CONTENTS LIST

2.1 LEGAL METROLOGY DOCUMENTATION

EC Directives
EC directives oblige member states (through the Treaty of Rome) to incorporate their requirements into national law. One of the objectives is to remove barriers to free trade and promote free movement of goods and services within the EU. They also make it easier for nations outside the EU to trade with member states as there is one set of standards rather than differing regulations between each nation.

Most of the directives that apply to weighing equipment are “new approach” directives. As such, the directives are limited to specifying the “essential requirements”. Conformity with these requirements may be met through specific technical solutions identified in separate “harmonised standards” or “normative documents”. One other characteristic is the requirement for CE marking to show that the equipment conforms to the requirements each of the applicable directives.

The principle of having separate harmonised standards or normative documents allows the technical details to be produced by specialist technical groups (such as, CEN, CENELEC, ETSI and OIML) rather than having to pass through the full EU legislative procedure. There is a “presumption of conformity” in that if the equipment complies with the relevant standard or normative document, it is presumed to conform to the essential requirements of the directive. Note: The normative document route is only applicable to automatic weighing instruments.

In theory, a manufacturer has the option of not working to the specified standard or normative document but proving through other means that the equipment conforms to the essential requirements of the directive. In practice this would be a very arduous method.

Acts and Regulations
The primary legislation in the UK has traditionally come from the Weights and Measures Act 1985 for GB (with similar provisions for NI). Various sections within the Act authorise the Secretary of State to make regulations and orders for specific weights and measures matters.

For the implementation of EC Directives, these are transposed into UK law under the 1972 European Communities Act (ECA). An example of this is the Non-automatic weighing instruments regulations 2000, which implement the NAWI directive 2009/23/EC

The W&M Act and the ECA and the associated regulations and orders form the national metrological legislation. All other documentation (i.e. directives, standards, guides etc.) only have indirect legal relevance.

WELMEC
WELMEC is a collaboration of national legal metrology organisations across the member states of the EU (European Union) and EFTA (European Free Trade Association). Various committees within WELMEC address specific subjects and produce guides on the implementation of European legislation. WELMEC is consulted in the formation of European legislation and hence plays a major part in its content. Additionally, members will be heavily involved in their own national legislation.

Although the WELMEC guides have no legislative powers themselves, if the guidance within them is followed, it can be assumed that an application complies with the essential requirements of the directive. However, if an approach is adopted that does not follow the guidance or even contradicts it, any application will have to provide very thorough proof that it is compliant and undergo very rigorous examination.

OIML

The International Organisation of Legal Metrology (OIML) is an intergovernmental treaty organization consisting of the legal metrology authorities of member states, established to promote the global harmonization of legal metrology procedures. Member authorities will work to the standards defined by OIML.

The OIML website states “Cooperative agreements are established between the OIML and certain institutions, such as ISO and IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML Publications and those of other institutions”. To illustrate this, the content of European harmonised standard EN45501 for NAWIs is taken directly from OIML R76, the International Recommendation for NAWIs, and OIML definitions are referred to directly in Directive 2009/23/EC, whereas the content of normative document on automatic gravimetric filling instruments is based on OIML R61, the International Recommendation for AGFIs.

OIML produce various publications including International Recommendations such as R76 Non-automatic weighing instruments and R60 Metrological regulation for load cells. Issuing Authorities established by OIML Member States may provide OIML certificates and test reports indicating compliance with the relevant recommendation. Any certificate must be registered with OIML and there is a fee for this registration. Although acceptance of OIML certificates by national metrology services is voluntary this is now widespread.

2.1.1 EC DIRECTIVES

Listed below are the key EC Directives that are linked to the weighing industry. They will also appear in section 2.1.2, which covers how they are regulated and implemented in UK legislation.

Directive 2009/23/EC on Non-automatic Weighing Instruments
The directive consists of 19 articles and 8 annexes. Article 1 includes the definition of a non-automatic weighing instrument and the often quoted second clause (article 1.2(a))providing a list of categories of use, for which the essential requirements of the directive must be satisfied. The remainder of the articles are largely administrative or procedural and refer to the annexes.

The annexes form the bulk of the directive. Annex I specifies the essential requirements that must be satisfied for all categories listed in article 1.2(a). The essential requirements specify the criteria that must be met (for example the maximum permissible errors) but not the methods of testing and proving conformity. Detailed test methods are specified in the relevant harmonised standard which is EN 45501 (equivalent in content to OIML R76).

The remainder of the annexes cover type approval, verification, notified bodies, documentation and markings required.

Directive 2004/22/EC on measuring instruments
The Measuring Instruments Directive (MID) consists of 27 Articles and a large number of Annexes. The MID covers a whole range of measuring equipment, including automatic weighing instruments of the following types:

- Automatic Gravimetric Filling Machines
- Automatic Checkweighers
- Automatic Catchweighers
- Continuous Totalisers
- Discontinuous Totalisers
- Automatic Rail Weighbridges

The MID contains general and instrument specific “essential requirements” (Annex 1 plus MI Annexes) which the equipment must meet it is used for controlled applications. However, unlike the NAWI Directive which details applications that must be controlled in all Member States, the MID leaves it up to each Member State to define the applications that it will control. If a Member State decides not to control a particular type of automatic weighing instrument, it cannot then impose any country specific requirements. For example, the UK has decided it will not control automatic checkweighers and therefore, a manufacturer can place any design of checkweigher on the UK market without the need for any form of Type Approval or verification. As well as the general essential requirements in Annex 1, for example for automatic gravimetric filling instruments, these can be found in Annex MI-006, Chapter I and Chapter III.

Other Annexes deal with the various forms of conformity assessment, including Type Approval, Design Examination, and verification. Requirements in relation to notified bodies technical documentation and markings required can be found in the directive itself.

OTHER METROLOGICAL DIRECTIVES

71/317/EEC on 1 g to 50 kg medium accuracy weights

74/148/EEC on weights from 1 mg to 50 kg of above medium accuracy

73/360/EEC on non-automatic weighing machines
Superseded by 2009/23/EC (the NAWI Directive).

75/410/EEC on continuous totalizing weighing machines
Superseded by the MID.

78/1031/EEC on automatic checkweighing and weight grading machines
Superseded by the MID.

References

All of the directives are available from the commission website for legislation (EUR-Lex): http://eur-lex.europa.eu/en/index.htm

Note that the first part of the number of a directive (2 or 4 digits) represents the year of issue and the second is the document number. The most direct method of finding a document is to search by “Natural number” and enter the two figures.

2.1.2 ACTS AND REGULATIONS

The Weights and Measures Act 1985
The primary legislation governing weights and measures in GB is the Weights and Measures Act 1985. This supersedes all previous weights and measures acts. The equivalent for NI is the 1981 Northern Ireland Order.

The Act includes the following:

- Units and standards of measure with requirements for holding national, local and working standards for the UK
- Requirements for weighing and measuring for trade, transactions of goods, and packaged goods
- Definition of offences and possible defences
- Roles and responsibilities of various bodies and individuals including the Secretary of State, the Department of Innovation, Universities and Skills (in practice implemented through NMO), Local Weights and Measures Authorities, and Inspectors
- Authority for the Secretary of State to make Orders and Regulations for specific matters

The Act also includes various schedules which are enabled by specific sections within the main body and contain more detailed information such as definitions of units of measure, lists of units which may be used for trade and those which may not, primary standards, etc.

The European Communities Act 1972
The primary legislation used to implement European Directives e.g. in the field of legal metrology, for the UK is the European Communities Act 1972 (ECA).

Unlike the W&M Act, all provisions in relation to the control of weighing and measuring instruments are contained within the Regulations themselves.

REGULATIONS

Non-automatic Weighing Instruments Regulations 2000, SI 2000/3236 implements under the ECA directive 2009/23/EC on non-automatic weighing instruments and provides the structure for metrological control in the UK. This includes an expansion of controlled applications from “use for trade” as defined by the W&M Act 1985 to include other uses such as medical weighing and application of laws and regulations, as well as type-approval and unit verification procedures described by the NAWI directive. Separate in use provisions made under the W&M Act cover how NAWI can be used on the GB market place. Equivalent in use provisions exist for NI.

The Weighing Equipment (Non-automatic Weighing Machines) Regulations 2000, SI 2000/932 consolidate and revoke a series of previous regulations on non-automatic weighing machines and provide the provisions for control on the use of existing machines with GB national approval in GB. Equivalent provisions exist for NI.

Weights Regulations 1986, SI 1986/1683 define the specifications for “traders” weights in GB; denominations, markings, shapes and limits of error. Equivalent provisions exist for NI.

The Weights and Measures (Local and Working Standard Weights and Testing Equipment) Regulations 1986, SI 1986/1684 as amended by SIs 1991/1775 and 1994/1851 provides, in sections 4 and 5, for certain aspects of the standards and equipment used by inspectors (Trading Standards Officers) to be set out in Regulations. These aspects include the limits of error and intervals between calibrations. Equivalent provisions exist for NI.

Measuring Instruments (EEC Requirements) Regulations 1988, SI 1988/186
Implemented under the ECA the following directives:

- 71/316/EEC on common provisions for both measuring instruments and methods of metrological control
- 71/317/EEC on weights from 5 g to 50 kg of medium accuracy
- 73/360/EEC on non-automatic weighing machines
- 74/148/EEC on weights from 1 mg to 50 kg of above medium accuracy
- 75/410/EEC on continuous totalizing weighing machines (Superseded by the MID)
- 78/1031/EEC on automatic checkweighing and weight grading machines (Superseded by the MID)

REGULATIONS AMENDING THE W&M Act 1985

The Units of Measurement Regulations 1986, SI 1986/1082 consolidate and revoke previous regulations and define units of measurement. They do not affect the units which may lawfully be used for trade but simply provide definitions.
Section 8(5)(b) updated (regulation 10).

The Weights and Measures Act 1985 (Metrication) (Amendment) Order 1994, SI 1994/2866 together with SI 1994/2867 (below) end the authorised use, except in specified circumstances, of imperial units of measurement.
Section 8(2) and Schedules 3 to 7 amended.

The Units of Measurement Regulations 1994, SI 1994/2867
Sections 1, 3 and 27 and Schedules 1, 5 and 11 amended (The Units of Measurement Regulations 1986 also amended).

The Deregulation (Weights and Measures) Order 1999, SI 1999/503 provides for self-verification of machines by an approved verifier within GB and requires acceptance of machines tested by "official testers" elsewhere in the European Economic Area (EEA) by an Inspector.
Sections 11, 14, 16, 74, 75, 79, 84 and 94 amended; new sections 11A, 11B and 15A and Schedule 3A added.

The Units of Measurement Regulations 2009, SI 2009/3046 amend the Weights and Measures Act 1985 by removing a deadline of 31 December 2009 for the end of the authorised use of non-metric units in conjunction with metric units.

REGULATIONS GOVERNING AUTOMATIC WEIGHING INSTRUMENTS
Part A below details the GB Regulations that applied to automatic weighing instruments that were in use before the Measuring Instruments Directive came into force on 30th October 2006 and continue to apply to those instruments outside the scope of MID. Although now superseded in relation to MID instruments, these Regulations continue to apply to that equipment whilst it remains in use. Any equipment that has a national Type Approval under the 1985 Weights and Measures Act can continue to be manufactured, verified and taken into service until the Type Approval Certificate expires.

Part B below details the UK Regulations, implementing the provisions of the Measuring Instruments Directive, under the ECA, that relate to Automatic Weighing Instruments (AWIs). The instrument specific regulations provide the structure for metrological control in the UK. Separate in use provisions made under the W&M Act cover how AWIs can be used on the GB market place. Equivalent in use provisions exist, in most cases, for NI.

PART A

The Weights and Measures Regulations 1963, SI 1963/1710
Although mostly revoked by succeeding regulations, still governs dynamic axle weighers (road).

The Weighing Equipment (Filling and Discontinuous Totalising Automatic Weighing Machines) Regulations 1986, SI 1986/1320
Automatic weighing equipment:
- filling instruments (gravimetric filling instruments now approved under SI 2000/388)
- discontinuous totalisers

The Weighing Equipment (Automatic Gravimetric Filling Instruments) Regulations 2000, SI 2000/388
Automatic gravimetric filling instruments which sub-divide from bulk into pre-determined quantities

The Weighing Equipment (Beltweighers) Regulations 2001, SI 2001/1208
Beltweighers (continuous totalising automatic weighing machines). Replaced SI 1983/914

The Weighing Equipment (Automatic Rail-weighbridges) Regulations 2003, SI 2003/2454
Automatic rail-weighbridges

The Weighing Equipment (Automatic Catchweighing Instruments) Regulations 2003, SI 2003/2761
Automatic catchweighers, e.g. weigh-price labellers, garbage weighers, front-end loaders

PART B

The Measuring Instruments (Automatic Discontinuous Totalisers) Regulations 2006; SI 2006/1255

The Measuring Instruments (Automatic Rail Weighbridges) Regulations 2006; SI 2006/1256

The Measuring Instruments (Automatic Catchweighers) Regulations 2006; SI 2006/1257

The Measuring Instruments (Automatic Gravimetic Filling Instruments) Regulations 2006; SI 2006/1258

The Measuring Instruments (Beltweighers) Regulations 2006; SI 2006/1259

The Measuring Instruments (Non prescribed Instruments) Regulations 2006/1270
These regulations provide for the conformity assessment i.e. approval and verification, of instruments not prescribed in the UK e.g. checkweighers, by, or on behalf of, UK notified bodies, which are regulated on other Member States markets.

2.1.3 WELMEC DOCUMENTATION

The principal aim of WELMEC is to establish a harmonised and consistent approach to European legal metrology. Currently 30 countries are represented on the WELMEC committee and the contact details for these individuals can be found on the following website: http://www.welmec.org/

Much of WELMEC's work is done by its Working Groups. These groups produce guidance documents which are important for the manufacturers and suppliers of weighing instruments, and are detailed below:

Guide	Title	Version	Produced by
1	An Introduction to WELMEC	5	Secretariat
2	Directive 90/384/EEC: Common Application	4	WG2 (Weighing instruments)
2.1	Guide for Testing Indicators	4	WG2 (Weighing instruments)
2.2	Guide for Testing Point of Sale Devices	3	WG2 (Weighing instruments)
2.3	Guide for Examining Software	3	WG2 (Weighing instruments)
2.4	Guide for Load Cells	2	WG2 (Weighing instruments)
2.5	Guide for Modular Approach and Testing of PCs and other Digital Peripheral Devices	2	WG2 (Weighing instruments)
2.6	Guide for the Testing of Automatic Catchweighing Instruments	3	WG2 (Weighing instruments)
2.7	Explanations and Interpretations	1	WG2 (Weighing instruments)
4.1	Guide for Notified Bodies performing Conformity Assessment of Measuring Instruments	2	WG4 (EN4500 standards)
5.1	European Directory of Legal Metrology	-	WG5 (Market supervision)
5.2	Guide on market surveillance	2	WG5 (Market supervision)
5.3	Risk Assessment Guide for Market Surveillance: Weighing and Measuring Instruments	1	WG5 (Market supervision)
6	Introduction to WELMEC documents on "e"-marked pre-packages	3	WG6 (Pre-packages)
6.1	Application of Directives 75/106/EEC and 76/211/EEC concerning the marking and quantity control of “e”-marked pre-packages: Definition of terms	1	WG6 (Pre-packages)
6.2	An Application of Directives 75/106/EEC and 76/211/EEC concerning the marking and quantity control of “e”-marked pre-packages: Translation of terms	1	WG6 (Pre-packages)

6.3	Guidance for the Harmonised Implementation of Council Directive 76/211/EEC	2	WG6 (Pre-packages)
6.4	Guide for packers and importers of e-marked pre-packed products	1	WG6 (Pre-packages)
6.5	Guidance on Controls by Competent Department's on "e"-marked Pre-packages	1	WG6 (Pre-packages)
6.6	Guide for the recognition of procedures	1	WG6 (Pre-packages)
6.7	Guidance for Market Control of Pre-packages for Competent Departments	1	WG6 (Pre-packages)
6.8	Guidance for the verification of drained weight, drained washed weight, and deglazed weight and extent of filling of rigid food containers	1	WG6 (Pre-packages)
6.9	Pre-packages - Uncertainty of Measurement	1	WG6 (Pre-packages)
7	Guidelines for Examination and Testing of Interfaces and Peripheral Equipment	1	WG7 (Software)
7.1	Software Requirements on the Basis of the Measuring Instruments Directive (MID)	2	WG7 (Software)
7.2	Software Guide (Measuring Instruments Directive 2004/22/EC)	5	WG7 (software)
8.1	Terms and definitions in MID and their relationship to terms defined on other international metrologically relevant documents	1	WG8 (MID)
8.16-1	Guide for Measuring Instruments Directive 2004/22/EC Automatic Catchweighers; Corresponding Tables OIML R51-1 1995 - MID-006-II	1	WG8 (MID)
8.16-2	Guide for Measuring Instruments Directive 2004/22/EC Automatic Gravimetric Filling Machines; Corresponding Tables OIML R61-1 2004 - MID-006-III	1	WG8 (MID)
8.16-3	Guide for Measuring Instruments Directive 2004/22/EC Discontinuous Totalisers; Corresponding Tables OIML R107-1 1997 - MID-006-IV	1	WG8 (MID)
8.16-4	Guide for Measuring Instruments Directive 2004/22/EC Continuous Totalisers; Corresponding Tables OIML R50-1 1997- MID-006-V	1	WG8 (MID)
8.16-5	Guide for Measuring Instruments Directive 2004/22/EC Automatic Rail Weighbridges; Corresponding Tables OIML R106-1 1997 - MID-006-VI	1	WG8 (MID)
9	WELMEC Type Approval Agreement	5	Secretariat

10.1	Guide for Pattern Examination	1	WG10 (Measuring Systems for Liquids Other Than Water)

WELMEC Working Groups are continuously working on many aspects of legal metrology and it is always worth checking the WELMEC website, www.welmec.org, to ensure that you have the latest version of any document. The WELMEC Guides are freely downloadable from the same site.

2.1.4. OIML PUBLICATIONS

The International Organization of Legal Metrology (OIML) is an intergovernmental treaty organization whose membership includes Member States, countries which participate actively in technical activities, and Corresponding Members; countries which join the OIML as observers. It was established in 1955 in order to promote the global harmonization of legal metrology procedures.

OIML publications are available to download free of charge from the OIML website, http://www.oiml.org/publications/

The main recommendations that are relevant to the weighing industry are as follows:

Ref	Title	Edition
R47-EN	Standard weights for testing of high capacity weighing machines	1979
R50-1-EN	Continuous totalizing automatic weighing instruments (belt weighers). Part 1 : Metrological and technical requirements - Tests	1997
R51-1-EN	Automatic catchweighing instruments. Part 1 : Metrological and technical requirements - Tests	2006
R52-EN	Hexagonal weights – Metrological and technical requirements	2004
R60-EN	Metrological regulation for load cells	2000
R60-sup-EN	Metrological regulation for load cells: Certificate transformation requirements	2000
R61-1-EN	Automatic gravimetric filling instruments. Part 1 : Metrological and technical requirements - Tests	2004
R61-sup-EN	Automatic gravimetric filling instruments: Certificate transformation requirements	2004
R76-1-EN	Non-automatic weighing instruments. Part 1 : Metrological and technical requirements - Tests (integrate Amendment No. 1 of 1994)	2006
R79-EN	Labelling requirements for pre-packaged products	1997
R87-EN	Quantity of product in pre-packages	2004
R106-1-EN	Automatic rail-weighbridges. Part 1 : Metrological and technical requirements - Tests	2011
R107-1-EN	Discontinuous totalizing automatic weighing instruments (totalizing hopper weighers). Part 1 : Metrological and technical requirements – Tests	2007
R111-1-EN	Weights of classes E1, E2, F1, F2, M1, M1–2, M2, M2–3 and M3 Part 1: Metrological and technical requirements	2004
R125-EN	Measuring systems for the mass of liquids in tanks	1998
R134-1-EN	Automatic instruments for weighing road vehicles in motion. Total vehicle weighing	2006

2.1.5. EN STANDARDS FOR LEGAL METROLOGY

Following Harmonised European Standards is one of the methods that manufacturers can use to demonstrate compliance with the essential requirements of European Directives in many fields.

Directive 2009/23/EC dealing with Non-automatic weighing instruments (NAWI) details the essential requirements that NAWI must meet before they can be placed on the European market and/or be taken into use in the EC. When the Directive was adopted in 1990, the European Commission issued a mandate to CEN/CENELEC, two of the bodies that develop European Standards, to produce a Standard that would ensure compliance with the Essential Requirements of the Directive. They came up with EN 45501, which was then recognised by the European Commission as being a Harmonised Standard giving as presumption of conformity to the Essential Requirements. The Standards making organisations in each of the Member States then transposed EN 45501 into a national standard. So in the UK, we now have BS EN 45501;1994 Specification for Metrological aspects of non-automatic weighing instruments, which is the exact equivalent of EN 45501:1992 as amended and corrected.

EN 45501 was itself an almost exact copy of OIML R 76-1 1992, Non-automatic weighing instruments Part 1 Metrological and technical requirements – Tests.

When the Measuring Instruments Directive 2004/22/EC was drafted, the provision regarding the use of Harmonised Standards was include, but the Directive also introduced a new concept, that of the “Normative Document”. Under this provision the European Commission can adopt documents developed by other organisations which will provide the same presumption of conformity as a Harmonised Standard.

Using this principle, the EC has agreed, with the advice of the Measuring Instruments Committee to give a number of OIML Recommendations the status of Normative Documents. This will avoid the need for CEN/CENELEC to go through the process of turning the Recommendations into European Standards and will overcome the problem that now exists with EN 45501 in that it did not keep up with the amendments to R76-1 1992, and is now even further out of step as a new revision of R76 was adopted in 2007.

The following list details the OIML Recommendations that have been adopted as Normative Documents:

R50-1:1997	Continuous Totalising automatic weighing instruments
R51-1: 2006	Automatic Catchweighing instruments
R61-1:2004	Automatic Gravimetric Filling instruments
R106-1:1997	Automatic Rail weighbridges
R107-1:2007	Discontinuous totalizing automatic weighing instruments

WELMEC have published Guidance documents detailing the Essential Requirements of the Measuring Instruments Directive and the corresponding provision of the OIML Document. These documents can be downloaded from the WELMEC website. They are:

WELMEC Guide 8.16-1	Automatic Catchweighers
WELMEC Guide 8.16-2	Automatic Gravimetric Filling Instruments
WELMEC Guide 8.16-3	Discontinuous Totalisers
WELMEC Guide 8.16-4	Continuous Totalisers
WELMEC Guide 8.16-5	Rail Weighbridges

2.2 GUIDANCE NOTES

There are many sources of information providing additional guidance on a wide variety of subjects related to weighing. Some specific sets of guidance notes are discussed in following subsections:

- NMO guidance notes for the NAWI regulations
- European Commission guidance notes on the New Approach directives
- The packers guide
- The WELMEC Guides

In addition to these, guides and information are provided by the following organisations.

WELMEC
The WELMEC guides are listed in section 2.1.3 and are used by regulatory authorities to provide a common interpretation of European metrology legislation.

OIML
Many of the relevant OIML documents are strictly 'recommendations' but they provide essential information regarding the standards and procedures used in legal metrology. These are listed in section 2.1.4.

NMO
The National Measurement Office produce various notes for guidance in addition to those on the NAWI regulations referred to in section 2.2.1. These can be obtained from the NMO website.

National Physical Laboratory (NPL) / Institute of Measurement and Control (IMC)
The NPL and IMC have a variety of guides on the measurement of mass and weight and industrial weighing. The guides are available from the NPL website.

United Kingdom Accreditation Service (UKAS) / European Accreditation (EA)
The UKAS and EA guides cover calibration and uncertainty. The guides are available from the respective websites.

European Commission
The so-called 'Blue Guide' to the New Approach directives is discussed in section 2.2.2. This guide is available from the Europa website.

Health and Safety Executive (HSE)
Amongst the many guides produced by the HSE, there are two in particular that may be of interest to the weighing industry on risk assessments and lifting operations and lifting equipment. These are available from the HSE website.

2.2.1. NAWI REGULATIONS 2000; NOTES FOR GUIDANCE

The Notes for Guidance on the NAWI Regulations 2000 has been published by the National Measurement Office (NMO) and is available to download free of charge from their website:

http://www.bis.gov.uk/assets/nmo/docs/legislation/legislation/nawi/nawi-amendment-nfg

The initial sections include some background information, conformity assessment procedures, and notes on the implementation of the NAWI directive 2009/23/EC

The bulk of the guide analyses the Regulations clause-by-clause with comment on each one. The notes relate the regulations to other documents such as the NAWI and other directives, the harmonised standard EN45501 (OIML R76), and other regulations. They also provide details of various associated organisations such as WELMEC, UKAS, EMeTAS, OIML, etc.

The annexes provide additional information as follows:

Annex 1	Extracts from the Weights and Measures Act 1985
Annex 2	Verification paths flowchart
Annex 3	Gravity Table
Annex 4	Form of the information on judicial remedies
Annex 5	Bibliography
Annex 6	Descriptions of the stickers and the identification number
Annex 7	Descriptions of supplementary legislation
Annex 8	Applicability of Regulations
Annex 9	Guidance notes for use by approving authorities undertaking initial verification of non-automatic weighing instruments in accordance with the International Recommendation R76-1 Edition 1992 *(notes providing a consolidation of the tests described in R76)*

2.2.2 GUIDE TO THE IMPLEMENTATION OF DIRECTIVES BASED ON THE NEW APPROACH AND THE GLOBAL APPROACH

The CE marking on a product indicates that it complies with all relevant directives. The so-called "new approach" directives that have adopted the CE mark are the more technical directives that have separated out the "essential requirements" specified in the directives themselves from the detailed technical standards that are used to demonstrate compliance.

The Guide is a lengthy (112 page) document that discusses all aspects of the New Approach and Global Approach directives and CE marking. It is written from an EU point of view, so much of the emphasis is on the requirements of member states rather than users of equipment or those involved in the supply chain. However, it is an invaluable resource in helping to understand the principle of CE marking, as it comes directly from the European Commission and provides an overview of all aspects.

The Blue Guide is at present being reviewed, but it remains a useful document in the understanding of the operation and function of new approach directives.

The Guide includes the following sections:

1. Introduction
2. Scope of the New Approach directives
3. Responsibilities (including manufacturer, authorised representative, importer, distributor, assembler/installer and user/employer)
4. Compliance with directives
5. Conformity assessment procedure
6. Notified bodies
7. CE marking
8. Market surveillance
9. External aspects

The following quotes are taken from the Guide:

Introduction

A new regulatory technique and strategy was laid down by the Council Resolution of 1985 on the New Approach to technical harmonisation and standardisation, which established the following principles.

~ Legislative harmonisation is limited to essential requirements that products placed on the Community market must meet, if they are to benefit from free movement within the Community.

~ The technical specifications of products meeting the essential requirements set out in the directives are laid down in harmonised standards.

~ Application of harmonised or other standards remains voluntary, and the manufacturer may always apply other technical specifications to meet the requirements.

~ Products manufactured in compliance with harmonised standards benefit from a presumption of conformity with the corresponding essential requirements.

New Approach directives are based on the following principles.

~ Harmonisation is limited to essential requirements.

~ Only products fulfilling the essential requirements may be placed on the market and put into service.

~ 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.

~ Application of harmonised standards or other technical specifications remains 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.

New Approach directives are addressed to the Member States, which have an obligation to transpose them into their national legislation as appropriate.

Scope

2.3. Placing on the market and putting into service

~ Placing on the market is the initial action of making a product available for the first time on the Community market, with a view to distribution or use in the Community. Making available can be either for payment or free of charge.

~ Putting into service takes place at the moment of first use within the Community by the end user. However, the need to ensure, in the framework of market surveillance, that products are in compliance with the provisions of the directives when being put into service is limited.

~ A product must comply with the applicable New Approach directives when it is placed on the Community market for the first time and put into service.

~ Member States are obliged:

** not to prohibit, restrict or impede the placing on the market and putting into service of products that comply with the applicable New Approach directives; and*

** to take any measures necessary to ensure that products are placed on the market and put into service only if they do not endanger the safety and health of persons, or other interests covered by the applicable directives, when correctly constructed, installed, maintained, and used in accordance with their purpose.*

Responsibilities

3.1. Manufacturer

~ A manufacturer, in the meaning of New Approach, is the person who is responsible for designing and manufacturing a product with a view to placing it on the Community market on his own behalf.

~ The manufacturer has an obligation to ensure that a product intended to be placed on the Community market is designed and manufactured, and its conformity assessed, to the essential requirements in accordance with the provisions of the applicable New Approach directives.

~ The manufacturer may use finished products, ready-made parts or components, or may subcontract these tasks. However, he must always retain the overall control and have the necessary competence to take the responsibility for the product.

3.2. Authorised representative

~ The manufacturer may appoint any natural or legal person to act on his behalf as an authorised representative.

~ For the purposes of New Approach directives the authorised representative must be established inside the Community.

~ The authorised representative is explicitly designated by the manufacturer, and he may be addressed by the authorities of the Member States instead of the manufacturer with regard to the latter's obligations under the New Approach directive in question.

~ The manufacturer remains generally responsible for actions carried out by an authorised representative on his behalf.

3.3. Importer/person responsible for placing on the market

~ An importer (a person responsible for placing on the market)– in the meaning of New Approach directives – is any natural or legal person established in the Community who places a product from a third country on the Community market.

~ The importer must ensure that he is able to provide the market surveillance authority with the necessary information regarding the product, where the manufacturer is not established in the Community, and has no authorised representative in the Community.

~ The natural or legal person who imports a product into the Community may, in some situations, be considered as the person who must assume the responsibilities placed on the manufacturer according to the applicable New Approach directives.

3.4 Distributor

~ Provisions regarding distribution are in general not included in New Approach directives.

~ A distributor is to be considered as any natural or legal person in the supply chain who takes subsequent commercial actions after the product has been placed on the Community market.

~ The distributor shall act with due care in order not to place clearly non-compliant products on the Community market. He shall also be capable of demonstrating this to the national surveillance authority.

3.5. Assembler and installer

~ The installer and assembler of a product, which is already placed on the market, should take necessary measures to ensure that it still complies with the essential requirements at the moment of first use within the Community. This applies to products where the directive in question covers putting into service, and w here such manipulations may have an impact on the compliance of the product.

3.6 User (employer)

~ New Approach directives do not lay down obligations for users, apart from those related to putting into service.

~ Community legislation concerning the health and safety of the workplace has an impact on the maintenance and use of products covered by New Approach directives that are used at the workplace.

Compliance with directive

4.1. Essential requirements

~ Essential requirements lay down the necessary elements for protecting the public interest.

~ Essential requirements are mandatory. Only products complying with essential requirements may be placed on the market and put into service.

~ Essential requirements must be applied as a function of the hazards inherent to a given product.

4.3. Presumption of conformity

~ Conformity with a national standard that transposes a harmonised standard, whose reference has been published, confers a presumption of conformity with the essential requirements of the applicable New Approach directive that is covered by such a standard.

~ References (such as titles, identification numbers) of harmonised standards are published in the Official Journal for the directive in question.

Editor's note: The website link given in the guide is no longer current but the documents referred to can be found at the following address:
http://ec.europa.eu/enterprise/sectors_en.htm

The NAWI and MID directives can be found through the "Metrology, pre-packaging" tab.

~ Member States must publish the reference of the national standard that transposes a harmonised standard. It is useful to indicate in the publication the link with the legislation in question.

~ The application of harmonised standards, which give a presumption of conformity, remains voluntary in the field of New Approach directives. Thus, the product may be manufactured directly on the basis of the essential requirements (83).

Conformity assessment procedure

5.1. The modules

~ Conformity assessment is subdivided into modules, which comprise a limited number of different procedures applicable to the widest range of products.

~ The modules relate to the design phase of products, their production phase or both. The eight basic modules and their eight possible variants can be combined with each other in a variety of ways in order to establish complete conformity assessment procedures.

~ As a general rule, a product is subject to conformity assessment according to a module during the design as well as the production phase.

~ Each New Approach directive describes the range and contents of possible conformity assessment procedures, which are considered to give the necessary level of protection. The directives also set out the criteria governing the conditions under which the manufacturer can make a choice, if more than one option is provided for.

5.4. EC declaration of conformity

~ The manufacturer or the authorised representative established within the Community must draw up an EC declaration of conformity as part of the conformity assessment procedure provided for in the New Approach directives.

~ The EC declaration of conformity should contain all relevant information to identify the directives, according to which it is issued, as well as the manufacturer, the authorised representative, the notified body if applicable, the product, and where appropriate a reference to harmonised standards or other normative documents.

CE marking

7.1 Principles of CE marking

The CE marking symbolises the conformity of the product with the applicable Community requirements imposed on the manufacturer.

The CE marking affixed to products is a declaration by the person responsible that:

~ the product conforms to all applicable Community provisions, and

~ the appropriate conformity assessment procedures have been completed.

7.2 Products to be CE marked

~ The CE marking is mandatory and must be affixed before any product subject to it is placed on the market and put into service, save where specific directives require otherwise.

~ Where products are subject to several directives, which all provide for the affixing of the CE marking, the marking indicates that the products are presumed to conform to the provisions of all these directives.

~ A product may not be CE marked, unless it is covered by a directive providing for its affixing.

Market surveillance

8.1. Principles of market surveillance

Market surveillance is an essential tool for the enforcement of New Approach directives.

~ The purpose of market surveillance is to ensure that the provisions of applicable directives are complied with across the Community. Citizens are entitled to an equivalent level of protection throughout the single market, regardless of the origin of the product. Further, market surveillance is important for the interest of economic operators, because it helps to eliminate unfair competition.

Member States must nominate or establish authorities to be responsible for market surveillance. These authorities need to have the necessary resources and powers for their surveillance activities, ensure technical competence and professional integrity of their personnel, and act in an independent and non-discriminatory way respecting the principle of proportionality.

Notified bodies should, basically, be excluded from the responsibility of market surveillance activities. This is to avoid conflicts of interest.

New Approach directives provide for two different tools that enable surveillance authorities to receive information on the product: the EC declaration of conformity and the technical documentation. These must be made available by the manufacturer, the authorised representative established within the Community, or under certain circumstances by the importer or person responsible for placing on the market. Other natural or legal persons, such as notified bodies, distributors, retailers, suppliers or subcontractors, cannot be obliged to make these available. However, they can assist the surveillance authority in obtaining them. Further, the surveillance authority may request the notified body to provide information on the conduct of conformity assessment for the product in question. …The EC declaration of conformity must be made available for the market surveillance authority immediately upon request. Therefore, it should be kept inside the Community.

2.2.3. THE PACKERS GUIDE

The "Code of practical guidance for packers and importers (Weights and Measures Act 1979)" is more colloquially known as "The Packers Guide". It was published by the DTI and HMSO (Her Majesty's Stationery Office) and, although it refers to the 1979 Act which has now been superseded, it was exp
licitly referred to in The Weights and Measures (Packaged Goods) Regulations 1986. The guide is again referred to in the guidance note to the 2006 Regulations published by the DTI and is still considered relevant to average weight control, although reference to any requirements of the 1986 Regulations is no longer valid. It must, however, be remembered that the packers guide does not have the legal significance that it had under the Packaged Goods Regulations 1986.

The main focus of the guide is to provide information on how to comply with legislation if operating to an "average system" that was effectively implemented in the 1979 Act and the associated packaged goods regulations. There is also an Inspectors' Manual that the packers guide refers to and suggests that packers may also wish to be familiar with the guidance for inspectors.

The guide is made up of 6 chapters and 8 appendices as follows.

Chapter 1 Background to the average system
Basic information outlining the average system. This chapter notes that:

> "…the *average* contents must not be less [than the nominal quantity]. The legislation achieves this object by requiring the packer or importer of packages to ensure that, whenever an Inspector carries out what is known as a *reference test* on a group of packages, the test is passed."

However, without an inspector continually performing such a test, a packer will not know if he is complying with the law. The text goes further to say:

> "Although the primary legal duty of a packer or importer is to ensure that the Inspectors' reference test is passed, he can do this by ensuring that his packages comply with three rules, referred to in this Code as the *Three Rules for Packers*.
>
> *Rule 1* The actual contents of the packages shall be not less, on average, than the nominal quantity.
>
> *Rule 2* Not more than $2^1/_2$% of the packages may be non-standard, i.e. have negative errors larger than the TNE specified for the nominal quantity.
>
> *Rule 3* No package may be inadequate, i.e. have a negative error larger than twice the specified TNE."

Regulation 4(1) of the 2006 regulations lists the three packers' rules with rule 2 requiring that "the proportion of packages … shall be sufficiently small". The inspectors reference tests defined in schedule 2 of the 2006 regulations specify the number of non-standard packages ("defective packages" in the 2006 regulations) for various test schemes, all of which are equivalent to more than $2^1/_2$%, meaning that compliance with the above packers rules should ensure a reference test is passed allowing for statistical uncertainty.

The guide does emphasise the need to carry out checks and maintain records:

> "To ensure that the packages he is producing or importing comply with the law at all times, the packer or importer is required to carry out checks on the contents of the packages … and must keep for one year records of the checks."

Although:

> "A packer who is making up each package using equipment prescribed in Part II of Schedule 4 to the 1979 Regulations is however exempt from this requirement."

Note that the 2006 regulations state that the relevant date for keeping records is the date by which the product ought to be consumed, or one year after the packages have left the possession of the packer or importer, whichever occurs first (regulation 9).

The table of tolerable negative errors (TNE) is reproduced from the 1979 regulations and is the same as that in schedule 3 of the 2006 regulations:

Nominal quantity (Q_n) g or ml		Tolerable negative error (TNE) as % of Q_n	Tolerable negative error (TNE) g or ml
5 to	50	9	-
50 to	100	-	4.5
100 to	200	4.5	-
200 to	300	-	9
300 to	500	3	-
500 to	1,000	-	15
1,000 to	10,000	1.5	-
10,000 to	15,000	-	150
above	15,000	1	-

The meaning of the 'e' mark is also explained:

> "The 'e' mark … is not obligatory but, when used, is a guarantee recognised throughout the EEC that the goods to which it is applied have been packed by weight or volume in accordance with the relevant EEC Directive."

Chapter 2 Packers' and importers' responsibilities

Duties and responsibilities are described in relation to; the Inspectors' test, labelling, checks and records, export, equipment, and density determination.

With regard to equipment for checking packages, it states:

> "Non-automatic weighing machines used for checking packages after they have been made up … may be stamped or not."

But also:

> "The accuracy of the equipment is to be verified every working day by applying stamped weights equal to the nominal quantity of the packages checked, and also to the maximum capacity of the equipment."

Note that this is now superseded by the guide on the 2006 Regulations which stipulates that non-automatic weighing instruments must be stamped and the use of unverified instruments is not legal.

Chapter 3 Quantity control of packages

Control systems are discussed but reference is made to the appendices which go in to significantly more detail.

Chapter 4 Rectification of unacceptable packages

Possible reasons for requiring rectification are given together with procedures for handling them and various methods of rectification.

Chapter 5 The National Metrological Co-ordinating unit

The role and function of the unit are described. (This unit has now been abolished, SI 1987 No. 2187.)

Chapter 6 Importers

The definition of an importer is given together with their duties. A worked example is also provided giving a demonstration of a sampling scheme and associated calculations and records.

Appendix A Glossary
Terms specific to the Code and the subject matter are defined.

Appendix B The e-mark
The definition of the e-mark is reproduced from the Measuring Instruments (EEC Requirements) Regulations 1975.

Appendix C Control by sampling
This appendix provides very detailed information on the requirements of sampling procedures based on statistical methods. These procedures include the requirement on the packer to:

> "…obtain more information about his filling process and to use that information to set up an effective control system."

and:

> "A packer needs information about the performance in order to decide at what level to direct the filling process i.e. the target quantity, Q_t"

It explains that:

> "Under very favourable circumstances and tight control it might be possible for the minimum target quantity [Q_t] to coincide with the nominal quantity, Q_n, …"

i.e. the packer is likely to have to set a target value higher than the nominal quantity to allow for various factors.

It is worth noting that the procedures described are much more than checking that the samples comply with the Three Rules for Packers, as the samples taken may not necessarily be representative of the production batch as a whole. Also, a complete sampling system must include a consideration of the sampling frequency, the possibility of false errors and procedures to follow if results are outside of specified limits.

The guide gives details of how to perform an initial process capability study and obtain the necessary information to determine the target quantity and set up a control system. The following factors are discussed:

a. process variability allowance;
b. additional allowance for wandering average;
c. sampling allowance;
d. storage allowance;
e. tare variability allowance (where checks are made on gross weights);
f. miscellaneous factors.

It is worth noting that the sampling allowance factors have the effect that the more frequent the sampling and the more items per sample, the lower the target quantity needs to be above the nominal quantity.

Appendix D Control by checkweighers
The use of automatic checkweighers is permitted within the guide but procedures must be put in place to ensure that they are operating correctly. This appendix details the requirements of those procedures and gives some worked examples.

Appendix E Use of measuring container bottles
Measuring container bottles and templets are permitted. However, by its nature no weighing is required.

Appendix F An 'off the peg' control system
A simplified control system is described that is easier to implement than following the detailed requirements outlined in appendix C but is more restrictive.

Appendix G Assessment of alternative control systems
Different control systems are evaluated, mainly for the benefit of packers who already have systems in place and need to determine whether they are sufficient to comply with the legislation.

Appendix H Modification of the 1979 Act in respect of class B packages
Sections of the 1979 Act as amended by the 1979 Regulations are reproduced.

2.3.1. CE MARKING DOCUMENTATION

In European law, the so-call “New Approach” separates essential requirements from the detailed technical specifications. The directives themselves identify the essential requirements and the technical specifications and tests are detailed in harmonised standards, which are incorporated into national standards. The essential requirements identified in the directives must be satisfied and compliance with the harmonised standards is sufficient to prove that. However, a manufacturer (or other body having to satisfy such a directive) may choose another method to prove that the essential requirements are met.

Each directive will identify the possible routes to compliance and some of those routes require the involvement of a notified body for examination and/or verification. The directives will require the following:

- The manufacturer or representative to affix the CE mark to each product. Specific directives may allow the mark to be displayed on the packaging and/or documentation as an alternative. Depending on the directive and the route to compliance, the identification number of the notified body may also be required.
- A Declaration of Conformity to be at the disposal of the national authorities with some directives requiring a copy supplied with each unit (or a batch of units delivered to a single user).
- A technical documentation file including information such as; a technical description, tests and standards applied, any other steps taken to ensure compliance.

Depending on the route to compliance, additional information such as procedures, reports & records relating to the quality system may also be required.

Some of the directives and compliance methods require the Declaration of Conformity, the technical file, and other documentation to be available for 10 years after the last product has been manufactured.

National legislation will implement the directives and the following is a non-exhaustive list of directives that may have to be considered for weighing equipment:

2009/23/EC	Non-automatic weighing instruments
2004/22/EC	Measuring instruments (automatic weighing instruments)
2004/108/EC	Electromagnetic compatibility (EMC)
2006/95/EC	Electrical equipment designed for use within certain voltage limits (low voltage directive)
2006/42	Machinery
94/9/EC	Equipment and protective systems for use in potentially explosive atmospheres
93/42/EC	Medical Devices

Some of the above directives will have been amended by directive 93/68/EEC to bring them in to line with the general requirements for CE marking and Decision 768/2008 which details those requirements with modules for the various phases of conformity assessment procedures.

The exact format of the Declaration of Conformity is not specified, but an example layout is given in an annex to this article for an item of equipment relating to the EMC Directive.

See also sections on specific Directives and the general section on the notes for guidance on New Approach Directives.

References

Specific Directives mentioned directly in this article.

"Guide to the implementation of directives based on the New Approach and the Global Approach", available from the EU website.

2.3.2 ELECTROMAGNETIC COMPATIBILITY (EMC) DOCUMENTATION

The Electromagnetic Compatibility (EMC) Directive 2004/108/EC is incorporated into UK law by the Electromagnetic Compatibility Regulations SI 2006 3418. The Directive is applicable to most electronic appliances with "active" components which are likely to produce, or be affected by, electrical interference. The EMC Directive changes made since the original publication are in essence procedural and do not affect the route to compliance for non-complex installations. For most applications within the industry, the self certification route to compliance should be used. For complex installations, guidance should be obtained from a notified body or similar.

The Directive requires anyone placing relevant equipment on the market to;

1. Affix a CE mark to the product or, if this is impractical, the packaging and/or documentation.
2. Raise a Declaration of Conformity (DoC).
3. Compile a technical documentation file.

The "self certification" route to compliance.
There is no specific requirement to test equipment to a particular Standard, but there is the requirement to be able to demonstrate compliance. If a manufacturer DOES carry out testing to a relevant Harmonised EMC Standard (one published in the Official Journal of the European Community) then he can PRESUME conformity to the Directive without any further reasoning. If the manufacturer decides to demonstrate compliance by using a set of tests not Harmonised by publication in the Official Journal, he cannot presume conformity and may have to justify that the test plans he used are sufficiently rigorous.

In the majority of cases, this route is the cheapest and simplest method of demonstrating compliance as it does not require the intervention of a notified body.

Test requirements
The electrical noise produced by the equipment must meet limits which tend to be the same irrespective of the standard that is applied (there are two sets of levels, one for the Residential, commercial & light industry environment and one for the Industrial environment), the requirements being associated with noise being generated down the power cable on to the public supply network (inducted) and to that radiated from the enclosure and cables (radiated).

There are requirements for Immunity (similar to those requirements set by EN45501 for the Non Automatic Weighing Instruments Directive) which require the equipment to work as intended (bearing in mind the expectations of the user and consequences of a failure) when subjected to continuous and transient interference; again there are different sets of interference test levels depending on the intended operating environment.

As the manufacturer is the person who is going to raise the DoC, it is he who will define the normal operation of the equipment and the significance of any failure (this is usually done in conjunction with a test house or test department to produce an EMC Test Plan to set the scope of the testing). He will then incorporate the test results into the mandatory Technical Documentation with, when necessary, an explanation as to why the performance of the item is deemed to comply with the protection requirements of the Directive.

Test standards

There are no specific Harmonised EMC test standards for weighing equipment. While this would seem to be a problem in certifying this type of equipment, in reality, the test requirements are very similar for all types of equipment - general test levels are usually identical and product specific test Standard simply specify additional testing or a particular method of testing which is applicable to that equipment. In the situation where there is no specific product Standard, the Generic EMC Standards are used.

There are four Generic Standards;

BS EN 61000-6-1:2007
EMC Immunity for the residential, commercial & light industry environment.
BS EN 61000-6-2:2005
EMC Immunity for the industrial environment.
BS EN 61000-6-3:2007
EMC Emissions for the residential, commercial & light industry environment.
BS EN 61000-6-4:2007
EMC Emissions for the industrial environment.

The complete suite of tests for a particular piece of equipment is dependant on how it is powered (AC /DC / Internal battery) and the type and length of any interface cables. The performance criteria for a test is set by the Standard but the interpretation of the significance of the results is decided by the manufacturer – the test house or department can explain the performance of the equipment when subjected to interference and state an opinion, but it is the manufacturer who is going to sign the DoC.

References

The Electromagnetic Compatibility (EMC) Directive 2004/108/EC

The Electromagnetic Compatibility Regulations SI 2006 3418

2.3.3. LOW VOLTAGE EQUIPMENT DOCUMENTATION

The low voltage directive, “Electrical equipment designed for use within certain voltage limits” 2006/95/EC, replaces the previous directive 73/23/EEC. The directive is applicable to equipment with a supply voltage of 50 – 1000V AC or 75 – 1500V DC. If equipment itself takes a supply voltage of less than 75V DC but a mains adaptor is supplied with the equipment then it will all be subject to the requirements of the directive.

The Directive requires anyone placing relevant equipment on the market to;

1. Affix a CE mark
2. Raise a Declaration of Conformity (DoC)
3. Compile technical documentation.

The “self certification” route to compliance
There is no specific requirement to test equipment to a particular Standard, but there is the requirement to be able to demonstrate compliance. If a manufacturer DOES carry out testing to a relevant Harmonised EMC Standard (one published in the Official Journal of the European Community) then he can PRESUME conformity to the Directive without any further reasoning. If the manufacturer decides to demonstrate compliance by using a set of tests not Harmonised by publication in the Official Journal, he cannot presume conformity and may have to justify that the test plans he used are sufficiently rigorous.

In the majority of cases, this route is the cheapest and simplest method of demonstrating compliance as it does not require the intervention of a notified body.

Test standards
A list of test standards for this directive can be found on the Europa website in the following document:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:208:0001:0089:EN:PDF

2.3.4 MACHINERY DIRECTIVE REQUIREMENTS

Introduction
In common with the other CE marking directives, the Machinery Directive 2006/42/EC is primarily a free market measure. However, it also provides for a widely applicable framework for safety assessment and even when it is not strictly applicable, it can provide a good basis for risk assessment and documentation in order to demonstrate due diligence on the part of a manufacturer or supplier.

Directive 2006/42/EC is fully implemented into UK law by The Supply of Machinery (Safety) Regulations 2008 (SI 2008 No.1957) All new machinery introduced into the EEA must now comply with this Directive.

Scope
The definition of machine is very broad and will include an assembly fitted with, or intended to be fitted with, a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application.

There are some specific exclusions from the Directive - for example military equipment and machines which are already covered by other, more specific, directives (e.g. lifts and medical devices). However, there is also a general exclusion from the Machinery Directive for equipment which falls within the scope of the Low Voltage Directive and which presents hazards which are primarily of an electrical nature. This is an important exclusion and will be relevant to many weighing applications where, although there are moving parts, they do not present any significant hazards.

Second-hand machinery which was first used within the EEA prior to the date of the implementation of the directive (i.e. before 1 January 1995) is excluded from having to comply with the Directive itself. However, any machinery which was manufactured before 1 January 1995 must be made to comply with the Directive if it is subsequently brought into Europe from outside, just as any newer machinery would that is manufactured outside the EU.

Equipment manufactured for the manufacturer's own use is not excluded from the requirements, but may be subject to slightly lesser obligations with respect to marking and documentation.

In the context of weighing and lifting equipment, it's important to understand that lifting accessories such as chains, strops, shackles and load-cells are all also within the scope of the Directive, whether or not they meet the strict definition of being 'an assembly of linked parts'.

History
The original Machinery Directive was numbered 89/392/EEC. This was modified by a number of amendments which extended the scope to equipment which was originally excluded, and clarified the requirements. Then, in 1998, Directive 98/37/EC provided a consolidation of the previous directives into one document, although it made no changes in the actual requirements. Finally, in 2006, the Commission completed work on a replacement Directive, 2006/42/EC, which is the one in force at the moment.

Requirements
The requirements of the directive can essentially be split into two sections – the 'essential protection requirements' and administrative provisions.

The essential protection requirements demand that machine manufacturers identify the hazards which their products contain and then assess the risks which these hazards present to users. Any risks thus identified must be reduced to as low a level as is reasonably practicable.

Annex I of the Directive gives a comprehensive list of the potential hazards which may arise from the design and operation of machinery, and gives general instructions on how the risks from these hazards must be avoided. Detailed requirements are laid out in a series of safety standards. The standards are drafted by multi-national committees of industry experts and reflect design requirements for particular pieces of machinery much more closely than could ever be achieved by specific legislation. Once a standard has been accepted by the European Commission (the process of 'harmonisation'), it is given the 'EN' prefix. This means conformity with the requirements of the standard gives a 'presumption of conformity' with the requirements of the Directive.

Because so many standards are required to cover the full range of machines covered by the Directive, the European Standards bodies have devised a hierarchy which can be applied in every situation. The most basic standards, known as 'Type A standards', set out requirements for the safety of machines only in the most general terms: indeed, part 2 of EN ISO 12100 is essentially a reproduction of annex 1 of the Machinery Directive. 'Type B' standards deal with more specific issues: design of emergency stops (EN ISO 13850); prevention of unexpected start-up (EN 1037); pneumatic systems (EN 983); temperature of touchable surfaces (EN ISO 13732-1) and many others. Finally, 'Type C' standards deal with specific classes of machinery: for example, EN 619 and EN 620 deal with safety of conveyors; EN 415 deals with packaging machinery and EN 201 deals with injection moulding machines.

The administrative provisions of the Directive (at least so far as manufacturers are concerned) are primarily aimed at forcing manufacturers to provide documentary evidence that the machinery complies with the Directive. This is done via the creation of a "Technical File". The general form and content of the Technical File is dictated in the Directive and manufacturers must be able to make this information available for inspection by the authorities (the HSE in the UK) for up to 10 years after date on which the machine was sold. However, except for Annex IV machines (see below), there is no obligation to produce a copy of the file unless demanded to do so by the enforcement authority, and only the enforcement authority has a right to see it. The manufacturer does not have to provide a copy to the customer unless they choose to.

Machinery meeting the requirements of the Directive is required to have the CE symbol clearly affixed to indicate compliance. It must also show the year of manufacture, some form of serial number, and other ratings as required by the relevant standards. An item of equipment may only display the CE mark when the equipment satisfies all relevant directives; for instance, machines with electrical controls must also comply with the requirements of the Low Voltage and EMC Directives.

Where volume production is envisaged, the Directive requires that control measures must be identified to ensure that all of the machines manufactured will conform to the provisions of the Directive.

Finally, the manufacturer must prepare and sign an 'EC Declaration of Conformity'. This is basically a statement which confirms the identity of the manufacturer and the machinery for which they are claiming compliance, and is signed to confirm that the correct procedures have been followed.

Annex IV machines

The vast majority of machinery may be self-certified by the manufacturer. What this means is that so long as the administrative and protection requirements of the Directive are properly completed, the manufacturer can perform all of the assessment and documentation procedures in-house and does not need to submit to any form of external test or approval.

However, annex IV of the Directive contains a list of about 15 types of machine which are subject to special procedures. Machines in this list must either be made fully in accordance with the provision of the relevant type C standard, or they must be subject to a type examination by a

Notified Body. In either case, a copy of the technical file for the machinery must be lodged with a Notified Body before the CE mark is applied.

Declaration of Incorporation

The application of the CE mark under the Machinery Directive is in effect a statement which confirms that the machinery fully complies with the requirements of the Directive and is safe to use. Clearly, this is not appropriate for partly completed machines which are intended to be incorporated into another machine or which cannot function unless they are built into a complete production line. For these circumstances, instead of signing a Declaration of Conformity, the manufacturer does what they can to assess the machine they have built and to mitigate any risks to the user, and then signs a document called a 'Declaration of Incorporation'. This basically states that the machinery is incomplete and must be made to fully conform with the requirements of the Directive before it is brought into service. The manufacturer must provide information on the residual risks which the machine contains and on the assessment work which they have completed.

The Declaration of Incorporation is a concept which exists only in the Machinery Directive and so, if other CE marking directives apply (e.g. a check-weigher which is intended for incorporation into a packaging line, and which is covered by the EMC and Low Voltage directives as well as being a machine) then the machinery must carry the CE mark for these directives even though it is not CE marked as a machine.

Future Developments

In December 2006, after a long gestation, the European Commission finally published a new Machinery Directive, 2006/42/EC. So far as the vast majority of manufacturers and users are concerned, the basic requirements of the Directive remain unaltered, and in particular the assessment and documentation requirements are basically the same. Annex IV is also untouched. In general terms, the key differences between the new and old directive are:

- Greater clarity and more explanations of the scope and certain definitions;
- A narrowing of the scope of the exclusion which permits certain equipment also covered by the LVD to be excluded from the scope of the Machinery Directive;
- Greater clarity in the requirements for partly completed machinery

The Directive 2006/42/EC is implemented via the Supply of Machinery (Safety) Regulations 2008.

References

The European Commission have a special section on machinery with a great deal of useful information on their EUROPA server. This includes the full text of the directive and lists of the current harmonised standards.

Main Europa page on the Machinery Directive:
(http://europa.eu.int/comm/enterprise/mechan_equipment/machinery/index.htm).

List of current harmonised standards:
(http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/machines.html)

For details of draft standards, the New Approach web site is a good EU-funded resource. (http://www.newapproach.org/Directives/ProductFamilies.asp?98/37/EC)

The UK government's Department for Business, Enterprise and Regulatory Reform (BERR) publishes a number of useful guides on the Directive and these are available for download from the following address:. (http://www.berr.gov.uk/dius/innovation/regulations/ecdirect/page12543.html)

2.3.5 ATEX DOCUMENTATION

The term 'ATEX' is taken from the French 'Atmospheres Explosibles', which refers to two specific European Directives issued in 1994 and 1999. These are aimed at industrial premises that operate with Hazardous Areas (See section 1.8).

The first one, 94/9/EC, is called the 'Product' Directive or the '100a'. It defines 'equipment and protective systems designed for use in potentially explosive atmospheres'. The UK issued this as a Statutory Instrument: SI 1996 No. 192; "Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres", which came into force as from 1st March 1996.

The second, 1999/92/EC, is called the 'Safety of Workers' Directive or the '137'. It states the requirements that must be met for the use of equipment covered by the first directive in a place where a potentially flammable atmosphere may be present.

Only in the UK, the 'Safety of Workers' Directive has been combined with the Chemical Agents Directive. Together, these have been issued and implemented as the Dangerous Substances and Explosive Atmospheres Regulations (referred to as DSEAR). The opportunity was taken by authorities in the UK to repeal old Regulations that were considered to be out of date. The UK issued this as a Statutory Instrument: SI 2002 No. 2776; "The Dangerous Substances and Explosive Atmospheres Regulations 2002", which came into force in all parts from 1st July 2003.

From 1st July 2003, all new installations involving hazardous areas must use ATEX compliant 'equipment and protective systems'.

Installations completed before this date must have been shown to comply with the DSEAR and therefore the ATEX Directives before 1st July 2006.

The need for ATEX
The Directives have been put in place to establish a uniform approach to explosion protection throughout Europe, principally to facilitate trade between member nations. It achieves this by ensuring that all equipment and protective systems for use in hazardous areas meet stated technical requirements that apply in all EC countries. As a result, trade barriers cannot be raised on the basis that equipment is unsuitable. It is comprehensive and thorough in its approach.

Health and Safety Law that is already in place in the UK requires industry to operate with safety in mind. ATEX formalises this approach, specifying what organisational and technical requirements must be in place. In summary, it requires:-

- Proper management of hazardous areas
- Good communication throughout organisations by appropriate documentation
- Competency of personnel through proper training at all levels
- Identification of hazardous areas
- Marking and identification of apparatus
- Safe working procedures

ATEX Compliance
The Product Directive requires that if 'equipment and protective systems' are to be designed, manufactured or supplied as intended for use in hazardous areas, they must be assessed to determine if they could be 'ignition capable'. If not, then no further consideration is required.

If they can provide a source of ignition, by whatever means, then precautions must be taken in the design, manufacture, installation, operation and maintenance, such that they are adequately protected by type(s) of explosion protection that meet the requirements of European Standards.

This applies to equipment and protective systems, whether it is electrical or non-electrical. The ATEX 100a Directive lays down 'Essential Health and Safety Requirements' (E.S.R.s) in Annex II that must be met. The process of assessment of ignition capability is to be performed by the manufacturer; the organisation 'placing the equipment on the market'. Thus, manufacturers of weighing equipment must determine if their products designed for use in the hazardous area are ignition-capable.

Where electricity is used, there is a risk that heat or sparks could be generated. Protection must be applied according to the existing European EN50 series Standards discussed under 'Hazardous Areas' (section 1.8 of the Technical Articles). Thus, the apparatus is certified to these Standards and marked accordingly. The certification process will also confirm that the apparatus meets the requirements of the ATEX 100a Product Directive and additional marking is applied.

In addition, any non-electrical aspect of any products that may be ignition capable must also be assessed and certified to a new series of Standards in EN13463. If equipment uses springs, for example, this may be cause for concern owing to the likelihood of breakage and the potential creation of frictional sparking and/or heating. The accumulation or generation of static charge must be considered. Mechanical movement and stored energy in load-cells are normally quite small and so, the risk of ignition may be adequately low. In contrast, electric motors are an example of where rotating bearings are used in equipment; mechanical failure would cause rubbing of surfaces and would therefore generate considerable heat.

The material used in construction of equipment may also need to be considered. For example, if aluminium is used for load-cells, which contains a high percentage of magnesium, then there may be a risk of 'thermite reaction' from impact with rusty iron. This can liberate incendive sparks. Maintaining a low percentage of magnesium reduces the risk. Where this is not possible, other precautions may need to be taken to ensure that impact risks are adequately low.

Once equipment has been designed and certified it is placed in one of three categories:

Equipment	**Level of Protection**	**Permitted Zones of use**
Category 1	Very High Level of protection	Used in Zone 0, 1 or 2
Category 2	High Level of protection	Used in Zone 1 or 2
Category 3	Normal Level of protection	Used in Zone 2 only

Standards
British Standards for explosion protected apparatus have been harmonised with European Standards: BS5501 has now been replaced with the EN50 series. More recently, the IEC Standards are being adopted in Europe and are issued as, in the case of the UK, BS EN 60079 series. It is the same document as the IEC79 Series for electrical apparatus and systems.

In Europe, Standards for non-electrical equipment are also emerging; BS EN 13463. Part 1 covers the requirements for all explosion-protected non-electrical equipment whilst subsequent parts (some currently still in draft form) detail the types of protection for certification and assessment purposes; the important standards are referred to at the end of this section.

Marking
Equipment complying with the ATEX 100a Directive will now be additionally marked, for example:

CE ⟨Ex⟩ II 1 G/D

- The CE mark confirms that the product meets all relevant European Directives
- The Ex in the Hexagon now means that the Product meets the ATEX Directive when used as part of the above marking system
- The Roman II indicates the suitability for Surface industry use in Hazardous Areas
- The Arabic 1 permits the use of the apparatus in Zone 0 as it has a very high level of protection applied
- G allows the use of the apparatus in Gaseous and Vapour hazards
- D permits its use in Dust hazards

The EEx marking discussed in Section 1.8 of the Technical Articles will also appear after the ATEX Marking. Thus, all apparatus must be marked to show that it is suitable for the place in which it is to be used.

	Category 1	**Category 2**		**Category 3**	
Equipment Type	***Electrical AND Non-Electrical***	***Electrical***	***Non-Electrical***	***Electrical AND Non-Electrical***	***Annex ref***
Certification Phase					
Certification by Notified Body	Required	Required			III
Certification by manufacturer			Permitted	Permitted	VIII
Unit verification by Notified Body	Universal option				IX
Surveillance					
QA of production by Notified Body	Required				VI
QA of product by Notified Body		Required			VII
QA by manufacturer			Permitted	Permitted	VIII

The above table shows the various options available to a manufacturer when designing hazardous area equipment. All ‘Category 1’ equipment must be certified by a Notified Body, as must ‘Category 2’ electrical. ‘Category 2’ non-electrical and all ‘Category 3’ equipment can be self-certified. The appropriate Annexes of the Directive are given for reference and should be consulted.

In addition, manufacturers must have appropriate Quality Assurance (QA) in place as stated in the appropriate Annexes.

The ATEX Product Directive permits a new system of manufacturer 'self-certification'. The manufacturer can assess the design to a recognised construction Standards without gaining external certification. The design documentation would then be submitted to a Notified Body (NB) for safe keeping but would not be assessed by the NB unless there is cause for concern that the equipment is unsafe. This arrangement relieves the financial overhead on manufacturers for the certification of equipment used in lower risk circumstances.

The Universal Option alternative covers submission to a NB of an arrangement of items for independent testing. The other requirements are set out in the Directive and manufacturers must be familiar with these.

One important criteria is that of the requirement for manufacturers to supply adequate instructions for safe use and operation. This has always been good practice and a selling point but never before been formalised as a legal obligation.

The Safety of Workers (137) Directive
The principle aim of this Directive is to place clear requirements on the owners of industrial plants containing hazardous areas.

Owners of industrial plants must implement formal systems relating to:

- Proper Area Classification
- Identification of Hazards
- Provision of Personal Protective Equipment
- Plant modification review procedures
- Inspection and Maintenance requirements and routines
- Training and competency assessment of personnel and contractors
- Appointment of a 'responsible person' competent to oversee the safety of the above systems

The '137' Directive cross-refers to the '100a', to use the same technical terminology, for example choosing Category 2 equipment for a Zone 1 hazard.

Owners must familiarise themselves with the detailed requirements of this Directive and implement it according to their plant operational arrangements. Thus, the Directive may be regarded as one aimed principally at management.

Documentation
The '137' Directive requires the generation of an 'Explosion Protection Document' (EPD) in which all aspects of safety, both technical and organisational, are formally laid down.

The 'Apparatus Certificates of Conformance' issued by Notified Bodies or manufacturers must also state compliance with the ATEX requirements. These will form part of the EPD. In addition, Area Classification, including the supporting calculations; other instructions, provided by manufacturers; system descriptive documents, covering Ex i interconnected apparatus; procedures for inspection and maintenance and 'Permit to Work' systems will all need to be cited. The 'EPD' thus becomes a central repository for all safety-related information. Work on any site must be co-ordinated and controlled by the owner in a safe manner by reference to the information it contains.

DSEAR in the UK

The implementation of the '137' Directive in the UK was combined with the requirements of another, called the Chemical Agents Directive. These two have been issued under the Dangerous Substances and Explosive Atmospheres Regulations (2002); it is known as the 'DSEAR'.

The DSEAR provides requirements under each of the following section headings:

1. Citation and commencement.
2. Interpretation.
3. Application.
4. Duties under these Regulations.
5. Risk assessment.
6. Elimination or reduction of risks from dangerous substances.
7. Places where explosive atmospheres may occur
8. Arrangements to deal with accidents, incidents and emergencies.
9. Information, instruction and training.
10. Identification of hazardous contents of containers and pipes.
11. Duty of co-ordination.
12. Extension outside Great Britain.
13. Exemption certificates.
14. Exemptions for Ministry of Defence etc.
15. Amendments.
16. Repeals and revocations.
17. Transitional provisions.

Owners of companies must indicate how they have complied with the requirements embodied in the above sections, by reference to adequate documentation and procedures. The DSEAR does not refer to the production of an EPD. In the UK, the 'Control of Substances Hazardous to Health', (COSHH: 2002) and the 'Management of Health and Safety at work', (MHS: 1999) are regulations which require owners to implement, and then to document, procedures which demonstrate compliance. The DSEAR recognises this and permits the integration of safety documentation within a 'Risk Assessment'. This is sometimes referred to as a Safety Case or a Technical File in other UK regulations.

The owner is ultimately responsible for the generation of such documentation. The DSEAR does not prescribe how this should be done, as the individual owners must generate the systems to suit the operation of their plant.

Conclusion

For all new equipment and protective systems installed after 1st July 2003, Certificates of Conformance to the explosion protection Standards, provided by equipment manufacturers, will state that the equipment complies with the minimum requirements, (the ESRs) of the ATEX 100a Directive.

Retrospectively, the owners must assess their premises to ensure that their equipment and the installations meet the requirements of the ATEX 100a Directive and DSEAR respectively.

Installations completed before 1st July 2003 will need to be re-examined to ensure that they meet the criteria outlined in this section. The owner may choose to do this, requesting supporting documentation from the manufacturers and suppliers. Alternatively, the owners may request that the manufacturers/suppliers provide assessments for their equipment.

The onus has always been placed on the manufacturers to provide the specification for their products, from which the owners must select equipment suitable for their application. The explosion protection and, now through ATEX, the documentation provided by the manufacturer becomes a significant part of the owners' evaluation. The formal date set for completion of this assessment was by 1st July 2006.

When first introduced, the Directives and Regulations were viewed as yet another burden on the processing industry and its suppliers. Ultimately, this must be set against the need to raise and maintain the standard of safety. The European-wide approach will be successful if it influences the management of safety at a philosophical level. Signs are that this is happening and other countries are now monitoring its progress with a view to adopting ATEX.

Further information on the implementation of ATEX can be found on a website:
http://europa.eu.int/comm/enterprise/atex/index.htm

2.4 GENERAL DOCUMENTS REQUIRED

There are a number of documents that are necessary when supplying weighing instruments or placing them on the market. The list below identifies these documents and gives advice on retention and content. Unless specified the document can be kept centrally, i.e. a copy does not have to accompany the instrument.

Documentation

Type Approval Certificate
For prescribed weighing instruments that are used for a legally controlled purpose. The prescribed types are: non-automatic weighing instruments, beltweighers, gravimetric filling machines, in-motion rail weighbridges and discontinuous totalisers. The Type Approval Certificate (TAC) describes the weighing instrument and any peripheral equipment that may be connected to it. If initial verification by a Trading Standards Officer is required, the TSO is entitled to ask for a copy of the TAC. Where the TAC is issued in another EU Member State in a language other than English, the TSO can ask for a translation to be provided - this can be an unofficial translation. The TAC remains valid for weighing equipment in use even after it has expired as far as new instruments are concerned. It should be retained as long as the instrument is in service.

EC Declaration of Conformity (D of C)
The D of C is drawn up by the manufacturer, or in the case of instruments imported from outside the EU it can be drawn up by the importer. It certifies that the instrument complies with all relevant Directives and if compliance with the Directives has been achieved by following harmonised standards, it should list all of the relevant standards that have been used. It will identify the manufacturer, the model / type, and must be signed on behalf of the manufacturer / importer. The document is required to be retained for 10 years after the last instrument of that type has been put on the market.

Design Documentation (Technical File)
The design documentation should be held by the manufacturer or importer. It will include drawings, circuit diagrams, schematics, design calculations and any other relevant drawings / specifications needed for production and if necessary, type approval. It should be retained for as long as the D of C. Where testing has been performed during the design/ prototype production phases or has been performed to confirm compliance with Directives such as the Low Voltage Directive or EMC Directive, the test results / reports should form part of the Design Documentation. The documentation need not be stored in one place as a specific file but it must be available to be compiled into a **Technical File,** should an enforcement official or market surveillance authority require it. It may be kept in an electronic format rather than as a set of papers, but if it is kept in electronic format it should be securely backed up.

Verification Records
Companies that are accredited for “self-verification” (including re-verification) will be required under their accreditation to store the records, including the results of tests performed during verification, for assessment and monitoring by the organisation that accredited them. Records may be stored electronically. They should be retained for at least three years.

Service Instructions
These documents should be available to anyone authorised or permitted to carry out servicing. There is no legal obligation to make them available to anyone else but for instruments that are submitted for Type Approval the service instructions will normally form part of the documentation submitted in support of the application for approval. Many manufacturers now make them available on their websites.

User's instructions
These normally accompany the instrument when it is supplied to the end user, though where a number of instruments of the same type are supplied it may be sufficient to only supply one or two sets. Again, where Type Approval is required these instructions will normally be included in the submission documentation. There is no legal obligation to supply user's instructions for weighing machines as such, but where the machine is also covered by the Machinery Directive then users instructions in the official language(s) of the country of use are mandatory. Where there are no users instructions supplied, the manufacturer must accept responsibility for warranty even if the fault was caused by misuse, if that misuse was foreseeable.

Certificate of Conformance
Under the NAWI Directive and the MID, where verification is carried out by a Notified Body, the verifier must issue a Certificate of Conformity after the verification is completed. This Certificate should be retained by the manufacturer / submitter and must be made available to enforcement agencies and market surveillance authorities when requested.

Compatibility of Modules data sheets
Where a TAC allows the use of alternative modules, such as load cells, the manufacturer must complete a Compatibility of Modules data sheet before submitting the complete instrument for verification. The verifier is entitled to request a copy of the sheet before verifying the instrument. For serial production instruments, it is only necessary to complete one sheet for the range. The sheet should be retained as part of the design documentation / Technical File.

Labelling
There are certain pieces of information that should be included on any weighing instrument. Unless specified in the TAC, the information must be permanently and indelibly marked on the instrument.

Type Approval details
The information required here will be such things as Max, Min, e, TAC number and Class number, plus any other data specified in the TAC. For automatic weighing instruments this will include any operational parameters that could affect weighing performance, (e.g. operating speed, packs per minute, maximum throughput).

Manufacturers name or mark
This is mandatory for Type Approved instruments and must be sufficient to identify the manufacturer / importer. It is mandatory also under other Directives and should therefore be on all instruments whether type approved or not. A registered Trade Mark will be accepted as sufficient to identify the manufacturer.

Weighing Capacity
Non-automatic weighing instruments that are not type approved must be marked with the maximum weighing capacity (in the form Max ……) as well as the manufacturers name or mark.

Electrical Safety Information
For electrical / electronic instruments sufficient electrical safety information to allow connection to the appropriate power supply must be provided. This may be the maximum input voltage, earthing requirements or any other data necessary for the safe connection and operation of the instrument.

CE Mark
Any instrument that is placed on the market and is subject to one or more of the New Approach Directives (NAWI, EMC, Low Voltage, Machinery) must carry the CE mark indicating compliance with all relevant Directives. Some, but not all Directives require the CE mark to be accompanied by the last two digits of the year in which the CE mark was affixed. As a general rule, it is best to include this information even where it is not specifically required by a Directive.

"M" mark

Instruments which are controlled either by the NAWI Directive or the MID, are required to carry an "M" mark to indicate compliance with the Directives. For NAWI this is a black M on a green background – there is no defined specification for the M on instruments covered by MID, but it would seem sensible to use the same "M" mark as for NAWI.

"Not to be used for direct sales to the public"

This marking is mandatory on NAWI of less than 100kg weighing capacity which are intended for industrial use but are of a design similar to that of an instrument intended for retail transactions. The marking should appear close to the display.