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WELMEC

European Cooperation in Legal Metrology

Market Surveillance Guide (NAWI and MID)

WELMEC

European Cooperation in Legal Metrology

WELMEC is a cooperation between the legal metrology authorities 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 EU 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.

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Foreword

This guide is a completely new issue of Guide 5.2 on Market Surveillance of Measuring Instruments. It replaces Issue 2, dating from May 2007. This guide will be applicable as from 20 April 2016. It can be used in the meantime, but the reader should be aware that the safeguard procedure reflected in this guide is the one from NLF MID and NAWI.
Of course, there are still wishes to expand the guide and inevitably an update will be necessary in the coming years.

This guide is primarily intended to provide guidance to market surveillance authorities and their employees. This guide also provides information on how market surveillance is performed to manufacturers of measuring instruments and to Notified Bodies responsible for conformity assessment of their products. Where issues are treated that are specifically mentioned in the Blue Guide references to the relevant passages are included in notes.

The Guide is purely advisory and does not impose any restrictions or additional requirements beyond those contained in MID, NAWI or Regulation 765/2008/EC. Alternative approaches may be acceptable, but the guidance provided in this guide represents the considered view of WELMEC as to the best practice to be followed. However, it is intended that the procedures as described in the guide must be followed if it is to be claimed that the guide has been applied.

References to Regulation 765/2008/EC are subject to change by the Proposal for a Regulation On Product Safety and Market Surveillance Package (Article 35.3 of COM(2013)57).

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1 Introduction

Market surveillance is an essential tool for enforcing New Approach directives, in particular by assessing if products meet the requirements of the directives, taking action to bring non-compliant measuring instruments into compliance and to apply sanctions when necessary. It contributes to a uniform level of protection in the different Member States, not only in the interests of consumers and other users, but also to the protection of the interests of Economic Operators from unfair competition.
The obligation for market surveillance is complementary to the provisions of the New Approach directives that require Member States to allow free movement of measuring instruments that are in compliance with the requirements.
The Member States must nominate or establish authorities 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.
Regulation 765/2008/EC creates an obligation on Member States to establish, implement and periodically update their market surveillance programmes.
Often, the non-compliance of a single instrument is not enough to conclude if there is a systematic problem. Therefore, it is important to keep in mind that the 'thinking' in market surveillance is one of surveys and campaigns and not of individual instruments. In this way market surveillance is able to present findings (either positive or negative) that are representative for e.g. a certain type of instrument, an instrument category, a manufacturer and so on.
The presence of good market surveillance in a Member State also creates trust needed for the mutual acceptance of non-harmonised products by other Member States (Regulation 764/2008/EC).
This guide for market surveillance is based upon the European framework for market surveillance: Regulation 765/2008/EC, setting out the requirements for accreditation and market surveillance relating to the marketing of products; Decision 768/2008/EC, on a common framework for the marketing of products; Regulation 764/2008/EC, laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State; and the current version of the Guide on the implementation of EU product rules (the Blue Guide, 2014).
This guide also makes use of the best practices gathered in the project Enhancing Market Surveillance through Best Practices in Europe (EMARS) of the Product Safety Enforcement Forum of Europe (PROSAFE). The end report of this project, Best Practice Techniques in Market Surveillance, is included in the references.

2 Scope of this guide

This guide is meant to be used by Market Surveillance Authorities dealing with measuring instruments, both under the NAWI Directive (2014/31/EU) and MID (2014/32/EU). It presents a general guidance that can be used for the development of market surveillance strategies and programmes. It also includes guidance for inspectors to be used on a day to day basis. In later versions the guide will be expanded with interpretations of the requirements for market surveillance in both directives and in Regulation 765/2008/EC and best practices in the market surveillance of measuring instruments in Europe.
The official definition of market surveillance in Regulation 765/2008/EC is very wide. For the purpose of this guide the definition is limited to activities carried out and measures undertaken by Market Surveillance Authorities, if applicable, in close cooperation with the Customs.
This guide presents a general introduction to market surveillance, especially with regard to where, in the 'lifecycle' of the instrument, market surveillance is placed in the metrological system. It describes how market surveillance can be performed and the tools that can be used. It pays special attention to the planning of market surveillance and the follow-up of market surveillance activities, including interventions. Finally guidance is given for the import from third countries and dealing with the customs.
The guide assumes the reader is familiar with Regulation 765/2008/EC. The articles 15(3) and 16 to 29 are applicable to measuring instruments. The requirements in Decision 768/2008/EC have been taken into account in the new NAWI and MID directives. All of these elements are subject of this guide. Specific requirements on the instruments itself are not covered by this guide. For this, the reader should refer to the applicable NAWI and MI directives.

3 General introduction to market surveillance

The instrument lifecycle starts with the design of a new instrument. When the manufacturer has chosen for the modules B+D, he makes a prototype and lodges an application for a type examination with a Notified Body of his choice. After he has gained the type approval certificate the manufacturer with an approved quality system (Module D) can start the production, ending with drawing up the declaration of conformity and affixing the required markings to the finished instrument. This is the design and production phase. After that, the instrument is brought to the market. It is first placed on the market and consequently being made available on the market. This stage ends when the instrument is taken into use, or put into service, by the end-user. Thereafter, the instrument is in use by the end-user. This is the stage of use of the instrument or the instrument being *in service*.

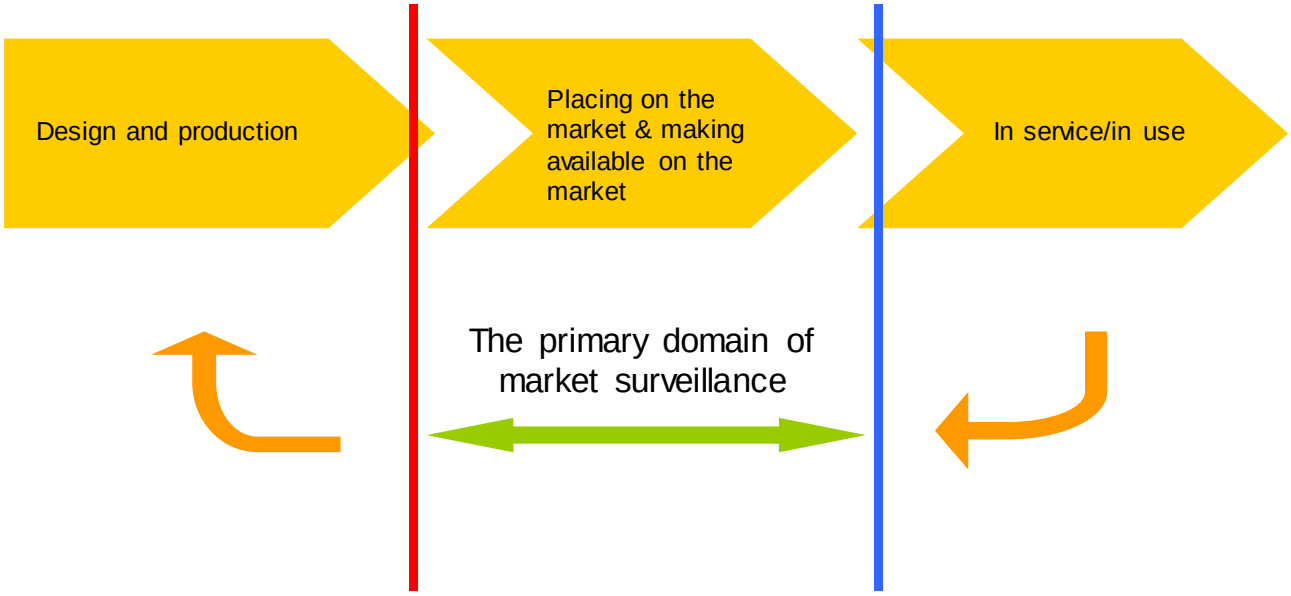


Figure 1

Market surveillance is primarily concerned with the period between the moment the instrument is placed on the market and the moment the instrument is put into use, i.e. between the red and blue line in Figure 1.
For quite a reasonable number of measuring instruments the distinction between the different stages is less pronounced, because placing on the market and putting into use take place at the same time, e.g. weighing bridges or fuel dispensers. In other words the production (including conformity assessment module F or D) ends on the premise of the end user and the instrument is put into use at the end of production. In those cases market surveillance should ideally take place as soon as possible. The later the market surveillance takes place, the more difficult it will be to provide evidence that a non-compliance is of a systematic nature. Nevertheless, also in these cases market surveillance can prove useful.
Information gathered after the instrument has been put into service and information derived from periodic reverification can be relevant for market surveillance. This is the case when it can be established that the problem is related to the design of the instrument or its production and thus can be expected also to have been present when the instrument was placed on the market. This is symbolised by the right arrow in Figure 1.
Information gathered during a market surveillance activity may regard the conformity assessment procedures and the operation of a Notified Body before the instruments are placed on the market. This is symbolised by the left arrow in Figure 1. However, the Market Surveillance Authority should take care not to duplicate the operation of the Notified Body.
If a Market Surveillance Authority is concerned about compliance with conformity assessment procedures or operation of a Notified Body, the information gathered may be passed on to the

Notifying Authority of the Member State in which the Notified Body was designated, who can take action accordingly.

4 How to carry out market surveillance?

Member States shall establish, implement and periodically update their market surveillance programmes (article 18(5) of Regulation 765/2008/EC). Member States shall draw up either a general market surveillance programme or sector specific programmes, covering the sectors in which they conduct market surveillance.
A general market surveillance programme is a description on how market surveillance in a Member State is done. A sector specific market surveillance programme is a description of the yearly activities carried out and measures taken by public authorities to ensure that products comply with the requirements. These programmes must be communicated to the Commission and other Member States. In addition, the functioning of the market surveillance activity must be reviewed every four years and the results of the review communicated to the Commission and the other Member States (article 18(6) of Regulation 765/2008/EC). It is important to note that Regulation 765/2008/EC places an obligation to consider risk assessment processes, complaints or any other information when deciding upon market surveillance activities (article 19(1) of Regulation 765/2008/EC). General guidance for that can be found in WELMEC Guide 5.3, Risk Assessment Guide for Market Surveillance; Weigh and Measuring Instruments.
Market surveillance should be carried out by officers who have a competent understanding of the instruments and processes they are surveying. Such officers will also have the authority to enter the premises of Economic Operators placing on the market, or putting instruments into service; to enter the premises of end-users of instruments and to take enforcement action if necessary. The Market Surveillance Authority or its officers may sub-contract re-assessment/testing or parts of it to expert organisations, but the decisions on non-compliances and possible enforcement actions shall always be made by the Authority.
Market surveillance of measuring instruments will be more efficient and effective when authorities cooperate and coordinate their activities cross border, because of:

- when the same instruments are marketed in many countries, the sampling plan can be more efficient;
- the risk of double testing of instruments and the associated waste of resources is minimized or eliminated;
- follow-up on non-complying instruments will be more efficient and probably more effective if it involves the Market Surveillance Authority or Notifying Authority in the Member State in which the manufacturer or importer is based and banned instruments can be more effectively prevented from entering the market;
- coordination and cooperation will improve the coherence in operation of the different Member States Market Surveillance Authorities, which strengthens their power.

Notified bodies should, basically, be excluded from the responsibility of market surveillance activities. This is to avoid conflict of interest.
There are different approaches to market surveillance, which in practice can be combined to an individual strategy. They differ in how they deal with the monitoring of the market and may cause differences in planning and the organisational framework. Four approaches relevant for measuring instruments can be distinguished:

4.1 Reactive market surveillance

Market Surveillance Authorities are forced to react to events such as accidents, consumer complaints and complaints from competitors, notifications from other Market Surveillance Authorities and from the media. This is referred to as reactive market surveillance.
All these events require similar reactions from the Market Surveillance Authority: they must be investigated, the potential risks must be assessed, conclusions must be drawn, actions must be taken if necessary and results must be reported back.
The investigations are triggered by outside events and cannot be planned in advance. The authority therefore needs the capability to improvise and that capability must be built into the organisation.

The focus of reactive market surveillance will most often be on one specific instrument and the aim will be to solve an emerging problem, whether concerning compliance to the requirements or unfair trade or competition.
Possible (safety) risks or media attention often require immediate action, which might conflict with the thoroughness of the investigation or the need to act in a legally correct way. Therefore great emphasis should be put on communication with the public, the media, the manufacturer etcetera.
The Market Surveillance Authority is not obliged to investigate every complaint or enquiry. Prioritising should be done on the basis of transparent criteria. Especially in potentially critical cases the authority should prepare an explanation if it decides not to take up the case.

4.2 Proactive market surveillance

Proactive market surveillance is a planned activity derived from the long- and short-term plans of the organisation, plans that are usually based on earlier experiences, risk analyses etcetera.
The focus of proactive market surveillance normally will be on a given instrument group or a given risk and the aim will be to clarify the status for the involved instrument group or risk and, of course, to solve any encountered problems with tested instruments. Contrary to reactive market surveillance activities are planned in advance and generally there is more time to prepare a careful communication.
For measuring instruments three different approaches can be recognised that are all pro-active:

4.2.1 Instrument focussed market surveillance

Demonstrating non-compliances may require laboratory investigations, which can be performed more efficiently when a series of instruments is tested. Therefore, there is a strong incentive to work in projects on specific instruments or instrument categories. The instrument focussed approach often goes well together with inspection in use, which often happens to be organised in instrument categories as well.
This approach is proactive as projects can be selected for their relevance to consumer safety, compliance and fair trade, planned in advance, and tuned for maximum efficiency.

4.2.2 Risk focussed market surveillance

Market surveillance activities can also follow a risk based approach. The goal of market surveillance activities can be the reduction of specific risks. Where information is available (for example from notifications or screening projects) indicating that specific instruments or instrument categories present a risk to fair trade or consumers, attention can be directed towards reducing this risk. But risk assessment can also be used for prioritising market surveillance efforts in general (see WELMEC guide 5.3).
Of course, the risk focussed approach often converges with the instrument oriented approach, because it requires the identification of instruments presenting a risk and the subsequent market surveillance of these types of instruments.

4.2.3 Screening projects/market monitoring

Screening projects are a special category of market surveillance actions. The main purpose of a screening project is to monitor the status of a particular part of the market, for example an instrument category, a category of businesses or a category of risks. Even though the main purpose of such projects is not to remove dangerous or non-complying instruments, the authority most likely will come across nonconforming instruments that cannot be left in the market.

Screening projects will often form the first part of a market surveillance action to allow the authority to gather knowledge about a particular area and thus increase the efficiency of the action.
Screening projects can also be a useful tool for checking the effectiveness of new legislation, a new standard or previous market surveillance activities.
In practice both pro-active and reactive market surveillance will be present simultaneously. Pro-active market surveillance is preferable to reactive market surveillance because it has the potential of preventive actions well before problems arise in practice. However, this approach requires essential skills and testing facilities, market insight and field data to perform the necessary risk assessments and prioritise the efforts. Therefore it is quite normal and acceptable for a Market Surveillance Authority to start with a reactive approach and successively grow into a more proactive approach.

5 The market surveillance toolbox

In principle market surveillance should cover all applicable requirements of the directives. Especially in reactive market surveillance it is expected that all requirements are evaluated, which does not mean that all requirements have to be tested. In proactive market surveillance, however, the depth of the investigations depends on the aim of the activity. So, individual market surveillance activities may focus on certain aspects of the requirements.
This chapter gives a description of different tools. In practice the different tools are almost complementary and it is up to the Market Surveillance Authority to decide on the priority between them.

5.1 Formal checks/documentation control

The purpose of formal checks or documentation control is to find out whether all necessary documents and markings are available and correct. It also shows if the instrument is suited for the purpose it is sold for.
For some purposes formal checks are sufficient, for example regarding the CE-marking and its affixing, the availability of the EC declaration of conformity, the information accompanying the instrument and the correct choice of the conformity assessment procedure. Some of these formal checks can also be performed through the internet and e-mail, which makes this approach suitable for larger scale screening projects.
The manufacturer's declaration of conformity, the supplementary metrological marking, the year mark and the number of the Notified Body, the CE marking on the instrument and access to the certificates will provide the surveillance authority with the necessary information about the instrument. To this end, it is important that the certificates are available on a national website. References to the national websites can be found through the WELMEC site: http://www.welmec.org/welmec/mid-certificates.html.
If necessary the technical documentation can be made available following a reasoned request.
The technical documentation must be made available by the manufacturer, the authorised representative established within the Union and under certain circumstances by the Notified Body, to the Market Surveillance Authority within a period of time dependent on its importance and the risk in question. Initially the Market Surveillance Authority may be provided with only a summary of the technical documentation and the full technical documentation should be requested only when considered necessary by the Market Surveillance Authority. Further, the Market Surveillance Authority may request the Notified Body to provide information on the conduct of conformity assessment for the product in question.

5.2 Indicative physical tests/field testing

The purpose of indicative physical testing is to give an indication if the instrument is in conformity with the essential requirements. Mostly, only the basic measurement characteristics can be tested in the field, together with the checking of the presence of the necessary seals. Other characteristics like EMC and temperature sensitivity are difficult to evaluate in the field.
Indicative physical testing often is used to find out if the instrument should be taken for further investigation or to decide which properties should be tested at the laboratory.
Indicative physical tests can be applied at the premises of the manufacturer, distributor or reseller. Indicative physical testing can also be performed at the end-user. Subsequently, there are more possibilities for testing, although you have to make sure that the testing does not put an unwanted and unnecessary burden on the end-user.

5.3 Full evaluation/laboratory testing

Full evaluation and laboratory testing are equivalent to conformity assessment in the design and production stage. All characteristics should be re-evaluated, but not necessarily all characteristics have to be (fully) tested.
There are high demands with regard to the laboratory selected for the test and to the testing procedures. In any case it is the responsibility of the Market Surveillance Authority to assure that the test results are reliable. The Market Surveillance Authority may use its own laboratory or instruct a third party laboratory. In case of contracting a laboratory, the Market Surveillance Authority must be convinced of its qualification (e.g. by accreditation).
Special precautions are necessary when involving the same Notified Body the manufacturer contracted in the design and production phase of the instrument. It is very important that there is impartiality with regard to the test results. In those cases the Market Surveillance Authority may decide to witness the actual testing.
The setup for the laboratory tests should be carefully chosen to be able to present reliable results. Although the appropriate harmonised standard or normative document provides a presumption of conformity with the (essential) requirements, it must be remembered that the Market Surveillance Authority must check for compliance with the essential requirements, not with the harmonised standard or normative document. The Market Surveillance Authority should also take into account results coming from application of other directives (for example LVD, EMC, Machinery), if relevant. If this is the case collaboration with other authorities may be necessary.
Also great care has to be taken with regard to confidentiality of the results. It should be prevented that knowledge about the performance of certain Notified Bodies in any way leads to unfair competition between the Notified Bodies involved.
It is considered good practice to evaluate the results of market surveillance activities with the relevant stakeholders before it is reported.

5.4 Market surveillance of individual instruments

For the market surveillance of individual instruments the three tools from the ‘toolbox’ can also be used as a sequence, which starts with superficial examination (formal checks/ documentation control). From that point the market surveillance officer may decide to move over to field testing. If the instrument passes these tests, the officer may decide to send the instrument in for laboratory testing when there are suspicions of compromised product quality (see annex 4).

6 Planning of market surveillance

For market surveillance to be effective, resources should be concentrated where it is likely that the risks are greater, non-compliance to the requirements is more frequent or where there is a special interest. Statistics and risk assessment may be used for this purpose. Ideally, the safety results or obtained conformity levels should justify the effort.
Because of the international character of the trade in measuring instruments, the high number of instruments involved and the costs of the evaluation of instruments on basis of the essential requirements, a truly statistically justified random sampling is nearly impossible. So, targeting of market surveillance efforts is inevitable.

There are several sources of information relevant for targeting and prioritising market surveillance efforts (among others):

- results from previous market surveillance (screening) projects;
- results from inspection in use;
- signals from inspectors in the field;
- information and results from other Market Surveillance Authorities;
- knowledge about the specific markets (market shares, categories, compliance-levels and levels of willingness to comply);
- complaints;
- information about non-compliant instruments from competitors, consumers or other end users.

At the planning stage of market surveillance issues can be prioritised either on the basis of experience and expert judgement or be based on risk assessment using guide 5.3. The latter method is highly recommended.
Voluntary initiatives, such as product certification or application of a quality management system, can contribute to the elimination of risks. However, Market Surveillance Authorities must be impartial to all voluntary marks, labels and arrangements, and they may only be taken into consideration, in a transparent and non-discriminatory way, for the risk assessment. Accordingly, products should not be excluded from market surveillance operations if they have been subject to these voluntary initiatives[1].
The prioritised issues are listed in the sector-specific market surveillance programme that should preferably be communicated to other Member States yearly before December 31st through CIRCABC. The market surveillance programmes are available on the website of the Commission: http://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance/organisation/index_en.htm.

For a sector-specific market surveillance program to be effective for initiating international cooperation it should at least contain the following information:

- the type of measuring instruments under investigation;
- information about the risk involved (risk assessment);
- the parameters that are going to be tested (what and how);
- the intended volume of the testing (e.g. number of instruments);
- what is intended to be reached (effect);
- when is the testing going to take place;
- when will the exercise be finished and the report be available;
- who is in charge of the planning;
- contact information regarding the exercise.

When other parties are invited to contribute to the exercise, the program should also contain:

- standardised protocols for easy summary of results.

[1] Blue Guide, page 84

When the cooperation between the Member States extends beyond exchange of information it takes the shape of joint cross-border activities. Joint cross-border market surveillance activities can take place at different levels:

- exchange of sampled instruments, tested instruments and test results;
- coordination of sampling plans and follow-up;
- joint drafting, production and dissemination of information material;
- coordinated testing by exchanging information on sampled instruments;
- joint organisation of the testing;
- joint organisation of the full market surveillance exercise.

In all cases the involvement of Member States may vary depending on the level of cooperation. The benefit increases as the commitment of the participating authorities increases. Basically, the benefit is an increased impact of the activity in combination with a decreased effort from the Market Surveillance Authorities.

Market surveillance efforts should preferably be evaluated on a yearly basis, with a thorough evaluation every four years. The results of the latter evaluation should be communicated to the Commission and other Member States (article 18(6) of Regulation 765/2008/EC).

7 Interventions/measures

Competent national authorities must take action to enforce conformity, when they discover that an instrument is not in compliance with the provisions of the applicable directives (article 37(1) of Directive 2014/31/EU; article 42(1) of Directive 2014/32/EU). The corrective action depends on the degree of non-compliance and, thus, must be in accordance with the principle of proportionality. Proportionality is a key management law, which contains two elements: actions against citizens must be necessary (necessity) and an intervention should not be more stringent than the purpose dictates (proportionality).
The incorrect affixing of the CE marking, the supplementary metrology marking, the required inscriptions or the identification number of the Notified Body involved in the production phase are considered as a formal non-compliance. Also when the EU declaration of conformity cannot be provided for immediately or it does not accompany the product when this is mandatory, or, when the technical documentation is either not available or not complete are typical examples of formal non-compliances (article 40 of Directive 2014/31/EU; article 45 of Directive 2014/32/EU).
In case of formal non-compliances the Market Surveillance Authority in first instance should oblige the manufacturer or his authorised representative to make the instrument comply with the provisions and to remedy the infringement. In case of non-conformity to essential requirements, and in case no result is achieved with formal non-compliances, the Market Surveillance Authority has to take appropriate measures, following the principle of proportionality, to enforce conformity. The Market Surveillance Authority should first give the opportunity and also the obligation to the relevant Economic Operator to take all appropriate corrective action to bring the instrument into compliance with the requirements[2]. This applies both for instruments in the market as also for those already in use. The Economic Operator concerned shall be notified and shall also be informed about remedies available under the national law in force in the Member State in question, and the time limits to which such remedies are subjected. If these corrective actions are not taken or are regarded as insufficient the Market Surveillance Authority has to consider further going measures. The authority shall, ultimately, restrict or prohibit the placing on the market and the putting into service, and, if necessary to ensure that the instrument is withdrawn from the market. The decision taken by national authorities to restrict or prohibit the placing on the market or putting into use, or to withdraw instruments form the market must state the exact grounds on which it is based. Unless the matter is urgent, the manufacturer or his authorised representative should be consulted in advance with an appropriate reaction time not less than 10 days (article 21 of Regulation 765/2008/EC). If action has been taken without the Economic Operator's being heard, the Economic Operator shall be given the opportunity to be heard as soon as possible and the action taken shall be reviewed promptly thereafter.
It is not possible to present a list of appropriate measures for all or frequent non-compliances which are expected to be found on the market. Appropriateness is always related to the particular case. The Market Surveillance Authority has to take into account the target of the directive to allow only compliant measuring instruments on the market and in use.

There are different types of interventions available to the Market Surveillance Authorities:

7.1 Prohibition of further use

When it concerns market surveillance of individual instruments (Annex 4) the prohibition of further use is a commonly used instrument. This intervention is a little bit atypical, because it is not directed at the Economic Operator, but directly at the owner or end-user of the instrument.

7.2 Alert to consumers/buyers of measuring instruments

[2] In practice this phase is often called the official warning. The official warning is not a decision but a message to an operator that the authority finds that the identified deficiencies shall be corrected.

Dangerous or otherwise deficient instruments must be published on the Market Surveillance Authorities website or in the EU market surveillance database, ICSMS. In the case of measuring instruments the alert is primarily directed to potential buyers of instruments.
The following information must generally appear on the website:

- information identifying the instrument;
- nature of the deficiency or the risk;
- the assessment of the risk;
- the measures taken.

If it is functional for the correction of non-compliances, information about interventions can be disclosed to the public. It is however important to note that business secrets should be protected. Information about interventions should only be disclosed if it is judged that it is necessary, e.g. to recall instruments. If the instrument has not yet been sold to potential buyers or if all buyers can be identified, it is not deemed necessary to publish this information on the public website.
The timeframe of publication depends on the risk involved. Basically, the Market Surveillance Authority should have taken a formal decision and should have informed the Economic Operator before any publication. Only in the case of particular danger for health and safety publication can take place before the Economic Operator is informed.
The information about the instrument is available on the public website until the Market Surveillance Authority determines that the company has made adequate steps to protect consumers from the non-compliant or dangerous instrument. Subsequently, data are moved to the archive.

7.3 Sales bans

A sales ban is a ban for an Economic Operator to sell a non-compliant instrument. The Market Surveillance Authority should consider whether to grant a deadline for meeting a sales prohibition or an injunction to stop sales, and the Market Surveillance Authority should conduct follow-up control and can inform about this in the letter to put extra pressure on the Economic Operator.

7.4 Withdrawals

Withdrawal shall mean any measure aimed at preventing an instrument in the supply chain from being made available on the market. The Market Surveillance Authority should consider whether to grant a deadline for fulfilment of an order to withdraw an instrument, and the Market Surveillance Authority should conduct follow-up control and can inform about this in the letter to put extra pressure on the Economic Operator.

7.5 Recalls

Recall shall mean any measure aimed at achieving the return of an instrument that has already been made available to the end user. The Market Surveillance Authority should consider whether to grant a deadline for fulfilment of an order to recall a series of instruments, and the Market Surveillance Authority should conduct follow-up control and can inform about this in the letter to put extra pressure on the Economic Operator.

7.6 Dealing with non-compliances of single instruments

If a Market Surveillance Authority discovers that there is a non-compliance of a single instrument, the authority takes care that the instrument is brought into conformity with the directive and informs the other Market Surveillance Authorities.

8 Mutual information procedures

Information is one of the important keys to insure effective, efficient and equal market surveillance in the EU. Therefore the Member States are obliged to inform each other as well as the Commission and if necessary the Notifying Bodies.

8.1 Information procedures and information systems

When, who and how to inform the relevant authorities are described in Annex 6, Follow the Chain. In general, it can be noted that information shall be delivered to the authorities as soon as possible to reach the targets of market surveillance. Therefore the European Commission (EC) introduced an Information and Communication System for (pan-European) Market Surveillance - so called ICSMS. ICSMS is an internet based information- and communication system to support market surveillance of (all) technical products.
All information in terms of market surveillance should be run through this system. Although the use of ICSMS is not binding, the system has a huge potential in information exchange because of its structuring capacity on the side of the authority entering the information and the personalised subscriptions and the possibility to react on the side of the receiver. Once an official user of ICSMS, it is well possible to receive notifications on all new or modified cases dealing with MID and NAWI. Alternatively, Member States can use any other way to fulfil the obligation of information exchange, e.g. by distributing the information via email to the competent authorities that have been designated for such exchange of information (article 17 of Regulation 765/2008/EC). Working Group 5 strongly recommends the use of ICSMS.
If products are posing a serious risk to the health and safety of consumers or users a rapid exchange of information is necessary. The RAPEX - rapid alert system for non-food dangerous products of the EC - facilitates the rapid exchange of information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to health and safety. As this will not often be the case with measuring instruments, RAPEX will only be briefly discussed in this guide.

8.2 ICSMS

ICSMS is the EU information system that enables a comprehensive exchange of information between all Market Surveillance Authorities. ICSMS consists of a closed and a public area. The closed area is for the use of Competent Authorities, Market Surveillance Authorities, Customs Authorities and the Commission – i. e. official agencies. It contains product information, test results, official measures taken, and so on. The public area is for the use of consumers and manufacturers. It contains, for example, official information about dangerous products, as well as voluntary industry recalls and postings made by manufacturers drawing attention to pirated copies.
ICSMS enables all users to carry out a specific search. A search can be made, for example, according to individual products, and according to test results for entire product groups. Test results can be obtained for products from specific countries; information can be obtained for products coming under certain directives, safeguard clause notifications, RAPEX notifications, as well as information about manufacturers, importers and dealers. Confidentiality aspects are protected by a complex system of access authorisations and the system and the data contained in it are protected against un-authorised access.

The product information in ICSMS contains the following details:

- general information such as the notifying Member State and the Notifying Body;
- product details such as Customs tariff number, EAN code, type number, serial number, place of manufacture, country of origin;
- party responsible for bringing the product into circulation;

- directives and relevant standards;
- proof of conformity;
- depth and scope of testing;
- test results;
- formal non-compliances and non-compliances to essential requirements;
- classification of non-compliances;
- nature and assessment of the risk;
- accidents;
- measures taken;
- additional documentation, such as test reports, photographs, declarations of conformity, or extracts from operating instructions.

For the assessment of the risk it is advised to follow the general rules established by the Commission and employ commonly used risk assessment tools when they are available.
As well as this information section, ICSMS has a communication section. Here, comments or supplementary remarks can be entered about the products and the test results.
Whenever a Market Surveillance Authority wants to exchange information about a product under investigation with other authorities in order to share resources (e.g. for product checks), carry out common actions or consult other authorities, it can input into ICSMS the relevant information[3]. This should preferably be done as early as possible and certainly well before the decision to adopt measures for products found to present a risk. E.g. if a Market Surveillance Authority cannot determine the level of the risk presented by a relevant product and carries out investigations, it is preferred practice to use ICSMS to communicate with the authorities of the other Member States.
Data for the public area can be generated automatically from the closed area. A forum is planned, enabling consumers to inform the surveillance bodies directly of their complaints and opinions.

8.3 RAPEX

In the RAPEX system the authority can do three different types of notifications:

- notification under article 12 of Directive 2001/95/EC or Article 22 of Regulation 765/2008/EC: notifications of measures or actions taken in relation to instruments presenting a serious risk.
- notifications under article 11 of Directive 2001/95/EC: notifications of measures or actions taken in relation to instruments presenting a moderate risk.
- notifications 'for information only': notifications of measures or actions taken in relation to instruments, disseminated 'for information only' because they do not fall under article 12 or article 11 of Directive 2001/95/EC.

A RAPEX notification contains information about the instrument (such as stakeholder consultation letter and response form), its risks and trade chain and should be sent as early as possible.
A RAPEX notification has to be sent to the commission if an instrument poses a serious risk and the instrument is also sold outside the Member State that finds the instrument. A notification has to be sent also if the instrument is only sold in the Member State, but it is considered that it may be of interest to other Member States for example because of a new type of risk. The decision as to what constitutes a serious risk shall be based on an appropriate risk assessment and any actions must be proportionate to that risk.

8.4 Union Safeguard Clause Procedure

It is considered appropriate for individual Member States to question the conformity of instruments at any time. The application of the safeguard clause[4], however, requires that the Market

[3] Blue Guide, paragraph 7.5.3.1, page 96
[4] Blue Guide, paragraph 7.4.2.1, page 91

Surveillance Authority decides to restrict or forbid the placing on the market and, possibly, the putting into service of the product, or has it withdrawn from the market. The contents of the decision should relate to all products belonging to the same batch or series. It must also have binding legal effect: it is followed by sanctions, if not respected, and can be subject to an appeals procedure. Further, the national measure must be based on evidence (for example tests or examinations) that constitutes sufficient proof of errors in the product design or the manufacture to indicate a foreseeable potential or actual danger or other substantial non-compliance.
The information presented to the Commission and other Member States (articles 42(4), 42(5) and 44(3) of MID; articles 37(4), 37(5) and 39(3) of NAWI) shall include all available details, in particular the data necessary for the identification of the non-compliant instrument, the origin of the instrument, the nature of the non-compliance alleged and the risk involved, the nature and the duration of the national measures taken, the arguments put forward by the relevant economic operator, and an indication if the non-compliance is due to the instrument not meeting the essential requirements or to shortcomings in the harmonised standards.
For serious risks, the notification to the Commission is done through RAPEX. Other notifications should be done through letter or e-mail as long as ICSMS is not fully equipped for this purpose. However, nearly all information can be entered into ICSMS and, subsequently this reference can be included in the communication to the Commission and other Member States. It is important that next to the Commission all contacts on the list of competent authorities according to article 17(1) of Regulation 765/2008/EC are informed. It is advised to channel this information through your countries permanent representation in Brussels and to use a formal letter to address the Commission.
Member States other than the Member State initiating the safeguard procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance or the instrument concerned, and, in the event of disagreement with the adopted national measure, of their objections.
Where, within three months of receipt of the information (articles 42(7) of MID and 37(7) of NAWI), no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by the filing Member State, the measure shall be deemed justified, even if the manufacturer disagrees with the decision.
In the case of objections, the Commission shall enter into consultation with the filing Member State, the objecting Member State(s) and the relevant Economic Operator(s) and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide by means of an implementing act whether the national measure is justified or not. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant Economic Operator(s) (articles 43(1) of MID and 38(1) of NAWI).
The national measure is considered justified, either after the three months period or (earlier) after the investigation by the Commission. All Member States shall take the measures necessary to ensure that the non-compliant instrument is withdrawn from their market, and shall inform the Commission accordingly (articles 43(2) of MID and 38(2) of NAWI). If the national measure is considered unjustified, the Member State concerned shall withdraw the measure (articles 43(2) of MID and 38(2) of NAWI).

It should be noted when there is no disagreement on the restrictive measure taken by one Member State within three months after the notification, all Member States must take appropriate actions in their territories and inform the Commission accordingly.

8.5 Voluntary exchange of information

A number of voluntary channels exist besides the mandatory means and ICSMS: the Expert Group on internal market for products (EGIMP), with a subgroup for market surveillance and a subgroup for ICSMS, WELMEC Working group 5 on market surveillance and the communication of finalised market surveillance actions and studies.
WELMEC Working group 5 deals with establishing confidence of all stakeholders in legal metrological provisions, by supporting the cooperation between WELMEC members and promoting

equivalent, effective and sufficient levels of metrological supervision across the EU. Furthermore WELMEC Working group 5 promotes and organises the exchange of information and guidance on metrological supervision matters, including market surveillance and field inspection, between WELMEC members. Finally WELMEC Working group 5 provides the means for dialogue with representatives of consumers, trade, industry and the Commission. WELMEC Working group 5 also functions as an administrative cooperation group (ADCO) under the Commission's Measuring Instruments Working Group. The effectivity of WELMEC Working group 5 is very much dependent on the input from Member States. So, input from all the participants is highly appreciated.

The communication of finalised actions and studies is valuable because it may describe good or best practice that other Member States can learn from. The same holds for the communication of failures as they can sometimes be even more instructive. Furthermore, information about the results will prove valuable for other Member States in their analysis and planning of upcoming activities. It is also useful to exchange results of periodic inspections on instruments in use, to the extent that they provide information on the compliance of these instruments when they were placed on the market.

9 Import from third countries/dealing with the Customs

A well-working cooperation between Market Surveillance Authorities and Customs ensures that measuring instruments imported from third countries can be checked at the border before they enter the internal market.
The customs authorities focus on risky products by applying risk profiles. A risk profile is a set of parameters that allow identifying products for further inspection. It is considered best practice for Market Surveillance Authorities to cooperate with the customs authorities in setting up the risk profiles. In any case it is recommended that the Customs are informed about the results of the risk assessment carried out by the Market Surveillance Authority. The cooperation may also include exchanges such as information about instrument categories that are known often to present non-conformities, high risk Economic Operators or manufacturers, information about already identified serious risks or non-compliances or basic knowledge on how to identify non-conforming instruments.
In case of measuring instruments only formal checks can be expected to be carried out by the customs authorities. For further checks, if necessary, the Market Surveillance Authority shall be involved while suspending the release of the instruments. The Market Surveillance Authority must notify the Customs within three working days (article 28 of Regulation 765/2008/EC) if the instruments can be released. In view of this very tight time-limit it must be ensured that the notification and where appropriate samples or pictures of the instrument, immediately reach the Market Surveillance Authority.
The entire procedure from the suspension until the release for free circulation or the prohibition of the goods by the Customs should be completed without delay to avoid creating barriers to trade but does not have to be necessarily completed within three working days. The suspension of release can remain valid for the time required by the Market Surveillance Authority to carry out appropriate checks on the instruments allowing them to take the final decision. In this case, the Market Surveillance Authority notifies Customs within these three days that their final decision on the goods is pending. The release for free circulation shall remain suspended until the Market Surveillance Authority has made a final decision.
If the Market Surveillance Authority ascertains that the instruments present a serious risk or are non-compliant, the instruments shall be prohibited to be placed on the EU-market. Nevertheless, the Market Surveillance Authority may also decide to destroy them or otherwise render them inoperable, where they deem it necessary.
In all other cases than release for free circulation the importer must be informed and consulted. In case the instrument has shortcomings that are not suspected to present a serious risk, the Market Surveillance Authority can contact the importer and inform him that the instrument will be released but it can be placed on the market only after having being brought into compliance with the directives.

Annex 1: applicable Directives and Regulations

Directive 2014/31/EU relating to non-automatic weighing instruments; the NAWI Directive. This directive covers all non-automatic weighing instruments.

Directive 2014/32/EU relating to measuring instruments; the MID. The MID covers water meters, gas meters and volume conversion devices, active electrical energy meters, thermal energy meters, measuring systems for continuous and dynamic measurement of quantities of liquids other than water, automatic weighing instruments, taximeters, material measures, dimensional measuring instruments, and exhaust gas analysers.

Directive 2001/95/EC on general product safety (GPSD)

Regulation 765/2008/EC setting out the requirements for the accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No.339/93. This regulation outlines the processes and procedures that Market Surveillance Authorities follow when undertaking market surveillance.

Decision 768/2008/EC on a common framework for the marketing of products and repealing Council Decision 93/465/EEC.
This decision lays down common principles and reference provisions intended to apply across sector-specific legislation. It is used in the recast of MID and NAWI in order to harmonise the conditions for the marketing of products.

Regulation 764/2008/EC, laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State. This is the mutual acceptance guideline.

Directive 85/374/EEC liability for defective products.

Directive 2005/29/EC unfair business-to-consumer commercial practices in the internal market.

Annex 2: definitions

Administrative cooperation group (ADCO; according to EU Glossary) is the informal group of the national administrations in charge of the market surveillance for a new approach directive. The ADCO group supports and complements the work of the formal committee or the working party of the directive. The ADCO group provides administrative cooperation and consistent application of surveillance. At European level, joint market surveillance campaigns are carried out and information is exchanged on irregularities found.

Making available on the market shall mean any supply of an instrument for distribution or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge. (article 2(3) of Directive 2014/31/EU and article 4(5) of Directive 2014/32/EU)

Market surveillance shall mean the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection. (article 2(17) of Regulation 765/2008/EC)

Market surveillance, specifically for this guide, shall mean the activities carried out and measures taken by *Market Surveillance Authorities* to ensure that instruments comply with the requirements set out in the relevant Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.

Placing on the market shall mean the first making available of an instrument on the Community market. (article 2(4) of Directive 2014/31/EU and article 4(6) of Directive 2014/32/EU)

Putting into use means the first use of an instrument intended for the end user for the purposes for which it was intended. (article 4(7) of Directive 2014/32/EU)

Recall shall mean any measure aimed at achieving the return of an instrument that has already been made available to the end user. (article 2(16) of Directive 2014/31/EU and article 4(19) of Directive 2014/32/EU)

Release for free circulation shall mean the procedure laid down in article 79 of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code. (article 2(19) of Regulation 765/2008/EC)

Safe guard procedure is the procedure to guarantee that all measures taken by the Market Surveillance Authority are not against European law and are appropriate. The former safeguard clause procedure has been revised. The new one introduces a phase of information exchange between Member States, and specifies the steps to be taken by the authorities concerned, when a non-compliant product is found. A traditional safeguard clause procedure – leading to a Decision at Commission level on whether a measure is justified or not - is only launched when another Member State objects to a measure taken against a product. Where there is no disagreement on the restrictive measure taken, all Member States must take the appropriate action on their territory.

Withdrawal shall mean any measure aimed at preventing an instrument in the supply chain from being made available on the market. (article 2(17) of Directive 2014/31/EU and article 4(20) of Directive 2014/32/EU)

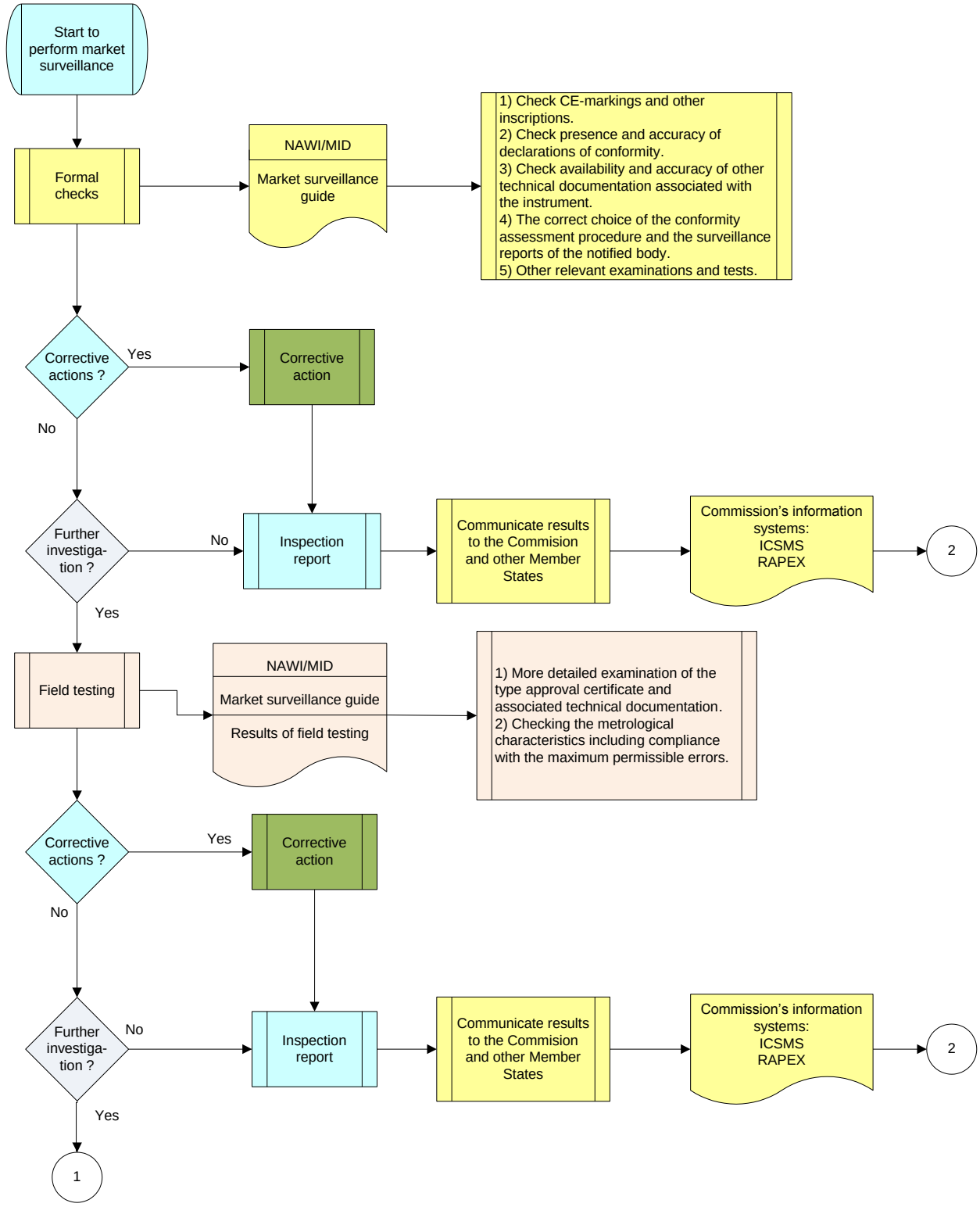
Annex 3: references

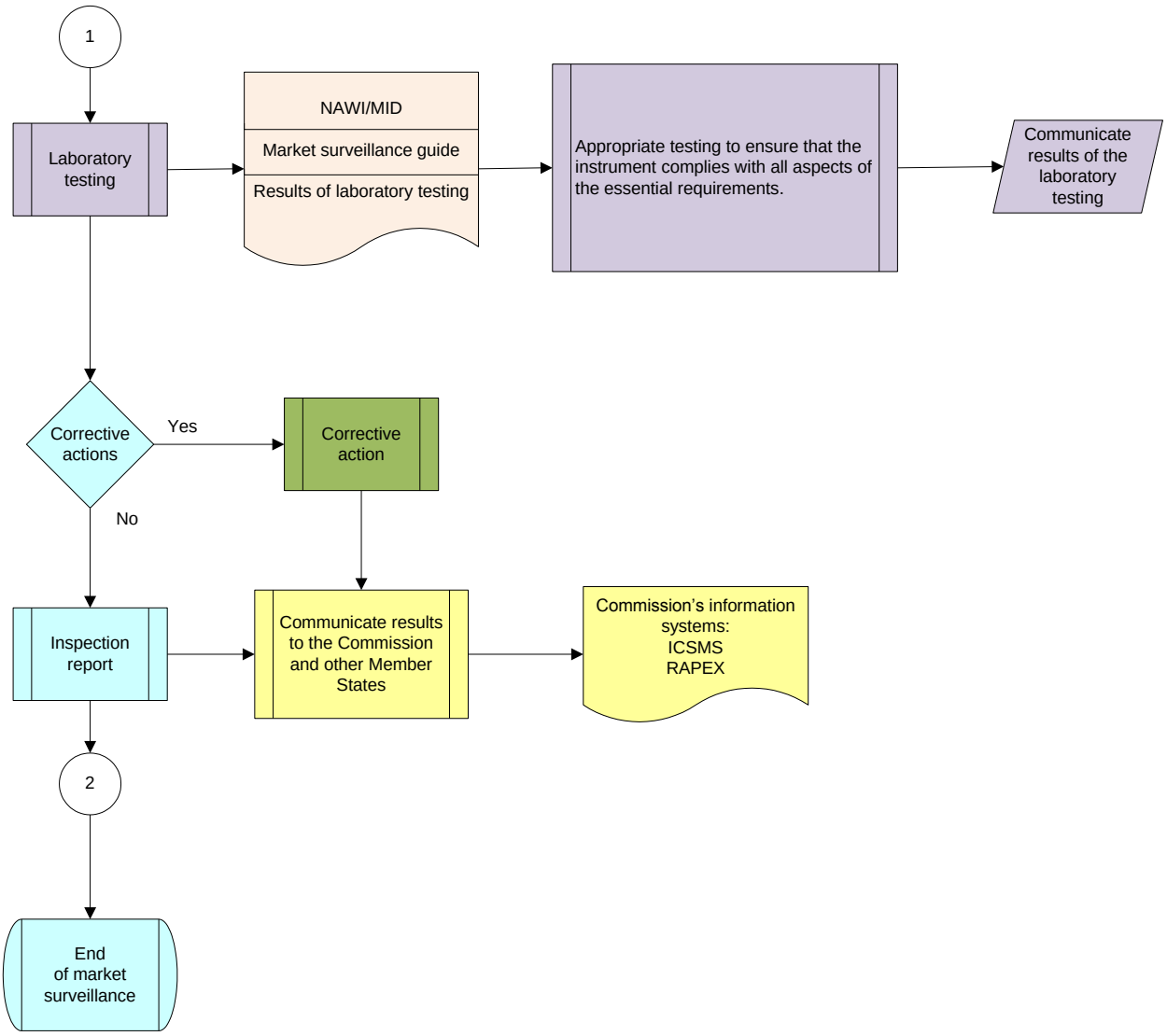
Best Practice Techniques in Market Surveillance; End report of the MARS project of the Product Safety Enforcement Forum of Europe (PROSAFE).

Guide on the implementation of EU product rules (the Blue Guide, 2014).

WELMEC Guide 5.3; Risk Assessment Guide for Market Surveillance: Weigh and Measuring Instruments; issue 1, May 2011

Annex 4: market surveillance of individual instruments

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Laboratory testing
NAWI/MID
Market surveillance guide
Results of laboratory testing
Appropriate testing to ensure that the instrument complies with all aspects of the essential requirements.
Communicate results of the laboratory testing
Corrective actions
Yes
Corrective action
No
Inspection report
Communicate results to the Commission and other Member States
Commission's information systems:
ICSMS
RAPEX
2
End of market surveillance

Annex 5: conformity assessment procedures MID/NAWI

Overview of the conformity assessment modules for the MID (Directive 2014/32/EU; as from 20 April 2016)

Module	Description	Technical documentation	Written declaration of conformity
A	Internal production control	X	X
A2	Internal production control plus supervised instrument checks at random intervals	X	X
B	EU Type examination	X	
C	Conformity to type based on internal production control[5]		X
C2	Conformity to type based on internal production control plus supervised checks at random intervals[5]		X
D	Conformity to type based on quality assurance of the production process[5]		X
D1	Quality assurance of the production process	X	X
E	Conformity to type based on instrument quality assurance[5]		X
E1	Quality assurance of final instrument inspection and testing	X	X
F	Conformity to type based on product verification[5]		X
F1	Conformity based on product verification	X	X
G	Conformity based on unit verification	X	X
H	Conformity based on full quality assurance	X	X
H1	Conformity based on full quality assurance plus design examination	X	X
B+D, B+E, B+F		X	X

[5] Due to the combination with Module B access to the technical documentation is required.

Overview of the Conformity Assessment Modules relating to Non-Automatic Weighing Instruments (Directive 2014/31/EU; as from 20 April 2016)

Mo-dule	Description	Technical docu-mentation	Written declaration of conformity
B	EU Type examination	X	
D	Conformity to type based on quality assurance of the production process[6]		X
D1	Quality assurance of the production process	X	X
F	Conformity to type based on product verification[6]		X
F1	Conformity based on product verification	X	X
G	Conformity based on unit verification	X	X
B+D, B+F		X	X

[6] Due to the combination with Module B access to the technical documentation is required.

Overview of type of instruments under the MID and NAWI related to the possible conformity assessment modules (as from 20 April 2016)

	A2	D1	E1	F1	B+D	B+E	B+F	G	H	H1
Water meters					√		√			√
Gas meters and volume conversion devices					√		√			√
Active electrical energy meters					√		√			√
Thermal energy meters					√		√			√
Measuring systems for the continuous and dynamic measurement of quantities of liquids other than water					√		√	√		√
Automatic weighing instruments:										
• Mechanical systems		√		√	√	√	√	√		√
• Electromechanical systems					√	√	√	√		√
• Electronic systems / systems containing software					√		√	√		√
Taximeters					√		√			√
Material Measures										
• Length		√		√	√			√	√	
• Capacity	√	√	√	√	√	√			√	
Dimensional measuring instruments										
• Mechanical or electromechanical		√	√	√	√	√	√	√	√	√
• Electronic instruments / instruments containing software					√		√	√		√
Exhaust Gas Analysers					√		√			√
Non-automatic weighing instruments (NAWI)										
• Instruments without electronic devices of which the load measuring device does not use a spring to balance the load		√		√	√		√	√		

• All other non-automatic weighing instruments					√		√	√		
	A2	D1	E1	F1	B + D	B + E	B + F	G	H	H1

Modules A, C & C2 never required
For NAWI, concerning modules F and F1, no statistical procedure is possible

The heritage of the Directives 2004/22/EC and 2009/23/EC

Certificates issued under the Directives 2004/22/EC and 2009/23/EC are valid under the Directives 2014/32/EU (article 50(1)) and 2014/31/EU (article 43), respectively.

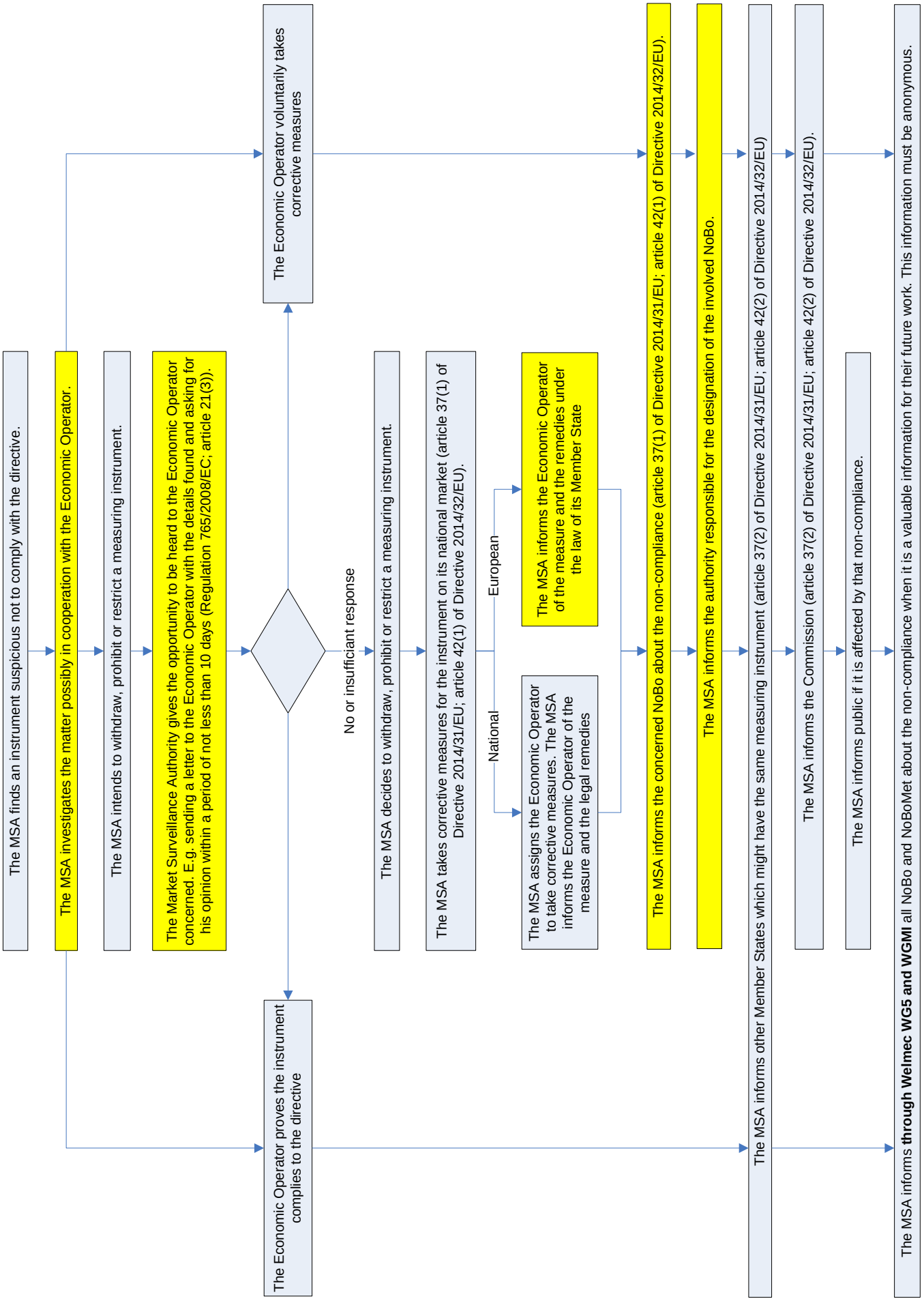
For the differences between the old and new directives the reader can refer to the correlation tables in Annex VI of Directive 2014/31/EU and Annex XV of Directive 2014/32/EU.

The essential requirements have remained unchanged (Annex 1 and MI-00x annexes).

Annex 6: general market surveillance measures: follow the chain!

When measuring instruments are suspected not to be in compliance with the directives the Market Surveillance Authority generally follows a more or less standard procedure with slightly different scenarios depending on whether the Economic Operator and the Notified Body involved are located in its own country or abroad.
In this Annex a common procedure is given that describes the steps to perform in general market surveillance practice. The legal basis for that is given by articles 15 to 29 of Regulation 765/2008/EC and the Chapters 5 of the NAW and MI directives. Note that the yellow blocks are the steps that can be run in close cooperation the Market Surveillance Authorities of the relevant Member States when the Economic Operator or the Notified Body is situated abroad. According to article 24(2) of Regulation 765/2008/EC the Member States concerned shall give assistance on an adequate scale by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measure and by participating in investigations of the initiating Member State.
The general procedure holds when there is no serious risk. A rapid intervention has to be taken if a serious risk is present (article 20 of Regulation 765/2008/EC). A serious risk is achieved when health and life is endangered. A serious risk may also be given if other public interests are concerned. Public interest in the field of legal metrology in this sense will be significantly wrong readings of measuring instruments, fraudulent use with high probability, or specific issues related to other directives (e.g. low-voltage). A procedure in case of a serious risk will be included in the next issue of this guide.

Abbreviations:
WELMEC WG5: WELMEC working group 5; administrative cooperation group for the market surveillance of measuring instruments
WGMI: the Commission's working group for measuring instruments


The MSA finds an instrument suspicious not to comply with the directive.
The MSA investigates the matter possibly in cooperation with the Economic Operator.
The MSA intends to withdraw, prohibit or restrict a measuring instrument.
The Market Surveillance Authority gives the opportunity to be heard to the Economic Operator concerned. E.g. sending a letter to the Economic Operator with the details found and asking for his opinion within a period of not less than 10 days (Regulation 765/2008/EC; article 21(3)).
The Economic Operator voluntarily takes corrective measures
The Economic Operator proves the instrument complies to the directive
No or insufficiant response
The MSA decides to withdraw, prohibit or restrict a measuring instrument.
The MSA takes corrective measures for the instrument on its national market (article 37(1) of Directive 2014/31/EU; article 42(1) of Directive 2014/32/EU).
European
National
The MSA informs the Economic Operator of the measure and the remedies under the law of its Member State
The MSA assigns the Economic Operator to take corrective measures. The MSA informs the Economic Operator of the measure and the legal remedies
The MSA informs the concerned NoBo about the non-compliance (article 37(1) of Directive 2014/31/EU; article 42(1) of Directive 2014/32/EU).
The MSA informs the authority responsible for the designation of the involved NoBo.
The MSA informs other Member States which might have the same measuring instrument (article 37(2) of Directive 2014/31/EU; article 42(2) of Directive 2014/32/EU)
The MSA informs the Commission (article 37(2) of Directive 2014/31/EU; article 42(2) of Directive 2014/32/EU).
The MSA informs public if it is affected by that non-compliance.
The MSA informs **through Welmec WG5 and WGMI** all NoBo and NoBoMet about the non-compliance when it is a valuable information for their future work. This information must be anonymous.