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Principles of assurance of metrological control

Principes d'assurance du contrôle métrologique

OIML D 16 Edition 20xx (E)

ORGANISATION INTERNATIONALE DE METROLOGIE LEGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

Contents

Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States. The main categories of OIML publications are:

- **International Recommendations (OIML R),** which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity. OIML Member States shall implement these Recommendations to the greatest possible extent;

- **International Documents (OIML D),** which are informative in nature and which are intended to harmonize and improve work in the field of legal metrology;

- **International Guides (OIML G),** which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology; and

- **International Basic Publications (OIML B),** which define the operating rules of the various OIML structures and systems.

OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which comprise representatives from the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements have been established between the OIML and certain institutions, such as ISO and the IEC, with the objective of avoiding contradictory requirements. Consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

International Recommendations, Documents, Guides and Basic Publications are published in English (E) and translated into French (F) and are subject to periodic revision.

Additionally, the OIML publishes or participates in the publication of **Vocabularies (OIML V)** and periodically commissions legal metrology experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus, they do not necessarily represent the views of the OIML.

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OIML Publications may be downloaded from the OIML web site in the form of PDF files. Additional information on OIML Publications may be obtained from the Organization’s headquarters:

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0 Introduction

Since its inception, the OIML has worked to harmonize laws and regulations on metrology amongst its Members. Efforts have been focused on defining the requirements for particular measurements or instruments. Such efforts make up, and will continue to make up, the main task of the OIML. A related task is to provide OIML Members with guidance on the ways to assure metrological control and on methods to verify that such control is effective.

Several approaches are presented and discussed in this International Document because there is more than one way to achieve effective metrological control. The structure of legal metrological control in any country must take into account the economic system of that country, the principles of its legal system, its territorial organization, and also its other features and specific conditions and other formal or informal mechanisms (such as the activities of consumer organizations). It is recognized that conditions and requirements differ from country to country and that the ideal control strategy for one country or region may not necessarily be ideal for another. Accordingly, this Document provides guidance and information that may be adapted to fit the circumstances of any particular jurisdiction.

Legal metrological control, according to its definition, includes three main elements:

- legal control of measuring instruments and of prepackages;
- metrological supervision;
- metrological expertise.

Any effective system of assurance of metrological control is based on a combination of all three elements, as appropriate to the local jurisdiction; the third element completes the system by enabling it to resolve disputes. Therefore, any suggestion that goods could be controlled, but equipment not, is not acceptable and would result in a gap in a suitable system of metrological control. As technology has changed, the system has been adapted so that the existing infrastructures of metrological control and their expertise can be used with advantage for those forms of control specified by other legislation. This applies to, for example, pre-packages subject to metrological legislation which in many countries has become the most common method for selling goods by weight or measure. Moreover, this applies also to various gaming machines as far as these machines are subject to metrological legislation in the countries. The legal control of prepackages based on the average approach is dealt with in OIML Recommendation R 87 *Quantity of product in prepackages* [5].

In some jurisdictions an extension of metrological expertise is used to put under regulation the whole measurement process when measurements are made to demonstrate compliance with statutory requirements (such as the measurement of the level of noise in public places, measurement of pollution, etc.).

This Document reflects the ongoing efforts to eliminate technical barriers to trade and to ensure equity in the marketplace, while ensuring that protection of public interest is not compromised. OIML Members are recommended to refer to OIML D 1 *Elements for a law on metrology* [3] when drawing up their metrological legislation concerning legal metrological control.

In the present time of fast technological and socio-economic changes (globalization) it is a considerable challenge to set down an effective system of legal metrological control satisfying everyone's needs. The matter is prone to intensive lobbying, especially on the part of the economic operators involved - on the other hand, consumers are never directly involved in this process. However, it is desirable to have discussion among different stakeholders including the consumer protection organizations. Furthermore, non governmental organizations involved in consumer protection are wary of involvement in these matters, which they regard as too technical[1]. In addition, cost considerations are tending to gain priority over quality matters.

Despite this rather hostile environment, the fundamental goal of legal metrology - to provide effective protection of public interests associated with measurements - should be strictly followed by responsible government departments in their day to day operations. The aim of this Document is to provide enough background information for them to draw upon in order to arrive at appropriate decisions when various possible arrangements in legal metrological control are under consideration.

1 Scope

The purpose of this OIML International Document is to provide elements and options to be considered for developing a model of legal metrological control in Member States which can be used as a basis for the harmonization of legal metrological control at an international level.

2 Terminology

See also the *International Vocabulary of Legal Metrology* (VIML) [2].

2.1

legal metrology

part of metrology related to activities which result from statutory requirements and concern measurement, units of measurement, measuring instruments and methods of measurement and which are performed by competent bodies

[VIML 1.2]

Note 1: The scope of legal metrology may be different from country to country.

Note 2: The competent bodies responsible for legal metrology activities or part of these activities are usually called legal metrology services.

[1] Consumer protection organizations mainly become active on an ad-hoc basis, if there are (real or supposed) problems, they hardly act in a preventive way. It is therefore a task for the Government to ensure a well-considered balance and to stand up for the vulnerable party.

2.2

legal metrological control

the whole of legal metrology activities which contribute to metrological assurance

[VIML 2.1]

Note: Legal metrological control includes:

- legal control of measuring instruments;
- metrological supervision;
- metrological expertise.

2.3

legal control of measuring instruments

generic term used to globally designate legal operations to which measuring instruments may be subjected, e.g. type approval, verification, etc.

[VIML 2.2]

2.4

prepackage

combination of a product and the packing material in which it is prepacked (see OIML R 87)

2.5

metrological supervision

control exercised in respect of the manufacture, import, installation, use, maintenance and repair of measuring instruments, performed in order to check that they are used correctly as regards the observance of metrology laws and regulations

[VIML 2.3]

Note: Metrological supervision includes checking the correctness of the quantities indicated on and contained in prepackages.

2.6

metrological expertise

all the operations for the purpose of examining and demonstrating, e.g. to testify in a court of law, the condition of a measuring instrument and to determine its metrological properties, amongst others by reference to the relevant statutory requirements

[VIML 2.4]

2.7

legally controlled measuring instrument

measuring instrument which conforms to prescribed requirements, in particular legal metrological requirements

[VIML 4.3]

Note 1: For the purposes of this Document the following instruments may fall under control according to national regulations: measuring instruments, coin counting machines, medical measuring instruments, water dispensing machines, timing instruments in vehicle washers.

Note 2: Legally controlled measuring instrument is hereafter referred to as a “measuring instrument”.

2.8

conformity assessment of a measuring instrument

testing and evaluation of measuring instruments to ascertain whether or not a single instrument, an instrument lot or a production series of instruments comply with all statutory requirements applicable to this instrument type

[VIML 2.11]

Note 1: Conformity assessment does not only concern metrological requirements but may also cover requirements relating to:

- safety;
- EMC;
- software identification;
- ease of use;
- marking, etc.

Note 2: Conformity assessment of a measuring instrument is hereafter referred to as “conformity assessment”.

2.9

type approval

decision of legal relevance, based on the evaluation report, that the type of measuring instrument complies with the respective statutory requirements and is suitable for use in the regulated area in such a way that it is expected to provide reliable measurement results over a defined period of time

[VIML 2.6]

2.10

verification of a measuring instrument

procedure (other than type approval) which includes the examination and marking and/or issuing of a verification certificate, that ascertains and confirms that the measuring instrument complies with the statutory requirements

[VIML 2.13]

2.11

initial verification

verification of a measuring instrument which has not been verified previously

[VIML 2.15]

2.12

subsequent verification

any verification of a measuring instrument after a previous verification and including mandatory periodic verification and verification after repair

[VIML 2.16]

Note: Subsequent verification of a measuring instrument may be carried out before expiry of the period of validity of a previous verification either at the request of the user (owner) or when its verification is declared to be no longer valid.

2.13

verification by sampling

verification of a homogenous batch of measuring instruments based on the results of examination of a statistically appropriate number of specimens selected at random from an identified lot

[VIML 2.14]

2.14

free trade area

area where two or more countries have harmonized legislation in place, on a national basis, to facilitate free cross-border movement of products and services that affect legal metrological control

Note: Such harmonized legislation may rely on conformity assessment procedures where, apart from public authorities, first party bodies (manufacturers) and other private bodies as third parties, carry out certain functions.

2.15

authority

central or local governmental body, or non-governmental body empowered by government to perform public tasks

2.16

manufacturer

any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark

2.17

manufacturer’s representative

any natural or legal person designated by the manufacturer to act on his behalf for specified tasks

2.18

consumer

each natural or legal person who acquires or buys products to use them (in some countries this applies only to individuals)

2.19

end user (of a measuring instrument)

legal person who acquires a measuring instrument with the intention to use it and not to sell it

2.20

placing on the market

making a measuring instrument or a prepackage available on the market for the first time in the specific country (or region). Making available can be either against payment or free of charge

2.21

putting into service (use)

first use of an instrument, intended for the end user, for the purposes for which it was intended, the use being defined by the manufacturer

2.22

quality surveillance

form of metrological supervision aimed at establishing that the quality systems of manufacturers, manufacturers' representatives (in relation to conformity assessment procedures) or authorized private bodies, as applicable, comply with the regulatory or statutory requirements of a country or free trade area

2.23

market surveillance

form of metrological supervision aimed at measuring instruments and prepackages intended to be placed on the market and/or put into service for the first time, to ensure that all the elements of the conformity assessment system function correctly, resulting in general compliance of the products with the provisions of the applicable regulations across a country or free trade area

Note: In the above definition the words "to be placed on the market and/or put into service" should be applied to describe different situations as follows:

- "to be placed on the market": should be used in the case when all the relevant conformity assessment procedures are to be finalized before measuring instruments or prepackages are put into service;
- "to be placed on the market and put into service": one or more conformity assessment procedures may be or have to be carried out when measuring instruments are put into service;
- "put into service": to describe the situation when a manufacturer manufactures a measuring instrument to be used (it is not necessary to place it on the market).

2.24

being in service (use)

operational life cycle of a measuring instrument after its putting into service, i.e. a measuring instrument in use, after repair, relocated, or rebuilt that may be resold

2.25

in-service surveillance (alternatively **"field surveillance")**

form of metrological supervision aimed at establishing that a measuring instrument in use in the field complies with the statutory requirements

Note 1: "Field surveillance" should not only cover the instrument itself but also the user, to evaluate the proper use of the instrument.

Note 2: on the relation between market surveillance and field surveillance:

Both types of surveillance can in principle overlap but where a conformity assessment of a measuring instrument indicates that the findings can be directly related to the responsibilities of manufacturers or their representatives, the matter should be dealt with by market surveillance.

2.26

principle of shared risk

signifies that the total uncertainty of a given measurement process, if sufficiently low as specified in the corresponding regulation, e.g. in an OIML Recommendation, is not taken into account when the decision on compliance with MPEs is made

3 Principles of assurance of metrological control

Certain principles are fundamental to achieving assurance of metrological control.

The first principle is that the assurance of metrological control depends on what one tries to achieve. If one tries to achieve the elimination of fraud, another system is needed than if one tries to ensure correct measurements.

The second principle is to consider the total measurement process before developing or changing a metrological control system. Analysis of the total process which includes the instrument, operator, environment, procedure and special characteristics of the item being measured allows attention and resources to be focused on those elements that most require control. It also allows methods to be selected that offer the greatest benefit for the control effort invested.

A third principle is to apply a feedback control to the process of making controlled measurements. The process outputs (the “product”) are the measurements actually made and the quality of that “product” should be evaluated and monitored with the aim of identifying and subsequently implementing opportunities for improvements. While using controlling elements under the first principle may provide the technical “capability to perform”, it does not ensure that this capability is properly used or maintained to yield accurate measurements. This “open-loop system” approach (i.e. without any feedback) is employed in most traditional metrology control systems.

A fourth principle is to provide flexibility. Flexibility in legal requirements allows officials to be selective in the application of controls. It allows consideration of enforcement history in designing and scheduling testing programs for both instruments and prepackaged goods. Flexibility also allows legal authorities to distribute the burden of compliance to both users and manufacturers (by allocating them various roles and obligations in the whole process).

A fifth principle is that the system has to be kept in line, with a necessary inertia providing stability, with current technological progress and with prevailing trends in an overall economic background, both locally and globally. As technology changes, the system should enable the identification and control of new kinds of fraud. It is also desirable for the system to be responsive to socio-economic developments, such as globalization and economic liberalization.

A sixth principle is that of proportionality: actions taken to ensure confidence in the reliability of measurement should be costed, and the costs considered with respect to the benefits. Ultimately, the consumer pays, either through product pricing, or through taxation, for metrological control.

4 General

4.1 For measuring instruments, countries normally adopt and publish a list of measuring instruments subjected to metrological control and/or a harmonized legislation is in place in a free trade area. The proper combination of elements of metrological control has to be considered (see 4.6). The scope of metrological control as defined in the VIML may be extended, if required, to cover prepackages, some aspects of measuring instruments in general and certain trade-related measurements.

4.2 Technical regulations for individual kinds of measuring instruments and of prepackages covering both their pre-market and post-market operational life, if applicable, have to be available to ensure that the principles of the total measurement process approach can be fulfilled in practice. Ideally, these regulations should also contain instructions, wherever applicable, for installation and use of those instruments. Arguably, a recommendable approach here might be that regulations of a strictly legal character contain only essential metrological and technical requirements and any technical details are given by normative standards (ideally internationally harmonized) as a presumption of conformity with those essential requirements. In this way the best possible stability of the technical regulation with a sufficient flexibility is achieved.

4.3 Harmonization of the technical regulations mentioned in 4.2 should be accomplished to the greatest extent possible - at least on a regional level, if not globally - to eliminate technical barriers to trade. An example of negative consequences of non-harmonization is given in Annex 1. In this respect the existence of up to date and technically sound OIML Recommendations is an ideal resource to be exploited to achieve that goal.

4.4 It should not be assumed that to assure metrological control, instruments can only be tested by a legal metrology agency or another government service. Testing must be accurate but, if laws and regulations permit, a qualified and authorized independent testing service can conduct the tests. Such a service organization should, however, be licensed or authorized by the legal metrology authority. It may also be possible to have type evaluation and/or initial verification tests performed by the manufacturer (or a representative of the manufacturer) under conditions specified in a regulation (e.g. if the legal metrology officials have access to all the data and can witness tests whenever they wish - see also [8] for the case of initial verification). Similarly, when instrument repair firms demonstrate their competence, they might be authorized to perform verifications following instrument repair. Where possible, these alternatives should be recognized in regulations, recommendations, and advisory documents.

4.5 In response to recent changes in the global economy, metrological legislation over measuring instruments often has to be split into two parts covering measuring instruments being put on the market (the market stage) and measuring instruments in use (the in-service stage). This enables legal metrology to be adapted to the requirements of free trade agreements and at the same time can provide scope for a direct and more extensive involvement of manufacturers not limited to carrying out the tests only in their metrological control as appropriate. To reflect these changes, this type of legal control over measuring instruments is therefore generally called *conformity assessment activities*.

4.6 Careful attention should be paid to the proper selection (combination) of control elements to individual measurements (measuring instruments). In some cases, measurement process performance is so highly dependent on instrument capability, and the failure modes of the instrument are so readily observable by the user, that type evaluation alone (perhaps coupled with occasional verification by sampling at the factory) is sufficient to achieve adequate control, although this cannot protect against fraud. A case in point is a liquid-in-glass thermometer that meets legal requirements when manufactured and that will generally remain accurate throughout its life unless the liquid column separates. In other cases, such as capacity serving measures, initial verification may serve the purpose by itself. On the other hand, there are complex measurement processes for which type approval with frequent subsequent verification of the instrument involved does not ensure adequate measurements for the application. This might be the case for a process with a very highly operator-dependent accuracy. In such a case, a special control procedure, such as operator certification [4], may have to be developed.

4.7 A large number of OIML Documents and Recommendations provide guidance on how to control the individual elements of a measurement process. Assurance of metrological control, however, involves more than the ensemble of the independent controls of these elements, no matter how well each may be controlled. Only by adopting a total systems approach can the elements of the process be put into proper perspective and the total process performance adequately assessed. The systems approach may allow one to prove that measurements retain sufficient accuracy on a continuing basis to meet requirements, even though certain control elements may have been relaxed or eliminated, e.g. through the optimization of reverification periods. Considerable resources can be saved by using only the minimum controls required to ensure adequate accuracy. However, to realize such savings one must be able to quantify the effectiveness of the control methods employed. Excessive controls can stifle innovation and can be unduly costly. Assurance of metrological control does not necessarily require rigorous or redundant controls. The simultaneous use of several metrological controls when a single carefully-designed control mechanism would suffice should therefore be avoided.

5 An adaptive system of metrological control

5.1 The systems approach to assurance of metrological control with feedback and adaptive response can rest on the following technical elements as given by corresponding regulations:

a) A set of maximum permissible errors (MPEs) is defined for each controlled measurement category of instruments. Each set includes MPEs for verification and MPEs for in-service surveillance (usually extended MPEs for verification).

b) The total uncertainties of the tests (measurements) made by verification officers are continually monitored and kept sufficiently small as required by regulations so that accept/reject decisions are reasonably little influenced by these uncertainties (but still a grey zone exists). The regulations must specify how to take these uncertainties into account when making decisions on compliance (the principle of shared risk is often applied here).

c) To the greatest extent possible, tests are carried out under actual or simulated conditions of use.

d) A reasonable amount of data is routinely gathered, so that causes of non-compliance can be identified by data analysis.

e) Institutional factors (social, legal, and economic) are arranged, if possible, so that rapid, appropriate action can be taken by legal metrology officials, manufacturers, instrument services, etc., to reallocate surveillance efforts by metrology officials or to correct conditions producing non-conformance.

5.2 The following comments can be made on the elements mentioned above:

a) The MPEs for in-service surveillance play a crucial role in the whole system as they provide for normal wear and tear of the metrological properties of measuring instruments in use during reverification periods, which can sometimes be quite long. Their ratio to MPEs for verification can be different for various categories of instruments and should be laid down individually in the technical regulations mentioned in 4.2. (as a rule of thumb, the factor of 2 is frequently used here but other factors such as 1 and 1.5 are also found).

b) To make the system more robust and transparent to laymen the uncertainties for verification are not taken into account during the assessment of conformity in legal metrology. Instead, limits are placed on uncertainties of measurement during verification in regulations - the so-called principle of shared risk. Otherwise, the limits of conformity would be variable, depending on specific conditions during individual tests and highlighting the existence of uncertainties - matters hardly acceptable in legal disputes. On the other hand, it is a requirement of the ISO/IEC 17025 standard for calibration and testing ([6], par. 5.10.4.2) that uncertainties be taken into account when statements of compliance are made. These are obviously contradictory requirements - it should be the aim of project p2 of OIML TC 3/SC 5 “Expression of uncertainty in measurement in legal metrology applications” to resolve it.

The total uncertainty of a measurement in use, in general, depends on the instrument, the environment, the procedures used, the standard equipment, the skill of the operator, data reduction (round-off procedures, algorithms used, etc.), and other elements. When the dependence on such influences is strong or the measurement is critical, special effort is needed to establish the validity of each measurement. On the other hand, when the measurement accuracy is relatively insensitive to elements other than the instrument itself, as is often the case in legal metrology, the use of a verified instrument may be sufficient to ensure correct measurements. Nevertheless, measurement uncertainty relates to the measurement process, not only to the instrument itself. Note that throughout this Document primary concern is with measurement errors rather than instrument errors (that is, intrinsic errors of measuring instruments). Wherever possible, a legal metrology control system should not merely aim to ensure that the controlled measuring instruments are adequate; it must strive to ensure that the end product, namely the measurements, are adequate so that the ultimate objectives of equity in the marketplace and protection of the health and safety of the general public are achieved.

c) Among others, for traditional weights and measures (W&M) instruments, which play a crucial role in the protection of consumers (weighing instruments, fuel dispensers, taximeters, material measures) when tests on instruments are made in-situ the above mentioned condition (i.e. that the measurement accuracy is relatively insensitive to elements other than the instrument itself) is fulfilled.

d) Data gathering in legal metrology in general can be obstructed by the activities of servicing organizations: the metrological properties of measuring instruments before any repair are not known if repairers are not obliged by regulations to make the corresponding tests and to report the results to authorities. These operations carry additional costs to be borne either by users or by the government. Users, at least, tend to be extremely reluctant to bear them, since they do not see why they should take on these additional costs of consumer protection. In some jurisdictions instruments are verified, nearly totally, only after repair or servicing (whether it is technically necessary or not is a different matter). Under these special circumstances, government funded projects aimed at such data gathering and analysis are expected to be launched where accuracy tests on measuring instruments coming in from the field are carried out before any servicing. As a by-product, even causes for non-compliance can be analyzed and identified during such exercises. An example of such a project and its implications is given in Annex 2.

To assure metrological control, in general one is expected to specify in such projects the following three performance objectives at and above which performance is to be considered adequate:

- maximum permissible errors (for in-service inspection);
- minimum compliance percentage (or target compliance), compliance percentage being the percentage of the controlled measurements made within MPEs;
- desired level of confidence.

In the course of control of measurements, one then:

- compares the error of each controlled measurement with the MPEs;
- analyses the data to obtain the compliance percentage at the desired level of confidence; and
- compares the compliance percentage obtained to the target compliance.

Special in-service MPEs may provide even for 100 % target compliance. Metrological control is assured as long as the compliance percentage equals or exceeds the target compliance on a continual basis.

Verification of the continued compliance of a measurement process with the legal requirements described above is necessary wherever measurement accuracy may decrease over time. Frequent, periodic verification is usually appropriate for new instruments whose reliability is unknown. It may be possible to discontinue periodic verification or at least to lengthen the intervals between verifications if, as experience is gained, data from the field indicate that the instrument does not degrade appreciably during its useful life. Also, experience may show that the verification intervals of instruments which appear to degrade with age should be shortened after several years of service. Verification intervals should not be arbitrarily established and then held fixed, but should be adjusted on the basis of actual experience. Wherever possible, legal metrology officials should keep data by type (model number) and by serial number for each instrument so that those with consistently good performance and those with consistently poor records of compliance can be identified. Where data show that a type is highly reliable, control and/or surveillance can be reduced and resources reallocated to areas where compliance is poor.

6 Framework systems of assurance of metrological control

The framework systems of metrological control (typical combinations of control elements) to be used in application to the various existing situations in the present-day legal metrology are as follows:

- Measuring instruments at the market stage;
- Measuring instruments in service;
- Metrological control of prepackages;
- Complementary activities of metrological control.

These will now be addressed in turn.

6.1 Measuring instruments at the market stage

6.1.1 Pre-market approach

Three basic types of arrangements can be distinguished here.

6.1.1.1 A highly restrictive legal metrology control system typically includes, by law and regulation, all of the following:

- type evaluation and type approval of measuring instruments;
- installation requirements;
- initial verification both at the factory and at point of use;
- environmental requirements.

All the operations are performed by legal metrology officials for a fee.

6.1.1.2 A balanced system can be based on:

- type evaluation and type approval carried out by competent bodies (accredited or peer reviewed - generally called conformity assessment bodies) with a maximum mutual recognition of either type approval certificates or corresponding test reports (e.g. OIML MAA, EU global approach);

- initial verification by the manufacturer (in the factory) based on an assessment of his quality management system by a competent body (an accredited certification body for quality management systems having expertise in the given field). In this specialized assessment concentrated on conformance of any individual measuring instrument to the approved type the existence of an over-arching certified quality management system (QMS, based on the ISO 9000 family of standards) is taken into account.

Type approvals are not required when they are impractical and they do not add much to the protection of the public interest (e.g. capacity serving measures). In those cases, only initial verification is carried out.

The QMS assessed in this way is subsequently subject to regular quality surveillance as one form of metrological supervision (see OIML D 9 - [9]). The activities of legal metrological control over measuring instruments in such a case should be completed by so-called market surveillance (see OIML D 9) performed by a government body, especially when the system is applied in a whole region such that conformity assessment bodies can compete with one another. As to initial verification, this system is applicable to a majority of measuring instruments with the exception of those which, for various reasons, have to be verified in-situ (e.g. instruments of which the measuring performance can be typically dependent on the location of use, for instance the height above sea level, e.g. non-automatic weighing instruments of class I, II, sometimes III and exhaust gas analyzers - OIML R 99 [10], weighbridges, some automatic weighing instruments, etc.). In this case an independent, competent, third-party body should be available to perform the initial verification (assessment of conformity with the approved type) if this is not done by the manufacturer himself (to be decided by the user). This system, based on the direct involvement of manufacturers, can be made more robust by making manufacturers liable by law for any damage to public interests caused by their products that can be legally traced back to them.

6.1.1.3 A highly liberal system can be developed from the balanced system by extending the assessed QMS to cover the design stage of those measuring instruments (the R&D operations of the manufacturer). The relevant competent body, having assessed this more complex QMS, would subsequently assess technical documentation of any new type (design) of the measuring instrument (resulting eventually in the issuance of a design certificate). In this system no third-party testing is required. It can be assumed that the majority of tests will be carried out by the actual manufacturer. Instead, there is third-party assessment of the technical documentation.

6.1.1.4 When all the intervention strategies according to 6.1.1.1 in the restrictive system are used, much of the burden incurred in meeting legal requirements is removed from the manufacturer, because legal metrology officials accept the responsibility for making both the effort and many of the decisions necessary in the control process. From the consumer protection point of view such a system is ideal but at the same time it is a significant burden for manufacturers from both a financial and logistical point of view. The choice of strategy also depends on how much of the responsibility for the total process the metrology officials can accept even if the responsibility of individual metrology officials in the field can never go beyond the moment of their observations - the manufacturer or owner/user as appropriate always remains primarily responsible. Where legal metrology resources are limited, which appears to be the case around the world, a strategy of limited intervention by authorities in the process of putting instruments on the market and into use may be employed. The practical implications of the fact that all the instruments in the pre-market stage are with the manufacturer have to be taken into account as well (the manufacturer is therefore well positioned to play a major role here). The balanced system is more manufacturer-friendly, and at the same time can retain an effective degree of protection of public interests. It also allows legal metrology authorities to focus on measurement processes in use. At the other extreme, the liberal system minimizes any third-party intervention in this regulated area to nearly zero which would hardly be acceptable even in the non-regulated area in general. The replacement of a third-party testing by a mere assessment of documentation is highly controversial. Such self-operation on the part of manufacturers can potentially lead to a non-level playing field for them and protection of public interests is extremely endangered here, especially when manufacturers (or their representatives) play a dominant role in in-service operations of metrological control in some jurisdictions, such as in the case of weighing instruments. On the other hand, the reasoning based on total measurement controls (analogue to that under point 4.6 that a type approval for liquid in glass thermometers is sufficient, and that in point 6.1.2) can provide arguments that for certain types of instruments the highly liberal system can be used.

6.1.2 Post-market approach

In the pre-market approach (6.1.1) the operation of type approval (or conformity to essential requirements) plays a crucial role. This is done on one or more samples of the type under investigation as supplied by the manufacturer. There is thus an incentive for manufacturers to submit instruments that have been extensively tested in their own labs (so-called “gold-plated” instruments). Obviously, if this practice became widespread, the instruments tested for type approval would bear little relation to those available for sale. In addition, manufacturers can exert considerable pressure on the responsible bodies to perform the tests in the shortest possible time period (especially where there is a competitive market for testing). The validity of initial verification done by manufacturers on their own sites can be compromised by long logistical routes (such as overseas transportation) or by exposure to external influence factors (e.g. electromagnetic interference, extreme ambient conditions).

Therefore, the effectiveness of such kinds of metrological control may be questioned. Evidence supporting these doubts was obtained in an exercise carried out in Australia (see Annex 3 and [13]). The solution might be to reduce the activities of metrological control at the market stage to their bare essentials (possibly only initial verification) and at the same time to strengthen market surveillance. Initial verification done by manufacturers at their sites (wherever possible - see 6.1.1.2) would be recognized until actions of market surveillance clearly demonstrate an unacceptable performance. In such a case, legislation could require initial verification to be done in-situ at the expense of the manufacturer. Such a system based on a minimum of pre-market controls and a recognition of initial verification done by manufacturers at their sites could present very effective, flexible and ideally impartial control over the everyday performance of the manufacturer of measuring instruments under scrutiny. It would also focus attention on the most important part of the process, that is, the use of instruments in the market. Its only disadvantage would be the additional costs to be borne by the government.

Such a strategy may also be based on the idea that the proper role of legal metrology is to assure accuracy in the user's measurement process by emphasizing supervision rather than provision of a direct service. Even if a strategy emphasizing supervision is applied only at the point of use, it places the responsibility for accuracy on the user and the manufacturer who presumably have sufficient incentives to maintain accurate measurements. The threat of legal sanctions by metrology officials reinforces this incentive. The point-of-use or end-point strategy offers a robust protection to the public, often the most vulnerable party in the measurement process.

6.2 Measuring instruments in service

As mentioned above, measuring instruments in service influence public interests most profoundly so that a good strategy in metrological control is to concentrate more on their operation after having been put in service (in use). Various combinations of activities of legal metrological control to tackle effectively the protection of public interest associated with measurements in use (in service) are imaginable but the intervention strategies can be best exemplified on three basic real-life models. They will now be discussed in turn.

6.2.1 Subsequent verification of legally controlled measuring instruments charged to their users complemented by actions of in-service surveillance as a form of metrological supervision (the German model) - see OIML D 9.

All the activities are normally carried out by a single government body (authority) in any given constituency. The fee to be charged for verification was originally an administrative fee, in the sense that it was treated as part of government revenue. Nowadays it is frequently a contractual payment (including a profit margin), as it is an income of the body charging it. The characteristic feature of this arrangement is that users cannot be held solely responsible for non-compliances with the regulations after being subject to a mandatory operation in fixed intervals for which they have to pay. Together with type approval and initial verification, the whole system by itself should guarantee the continual compliance of those measuring instruments with the regulations[2]. This is a system which happens to have been applied predominantly in European countries; its origin could be traced back to German speaking countries and countries in their circle of influence. This system of legal metrology has been designed to impose a minimal burden on taxpayers. That is an obvious advantage, but may be a two-edged sword, since the existence of fees attracts the interest of the private sector. Otherwise, with a relatively high degree of impartiality (since tests are performed by a third party body but charged to those being controlled) this arrangement is the best one if the government legal metrology services involved are flexible enough in their operation to be able to manage the necessary coordination with servicing organizations when verification is performed in-situ.

In a relatively high number of OECD countries verification has been passed over to licensed (authorized) or accredited bodies either fully (France, Sweden) or only for measuring instruments outside W&M (Germany, Switzerland, Austria until 2004, Czech Republic, Slovakia). The area of classical W&M (weighing instruments, fuel dispensers, taximeters, material measures) can be distinguished here: these instruments are characterized by their subsequent verification being performed on site and by their use for direct charging of payments (for a delivery of quantity of goods) to consumers (citizens). Furthermore, any action of metrological supervision in the area of W&M is rendered ineffective when private bodies verify the instruments, because it is often difficult to establish who (the user or the verification body) is to blame in case of any non-conformity, especially since such actions could take place a relatively long time after the last verification. As mentioned above, if users are subject to verification fees then they cannot be held solely responsible for any violations. Therefore, as a minimum, for subsequent verification in the area of W&M principles of impartiality and freedom from commercial interests should be strictly applied.

This model, while being the most effective for taxpayers, would provide by itself minimum data to be used as feedback to adjust the controlling elements – the pressure exerted by users to keep the fees as low as possible does not usually enable a systematic gathering of data (see 5.1 d) in the process of verification itself. Therefore, the model should be completed by regular actions of data gathering organized by legal metrology authorities.

6.2.2 Subsequent verification of legally controlled measuring instruments not charged to their users (the American model)

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2 The whole system was originally designed with the aim of really providing this guarantee but in the course of development the amount of testing had to be reduced due to various pressures. The integrity of the system, if additional counter-provisions have not been employed, has therefore been relaxed so that sometimes we can speak only about a minimization of the associated risk.

The scope of regulation is limited to W&M and measuring instruments are verified (inspected) at fixed time intervals by (national or local) government authorities. No fee is charged to the users in line with the argument that users of measuring instruments should not subsidize any protection of public interests in metrology. The logical consequence is that the user is solely responsible for keeping his/her instruments in compliance with the regulations. The term “subsequent verification” is used here to retain some sort of unified terminology – it is clearly a combination of verification and supervision (which is sometimes called enforcement, sometimes inspection, adding to the confusion – see VIML and OIML D 9). In the current circumstances the obvious liability in this system is its sole dependence on funding from public sources – these are becoming scarce and the operation of authorities could be severely hit by budget cuts. Another disadvantage might be the difficulty in motivating officers to be flexible enough in their operation – such government bodies are normally exposed to various limitations such as staff and salary caps. On the other hand, the ability to make hard decisions impartially is ideal here, and the system presents no financial burden to users. From the viewpoint of feedback, this model is nearly ideal for systematic data gathering on the performance of the control system. Some States in the USA currently use this model.

6.2.3 Metrological supervision (the Dutch model)

This is a variation of the previous model. Here, the government authority carries out supervision over measuring instruments specified by the regulations based on its own plan of inspections in the field. At the very least, this would apply to W&M instruments. The authority could be a government executive agency or a nominated private body. There is no fixed period of time to make an inspection. It depends on the outcome of the results each year and is based on risk analysis. Every measuring instrument is inspected once every four or five years. No subsequent verifications in regular intervals are carried out by force of legislation. In The Netherlands, however, subsequent verification is mandatory after repair or when a seal is broken. Users are solely responsible for compliance of their instruments with the regulations in place and are free to take any measures that are necessary to achieve that. Again, being financially dependent solely on public funding, the stability of this system is questionable under the current circumstances when public funds are under a severe squeeze almost everywhere. On the positive side, the system is impartial and is of no burden to any stakeholders in this business, whether they be users, manufacturers or servicing organizations. Another advantage is the flexibility of the officers in their operation, because the nominated independent private body is aware of the needs of their clients. This is an example of a model based on metrological supervision (enforcement) with minimum control interventions and no service provision on the part of the government.

The fact that the government effectively withdraws here from any control operations, except for mandatory verification mentioned above, has a direct consequence that in-service surveillance which has to be carried out against the extended MPEs is the basis of metrological control. Consumers may be dismayed to discover that in the absence of periodical subsequent verification the error ranges to be found in practice have effectively been broadened.

From the viewpoint of feedback, this model is the second most effective one after the American model due to the fact that the frequency of supervision actions is naturally less than that of subsequent verifications.

6.2.4 Assurance of metrological control over measuring instruments in service can be extended by the following minor elements:

- specified requirements on the operator, such as licensing or personal certification;
- usage requirements, such as the collection of data and the establishment of limits on items to be measured;
- specified service-personnel requirements such as licensing (registration of repairers) and calibration/verification of testing standards and instruments;
- completing supervision by checking the correspondence of bar codes on products with prices charged to customers.

On the other hand, subsequent verification should not be required when the metrological properties of some measuring instruments cannot technically change until they are broken (capacity serving measures, liquid-in-glass thermometers, etc.).

6.2.5 Subsequent verification is always required after repair, and whatever the circumstances there are always some arguments that repairers should be authorized to perform it. On the other hand, if impartiality is considered more important, measures have to be taken to secure a fast and flexible service on the part of the legal metrology authority. (In this case, instruments can immediately be put into service after repair by way of a special repairer’s stamp valid for a fixed period of time – e.g. three weeks).

6.2.6 When the possible involvement of private bodies in in-service metrological control is contemplated, attention has to be paid to the issue of whether an adjustment to the measuring instrument under test can only be part of a repair, or whether it can be part of subsequent verification as well. Servicing organizations sometimes argue that no adjustments should be made by government legal metrology services during verifications, regardless of whether they have the necessary technical knowledge. On the other hand, in the related activity of calibration it is rather unimaginable that a calibration laboratory should offer only a partial service of calibration without an adjustment when applicable and necessary and agreed with the customer. Thus, adjustments lie in a grey area. It is reasonable that they should be part of both operations (repair or verification) provided that both types of agency are technically competent to perform them. It can, however, be argued that when adjustments are made by government legal metrology services during verification, the user might no longer be responsible for non-compliance with respect to the MPE – but this is applicable to the American model only where such responsibility rests solely with the user.

6.2.7 Verifications (initial and subsequent) used to be performed on every single measuring instrument. With the advent of utility meters such as electricity meters, gas meters, water meters, heat meters, etc., often manufactured on highly automated production lines and installed in batches, a suitable environment has been created for the application of statistical methods to their verification (verification by sampling), and for an extension of the reverification periods of individual batches. Such methods can be based on international ISO standards for the acceptance of products by attributes. In arriving at a sampling plan, one first decides what is a sufficiently low level of risk of accepting non-complying instruments and of rejecting complying instruments. Next, one derives (from the level of risk decided upon) the target compliance and confidence level and then selects a sampling plan which will produce that level of confidence. Decisions to accept or reject any given lot are based on a comparison of the number of complying instruments in the lot, on one hand, with the target compliance, on the other. This may be an iterative process in which risks and costs are carefully balanced.

Usually a sampling plan, for a lot of given size, will be roughly as follows: if x instruments of a lot are tested and z or more are found not to comply, the lot must be rejected; otherwise the lot is accepted. If type evaluation is thorough and the sampling plan valid and rigorously followed, any desired degree of assurance of control can be achieved. A correlation analysis and a sampling plan of this kind are very much in place, for example, in the case of the clinical thermometers discussed in Annex 4. Under the auspices of OIML TC 3/SC 4 an OIML document called “Surveillance of utility meters in service on the basis of sampling inspections” is being developed where detailed guidance on this issue will be found. The above-mentioned framework systems of metrological control can therefore be modified in cooperation with utilities (users of those instruments) to cover this option in metrological legislation.

6.2.8 In statistical quality control, one examines data to determine the “assignable cause” whenever the data indicate that the production process is no longer in a state of statistical control. (A measurement process is said to be in a state of statistical control if the amount of scatter in the data from repeated measurements of the same item over a period of time does not change with time, and if there are no unpredictable drifts or sudden shifts in the mean of repeated measurements on the same item). The same approach can be used in legal metrology when compliance data indicate less than the minimum required level of compliance. If compliance data are periodically collected, say monthly, and plotted on a control chart, the chart will graphically indicate the degree to which assurance of metrological control has been achieved. In some real situations, the assessment of the success of the controls may, however, be more complicated because the measure of compliance may include factors other than the compliance percentage relative to the target compliance, or because the collection of data is obstructed by activities of other stakeholders in legal metrology. Some Annexes provide examples of the application of the systems approach to specific cases: Annex 5 discusses non-traditional ways of checking truck-weighing devices in the field, and Annex 4 treats the selection of control mechanisms for clinical thermometers. One can examine the examples in these Annexes with the view that a well-designed system of metrological controls is a system with feedback and adaptive response.

6.2.9 In deciding how to set up or modify legal metrological control in any country it is naturally highly important, as part of the systems approach, to analyze modern trends in frauds associated with measuring instruments and to design appropriate countermeasures. Frauds on instruments based on mechanical principles in use, especially an adjustment outside maximum permissible errors, were effectively eliminated by the introduction of subsequent verification, at least on instruments where the access to their measuring elements could be sealed. With the arrival of electronic instruments, opportunities for fraudulent manipulations widened. The most popular method, known as “turbo”, uses a device that adds pulses to the output from the measuring transducers to simulate a higher quantity delivered. Such frauds have been identified in a number of European countries over a range of instrument types, including taximeters (Czech Republic) and fuel dispensers (Spain). These devices are tricky to detect during normal verification as they can be covertly (remotely) switched on and off by the users. Their installation requires a cooperation of users with repairers – another reason to hesitate before licensing such bodies to take over subsequent verification aimed at protecting the public interest. It is clear that subsequent verification is nearly powerless in eliminating such malpractices – this might be a reason to contemplate the Dutch model. Additionally, unannounced actions of metrological supervision consisting of purchasing goods in the field by inspectors pretending to be normal customers are remedy here. Therefore, if subsequent verification is applied, it has to be accompanied by a fairly high degree of metrological supervision. Otherwise, references to the effective protection of public interests will be nothing but empty talk.

6.2.10 With rising energy prices, however, another kind of fraud is rising steeply: the manipulation of errors within MPEs. This is becoming ubiquitous in the area of fuel dispensing pumps. It has to be pointed out here that under current conditions, given that such practices would not normally be covered by laws on metrology, they are perfectly legal despite involving considerable amounts of money. They can therefore be called “soft frauds”. They have been rendered possible by progress in technology: metrological characteristics of measuring instruments are now stable enough for such “soft frauds” to be feasible and worth attempting. It should be pointed out that such exploitation of maximum permissible errors is possible only when the measuring instrument has been adjusted by the manufacturer or a repairer accordingly (the user shall not adjust the sealed instrument). Naturally, the MPEs could be continuously adjusted in the legislation to keep pace with the quality of modern technology, so as to make “soft fraud” more difficult. However, there are currently no signs of any efforts in this direction, not to mention the fact that any such action would probably meet opposition from all interested parties with the exception of consumers. This kind of response to the problem, if possible at all, could expect to encounter considerable delays. Furthermore, in the context of global trade, such a change would have to be made in an international normative document, such as an OIML Recommendation, rendering it even more difficult to achieve. The case is demonstrated in Annex 6 in an example of fuel dispensers in the Czech Republic. To tackle these “soft frauds”, legislation has to be adapted, as is already the case in some Member countries, to support an action against them and procedures of metrological control have to be modified accordingly. This has already been done in some legislations – an example of such a regulation: any bias away from zero error is not permitted and instruments should always be adjusted and corrected so as to ensure that any indication errors are as close to zero as possible.

6.2.11 A problem has been identified in some Member countries, while performing activities of metrological control, in the EMC susceptibility of weighing instruments. Although a well-defined, internationally accepted EMC test method does not yet exist for in-service metrological controls of electronic measuring instruments, it has been discovered with systematic investigations using 500 mW (analogue) walkie-talkies that 29 % of more than 300 weighbridges (for vehicles) are sensitive to electromagnetic interference, especially when the distances were 0.5 m and less, corresponding to field strengths of 50 V/m and higher. The problem is that the 1992 edition of OIML R 76 required immunity to radiated electromagnetic fields to a field strength of 3 V/m (in the revised current OIML R 76-1 [14] this limit has been increased to 10 V/m in line with OIML D11:2004[3]) while current (analogue) walkie-talkies and digital cellular phones are able to generate up to 100 V/m, depending on the distance. Cases have been identified when a walkie-talkie in operation close to the indicator or the load cells (but in some cases there were significant errors in distances longer than 1 m) was able to change the mass indication of a weighbridge by 1 or 2 T (and the indication was stable during the operation of the walkie-talkie in the given position). An impaired conformity to the approved type (caused e.g. by improper installation of the relevant parts of the weighbridge) might be one of the reasons but this cannot easily be checked in situ. The national authorities

[3] In D 11, there are in general 2 severity levels: 3 V/m for “residential, commercial and light industrial environment”, and 10 V/m for “industrial environment”. Only for digital radio telephones in the frequency ranges 800–960 MHz and 1400–2000 MHz, 10 V/m and 30 V/m are suggested. A 2 W GSM telephone typically produces field strength of 10 V/m at a distance of 0.6 m.

concerned have not yet found a satisfactory solution to this problem, because not only the EMC requirements for electronic measuring instruments - especially as regards the influence of mobile radiotelephones and other mobile sources of EM emission - need to be adapted in several international Recommendations and standards, but also an appropriate, well-defined and internationally accepted test method for in-situ EMC tests of installed measuring instruments has to be developed which is not an easy task. The results so far demonstrate some interesting trends but before final conclusions (of quite serious consequences) are drawn additional data should be collected and made available on larger batches to achieve statistically reliable results. It is hoped that this important feedback from the post-market metrological control activities, if found to be relevant, will attract immediate attention so that not only the technical requirements will be adapted but also an appropriate test method will become available as soon as possible in order to overcome the serious problem detected.

6.3 Metrological control of prepackages

6.3.1 Over the last century, the emphasis in terms of packing goods for sale has moved from commodities sold in bulk to prepacking. A prepackaged product is a single item for presentation as such to a consumer. It consists of a product of predetermined quantity, and the packing material into which it was put before being offered for sale. The packing material may enclose the product completely or only partially, provided that the actual quantity of product cannot be altered without the packing material either being opened or undergoing a perceptible modification. As vast quantities of goods are sold in the form of prepackages, metrological control over them is an essential part of any viable control system.

6.3.2 As the quantity of product in prepackages on the market can only be found out in a destructive way any reasonable system of metrological control has to be based on a control at the manufacturing stage with some coordination and exchange of information in regional or international arrangements. Legal metrological control is based here on an assessment of the QMS of the packer aimed specifically at compliance of the system with the requirements of the relevant regulations during packing. The assessment is followed by regular quality surveillance. To protect against any non-compliance imports the system can be strengthened by market surveillance over prepackages operated by e.g. trade inspection authorities.

6.3.4 In some free trade areas (e.g. the EU) there is a tendency to push the aspect of facilitating trade with prepackages more to the foreground. Metrological control is viewed here predominantly as a tool to eliminate technical barriers to trade with these products by a voluntary system based on a special marking (the “e” mark in the EU). Such a system is, however, not defect-prone from the viewpoint of consumer protection: any fine under-filling conceived by the manufacturer is now technically feasible by modern instrumentation, especially when legislation is often based on maximum negative deviations. Manufacturers therefore can operate one production line complying with the prepackage regulation for exports while the line aimed at domestic consumption would produce under-filled packages (a finding from the Czech Republic based on a project similar to one described in 5.2.d). On the other hand, a provision can exist in the general consumer protection legislation that all the packages labeled with a quantity of the product must contain at minimum the quantity on the label where applicable tolerable deficiency could be applied – a requirement stricter than the normally applied regulation for prepackages based on the average requirement. Accordingly, any regulation here should ideally cover all the prepackaged products without any limitations (no nominal quantities, limiting sizes, metrological quantity, nature of products). It may be worth noting that not all Member States have implemented the batch average provision and as such those Member States who have are at a commercial disadvantage as they are unable to compete effectively. Routine weights and measures checks that ‘importers’ have identified particular countries where the evidence points to the ‘set point’ being below the nominal even though the batch passes the tolerable negative errors.

6.3.5 The range of prepackaged products is very wide, and growing, with various specific technical problems. Therefore, it is not easy to master all the technical aspects of this matter. The details of the average approach are given in OIML R 87 “Quantity of product in prepackages” or corresponding regional regulations (the EC Directives, NCWM Handbook 133 in the USA, etc.).

6.4 Complementary activities of metrological control

6.4.1 Any jurisdiction has to establish how to make measurements that could be used in court or to decide upon infringements on the rights of various bodies. The total measurement process should be captured here, not only the measuring instrument itself. This can be viewed as an extension of metrological expertise. Technical competence of those bodies making official measurements can be demonstrated by accreditation or by assessment on the part of the metrology authorities. Though this field is normally regulated separately by various government departments, it could usefully be included in metrological legislation.

6.4.2 It was mentioned above that the system of metrological control for measuring instruments in service often rests on mandatory subsequent (periodic) verification. It is essential here to define the appropriate reverification periods for regulated measuring instruments. This is normally not based on any long-term tests; instead, one relies on past experience and advice from abroad. Furthermore, nearly all the stakeholders (naturally, with the exception of repairers) prefer longer periods to shorter ones, and may lobby hard to obtain them. There is a growing demand to verify the validity of these periods, and also to make metrological legislation more watertight in response to a higher rate of disputes (see 6.4.1). To collect such information is relatively easy in jurisdictions when metrological tests are carried out on instruments as delivered from the field for subsequent verification prior to any repair. As pressure to reduce verification fees increases, as a result these tests can be dropped from the system altogether. In such cases legal metrology authorities should occasionally launch publicly financed projects on the basis of risk assessment, to review and verify the validity of reverification periods. By way of such projects the performance of the necessary tests and collection of data are facilitated. An example of such a project aimed at water meters resulting in some surprising conclusions is given in Annex 2.

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Annex 1

Effects of non-harmonization - capacity serving measures

Prior to October 30, 2006 capacity serving measures (CSMs) in Slovenia were subject to the following regulations:

- national legislation in general;
- OIML R 29 for CSM.

After October 30, 2006 a new EU Directive MID was made effective bringing about a change in these regulations:

- MID (2004/22/EC; annex MI-008,chapter II);
- new OIML Recommendation R 138 as a normative document to be used with the MID.

Maximum permissible errors given by OIML R 29 are as follows (for T = 20.0 °C):

CSM	Nominal capacities (V_n)	MPE
Transfer measures	All	±3 % of V_n
Drinking measures	$V_n < 100$ ml $V_n \geq 100$ ml	±5 % of V_n ±3 % of V_n

An action of market surveillance was launched by Slovenian authorities based upon statistical sampling on batches of CSMs in accordance with ISO 2859-1: 1989. The criteria for sampling were as follows (see [12]):

- Table 1 – Sampling size code letters, General inspection levels: II);
- Table III-A – Double sampling plans for normal inspection, acceptable quality levels: 2,5.

Example:

Batch size: 5 000

Sample size:

- first sample – 125 items ⇒ Ac number: 5; Re number: 9
- cumulative sample – 250 items ⇒ Ac number: 12; Re number: 13

The results of this exercise can be summarized as follows:

- number of products (types of CSMs): 17
- number of manufacturers: 8
- number of complying products: 7
- number of non-complying products: 10

Glass chalices extensively used in practice were identified as the most problematic capacity serving measure. A detailed technical analysis of these results showed that different criteria and approaches to read gauge marks against meniscuses were the main reason for non-compliance here as summarized below:

- OIML R 29, MID annex MI-008 – not covered
- DIN EN 76, Germany and Austrian legislation:

  “The filling volume is the volume of water that can be filled up to the **lower rim** of the gauge when the item is set on a plane surface.”

- practice in chemical laboratory - ISO 4787-1984 standard:

  The meniscus shall be set so that the plane of the **upper edge** of the graduation line is horizontally tangential to the lowest point of the meniscus…”

- OIML R 138:2007 [11]:

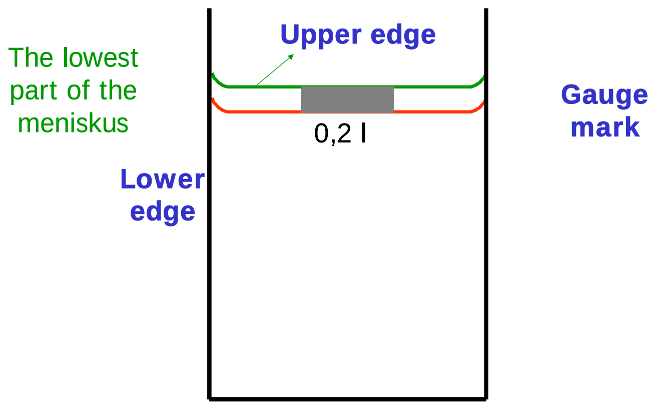
  Vessels for commercial transactions (supersedes R 4, R 29, R 45, R 96)

  4.6. FILLING REQUIREMENTS

  4. 6.1 Vessels with gauge marks

  “Filled to the gauge mark” is when the lowest part of the meniscus formed by the liquid is tangential to the **upper edge of the gauge mark**.

The difference between the two approaches used in practice are illustrated in the following figure:



The following general conclusions can be drawn form this exercise:

- regular actions of market surveillance of CSM should be considered here;
- bodies responsible for market surveillance in individual countries need common criteria for evaluation of tests, in this case for reading meniscuses against gauge marks.

This case can serve as an example of how legal metrological control can be negatively influenced by insufficient harmonization of technical regulations in different countries even at present when a nearly complete alignment of the underlying standards can be expected. Often this happens when standardization activities of different standardization bodies overlap as in this case (e.g. OIML versus ISO, OIML versus IEC), arguably as a result of a different representation of interest groups on the responsible technical committees. The importance of proper metrological control in this case is especially crucial as CSMs are often not subject, for practical reasons, to subsequent verification so that initial verification is for CSMs the **only** element of legal metrological control in place.

Annex 2
Reverification periods – water meters

In laying down the parameters for legal metrological regulation, such as reverification periods, there are always conflicting interests, including those of stakeholders with strong economic motivations. As a result, the reverification periods of some measuring instruments are not in line with the strictly technical metrological considerations.

Economic pressures cannot be ignored, even in principle, since an item's purchase price must include the cost to install it, the cost of taking it from its place of use to reverify it, and the cost of repairing it if necessary. Such considerations have led to an ever-increasing use of statistical approaches to verification of measuring instruments or to their metrological control.

On the other hand, governments must also take into account the interests of consumers and act as their protector against manufacturers, vendors/merchants and other, more audible, lobby groups. Collection of data on metrological properties and their time dependence in real conditions is a preferable option here. In the case of water meters, that means gathering data from distribution networks prior to any external interventions (cleaning, repair, etc.) that would normally precede the tests for subsequent verification. This matter has two important stumbling blocks:

1. the costs associated with these additional operations that will be eventually passed on to the user;

2. technical complications, such as the fact that testing equipment can be contaminated by impurities released from uncleaned water meters.

It is therefore clear that collection and evaluation of such data in the public interest has to be financially supported by the government. The data obtained in this way can be used as a feedback to analyze whether reverification periods have been correctly laid down, or to assess the consequences of the observed deviations from any optimal performance.

A program of such systematic studies of the correctness of reverification periods has been in existence in the Czech Republic (on water meters, and a similar project on gas meters has been initiated). Under its carefully crafted terms of reference, data on water meters were collected in 2003 and 2004 in cooperation with the utility companies. A sampling plan was chosen with the aim of covering the most frequent measuring ranges and types of those measuring instruments. The compliance was assessed against MPEs for verification. The data exhibit a much greater dependence on specific conditions in various localities, the quality of the distribution networks (piping, etc.) and the quality of the media being measured, than on types and ranges of those measuring instruments. The results so far demonstrate some interesting trends but before final conclusions (having relatively serious consequences) are drawn it appears that additional data on larger batches have to be collected to achieve statistically reliable results.

To illustrate the findings some results for water meters are given in the following tables (distribution networks mentioned are various regions in the country):

Table 1 Distribution network A

Type X **Q_n 2.5**	Number of units tested	**Non-compliance**	
		Units	**%**
after 1 year	50	9	**18**
after 3 years	50	10	**20**
after 5 years	50	12	**24**
after 6 years	50	12	**24**

Table 2 Distribution network B

Type X **Q_n 2.5**	Number of units tested	**Non-compliance**	
		Units	**%**
after 2 years	186	99	**53.2**
after 4 years	120	91	**75.8**
after 6 years	190	124	**65.3**

Type Y **Q_n 6**	Number of units tested	**Non-compliance**	
		Units	**%**
after 2 years	51	29	**56.8**
after 4 years	55	38	**69.0**
after 6 years	30	10	**30.3**

Table 3 Summary of results highlighting the time dependence and the rate of non-conforming measurements for individual flowrates of Q_n 2.5 water meters

Number of units		Distribution network A		Distribution network B	
Tested		Units		Units	
	in total	200		496	
	after 1 year	50		-	
	after 3 (2) years	50		186	
	after 5 (4) years	50		120	
	after 6 years	50		190	
Non-complying		Units	%	Units	%
Total	in total	43	21,5	314	63.3
	after 1 year	9	18,0	-	-
	after 3 (2) years	10	20,0	99	53.2
	after 5 (4) years	12	24,0	91	75.8
	after 6 years	12	24,0	124	65.3
Q_{min}	in total	24	55.8	156	49,7
	after 1year	4	44.4	-	-
	after 3 (2) years	7	70.0	25	25.3
	after 5 (4) years	9	75.0	37	40.7
	after 6 years	4	33.3	94	75.8
Q_t	in total	17	39.5	233	74.2
	after 1year	4	44.4	-	-
	after 3 (2) years	2	20.0	56	56.6
	after 5 (4) years	3	25.0	68	74.7
	after 6 years	8	18.6	109	87.9
Q_n	in total	7	16.3	233	74.2
	after 1year	2	22.2	-	-
	after 3 (2) years	2	20.0	69	69.7
	after 5 (4) years	2	16.7	64	70.3
	after 6 years	1	2.3	100	80.6
Q_{min} & Q_t	in total	4	9.3	130	41.4
	after 1year	0	0,0	-	-
	after 3 (2) years	1	10.0	14	14.1
	after 5 (4) years	2	16.7	30	33.0
	after 6 years	1	2.3	86	69.4
Q_{min} & Q_n	in total	0	0.0	118	37.6
	after 1year	0	0.0	-	-
	after 3 (2) years	0	0.0	11	11.1
	after 5 (4) years	0	0.0	27	29.7
	after 6 years	0	0.0	80	64.5
Q_t & Q_n	in total	1	2.3	172	54.8
	after 1year	1	11.1	-	-
	after 3 (2) years	0	0.0	34	34.3
	after 5 (4) years	0	0.0	45	49.5
	after 6 years	0	0.0	93	75.0

Q_{min} & Q_t & Q_n	in total	0	0.0	112	35.7
	after 1year	0	0.0	-	-
	after 3 (2) years	0	0.0	8	8.1
	after 5 (4) years	0	0.0	24	26.4
	after 6 years	0	0.0	80	64.5

Annex 3

Pattern compliance or conformity to type [13]

(This text is an exact copy of the article referred to in [13])

For many years, testing authorities around the world have believed that instruments submitted for type approval are carefully selected and tested instruments – often referred to as “gold plated instruments”. However, there is little evidence to support this perception, despite the fact that it was unlikely that a manufacturer would submit for type testing an instrument in which he did not have a certain degree of confidence that it would perform satisfactorily. Many testing authorities required manufacturers to provide test results in support of their application, again ensuring that the instrument submitted would be a good quality one.

In the late 1980’s the then National Standards Commission of Australia (NSC) (now the National Measurement Institute) was requested to carry out testing on some approved load cells that were to be used in weighbridge upgrades in one of the small countries in the South Pacific Region. Sixteen load cells from different manufacturers (all approved in Australia and in various other countries) were tested and only one met the performance requirements necessary for the number of scale intervals that their approvals allowed. Some performed as less than 20 % of the required standard for their existing approval.

Pattern compliance has always been a difficult activity to introduce because of the lack of funding necessary for carrying out the tests. Manufacturers were reluctant to fund repeat testing of already approved equipment as any additional costs had an impact on their ability to recover the development costs on new and existing technology.

Other examples of production instruments failing to meet the same standard as the tested and approved instrument were uncovered accidentally as there was no process of post approval testing other than the in field verification process, which cannot ensure compliance with most of the environmental and influence requirements that the instruments are exposed to during type testing. Examples that were discovered showed that screening of displays against EMC was not supplied on production models. Similarly ferrite beads on data cable were not supplied on standard production models.

In 2001 the Australian Government recognized that with mutual recognition agreements reducing the amount of testing globally, the risks of non complying instruments being supplied into the Australian market could increase and as a result they provided funding to allow random post approval testing to be carried out.

As the Government was funding the project there was to be no cost to manufacturers and as most suppliers of instruments in Australia are importing agents they were willing to voluntarily provide production instruments for pattern compliance testing.

Since the scheme was introduced tests have been carried out on over 80 instruments with the tests being restricted to those aspects which cannot be checked in the field. In order to make some allowance for manufacturing variables the non-compliance was broken up into two categories “minor failure” = no more than l.5 × MPE for type approval and “major failure” = greater than 1.5 × MPE for type approval.

Of the tests carried out to date there have been 15 “minor failures” and 6 “major failures”.

As part of the incentive for manufacturers to cooperate it was agreed that there would be no penalty for minor failures. This meant that manufacturers were very interested in the results of the testing with many going back to their supplier to have the design checked for the causes of the minor failures.

With the major failures, manufacturers voluntarily withdrew their product from the market until the causes of the failures had been determined and rectified.

This program has demonstrated that there is a need for pattern compliance testing after approvals have been granted and this will become more important as the OIML MAA has the effect of significantly reducing the amount of independent testing that instrument prototypes must be subjected to as part of the type approval process.

Annex 4
Clinical thermometer example

This example dating back to 1986 is intended to illustrate how metrological control for clinical thermometers can be assessed, not to recommend legal requirements for them. In some countries, voluntary standards (norms) with which all thermometer manufacturers comply and a general policy of users to buy only thermometers guaranteed by the manufacturer to comply with these standards may reduce the need for legal controls.

Let us consider controls on liquid-in-glass clinical thermometers and/or on their use. Their accuracy is almost entirely determined by their quality at the time of manufacture and, provided the liquid column has not separated and the glass is not broken, their accuracy does not generally deteriorate. When thermometers have been checked at the factory and are used in hospitals only by trained nurses or technicians, the probability of incorrect measurements due to operator error, environmental conditions, etc., is low and one can dispense with initial and subsequent verification. In such cases, one usually does not impose legal metrology requirements on operator training or environmental requirements. It is more usual to control liquid-in-glass thermometers by type evaluation following the OIML R 7 [15] and/or by either 100 % verification or lot sampling at the factory (R 7 does not specify what constitutes adequate assurance of metrological control based on pattern evaluation, lot sampling, and testing according to R 7) without any subsequent verification. If officials are satisfied with a manufacturer's quality assurance, their verification may be limited to periodically witnessing lot sampling and testing at the factory (quality surveillance). It is inefficient and unnecessary for the officials to duplicate the manufacturer's quality assurance if it continues to be adequate.

Legal metrology officials and thermometer manufacturers should ensure temperature measurement accuracy by monitoring the errors of the temperature measurement process used to evaluate the liquid-in-glass thermometers. Regular measurements on stable control thermometers and the keeping of control charts can provide information on the process precision. Calibrations of standard thermometers by a higher level laboratory and interlaboratory comparisons with other laboratories involved in temperature measurements at comparable levels of accuracy can provide information on systematic errors.

When, for example, the maximum permissible error for thermometers is + 0.1 °C, – 0.15 °C, as recommended in R 7, the uncertainty of the temperature measurement process used to test these thermometers should be quantified and shown to be much less than 0.1 °C. If R 7 is chosen as the basis for thermometer type evaluation and for factory qualification, and this is supplemented with production lot sampling, a valid procedure for production lot sampling is still necessary even if a submitted pattern meets all the requirements[4]. Legal metrology officials should also be concerned with whether rejected thermometers are destroyed, remanufactured or repaired, or relabeled and sold for less demanding applications. In any case, it should be ensured that, following the tests, complying thermometers are not confused with non-complying thermometers. If marks are affixed to those that comply, immediately

[4] Examples of standards providing guidance on lot sampling are:
- ISO 2859 "Sampling procedure and tables for inspection by attributes" (see also ISO Guide 3319).
- United States - ANSI Standards Z1.4 and Military Standard 105D.

following the tests, this should not be a problem. Also, one should ensure that unscrupulous manufacturers do not include rejected thermometers in lots later submitted for testing, in the hope that the sampling process will miss them.

The situation changes when one considers electronic, digital readout clinical thermometers. Subsequent verification is generally not needed for liquid-in-glass thermometers as already mentioned because of their stable properties, but should be considered for electronic devices whose performance may change as components age or fail. This is particularly true for a new technology for which type evaluation may not adequately assess all relevant factors.

In one instance, a hospital purchased a large number of electronic thermometers that had performed accurately and reliably in laboratory tests but which, when placed in service, frequently produced erroneous readings. The problem was traced to the electromagnetic fields of a nearby radio station (see also 6.2.11). This is a justification of the current practice that there are always EMC requirements and tests for electronic measuring instruments under legal metrological control. Another approach is to control the environment of device use by prohibiting device use in locations where EMI exceeds a specified threshold. But because most hospitals have no capability for measuring or controlling EMI levels, this is impractical. Because electronic thermometers may also be sensitive to other environmental conditions (ambient temperature, etc.) their subsequent verification, where required, should be performed under realistic conditions of use, for example, by checking them at regular intervals at the user’s location (for example, hospital, clinic, or doctor’s office) against calibrated standards (for example, liquid-in-glass thermometers). Placing requirements on the user, rather than relying only on official inspections, conserves the resources of the legal metrology service.

Annex 5
Permanently installed truck weighing device example

Because permanently installed truck weighing devices must be assembled at the installation site, their initial verification in the field is an important part of their metrological control in many legal metrology jurisdictions.

Since the weighing platforms of most of these devices are located outdoors, frequently in dirty environments, degradation of performance over time is probable, particularly if they are not adequately maintained.

For this reason, many jurisdictions also perform subsequent verification on truck weighing devices. Typically, an inspector visits the site periodically and uses a set of well calibrated weights to verify the performance of the weighing device over its range. If these weights are correctly calibrated and the inspector carefully follows valid procedures, this approach can provide considerable confidence that the device is performing correctly. With this approach one evaluates the device and its environment, but may not be able to evaluate the accuracy of the actual measurements, which may be affected by the device operator, the truck driver and occasional external conditions (such as wind).

For example, if the truck tare weight is determined with the driver not in the truck, but the loaded weight is determined with the driver in the truck, the weight of the load is not measured correctly. An approach that promises to permit longer intervals between comprehensive verifications, using classical techniques, is based on a group of “reference truck weighing devices” strategically located within the jurisdiction. The reference devices are verified frequently with check weights to establish their stability and errors. With tare weight carefully controlled, an ordinary truck is weighed on a reference device, driven sequentially to several nearby weighing devices that are to be verified, and then driven back to be reweighed on the reference device. Ordinary trucks of varying sizes and configurations covering the range of weights, number of axles, etc., of interest for verification can be used as transfer standards in periodic “round robin” verifications of this kind.

Records of the measurements on each device are kept so that the data are sufficient to suggest the causes of any problems that may arise. One can also use a verification system based on sampling for this application. Such a system has the advantage of sampling the actual measurements made with the devices to be controlled. A truck that has just been weighed with the weighing device to be verified is selected at random and its driver is requested to bring it to the nearest reference weighing device for reweighing. This approach is feasible only where local laws, policies, or logistics considerations permit; also, some truck drivers may object to having their trucks rerouted to reference weighing devices. However, it has the advantage of realistically evaluating the entire measurement process (operator, device, environment, and measurement procedures).

In this last approach and in the round robin approach, one must consider possible special sources of error, for example, the truck fuel consumed in driving between the device being verified and the reference device; also ice, snow, rain, or dirt picked up or lost by the truck between device sites. Such error sources should be assessed for each particular verification plan and either should be eliminated or appropriate corrections should be made. In any case, good technical judgment should be exercised. It is not intended here to recommend any particular method for verifying truck weighing devices, but to illustrate the importance of exploring possible alternatives in assuring metrological control.

Annex 6
Manipulation with errors within MPEs – fuel dispensers

In the case of fuel dispensers, which have MPEs of 0.5 % for normal fuels (not for liquefied gases), “soft fraud” consists in setting the error to a level very close to the tolerance limit, in favor of the user of the fuel dispenser. This requires collusion between repairers and users on demand from the latter and this could happen any time, not just immediately before verification.

An example can be given of a major distributor of fuels who did this on its petrol stations just 6 months after the last verification of the dispensing pumps (the reverification period being 2 years). These “soft frauds” are much more attractive to users than any reduction in verification fees that may result from liberalization. The authorities in the Czech Republic have made an effort to counter it by issuing an internal guide for inspectors, asking them to use narrower MPEs when pumps are adjusted. However, since this action is not supported by legislation, it could only be called half-hearted. Users can decide to have fuel dispensers adjusted at any time; they do not care about any additional verification fees. It is possible to estimate what this implies for consumers. In the Czech Republic, an OECD member, this 0.5 % means 300 ppm of GDP of unjustified profit in favor of fuel distributors at the expense of consumers annually. It can be assumed that this surprisingly high number is approximately the same in other developed countries - it is roughly ten times greater than the total amount of subsidies which those countries invest annually in their national metrology systems (as established by the BIPM in its Report BIPM-94/5, see [16], the average range is 40–70 ppm of GDP).

This matter does not stop at the above-mentioned 0.5 %: when actions of metrological supervision are carried out between verifications the errors found have to be compared with the so called expanded MPEs, which are usually twice as large as the MPEs for verification, to take into account effects of normal wear and tear over time. Now if authorities abandon subsequent verification by privatizing it to licensed bodies, and confine themselves to mere supervision over instruments in use, it could drive these “soft frauds” to new highs of nearly 1 %. This would be a direct consequence of the competitive environment: licensed verification bodies would like to satisfy the wishes (the word “needs” is purposefully avoided here) of users of whatever measuring instruments are under consideration: for them any such “soft fraud” is much more lucrative than any reduction of verification fees due to competition. Surely, to increase retailers’ revenues by 0.5 % to 1 % without any costs is tempting enough not only in fuel distribution (and in future the situation will be much tighter here) but e.g. in weighing as well (the first such case was identified in France as mentioned during one of the CIML associated meetings in 2007).

Although this may not be appreciated by all the parties involved, freedom from commercial interests (in other words, a monopoly of an authority or a body linked to the local government) is the only way to bring this kind of fraudulent behavior under control. The same type of argument is used to justify the national monopoly position of accreditation bodies – it can well be argued that the reasons are at least equally strong here as in accreditation. Everybody is aware of the traps presented by monopolies, but under certain conditions these are manageable. Another aspect of this matter is that any legal provisions aimed at minimizing these “soft frauds” can effectively be enforced, until the MPEs are adjusted in the legislation, only by application of subsequent verification (in both versions, after repair and periodic): the check that the error after an adjustment complies with whatever is stipulated by law can only be made immediately after the adjustment and the best tool for it is subsequent verification.