National Measurement Office

WEIGHTS AND MEASURES

The Measuring Instruments (Non-Prescribed Instruments) Regulations 2006 (S.I. 2006 no 1270)

as amended by

The Measuring Instruments (Amendment) Regulations 2010 (SI 2010/2881)

Guidance on Regulation

March 2011

Version 6

BIS Department for Business Innovation & Skills

This guidance is addressed to organisations that are required to comply with weights and measures law. Following the guidance is not in itself obligatory but, if you do follow it, this should help your organisation to meet its legal obligations.

Ultimately, only the courts can provide a definitive interpretation of the law. However, for further guidance on how to comply with the law, you can contact your local trading standards department, who provide this service free of charge:

www.tradingstandards.gov.uk - simply type in your postcode and press "go".

This guidance complies with the Government Code of Practice on Guidance and will be reviewed in October 2016

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Version / Date of change	Sections affected
Version 1	First issue March 2007
Version 2 / December 2007	Inclusion of amendment sheet
Version 3 / February 2009	Details of CEN standards/BS EN standards added (para 41) Revised Schedule 4 – markings and inscriptions
Version 4 / July 2009	Corrects error in Schedule 4
Version 5 / December 2010	Updates guidance to comply with the BRE 'Code of Practice on Guidance on Regulation
Version 6 / March 2011	Amendment to incorporate changes from the Measuring Instruments (Amendment) Regulations 2010 – paras 2, 4, 12, 15B, 15C, 17B, (Schedule 1) 57, 81, 83, 85, 92 to address the implementation of Commission Directive 2009/137/EC; and miscellaneous typographical errors.

Contents

Health and Safety at Work Act 1974

1 Nothing in these Notes for Guidance should be construed as overriding, amending or deferring safety regulations and requirements issued by the Health and Safety Executive (in Northern Ireland the Health and Safety Executive for Northern Ireland), in connection with the conduct of persons and the condition and use of machinery and equipment on any premises.

Foreword

2 The Measuring instruments (Non-Prescribed Instruments) Regulations 2006 ("the Regulations"), as amended by the Measuring Instruments (Amendment) Regulations 2010, SI 2010/2881 ("the Amendment Regulations") implement Council Directive 2004/22/EC ("the Directive"), as amended by Commission Directive 2009/137/EC[1] ("the Amendment Directive"), in relation to certain non-UK prescribed instruments covered by the Directive. The Regulations, as amended, provide for the harmonisation of laws on certain non-UK prescribed instruments within Member States, thereby creating a single market for these instruments.

3 Separate measuring instrument regulations have been made to implement each of the instrument types prescribed in the UK under the Directive. They have been written so that for each type of instrument (measure) their field of application and in-service control mirror the scope of regulations made previously under the Weights and Measures Act 1985 and the Weights and Measures (Northern Ireland) Order 1981. This regulation relates to instruments covered by the Directive, but not regulated within the UK. It provides a means by which UK manufacturers can be permitted to undertake conformity assessment procedures on these instruments. This will allow them to export to other Member States where the particular instruments are regulated.

4 The Regulations came into force on 30 October 2006 after which date new designs of non-UK prescribed instruments for placing on other member States markets (where regulated) must comply with the Regulations. The provisions of the Amendment Regulations must also be complied with from 1 June 2011 when they come into force. This guidance is intended to assist manufacturers and notified bodies in meeting the requirements of the Regulations.

5 There is significant input from WELMEC, the European Co-operation in Legal Metrology, to the understanding and interpretation of the Directive. WELMEC has already convened a number of working groups for this purpose. WELMEC considers questions of application and implementation, particularly in areas of technical uncertainty and acts as a forum for seeking advice from the European Commission on common issues. Information regarding WELMEC and its decisions and publications can be found at **www.welmec.org**.

Background

[1] Commission Directive 2009/137/EC of the European Parliament and of the Council on measuring instruments in respect of exploitation of the maximum permissible errors, as regards the instrument-specific annexes MI-001 to MI-005

6 The Directive is a “New Approach” Directive and was adopted by the EC Council of Ministers and European Parliament in April 2004. It consists of 27 Articles, 14 annexes and 10 instrument specific annexes.

7 Member States were required to implement the provisions of the Directive into their national law by 30 April 2006 and to apply the new legislation with effect from 30 October 2006.

8 The Directive extends to all measuring instruments listed in Article 1 of the Directive and provides that Member States may prescribe use of them for measuring tasks for reasons of public interest, public health, public safety, public order, protection of the environment, protection of consumers, levying of taxes and duties and fair trading where they consider it justified. Following a public consultation it was decided that the UK prescription should apply to areas covered by existing regulations only. Consideration about whether to extend the scope of the requirements to previously unregulated instruments or applications may be the subject of further consultation at a later date.

9 The Directive is the second "New Approach" Directive adopted in respect of measuring instruments. The first was Directive 2009/23/EC (formerly 90/384/EEC) and relates to non-automatic weighing instruments and came fully into force in January 2003.

10 The Commission has issued guidance on “New approach” directives “Guidance on the implementation of directives based on the New and Global Approach” which can be found at

http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf

11 The principals of the “New approach” are set out in the Commission Guidance as follows:

- Harmonisation is limited to essential requirements**.**
- Only products fulfilling the essential requirements may be placed on the market and putting into use.
- Harmonised standards, the reference numbers of which have been published in the Official Journal and which have been transposed into national standards, are presumed to conform to the corresponding essential requirements.
- Normative documents drawn up by OIML and the list of the parts thereof corresponding to the essential requirements (in conformity with Article 16.1 of the Directive for which the Commission has published the references in the Official Journal.
  Application of harmonised standards or other technical specifications remain voluntary, and manufacturers are free to choose any technical solution that provides compliance with the essential requirements.
- Manufacturers may choose between different conformity assessment procedures provided for in the applicable directive.

12 The "New Approach" to Technical Harmonisation is an important part of the process for achieving the single market. It is intended to remove the technical barriers to trade caused by differing national laws. Directives agreed under the New Approach allow for the free movement, (placing on the market and putting into service) in the Community of

goods that conform to the essential and other requirements of those Directives. Such products carry the "CE marking", and no Member State is allowed to refuse complying products access to its market. In this case all instruments covered by the Directive (as amended by Directive 2009/137/EC) have free movement throughout the Community.

13 In the 10 instrument specific Regulations, as amended, it is important to distinguish between when instruments are first placed on the market or put into service and requirements that relate to in-service provisions. The first are requirements of the Directive, as amended; the second are national provisions and will therefore apply only to Great Britain.

14 The Directive provides an 'optionality clause' This means that Member States may prescribe the category and range of applications for measuring instruments they wish to control. This will lead to a variation between Member States which will mean that for the same use, instruments in some Member States will be regulated, whereas in other Member States they will not.

15A For instruments not controlled in the UK, the Regulations have been made which permit UK manufacturers of such instruments to demonstrate conformity with the Directive and so meet the legislative requirements for placing them on the market in other Member States. For the scope of regulatory provisions manufacturers should consult the implementing legislation in other Member States.

15B The Amendment Directive was agreed on 10 November 2009 and entered into force on 1 December 2009. Member States were required to implement the Amendment Directive into their national law by 1 December 2010[2] and to apply the new legislation with effect from 1 June 2011.

15C Regulation 5 of the Amendment Regulations implements the Amendment Directive in respect of non-prescribed instruments by amending the essential requirements so as to explicitly prohibit systematic exploitation of these instruments.

Provisions

16 The Regulations have been made using powers under the European Communities Act 1972.

CITATION AND COMMENCEMENT

Regulation 1

17A This gives the title of the regulations and states the coming into force dates of 30 May 2006 for the regulations listed in Regulation 1(2) relating to the designation of notified bodies for the purpose of the Regulations and 30 October 2006 for the remaining regulations.

17B Regulation 1 of the Amendment Regulations gives the title and coming into force date of 1 June 2011 of the changes to the Regulations.

[2] The Amendment Directive was implemented into UK law on 2 December 2010.

Regulation 2

18 This gives definitions of many of the terms used in the Regulations. Other terms may be defined where they appear. Definitions of terms which are only used once have been excluded.

19 The following definitions are important to consider if we are to understand the regulations.

- **Manufacturer-** means the person responsible for the conformity of a non-prescribed measuring instrument with the Regulations with a view to either placing it on the market under his own name or putting it into use for his own purposes, or both.

- **Authorised representative**- The manufacturer may appoint any natural or legal person to act on his behalf as an authorised representative.
  The authorised representative must be established in a Member State. The authorised representative must be authorised by the manufacturer in writing to act on his behalf. The manufacturer remains generally responsible for actions carried out by an authorised representative on his behalf.

- **Notified Body**- This means

  (a) the Secretary of State i.e. NMO Services; or

  (b) a person designated under regulation 4;

  and who has been notified to the Commission and the other Member States pursuant to Article 11.1.

20 At the time of drafting this guidance the bi-lateral agreement between Switzerland and the European Community has not been amended to include the Measuring Instruments Directive. It is expected that this amendment will be made in due course.

APPLICATION

Regulation 3(1)

21 The Regulations apply to heat meters, dimensional measuring instruments and gas meter volume conversion devices as well as to automatic weighing instruments, material measures, measuring systems for liquids other than water and water meters to which the instrument specific regulations do not apply. It covers the full scope of legal metrological control, other than use for trade where instrument specific regulations apply, and is effective in order that instruments may, where regulated, be first placed on the market or put into use in another member State on or after the 30 October 2006.

22 The Regulations fully cover automatic checkweighers ie class X automatic catchweigher type of automatic weighing instrument, strapping and dipping tapes ie class S and D material measures of length, and measuring systems on pipelines, loading

and unloading ships and road and rail tankers, for milk, for refuelling aircraft, ships or hovercraft, for liquefied petroleum and natural gases under the category of liquids other than water, and hot water meters.

For all other possibilities please consult the instrument specific regulations in relation to the applicability of those regulations.

DESIGNATION OF NOTIFIED BODIES

Regulation 4(1)

23 Under Article 11 of the Directive notified bodies are required for the tasks relating to the conformity assessment of modules A to H1 (see paragraph 42 of this guidance for those relevant to the different instrument types). The criteria for designation of these bodies in accordance with Article 12 are included in Schedule 2 Part 1 of the Regulations

24 If an organisation meets the requirements of Schedule 2 Part 1 the regulations permit the designating authority to designate a person, whether that is a person resident or incorporated or carrying on a business in the United Kingdom or any other type of person e.g. a local weights and measures authority, to be a notified body. The definition of a notified body includes a person although it would appear unlikely that an individual person would be appointed. Where the designation is in respect of a particular description of a measuring instrument the Secretary of State must be satisfied that the applicant meets the criteria as respects that instrument. In line with Schedule 1 of the Interpretation Act 1978, a person includes a body of persons corporate or unincorporated in that it applies to both a natural or a legal person.

Under these Regulations the designating authority is the Secretary of State except for the designation of notified bodies for the assessment of volume conversion devices (Schedule 1 Part 2 Part G) where the responsibility rests with the Gas and Electricity Markets Authority (for Great Britain) and the Northern Ireland Authority for Energy Regulation.

Regulation 4(3)

25 If a person applying to be a notified body operates an approved quality system under a relevant harmonised standard e.g. EN 17025/17020 and EN45011/45012 he shall be presumed to meet the criteria of the Directive only to the extent that the standard corresponds with the criteria of the Directive

Regulation 4(4)

26 Designations under the Regulations must l be in writing which may be either in electronic or hard copy format. They may include conditions such as the scope of the designation.

Regulation 4(5)

27 In addition to the criteria in Schedule 2 Part I of the Regulations the designating authority may have regard to any matter appearing to it to be relevant. The functions of a notified body (Regulation 5) are set out in Part 2 of Schedule 2 to the Regulations and in Schedule 2 of this guidance.

PROVISIONS SUPPLEMENTAL TO REGULATION 4

Regulation 6(1)

28 The provisions of Regulation 6 deal with the publication of lists of notified bodies and the inspection of notified bodies.

29 The designating authority will periodically carry out an inspection of UK notified bodies. The purpose of that inspection shall be to assess whether the notified body meets the notified body criteria and complies with any designation to which it is subject and complies with the Regulations. It is important to remember that although such an inspection may result in a visit to a manufacturer, it is the notified body that will be being inspected, not the manufacturer.

30 Member States must give the Commission and other Member States details of the notified bodies designated under the Regulations. The Secretary of State will publish a list of notified bodies indicating the scope of the capacity serving measures in respect of which each is authorised.

31 The Secretary of State will also publish a list which specifies for which instruments/ measures the Notified Body is designated and any conditions to which it is subject. These details will be available on the NMO website at NMO.gov.uk under 'enforcement'.

32 The European Commission also publishes a list of notified body numbers which gives details of the notified body and the instruments/measures covered.

NANDO **http://ec.europa.eu/enterprise/newapproach/nando/**

Directive 2004/22/EC
http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.annex&dir_id=125641&type_dir=NO%20CPD

33 Search by Annex for the relevant declaration of conformity and then by instrument type. Search by country and then by notified body number to give name and directives and for MID both the instruments for which it has been notified and the applicable procedures/ annexes.

33 This site will enable you to find the European notified bodies as well as third country bodies designated under formal agreements [Mutual Recognition Agreements (MRAs), Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECAs) and European Economic Area (EEA)] responsible for carrying out the conformity assessment procedures.

FEES

Regulation 8

34 This Regulation permits notified bodies other than the Secretary of State to charge such fees in connection with, or incidental to, the carrying out of the conformity assessment procedures or specific tasks as it may determine.

35
Section 56 of the Finance Act 1973 requires the Secretary of State to define by statute the fees he charges for certain tasks to be carried out in relation to EU commitments/obligations. The Measuring Instruments (EEC Requirements (Fees) (Amendment) Regulations 2004 (S.I. 2004 No 1300 were amended to add the MID Regulations to the existing list of regulations by the Measuring Instruments (EEC Requirements (Fees) Regulations 2006 (S.I. 2006 No 604), the Measuring Instruments (EEC Requirements (Fees) (Amendment No 2) Regulations 2006 (S.I. 2006 No 2679) and the Measuring Instruments (EEC Requirements (Fees) Regulations 2008 (S.I. 2008 No 732).

36 The Regulations do not govern the fees that may be charged by other notified bodies other than identifying broad parameters in which all notified body fees should be set.

Regulation 8(4)

37 Provides that, in cases where fees charged after work is completed or payment of fees has been requested in writing have not been paid the notified body within a period of 28 days the notified body may give 14 days notice in writing that the certificates or notification appropriate to the conformity assessment will be suspended until the fees have been paid.

COMPLIANCE WITH THE ESSENTIAL REQUIREMENTS

Regulation (9)(1)

38 Manufacturers can use more than one method to demonstrate compliance with the essential requirements. These methods are identified as:-

(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 10.

Regulation 9(2)

39 This includes the presumption that instruments which conform fully or in part to relevant national standards or normative documents will be presumed to conform fully or in part with the essential requirements. Details of the relevant national standards and normative documents for this purpose will be published by NMO, or the competent authority in another Member State. Normative document references for instruments identified by the Commission are published on the NMO website and can be found at **http://www.nmo.gov.uk/mid.aspx**

Regulation 9(3)

40 Where conformity is only in part to relevant national standards or normative documents then either the alternative, where available, should be used to give full conformity or through the issue of other technical solutions. Other technical solutions could include the use of European standards which are not harmonised standards and international standards such as OIML Recommendations which are not normative documents.

41 In relation to other technical solutions OIML Recommendations exist for each of the following instrument categories and types:

Automatic weighing instruments	
Discontinuous totalisers	R107 (2007)
Rail-weighbridges	R106 (1997)
Catchweighers	R051 (2006)
Gravimetric filling instruments	R061 (2004)
Continuous totalisers (Beltweighers)	R050 (1997)
Material measures	
Capacity serving measures	R138 (2007)
Measures of length	R085 (2007)
Water meters	
Cold/hot water meters	R049 (2006)
Measuring systems for liquids other than water	R117 (2007)
Heat meters	R075 (2002)
Dimensional measuring instruments	
Length measuring instruments	R066 (1985)
Area measuring instruments	R136 (2004)
Multidimensional measuring instruments	R129 (2000)
Volume conversion devices (Gas meters)	R140 (2007)

These can all be found on the OIML web-site at http://www.oiml.org/publications/ .

41A In relation to other technical solutions European Standards exist for each of the following instrument categories and types:

Water meters	EN 14154 (2005)
Heat meters	EN 1434 (2007)
Volume conversion devices (Gas meters)	EN 12405 (2005)
Diaphragm Gas meters	EN 1359 (1998)

Turbine gas meters	EN 12261(2002)
Rotary displacement meters	EN 12480 (2002)
Ultrasonic domestic gas meters	EN 14236 (2007)

All the standards have been adopted as BS/EN standards.

CONFORMITY ASSESSMENT PROCEDURES

Regulation 10(1)

42 The different conformity assessment procedures available to manufacturers are set out as modules in the annexes of Directive 2004/22/EC. These are number A to H1. The modules available to manufacturers are shown in the table below.

		A1	D1	E1	F1	B+D	B+E	B+F	G	H	H1
Automatic weighing instruments	**Mechanical**		•			•	•	•	•		•
	Electro-mechanical					•	•	•	•		•
	Electronic/ software					•		•	•		•
Capacity Serving Measures		•	•	•	•	•	•			•	
Dimensional measuring instruments	**Mechanical/ electro-mechanical**		•	•	•	•	•	•	•	•	•
	Electronic/ software					•		•	•		•
Heat meters						•		•			•
Measures of length			•		•	•			•	•	
Measuring systems for LOTW						•		•	•		•
Volume conversion devices						•		•			•

Water meters						•		•			•

The options above for specified instrument types represent:

- Declaration of conformity by manufacturer based on internal production control plus random 3rd party checking (Module A1)
- Declaration of conformity by the manufacturer based on formal quality assurance of the production process (including test and final inspection) but without the need for type examination (Module D1)
- Declaration of conformity by the manufacturer based on formal quality assurance of product testing and final inspection but without the need for type examination (Module E1)
- 3rd Party verification but without the need for type examination (Module F1)
- Type examination followed by declaration of conformity by the manufacturer based on formal quality assurance of the production process (including test and final inspection) as two separate processes (Modules B + D)
- Type examination followed by declaration of conformity by the manufacturer based on formal quality assurance of product testing and final inspection only, as two separate processes (Modules B + E)
- Type examination followed by 3rd Party verification (Modules B + F)
- 3rd Party verification for one off 'bespoke' instruments which would otherwise need type examination (Module G)
- Declaration of conformity by the manufacturer based on full formal quality assurance of the design and production process (including test and final inspection) but without the need for design examination (Module H)
- Design examination together with declaration of conformity by the manufacturer based on full formal quality assurance of the design and production process (including test and final inspection) as part of an integrated process (Modules H1)

The procedures that manufacturers must follow in order to meet the requirements of the individual modules are considered in Schedule 1 to this guidance.

43 For further information on conformity assessment procedures and other aspects regarding the interpretation of the Directive reference should be made to "Guide to the implementation of directives based on the New Approach and the Global Approach" This document can be found at the following website.

http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf

44 For Module F1 under points 6.1 and 7.2 the recommended tests to be carried out for initial verification should be identified together with the standards necessary to ensure traceability of measurement (see Schedule 7).

45 The EU Commission in relation to the Directive have published a list of OIML normative references in the Official Journal which in part gives presumption of conformity to the essential requirements. In relation to the Regulations these include details on the following instruments:

Automatic weighing instruments (MI-006)

Discontinuous totalisers (Chapter IV)	R107 (1997)
Rail-weighbridges (Chapter VI)	R106 (1997)
Catchweighers (Chapter II)	R051 (1996)
Gravimetric filling instruments (Chapter III)	R061 (2004)
Continuous totalisers (Beltweighers) (Chapter V)	R050 (1997)

Material measures (MI-008)

Capacity serving measures (Chapter II)	R138 (2007)

Water meters (MI-001) R049 (2006)

Measuring systems for liquids other than water (MI-005) R117 (1995)

Heat meters (MI-004) R075 (2002)

Dimensional measuring instruments (MI-009)

Length measuring instruments (Chapter II)	R066 (1985)
Area measuring instruments (Chapter III)	R136 (2004)
Multidimensional measuring instruments (Chapter IV)	R129 (2000)

It should be noted that at present there is no normative reference in relation to material measures of length. This is likely to be developed once the revision of OIML R49 has been completed.

This information can be found on the NMO web-site under the MID header at:

http://www.nmo.gov.uk/

or by reference to the OJ (2006/C 269 and 2009/C268) on the EU web-site at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:269:0001:0028:en:PDF or **http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:268:0001:0012:EN:PDF**

46 The Normative references address all the relevant provisions of the Directive ie both the general and instrument specific requirements, in tabular form, in relation to the corresponding paragraphs of the respective OIML Recommendation and makes comment, in general terms only, of any differences.

47 WELMEC documents, published on the WELMEC website, set out as guidance full versions of these simplified tables with background information and comment for interested parties. Documents exist for certain normative references for which the Commission has not yet published in the Official Journal.

48 WELMEC documents exist in relation to the following instruments:

Water meters: MID-001	Guide 8.11 (Issue 1)
Gas volume conversion devices: MID-002 II	Guide 8.12-2 (Issue 1)
Heat meters: MID-004	Guide 8.14 (Issue 1)
Measuring systems for liquids other than water: MID-005	Guide 8.15 (Issue 2)
Automatic catchweighers: MID-006 II	Guide 8.16.1(Issue 2)
Automatic gravimetric filling instruments: MID-006 III	Guide 8.16.2 (Issue 1)
Discontinuous totalisers: MID-006 IV	Guide 8.16.3 (Issue 1)
Continuous totalisers: MID-006 V	Guide 8.16.4 (Issue 1)
Automatic rail weighbridges: MID-006 VI	Guide 8.16.5 (Issue 1)
Capacity serving measures: MID-008 II	Guide 8.18-2 (Issue 1)
Length measuring instruments: MID-009 II	Guide 8.19-1 (Issue 1)
Area measuring instruments: MID-009 III	Guide 8.19-2 (Issue 1)
Multidimensional measuring instruments: MID-009 III	Guide 8.19-3 (Issue 1)

It will be for the Notified Body to decide how to interpret the guidance.

49 The EU Commission in relation to the Directive have published a list of harmonised standards in the Official Journal 2007/C 162/06 which gives presumption of conformity to the essential requirements. In relation to these Regulations this covers the following instruments:

Heat meters – EN 1434: 2007
Gas meters - Volume conversion devices (Part 1): EN 12405-1:2005 / A1: 2006
Water meters – EN 14154: 2005 / A1: 2007

This information can be found by reference to OJ on the EU web-site at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2007:162:0013:0014:EN:PDF

Regulation 10(2)

50 Schedule 3 of the Regulations outlines the nature of the technical documentation that a manufacturer or his authorised representative must maintain. This information must be provided to a notified body to enable them to carry out the relevant assessment. This documentation must be provided in the language of the notified body or any other acceptable language in compliance with paragraph 10 of Part 2 of Schedule 2.

MARKING AND IDENTIFICATION REQUIREMENTS

Regulation 11

51 Schedule 4 to this guidance describes the CE marking, supplementary metrology (M) marking and the identification number of the notified body concerned with the conformity assessment which must be affixed to each instrument so as to be visible and legible. The M marking denotes that the instrument/measure specifically meets the requirements of the MID.

52 It should be noted the supplementary markings are different from those in NAWI Directive 90/384/EEC .For the purposes of the MID; the M marking does not have to be on a green background as it does under the NAWI Directive 90/384/EEC but it must be accompanied by the last two digits of the year in which it is affixed. For the precise detail and explanation of the marking requirements refer to Schedule 4 to this guidance.

CONFORMITY WITH OTHER DIRECTIVES

Regulation 12

53 Where a measuring instrument falls within the scope of other directives which provide for the affixing of the CE marking the CE marking affixed to the instrument shall, in addition to conformity with the Directive, indicate conformity with those other directives. Those directives could include the following

•2004/108/EC on electro-magnetic compatibility, as implemented by the Electromagnetic Compatibility Regulations 2006 (2006/3418));

2006/42/EC on machinery safety, as implemented by the Supply of Machinery (Safety) regulations 2008 (20081597); and

• 2006/95/EC on low voltage, codifying 73/23/EEC (amended by 93/68/EEC), as implemented by the Electrical Equipment (Safety) Regulations 1994.

This list is not exhaustive

THE ELECTROMAGNETIC COMPATIBILITY REGULATIONS 2005

54 The Electromagnetic Compatibility Directive was implemented in the UK by the Electromagnetic Compatibility Regulations 2005 (S.I. 2005 No 281) and applies to all relevant instruments. The Directive specifically provides immunity requirements in relation to instruments within its scope and therefore these implementing regulations have been disapplied for all instruments covered by the Directive by Regulation 33 of the Measuring Instruments (Automatic Gravimetric Filling Instruments) Regulations 2006 (S.I. 2006 No. 1258). The EMC Regulations 2005 remain in force for all measuring instruments not subject to these or other regulations i.e. all those instruments that are not regulated whether because the instrument type is not regulated in the UK or is a regulated instrument that is not in use for trade. The EMC Regulations continue to apply to emissions.

Schedule 1

PART 1 – ESSENTIAL REQUIREMENTS

55 There are two elements to the essential requirements. This part covers Annex I of the Directive which outlines the essential requirements with which all measuring instruments must comply.

56 The preamble to Annex I of the Directive, see below, should be noted as it sets out the underlining principle behind the essential requirements:

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

57 This principle represents an implicit general protection against the systematic exploitation of the maximum permissible errors of measurement (inside the controlled range) for measuring instruments. The Amendment Directive provides in addition a specific protection against such systematic exploitation for the following measuring instruments:

- water meters (at point 6a, MPE, Annex MI-001)
- volume conversion devices (at point 8, Part II MPE, Annex MI-002)
- heat meters (at point 3, MPEs applicable to complete heat meters, Annex MI-004**)**
- measuring systems for the continuous and dynamic measurement of quantities of liquids other than water (at point 2.8, Accuracy classification and maximum permissible errors (MPEs), Annex MI-005)

58 The method of test and the standards to be used for testing is one that would be determined by application of the relevant harmonised standard or normative document, where available, or by the Notified Body appropriate for the particular conformity assessment module. Notified Bodies responsible for quality system certification would be looking to ensure that appropriate equipment traceable to national standards was being used by trained personnel to carry out checks and tests on instruments.

2. Definitions

59 The principle definitions are to be found in Regulation 2(1). This paragraph contains the general definitions for the terminology not found in the Regulations whilst the terminology specific to a particular instrument category or type can be found in Part 2 of this Schedule.

3. Allowable errors

60 Refer to OIML D11 Edition 2004.

61 Sub-paragraphs 5(a) of the relevant part of Schedule 1 Part 1 of the Regulations sets out the general requirements for climatic environments in which the instrument is intended to be used. It is important to recognise that these requirements may be restricted by instrument specific limitations as set out in Part 2 of Schedule 1 of the Regulations, Parts A to G. Table 1 may be replaced by a specified minimum temperature range which could vary dependant on the Class of instrument type. However, this range still however has to remain within the overall maximum temperature limits of -40 ^{o}C and 70 ^{o}C eg automatic weighing instruments (Part D). It may be that the Table is replaced by a specific reference temperature and temperature limits eg material measures (Part E).

62 Other member States may also place national temperature limitations on the use of certain instruments as a consequence of local climatic conditions by choosing appropriate upper and lower temperature limits from Table 1. Manufacturers should make themselves aware of such limitations by reference to placing on the market and putting into use requirements in other member States MID implementing legislation. This is more likely to occur in member States with extremely hot and/or cold environments which may only be applicable in certain regions or parts of the country.

63 In relation to mechanical environments under sub-paragraph 5(c) there are no instrument specific limitations other than in relation to automatic weighing instruments (Part D) where the requirements are disapplied and other general conditions added.

64 In relation to electromagnet environments under sub-paragraph 5(c) it is for the manufacturer to decide on the appropriate class dependent upon the intended use of the instrument. The classes which are referred to as E1, E2 and E3 relate to disturbances which are likely to be found in residential, commercial and light industrial buildings, found in other industrial buildings and supplied by the battery of a vehicle respectively.

65 Residential, commercial and light industrial buildings (E1) would generally cover locations such as houses and apartments, shops and supermarkets, offices and banks, cinemas, public bars and halls, petrol stations and amusement and sports centres, and workshops, laboratories and service centres. This classification should be applied if the instrument is intended to be directly connected to a low-voltage public mains network or indirectly via a dedicated dc source.

66 Other industrial buildings (E2) are characterised by the existence of one or more of the following; a power network powered by a high or medium voltage power transformer dedicated for the supply of an installation feeding manufacturing or similar plant, industrial, scientific and medical apparatus, frequently switched heavy inductive or capacitive loads or high currents and associated magnetic fields

67 Instruments either specifically designed to be vehicle mounted or instruments which can be mounted and used from a vehicle, and powered from the vehicle battery source should comply with the requirements of E3. Vehicle mounted instruments powered from a separate independent source would be expected to at least meet the requirements of E2.

68 A manufacturer should consider his potential market scope before deciding on is the most appropriate environment class as the costs of upgrading an instrument at a later date to a higher class could be significant.

4. Reproducibility

69 No added general comments.

5. Repeatability

70 No added general comments.

6. Discrimination and Sensitivity

71 No added general comments.

7. Durability

72 No added general comments

8. Reliability

73 No added general comments.

9. Suitability

74 Refer to WELMEC guide 7.2 (Issue 1) for matters relating to software.

10. Protection against corruption

75 Refer to WELMEC guide 7.2 (Issue 1) for matters relating to software.

11. Information to be borne by and to accompany the instrument

76 No added general comments.

12. Indication of result

77 Refer to WELMEC guide 7.2 (Issue 1) for matters relating to software.

13. Further processing of data to conclude the trading transaction

78 No added general comments

14. Conformity evaluation

79 No added general comments

PART 2 – INSTRUMENT SPECIFIC REQUIREMENTS

Part A – Water meters

80 Refer to WELMEC guide 8.11 (Issue 1)

MPE - Paragraph 18(3)

81 The Amendment Regulations make additional provision that a water meter must be set as accurately as possible i.e. as closely as possible to zero for placing on the market and putting into use with the aim of preventing short measure from within the given tolerances.

Part B – Heat meters

82 Refer to WELMEC guide 8.14 (Issue 1)

MPE applicable to complete heat meters - Paragraph 27

83 The Amendment Regulations make additional provision that a complete heat meter must be set as accurately as possible i.e. as closely as possible to zero for placing on the market and putting into use with the aim of preventing short measure from within the given tolerances.

Part C – Measuring systems for the continuous and dynamic measurement of quantities of liquids other than water

84 Refer to WELMEC guide 8.10 (Issue 1).

10.1 (Issue 1) - Guide for Pattern Examination
10.2 (Issue 1) - Guide to Metrological Devices for Transferring Measured Quantities (DTMQ) associated to bottom loading measuring system**s**
10.3 (Issue 1) - Guide for the use of an alibi recording device (printer or memory) in Measuring Systems for Liquids other than Water
10.4 (Issue 1) - Guide for Testing of Electronic Calculators with Conversion Function and Conversion Devices
10.5 (Issue 1) - Guide for Guide for Common Application of Marking of Fuel Dispensers

Accuracy classification and maximum permissible errors (MPEs) - Paragraph 36

85 The Amendment Regulations make additional provision that a measuring system for the continuous and dynamic measurement of quantities of liquids other than water must be set as accurately as possible i.e. as closely as possible to zero for placing on the market and putting into use with the aim of preventing short measure from within the given tolerances.

Part D – Automatic weighing instruments

86 Refer to WELMEC guides:

8.16.1 (Issue 1) – Catchweighers
8.16.2 (Issue 1) – Gravimetric filling instruments
8.16.3 (Issue 1) – Discontinuous totalisers
8.16.4 (Issue 1) – Continuous totalisers (beltweighers)
8.16.5 (Issue 1) – Rail-weighbridges

87 Other WELMEC documents which provide relevant information are:

2.4 (Issue 2) - Guide for Load Cells
2.6 (Issue 2) - Guide for the testing of automatic catchweighing instruments

Part E – Material measures

88 No WELMEC guides are yet available for length measures. For capacity serving measures refer to guide 8.18.2 (Issue 1).

89 Manufacturers should be aware that other member States implementing legislation may, where length measures and/or capacity serving measures are prescribed, restrict measures to certain quantities for particular purposes as is the case in the United Kingdom.

Part F – Dimensional measuring instruments

90 Refer to WELMEC guides

8.19.1 (Issue 1) – Length measuring instruments
8.19.2 (Issue 1) – Area measuring instruments
8.19.3 (Issue 1) – Multidimensional measuring instruments

Part G – Volume conversion devices

91 A volume conversion device is a separate sub-assembly which can be added to a gas meter. Devices which are integrated ie built in, to a gas meter are not considered under these Regulations. Refer to WELMEC guide 8.12.2 (Issue 1).

MPE - Paragraph 64

92 The Amendment Regulations make additional provision that a volume conversion device must be set as accurately as possible i.e. as closely as possible to zero for placing on the market and putting into use with the aim of preventing short measure from within the given tolerances

Schedule 2 - Notified Bodies

PART 1 – CRITERIA TO BE SATISFIED BY NOTIFIED BODIES

This schedule sets out the criteria that a notified body must meet in order to satisfy the designating authority that the body is suitable to be designated a Notified Body under the Regulations. This includes demonstrating that the body, its director and staff involved in the conformity assessment are professional and not subject to financial inducements, has at its disposal all the staff and facilities necessary to carry out the conformity assessment in a proper manner, will be impartial and observe professional secrecy and hold adequate civil liability insurance.

Where the body sub-contracts specific tasks it will need to ensure that the sub-contractor meets the requirements of the Regulations. The body must keep relevant documents assessing the sub-contractor's qualifications and the work carried out by him under these regulations at the disposal of the designating authority.

The applicant body shall demonstrate that it meets the core criteria set out in the Directive. It is the designating authority that will assess whether an organisation meets the core criteria necessary to enable them to be designated as a notified body.

The following standards act as guidelines for the operation of various notified bodies.

The ISO/IEC 17000 Series
Council Decision 93/465/EEC set out the general framework for the assessment of notified bodies. It includes the policy that Member States should use the EN 45000 series of standards as the basis for the assessment of an applicant body against the core criteria.
These standards are being replaced progressively by standards in the ISO/IEC17000 series and the standards that are relevant for these guidelines are listed below. They are referred to collectively as the 'conformity assessment body standards'. The conformity assessment body standards cover different types of body but in general terms they have a similar structure, consisting of parts dealing with the organisation and management of a body, and parts dealing with the technical requirements relating to the operation of the body in the areas of testing, inspection, product certification and management systems assessment.

BS EN ISO/IEC 17025:2005 ***General requirements for the competence of testing and calibration laboratories*** (The contents of this standard differ considerably from BS 45001:1989 that it has superseded.)

BS EN ISO/IEC 17020:2004 ***General criteria for the operation of various types of bodies performing inspection*** (This standard has superseded BS EN 45004:1995 but the contents are identical.)

BS EN 45011:1998 ***General requirements for bodies operating product certification Systems***

BS EN 45012:1998 ***General requirements for bodies operating assessment and certification/registration of quality systems.***
(This standard will be superseded by ISO/IEC 17021.)
Note 1 Official Journal L220 30 August 1993. 93/465EEC Council Decision of 22 July 1991 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing of the CE Marking, which are intended to be used in the technical harmonisation directives. ("The Modules Decision").

PART 2 – FUNCTIONS

The notified body is required to assess the application from the manufacturer for a certificate of conformity, design or type examination certificate or notification (approval of the manufacturers' quality system), taking account of the actual or usual environment of the instrument type(s) together with any other technical criteria appearing to it to be relevant.

Paragraph 9(5) requires the notified body (other than the Secretary of State) to send a copy of;

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

to the designating authority from which it obtained its designation once it has been issued.

Specific arrangements will be made with notified bodies issuing certificates in categories b and c as part of their designation process.

For notified bodies appointed to conduct tasks under annexes that require the issuing of certificates of conformity the process is more general. In the first instance the notified body is required to report a summary of actions as part of their designation letter (annex1). The notified body is also required to retain the certificate of conformity for assessment by the bodies designated auditor on behalf of the designating authority and if requested inspection directly by the designating authority.

Schedule 3 - Technical Documentation

This section describes the requirements in terms of the detail that must be provided to ensure that the instrument meets the essential requirements.

SCHEDULE 4
MARKING AND INSCRIPTIONS

Regulation 11(3) (Sticker 3 only)

Supply of Stickers

The Secretary of State has decided that it is necessary to provide a long term, professional solution to resolve the difficulties that have arisen in securing a consistent good quality source for the supply of the metrology stickers that local authorities and others require to fulfil their statutory obligations for both initial verification, disqualification and subsequent re-qualification activities.

A new solution has been identified which will enable NMO to produce printed versions of the stickers described below on demand. The system has the capability to incorporate the specific identification data required in thermal printed form. This solution will replace the current stop-gap solution introduced in 2006 to allow for the changes to the marking requirements in the MID which meant that, when re-qualifying an instrument, an inspector has to apply both his number and the year of re-qualification in manuscription on a modified NAWI sticker using a "permanent" marker. It has become clear that these marks were not sufficiently permanent so as to withstand the harsh cleaning requirements in some conditions of use particularly in the food preparation sector.

The new stickers have been tested and performed well in a harsh cleaning environment and have been found to meet the requirements applicable in the food industry.

It is the opinion of the Secretary of State that the following stickers should be required to be used for the statutory marks. The new stickers are 12.7 mm x 11.10 mm.

It is not envisaged that the Weights and Measures (Prescribed Stamp) Regulations 1968 (SI. 1968/1615) will need to be amended as re-qualification is carried out under the provisions of these regulations.

The Green M metrology mark, and the CE mark for initial verification which are the responsibility of the instrument manufacturer will not be supplied centrally.

The new stickers will also be relevant to local authorities who are notified bodies and to approved verifiers under the regulations. Commercial organisations which need to obtain supplies are invited to contact **stickers@nmo.gov.uk** to discuss availability and prices.

The Secretary of State has determined that there will be benefits arising from a change of process with the stickers produced centrally and supplied by NMO directly to local authorities. To that end the decision has been made to supply a limited quantity of stickers free of charge to all inspectors. The stickers used for re-qualification of NAWI and MID instruments will be supplied overprinted with the inspector's number and on an annual basis with the year also overprinted. Stickers can also be overprinted with the relevant Notified Body/Approved Verifier numbers on request

If you have a requirement for a larger quantity , or you are not a local authority, please contact **stickers@NMO.gov.uk**. It will be possible to agree terms under which larger numbers/other stickers can be provided (at a cost).

STICKER 3 - NOTIFED BODY IDENTIFICATION NUMBER FOR INITIAL VERIFICATION

NB 0126

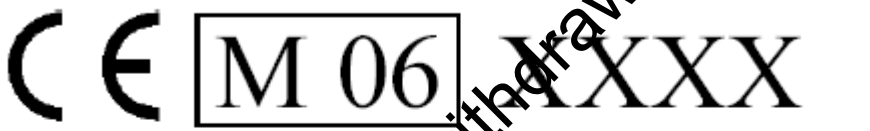
This is a plain white label in which the Notified Body number has been overprinted using a thermal printer. It is not a requirement for the number to be pre-fixed by NB.

Other marks and requirements for MID instruments

1. The CE marking consists of the symbol “CE” according to the design laid down in paragraph I.B(d) of the Annex to Decision 93/465/EEC. 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 shall follow the CE marking and the M Marking.
4. 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.”

Directive 2004/22/EC does not itself contain diagrams for any of these marks although **the CE mark** is prescribed by reference to paragraph I.B(d) of the Annex to Decision 93/465/EEC.

Possible Examples of Article 17 Markings required by the MID Directive

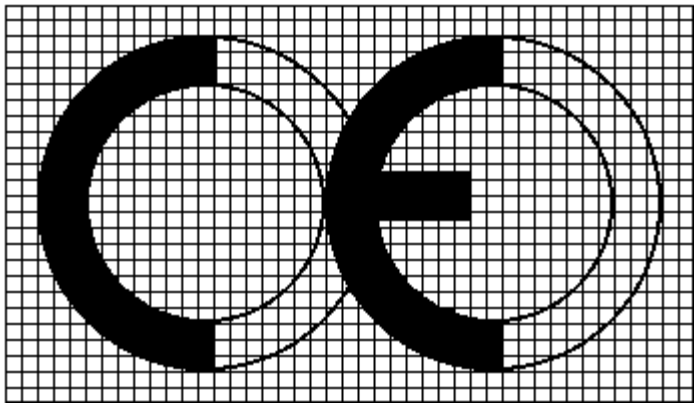


CE Mark
At least 5 mm high

Supplementary metrology mark
Rectangle height the same as CE
‘Immediately follows’ CE

Identification number of the notified body
‘Follows’ CE and Supplementary metrology mark

“The CE mark must not be less than 5mm in its vertical height, and the proportions maintained. It is generally shown on a grid in the guidance booklets, as below (the grid does not form part of the marking and is for information only):



This mark looks the same as some previous marks, but there are subtle changes, and it should be studied closely. It should be noted, for example, that the C and E are not formed by perfect semi-circles, i.e. the top and bottom arms extend one square beyond the semi-circles, and the middle arm of the E stops one square short.

The graphic is not made available for download from any official sources, but can be obtained in a wide variety of file formats from commercial organisations, sometimes freely available for download. One such organisation in the UK is **Conformance**, but please note that the NMO makes no guarantee of accuracy or suitability of any files obtained from commercial sources.

As far as **the M mark** is concerned, the manufacturer applying the mark has freedom over the design provided that the M marking meets the criteria set down in Paragraph 2 of Schedule 4 of Directive 2004/22/EC, as to being surrounded by a rectangle also containing the last two digits of the year of affixing, and is placed immediately after the CE mark.

Similarly **the Notified Body** must place its mark, or authorise the manufacturer to do so on its behalf, so that it follows the CE and M markings.

The identification number of the notified body concerned shall follow the CE marking and M marking.

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

The Directive does not specify in detail the form and appearance of all the various markings. It has therefore been necessary to decide on the details that will apply under the Regulations as indicated in the examples statutory marks above.

Schedule 5 – This is not part of the Regulations

Work instructions etc for 3rd party verification

Local Government Regulation (formerly LACORS) work instructions should be used as guidance in carrying out 3rd party verification. These instructions are available for non-subscribers from **www.lacors.gov.uk** . You should then click on Publications at the top, scroll down to Trading Standards, then click on Metrology, then Measuring Instruments Directive (MID), and open the page called MID Equipment Test Forms. This is the same page as seen by Local Government Regulation's subscribers. You will find the documents for the following instruments on the list:

- Automatic gravimetric filling instruments (MI-006 Chapter III)
- Automatic railweighers (MI-006 Chapter VI)
- Capacity serving measures (MI-008 Chapter II)
- Liquid fuel dispensers (MI-005)
- Road tanker mounted meter measuring systems for liquid fuel (MI-005).

Documents for other instrument types are in preparation and will be available at a later date.

- Automatic Continuous Totalisers (Beltweighers) (MI-006 Chapter V)
- Automatic Catchweighers (MI-006 Chapter II Category Y)
- Automatic Discontinuous Totalisers (MI-006 Chapter IV)
- Measures of Length (MI-008 Chapter II)
- Automatic Checkweighers (MI-006 Chapter II Category X)

The above instructions along with test forms and conformity certificates provide guidance for those notified bodies designated to carry out declaration of conformity based on product verification (Module F1) ie 3rd party initial verification. It is primarily aimed at Trading Standards services but could be used by other organisations carrying out verification activities.

Sections of the instructions cover: staff, equipment (including documentation), and verification procedures along with a separate 'check list' test form and proforma Certificate of Conformity and Refusal to Issue Certificate of Conformity.

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