

WELMEC 5.2

Issue 1

WELMEC

European cooperation in legal metrology

GUIDE ON MARKET SURVEILLANCE



June 2004

Foreword

WELMEC is a cooperation between the legal metrology services of the Member States of the European Union and EFTA. This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to notified bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

Published by:
WELMEC Secretariat
Federal Office of Metrology and Surveying (BEV)
Arltgasse 35
A-1160 Vienna
Austria
Tel: +43 676 8210 3608
Fax: +43 1 49 20 875 8006
e-mail: welmec@metrology.at

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1 INTRODUCTION

1.1 Directive 90/384/EEC¹ does not mention the words “market surveillance”. It does, however, require the Member States to carry out market surveillance (see 2.1 below). Market surveillance can be described as the procedure operated by the Member States in liaison with one another to ensure that all non-automatic weighing instruments put on to the market comply in all relevant respects with the Directive. It establishes that the manufacturers and the Notified Bodies are fulfilling their rôles under the Directive.

1.2 Market surveillance is an essential tool in the overall concept of the New Approach. The manufacturer makes the non-automatic weighing instruments. The Notified Body has a rôle in the application of the chosen conformity assessment procedures (except for instruments intended for Article 1.2(b) purposes²). The Member State checks that non-automatic weighing instruments put onto the market for Article 1.2(a) purposes meet the essential requirements in Annex I to the Directive.

1.3 Therefore, this guide is intended in the main for the bodies in the Member States who carry out market surveillance, but it will also be of interest to manufacturers of non-automatic weighing instruments, to their authorised representatives, to Notified Bodies, and to others with a wider interest in the operation of the Single Market, such as those concerned more generally with consumer protection and fair trade.

2 THE REQUIREMENTS OF THE NAWI DIRECTIVE

2.1 This requirement for market surveillance is set out in Article 2 of the Directive, as follows:

Article 2

1 Member States shall take all steps to ensure that instruments may not be placed on the market unless they meet the requirements of this Directive which apply to them.

2 Member States shall take all steps to ensure that instruments may not be [brought into service for the uses set out in Article 1(2)(a) unless they meet the requirements of this Directive which apply to them, including the conformity assessment procedures referred to in Chapter II, and accordingly bear the CE marking provided for in Article 10.]

2.2 It will be seen that this Article relates to all non-automatic weighing instruments for placing on the market, but only to those for Article 1.2(a) applications as regards bringing into service.

¹ Published in the Official Journal OJ L189 of 20/07/90 with a corrigendum in OJ L258 of 22/09/90. The Directive was amended by Directive 93/68/EEC, OJ L220 of 30/08/93.

² Unless they have voluntarily gone through the conformity assessment procedures.

2.3 The Directive also contains Article 13, which provides for the Member States to control instruments in service. Article 2 needs to be distinguished from Article 13, since they operate at different points in time.

2.4 Article 13 needs to be read with those essential requirements that relate to instruments in service: -

Article 13

Member States shall take all steps to ensure that instruments bearing the [CE marking] attesting conformity with the requirements of this Directive continue to conform to those requirements.

2.5 The Essential Requirements section 4.2 states “The maximum permissible errors in service are twice the maximum permissible errors fixed in section 4.1.”

2.6 Article 2 applies when non-automatic weighing instruments are to be put onto the market and reflects the involvement of manufacturers, authorised representatives and Notified Bodies. Article 13 applies when non-automatic weighing instruments are already in service, and this will be of interest to users of those instruments and maintenance/repair organisations.

2.7 In some Member States, different expressions may be used to cover or describe the various enforcement activities that are carried out. In some cases, data gathered at periodic re-verification or on inspection may be useful in contributing to market surveillance work, even though they are carried out in fulfilment of Article 13. (Annex 5 relates).

2.8 Other possible actions can also contribute to market surveillance. The competent authorities could provide advice or guidance to economic operators, such as repairers, local representatives of manufacturers, owners of large numbers of instruments, trade associations, etc. In some Member States there are formal arrangements under which manufacturers, for example, can be linked with specific authorities to assist with the flow of advice and guidance.

2.9 Information on the following issues would be considered relevant in order to prevent the wrong affixing of the CE marking and the green M label and to facilitate the correct operation of the conformity assessment procedures: -

- regulated fields of use;
- meaning of the CE marking and green M;
- responsibility of manufacturers concerning the declaration of conformity;
- different activities and responsibilities of notified bodies in EC verification and in EC declaration of type conformity;
- modular approach especially as per WELMEC 2.4, compatibility forms;
- etc.

2.10 General information could also be provided on the websites of legal metrology authorities.³

³ These can be found through the links provided on the WELMEC website, www.welmec.org .

2.11 It is also appropriate to draw attention to two other Articles in the Directive. Articles 7 and 11 are relevant here. Article 7 sets out the responsibilities of the Member States and the Commission where instruments are found that do not meet the requirements of the Directive. This relates to systematic failure to meet the requirements and includes both incorrect application of the standards and shortcomings in the standards⁴. The procedures may be summarised as follows: -

- during market surveillance the Member State finds instruments that it considers do not comply;
- the Member State takes action to withdraw, restrict or prohibit those instruments;
- the Member State informs the Commission of its action, giving the reasons and stating how the non-compliance may have arisen;
- the Commission consults with the parties concerned;
- the Commission informs the Member State that took the action of the results of its consultation;
- if the action of the Member State was justified, the Commission informs the other Member States;
- where there is a problem with the standards, the Commission follows up with the Committee (set up under Directive 98/34/EC, formerly Directive 83/189/EEC); and
- the Commission has a continuous obligation to keep the parties informed of progress.

2.12 Article 11 is expressed as being without prejudice to Article 7. It sets out the responsibilities of Member States in cases that are not so serious as those envisaged in Article 7. Here, where the Member State finds that the CE marking has been wrongly affixed to instruments, the Member State shall oblige the manufacturer or his authorised representative to make the instruments conform to the requirements of the Directive so that the CE marking is justified. The Member State may impose conditions to this end.

2.13 This Article also deals, in paragraph 2, with the situation where the non-conformity continues. In these cases the Member State is to act to withdraw, restrict or prohibit those instruments from being placed on the market or withdrawn from it, as may be appropriate. The procedure under Article 7 is then brought into play.

2.14 Annex 2 sets out, among other things, how the Member States have transposed the provisions of Articles 7 and 11 into their own legislation.

2.15 WELMEC has produced other guides, which assist in understanding the requirements of the Directive. These include: -

GUIDE NO.	TITLE
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⁴ These are the national standards that implement the harmonised standard EN45501.

GUIDE NO.	TITLE
2 (sections 1,3.3, 3.4, 11 & 12)	Directive 90/384/EEC Common Application Non-automatic Weighing Instruments
2.2	Guide for Testing Point of Sale (POS) Devices
2.4 (part 1)	Guide for Load Cells
2.5	Guide for Modular Approach and Testing of PCs and other Digital Peripheral Devices (Non-automatic Weighing Instruments)
3.1 (chapters 3, 7, 8, 9, 10 & 14)	Directive 90/384/EEC: Explanation and Interpretation Non-automatic Weighing Instruments
In addition the following Guides also relate to non-automatic weighing instruments:	
2.1	Guide for Testing Indicators
2.3	Guide for Examining Software

The WELMEC website should be consulted for the latest version of these guides⁵.

2.16 The WELMEC Committee has agreed that EMeTAS is the medium for the exchange of documentation on non-automatic weighing instruments. EMeTAS is a commercial product that includes the type approval certificates, additions and test certificates. The regularly updated EMeTAS CD-ROM provides access to the documentation via multiple indexes, links and search functions, while the EMeTAS website contains new documents prior to release on CD-ROM. EMeTAS also gives access to related information, including WELMEC Guides and databases of Notified Bodies and seals.

3 "GUIDE TO THE IMPLEMENTATION OF DIRECTIVES BASED ON THE NEW APPROACH AND THE GLOBAL APPROACH"⁶

3.1 The Commission published this Guide in 2000 to replace an earlier Guide known as the "Vade mecum". The new Guide is sometimes referred to colloquially as the "Blue Guide" from the colour of its cover. This WELMEC Guide takes the Blue Guide as its starting point.

3.2 Chapter 8 in the Blue Guide is entitled "Market surveillance" and is written in general terms to cover all the New Approach Directives.

3.3 This chapter sets out:

- principles of market surveillance;

⁵ www.welmec.org

⁶ Available from the Europa website in various Community languages: <http://europa.eu.int/comm/enterprise/newapproach/legislation.htm>

- activities involved in it;
- corrective actions to be taken;
- complementary activities;
- safeguard clause procedure;
- protection of CE marking;
- information exchange systems;
- administrative cooperation; and
- products imported from third countries.

3.4 The Blue Guide also contains, on page 96, a flow chart for the conformity assessment procedures relating to non-automatic weighing instruments.

3.5 The chapter 8 explains that *“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.”*

3.6 Effective market surveillance ensures that all non-automatic weighing instruments put onto the market comply in all relevant respects with the Directive. It establishes that both the manufacturers and the notified bodies are fulfilling their roles under the Directive.

3.7 The Blue Guide stresses that efficient market surveillance will usually require surveillance authorities to act in collaboration with the manufacturers and suppliers on their territory. The manufacturer’s declaration of conformity and the associated technical documentation will provide the surveillance authority with basic starting information about the non-automatic weighing instrument, but market surveillance cannot rest with a study of the paperwork. Inevitably, it will involve the taking of samples of instruments that have not been put into service, their testing and examination, and the requesting of further information or clarification.

3.8 Member States need to consider where market surveillance should be carried out. In the first place there may be no information to guide the decision beyond such data as may be obtained from inspection activities or from complaints. As far as possible the decision should be based on factors that make the most efficient use of resources. This may involve discussions with the other Member States (for example through WELMEC Working Group 5 - see section 5.6), so that effort is not duplicated needlessly and problem areas are not overlooked. The use of statistics and risk assessment may be appropriate.

3.9 Once a decision has been taken, the following sections of this Guide set out how the market surveillance can be carried out.

3.10 The present activities performed in the EEA Member States to ensure accurate and secured measurements need also to be considered when a decision on carrying out “market surveillance” shall be taken. These activities are described and listed in Annex 5 and may in many cases give useful information to the decision for future market surveillance and for avoiding duplication of work.

4 HOW TO CARRY OUT MARKET SURVEILLANCE

4.1 Market surveillance can only be carried out on instruments that have been placed on the market. Therefore the first step is to find out where complete non-automatic weighing instruments are being 'put onto the market'. This may be at the manufacturer's premises, where complete instruments are stored after production and completion of conformity assessment procedure (including EC declaration of conformity by the manufacturer), but before they are despatched to the place of use or to some other destination, such as to a wholesaler.

4.2 It should be noted that instruments may be 'complete' in several different forms: with or without a printer, for example, according to the details set out in the type approval certificate. In addition a complete instrument may be made up of a number of modules covered by test certificates. Research will show the range of possibilities for each type, and what should have gone through the conformity assessment procedures. (General questions about responsibilities for 'complete' instruments and the declarations of conformity come within the scope of WELMEC Working Group 2.)

4.3 Arrange a preliminary visit to these premises. Explain to the manufacturer the purpose and nature of market surveillance. Understand the general arrangements of the premises, where the instruments are produced, where verified, where stored ready for despatch, so that market surveillance can be carried out with minimal disruption to the manufacturer's processes. Decide how best any tests normally done in a laboratory can be done, whether at a nearby laboratory or at some other place. Agree on the timing of another visit.

4.4 Visit the premises with any necessary test equipment, and necessary transport if non-automatic weighing instruments are to be removed for testing. Carry out the tests and examinations on the sample of instruments that has been selected, recording the results. Take away any instruments agreed for testing.

4.5 Back at base, compile and review the test results and record any associated commentary about the market surveillance visit. Where the modular approach has been used and a module has been found to be non-compliant, action should be taken to trace the other types in which the same or different manufacturers may have used that module.

4.6 Ensure that the instruments removed for testing are returned promptly to the manufacturer. When necessary, the instrument shall be retained as long as there is a possibility for the manufacturer to react to the conclusions of the market surveillance authority. Add these test results to the other results. It should be noted that when a tested instrument is returned to the manufacturer, it should be made

clear, if appropriate, that certain tests have been applied that might have an effect on the future performance of the instrument.

4.7 Consider what further action is required and organise it, including arrangements for another visit after an appropriate lapse of time.

4.8 Report the results to the contact for the territory. (These are listed in Annex 1.)

4.9 Market surveillance may take place at other premises. These other premises may include those of an authorised representative, of a wholesaler or of an importer. However, in many cases the procedure will be the same as for instruments verified at the manufacturer's premises *mutatis mutandis*, for example if the instruments are subject to completion of conformity assessment procedures.

4.10 The task will inevitably be slightly different where instruments are subject to completion of conformity assessment procedures at place of use, and this circumstance might cover those instruments that have been subjected to the EC unit verification procedure described in Annex II.4 to the Directive⁷.

4.11 There are two main considerations. Firstly, there will be other parties involved, namely the owners or occupiers of the premises and the users or soon-to-be-users of the instruments. A case in point would be a weighbridge installed at a factory. Secondly, it may be difficult or impossible to carry out some tests and examinations that would either involve the substantial dismantling of the instrument or its removal to a laboratory for other tests.

5 PROCEDURE AND ARRANGEMENTS FOR EXCHANGE OF RESULTS OF MARKET SURVEILLANCE

5.1 The contact for the territory will be the first recipient of the results.

5.2 Once the contact is satisfied with the results, having for example checked with the manufacturer or other parties involved, he should post them to the WELMEC Working Group 5 website and notify the other contacts by email that the results are there for examination and comment. This website area is confidential to Working Group members.

5.3 Any comment should be given within two months.

5.4 The results of market surveillance that identify the manufacturer and/or the instruments by recognisable names or characteristics must be kept confidential so as to avoid adverse effects on the market. The manufacturer may agree to the release of market surveillance results, if he so wishes. In some Member States there may be overriding requirements relating to public access to information.

⁷ This procedure is for instruments designed for specific applications, that is to say instruments not manufactured in series. The procedure is generally considered to apply to instruments verified at place of use, though it is not in fact restricted to place of use and could be carried out at any place.

5.5 (The need for confidentiality does not apply where the procedure in Article 7 has been followed, when and only when the Commission has confirmed that the action taken by the Member State was justified.)

5.6 WELMEC Working Group 5 should adhere to the following cycle: -

- (a) propose and plan what market surveillance is appropriate (this may differ from Member State to Member State), having regard to the views of interested parties such as CECIP and Notified Bodies;
- (b) note what each participating Member State is planning to do;
- (c) Member States carry out market surveillance activities;
- (d) collect the results on the website;
- (e) review those results with all interested parties including CECIP, other manufacturers who are not members of CECIP, and representatives of the Notified Bodies;
- (f) some publication of a summary and analysis, which is circulated widely and on publicly accessible websites, including to the Commission, to show that (i) the Member States are carrying out their responsibilities, (ii) buyers and users of non-automatic weighing instruments may have confidence in them, (iii) manufacturers and Notified Bodies are being treated on an equal basis; and
- (g) go back to (a).

5.7 The exchange of results will inform the Member States of what has been found. The initial planning of a cycle of market surveillance activities can, as a consequence, take account of what has been done previously and the results that were found. In this way the new work can focus on where market surveillance is needed and avoid areas where it is not needed, thus leading to better use of resources. The exchange will also show whether or not an equivalent level of protection is being achieved.

ANNEX 1

CO-ORDINATION OF MARKET SURVEILLANCE ON NON-AUTOMATIC WEIGHING INSTRUMENTS IN THE MEMBER STATES

List of contacts: -

	Name Organisation	telephone fax email
Commission	Daniel Hanekuyk DG Enterprise Unit G4	+322 2960150 +322 2966273 daniel.hanekuyk@cec.eu.int
EEA Member States		
Austria	Ludwig Turnwald BEV (Bundesamt für Eich- und Vermessungswesen)	+43 1 21176 3700 +43 1 21176 3623 ludwig.turnwald@bev.gv.at
Belgium	Roger Melotte Metrology Service	+32 2 206 46 97 +32 2 201 65 82 Roger.Melotte@mineco.fgov.be
Denmark	P. Claudi Johansen Den Danske Akkrediterings- og Metrologifond	+45 3546 6224 +45 3546 6202 cj@danak.dk
Finland	Tuomo Valkeapää Safety Technology Authority TUKES	+358 9 6167 241 +358 9 6167 590 tuomo.valkeapaa@tukes.fi
France	Corinne Lagauterie SDM	+33 1 43 19 52 10 +33 1 43 19 65 01 corinne.lagauterie@industrie.gouv.fr
Germany	Günther Volk Mess- und Eichwesen Baden Württemberg (MEBW)	+49 0711 4071 243 +49 0711 4071 200 Guenther.Volk@me.bwl.de
Greece		
Iceland		

	Name Organisation	telephone fax email
Ireland	P Farragher Legal Metrology Service	+ 350 1 8073807 + 350 1 8073808 pat.farragher@nsai.ie
Italy		
Luxembourg		
Netherlands	C.J. van Mullem Verispect bv	+31 15 2691527 +31 15 2850507 cvanmullem@verispect.nl
Norway	Knut Lindløv Justervesenet (Norwegian metrology and accreditation service)	+47 64 84 84 84 +47 64 84 84 85 knut.lindlov@justervesenet.no
Portugal		
Spain	Rogelio Garrido General Office for Industry, Trade, Tourism and New Technologies Regional Government of Madrid	+34 91 580 2192 +34 91 580 2103 rogelio.garrido@comadrid.es
Sweden	Hillevi Stein SWEDAC	+46 8 406 83 11 +46 8 791 89 29 hillevi.stein@swedac.se
United Kingdom	Sue Billing National Weights and Measures Laboratory	+44 20 8943 7277 +44 20 8943 7270 sue.billing@nwm.gov.uk
OTHER STATES		
Bulgaria		

	Name Organisation	telephone fax email
Czech Republic	Milan Bousa Czech Trade Inspection (Ceska obchodni inspekce), Regional Inspectorate Liberec, P.O.Box 144, 460 31 Liberec, CR	tel. 00420 485 244 320 fax 00420 485 244 207 e-mail: mbousa@coi.cz
Estonia		
Hungary		
Latvia		
Lithuania		
Poland		
Romania		
Slovakia		
Slovenia		
Switzerland ⁸	Jean-Georges Ulrich Swiss Federal Office of Metrology and Accreditation	+41 31 32 33 261 +41 31 32 33 210 jean-georges.ulrich@metas.ch

⁸ Switzerland is a full member of WELMEC but is not a member of the EEA. A Mutual Recognition Agreement between the EU and Switzerland was concluded in summer 2002. This includes non-automatic weighing instruments.

ANNEX 2

POWERS AND RESPONSIBILITIES OF THOSE RESPONSIBLE FOR MARKET SURVEILLANCE ON NON-AUTOMATIC WEIGHING INSTRUMENTS IN THE MEMBER STATES

Country	Who?	What powers and responsibilities do they have?
EEA Member States		
Austria from: 22/01/2003	Authorised inspectors of BEV and verification offices	<p>They can enter all places where instruments under verification obligation are used, stored or produced. They do not have to announce their visits in advance. Proprietors of companies, their representatives and agents, are obliged to facilitate the official operations of the surveillance authority.</p> <p>Illegal, incorrect or otherwise not complying instruments may be put out of use. The further use of disputed objects can be prevented by their total or partial confiscation into official safekeeping or by the creation of a disabling device for a maximum period of six months (immediate enforcement action).</p> <p>This may be associated with advice to an administrative body, which can set a fine and take further measures.</p> <p>If non-compliant instruments are revealed, the following measures can be taken:</p> <ol style="list-style-type: none"> 1. a ban on further marketing, 2. requisition of lists of suppliers, 3. order to revert to the statutory condition, for which an appropriate period must be specified, 4. notification to the notified body or the type approval body involved, 5. implementation of suitable measures, in order to prevent unintentional use, 6. publication in the Official Journal for the Verification Service and in the appropriate media for the sales channels concerned.
Belgium from: [date of regulation]	Verification officers mandated by the Federal Government	<p>The power and responsibilities are regulated by :</p> <ol style="list-style-type: none"> 1. - articles 12, 24, 26 and 27 from the

Country	Who?	What powers and responsibilities do they have?
		<p>Law on weights and measures of 16 June 1970;</p> <p>2. - article 1 from the Royal Decree of 5 December 1978;</p> <p>3. - article 7 from the Royal Decree of 4 August 1992.</p> <p>4. They can enter all places where instruments under verification obligation are used, stored or produced.</p> <p>5. There is no obligation to announce the inspections in advance.</p> <p>6. Illegal, incorrect or uncomplying instruments shall be disapproved.</p> <p>7. Legal proceedings (enforcements) are foreseen in collaboration with the court</p>
Denmark from: 29/06/1994	Den Danske Akkrediterings- og Metrologifond or persons or organisations authorised by Den Danske Akkrediterings- og Metrologifond according to Statutory Order no: 597 dated 29. June 1994 ⁹	<p>Ref. Made to specific §§ in Statutory Order no: 597 dated 29. June 1994:</p> <p>§6, §10 Den Danske Akkrediterings- og Metrologifond may stop marketing and use of CE-marked non-automatic weighing instruments not fulfilling requirements of the Directive.</p> <p>§14 Authorised persons have the power to enter certain premises to inspect and test non-automatic weighing instruments. They may enter premises by force. They do not have to announce their visits in advance.</p>
Finland Verification Act from 1965 last modified 1999 Degree from 1992 last modified 1999 Degree on measurement units 1992 last	Authorised inspectors of TUKES and Provincial Authorities	<p>1. May limit or stop marketing and use of instruments not fulfilling requirements</p> <p>2. May issue injunctions and prohibitions as required in any particular case in order to ensure compliance with the Act and the regulations. Such injunctions or prohibitions may be associated with fines.</p> <p>3. Authorised persons have the power to enter certain premises to inspect and test instruments. They do not have to</p>

⁹ <http://www.retsinfo.dk/GETDOC/ACCN/B19940059705-REGL>

Country	Who?	What powers and responsibilities do they have?
modified 2001 Regulations V10-92, V1-93, V1-94 and V2-93		announce their visits in advance. 4. Proprietors of companies, their representatives and agents, are obliged to facilitate the official operations of the surveillance authority. 5. The right to get the information necessary for supervision from the owner, user or other body the regulations concern. 6. The police and customs may provide executive assistance if needed.
France from: 27/03/1991	Agents from SDM and DRIRE. They are mentioned in the décret of 1991(modified in 1993 and 1996) transposing the Directive by way of a reference to the Code de la consommation (Loi du 1er février 1995)	<p>They can take the instrument and ask that they are put in conformity. It goes with a juridical procedure (papers and information of justice authorities and final decision by them).</p> <p>They can enter any place mentioned in the décret of 1944 (places open to the public as well as shops, workshops, factories, co-operatives, stations, airports, hospitals, governmental premises...). If access is refused to them, then they have to request that a policeman or a representative of the city mayor or a judge accompany them and these required persons cannot refuse to accompany them.</p> <p>The amount of the penalties are fixed in the décret transposing the directive by reference to a general rule. Physical persons and companies (moral persons) can be punished.</p>
Germany from: 23/03/1992	Verification officers mandated by the verification authorities of the federal states	They have the power to enter certain premises to inspect and test non-automatic weighing instruments subjected to legal metrological control. They do not have to announce their visits in advance and may take appropriate enforcement actions, where the essential requirements are not satisfied or when the marking is not correct.
Greece from: [date of regulation]		

Country	Who?	What powers and responsibilities do they have?
Iceland from: [date of regulation]		
Ireland from: 23/12/1992 for NAWI Regulations, from 12/5/1997 for the Metrology Act 1996	Inspectors authorised under the NAWI Regulations 1992 and the Metrology Act, 1996	<p>Authorised officers are authorised:</p> <ul style="list-style-type: none"> • to enter any premises for the purposes of inspecting measuring instruments • to examine and test instruments • To take away instruments from the premises for testing • To examine and take extracts of records <p>An offence is created by any person who places on the market any instrument which does not meet the requirements of the Regulations</p>
Italy from: [date of regulation]		
Luxembourg from: [date of regulation]		
Netherlands from: 4 December 1997	Inspectors of Verispect bv mandated by the Central Government	<p>1. Inspectors of Verispect bv have the power to enter certain premises to inspect and test non-automatic weighing instruments. In certain circumstances, they may enter premises by force. They do not have to announce their visits in advance.</p> <p>2. Inspectors of Verispect bv may take immediate enforcement action, where for example the essential requirements are not met, with the effect that instruments must be withdrawn from the market.</p> <p>3. Inspectors of Verispect bv may issue a compliance notice, where the CE marking</p>

Country	Who?	What powers and responsibilities do they have?
		is being affixed to instruments in contravention of a provision concerning CE marking.
Norway from: [date of regulation]	Justervesenet	Reference is made to the Law on weights and measures and the following regulation. Justervesenet have the power to enter all premises (by force if necessary) where it is likely that measurements regulated by the law are done. Such visits shall generally not be announced in advance. If instruments are incorrect or illegal, they may be put out of use. If they are approved but do not fulfil the verification requirements, the inspector may give permission for use until they are repaired; not more than 1 month.
Portugal from: [date of regulation]		
Spain from: [date of regulation]	Regional Governments (Comunidades Autónomas)	The inspectors and agents of the Comunidades Autonomas have the power to enter certain premises to inspect and test NAWIs (ex: shops, workshops, factories, public places, ...). They do not have to announce their visit in advance. They are capable to take immediate enforcement action and put out of use the instrument when some irregularities or non-conformities are detected. Such actuation may be associated with penalties.
Sweden from: 17 December 1992 and 23 September 1993h	Act (1992:1514) Concerning Quantity Units, Measurements and Measuring Devices and the Ordinance (1993:1066) Concerning Quantity Units,	1. SWEDAC is granted access to areas and premises in which there are measuring devices or where goods are packaged, stored or sold. The person on whose areas or premises inspection or surveillance is taking place is required to facilitate the work of the surveillance authority. In case refusal of access, SWEDAC is entitled to call upon the assistance of the executory authority in

Country	Who?	What powers and responsibilities do they have?
	Measurements and Measuring Devices	<p>order to perform the work.</p> <p>2. SWEDAC may issue injunctions and prohibitions as required in any particular case in order to ensure compliance with the Act and the regulations. Such injunctions or prohibitions may be associated with fines.</p>
United Kingdom from: 01/01/2001	Authorised persons, an inspector or some other person employed by a local weights and measures authority, who is authorised by the chief inspector of weights and measures of that authority to exercise functions under the Non-automatic Weighing Instruments Regulations 2000 ¹⁰	<p>References in () are to the specific regulations in the Non-automatic Weighing Instruments Regulations 2000.</p> <p>1 Authorised persons have the power to enter certain premises¹¹ to inspect and test non-automatic weighing instruments. In certain circumstances, they may enter premises by force. They do not have to announce their visits in advance. (regulation 38)</p> <p>2 They may suspend, for a period upto 28 days, a manufacturer's or authorised representative's authority to make EC declarations of type conformity, where the CE marking or stickers are being affixed to instruments contrary to the Directive. (regulation 16)</p> <p>3 A person commits an offence who puts an instrument on the market which to his knowledge bears any CE marking, inscriptions, etc, that are forgeries or counterfeit. (regulation 22)</p> <p>4 An authorised person may take immediate enforcement action, where for example the essential requirements are not met, with the effect that instruments must be withdrawn from the market. (regulation 25)</p> <p>5 An authorised person may issue a compliance notice, where the CE marking is being affixed to instruments in contravention of a provision concerning CE marking, but the matter is not so</p>

¹⁰ www.legislation.hmsso.gov.uk/si/si2000/20003236.htm

¹¹ These premises include places where instruments are manufactured or are being used.

Country	Who?	What powers and responsibilities do they have?
		serious as under 4 above. (regulation 26)
Other States		
Bulgaria from: [date of regulation]		
Czech Republic from: [date of regulation]		
Estonia from: [date of regulation]		
Hungary from: [date of regulation]		
Latvia from: [date of regulation]		
Lithuania from: [date of regulation]		
Poland from: [date of regulation]		
Romania from: [date of regulation]		
Slovakia from: [date of regulation]		
Slovenia from: [date of		

Country	Who?	What powers and responsibilities do they have?
regulation]		
Switzerland ¹² from: 06/10/1995	Authorised persons, inspector or some other person mandated by the cantonal (local) weight and measures authority for surveillance and enforcement functions ¹³	Authorised persons have the power to enter certain premises, to inspect and test non-automatic weighing instruments subjected to legal metrological control. They may take appropriate enforcement actions, where the essential requirements are not satisfied or when the marking is not correct.

¹² Switzerland is a full member of WELMEC but is not a member of the EEA. A Mutual Recognition Agreement between the EU and Switzerland was concluded in summer 2002. This includes non-automatic weighing instruments.

¹³ Federal law on metrology; federal law relating to technical barriers to trade

ANNEX 3

EXAMINATIONS AND TESTS TO BE CARRIED OUT

1 Instruments intended for use for one or other of the applications listed in Article 1.2 (a) and bearing the CE marking and the green M or which should bear those markings according to their intended use: -

1.1 Check that all

- markings,
- units of measurement,
- inscriptions, and
- associated documentation

are present and correct.

Check conformity with the type-approval certificate (if relevant), including

- identification of any software,
- the presence and operation of approved functions, and
- the sealing arrangements (physical or electronic).

1.2 Having established the gravity zone or setting for the instruments, carry out the following examinations and tests from Annex I to the Directive:-

- 4.1 maximum permissible errors;
 - 8.5 fraudulent use; user access to components;
 - 9 weighing indications;
 - 14 direct sales to the public; and
- any other requirements considered or suspected to be relevant.

1.3 If feasible, test the instrument against other requirements in Annex I to the Directive; this may include EMC, and the provisions on influence quantities and time:

-

- 7.1 insensitive to tilting
- 7.2 accurate over the temperature range
- 7.3 fluctuations in power supply, mains or battery
- 7.4 high relative humidity at upper limit of temperature range
- 7.5 loading for a prolonged period of time

1.4 The harmonised standard EN45501 sets out tests, and WELMEC Guides 2 and 2.2 cover the compatibility of modules and testing of point of sale devices respectively.

2 Other instruments:-

2.1 Check that the marking requirements of the Directive are present and correct.
The requirements are:-

• the manufacturer's name or mark	yes
• maximum capacity in the form Max ... (e.g. Max 15 kg)	yes
• the green M sticker	no

ANNEX 4

FORM FOR SENDING THE RESULTS TO THE OTHER MEMBER STATES VIA THE WELMEC WORKING GROUP 5 WEBSITE

TO MARKET SURVEILLANCE CONTACTS	CONFIDENTIAL	SERIAL NUMBER OF THIS REPORT:-
FROM: name, address, etc		
REPORT ON EXAMINATIONS AND TESTS CARRIED OUT ON: instrument category, serial number(s), type approval certificate (if relevant), class of accuracy, intended use, gravity zone or setting, name of manufacturer or authorised person, place of examination/test, date of examination/test		
COMMENTS:		
RECOMMENDATIONS:		

INSTRUMENTS INTENDED FOR USE FOR ONE OR OTHER OF THE APPLICATIONS LISTED IN ARTICLE 1.2 (a) AND BEARING THE CE MARKING AND THE GREEN M OR WHICH SHOULD BEAR THOSE MARKINGS ACCORDING TO THEIR INTENDED USE	AGAINST REQUIREMENTS IN DIRECTIVE, INCLUDING THE ESSENTIAL REQUIREMENTS, CORRECT: - Yes/No	COMMENTS (Test results should be attached.)
PART A		
check markings		
check units of measurement		
check inscriptions		
check associated documentation		
check conformity with the type-approval certificate (if relevant), including		
<ul style="list-style-type: none"> • identification of software 		
<ul style="list-style-type: none"> • presence and operation of approved functions 		
<ul style="list-style-type: none"> • sealing arrangements (physical or electronic) 		
PART B		
carry out the following examinations and tests from Annex I to the Directive		
4.1 maximum permissible errors		
8.5 fraudulent use etc		
9 weighing indications		
14 direct sales to the public		

other requirements		
PART C		
other testing		
EMC		
7.1 tilt		
7.2 temperature		
7.3 power supply		
7.4 humidity		
7.5 time		
OTHER INSTRUMENTS		
the manufacturer's mark or name		
the maximum capacity in the form "Max ..."		
the green M sticker		

ANNEX 5

RELATED ACTIVITIES PERFORMED IN THE EEA MEMBER STATES

Introduction

This Annex lists the different activities performed in EEA Member States in the field of legal metrology dealing with non-automatic weighing instruments. Furthermore it describes the purposes for which the activities are performed as well as the actions taken when requirements are not met.

The scopes of the various activities overlap to some extent. Accordingly no Member State should perform all activities. The list shows possible approaches to fulfil the requirements of 90/384/EEC as well as what is necessary to ensure accurate and secured measurements (ASM) and at the same time are in accordance with the metrological organisation / resources of the country.¹⁴

The guide is only dealing with instruments covered by Directive 90/384/EEC. Instruments / activities etc. legally in use according to national regulations preceding 90/384/EEC are excluded.

	Activity	Purpose(s)	Action if infringements (may vary due to national legislation)
A	Random inspection at place of use (1.2.a)¹⁵ (mainly visual)		
	Is instrument marked with CE+M+NB-number ¹⁶ ?	Art. 2.2 + ASM	In case of one instrument: Request owner/user of the NAWI to take it out of use (or request conformity assessment procedure to be completed) If systematic: Contact manufacturer (possibly prohibition of marketing the NAWI and/or inform the Commission)

¹⁴ A table showing activities applied in each EEA Member State is given on the last page of this Annex.

¹⁵ Notice: Random inspection at manufacturer/importer or other places different from place of use may cause problems because the requirements for NAWIs in 90/384/EEC are related to the use. Furthermore the conformity assessment procedure for NAWIs often is not completed before the instrument is installed at its place of use.

¹⁶ 2 NB numbers in cases where 2 NBs are involved

Has NB (NBs) indicated through number on instrument been involved in the conformity assessment procedure?	Art. 2.2 + ASM	Contact manufacturer (possibly prohibition of marketing the NAWI and/or inform the Commission)
Is marking correct?	Art. 10 + ASM	In case of one instrument: <ul style="list-style-type: none"> • Request marking to be completed or, if not fully certified: • Request owner/user of the NAWI to take it out of use (or request conformity assessment procedure to be completed) If systematic: <ul style="list-style-type: none"> • Request relevant NB to take action and: • Contact manufacturer (possibly prohibition of marketing the NAWI and/or inform the Commission)
Is instrument appropriate for its use? (e.g. class II for precious metals, not used for weighing below Min, direct sales to the public...)?	ASM	Instruct user
Are special requirements for direct sales to the public fulfilled? ¹⁷	Annex I	Instruct user
Is instrument correctly corrected for gravity? (check gravity zone marking and/or test with weights)	Annex II,5 + ASM	Request owner/user to take it out of use until (re)verification
Is date for next periodic verification exceeded? ¹⁸	ASM	Take appropriate measures, eg <ul style="list-style-type: none"> · Request reverification · Request owner/user to take it out of use until (re)verification
Is sealing intact?	ASM	Request owner/user to take it out of use until (re)verification
Is written declaration of conformity issued?	Annex II	Request owner/user to take it out of use until conformity assessment procedure has to been completed

¹⁷ For instruments used for direct sales to the public

¹⁸ For countries requiring periodic verification

B	Periodic reverification		
	Is instrument marked with CE+M+NB-number ¹⁶ ?	Art. 13 + ASM	Seek evidence that the instrument has passed conformity assessment (e.g. by checking written declaration of conformity, by finding traces of original marking). <ul style="list-style-type: none"> • If evidence is found: Perform reverification. • If no evidence is found: Request declaration of conformity to be performed.
	Is instrument in conformity with type approval? ¹⁹	Art. 13 + ASM	Request manufacturer to <ul style="list-style-type: none"> • Have the type approval extended to cover the modification made + new declaration of conformity to be performed or • get unit verification carried out
	Are MPE requirements fulfilled? (Perform testing according to test procedures in EN45501 or national procedures – if available)	Art. 13 + ASM	Refuse reverification and inform owner / authority according to national legislation
C	Verification after repair		
	Is instrument marked with CE+M+NB-number. ¹⁶ ?	Art. 13 + ASM	Seek evidence that the instrument was originally declared in conformity (e.g. by checking written declaration of conformity, by finding traces of original marking). <ul style="list-style-type: none"> • If evidence is found: Perform reverification. • If no evidence is found: Request declaration of conformity to be performed.

¹⁹ For categories of instruments requiring type approval as part of conformity assessment procedure

	Is instrument in conformity with type approval? ²⁰	Art. 13 + ASM	Request manufacturer to <ul style="list-style-type: none"> • Have the type approval extended to cover the modification made + new declaration of conformity to be performed, or • get unit verification carried out
	Is MPE requirements fulfilled? (Perform testing according to test procedures in EN45501 or national procedures – if available)	Art. 13 + ASM	Refuse reverification and inform owner / authority according to national legislation
D	Random technical inspection at place of use (visual + testing)		
	Is instrument marked with CE+M+NB-number ²¹ ?	Art. 2.2 + ASM	In case of one instrument: Request conformity assessment procedure to be completed If systematic: Contact manufacturer (possibly prohibition of marketing the NAWI and/or inform the Commission)
	Has NB (NBs) indicated through number on instrument been involved in the conformity assessment procedure?	Art. 2.2 + ASM	Contact manufacturer (possibly prohibition of marketing the NAWI and/or inform the Commission)

²⁰ For categories of instruments requiring type approval as part of conformity assessment procedure

²¹ 2 NB numbers in cases where 2 NBs are involved

Is marking correct?	Art. 10 + ASM	In case of one instrument: <ul style="list-style-type: none"> Request marking to be completed or, if not fully certified: Request owner/user of the NAWI to take it out of use (or request conformity assessment procedure to be completed) If systematic: <ul style="list-style-type: none"> Request relevant NB to take action and: Contact manufacturer (possibly prohibition of marketing the NAWI and/or inform the Commission)
Is instrument used as intended (e.g. class II for precious metals, not used for weighing below Min, direct sales to the public...)?	ASM	Instruct user
Are special requirements for direct sales to the public fulfilled? ²²	Annex I	Instruct user
Is sealing intact?	ASM	Request owner/user to take it out of use until (re)verification
Is instrument in conformity with type approval? ²³	Art. 13 + ASM	Request manufacturer to <ul style="list-style-type: none"> get addition to type approval covering the modification made + new declaration of conformity to be performed, or get unit verification carried out
Is written declaration of conformity issued?	Annex II	Request conformity assessment procedure to be completed
Is MPE requirements fulfilled? (Perform testing according to test procedures in EN45501 or national procedures – if available)	Art. 13 + ASM	Request owner/user to take it out of use until reverification
E Random inspection at manufacturers, importers and shops selling 1.2.b NAWIs		

²² For instruments used for direct sales to the public

²³ For categories of instruments requiring type approval as part of conformity assessment procedure

	Is marking correct?		Stop marketing
F	Check that new NAWIs certified to 1.2.a use <u>do</u> fulfil requirements		
	<p>Sample new²⁴ NAWIs and complete type approval testing (incl. Checklist) partly or in full.</p> <p>Examples:</p> <ol style="list-style-type: none"> 1) Run programs on specific parameters (e.g. temperature testing, EMC testing or durability) 2) Agree programs between WELMEC members in order to share costs. 		<p>Contact manufacturer to find the reason for failure and inform relevant Member State. Then depending on findings:</p> <ul style="list-style-type: none"> • Simple fault: solve the case and inform the relevant Member State • Systematic fault: Contact manufacturer (possibly prohibition of marketing the NAWI and/or inform the Commission) • Systematic fault due to fault in QS: through relevant Member State request NB to explain how the failure could happen.
G	Reactive actions		
	Reaction to complaint and other information		

²⁴ New = ready to be taken into use but never used (i.e. the complete conformity assessment procedure has been completed).

ACTIVITIES APPLIED IN EACH EEA MEMBER STATE							
Activity	A	B	C	D	E	F	G
AT	+	+	+	+	+		+
CH	+	+	+	(+)			+
DE	+	+	+	+		(+)	+
DK	+	+	+				+
FI	+	+	+	(+)	(+)	+	+
FR	+	+	+	+	(+)	+	+
GB	+		+	+		+	+
IE			+	+			+
NL	+	(+)	+	+			+
NO	+	+	+				+
SE	+	+ ²⁵	+	(+)		+	+
SI	+	+	+				+

(+) indicates that is legally possible but not systematically performed unless it is a random inspection at manufacturers, importers and shops selling 1.2.b NAWIs

²⁵ Sweden does not make periodic reverification of all instruments listed in Art. 1.2.a