# 2006 No.

# WEIGHTS AND MEASURES

# The Measuring Instruments (Automatic Discontinuous Totalisers) Regulations 2006

Made	2006
Laid before Parliament	2006
Coming into force	
Regulations 1, 2, 3, 6, 7, 8, 9, 10 Schedules 1, 2, 3, 4 and 5	0, 11, 12 and 13 and 30th April 2006
Remaining regulations	30th October 2006

The Secretary of State, being a Minister designated (a) for the purposes of section 2(2) of the European Communities Act 1972 (b) in relation 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 or for purposes ancillary thereto, in exercise of the powers conferred upon him by that section, and (as respects Part III hereof) of the powers conferred on him by sections 15(1), 86(1) and 94(1) of the Weights and Measures Act 1985 (c) hereby makes the following Regulations:

# PART 1

## PRELIMINARY

#### **Citation and commencement**

**1.**—(1) These Regulations may be cited as the Measuring Instruments (Automatic Discontinuous Totalisers) Regulations 2006.

(2) This regulation, regulations 2, 3, 6, 7, 8, 9, 10, 11, 12 and 13 and Schedules 1, 2, 3, 4 and 5 shall come into force on  $30^{\text{th}}$  April 2006.

(3) The remaining regulations shall come into force on 30th October 2006.

#### Interpretation

2.—(1) In these Regulations—

<sup>(</sup>a) S.I. 1975/427

**<sup>(</sup>b)** 1972 c.68

<sup>(</sup>c) 1985 c.72

"accuracy class" means the classification of an automatic discontinuous totaliser in accordance with the provisions of paragraph 16 of Schedule 1;

"authorised representative" means a natural or legal person who is established in a member State and is authorised by a manufacturer, in writing, to act on his behalf;

"automatic discontinuous totaliser" means an automatic weighing instrument that determines the mass of a bulk product by dividing into discrete loads. The mass of each discrete load is determined in sequence and summed. Each discrete load is then delivered to bulk;

"automatic weighing instrument" means 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 intended to determine the mass of a body by using the action of gravity on that body;

"automatic weighing range" means the range from minimum to maximum capacity;

"CE marking" means the marking -

- (a) referred to as such in the Directive the form of which is prescribed in Schedule 4; or
- (b) affixed under the provisions of the law of another member State corresponding to these Regulations;

"the Commission" means the European Commission;

"compliance notice procedure" means the procedure provided for in regulation 24 or any procedure (however described) invoked by the authorities of another member State for the purposes of obliging the manufacturer or his authorised representative to make an automatic discontinuous totaliser conform to the provisions of the Directive concerning the requirements relating to marking pursuant to regulation 12;

"conformity assessment procedures" means the procedures referred to in regulation 7;

"the Directive" means Directive 2004/22/EC of the European Parliament and of the Council of 31st March 2004 on measuring instruments (c);

"disqualification sticker" means-

(a) a sticker the design of which is published in the United Kingdom by the Secretary of State; or

(b) a sticker, symbol, inscription or other device the design of which is approved in another member State by the competent authority,

and which indicates that the automatic discontinuous totaliser to which it is affixed does not satisfy the essential requirements, or the corresponding provisions under the law of another member State, or regulation 14;

"enforcement authority" means any person who is, pursuant to the provisions of regulation 17, authorised to enforce any Part of these Regulations;

"essential requirements" means the requirements of Annex I and Annex MI-006 as

set out in Schedule 1;

"harmonised standard" means a technical specification adopted by the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI) or jointly by two or all of these organisations, at the request of the Commission pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22nd June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society Services (**a**), as amended by Directive 98/48/EC (**b**) and

<sup>(</sup>a) OJ No. L204, 21.7.98, p.37.

<sup>(</sup>**b**) OJ No. L217, 5.8.98 p.18.

prepared in accordance with the General Guidelines agreed between the Commission and the European standards organisations;

"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;

"load receptor" means a part of an automatic discontinuous totaliser on which loads are placed for the purpose of their being weighed;

"M marking" means the supplementary metrology marking -

- (a) referred to as such in the Directive the form of which is prescribed in Schedule 4; or
- (b) affixed under the provisions of the law of another member State corresponding to these Regulations;

"manufacturer" means a natural or legal person responsible for the conformity of an automatic discontinuous totaliser with these Regulations with a view to either placing it on the market under his own name and/or putting it into use for his own purposes;

"maximum capacity" for the purposes of Part III of these Regulations means the largest discrete load which the automatic discontinuous totaliser is authorised to weigh and that can be weighed automatically on a load receptor;

"maximum permissible errors" means in relation to -

(a) placing on the market of an automatic discontinuous totaliser falling within the accuracy class set out in column 1 of the Table in paragraph 17 of Schedule 1, the error set out in column 2 of that Table in respect of that accuracy class; and

(b) use for trade of an automatic discontinuous totaliser falling within the accuracy class

set out in column 1 of the Table in regulation 14(1)(c), the error set out in column 2 of that

Table in respect of that accuracy class;

"minimum capacity" for the purposes of Part III of these Regulations means the smallest discrete load which the automatic discontinuous totaliser is authorised to weigh and that can be weighed automatically on a load receptor;

"minimum criteria" means the criteria set out in Part 1 of Schedule 3;

"minimum totalised load" means the value of the smallest bulk load that can be totalised without exceeding the maximum permissible error when the automatic operation is comprised of discrete loads, each within the automatic weighing range;

"non-automatic zero-setting device" means a device for setting the indication by an operator;

"normative document" means a document containing technical specifications adopted by the Organisation Internationale de Metrologie Legale (OIML), subject to the procedure stipulated in Article 16.1, the reference of which is for the time being published by the Commission in the Official Journal of the European Communities pursuant to Article 16.1(b);

"notified body" means

(a) the Secretary of State; or

(b) a person designated under regulation 8,

and whose name is notified to the Commission and the member States under Article 11;

"place on the market" means making available for the first time in a member State an instrument intended for an end user, whether for reward or free of charge;

"put into use" means the first use of an instrument intended for the end user for the purposes for which it was intended;

"relevant national standard" means a standard implementing a harmonised standard, the reference number of which is published -

(a) in the United Kingdom by the Secretary of State; or

(b) in another member State by the competent authority pursuant to the third sub-paragraph of Article 13.1;

"relevant normative document" means a normative document, the reference of which is published -

(a) in the United Kingdom by the Secretary of State; or

(b) in another member State by the competent authority pursuant to the third sub-paragraph of Article 13.2;

"re-qualification sticker" means a sticker the design of which is published in the United Kingdom by the Secretary of State and which indicates that the automatic discontinuous totaliser to which it is affixed satisfies the essential requirements;

"semi-automatic zero-setting device" means a device for automatically setting the indication to zero following a manual command;

"totalisation indicating device" means the part of an automatic discontinuous totaliser that indicates the sum of consecutive loads weighed and discharged to bulk;

"totalisation scale interval" means the scale interval of the totalisation indicating device, that is to say the part of an automatic discontinuous totaliser which indicates the sum of all the loads weighed and discharged to bulk; and

"zero-setting device" means a device for setting the indication to zero when there is no load on the load receptor.

(2) Other expressions used in these Regulations have the same meanings as in the Weights and Measures Act  $1985(\mathbf{a})$  or, in Northern Ireland, the Weights and Measures (Northern Ireland) Order 1981 (b).

[(3) For the purposes of these Regulations, a reference to a member State includes Norway, Iceland, Liechtenstein and Switzerland.]

(4) References in these Regulations to an Article, Annex or a part thereof are references to an Article, Annex, or part of an Annex, to the Directive.

#### Application

**3.**—(1) Subject to paragraphs (2) and (3), these Regulations apply to automatic discontinuous totalisers intended for use for trade.

(2) These Regulations do not apply to an automatic discontinuous totaliser -

- (a) in respect of which a certificate of approval has been granted or renewed before 30<sup>th</sup> October 2006 and which is in force; and
- (b) which has been first passed as fit for use for trade and stamped under the Weighing Equipment (Filling and Discontinuous Totalising Automatic Weighing Machines) Regulations 1986 (a).

(3) These Regulations do not apply to any automatic discontinuous totaliser which is presented at any trade fair, exhibition, demonstration or the like and which is not in conformity with the provisions of these Regulations provided a visible sign clearly indicates that the instrument in question does not comply with those provisions and it may not be acquired or used until it has been made to comply with them by the manufacturer.

#### **Transitional provisions**

4.— A certificate of approval referred to in regulation 3(2)(a) and any authorisation of modification to that certificate shall continue to have effect until the expiry of the validity of the certificate.

# PART II

# GENERAL REQUIREMENTS FOR PLACING ON THE MARKET AND PUTTING INTO USE

#### Placing on the market and putting into use of automatic discontinuous totalisers

**5.**—(1) No person shall place on the market or put into use an automatic discontinuous totaliser unless the following requirements, or the corresponding requirements of the Directive as implemented under the law of another member State are met -

(a) the instrument satisfies the essential requirements;

(b) the manufacturer has demonstrated its conformity to the essential requirements; and

(c) the instrument has affixed to it the CE marking, the M marking and the identification number of the relevant notified body in accordance with regulation 12.

(2) A person who fails to comply with paragraph (1) shall be guilty of an offence and any automatic discontinuous totaliser to which the offence relates shall be liable to be forfeited.

#### **Compliance with the essential requirements**

6.--(1) A manufacturer may demonstrate compliance with the essential requirements by -

- (a) using any technical solution that complies with the essential requirements;
- (b) correctly applying solutions set out in the relevant national standard; or
- (c) correctly applying solutions set out in the relevant normative document,

and selecting and following one of the conformity assessment procedures referred to in regulation 7.

(2) An automatic discontinuous totaliser which complies with the relevant national standard or relevant normative document applicable to the instrument shall be presumed to comply with the essential requirements. Where the instrument complies only in part with the relevant national standard or relevant normative document, it shall be presumed to conform only with those parts of the essential requirements which correspond to the elements of the relevant national standard or relevant normative document with which the instrument complies.

(3) In cases where an automatic discontinuous totaliser includes or is connected to a device which is not used for trade, such a device shall not be subject to the essential requirements, and accordingly for the purposes of these Regulations an automatic discontinuous totaliser may be considered to satisfy the essential requirements notwithstanding that the conformity of such a device to the essential requirements has not been established

### **Conformity assessment procedures**

7.—(1) The conformity assessment procedures referred to in regulation 6 are the procedures as follows -

(a) for mechanical systems: B and D, B and E, B and F, D1, F1, G or H1;

(b) for electromechanical instruments: B and D, B and E, B and F, G or H1;

(c) for electronic systems or systems containing software: B and D, B and F, G or H1,

where-

(i) "B" means type examination, as set out in Annex B.

(ii) "D" means declaration of conformity to type based on quality assurance of the production process, as set out in Annex D;

(iii) "D1" means declaration of conformity based on quality assurance of the production process, as set out in Annex D1;

(iv) "E" means declaration of conformity to type based on quality assurance of final product inspection and testing, as set out in Annex E;

(v) "F" means declaration of conformity to type based on product verification, as set out in Annex F;

(vi) "F1" means declaration of conformity based on product verification, as set out in Annex F1;

(vii) "G" means declaration of conformity based on unit verification, as set out in Annex G; and

(viii) "H1" means declaration of conformity based on full quality assurance plus design examination, as set out in Annex H1.

(2) The manufacturer or his authorised representative shall provide to the notified body carrying out the conformity assessment procedure technical documentation as set out in Schedule 2.

#### **Designation of notified bodies**

**8.**—(1) Subject to the following provisions of this regulation, the Secretary of State may, on the application of a person resident, incorporated or carrying on business in the United Kingdom, designate that person to carry out any of the functions of notified bodies under these Regulations.

(2) The Secretary of State shall not make a designation under paragraph (1) unless -

- (a) he is satisfied that the applicant satisfies the minimum criteria; or
- (b) where the designation is in respect of a particular description of automatic discontinuous totaliser, he is satisfied that the applicant meets the minimum criteria in respect of that description of the instrument.

(3) A person who complies with the assessment criteria fixed by a standard which is a relevant harmonised standard within the meaning of Article 11.2 shall be presumed to meet the minimum criteria.

- (4) A designation under this regulation -
  - (a) shall be in writing;
  - (b) may be made subject to such conditions as may be specified in the designation, which may include conditions which -
    - (i) are to apply upon or following termination of the designation;
    - (ii) require the person, whether generally or in specified circumstances, which may include upon the direction of the Secretary of State, to carry out the procedures or specific tasks to which the designation relates;
    - (iii) require the use of test equipment for the purpose of conformity assessment appropriate to the automatic discontinuous totaliser being assessed; and
    - (iv) limit the description of automatic discontinuous totalisers for which the person is designated;
  - (c) subject to regulation 10, may be for the time being or for such period as may be specified in the designation; and
  - (d) shall specify the conformity assessment procedures and specific tasks (which may be framed by reference to any circumstances) which the body has been appointed to carry out.

(5) In exercising the power conferred on him by paragraph (1), the Secretary of State may (in addition to the matters of which he is required to satisfy himself pursuant to paragraph (2)) have regard to any matter appearing to him to be relevant.

(6) Part 2 of Schedule 3 has effect for the purposes of setting out the functions of notified bodies.

#### **Provisions supplemental to regulation 8**

**9**. -(1) The Secretary of State shall, from time to time, publish a list of notified bodies indicating the descriptions of automatic discontinuous totalisers in respect of which each body is authorised; and such a list may include information concerning any condition to which the designation of any notified body is for the time being subject. The Secretary of State shall notify the Commission and the other member States of any person designated under regulation 8.

(2) The Secretary of State shall, from time to time, carry out an inspection of the functions of each notified body with a view to verifying that it -

- (a) meets the minimum criteria;
- (b) complies with any conditions subject to which its designation is authorised; and
- (c) complies with the provisions of these Regulations

but, unless it appears to him that there are circumstances which make it necessary or expedient to do so, he shall not carry out an inspection within two years from the date of designation of the body or any later inspection under this paragraph.

10— (1) The Secretary of State may vary a designation if—

- (a) the notified body so requests; or
- (b) having regard to these Regulations, it appears to him necessary or expedient to do so.

(2) Subject to paragraph (4), the Secretary of State may terminate the designation-

- (a) upon 90 days' notice in writing at the request of the notified body; or
- (b) if it appears to the Secretary of State that any of the conditions of the designation are not complied with; or
- (c) if in his opinion the notified body ceases to satisfy the minimum criteria.

(3) If, for any reason, a designation is terminated under paragraph (2), the Secretary of State may-

(a) give such directions (either to the notified body the subject of the

termination or to another notified body) for the purposes of making arrangements for the determination of outstanding applications as he considers appropriate; and

(b) without prejudice to the generality of the foregoing, authorise another notified body to take over its functions in respect of such cases as he may specify.

(4) Where the Secretary of State is minded to terminate the designation pursuant to paragraph (2), he shall—

- (a) give notice in writing to the body of his reasons; and
- (b) give the body the opportunity to make representations within a period of 21 days of such notice being given and consider any representations made to him within that period.
- (5) In these Regulations—
  - (a) a reference to a notified body includes a reference to another notified body which has taken over the first notified body's functions under regulation 10(3) or the equivalent provisions of the law of another member State; and
  - (b) a reference to the action (howsoever expressed) of either notified body includes a reference to the action of the other notified body.

#### Fees

11—(1) Without prejudice to the power of the Secretary of State, where he is acting as a notified body, to charge fees pursuant to Regulations made under section 56 of the Finance Act 1973(a),

and subject to paragraphs (2) and (4), a notified body other than the Secretary of State may charge such fees in connection with, or incidental to, carrying out the conformity assessment procedures or specific tasks as it may determine, provided that such fees shall not exceed the following—

(a) the costs incurred or to be incurred by the 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 the body on behalf of the applicant; and
- (ii) the commercial rate normally charged on account of profit for that work or similar work.

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

(3) Where any fees payable to a notified body pursuant to this regulation remain unpaid 28 days after either the work has been completed or payment of the fees has been requested in writing, whichever is the later, the 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 will be suspended until payment of the fees has been received.

(4) Without prejudice to the generality of regulation 8(4)(b), the conditions to which a designation under regulation 8 may be subject may include a requirement to publish from time to time the scale of fees which the notified body charges pursuant to this regulation or such information about the basis of calculation of such fees as may be specified in the condition.

#### Marking and identification requirements

12 - (1) Schedule 4 has effect for the purpose of setting out the requirements of these Regulations in relation to the CE marking, the M marking and the identification number of the notified body concerned with the conformity assessment procedure.

(2) The markings referred to in paragraph (1) shall be affixed to an automatic discontinuous totaliser which has been certified pursuant to the conformity assessment procedures as satisfying the essential requirements.

(3) Any other marking may be affixed to an automatic discontinuous totaliser provided that the visibility and legibility of the markings and the identification number referred to in paragraph (1) are not reduced.

#### **Conformity with other directives**

13 —(1) Subject to paragraph (2), where a CE marking is affixed to an automatic discontinuous totaliser, the affixing of that marking shall indicate that the instrument conforms also with any directive other than the Directive which provides for the affixing of the CE marking to that instrument

(2) Where, during a relevant transitional period specified in any such other directive, a manufacturer chooses not to apply provisions adopted pursuant to the directive in question, paragraph (1) shall not apply if that fact and particulars of that directive as published in the Official Journal of the European Communities are stated in the documents, notices or instructions required to accompany the instrument.

# PART III

## USE FOR TRADE OF AUTOMATIC DISCONTINUOUS TOTALISERS

#### **Requirements for use for trade**

14 - No person shall use for trade or possess for use for trade an automatic discontinuous totaliser unless—

(a) the requirements of regulation 15 in respect of its use are complied with;

(b) it has been erected and installed in accordance with the requirements of regulation 16; and

(c) on testing, in the case of an instrument falling within an accuracy class set out in column 1 of the Table below, it falls within the maximum permissible error for that class set out in column 2 of that Table.

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(1) Accuracy class	(2) Maximum permissible error of totalised load
0.2	± 0.2 %
0.5	± 0.5 %
1	± 1.0 %
2	± 2.0 %

#### Manner of use

**15**—(1) Where an automatic discontinuous totaliser is marked with a temperature range, it shall not be used in temperatures outside that range.

(2) Where such an instrument bears a mark which signifies the manner and purpose of use, it shall not be used in a manner or for a purpose which does not accord with that marking.

(3) An automatic discontinuous totaliser shall only be used for trade for the purpose of weighing material the values of which, expressed in units of measurement of mass, are neither-

- (a) less than the value of the minimum totalised load;
- (b) less than the value of the minimum capacity unless processed as the last discrete load of a trade transaction; or
- (c) more than the value of the maximum capacity.
- (4) An automatic discontinuous totaliser shall not be used for trade in such a manner as to cause -
  - (a) spillage of material from the load receptor; or
  - (b) loading of the weighing unit above its maximum capacity.
- (5) An automatic discontinuous totaliser shall not be used for trade in circumstances—
  - (a) in which it may be prevented from operating consistently or accurately; or
  - (b) which are likely prematurely to degrade its metrological characteristics.

#### Manner of erection and installation

**16**—(1) Every automatic discontinuous totaliser shall be so positioned as to facilitate cleaning and testing.

(2) If any special equipment for an automatic discontinuous totaliser, as referred to in paragraph 9.5 of Schedule 1, is not a permanent fixture of the instrument, it shall be kept in the vicinity of the instrument.

(3) An automatic discontinuous totaliser which has either a non-automatic zero-setting device or semi-automatic zero-setting device shall be erected in such a manner that the operator can, notwithstanding the nature of the instrument or its surroundings, readily take up a single position from which he can check the zero and operate the zero setting controls.

# PART IV

## ENFORCEMENT

#### **Enforcement authority**

17—(1) The following authorities shall enforce these Regulations—

- (a) in respect of Part II of these Regulations-
  - (i) a local weights and measures authority; or
  - (ii) any other third party designated to act on behalf of the Secretary of State; and
- (b) in respect of Part III of these Regulations, a local weights and measures authority.
- (2) The Secretary of State may enforce Part II of these Regulations.

(3) No proceedings for an offence under these Regulations may be instituted in England, Wales and Northern Ireland, except by or on behalf of an enforcement authority, and in Northern Ireland, by the Director of Public Prosecutions for Northern Ireland.

(4) Nothing in this regulation shall authorise any enforcement authority to bring proceedings in Scotland for an offence.

#### Unauthorised application of authorised marks

18-(1) Subject to paragraph (2), a person who, in the case of an automatic discontinuous totaliser-

- (a) affixes an authorised mark to the instrument except in accordance with these Regulations;
- (b) contravenes regulation 12;
- (c) forges or counterfeits or in any manner alters or defaces an authorised mark;
- (d) removes an authorised mark affixed to the instrument in accordance with one of the

conformity assessment procedures;

(e) removes a re-qualification sticker and affixes it to another instrument;

(f) makes an alteration to the instrument after an authorised mark has been affixed to it in accordance with these Regulations so that the instrument no longer complies with the requirements of these Regulations; or

(g) affixes any other marking or identification number on the instrument which is likely to deceive third parties as to the meaning and form of the markings and the identification number referred to in regulation 12 (1),

shall be guilty of an offence.

(2) Where the alteration, defacement or removal of an authorised mark is occasioned solely in the course of the adjustment or repair of an automatic discontinuous totaliser by -

(a) a manufacturer of automatic discontinuous totalisers regularly engaged in the business of

repair of such instruments, or by his duly authorised agent; or

(b) a person (other than a manufacturer) regularly engaged in the business of repair of such

instruments or by his duly authorised agent,

that person shall not be guilty of an offence under paragraph (1)(c), unless the alteration, defacement or removal amounts to forging or counterfeiting as described in that sub-paragraph, or under paragraph (1)(f).

(3) A person who places on the market, puts into use or uses for trade an automatic discontinuous totaliser which to his knowledge—

(a) bears a mark which is a forgery or counterfeit, or which has been transferred from another instrument, or which has been altered otherwise than in accordance with these Regulations; or

(b) does not comply with the essential requirements by reason of any alteration made to it after an authorised mark was affixed to it in accordance with these Regulations,

shall be guilty of an offence.

(4) An automatic discontinuous totaliser 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) References in this regulation to other provisions of these Regulations include references 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 relevant notified body, disqualification sticker, re-qualification sticker, and any other inscription provided for in these Regulations.

#### Disqualification

**19**—(1) Subject to paragraph (2), if it appears to an inspector that an automatic discontinuous totaliser which bears the CE marking and the M Marking is used for trade in circumstances where

(a) the instrument no longer conforms to the essential requirements, other than the

- requirements relating to maximum permissible errors referred to in Schedule 1;
- (b) the instrument no longer conforms to the requirements of regulation 14; or
- (c) by reason of any alteration, it is likely that the instrument has ceased to conform with the

requirements referred to in sub-paragraphs (a) or (b),

the inspector may affix a disqualification sticker to the instrument.

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

(3) If a notice given under paragraph (2) is not complied with, the inspector shall affix a disqualification sticker to the automatic discontinuous totaliser.

(4) Any disqualification sticker which is affixed to an automatic discontinuous totaliser under this regulation shall be affixed in such a position that it is clearly visible when the instrument is in its regular operating position.

**20.** No person shall use for trade an automatic discontinuous totaliser to which there is affixed a disqualification sticker, unless a re-qualification sticker has been affixed to it in accordance with regulation 21.

#### **Re-qualification**

21. (1) Where—

(a) a disqualification sticker has been affixed to an automatic discontinuous totaliser in accordance with regulation 19(1) or (3); or

(b) a notice has been served under regulation 19(2),

an inspector or approved verifier may affix a re-qualification sticker to that automatic discontinuous totaliser if satisfied that the instrument conforms to the essential requirements.

(2) A person requiring a re-qualification sticker to be affixed to an automatic discontinuous totaliser to which this regulation applies shall submit the instrument, in such manner as may be directed, to an inspector or approved verifier and provide such assistance as the inspector or approved verifier may reasonably require.

(3) For the purposes of being satisfied that a re-qualification sticker may be affixed to an automatic discontinuous totaliser under this regulation, an inspector or approved verifier 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.

(4) There may be charged in respect of any steps taken under paragraph (3) such reasonable fees as the local weights and measures authority may determine.

(5) The inspector or approved verifier shall keep a record of any test carried out under paragraph (3).

(6) Where a re-qualification sticker is affixed to an automatic discontinuous totaliser pursuant to paragraph (1) it shall be affixed in such a position that it obliterates as far as possible any disqualification sticker.

## Testing of automatic discontinuous totalisers

**22**. Where an inspector or approved verifier considers that a test of an automatic discontinuous totaliser is necessary, 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 with such equipment, materials, qualified personnel or other assistance as the inspector or approved verifier may reasonably require.

#### Immediate enforcement action

**23**—(1) Where an enforcement authority has reasonable grounds for considering that an automatic discontinuous totaliser to which these Regulations apply and which bears the CE marking and the M marking does not meet all the essential requirements when placed on the market, properly installed and put into use in accordance with the manufacturer's instructions, the following provisions of this regulation shall have effect.

(2) The enforcement authority shall give notice to the manufacturer or his authorised representative sufficiently describing the instrument to which the notice applies and specifying the respects in which the requirements of this regulation have not been satisfied.

(3) A notice under this regulation may—

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

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

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

(i) that the instrument does so conform or comply; or

(ii) that the manufacturer or his authorised representative does so act,

any certificate or notification issued by a notified body in accordance with any of the conformity assessment procedures that the instrument satisfies the essential requirements may be withdrawn.

(4) A notice under paragraph (2) shall be in writing and shall—

(a) specify the date on which it is to take effect; and

(b) specify the grounds for the decision.

(5) Where an enforcement authority other than the Secretary of State gives a notice under paragraph (2), it shall at the same time send a copy of the notice to the Secretary of State.

(6) If the Secretary of State—

(a) in the case of a certificate or notification which he has granted, after giving the

manufacturer the opportunity of making representations as to why it should not be withdrawn, decides that the certificate or notification should be withdrawn, he shall immediately—

(i) give notice of the decision to the manufacturer; and

(ii) inform the other member States and the Commission of the decision;

(b) in the case of a certificate or notification granted by a notified body, is of the opinion that consideration ought to be given to whether the certificate or notification should be withdrawn, he shall inform the notified body of that fact; and

(c) in the case of a certificate or notification granted under the law of another member State, is of the opinion that consideration ought to be given to whether the certificate or notification should be withdrawn, he shall immediately inform the relevant competent authority of that fact.

(7) The Secretary of State shall publish, in such manner as he considers appropriate, particulars of any notice issued under these Regulations withdrawing a certificate or notification.

#### **Compliance notice procedures**

**24**. (1) Where an enforcement authority establishes that the CE marking, the M marking, or both, has been affixed unduly, it shall serve a notice in writing (a "compliance notice") on the manufacturer or his authorised representative, which shall -

- (a) contain a sufficient description of the automatic discontinuous totaliser to which it relates;
- (b) state that the enforcement authority is of the opinion that the CE marking , the M marking or both has been affixed to the instrument unduly, specifying which provisions of these

Regulations have, in the opinion of the enforcement authority, been contravened;

- (c) require the person on whom the notice is served to end the infringement under conditions specified in the notice;
- (d) specify the time limit within which the infringement must be ended; and
- (e) warn that person that, where the non-conformity continues, the enforcement authority will take all appropriate measures to restrict or prohibit the placing on the market of the instrument in question or to ensure that it is withdrawn from the market.
- (2) For the purposes of this regulation—

(a) the CE marking and the M marking shall be considered to have been affixed unduly if the automatic discontinuous totaliser does not comply with the requirements of regulation 12 and Schedule 4;

(b) it shall be considered as established that the CE marking or the M marking has been affixed unduly where the enforcement authority, being of the opinion on reasonable grounds that this is the case, has—

- (i) given the manufacturer or his authorised representative the opportunity of making representations;
- (ii) considered any representations made; and
- (iii) remains of that opinion.

(3) Except where the compliance notice is served by the Secretary of State, the enforcement authority shall, following the service of a compliance notice, send a copy to the Secretary of State.

(4) Where an enforcement authority has served a compliance notice pursuant to paragraph (1), it shall take no further action in relation to the contravention referred to in that notice until the time limit referred to in paragraph (1)(d) has expired.

(5) Where an enforcement authority is of the opinion that any other contravention of the requirements of these Regulations (not involving a contravention of a provision of Part III alone) is of a nature or extent that is not substantial, it may serve a compliance notice on the manufacturer or his authorised representative in accordance with paragraph (1); and thereafter no further action may be taken by the enforcement authority in relation to such contravention until the time limit referred to in paragraph (1)(d) has expired.

#### Powers of entry and inspection

**25**—(1) Subject to the production if so requested of his credentials, a duly authorised officer of an enforcement authority may for the purpose of these Regulations, at all reasonable times—

(a) inspect and test any automatic discontinuous totaliser in such manner as he considers appropriate;

(b) inspect and take copies of any document relating to an automatic discontinuous totaliser; and

(c) enter any premises at which he has reasonable cause to believe there to be an automatic discontinuous totaliser, not being premises used only as a private dwelling house.

(2) Subject to the production if so requested of his credentials, a duly authorised officer of an enforcement authority may, at any time, seize and detain—

(a) an automatic discontinuous totaliser which he has reasonable cause to believe is liable to be forfeited under these Regulations; and

(b) any document or goods which he has reason to believe may be required as evidence in proceedings for an offence under these Regulations.

(3) If a justice of the peace, on written information on oath—

(a) is satisfied that there are reasonable grounds to believe that any such automatic discontinuous totaliser or document as is mentioned in paragraph (1) or (2) is on any premises, or that an offence under these Regulations has been, is being or is about to be committed on any premises, and

(b) is also satisfied either that—

(i) admission to the premises has been refused, or a refusal is apprehended, and that notice of intention to apply for a warrant has been given to the occupier; or

(ii) an application for admission, or the giving of such a notice would defeat the object of the entry, or that the case is one of urgency, or that the premises are unoccupied or the occupier is temporarily absent,

the justice may by warrant under his hand, which shall continue in force for a period of one month, authorise the enforcement authority to enter the premises, if need be by force.

(4) In the application of paragraph (3) to Scotland, "justice of the peace" includes a sheriff and references to written information on oath shall be construed as references to evidence on oath.

(5) A duly authorised officer of an enforcement authority entering any premises by virtue of this regulation may take such other persons and such equipment as may appear to him necessary, and on leaving such premises which he has entered by virtue of a warrant under paragraph (3), being premises which are unoccupied or the occupier of which is temporarily absent, he shall leave them as effectively secured against a trespasser as he found them.

(6) If a duly authorised officer of an enforcement authority or other person who enters any workplace by virtue of this regulation discloses to any person any information obtained by him in the work-place with regard to any secret manufacturing process or trade secret, he shall, unless the disclosure was made in the performance of his duty, be guilty of an offence.

(7) Nothing in this regulation shall authorise any person to stop any vehicle on a highway.

(8) In this regulation, "credentials" means evidence of appointment or designation as a duly authorised officer of an enforcement authority.

#### **Obstruction of enforcement authority**

26—(1) A person who—

- (a) wilfully obstructs a duly authorised officer of an enforcement authority in the execution of any of his functions under these Regulations; or
- (b) without reasonable cause fails to give that officer any assistance or information which the officer has reasonably required of him for the purpose of the performance by the

enforcement authority of its functions under these Regulations,

shall be guilty of an offence.

(2) If a person, in giving a duly authorised officer of an enforcement authority such information as is mentioned in paragraph (1)(b), gives any information which that person knows to be false, he shall be guilty of an offence.

(3) Sub-section (1) of section 14 of the Civil Evidence Act 1968(**a**) (which relates to the privilege against self-incrimination) shall apply to the right conferred by paragraph (3) as it applies to the right described in sub-section (1) of that section; but this paragraph does not extend to Scotland.

#### Review of decisions of enforcement authority

**27** (1) Where a decision under regulation 23 or 24 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 enforcement 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 23 give instructions for the withdrawal of the notice given under paragraph (2) of that regulation; or
- (ii) where the review relates to regulation 24, give instructions for the withdrawal of the notice given under paragraph (1) of that regulation.

#### **Provision of information**

**28.** A person aggrieved by a decision of an enforcement authority that an automatic discontinuous totaliser should be withdrawn from the market, or prohibited or restricted from being placed on the market or put into use under Part III of these Regulations shall, at the same time he is notified of the decision, be given information about the judicial remedies available to him.

#### **Offences and Penalties**

**29**. A person guilty of an offence under these Regulations shall be liable, on summary conviction, to a fine not exceeding level 5 on the standard scale.

#### **Defence of due diligence**

**30**—(1) Subject to the following provisions of this regulation, 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—

- (a) to the act or default of another; or
- (b) to 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 under paragraph (3) on the person bringing the proceedings.

(3) A notice under this paragraph 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

**31.**—(1) Where the commission by a person of an offence under these Regulations is due to the act or default committed by some other person in the course of any business of his, the other person shall be guilty of the offence and may be proceeded against and punished by virtue of this paragraph whether or not proceedings are taken against the first-mentioned person.

(2) Where a body corporate is guilty of an offence under these Regulations (including where it is so guilty by virtue of paragraph (1)) in respect of an act or default which is shown to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or any person who was purporting to act in any such capacity he, as well as the body corporate, shall be guilty of an offence and shall be liable to be proceeded against and punished accordingly.

(3) Where the affairs of a body corporate are managed by its members, paragraph (2) shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(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 V

## MISCELLANEOUS AND SUPPLEMENTAL

### Adaptation for Northern Ireland

**32**. In their application to Northern Ireland, these Regulations shall have effect subject to Schedule 5.

#### Service of documents etc.

**33**—(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; or
- (c) if the person is a partnership, by serving it in accordance with that sub-paragraph 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 by virtue of 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.

#### Duty of an enforcement authority to inform the Secretary of State of action taken

**34**. An enforcement authority other than the Secretary of State shall, where action has been taken by it to prohibit or restrict the placing on the market or putting into use (whether under these Regulations or otherwise) of any automatic discontinuous totaliser, immediately inform the Secretary of State of the action taken, and the reasons for it, with a view to this information being passed by him to the Commission.

#### Savings for certain privileges

**35**.—(1) Nothing in these Regulations shall be taken as requiring a person to produce any documents or records if he would be entitled to refuse to produce those documents or records in any proceedings in any court on the grounds that they are the subject of legal professional privilege or, in Scotland, that they contain a confidential communication made by or to an advocate or solicitor in that capacity, or as authorising a person to take possession of any documents or records which are in the possession of a person who would be so entitled.

(2) Nothing in these Regulations shall be construed as requiring a person to answer any question or give any information if to do so would incriminate that person or that person's spouse.

<sup>(</sup>a) 1978 c.30.

Signatory text

Address Date Name Parliamentary Under Secretary of State Department

# SCHEDULE 1

## ESSENTIAL REQUIREMENTS

## 1. The requirements that shall be met by automatic discontinuous totalisers are set out below.

## 2. Definitions

#### 2.1 Measurand

The measurand is the particular quantity subject to measurement.

#### 2.2 Influence quantity

An influence quantity is a quantity that is not the measurand but that affects the result of measurement.

#### 2.3 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.

#### 2.4 Disturbance

An influence quantity having a value within the limits specified in the appropriate requirement but outside the specified rated operating conditions of the automatic discontinuous totaliser. An influence quantity is a disturbance if for that influence quantity the rated operating conditions are not specified.

#### 2.5 Critical change value

The critical change value is the value at which the change in the measurement result is considered undesirable.

#### 2.6 Climatic environments

Climatic environments are the conditions in which automatic discontinuous totalisers may be used. To cope with climatic differences between the member States, a range of temperature limits is specified in paragraph 3.3.1

#### **3** Allowable Errors

3.1 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 set out below.

MPE is expressed as a bilateral value of the deviation from the true measurement value.

3.2 Under rated operating conditions and in the presence of a disturbance, the performance requirement shall be as set out below.

Where the automatic discontinuous totaliser 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.

3.3 The manufacturer shall specify the climatic 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 in this Schedule.

#### Climatic environments

3.3.1 The manufacturer shall specify the temperature range. The minimum temperature range is 30 °C and shall be within the upper temperature limit of 70 °C and the lower temperature limit of -40 °C. The manufacturer shall indicate whether the automatic discontinuous totaliser is designed for condensing or non-condensing humidity as well as the intended location for the instrument, i.e. open or closed.

#### Electromagnetic environments

- 3.3.2. (a) Electromagnetic environments are classified into classes E1 or E2 as described below-
  - E1 This class applies to automatic discontinuous totalisers 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.
  - (b) The following influence quantities shall be considered in relation with electromagnetic environments-
    - (i) Voltage interruptions;
    - (ii) Short voltage reductions;
    - (iii) Voltage transients on supply lines and/or signal lines;
    - (iv) Electrostatic discharges;
    - (v) Radio frequency electromagnetic fields;
    - (vi) Conducted radio frequency electromagnetic fields on supply lines and/or signal lines; and
    - (vii) Surges on supply lines and/or signal lines.
- 3.4 Other influence quantities to be considered, where appropriate, are:
  - (a) Voltage variation,
  - (b) Mains frequency variation,
  - (c) Power frequency magnetic fields,
  - (d) Any other quantity likely to influence in a significant way the accuracy of the

instrument.

3.5 When carrying out the tests as envisaged in these Regulations, the following paragraphs apply:

#### Basic rules for testing and the determination of errors

3.5.1 Essential requirements specified in 3.1 and 3.2 shall be verified for each relevant influence quantity. 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.

#### Ambient humidity

3.5.2

- (a) According to the climatic operating environment in which the automatic discontinuous totaliser 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.

## 4 Reproducibility

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.

#### 5 Repeatability

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.

#### 6 Discrimination and Sensitivity

An automatic discontinuous totaliser shall be sufficiently sensitive and the discrimination threshold shall be sufficiently low for the intended measurement task.

#### 7 Durability

An automatic discontinuous totaliser 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.

## 8 Reliability

An automatic discontinuous totaliser 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.

#### 9 Suitability

- 9.1 An automatic discontinuous totaliser shall have no feature likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal.
- 9.2 An automatic discontinuous totaliser 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.
- 9.3 Where an automatic discontinuous totaliser is designed for the measurement of values of the measurand that are constant over time, the instrument shall be insensitive to small fluctuations of the value of the measurand, or shall take appropriate action.

- 9.4 An automatic discontinuous totaliser shall be robust and its materials of construction shall be suitable for the conditions in which it is intended to be used.
- 9.5 An automatic discontinuous totaliser 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 an 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.

- 9.6 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.
- 9.7 Adequate material handling facilities shall be provided to enable the instrument to respect the MPEs during normal operation.
- 9.8 Any operator control interface shall be clear and effective.
- 9.9 The integrity of the display (where present) shall be verifiable by the operator.
- 9.10 Adequate zero setting capability shall be provided to enable the instrument to respect the MPEs during normal operation.
- 9.11 Any result outside the measurement range shall be identified as such, where a printout is possible.

#### **10 Protection against corruption**

- 10.1 The metrological characteristics of an automatic discontinuous totaliser 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 measuring instrument.
- 10.2 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.
- 10.3 Software that is critical for metrological characteristics shall be identified as such and shall be secured.

Software identification shall be easily provided by the automatic discontinuous totaliser.

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

10.4 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.

#### 11 Information to be borne by and to accompany the automatic discontinuous totaliser

- 11.1 An automatic discontinuous totaliser shall bear the following inscriptions-
  - (a) manufacturer's mark or name;
  - (b) information in respect of its accuracy,

plus, when applicable:

- (c) information in respect of the conditions of use;
- (d) measuring capacity;

- (e) measuring range;
- (f) identity marking;
- (g) number of the EC-type examination certificate or the EC design examination certificate; and
- (h) information whether or not additional devices providing metrological results comply with the provisions of these Regulations.
- 11.2 The instrument shall be accompanied by information on its operation, unless the simplicity of the automatic discontinuous totaliser makes this unnecessary. Information shall be easily understandable and shall include where relevant
  - (a) rated operating conditions;
  - (b) 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; and
  - (f) conditions for compatibility with interfaces, sub-assemblies or other measuring instruments.
- 11.3 Groups of identical automatic discontinuous totalisers used in the same location do not necessarily require individual instruction manuals.
- 11.4 The scale interval for a measured value shall be in the form  $1 \ge 10^n$ ,  $2 \ge 10^n$  or  $5 \ge 10^n$ , where n is any integer or zero. The unit of measurement or its symbol shall be shown close to the numerical value.
- 11.5 The units of measurement used and their symbols shall be in accordance with the provisions of Community legislation on units of measurement and their symbols.
- 11.6 All marks and inscriptions required under any requirement shall be clear, non-erasable, unambiguous and non-transferable.

#### 12 Indication of result

- 12.1 Indication of the result shall be by means of a display or hard copy.
- 12.2 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.
- 12.3 In the case of hard copy the print or record shall also be easily legible and non-erasable.

#### **13** Further processing of data to conclude the trading transaction

- 13.1 An automatic discontinuous totaliser 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 automatic discontinuous totaliser is normally intended for use in the absence of one of the trading parties.

13.2 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.

#### 14 Conformity evaluation

An automatic discontinuous totaliser shall be designed so as to allow ready evaluation of its conformity with the appropriate requirements of these Regulations.

#### **15 Rated Operating Conditions**

The manufacturer shall specify the rated operating conditions for the automatic discontinuous totaliser as follows-

15.1 For the measurand:

the measuring range in terms of its maximum and minimum capacity.

15.2 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.

15.3 For other influence quantities (if applicable)-

(a) the rate(s) of operation.

(b) the characteristics of the product(s) to be weighed.

#### 16 Accuracy Classes

16.1 Automatic discontinuous totalisers are divided into four accuracy classes, as follows-

0.2, 0.5, 1, 2.

## 17. MPEs

Table 1		
(1) Accuracy class	(2) MPE of totalised load	
0.2	± 0.10 %	
0.5	± 0.25 %	
1	± 0.50 %	
2	± 1.00 %	

#### **18** Totalisation scale interval

The totalisation scale interval (d<sub>t</sub>) shall be in the range:

 $0.01 \% \text{ Max} \le d_t \le 0.2 \% \text{ Max}$ 

#### **19** Minimum Totalised Load ( $\Sigma_{min}$ )

The minimum totalised load ( $\Sigma_{min}$ ) shall be not less than the load at which the MPE is equal to the totalisation scale interval ( $d_t$ ) and not less than the minimum load as specified by the manufacturer.

## 20 Zero Setting

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-

- (a)  $1 d_t$  on instruments with automatic zero setting device; or
- (b)  $0.5 d_t$  on instruments with a semi-automatic, or non-automatic, zero setting device.

## 21 Operator Interface

Operator adjustments and reset function shall be inhibited during automatic operation.

## 22 Printout

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.

## 23 Performance under influence factors and electromagnetic disturbances

23.1 The MPEs due to influence factors shall be as specified in Table 2.

Load (m) in totalisation scale intervals d <sub>t</sub>	MPE
$0 < m \le 500$	$\pm 0.5 d_t$
$500 < m \le 2\ 000$	± 1.0 d <sub>t</sub>
$2\ 000 < m \le 10\ 000$	± 1.5 dt

## Table 2

23.2 The critical change value due to a disturbance is one totalisation scale interval for any weight indication and any stored total.

# SCHEDULE 2

# TECHNICAL DOCUMENTATION

1. The technical documentation shall render the design, manufacture and operation of the automatic discontinuous totaliser intelligible and shall permit an assessment of its conformity with the appropriate requirements of these Regulations.

- 2. The technical documentation shall be sufficiently detailed to ensure-
  - (a) the definition of the metrological characteristics,
  - (b) the reproducibility of the metrological performances of produced instruments when properly adjusted using appropriate intended means, and
  - (c) the integrity of the instrument.
- 3. The technical documentation shall include insofar as relevant for assessment and identification of the type and/or instrument-
  - (a) a general description of the instrument;
  - (b) conceptual design and manufacturing drawings and plans of components, subassemblies, circuits, etc;
  - (c) manufacturing procedures to ensure consistent production;
  - (d) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;
  - (e) descriptions and explanations necessary for the understanding of paragraphs (b),
    (c) and (d), including the operation of the instrument;
  - (f) a list of the standards and/or normative documents referred to in regulation 6(1), applied in full or in part;
  - (g) descriptions of the solutions adopted to meet the essential requirements where the standards and/or normative documents referred to in regulation 6(1) have not been applied;
  - (h) results of design calculations, examinations, etc;
  - (i) the appropriate test results, where necessary, to demonstrate that the type and/or instruments comply with the requirements of these Regulations under declared rated operating conditions and under specified environmental disturbances.

If the corresponding test programme has been performed in accordance with the relevant national standard or relevant normative document, and if the test results ensure compliance with the essential requirements, compliance with the appropriate tests shall be presumed; and

- (j) the EC-type examination certificates or EC design examination certificates in respect of instruments containing parts identical to those in the design.
- 4. The manufacturer shall specify where seals and markings have been applied.
- 5. The manufacturer shall indicate the conditions for compatibility with interfaces and subassemblies, where relevant.

# SCHEDULE 3

# NOTIFIED BODIES

# PART 1

## **CRITERIA TO BE SATISFIED BY DESIGNATED BODIES**

The Secretary of State shall apply the following criteria for the designation of bodies in accordance with regulation 8.

1. The body, its director and staff involved in conformity assessment tasks shall not be the designer, manufacturer, supplier, installer or user of the automatic discontinuous totaliser that they inspect, nor the authorised representative of any of them. In addition, they may not be directly involved in the design, manufacture, marketing or maintenance of the instruments, nor represent the parties engaged in these activities. The preceding criterion does not, however, preclude in any way the possibility of exchanges of technical information between the manufacturer and the body for the purposes of conformity assessment.

2. The body, its director and staff involved in conformity assessment tasks shall be free from all pressures and inducements, in particular financial inducements, that might influence their judgement or the results of their conformity assessment, especially from persons or groups of persons with an interest in the results of the assessments.

3. The conformity assessment shall be carried out with the highest degree of professional integrity and requisite competence in the field of metrology. Should the body sub-contract specific tasks, it shall first ensure that the sub-contractor meets the requirements of these Regulations, and in particular of this Schedule. The body shall keep the relevant documents assessing the sub-contractor's qualifications and the work carried out by him under these Regulations at the disposal of the notifying authority.

4. The body shall be capable of carrying out all the conformity assessment tasks for which it has been designated, whether those tasks are carried out by the body itself or on its behalf and under its responsibility. It shall have at its disposal the necessary staff and shall have access to the necessary facilities for carrying out in a proper manner the technical and administrative tasks entailed in conformity assessment.

5. The body's staff shall have-

- (a) sound technical and vocational training, covering all conformity assessment tasks for which the body was designated;
- (b) satisfactory knowledge of the rules governing the tasks which it carries out, and adequate experience of such tasks; and
- (c) the requisite ability to draw up the certificates, records and reports demonstrating that the tasks have been carried out.

6. The impartiality of the body, its director and staff shall be guaranteed. The remuneration of the body shall not depend on the results of the tasks it carries out. The remuneration of the body's director and staff shall not depend on the number of tasks carried out or on the results of such tasks.

7. The body shall satisfy the Secretary of State that it has adequate civil liability insurance.

8. The body's director and staff shall be bound to observe professional secrecy with regard to all information obtained in the performance of their duties pursuant to these Regulations, except vis-à-vis the authority of the member State.

## PART 2

## **FUNCTIONS**

# Applications for issue of certificates or notification as appropriate to the conformity assessment tasks

1.—(1) Subject to paragraph 2, a notified body shall assess an application made by a manufacturer for the issue of—

- (a) a certificate of conformity;
- (b) a design or type examination certificate; or
- (c) a notification (approval of the manufacturer's quality system)

in respect of an automatic discontinuous totaliser.

- (2) In determining an application, the notified body—
  - (a) shall have regard to the actual or usual environment of the automatic discontinuous totaliser; and
  - (b) may have regard to any other standards or other technical criteria appearing to it to be relevant.

(3) Where in the opinion of the notified body the automatic discontinuous totaliser to which an application relates conforms with the appropriate requirements of these Regulations, it shall issue a certificate or notification which complies with the requirements of paragraph 4.

#### Limitations on duties to exercise functions

**2.**—(1) A notified body shall not accept an application for a certificate or notification in respect of an automatic discontinuous totaliser unless the application—

- (a) is in writing, in English or another language acceptable to that body;
- (b) is accompanied by all relevant documentation, in writing in English or another language acceptable to that body; and
- (c) includes particulars of which applicable standards the manufacturer has applied or proposes to apply in respect of the instrument.

(2) A notified body shall not be required to determine an application for a certificate or notification where the manufacturer has not-

- (a) granted the body access to an instrument to which the application relates or the production facilities for the instrument (including where applicable the production envisaged in relation to a representative) to the extent that the body reasonably requests; and
- (b) made available to the body such information as it may reasonably require to determine the application.

(3) A notified body shall not be required to carry out the functions referred to in regulation 8 (4) (d) if—

- (a) the person making the application has not submitted with the application the amount of the fee which the body requires to be submitted with the application pursuant to regulation 11; or
- (b) the body reasonably believes that, having regard to the number of applications made to it pursuant to its designation which are outstanding, it will be unable to commence the required work within three months of receiving the application.

#### **Contractors etc**

3.—(1) Subject to sub-paragraphs (2) and (3), a notified body may, in exercising its functions—

- (a) arrange for some other person to carry out any test, assessment or inspection on its behalf; or
- (b) require the applicant to satisfy another person with respect to any matter at the applicant's expense.

(2) Nothing in sub-paragraph (1) authorises a notified body to rely on the opinion of another person with regard to whether an automatic discontinuous totaliser conforms with the appropriate requirements of these Regulations.

(3) Nothing in these Regulations shall preclude a person referred to in paragraph (1)(a) or (b) from charging any fee in respect of any work undertaken by him in pursuance of those paragraphs.

#### Form of certificate and notification

**4.**—(1) A certificate or notification issued by a notified body shall be in writing and, in addition to the requirements provided for in the various conformity assessment procedures shall—

- (a) be in English;
- (b) give the name and address—
  - (i) of the applicant;
  - (ii) where the person is not the manufacturer, of the manufacturer;
- (c) be signed on behalf of the body and identify the signatory with its number;
- (d) bear—
  - (i) the date of issue; and
  - (ii) the number of the certificate or notification;
- (e) give particulars of the relevant automatic discontinuous totaliser (where applicable, in relation to each variant) to which it relates sufficient to identify it, and shall state whether the instrument to which it relates is a single item or a representative, or a number of variants thereof; and
- (f) certify that the instrument to which it relates conforms with the appropriate requirements of these Regulations.

#### Conditions of certificate or notification

**5.**—(1) A certificate or notification may be unconditional or may be subject to such conditions which must be complied with if the certificate or notification is to apply, as the body considers appropriate.

(2) Such conditions may include—

- (a) a limitation on the environment for which the automatic discontinuous totaliser may be stated to be suitable; or
- (b) a limitation that the instrument is only to be installed at a specific site.

(3) The conditions imposed pursuant to sub-paragraph (1) may be varied by the notified body which issued the certificate or notification and a variation under this paragraph may include the imposition of new conditions or the removal of conditions.

#### Withdrawal of certificate or notification

**6.**—(1) The notified body which issued a certificate or notification shall withdraw that certificate or notification if it appears that the automatic discontinuous totaliser to which it relates does not conform with the appropriate requirements of these Regulations.

(2) A withdrawal of a certificate or notification shall be by notice in writing stating the reasons for the withdrawal.

# Procedure where a notified body is minded to refuse to give or to withdraw any certificate or notification

7.—(1) Where a notified body is minded to—

- (a) refuse to issue any certificate or notification applied for; or
- (b) withdraw or make any addition or amendment (other than at the request of the person to whom it was given) to such certificate or notification,

it shall give to the applicant or the person to whom the certificate or notification was given a notice in writing -

- (i) stating its reasons;
- (ii) specifying the date on which it is to take effect;
- (iii) giving that person the opportunity to make representations within a period of 21 days of such notice and consider any representations made within that period by that person; and
- (iv) giving that person information about the judicial remedies available to him.

(2) Where the notified body is not the Secretary of State it shall send to him a copy of any notice given by it under sub-paragraph (1) with a view to his notifying the other member States.

# SCHEDULE 4

Regulations 2(1) and 12

# MARKING AND INSCRIPTIONS

1. The CE marking consists of the symbol "CE" according to the design laid down in paragraph 1.B(d) of the Annex to Decision 93/465/EEC(a). The CE marking shall be at least 5 mm high.

**2.** The M marking consists of the capital letter "M" and the last two digits of the year of its affixing, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the CE marking. The M marking shall immediately follow the CE marking.

**3.** The identification number of the notified body concerned, if prescribed by the conformity assessment procedure, shall follow the CE marking and the M marking.

4. When an automatic discontinuous totaliser consists of a set of devices, not being subassemblies, operating together, the markings shall be affixed on the instrument's main device.

**5.** The CE marking and the M marking shall be indelible. The identification number of the notified body concerned shall be indelible or self-destructive upon removal. All markings shall be clearly visible or easily accessible.

<sup>(</sup>a) OJ No. L220, 30.8.93, p.23

# SCHEDULE 5

Regulation 32

# ADAPTATIONS FOR NORTHERN IRELAND

1. For the purposes of these Regulations, references to a local weights and measures authority are references to the Department of Enterprise, Trade and Investment.

- 2 Part III does not apply to Northern Ireland.
- 3. In regulation 25-

(a) the references in paragraph (3) to any written information on oath shall be construed as references to any complaint on oath; and

(b) for paragraph (8) there shall be substituted the following paragraph—

"(8) In this regulation, "credentials" in relation to an authorised person, means some duly authenticated document showing that he is authorised to act to exercise the powers conferred on him by this regulation.".

# **EXPLANATORY NOTE**

(This note is not part of the Regulations)

## Partial Regulatory Impact Assessment on the Measuring Instruments Directive (MID)

## The issue and objective:

- The impact of transposing the Measuring Instruments Directive (MID), 1. Issue: on the basis of status guo on regulatory control, into UK legislation.
- 2. Objective: To implement the MID, which aims to harmonise essential requirements on measuring instruments across the EUa. The objective is to open markets to competition; provide opportunities to innovate and export; improve choice for consumers and remove barriers to trade, through this deregulatory measure.

## **1.**Risk assessment

3. The intention is to maintain the status quo; that is to introduce new Regulations covering only the instruments that the UK currently regulates and not to introduce further Regulations which would act as a burden on business. The risks of pursuing this course, and alternative courses of action, are covered under the three options set out below. In the initial consultation documentb we sought information about the level of interest in deregulating some instruments. There was no great impetus for deregulation. We did receive feedback about the risk to the levels of consumer protection if the number of instruments regulated were reduced.

## **2.**Identify Options

4. The three original options, and the risks associated with each, are set out below. These options were explored during the initial consultation. In view of the responses to the consultation, we are proposing to proceed with option 2 below.

## **Results of consultation**

- 5. An initial consultation document was issued in November 2004. The consultation document was circulated to over five hundred stakeholders and was made available on the NWML website. Forty one responses to the proposals were received, of which seventeen were from the enforcement community (Local Authority Trading Standards Departments, regional Trading Standards groups, the Local Authorities Co-ordinators of Regulatory Services (LACORS) and the Trading Standards Institute (TSI)). Responses were also received from the business community, including twelve from individual businesses and four responses from trade associations. Five government organisations responded, along with one consumer organisation, BSi and one individual. In addition, three meetings with stakeholders were carried out during the consultation period.
- 6. Responses were very positive overall, with a substantial majority of respondents supporting the proposed approach to implementation in principle.
- 7. 95% of respondents who provided an answer to the question about status quo agreed that this would be the preferable way forward. 86% of those who replied

a EU includes EEA and Switzerland, once the bilateral agreement is implemented.b Measuring Instrument Directive: Consultation on the approach to implementation can be found on the NWML website http://www.nwml.gov.uk/MID consultation document.pdf

to the question about deregulation did not want any instruments deregulated. Ten respondents said they would like to see Liquid Petroleum Gas (LPG) dispensers regulated, with a further four saying that they would like the situation regarding LPG to be reviewed – together they make up 66% of respondents to this question.

- 8. 78% of respondents agreed with the proposal to produce a Statutory Instrument (SI) for each type of instrument to be regulated.
- 9. We received useful information about the costs and benefits of MID in response to the initial consultation document. Overall, we are satisfied that the costs to manufacturers of implementing the MID are not unreasonable, indeed several responses explained that there would be benefits in terms of costs and time of getting their products to market.
- 10. Some of the Trading Standards community expressed views that the implementation of the MID would adversely affect their levels of income. Whilst these comments touch on issues that are, strictly speaking, outside the scope of the MID implementation project, we have noted these comments and will be integrating them into our future strategies for the infrastructure of weights and measures enforcement.

## Option 1

- 11. Do nothing.
  - a) face infraction proceedings against the UK for not implementing an agreed Directive.
  - b) miss out on the benefits of a harmonised set of requirements
  - c) goes against the feedback received from the initial consultation document

## **Option 2**

12. Implement on the basis of status quo.

- (a) maintains consumer protection
- (b) does not introduce further burdens on business
- (c) is in line with feedback from consultation document

# **Option 3**

13. Change the scope of regulation

- (a) technical expertise and evidence base not in place, in order to support the introduction of further regulations by deadline for implementation
- (b) risks unintended consequences
- (c) risks missing implementation deadline for whole Directive
- (d) goes against feedback from initial consultation document, which did not strongly support an increase or decrease in number of instruments regulated

**3.**Issue of Equity and Fairness

14. Implementation will be equal across the whole of the industries covered, although manufacturers will have to establish the extent of regulation in each of the Member States for each of the instrument types. The optionality clause of the Directive enables Member States to choose to regulate instruments for prescribed measurement tasks – as is currently the case, i.e. different Member States may regulate different instruments.

- 15. Certificates of conformity for type approval have a transition period under the Directive, to allow certificates of conformity to last for a period of up to ten years after the date on which the MID Regulations come into force. However, other instruments, e.g. capacity serving measures and length measures, that do not have to be type approved, do not have a transitional period under the MID. This means that products will need to move from crown stamp approval to a CE mark on 30<sup>th</sup> October 2006. We have received feedback that this will present problems for manufacturers, the majority of which are small businesses. This is, however, the position under the MID which, though adopted in March 2004, doesn't come into force until 30<sup>th</sup> October 2006, thus providing a long lead-in period for manufacturers to plan for change accordingly.
- 16. Notwithstanding the capacity serving measures issue, the likely burden on small businesses is not considered to be any greater than for large businesses apart from familiarisation with the new legislation, where the small business has less administrative capacity.
- (2) Identify the Benefits

## Option 1

17. The only benefit to UK manufacturers is that they would continue as at present. However, it is a disadvantage to the UK manufacturing base to remain regulated solely by UK legislation, as it is a disincentive to export to the EU marketplace, which will be closed to non-compliant measuring instruments in Member States that have opted to implement the MID. UK manufacturing would be limited to the UK marketplace.

# Option 2

- 18. The first benefit of implementation will be the removal of technical barriers that currently exist, caused by dissimilar national regulation across the EU and the provision of a harmonised set of requirements for each of the instrument categories. However, most Member States support the Organisation Internationale de Métrologie Légale (OIML) Recommendations, which means that, even under current national legislation, the technical requirements are already the same.
- 19. For instrument types that are subject to approval, the cost of testing and certification will be reduced, as only one type or design approval will be required for the whole of the Community. However, the WELMEC Type Approval Agreement, whereby test results are accepted between test houses reducing the work needed to provide approval, has already reduced costs and time. The MID should provide further reductions in cost and time to market. Exporting should be easier and will become an option for companies that have, not already explored that option.
- 20. Under MID there are choices for manufacturers about the routes to obtaining conformity assessment (previously called type approval). Options include self-verification and sample testing of instruments, depending on the type of instrument and the quality systems the manufacturer has employed, thus

enabling the manufacturer to have more control over the conformity assessment of his products and to reduce costs.

- 21. Not only do manufacturers have choice about how to obtain conformity assessment, they also have a choice about where to obtain that assessment introducing an element of competition into the marketplace and enabling manufacturers to shop around for high quality and value for money services and hence removing the potential monopoly of the individual Member State.
- 22. There is a derogation period proposed for up to ten years before the Directive comes fully into force. Therefore, in theory, a manufacturer could obtain a national approval up until 29<sup>th</sup> October 2006 for a maximum period of 10 years. This exceeds product development times and is comparable with product lifetimes etc, so it is possible that, in practice, no significant non-recurring costs will be attributable to the Directive.
- 23. The Directive also has no impact on existing instruments already placed on the market, which will remain controlled by national legislation.

## **Option 3**

- 24. Possibility of greater benefits for consumers, since they would enjoy greater protection if the number of instruments regulated increases. However, businesses could experience an increase in the burden resulting from compliance with a greater number of regulations. Their marketplace would, however, be opened up to extend to all Member States.
- 25. If the number of instruments controlled through regulation was reduced, businesses would have greater benefits through a reduction in the burdens resulting from compliance with regulations. However, there would be a corresponding reduction in the level of consumer protection.
- (3) Quantifying and Valuing Benefits

## Option 1

26. No change - current national position prevails

## Option 2

27. In response to the initial consultation document: two companies and one trade association said that post MID time to market should be reduced, in some cases significantly. One company said that they expect time to market and costs to remain almost the same, though they recognise that there would be some paperwork benefit. One trade association said that their members do not expect there to be any significant increases in Type Approval costs in the Member State where the EU type approval is obtained. One company said that there may be future benefits in the wide range of conformity assessment modules available.

## Option 3

28. If the number of instruments regulated increases, then the benefits of increased consumer protection will increase proportionally, along with the burdens on

business. Conversely, if the number of instruments regulated goes down, then benefits to business will increase, as consumer protection decreases.

## Costs

- 29. In response to the initial consultation four businesses and one trade association provided detailed information about costs to their organisation.
- 30. One of the costs of getting a new product to market is the time taken to get a product onto that market. It takes one to two years to take a new product from initial concept to market. Development costs, including tooling, range from £150,000 up to about £2m, depending on the complexity of the instrument. Approval time varies from about four weeks, where test results from another body support an application, to between six to twelve weeks in the UK. Costs range from £3,500 to £15,000. Similar timescales and costs exist for gas and electricity meter approvals, with, again, amounts dictated by complexity of the instrument and scope of approval. It was pointed out that approval in other parts of the world can take a lot longer, e.g. in Canada, approvals can take up to nine months.
- 31. Exporting products has costs attached. Costs within the EU can amount to £80,000, based on an initial £30,000, plus £2,000 per country. The trade association represents companies that export to most EU countries and many outside the EU. They state that exporting within Europe is fairly straightforward, as a result of the WELMEC Type Approval Agreement (whereby test results are accepted between test houses reducing the work needed to provide approval). They go on to state that the OIML Certificates of Conformity ease the type approval process outside the EU, with the notable exception of North America.
- 32. In response to a question in the initial consultation document about costs of gearing up for MID, three companies said that they were anticipating the gearing up costs to be zero or very small. One trade association does not expect costs to increase significantly. They themselves are planning to provide training, but expect the costs of this training to be reasonable.
- 33. However, type approval is not required for material measures, including capacity serving measures and length measures. Therefore there is no transitional period for these measures. This means that manufacturers of capacity serving measures (generally glassware) and length measures will need to change from making products that bear a crown stamp to those which bear a CE mark overnight. One small company said that it would be very costly to change their production process in order to comply with the legislation. Several manufacturers have pointed out that they also run the risk of loss of redundant stock immediately post implementation, which will be a cost to their businesses.

## **Opportunities and Threats**

34. Two trade associations and one company, who responded to the question in the initial consultation document, saw implementation of the MID as an opportunity. Respondents stated that the opportunities include costs and time to market, based on the advantage that one approval ensures compliance in all EU countries.

- 35. The perceived threat is that countries will regulate different instruments, so there will be the case whereby a manufacturer of an MID compliant product will not be able to compete equally in a country that does not regulate in line with the MID, because a non-compliant product will be cheaper and easier to make. This point was echoed by one of the trade associations, which stated that the lack of uniformity in prescription across the EU is seen as unhelpful and not in the spirit of the internal market. However, a Member State that does not regulate in accordance with the MID cannot prevent compliant instruments being placed on its market or put into use.
- 36. The ten other respondees to this question saw the implementation of the MID as both a threat and an opportunity. One comment made was that, unless appropriately implemented, it could become a threat to consumer protection. In general, the trading standards organisations were concerned about how the implementation would affect the viability of their services and whether or not there would be sufficient demand to make it justifiable for Local Authorities to become Notified Bodies (NBs). Some comments were around the possibility of Local Authorities working in partnership with others to provide a regional service.

## Conclusion on costs and benefits

- 37. The comments received on the initial consultation were mixed, on whether the MID presents an opportunity or a threat. However, it is clear that there will be benefits to business of reduced regulatory burden, which will result in reduced time and costs of getting new products to the EU market. The Government accepts that prescription may not be the same across all Member States, since the optionality clause enables Member States to decide which instruments to regulate and which to not regulate. Where, however, instruments are prescribed, the requirements are identical. Where they are not, no national regulation is permissible and MID compliant products can freely circulate alongside non-MID compliant products. The fear is that non-compliant instruments will be cheaper to make and therefore will ultimately cost less, thus undercutting compliant instruments.
- (4) Business sectors affected
- 38. Research into the number of UK companies affected by the MID has concluded there are in excess of 260 companies affected. The following graph illustrates how the impact is spread across the MID market segments:



39. Following the initial research, we took a snap shot involving 148 of these companies to find out more about the impact the MID will have on them. We were able to establish that the combined turnover of the UK market is in excess of £450 million and more than 28,000 staff will be affected. We also researched, if the UK companies were international, which of the MID market segments they trade in and where in the EU they export to. The results are listed below:







- 40. The petrol pump industry is characterised by a small number of major players who tend to operate within Europe and more widely on an international basis. In addition, there are a small number of more minor players who tend to focus more on the UK marketplace. Organisations are a mixture of manufacturing and service based organisations, with the major players tending to combine the two functions. Most of the companies, even the major players, have around or less than 250 employees and so would be classified, (according to DTI convention) as a Small to Medium sized Enterprise (SME).
- 41. The automatic weighing machine industry is similarly characterised by a few major players and several smaller players. The major players generally operate on an international basis, along with several of the smaller players. The smaller players might well sell to an international customer, so whilst the sale may be made in the UK, the product will end up in another country e.g. Italy. In this instance, it would be the manufacturer, not the customer, who would obtain the type approval for use in Italy. These small companies need to be flexible; often customers will want to buy bespoke instruments. The smaller players are all

SMEs whilst the larger players may just be outside this definition, having more than 250 employees.

## Case Study: Gilbarco Veeder-Root

To place a new petrol pump onto the market Gilbarco, a petrol pump manufacturer, must currently ensure the new design obtains type approval. This includes type examination, testing and certification and can cost up to £30,000.

In the past, if the manufacturer then wanted to export his machine to, say, 24 EU countries, he would first obtain full OIML approval and a full OIML Test Report, again costing £30,000. Since the 24 EU countries generally accept OIML approval with full test data, the approval is then mainly a paperwork exercise and on average this would cost £2,000 per country. This makes the total cost for approval £76,000.

Once the MID is implemented, a saving can be made by the manufacturer. By obtaining one type approval, the whole European market is immediately open to the manufacturer. There will probably be a small charge for country specific documentation, including any special sealing requirements for that country and translation costs. It is estimated that this would cost on average £1,000 per country. So Gilbarco Veeder-Root will save a total of £23,000.

(5) Small Firms Impact Test

## Case Study: Fisco Products Ltd

Fisco Products Ltd manufactures tape measures of a number of different types, which are sold throughout the world, the largest markets being in Europe. The company is UK owned, employs 110 full time equivalent staff and has an annual turnover of over £6m. Annual production is about two million items but only a small proportion of these are subject to regulation in EC markets.

Type approval of new products and variants costs the company around £2,000 per annum and the company spends an additional £8,000 with Essex Trading Standards and £20,000 in-house for initial verification of individual tapes. Total costs add up to £30,000 per annum.

It is estimated that after investing  $\pounds 10,000$  for equipment and training of staff, inhouse verification can be carried out for  $\pounds 20,000$  per annum, giving an ongoing saving of about  $\pounds 10,000$ .

The chief executive said "The MID means that we will have the freedom to carry out in-house verification, which will reduce the cost and time of getting our new products onto the market."

42. As stated above, capacity serving measure manufacturers will need to switch from crown stamped to CE marked products on 30<sup>th</sup> October 2006. This sector is characterised by small manufacturers. In discussions with the manufacturers they have raised the issue of cost of changing tooling over and the cost of loss of crown stamped stock remaining at 30<sup>th</sup> October 2006. We have agreed to work with the sector to find ways of minimising the cost of changeover.

(6) Identify any other costs

## **Option 1**

43. None

## Options 2 and 3

- 44. No additional costs for the manufacturer, although, for the Member State as the designating authority, there are the additional costs, estimated at around £40,000, for setting up a designation and auditing programme for NB activities. The costs of the actual designation and audit will be met directly by the NB themselves. The costs of setting up a market surveillance programme will need to be met by the Member State, as well as the on-going operation of programme; the on-going cost is likely to be in the order of £100,000 per year for those instruments currently regulated by NWML.
- 45. Individual Trading Standards Departments, along with Trading Standards organisations, have raised the issue of impact of the MID on their operations. They have identified a number of costs associated with gearing up for the MID. Costs fell into the following categories:
  - Staff training estimated to be about £140,000 in total, to cover 200 TSOs;
  - Becoming an NB which includes maintaining competences, estimated at about £70,000 overall, and the costs of implementing, managing and auditing a quality system though this should only entail a broadening of existing quality procedures;
  - Actual designation and audit in order to become an NB costs are yet to be determined;
  - Acquiring the documentary information (Type Approval Certificates) which currently stands at about £2,000 per Local Authority, for membership of EMeTASa;
  - Third Party Insurance estimated to be about £1,000 per Local Authority;
  - Loss of income due to reduced verification revenue as a result of the increase in self-verification expected, post MID.
- 46. The main concern, raised by several bodies, was the impact of self-verification conformity assessment routes on the operations of Local Weights and Measures Authorities (LWMAs). Manufacturers will be able to carry out initial verification of their equipment and, under existing national provisions, approved verifiers will be able to carry out subsequent verifications of instruments in use for trade, thus reducing demand for this service from LWMAs. The result will be a significant loss of revenue for the LWMAs.
- 47. A further concern, voiced by a number of organisations, was the decision by LWMAs to become a NB, a necessary action if LWMAs are to be able to carry out conformity assessment under the MID. Because of the uncertainty surrounding the level of uptake of self-verification, it is difficult for LWMAs to be able to decide now whether or not to become a NB. The risk is that if LWMAs decide it is not economically viable to become a NB, but there is no provision of this service in a region, the costs to manufacturers of obtaining independent

a EMeTAS is the current EU information system, though the future system is still the subject of debate.

third party initial verification may rise steeply, because they will need to pay more for a NB to travel to undertake the verification.

## **Competition Assessment**

- 48. It is anticipated that manufacturers would not incur any significant additional costs as a result of the proposed Directive. It is probable that manufacturers already comply with the technical requirements of the International Recommendations of the OIML, on which the essential requirements of the Directive are based. The Directive will reduce barriers to trade by harmonising national legislative requirements at European level. It is not likely that implementation of the proposed Directive would result in any disproportionate costs or other effects between manufacturers of the same type/categories of instruments.
- 49. For manufacturers of products that require type approval, there is a 10-year transitional period from the date on which the proposed Directive comes into force, during which instruments may continue to be first passed as fit for use for trade under current national legislation, thereby allowing manufacturers to make full use of any type approval certificates that have been issued before 30<sup>th</sup> October 2006.
- 50. In the light of the above comments, it is not anticipated that implementation of the proposed Directive will have any (or any significant) impact on competition within any affected markets.

## **Rural Proofing**

- 51. Please see Annex 1.
- (7) Summary and recommendation
- 52. Evidence, provided in response to the consultation document, suggests that the time and cost of getting new products to market will be reduced as a result of implementing the MID. However, there will be some costs for Government, in providing the infrastructure for Notified Bodies; Trading Standards Departments, through potential loss of income and capacity serving measures manufacturers, as a result of switching overnight to a new system of product approval.
- 53. Notwithstanding these identified costs, the responses received to the initial consultation document were very positive overall, with a substantial majority supporting the proposed approach to implementation.
- 54. The recommendation is, therefore, to proceed with implementation along the lines set out in the initial consultation document:
  - Implementation on the basis of status quo of regulatory control
  - Produce an individual SI for each category of instrument
  - Include the in-service provisions in each SI.
- (8) Enforcement, Sanctions, Monitoring and Review
- 55. These activities are already carried out on those instruments currently controlled under national legislation and will equally be applied to the same instruments

regulated under the MID, by the respective regulatory authorities within the UK. Following the Hampton review, there will be no effect on the compliance regime.

56. The above report will be updated following responses to the second consultation document.

# Annex 1

4. Rural Proofing

- 1. Will the policy affect the availability of public and private services? No
- Is the policy to be delivered through existing service outlets, such as schools, banks and GP surgeries? No
- 3. Will the cost of delivery be higher in rural areas where clients are more widely dispersed or economies of scale are harder to achieve? No
- 4. Will the policy affect travel needs or the ease and cost of travel? No
- 5. Does the policy rely on communicating information to clients? Manufacturers and trade associations have been consulted at different times during the drafting of the Commission's proposal and during the negotiation phase. Further consultation is taking place now that the draft Regulations are ready. They will also be informed when the Regulations have been made and 12-week guidance leaflets will be issued at that time.
- 6. Is the policy to be delivered by the private sector or through a public-private partnership? No.
- Does the policy rely on infrastructure (e.g. broadband ICT, main roads, utilities) for delivery? No
- 8. Will the policy impact on rural businesses, including the self-employed? There has been no indication of significant costs.
- 9. Will the policy have a particular impact on land-based industries and, therefore, on rural economies and environments? No
- 10. Will the policy affect those on low wages or in part-time or seasonal employment? No
- 11. Is the policy to be targeted at the disadvantaged? No
- 12. Will the policy rely on local institutions for delivery? No.
- 13. Does the policy depend on new buildings or development sites? No
- 14. Is the policy likely to impact on the quality and character of the natural and built rural landscape? No
- 15. Will the policy impact on people wishing to reach and use the countryside as a place for recreation and enjoyment? No