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PRINCIPLES of ASSURANCE of METROLOGICAL CONTROL

WORKING DOCUMENT

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EXPLANATORY NOTE

The field of legal metrology has changed considerably in recent years, mainly due to the effects of liberalisation, elimination of technical barriers to trade on a regional basis, privatisation/contractisation and a wide use of accreditation. Firstly, voluntary accreditation and various mutual recognition agreements have now covered in a systematic way a number of areas in metrology that otherwise might be targets of metrological control (measuring instruments in non-regulated fields of metrology, national standards and dissemination of units of measurements etc.). Secondly, conformity assessment procedures based on quality systems and other tools are sometimes used for placing legally controlled measuring instruments on the market and putting them in use, replacing traditional type approval and initial verification procedures. A considerable part of responsibilities in metrological control has been transferred in this respect from the shoulders of third party public bodies onto manufacturers, distributors and owners. The driving force behind this development is the effort coordinated by World Trade Organisation (WTO) to facilitate trade among countries and regions in the world by removing technical barriers to trade (TBT). A number of free trade areas with harmonised legislation to that effect have thus come into existence based on regions (e.g. the European Union) or based on trade agreements introducing extensive mutual recognitions (e.g. NAFTA, the North American Free Trade Area). Recently, the introduction of the Mutual Acceptance Arrangement (MAA) by OIML has provided a global infrastructure for mutual acceptance in regard to pattern approval. Furthermore, these changes have enabled non-governmental and private bodies to become involved in activities of metrological control once third party assessment of their technical competence has been satisfactorily demonstrated. On the other hand, under the current circumstances, it has to be carefully studied whether protection of public interest, the principal goal of metrological control, has not been compromised as a result of all the changes mentioned above.

These developments have changed the traditional landscape in assurance of metrological control as a basic tool used by responsible public bodies to protect public interests in the liberalised world and have also widened the scope of possible regulations requiring an effective metrological control (prepackages, conformity assessment procedures). All these developments have led to the preparation of the OIML generic strategy document by K. Birkeland [1] and gradually they will require a complete overhaul of the corresponding OIML documents, especially those of general nature (D-type documents), to bring them up to date without compromising an effective consumer protection – since, in general, legal metrology is an area where government intervention is needed.

Naturally, the above-mentioned changes might not currently apply to all possible socio-economic environments of OIML Members, so the documents should be comprehensive enough to allow for this variety. Each one should offer a list of possible approaches to assurance of metrological control with their benefits and drawbacks to be used by national authorities in preparation of legislation. The

document D 16, which plays a crucial role in this respect, was officially approved in 1986 naturally not reflecting the recent changes so that its revision has been considered by TC 3/SC 2 to be long overdue. On the other hand, a number of concepts are still applicable so that the revision is based on an update of the existing document with a number of additions and annexes. A section on how to effectively fight frauds by way of metrological control has also been added.

Practical considerations in the preparation and implementation of legislation in various countries may require an extension of the scope of legal metrological control as defined in the International Vocabulary of Legal Metrology (VIML) [2] because the existing infrastructures of metrological control and their expertise can be used with advantage for the other forms of control specified by that legislation. This applies to, for example, pre-packages subject to metrological legislation and various gaming machines subject to legal control by laws on lotteries and similar games. In the former case, their metrological control is dealt with in the revised OIML Recommendation R 87 “Quantity of Product in Prepackages”.

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0. INTRODUCTION

Since its inception, OIML has worked to harmonize laws and regulations on metrology amongst its Members. Efforts have been focused on requirements for particular measurements or instruments. Such efforts make up, and will continue to make up, the main task of OIML. A related task is to provide OIML Members with guidance on the ways of assuring metrological control and on methods to verify that such controls are 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 organisation, and also its other features and specific conditions. 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 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 given system of assurance of metrological control is based on a combination of the first two elements, as appropriate to the local jurisdiction; the third element completes the system by enabling it to resolve disputes. As technology has changed, the system has been adapted so that it can apply to the prepackaging of goods, which has become the most common method for selling goods by weight or measure. 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).

This International Document reflects the ongoing efforts to eliminate technical barriers to trade and ensure equity in the marketplace while protection of public interest is not compromised. Member countries are recommended to refer to the OIML Document D1 “Elements for a Law on Metrology” [3] in preparation of their metrological legislation concerning legal metrological control.

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 harmonisation of legal metrological control at an international level.

2. TERMINOLOGY

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

2.1 **legal metrology (VIML 1.2):** part of metrology relating 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.

2.2 **legal metrological control (VIML 2.1):** the whole of legal metrology activities which contribute to metrological assurance.

NOTE
Legal metrological control includes:
- legal control of measuring instruments,
- metrological supervision,
- metrological expertise.

2.3 **legal control of measuring instruments (VIML 2.2):** generic term used to globally designate legal operations to which measuring instruments may be subjected, e.g. type approval, verification etc.

2.4 **prepackage:** combination of a product and the packing material in which it is prepacked (see OIML R 87).

2.5 **metrological supervision (VIML 2.3):** control exercised in respect of the manufacture, import, installation, use, maintenance and repair of measuring instruments and/or in respect of their use, performed in order to check that they are used correctly as regards the observance of metrology laws and regulations. It includes checking the correctness of the quantities indicated on and contained in prepackages.

2.6 **metrological expertise (VIML 2.4):** all the operations for the purpose of examining and demonstrating, e.g. to testify in the court of law, the condition of a measuring instrument and to determine its metrological properties, amongst others by reference to the relevant statutory requirements.

2.7 **legally controlled measuring instrument**, hereinafter referred to as a **"measuring instrument" (VIML 4.3):** a measuring instrument which conforms to prescribed requirements, in particular legal metrological requirements. For the purposes of this document the following instruments may fall under control according to national regulations: measuring instruments, gaming machines, coin counting machines, medical measuring instruments, water dispensing machines, timing instruments in vehicle washes.

2.8 **conformity assessment of a measuring instrument (VIML 2.11):** 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.

NOTE
Conformity assessment does not only concern metrological requirements but may also cover requirements relating to:
- safety,
- EMC,
- software identification,
- ease of use,
- marking, etc.

2.9 **type approval (VIML 2.6):** 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.

2.10 **verification of a measuring instrument (VIML 2.13):** a 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.

2.12 **initial verification (VIML 2.15):** verification of a measuring instrument which has not been verified previously.

2.13 **subsequent verification (VIML 2.16):** any verification of a measuring instrument after a previous verification and including:
- mandatory periodic verification
- verification after repair.

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.

2.14 **verification by sampling (VIML 2.14):** 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.

2.15 **free trade area:** an area where two or more countries have harmonised legislation in place, on a national basis, to facilitate free cross-border movement of products and services that affect legal metrological control.

NOTE
Such harmonised 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.

2.16 **authority:** a public (government or local government) body authorised by law on a national level to be responsible for legal metrology as a whole or in part.

2.17 **manufacturer:** is a registered business who is responsible for designing and manufacturing a measuring instrument or a pre-packaged product with a view of placing it lawfully on the market nationally or within a free trade area, on his own behalf.

2.18 **manufacturer's representative:** any registered business designated by the manufacturer to act on his behalf for specified tasks.

2.19 **consumer:** each natural person or registered business who acquires or buys products to use them. (In some countries this applies only to natural persons).

2.20 **end-user:** a registered business that acquires a measuring instrument with the intention to use it himself and not to sell it.

2.21 **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 for payment or free of charge.

2.22 **putting into service (use):** the moment of the first use of a measuring instrument for the purposes for which it was intended by the end user.

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

2.24 **market surveillance:** a form of metrological supervision aimed at measuring instruments and prepackages which are 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 work properly resulting in general compliance of the products with 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 finalised 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 by himself (it is not necessary to place it on the market).

2.25 **being in service (use):** the operational life cycle of measuring instruments after their putting into service, i.e. measuring instruments in use, after repair, relocated, or rebuilt that may be resold.

2.26 **field surveillance (**alternatively **"in-service surveillance"):** a form of metrological supervision aimed at establishing that measuring instruments being in use in the field comply with the statutory requirements.

3. PRINCIPLES OF ASSURANCE OF METROLOGICAL CONTROL

Certain principles are fundamental to achieving assurance of metrological control. The first 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 permits focusing attention and resources on those elements that most require control. It also permits the selection of methods that offer the greatest benefit for the control effort invested.

A second principle is to provide flexibility. Flexibility in legal requirements permits officials to be selective in the application of controls. It permits consideration of enforcement history in designing and scheduling testing programs for both instruments and prepackaged goods. Flexibility also permits legal authorities to distribute the burden of compliance to both user and manufacturer.

A third 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 new socio-economic developments, such as globalisation and economic liberalisation.

4. GENERAL

4.1 For measuring instruments, countries normally adopt and publish a list of measuring instruments submitted to metrological control and/or a harmonised legislation is in place in a free trade area. The proper combination of elements of metrological control has to be considered (see 4.8). The scope of metrological control as defined in 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. The best approach here is that regulations of 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. Ideally, these regulations should also contain instructions, wherever applicable, for installation and use of those instruments together with guidelines how to calculate the uncertainty of measurements in service.

4.3 Harmonisation of the technical regulation mentioned under 4.2 should be accomplished to a maximum extent possible—at least on a regional level, if not globally—to eliminate technical barriers to trade. An example of negative consequences of a 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 authorised independent testing service can conduct the tests. Such a service organisation should, however, be licensed or authorised by the legal metrology authority. It may also be possible to have pattern evaluation and/or initial verification tests performed by the manufacturer (or a representative of the manufacturer) if the legal metrology officials have access to all data and can witness tests whenever they wish (see also [8]). 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 2 parts covering measuring instruments being put on the market (the market stage) and measuring instruments in use (the in–service stage). This enables an adaptation of legal metrology to the requirements of free trade agreements and at the same time can provide scope for a direct involvement of manufacturers 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 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 and class of instruments. Each set

includes standard MPEs for verification, and extended MPEs for in-service inspection.

b) The total uncertainties of the measurements made by verification officers are continually monitored and kept sufficiently small as required by regulations so that accept/reject decisions are negligibly influenced by these uncertainties. 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 extent possible, tests are made 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 so that rapid, appropriate action can be taken by legal metrology officials, manufacturers, instrument services, etc., to reallocate surveillance efforts or to correct conditions producing non-conformance.

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

a) The MPEs for in-service inspection play a crucial role in the whole system as they provide for normal wear and tear of metrological properties of measuring instruments in use during (sometimes quite long) reverification periods. Their ratio to MPEs for verification can be different for various classes of instruments and should be laid down individually in the technical regulations mentioned under 4.2. (As a rule of thumb, the factor of 2 is frequently used here.)

b) To make the system more robust and transparent to laymen the uncertainties for verification are not taken into account during 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 court. 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.

The total uncertainty of a measurement in use, in general, depends on the instrument, the environment, the procedures used, 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) This condition is fulfilled, among others, when tests on instruments are made on the spot as is the case for traditional weights and measures (W&M) instruments, which play a crucial role in the protection of consumers (balances, fuel dispensers, taximeters, material measures).

d) Data gathering in legal metrology in general can be obstructed by the activities of servicing organisations: 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 after a 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 have to be launched where accuracy tests on measuring instruments coming in from the field are made before any servicing. An example of such a project and its implications is given in Annex 2.

   To assure metrological control, one must 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.

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 degrade with 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 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 pattern (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 pattern is highly reliable, control and/or surveillance can be reduced and resources reallocated to areas where compliance is poor.

4.8 Careful attention should be given 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 pattern 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 pattern approval with frequent subsequent verification of the instrument involved does not ensure measurements adequate 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.

4.9 A large number of OIML International 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 optimisation 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. This necessitates a total systems approach.

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. 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.

5.1 MEASURING INSTRUMENTS AT THE MARKET STAGE

5.1.1 Pre-market approach

Three basic types of arrangements can be distinguished here. (In practice, the details of each one may be modified slightly.)

5.1.1.1 A highly restrictive legal metrology control system could include, by law and regulation, all of the following:

- pattern evaluation and pattern 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 and they are made for manufacturers or their authorized representatives for a fee.

5.1.1.2 A balanced system can be based on:

- pattern evaluation and pattern approval made by competent bodies with a maximum mutual recognition of either pattern 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 its quality management system by a competent body. In this specialised 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.

Pattern 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 made.

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 testing agencies can compete with one another, as in the EU's common market. 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 on the spot (e.g. weighbridges, some automatic weighing instruments). In this case an independent, competent, third-party body should be available to perform the initial verification (assessment of conformity with the approved type). In a variant of this system, all initial verifications are carried out by a third-party body, known as a local legal metrology authority. The original model is preferable to this variant .

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.

5.1.1.3 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 authority, 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 made by the actual manufacturer. Instead, there is third-party assessment of technical documentation.

5.1.1.4 When all the above-listed intervention strategies in the restrictive system are used, much of the burden for 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. 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 has to be taken into account as well (it is well positioned to play a 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 minimises 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, such as in case of weighing instruments.

5.1.2 Post-market approach

In the pre-market approach the operation of pattern approval (or conformity to essential requirements) plays a crucial role. This is made on 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 pattern approval would bear little relation to the instruments available for sale. In addition, manufacturers can exert considerable pressure on the responsible bodies to make the tests in the shortest possible time period (especially where there is a competitive market for testing). As to initial verification made by manufacturers, its validity 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 called into question. Evidence supporting these doubts was obtained in a recent exercise made in Australia (see Annex 3 and [10]). The solution might be to reduce the activities of metrological control in the pre-market stage to their bare essentials, so that market surveillance can be strengthened. Initial verification made by manufacturers could be recognized until actions of market surveillance clearly demonstrate an unacceptable performance. In such a case, legislation could require initial verification to be made on the spot at the expense of the manufacturer. Such a system would be 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 emphasising supervision rather than provision of a direct service. Even if a strategy emphasising 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, the most vulnerable party in the measurement process.

5.2 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 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 there are three basic models currently in use. They will now be discussed in turn.

5.2.1 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 (inclusive of a profit) being 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 pattern approval and initial verification, the whole system by itself should guarantee the continual compliance of those measuring instruments with the regulations.[*] 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 involved Government legal metrology services are flexible enough in their operation to be able to manage the necessary coordination with servicing organisations when verification is performed on the spot. Those organisations are not usually very enthusiastic about making life easier for government authorities.

In a relatively high number of OECD countries verification has been passed over to licensed (authorised) or accredited bodies either fully (France, Sweden) or only for measuring instruments outside W&M (Germany, Switzerland, Austria till 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 made 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 made

[*] 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 under pressure from manufacturers. 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 minimisation of the associated risk.

solely responsible for any violations. Therefore, as a minimum, subsequent verification in the area of W&M should not be privatised.

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

The scope of regulation is limited to W&M and measuring instruments are verified (inspected) in fixed time periods 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 subsidise 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). In the current circumstances the obvious disadvantage of 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 of motivating officers to be flexible enough in their operation – such Government bodies are normally exposed to various limitations like 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. The USA currently uses this model.

5.2.3 Metrological supervision only (the Dutch model)

This is a variation of the previous model. Here, 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 even a government-owned private body. There is no fixed period of time to make an inspection; normally, every measuring instrument is inspected once every four or five years. No subsequent verifications in regular intervals are made by force of legislation. Users are solely responsible for compliance of their instruments with the regulations in place and free to take any measures to achieve that. Such a system was used in the Netherlands in the last decade of the last century. Again, being financially dependant 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 features an ideal impartiality and is of no burden to any stakeholders in this business, being those users, manufacturers or servicing organizations. The fact that the government effectively withdraws from any control operations here has a direct consequence that as the in-service surveillance is used here it has to be made against the extended MPEs. Consumers may be dismayed to discover that the error ranges to be found in practice have effectively been broadened.

5.2.4 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,
- use 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 alignment of bar codes on products with prices charged to customers.

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

5.2.5 Subsequent verification is always required after repair, and whatever the circumstances there are always some arguments that repairers should be authorised 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 be put immediately in service after repair by way of a special repairer's stamp valid for a fixed period of time – e.g. three weeks).

5.2.6 When an involvement of private bodies in in-service metrological control is contemplated, attention has to be given 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 unimaginable that a calibration laboratory should offer only a partial service of calibration without an adjustment when applicable and necessary. Thus, adjustments are 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.

5.2.7 Verifications (initial and subsequent) used to be performed on every single measuring instrument. With the advent of communal meters like electricity meters, gasmeters, watermeters, heatmeters 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 pattern 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 TC3/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 take this option on board in metrological legislation.

5.2.8 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 deals with the assurance of control for gasoline dispensers, Annex 6 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.

5.2.9 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 analyse 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 adding 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 whether such bodies should be licensed to take over subsequent verification aimed at protection of a 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. Unannounced actions of metrological supervision based on purchasing the goods in the field by inspectors pretending to be normal customers are the only remedy. Therefore, if subsequent verification is applied, it has to be accompanied by a fairly high amount of metrological supervision. Otherwise, references to the effective protection of public interests will be nothing but empty talk.

5.2.10 Recently, however, with rising energy prices, another kind of fraud is on a steep rise: 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 enabled by a progress in technology: metrological characteristics of measuring instruments are now stable enough for such soft frauds to be feasible and worth attempting. 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 7 on an example of fuel dispensers in the Czech Republic. To tackle these soft frauds, legislation has to be adapted to support an action against them and procedures of metrological control have to be modified accordingly.

5.2.11 Recently, a serious problem has been identified in Germany, while performing activities of metrological control, in EMC susceptibility of weighing instruments (see Annex 8). In relation to weighbridges it has been discovered that 30–40% of them are excessively sensitive to electromagnetic interference generated e.g. by cellular (mobile) phones. The problem is that the current version of OIML R 76-1 of 1992 requires immunity to radiated electromagnetic fields to a field strength of 3 V/m (in the revised OIML R 76 this limit is increased to 10 V/m) while the current cellular phones are able to generate up to 100 V/m. Cases have been identified when a cellular phone in operation close to the indicator or the load cells was able to change the mass

indication of a weighbridge by one or two tonnes (and the indication was stable until the phone was in operation in the given position). An impaired conformity to the approved type might be one of the reasons but it cannot be easily tested on the spot. German authorities have not yet found a satisfactory solution to this problem which has been presented to the European Commission as well (non-automated weighing instruments are regulated across Europe by a new EU Directive). This is an important feedback from the post-market metrological control activities to technical requirements and a serious problem needing immediate attention.

5.3 METROLOGICAL CONTROL OF PREPACKAGES

5.3.1 Over the last century, the centre of gravity 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.

5.3.2 As the quantity of goods 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 (e.g. in the EU on a national basis) with some coordination and exchange of information in regional 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.

5.3.4 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 underfilling conceived by the manufacturer is now technically feasible by the 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 underfilled packages (a finding from the Czech Republic based on a project similar to one described in 4.7.d). On the other hand, a provision can exist in the general consumer protection legislation that all the packages labelled with a quantity of the product must contain at minimum the quantity on the label – 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).

5.3.5 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 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.).

5.4 COMPLEMENTARY ACTIVITIES OF METROLOGICAL CONTROL

5.4.1 With growing energy prices consumers (citizens) pay increasing attention to the measuring instruments on which their energy bills are based. There is a similar level of concern about the instruments that determine regulatory sanctions such as speeding fines. This highlights the importance of metrological expertise which enters the area of metrological control when customers start complaining about the metrological properties of those measuring devices. Metrological legislation should carefully define the role and responsibilities of all parties, especially for financial matters. In systems without periodic verification, this can replace in-service surveillance. In France, for instance, electricity meters are tested on the spot by a dummy load in case of complaints. In specific cases (watermeters) the appropriate tests can only be made on the spot, that is, on the instruments as installed. Otherwise, their metrological properties will be changed by tampering in the process of putting them out of the network, cleaning them etc. This is an emerging activity for legal metrology authorities (national metrology institutes) of a high priority. Properly handled, it can be used to bring home a message about the importance of metrology, via the media, to the public.

5.4.2 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. It can be viewed as an extension of metrological expertise. Technical competence of those bodies making official measurements can be demonstrated by accreditation or an assessment on the part of metrology authorities. Though this field is normally regulated separately by various government departments, it could usefully be included in metrological legislation.

5.4.3 It has been mentioned above that the system of metrological control for measuring instruments in service often rests on mandatory periodic verification. It is essential here to define the reverification periods for all the kinds of measuring instruments regulated. 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 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 5.4.1). To collect such information is relatively easy in jurisdictions when metrological tests are made on instruments as delivered from the field for reverification prior to any repair. As the pressure to reduce verification fees is mounting these tests can be dropped from the system – as mentioned above, there might be a high involvement of private bodies in making reverifications. 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 necessary tests and collection of data are facilitated. An example of such a project aimed at watermeters resulting in some surprising conclusions is given in Annex 2.

6. CONCLUSIONS

6.1 In the present time of fast technological and socio-economic changes (globalisation) it is extremely difficult 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 economic operators involved – on the other hand, consumers are never directly involved in this process. Consumer protection NGOs are wary of involvement in these matters, which they regard as too technical. In addition, cost considerations are tending to gain priority over quality matters.

6.2 Despite this rather hostile environment, the fundamental goal of legal metrology—to provide an effective protection of public interests associated with measurements—should be strictly followed by responsible government departments in their everyday 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.

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