

(4) A requalification authority may affix a re-qualification mark to that instrument or to any sealing device on it if satisfied that the instrument is compliant with—

(a) the essential requirements; and

(b) where it is intended that the instrument is to be used for trade any requirements applicable to that instrument by virtue of Schedule 4.

(5) For the purposes of being satisfied that a re-qualification mark may be affixed to an instrument, a requalification authority may take such steps as he considers appropriate, including testing the instrument by means of such test equipment as he considers appropriate and suitable for the purpose.

(6) There may be charged in respect of any steps taken under paragraph (5) such fees as are reasonable in the circumstances.

(7) The requalification authority shall keep a record of any test carried out under paragraph (5).

(8) Where a re-qualification mark is affixed to an instrument pursuant to paragraph (4), it shall be affixed in such a position that it obliterates as far as possible any disqualification mark.

Testing of instruments

71.—(1) Where an inspector considers that a test of an instrument is necessary, otherwise than for the purposes of regulation 79(4), he may require the person who has control of the instrument, or whom he has reasonable cause to believe has control of the instrument, to provide to him such equipment, test liquid, materials, qualified personnel or other assistance as the inspector may reasonably require.

(2) Every instrument submitted for testing shall be in a clean condition.

Unsuitable use of instruments

72.—(1) This regulation applies to a regulated instrument.

(2) If it appears to an inspector that an instrument used for a purpose mentioned in regulation 3(2)—

(a) for a purpose for which it is unsuitable; or

(b) in circumstances where it is subject to any extraordinary environmental or operating conditions which—

(i) may prevent it operating consistently or accurately; or

(ii) are likely prematurely to degrade its metrological characteristics,

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

PART 9

GENERAL PROVISIONS ABOUT OFFENCES

Penalties for offences

73. A person guilty of an offence under any provision of these Regulations is on summary conviction—

(a) in England and Wales liable to a fine; and

(b) in Scotland or Northern Ireland liable to a fine not exceeding level 5 on the standard scale.

Defence of due diligence

74.—(1) In proceedings against a person for an offence under these Regulations, it shall be a defence for that person to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) Where, in proceedings against a person for such an offence, the defence provided by paragraph (1) involves an allegation that the commission of the offence was due to—

(a) the act or default of another; or

(b) reliance on information given by another,

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

(3) A notice under this regulation shall give such information identifying or assisting in the identification of the person who committed the act or default or gave the information as is in the possession of the person serving the notice at the time he serves it.

(4) A person shall not be entitled to rely on the defence provided by paragraph (1) by reason of his reliance on information supplied by another, unless he shows it was reasonable in all the circumstances for him to have relied on the information, having regard in particular to—

(a) the steps which he took, and those which might reasonably have been taken, for the purpose of verifying the information; and

(b) whether he had any reason to disbelieve the information.

Liability of persons other than the principal offender

75.—(1) Where the commission by a person of an offence under these Regulations is due to the act or default of another person in the course of any business of his, that other person shall be guilty of the offence and may be proceeded against and punished, whether or not proceedings are taken against the first person.

(2) Where a body corporate commits an offence and it is proved that the offence was committed—

(a) with the consent or connivance of an officer of the body corporate; or

(b) as a result of the negligence of an officer of the body corporate,

the officer, as well as the body corporate, shall be guilty of the offence.

(3) In paragraph (2), a reference to an officer of a body corporate includes a reference to—

(a) a director, manager, secretary or other similar officer of the body corporate;

(b) a person purporting to act as a director, manager, secretary or other similar officer; and

(c) if the affairs of the body corporate are managed by its members, a member.

(4) In this regulation, references to a "body corporate" include references to a partnership in Scotland, and in relation to such partnership, any reference to a director, manager, secretary or other similar officer of a body corporate is a reference to a partner.

PART 10

MISCELLANEOUS AND SUPPLEMENTAL

Service of documents

76.—(1) Any document required or authorised by these Regulations to be served on a person may be so served—

(a) by delivering it to him or by leaving it at his proper address or by sending it by post to him at that address;

(b) if the person is a body corporate, by serving it in accordance with sub-paragraph (a) on the secretary or clerk of that body corporate; or

(c) if the person is a partnership, by serving it in accordance with sub-paragraph (a) on a partner or on a person having control or management of the partnership business.

(2) For the purposes of paragraph (1), and for the purposes of section 7 of the Interpretation Act 1978(a) (which relates to the service of documents by post) in its application to that paragraph, the proper address of any person on whom a document is to be served in accordance with these Regulations shall be his last known address except that—

(a) in the case of service on a body corporate or its secretary or clerk, it shall be the address of the registered or principal office of the body corporate; and

(b) in the case of service on a partnership or a partner or a person having the control or management of a partnership business, it shall be the principal office of the partnership,

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

Review

77.—(1) The Secretary of State must from time to time—

(a) carry out a review of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other member States.

(3) The report must, in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved by a system that imposes less regulation.

(4) The first report under this regulation must be published no later than 5 years after the date of the coming into force of these Regulations.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

(**a**) 1978 c.30.

SCHEDULE 1

Regulation 10(2)

INFORMATION TO BE MARKED ON REGULATED INSTRUMENTS

1. The number of the EU-type examination certificate, where appropriate.

2. The manufacturer's name, registered trade name or registered trade mark.

3. The accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles.

4. Maximum capacity, in the form "Max ….".

5. Minimum capacity, in the form "Min …..".

6. Verification scale interval

7. Type, batch and serial number

8. When applicable the following:

(a) for instruments consisting of separate but associated units, the identification mark on each unit;

(b) scale interval if different from e, in the form "d =….";

(c) maximum additive tare effect, in the form "T = +…..";

(d) tare interval if it is different from d, in the form "d_T = ….";

(e) maximum safe load if it is different from "Max….", in the form "Lim….";

(f) the special temperature limits, in the form "...°C/…°C"; and

(g) ration between load receptor and load.

9. The requirements of points 1.2 to 1.5 of the Annex III to the Directive must be complied with.

SCHEDULE 2

Regulation 40(4)

REQUIREMENTS RELATING TO THE CARRYING OUT OF CONFORMITY ASSESSMENT PROCEDURES

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

2. Conformity assessment bodies must perform their activities taking due account of—

(a) the size of an undertaking;

(b) the sector in which it operates and its structure;

(c) the degree of complexity of the of the regulated instrument technology in question; and

(a) the mass or serial nature of the production process.

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

3. Where a notified body finds that the essential requirements have not been met by a manufacturer, it—

(a) must require that manufacturer to take appropriate corrective measures; and

(b) must not issue a certificate of conformity.

4. Where in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a regulated instrument no longer complies, it must require the

manufacturer to take appropriate corrective measures and must suspend or withdraw the certificate if necessary.

5. Where corrective measured are not taken or do not have the required effect, the notified body must restrict, suspend of withdraw any certificates, as appropriate.

6. Where a person is aggrieved at a decision taken by a notified body in relation to the conformity assessment of a measuring instrument, the notified body must have appropriate arrangements for the review of that decision by a person who was not involved in the taking of that decision

7. Notified bodies must inform the notifying authority of the following—

(a) the size of an undertaking;

(b) any refusal, restriction, suspension or withdrawal of a certificate;

(c) any circumstances affecting the scope of or conditions for notification;

(d) any request for information which they have received from market surveillance authorities regarding conformity assessment; and

(e) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

8. Notified bodies must provide other bodies notified under this Directive carrying out similar conformity assessment activities covering the same regulated instruments with relevant information on issues relating to negative and, on request positive conformity assessment results.

9. Notified bodies must—

(a) when requested by the Secretary of State, nominate a representative to attend a group convened by the Commission pursuant to Article 40 of the Directive; and

(b) ensure attendance of that representative at meetings of the group.

SCHEDULE 3

Regulation 53(4)

NOTIFIED BODIES

1. A conformity assessment body must have legal personality.

2. A conformity assessment body must be independent of the organisation or the instrument it assesses. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of instruments which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated be considered such a body.

3. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the instruments that they assess, nor the representative of any of those parties. This provision shall not preclude the use of assessed instruments that are necessary for the operations of the conformity assessment body or the use of such instruments for personal purposes.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those instruments, or represent the parties engaged in those activities. They must not engage in any activity that many conflict with their independent of judgement or integrity in relation to the conformity assessment activities for which they are notified. This also applies to consultancy services.

5. Conformity assessment bodies must ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

6. Conformity assessment bodies and their personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free all pressures and induces, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

7. A conformity assessment body must be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf under its responsibility.

8. At all times and for each conformity assessment procedure and each kind or category of instruments in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary—

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment task;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. The body shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities; and

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question, and the mass or serial nature of the production process.

9. A conformity assessment body must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to all necessary equipment or facilities.

10. The personnel responsible for carrying out conformity assessment tasks must have the following—

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the requirements set out in Annex I, of the applicable harmonised standards, and of the relevant provisions of European Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

11. Conformity assessment bodies, their top-level management and the personal responsible for carrying out conformity assessment tasks shall be impartial in the execution of their functions.

12. The remuneration of the top-level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

13. A conformity assessment body must satisfy the Secretary of State that it has adequate civil liability insurance.

14. The personnel of a conformity assessment body must observe professional secrecy with regard to all information obtained in carry out their tasks under Annex II, except vis- à-vis the Secretary of State. Proprietary rights must be protected.

15. Conformity assessment bodies must participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the European Union harmonisation legislation and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

SCHEDULE 4

Regulation 59

USE FOR TRADE OF REGULATED INSTRUMENTS

Restrictions on use of instruments for trade

1.—(1) An instrument marked with a weighing range may be used for trade for determining the weight of any item by ascertaining the difference between two weights (both of which fall within the weighing range).

(2) Save in accordance with paragraph (1) above, a person must not use for trade an instrument marked with a weighing range for determining a weight outside that range in relation to—

(a) articles made from, gold, silver, platinum or paladium;

(b) precious stones or pearls; or

(c) drugs or other pharmaceutical products.

(3) A person must not use for trade any instrument other than an instrument of accuracy classification Class I or Class II within the meaning of paragraph 2 of Annex 1 to the Directive in any transaction relating—

(a) to, or to articles made from, gold, silver, platinum or paladium;

(b) to precious stones or pearls.

(4) Where a regulated instrument bears a mark which signifies the manner and purpose of use, it must not be used for trade in a manner or for a purpose which does not accord with that marking.

(5) A person must not use a Class IIII instrument for trade for any purpose other than for weighing—

(a) any of the materials to which the expression “ballast” applies in Schedule 4 to the 1985 Act;

(b) any material the disposal of which constitutes a landfill disposal as defined in paragraph (2) of section 70 of the Finance Act 1996, whether or not the disposal amounts to a taxable disposal as defined in section 40 of that Act; or

(c) waste.

(6) A person must not use for trade any instrument for the purpose of multiple weighing, that is to say, determining the mass of a load by totalling the results of more than one static weighing operation during each of which the load is only partially supported by the load receptor.

(7) For the purposes of this paragraph, “waste” means any substance that its holder , discards, or intends or is required to discard, including any waste disposed of for reprocessing or recycling purposes.

Manner of erection of instruments

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

Instruments marked with temperature range

3. Where an instrument is marked with a temperature range, a person must not use the instrument for trade at temperatures outside that range.

Instruments marked with manner of use

4. Where an instrument is marked with the manner of use, a person must not use the instrument for trade in a manner which does not accord with the marking.

Instruments fitted with printing devices

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

Load receptors

6.—(1) A person must not use an instrument for trade unless it is erected and used in such a manner that, during a weighing operation, the load being weighed is stationary relative to the load receptor and supported only by the load receptor.

(2) A person must not use for trade an instrument for the purpose of sales by retail—

(a) unless—

(i) the load receptor is not less than 10 mm above any adjacent surface; or

(ii) where the load receptor is less than 10 mm above any adjacent surface, the boundary of the top surface of all adjacent surfaces is durably marked in a distinctive and contrasting manner with a band at least 15 mm in width; or

(b) if the load receptor is below the level of any adjacent surface.

Operation of instrument

7. A person shall not use an instrument for trade unless it is erected in such a manner that the operator can, readily take up a single position from which he can—

(a) see directly or with the aid of mirrors, closed-circuit television or other permanently installed facilities, the whole of the unladen load receptor;

(b) operate the instrument’s controls; and

(c) obtain a weight reading from the instrument.

Instruments to be set to zero or to be balanced before use

8.—(1) A person must not use an instrument for trade unless it is properly balanced or set to zero immediately prior to use.

(2) Paragraph (1) does not apply in the case of an instrument if it is designed so as not to balance when unloaded.