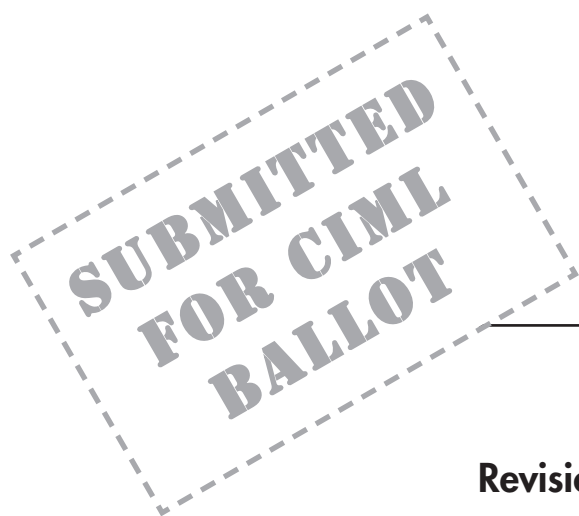


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Considerations for a Law on Metrology

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ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

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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; the OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and intended to improve the work of the metrological services.
- **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
- **International Basic Publications (OIML B)**, which define the operating rules of the various OIML structures and systems.
- **International Vocabularies (OIML V)**, e.g. International vocabulary of terms in legal metrology (VIML) and International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM).

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

International Recommendations and International Documents are published in French (F) and English (E) and are subject to periodic revision.

This publication - reference OIML D 1, edition 201x (E) - was developed by the OIML Technical TC 3 *Metrological control*. It was approved for final publication by the International Committee of Legal Metrology in 201x and supersedes the previous edition dated 2004.

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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Part 1 - Introduction

This Document, elaborated in liaison with the BIPM (Bureau International des Poids et Mesures) and the International Laboratory Accreditation Cooperation (ILAC), gives advice on the issues to be considered when drawing up national laws related to metrology, the need for which is reinforced by the increasing participation of States in trans-national, regional and international agreements following globalization of trade and services in which such laws provide the basis for dealing with the appropriate national measurement-based requirements.

The legislation for which this International Document provides advice may either be one general law covering all legal aspects of metrology or separate laws, each related to a specific aspect of metrology.

Considerations may be also found in other laws or binding regulations, such as a regulation on legal units of measurement, legislation on traceability, on measuring equipment (weights and measures act), etc., or provisions related to metrology and measurements in more general legislation such as a law on consumer protection or conformity assessment.

The bodies responsible for drawing up such laws are invited to select the appropriate elements from this Document, examine their relevancy and if necessary adapt them to their needs.

It should be noted that in different countries different terms are in use for binding regulations in legislation e.g. by-law, circular, decision, decree...”

This Document is presented in 6 parts:

- Part 1 - Introduction;
- Part 2 - Rationale, providing elements which justify the need for setting up legal provisions related to metrology and to metrological infrastructures;
- Part 3 - Guidelines for setting up structures in metrology and proposed articles for the law;
- Part 4 - Proposal for regulations;
- Part 5 - Proposal for the structure of a law on metrology;
- Part 6 - References.

The Parts should be considered, selected and adapted by each country according to specific needs, then incorporated into laws, government acts, ministerial acts, etc., according to the constitution and regulatory practice of the country.

While the intention is to address the regulated sector, many of these provisions also relate, and are applicable to, best internationally accepted metrology practice in the non-regulated sector.

Part 2 Rationale

2.1 What is metrology?

Metrology is the science of measurement and its application. Metrology includes all theoretical and practical aspects of measurement, whichever the measurement uncertainty and field of application.

2.2 Why a Law on Metrology?

Metrology is very broad, since there are many things that can be measured, many different ways that measurements can be carried out, and even different ways that measurement results can be expressed. The application of metrology underpins quality in manufactured goods and processes through accurate and credible measurement. Metrology plays a key role in the adoption of scientific and technological innovations, the design and efficient manufacture of products that comply with the needs of the marketplace, and the detection and avoidance of non-conformities. It provides fundamental support for health and safety testing, environmental monitoring, and food processing. It also provides the basis for fair-trading in a domestic economy and international trading in the global market place.

Many applications of metrology have a legal aspect, such as when there is a societal need to protect both the buyer and seller in a commercial exchange of a commodity or a service provided or where measurements are used to apply a sanction. While the details might vary considerably, virtually all countries provide such protections through their legal systems, and so they need a Law on metrology that covers how measurements and measuring instruments are to be treated in a legally acceptable manner. Furthermore, since there is an increasingly global aspect to many of these areas involving measurement, a country's Law on Metrology should take this global aspect into account as far as possible.

There are also other benefits for the society, see the Birch Report [8], such as:

- Reduced disputation and transaction costs;
- Consumer protection;
- Level playing field for commerce;
- Control of fraud;
- Full collection of taxes (when based on measurement);
- Full national benefit for commodity export;
- Support of trade in measuring instruments.

A country's Law on Metrology should nonetheless be as compact and simple as possible, providing enough detail to address the country's policies involving measurement, while providing enough flexibility to allow for changes in technologies and measurement procedures without having to change the law itself, leaving such details to decrees, regulations and other legal instruments. The Law on Metrology in a country should elaborate what needs pertaining to metrology exist in the country, without specifying how to meet those needs. While common needs of all societies result in many common concepts pertaining to metrology being used in all countries, the terms associated with the

concepts may be different from country to country (even for the same language), and so it is important that a single vocabulary be used and implemented into a country's Law on Metrology.

International mutual recognition of the measurement capability of an economy is critical to the removal of technical barriers to trade and, therefore, to participation in multilateral trade agreements such as those of the World Trade Organization (WTO). Countries should be encouraged to take part in the internationally agreed Mutual Recognition Agreements or Arrangements (MRAs) under the International Organizations (OIML, Metre Convention, ILAC) which provide the appropriate confidence between national measurement systems.

2.3 Further elaboration and examples of the value of metrology

Metrology encompasses measurement science and technology embedded in an infrastructure of measurement standards, dissemination of units, and science-based policy advice.

Metrology facilitates fair trade through harmonized written standards, consistent measurement standards and internationally accepted certificates.

- Parts manufactured in one country fit into machines in another country.
- A device tested and approved for use in one country may be also sold and used in another country, without further technical inspections.
- A prepackage labeled "1 kg" in one country contains the same quantity of product as in another country.

Metrology drives innovation: measurement science at the technological frontiers enables and drives industrial innovation in advanced production and instrumentation.

- Higher-precision manufacturing techniques must go hand in hand with higher-precision measuring techniques in order to be able to control the processes and also the assembly of, for instance, electrical and mechanical micro- and nanostructures.
- "One can manufacture only what one can measure"

Metrology supports regulation by providing measurement references for policy advice, directives, conformity assessment, and verification.

Examples:

- As an important part of consumer protection, metrological techniques determine and help enforce accurate measurement of gas, energy and water meters, fuel dispensers, breath alcohol testers, supermarket scales, etc within permissible errors.
- When paying for a liter of gasoline, it is expected that one liter of gasoline has been delivered.
- A measurement error of 1 % in the amount of natural gas consumed in the world in a year corresponds to an economic impact of billions of euro or dollars!

Metrology advances the protection of the citizen, for instance through reliable measurements of radioactivity or medical measurements.

Examples:

- Results of Blood tests should be independent of the laboratory performing the test.
- Unnecessary duplication of potentially harmful diagnostic procedures like X-ray exposure may be avoided when results are accepted and usable everywhere.
- The metrological infrastructure ensures that during the X-ray exposure the required dose of radiation will not be exceeded.
- Increasing reliability in measurements of medical parameters will help in a better determination on the need of medical treatment (Example: a 10% error in the determination of cholesterol levels implies that 13% of the population are not getting a treatment although they should, and 20% would unnecessarily be exposed to this treatment, including its adverse side effects.
- The continued refinement of methods supports for instance the detection of falsification of food-related measurements by illegal additives.

Metrology helps meet societal goals, such as increased energy efficiency and reduced consumption of resources.

Examples:

- The atomic-clock research helps in improving satellite navigation systems.
- Electricity meters with (near) real-time data (smart meters) enable greater efficiency through smart grids, and rationalized consumption with accessible energy usage data.
- Improved reliability and/or sensitivity of sensors provide more adequate data for close control of industrial processes, thus increasing efficiency and reducing waste.
- Support on the feasibility of research on the metering of new energy sources: (like biofuel, liquefied natural gas etc) is provided.

2.4 National quality infrastructure

Quality infrastructure, QI, refers here to all aspects of metrology, standardization, testing, and quality management including certification and accreditation. This includes both public and private institutions and the regulatory framework within which they operate.

Countries rely on many standards and technical regulations for their trade-related activities, consumer protection, etc. Therefore most countries have established a national quality infrastructure.

What is a quality infrastructure? Metrology, standards, calibration and testing and quality management are vital to products and product processes although consumers are not always aware of it. Yet these same consumers often use quality marks from product certifiers as a guide when making purchasing decisions. And their attention is drawn to the area in a negative way when, for example, technical equipment cannot be connected abroad.

2.5 What is legal metrology?

Legal metrology is the practice and the process of applying regulatory structure and enforcement to metrology. It comprises all activities for which legal requirements are prescribed on measurement, units of measurement, measuring instruments or systems and methods of measurement, these activities being performed by or on behalf of governmental authorities, in order to ensure an appropriate level of confidence in measurement results in the national regulatory environment. Legal metrology makes use of all developments in metrology to obtain appropriate references and traceability, and may apply to any quantity addressed by metrology.

Legal metrology applies not only to trading parties, but also to the protection of individuals and society as a whole (e.g. law enforcement, health and safety measurements). *Public authorities must pay special attention to measurement results and will need to rely on these results, especially* when there are conflicting interests in measurement results, thus necessitating the intervention of an impartial referee. Legal metrology is in particular necessary when forces on the market are not organized and/or competent enough or are unbalanced. Legal metrology generally includes provisions related to units of measurement, to measurement results (e.g. prepackages) and to measuring instruments and systems. These provisions cover the legal obligations related to the measurement results and the measuring instruments, as well as the legal control which is performed by or on behalf of the government.

Buying and selling of goods and services include the weighing or measuring of the quantity and/or quality of products, as well as pre-packaged products with a weight, number or volume declaration of quantity, and the measurement of service (e.g., time, distance). Governmental regulatory responsibilities also include health, safety and environmental law. While these functions are disparate in nature, a common feature is that compliance with the law depends upon measurement results. Therefore, the process of measurement is of direct concern to the government. Providing the laws and regulations, controlling measurement through market supervision and developing and maintaining the infrastructure that can support the accuracy of these measurements (e.g. through traceability) is essential in fulfilling the role of government.

The scope of the legal metrology regulations (e.g. types of measurements and measuring instruments or systems subject to legal requirements) will depend on markets important to the economy and the categories of users that the government considers necessary to protect, and on the ability of these users to protect themselves against abuse.

As another key purpose of legal metrology is to provide confidence in measurement results by legal provisions, needs and requirements on measurement results should be considered prior to addressing needs and requirements on measuring instruments.

Legal metrology includes four main activities:

- Setting up legal requirements;
- Control/conformity assessment of regulated products and regulated activities;
- Supervision of regulated products and of regulated activities; and
- Providing the necessary infrastructure for correct measurements.

2.6 Why is a metrological infrastructure necessary?

No quantity can be correctly and consistently measured without metrology and without a metrological infrastructure.

The importance of measurement results is ever increasing due to rapid technological development and the emergence of information technology. Consumers and industry must make decisions every day based on measurement results which affect their economic and personal well being, as well as having to judge the actions and efficiency of public authorities, enterprises and non-governmental organizations.

Since the manufacturers, importers and sellers of most products are responsible for the associated measurement processes, buyers (individuals as well as companies), who are generally not appropriately informed about these processes, are at a potential disadvantage regarding the measurement results and their interpretation. Fair and accurate measurements help to ensure fair competition.

Correct and traceable material measures and measuring instruments can be used for a variety of measurement tasks. Those corresponding to reasons of public interest, public health, safety and order, protection of the environment and the consumer, of levying taxes and duties and of fair trading, which directly and indirectly affect the daily life of citizens in many ways, may require the use of legally controlled measuring instruments.

2.7 What is the role of the government?

The role of the government in metrology is to provide society with the necessary means to establish confidence in measurement results.

This requires government to undertake a number of necessary activities to promote metrology, to develop appropriate infrastructures, to support research in metrology and to protect both individuals and companies against possible abuse related to measurements. It must be organized in a comprehensive and coherent policy, for which a law on metrology is advisable.

Considerations on metrology in this Document are not limited to the traditional issues of legal metrology. The importance of metrology for social and economic development calls for a comprehensive and coherent policy on metrology for which laws must take account of all the issues concerning consumers, enterprises, education, health, safety and the security of the population.

In setting up the national measurement system, governments should ensure that adequate transparency exists such that all parties are able to make informed decisions.

This Document proposes a hierarchical metrology structure with a Central Metrology Authority (CMA) to coordinate metrology policy and activities in the country. The CMA would normally be part of an existing government department and should also actively cooperate with the national bodies responsible for accreditation and standardization activities, as well as the relevant international metrological Organizations (i.e. the OIML and the Metre Convention). The structure of the metrology system and of the legal metrology system shall be adapted to the specificities of the country (e.g. size, economy, scientific and technological infrastructure, etc.).

2.8 Need for compatibility between national and international metrological requirements

Each nation has its own historical perspective on the development of metrological requirements.

The Technical Barriers to Trade (TBT) Agreement (Article 2.4), implemented within the World Trade Organization (WTO), makes an obligation for countries to base their national technical regulations on international documentary standards (norms) so as to harmonize the national requirements. It also requires signatories to take account of, and participate in, international systems of conformity assessment and mutual recognition agreements (Article 6).

The international community has adopted a system of units, measurement standards and requirements for measuring instruments and prepackages through treaties (i.e. the "Metre Convention" and the "Convention establishing an International Organization of Legal Metrology" In addition, Regional Metrology Organizations and Regional Legal Metrology Organizations are harmonizing requirements throughout their member economies. The intent of these organizations is to facilitate trade and the exchange of measurement results and measuring instruments. Documents and Recommendations published by these organizations are a primary resource for structuring a national metrological infrastructure.

The international organizations have also developed - or are currently developing - systems of mutual recognition or acceptance of the equivalence of measurement standards, of national measurement capabilities, of competences of calibration laboratories and of legal metrology evaluations.

Following due deliberations and depending upon its rulemaking procedures, a country may decide that a Document published by one of these international organizations contains applicable requirements for use in the country's metrology structure. Adoption of the Document's provisions may occur in one of several ways including:

- Reference to a specific edition;
- Inclusion of the verbatim text in the regulations;
- Inclusion of identical requirements, but not identical text; or
- Inclusion of compatible but not identical requirements.

It is important to note that successful engagement with, and recognition by, the international community requires dedicated resources to undertake both technical activities associated with demonstration of competence (comparisons for example) and to enable experts to participate in the various international fora.

Part 3 Guidelines for setting up structures in metrology and proposed articles for the law

PRELIMINARY NOTE

This chapter provides guidelines on the issues that should be considered when elaborating a law on metrology. These issues may be addressed in a single law covering all aspects, or, when such other legislation already exists, when adapting legislation on accreditation, on conformity assessment or on consumer protection, in which case the law on metrology will only include the specific issues that are not covered by this other legislation and will refer to them when necessary.

In the following guidelines, text contained in boxes (called “elements”) may be used directly for writing articles of the law, or may be reflected upon for developing similar but not verbatim text. Parts 4 and 5 of this Document give guidance on which elements should be written in the law as a minimum.

3.1 Definitions

Only those terms and definitions should be mentioned that provide for a better understanding of the law on metrology. Refer to VIML or VIM directly for most up to date definitions of terms included in this document.

For these and other definitions, see OIML V 1 International Vocabulary of Terms in Legal Metrology (VIML) and OIML V 2 International Vocabulary of Basic and General Terms in Metrology (VIM).

[Temporary note: the VIML is currently under revision in OIML TC 1. The definitions of some of the terms used in this document may change as a consequence.]

3.1.1 Legal document

Any legislative text adopted by, or by virtue of, government and/or parliament decision

Note 1: Legal documents may be primary legislation (for example named treaty, law or act) or secondary legislation (for example named decree, decision or regulation).

Note 2: “Legal document” is sometimes referred to as “Legal instrument”.

3.1.2 Metrological traceability

VIM 2.41 – metrological traceability

property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

3.1.3 Calibration

VIM 2.39 - calibration

operation that, under specified conditions, in a first step establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and

corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

3.1.4 Measuring instrument

In this Document, the term "measuring instrument" covers measuring instruments in the sense of the VIM (see VIM, 3.1), as well as measuring systems (VIM, 3.2), material measures (VIM, 3.6) and any part of a measuring instrument or measuring system which can be the object of specific requirements and of a specific evaluation of conformity.

VIM 3.1 - measuring instrument

device used for making measurements, alone or in conjunction with one or more supplementary devices

Note 1 A measuring instrument that can be used alone is a measuring system.

Note 2 A measuring instrument may be an indicating measuring instrument or a material measure.

VIM 3.2 - measuring system

set of one or more measuring instruments and often other devices, including any reagent and supply, assembled and adapted to give information used to generate measured quantity values within specified intervals for quantities of specified kinds

Note A measuring system may consist of only one measuring instrument.

VIM 3.6 - material measure

measuring instrument reproducing or supplying, in a permanent manner during its use, quantities of one or more given kinds, each with an assigned quantity value

3.1.5 Measurement standard

VIM 5.1 - measurement standard - etalon

realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference

Examples:

- a) 1 kg mass measurement standard with an associated standard measurement uncertainty of 3 μg .
- b) 100 Ω measurement standard resistor with an associated standard measurement uncertainty of 1 $\mu\Omega$.
- c) Cesium frequency standard with a relative standard measurement uncertainty of 2×10^{-15} .
- d) Standard buffer solution with a pH of 7.072 with an associated standard measurement uncertainty of 0.006.
- e) Set of reference solutions of cortisol in human serum having a certified quantity value with measurement uncertainty for each solution.
- f) Reference material providing quantity values with measurement uncertainties for the mass concentration of each of ten different proteins.

- Note 1* A “realization of the definition of a given quantity” can be provided by a measuring system, a material measure, or a reference material.
- Note 2* A measurement standard is frequently used as a reference in establishing measured quantity values and associated measurement uncertainties for other quantities of the same kind, thereby establishing metrological traceability through calibration of other measurement standards, measuring instruments, or measuring systems.
- Note 3* The term “realization” is used here in the most general meaning. It denotes three procedures of “realization”. The first one consists in the physical realization of the measurement unit from its definition and its realization in the narrowest sense. The second, termed “reproduction”, consists not in realizing the measurement unit from its definition but in setting up a highly reproducible measurement standard based on a physical phenomenon, as it happens, e.g., in case of use of frequency-stabilized lasers to establish a measurement standard for the metre, of the Josephson effect for the volt or of the quantum Hall effect for the ohm. The third procedure consists in adopting a material measure as a measurement standard. It occurs in case of the measurement standard of 1 kg.
- Note 4* A standard measurement uncertainty associated with a measurement standard is always a component of the combined standard measurement uncertainty (see GUM, 2.3.4) in a measurement result obtained using the measurement standard. Frequently, this component is small compared with other components of the combined standard measurement uncertainty.
- Note 5* Quantity value and measurement uncertainty must be determined at the time when the measurement standard is used.
- Note 6* Several quantities of the same kind or of different kinds may be realized in one device which is commonly also called a measurement standard.
- Note 7* The word “embodiment” is sometimes used in the English language instead of “realization”.
- Note 8* In science and technology, the English word “standard” is used with at least two different meanings: as a specification, technical recommendation, or similar normative document (in French “norme”) and as a measurement standard (in French “étalon”). This Vocabulary is concerned solely with the second meaning.
- Note 9* The term “measurement standard” is sometimes used to denote other metrological tools, e.g. ‘software measurement standard’, see ISO 5436-2.

3.1.6 Type of a measuring instrument

VIML 4.06 - type of a measuring instrument or module

definitive model of a measuring instrument or module (including a family of instruments or modules) of which all the elements affecting its metrological properties are suitably defined

3.1.7 Type evaluation of measuring instruments

VIML 2.05 - type (pattern) evaluation

conformity assessment procedure on one or more specimens of an identified type (pattern) of measuring instruments which results in an evaluation report and/or an evaluation certificate

Note “Pattern” is used in legal metrology with the same meaning as “type”; in the entries below, only “type” is used.

3.1.8 Verification of a measuring instrument

VIML 2.10 – verification of a measuring instrument

conformity assessment procedure (other than type evaluation) which results in the affixing of a verification mark and/or issuing of a verification certificate

3.1.9 Legal metrological control

VIML 2.01 – legal metrological control

the whole of legal metrology activities

Note Legal metrological control includes:

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

3.1.10 Legal control of measuring instruments

VIML 2.02 – 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.

3.1.11 Metrological supervision

VIML 2.03 metrological supervision

activity of legal metrological control to check the observance of metrology laws and regulations.

Note 1 Metrological supervision also includes checking the correctness of quantities indicated on and contained in pre-packages.

Note 2 For achieving these purposes, means and methods such as market surveillance and quality management may be utilized.

3.1.12 Market surveillance

OIML D 16, 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 1 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).

Note 2 Market Surveillance is exerted by enforcement authorities, for the purpose of detecting whether products placed on the national market (i.e. sold or offered for sale) fail to comply with the regulations that apply to them.

Note 3 This must be distinguished from "field surveillance" which consists in a surveillance by enforcement authorities, that instruments in use in marketplaces (in the field) do comply with the requirements that apply to them (required characteristics, integrity, accuracy, proper use).

3.1.14 Surveillance of the use of instruments

Part of the metrological supervision which consists in examining whether instruments subject to legal metrology control are correctly used.

For further terms and definitions see publications of BIPM, OIML and ILAC.

3.1.15 Accreditation

ISO 17000:2004, 5.6

third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks

Note: The national accreditation system, in general, is a voluntary system which establishes the competence and impartiality of:

- Calibration laboratories to perform traceable calibrations and measurements;
- Testing laboratories;
- Inspection bodies; and
- Certification bodies which perform product certification, quality systems certification or certification of personnel

Not all countries have a national accreditation system. If it exists, it should be recognized by the appropriate authorities.

3.2 National metrology

3.2.1 Policy

The policy for metrology should be a policy of the whole Government, aiming at providing the country with a metrology infrastructure able to ensure fair trade, foster the economic development and the economic efficiency, the technological and scientific progress of the country, the protection of health and of the environment and the protection of citizens and consumers. This policy should be clearly expressed so that all concerned parties can understand its goals and it should commit all the ministries and all the local authorities.

To elaborate and launch this policy, a lead government department should be designated and this government department should prepare, in cooperation with all other departments, a report on the status of metrology in the country and a declaration to be submitted to the highest level of the Government (e.g. Council of Ministers) and/or to the Parliament. The evaluation of the situation and the report should also associate national expert bodies such as academy of science, and/or international experts.

The declaration submitted to the highest level of the Government (e.g. Council of Ministers) and /or to the Parliament should:

- remind and explain the stakes of metrology for the country,
- identify metrology infrastructure as an essential component of the national infrastructure of the country,
- designate a lead government department for the national metrology policy and require other ministries to collaborate in the development and implementation of this policy.

The Government should set up a (permanent) national committee for addressing the national policy on metrology, which comprises in particular:

- orientations on metrology, goals to be attained in the medium term and long term,
- participation of the country in the international and regional metrology organizations and commitment in the work and recommendations of these organizations,
- priorities in terms of:
 - research in metrology and transfer of technologies to industry ,
 - infrastructures to be set up, supported or promoted to provide traceability to users,
 - education and training on metrology,
 - areas in which metrological regulations should be developed or coordinated,
 - areas of special governmental interest like precious metals and gem stones, gambling machines, voting machines, etc.,
- distribution of tasks between the public and the private sector,
- financial resources that the State should allocate to the support of metrology.

Examples of elements of policy that may be considered are the following:

- interdepartmental coordination in metrology,
- metrication (when the SI is not the national system of units used in the country),
- decision to create a single institute by merging several institutes,
- development of the effort for the research in metrology (improvement of the realization of the units),
- general criteria for determining the scope of regulated instruments,
- general policy about subcontracting tasks in legal metrology to bodies outside the administration - role of the state authorities
- support to the development of calibration laboratories, training to metrology, etc.
- becoming full member of the OIML and of the BIPM, or Corresponding / Associate Member
- becoming full or associate members of a relevant regional metrology or regional legal metrology organization.

This policy should be submitted for approval at the highest level of the Government (e.g. Council of Ministers) and/or to the Parliament. It will be the basis for the action of the Government and for justifying the yearly budgets allocated to metrology.

The report on the status of metrology in the country should be updated periodically (for example every four years) in consultation with the national committee, and it should be communicated to the Government and/or to the Parliament.

3.2.2 Infrastructure

The national metrology infrastructure should comprise:

3.2.2.1 *An authority in the Government, in charge of the national metrology policy, and of coordinating the action of other departments related to metrological issues*

This authority (see 3.2.4.3) should have a contact person for metrology in each of the other Departments, this contact person being in charge of:

- collecting information on the needs of the services of this Department in terms of measurement and metrology,
- collecting information about regulations made by this Department which include provisions on metrology or on measurements,
- transferring this information to the authority in charge of the national metrology policy,
- disseminating information in his/her Department about the national metrology policy, the available technical and scientific support in metrology, the work of regional and international metrology organizations, etc.

The authority in charge of the national metrology policy shall:

- consult with the other Departments for the elaboration of the national metrology policy and reach a consensus on this policy,
- ensure that laws and regulations relating to metrology take account of and are in accordance with relevant international provisions relating to metrology,
- ensure that the laws and regulations do not prevent the national bodies and authorities from entering into international agreements/arrangements.

See also 3.2.4 Organization of the Authorities

Element no. 1

The Government shall designate the government department in charge of developing and implementing the national metrology policy. This policy shall be submitted for approval to the Government (or Parliament) and shall commit all ministerial departments. This policy shall be implemented in coordination with all concerned ministerial departments and local authorities.

3.2.2.2 *A legal corpus, including the laws and regulations that have provisions related to metrology*

It is recommended to develop this set of laws and regulations progressively, taking into account the resources available for their enforcement and the budgets planned on the medium and long term.

The priority is to set up legal provisions related to:

- the status of the bodies to which tasks will be allocated, and the financial provisions that will ensure their sustainability (national institutes, accreditation bodies),
- the general framework for legal metrological control and the first list of priorities for categories to be subjected to legal control,
- the infringements, penalties and the powers of agents in charge of metrological supervision.

The scope of legal metrology, that is the list of categories of measuring instruments and prepackages subject to legal control, must start with the most important categories for which the available resources allow to enforce correctly the regulation. The scope can then be progressively extended as additional resources are available.

When studying new regulations or revising regulations, their impact should be studied, in terms of costs for the State (staff needed for its enforcement, equipment, operating costs), costs for the manufacturers and users of instruments, expected benefits.

The obligations resulting from the OIML Treaty and from the Technical Barriers to Trade Agreement (TBT Agreement) of the World Trade Organization (obligation to use OIML recommendations as far as possible, and encouragement made by the TBT Agreement to participate in OIML Recognition and Acceptance arrangements) should also be taken into account, as well as other obligations deriving from Regional treaties or agreements.

In some Regions, due to treaties or to agreements, regional legislation may have precedence over national laws and regulations or may be recommended to national authorities. This is the case for example in the European Union, where European Regulations and European Directives are accorded higher status than national legislation. This could also become the case in other Regions.

The regional legislation may be:

- Of total application. This means that the national legislation must be strictly identical to the regional legislation;
- Of optional application. This means that the national legislation may be of different scope or have different requirement levels but must be compatible with the regional legislation;
- Of voluntary application, allowing each Member State to consider their application.

When regional legislation is binding for Member States, its statute may be:

- Of direct application, this means that the provisions of this legislation are applicable in the countries without transcription in the national laws;
- Of indirect application, this means that national legislation is required to transcribe the regional legislation.

It is also recommended that Regional bodies take account of the present Document when preparing regional legislation. In particular, Regional bodies should take in consideration the obligations of their Members towards the OIML and the Metre Convention.

Element no. 2

The Government shall make appropriate regulations in application of the law on metrology, in order to define:

- the measurements and measuring instruments subject to legal control,
- the requirements applicable to these regulated measurements and measuring instruments,
- the procedures for the legal control of measurements and measuring instruments,
- the bodies in charge of carrying out certain tasks pertaining to this legal control and the requirements applicable to these bodies.

This law and regulations shall comply with the obligations deriving from treaties such as the Metre Convention, the OIML Treaty and the Technical Barriers to Trade agreement of the World Trade Organization as well as other obligations deriving from Regional treaties or agreements (these treaties shall be quoted in the law on metrology).

3.2.2.3 *One or several institutes in charge of tasks assigned at national level for the metrology policy*

If establishing a single national institute, it should be in charge of:

- establishing traceability to the SI, depending on the quantity, either by realizing the definition of the unit or by keeping, maintaining and continuously improving the national measurement standards traceable to a foreign institute,
- disseminating the units, which means providing traceability to the national references for calibration laboratories,
- carrying out research work on the improvement of national references,
- providing the necessary advice and support to the government, industry, commerce and the public on metrological and legal metrology issues,
- providing a sound metrological basis to the national accreditation scheme

- studying the requirements for new legal metrology regulations,
- studying the calibration and test equipment needed for legal metrology regulations and setting up this equipment,
- carrying out type evaluation activities in legal metrology, or supervising bodies designated for this function,
- providing training to legal metrology for other bodies in charge of legal metrology activities,
- participating in the corresponding international activities, e.g. comparisons.

However, depending on the infrastructure existing when the law is prepared, it may be appropriate:

- to define two institutes, one for scientific metrology (hereafter called NMI) and another one for legal metrology (hereafter called NLMI).
- and/or to define a network of laboratories coordinated with or subcontracted to the national institute.

Therefore, before deciding on the form of the national institute(s), it is recommended to carry out a survey on the main capabilities existing in the country, in private, semi-public and public laboratories, and to examine the different options:

- either to transfer some of these capabilities to a central institute,
- or to include and federate them in a national network.

The institutes must have the legal capacity to enter into international agreements or arrangements on mutual acceptance and mutual recognition in their domain of competence.

See also 3.2.3 about national institutes.

Element no. 3

The Government shall designate the institute or institutes in charge of:

- keeping and maintaining the national measurement standards and providing traceability to the International System of Units,
- carrying out and/or coordinating the research work in metrology,
- carrying out and/or coordinating certain tasks in legal metrology.

The designation of these institutes may be conditioned by appropriate evaluations, which may include peer assessments and/or accreditations.

Small countries may discuss having a regional infrastructure with one or more neighboring countries.

3.2.2.4 *System of national measurement standards and dissemination of legal units*

A system of national measurement standards is set up to maintain and disseminate legal units in order to meet the country's needs. National measurement standards are part of the national metrological infrastructure.

In the case that these standards are the primary standards that independently realize the legal units, regular comparison with *primary standards of other countries should be performed, utilizing the infrastructure established for that purpose by the BIPM and Regional Metrology Organizations.* In the case that the country does not maintain primary standards in all fields, national standards which are

not primary standards shall be traceable to the realization of the definition of units through primary standards maintained by another country.

The national measurement standards shall in all cases be those that are assumed to be the most accurate measurement standards of the country.

The system of national measurement standards shall include, as necessary, a system for providing certified reference materials.

Element no. 4

A system of national measurement standards and reference materials shall be set up to provide traceability to the International System of Units (SI) and to provide international compatibility and acceptance. These tasks shall be allocated by a Governmental decision to a designated institute.

3.2.2.5 *A (voluntary) system for accrediting calibration laboratories and, if required, testing laboratories, inspection bodies and certification bodies*

While for National Metrology Institutes peer assessment and accreditation of laboratories are considered equivalent tools, for the level below NMIs an accreditation system should exist and provide confidence in the competence and impartiality of laboratories, certification bodies and inspection bodies. In many countries, such a system is composed of one (or more) accreditation body(ies) which are independent of other interests and usually nonprofit organizations and which do not normally enter into competition.

Accreditation systems are harmonized and coordinated at the international level by the International Laboratory Accreditation Cooperation (ILAC) and by the International Accreditation Forum (IAF), depending on the scope of accreditation. Regional Cooperation Bodies, in liaison with ILAC and IAF, organize this harmonization and coordination at the regional level and also undertake the peer evaluation of accreditation bodies in these regions.

Both ILAC and IAF have implemented International Mutual Recognition Arrangements for accreditation bodies that have successfully undergone peer evaluation and met specified requirements (based on ISO/IEC 17011).

Accreditation is, in general, a voluntary system, which means that accreditation is not made mandatory and that industry or stakeholders are not obliged to use accredited bodies. Using accredited bodies is a choice of an industry and may be a contractual clause in the relations between contractors.

However, more specifically, for the enforcement of certain regulations, it may be required that bodies in charge of conformity assessment be accredited. This is highly recommended for conformity assessment bodies which do not form part of a NMI, but are in charge of the implementation of legal metrology activities.

Element no. 5

The regulations adopted in application of the law of metrology may require that implementing bodies in charge of certain tasks be appropriately accredited.

3.2.2.6 *Structures for disseminating knowledge and competencies in metrology (e.g. training, education, etc.)*

The national metrology infrastructure needs means to disseminate knowledge and competencies in metrology. This generally includes:

- incorporating basic notions of metrology in education, especially in scientific and technical matters,
- providing appropriate explanations and information to the public on metrological issues,
- incorporating practical notions on measurement, calibration and traceability in professional training,
- training of metrology specialists at different levels of qualification for the industry and for specialized testing and calibration laboratories,
- supporting research and technological progress in metrology and establishing partnerships between specialized bodies (laboratories, universities) and the industry in the field of metrology.
- regular and effective engagement by national experts in the appropriate international metrology fora will also help ensure that knowledge disseminated within the country is up to date and of the highest caliber.

The national metrology policy (see 3.2.1) should address these needs. Actions of the State may be required to support these structures.

3.2.2.7 *Services to industry and to the economy in the field of metrology*

In the same way as the economy and industry need infrastructure such as road, railways, ports, airports, banks, etc., metrological services to industry and to the economy are essential for an economically sustainable development.

The following services should exist in a country and be able to answer national needs:

- calibration services for ensuring traceability to the SI,
- testing services provided by specialized laboratories,
- service for the maintenance of measuring equipment,
- accreditation of calibration and testing laboratories, accreditation of certification bodies and inspection bodies,
- consulting services to support industries,
- third party experts to be consulted in case of disputes,
- etc.

The national metrology policy (see 3.2.1) should address these needs. Actions of the State may be required to support these structures.

3.2.2.8 *Supporting cooperation/participation in the metrological infrastructure*

While legal metrology should not merely be a one way enforcement item the infrastructure should provide for interaction between the stakeholders (government, industry and test- and measurement laboratories, users/consumers)

Especially for evaluation of the need for and effectiveness of enforcement, the following support could be provided to stimulate such institutional cooperation:

- set up of technology platforms (or networks) for collection and dissemination of expertise and experiences
- stimulation of cooperation in research projects (themes) in which all stakeholders take part
- stimulation of the development/provision of rationales supporting harmonized measurement and testing standards
- organization of meetings/conferences to which all stakeholders are encouraged to contribute
- etc.

3.2.3 National institutes

Two types of national institutes should be established, which may be either independent organizations or separate parts of one organization:

- A National Metrology Institute (NMI), consisting of one or more standards laboratories, which can also be part of for instance a university or other scientific institute; in general, due to the expanding scope of metrology, many countries traditionally distribute responsibility for different quantities/units among different institutes coordinated either by a principal institute or by an agency. This organization may be considered by small or developing countries, in order to make use of the existing competencies and capabilities;
- Generally one National Legal Metrology Institute (NLMI) in charge of studying technical specifications for legal metrology, issuing type approvals and providing technical coordination and support to other legal metrology bodies; this may also be distributed among several institutes specializing in different fields under an appropriate coordination.

Traditionally, N(L)MIs were nearly always entirely within the public sector. However, more recent policies have attempted to give N(L)MIs a degree of management freedom that is appropriate for the efficient and effective running of a research-based organization with services to the public. This has often required the introduction of more flexible accounting or management processes that are closer to private sector management models than to the rules that apply to administrative units in government.

In some cases, therefore governments have sought alternative models but have in all cases arranged matters so that the majority of funding of the institutes comes from public sources. In addition, and as metrology encompasses activities outside the traditional physics and engineering base - moving into the fields of metrology in chemistry, medicine, food etc. - it has been necessary to bring together a number of other organizations with a different ownership or legal status into a "distributed" or "virtual" N(L)MI.

In other cases where the required expertise is wholly within an industrial or commercial organization, governments have set up special contracts with industrial providers of metrology services for the country. In these cases, governments normally provide an official or legal designation of the organization concerned as a provider of the specific national service. The designated status only applies to the role of the organization within the country concerned and does not apply outside of that country. In such cases, it is important to ensure that the companies concerned do not develop unfair commercial or market positions as a result of their special contractual arrangements and official designation as part of a "distributed" N(L)MI.

An N(L)MI may have various possible structures:

- a public institute owning and running its own laboratories;

- a private institute owning and running its own laboratories, under the authority of the government, taking into account unfair competition and national security;
- a public agency coordinating public or private institutes.

In the field of metrology, the essential government functions relating to economic and social policy, support for industry and the making of legislation, are dependent on metrological and technical competence.

It is highly recommended to develop the synergies between scientific and legal metrology activities, in particular the study of technical requirements for new regulations, type testing and type approval issuing:

- either by combining scientific and legal metrology in the same institute;
- or, at least, by establishing close cooperation between the institutes in charge of these two fields of metrology.

The reasons for this are:

- new fields of legal metrology and new technologies in legal metrology are moving technically closer to the accuracies at the national standards level, and require new calibration, test and verification methods and new measurement standards to be developed by scientific metrology;
- high levels of competencies in metrology are more and more important in legal metrology; and
- including both activities in the same institute may help to achieve the critical minimum size of the institute, permitting better management of human resources and facilitating a coherent policy in metrology.

In all cases, special attention must be paid to the sustainability of the N(L)MIs, and appropriate financial resources must be provided for their long term stability.

The missions and tasks of N(L)MIs include tasks of general interest spread over the long term and services rendered to the administration and to clients on a contractual basis. The financial resources of these institutes must reflect these two kinds of missions.

These institutes are encouraged to enter into international agreements establishing the equivalence of national measurement standards of participating countries. In this case, establishing or revising the national law on metrology should be an occasion to consider the possibilities of legal recognition of traceability to other signatories of the Mutual Recognition Arrangement issued under the International Committee of Weights and Measures (CIPM MRA).

The institutes and authorities responsible for legal metrology missions are encouraged to enter into international agreements establishing the equivalence of the legal metrology systems and controls in the participating countries. They are also encouraged to participate in international legal metrology conformity assessment systems.

The institutes shall be impartial and their funding shall respect the following conditions:

- missions of general interest are financed by public funding; and
- products or services which are in the marketplace do not cause unfair competition.

Element no. 6

The missions of the institutes designated by the Government in application of Element no. 3 shall be defined by the Government.

- those missions that are of public interest shall be funded in an independent way - it could be by the State,
- the financing of activities for which the institute is in competition with commercial bodies should not cause unfair competition.

These institutes shall have the power and resources to enter in negotiation for international acceptance and recognitions in the scope of their activity

3.2.4 Organization of the authorities

3.2.4.1 Public administration and external bodies

It is recommended that, as a minimum, national government manages the national metrology policy, ensures the establishment and maintains an appropriate metrology infrastructure, and defines the regulations and their enforcement.

Technical tasks may be carried out by specialized institutes or bodies which may be public or private. Their operation should be monitored by and reported to the national government.

In practice, the role of the public administration in the implementation of metrology policy depends on the existing infrastructure and competencies in the country. In countries where institutes exist outside the public administration and have sufficient competencies, the tasks of the public administration may be limited to overseeing the activities.

In those countries where public administration bodies have the technical competencies, the metrology policy could include the development of infrastructure in the private sector to take over technical tasks. For example, accredited private calibration laboratories, verification laboratories or inspection bodies could take over appropriate calibration, verification or surveillance activities. However, the public administration needs to maintain competence to draft and enforce technical regulations.

When delegating activities to private bodies, the public administration has to ensure that public interests are protected. This means, for instance, that the private bodies perform these activities in a transparent manner, without conflict of interest and equally accessible for all stakeholders, and that these bodies are accountable to the public administration.

Two ways of delegating tasks to external bodies are possible:

- either to designate a single body,
- or to appoint bodies in competition, any body fulfilling specified requirements being eligible to be appointed.

The choice between these two ways must be carefully studied (which could include consultation with other States operating systems of interest) considering the tasks that are being delegated and the respective advantages and disadvantages of these two solutions (technical consistency, uniform coverage of the geographical area of the country, practicability of supervision of these bodies, risks of corruption, undesirable effects of commercial competition on the quality in running the tasks, positive effects of competition on costs and efficiency, etc.).

3.2.4.2 *Centralized and decentralized missions*

The level of centralization or decentralization is an essential issue of the political organization of the country. In the law on metrology, it will be defined in accordance with the fundamental texts (Constitution), with the political and administrative organization and with the general policy of the country. These higher principles will have to guide the delegation of powers and missions in legal metrology between the central authorities and the local authorities (municipalities, counties, regions within a country, States in a Federation, etc.).

3.2.4.3 *Central Metrology Authority (CMA)*

All the issues of the national metrology policy at the central level (e.g. scientific, industrial and legal) should be managed or coordinated by one single central authority of the country, hereafter called the Central Metrology Authority (CMA) (see 3.2.2.1). It would be inconsistent and inadvisable to have different central bodies in charge of different aspects of the metrology policy without coordination.

The missions of the CMA should be:

- studying the needs of the country for metrology and the orientations and priorities of the national metrology policy, for example with a national consultative committee made up of experts from various sectors,
- elaborating and formulating the national metrology policy that has to be endorsed by the government,
- coordination of the actions of the various ministries related to metrological issues, in order to ensure consistency,
- issuing of legal metrology regulations,
- coordination with the national accreditation system,
- organizing or ensuring international representation of the national metrology bodies and system,
- facilitating international recognition of the national metrology bodies and system,
- co-ordination of all legal metrology institutions, including the Local Metrology Authorities (LMAs),
- issuing the rules for all the local authorities and that those rules should be the same for all users and therefore independent from location and the local authority which is responsible in that special region,
- to establish a committee which is responsible for clarifying and harmonizing interpretations between the local authorities,
- supervision of the national bodies to which technical tasks are delegated, and
- providing appropriate information to the public about the national metrology system.

The CMA should undertake or commission sufficient foresight monitoring and studies to:

- ensure that any relevant changes in national legislation, or legislation of major trading partners, or recommendations from international organizations are identified in a timely manner,

- ensure the work of the NMI remains focused around national priorities, which inevitably change over time.

The CMA is responsible for ensuring consistency of regulations and their application to implement the law on metrology. The CMA should ensure that the following functions are performed:

- assurance that measuring instruments in trade, health, safety, law enforcement and environmental regulation are suitable for their intended use, properly installed, and accurate, and are so maintained by their owner or user,
- prevention of unfair or deceptive dealing by weight or measure in any commodity or service advertised, packaged, sold, purchased, or exchanged,
- promotion of uniformity, to the extent practicable and desirable, among all jurisdictions,
- encouragement of desirable economic growth while protecting consumers through the adoption by rule of legal metrology requirements as necessary to ensure fair competition and equity among buyers and sellers,
- protection of individuals by establishing and enforcing metrological requirements for measuring instruments used in trade, health, safety, law enforcement and environmental regulation,
- establishment of traceability of measurement results through internationally recognized and accepted processes,
- establishment of standards of weights or measures and standards of fill (average or minimum fill requirements) for any packaged commodity; possible establishment of requirements for unit pricing information,
- exemption from the provisions of the law on metrology or any regulations subsequently made when appropriate to the maintenance of good commercial practices, etc.

The CMA may enter into agreements with local jurisdictions to designate officials and prescribe powers and duties - any legal metrology official appointed for a local jurisdiction shall have the duties and powers enumerated in this Act, with the exception of those duties reserved for the CMA and for the national metrology or legal metrology institute(s) by law or regulation. No requirement laid down by local agencies may be less stringent than or conflict with the requirements of the CMA.

The head of the CMA should have the authority to enter into agreements to provide for assistance in the development of requirements for measuring instruments for use by other agencies with regulatory responsibilities, for example in health, safety law enforcement and the environment.

The head of the CMA should have the authority to recognize the legal acceptability of measurement results and measuring instruments established in other countries for importation or use in its own country so as to help reduce technical barriers to trade. In return, the head of the CMA should ensure that national arrangements provide adequate confidence in the results from the national measurement system. The best way of demonstrating that this is the case is through participation in the various international frameworks for acceptance/recognition of equivalence created by the Metre Convention, ILAC and the OIML.

Element 7

The Government shall designate a Central (National) Metrology Authority to be in charge of:

- the implementation of the national metrology policy,
- the enforcement of the legal metrology regulations at national level,
- the coordination of Local Metrology Authorities (see element no. 8)

3.2.4.4 *International relations*

The issues in relation to metrology which imply interfaces with overseas authorities and overseas economies should be coordinated by the CMA. This is the case for intergovernmental treaties (e.g. the Metre Convention, OIML Convention) and for the recognition or non-recognition of the legal acceptability of measurement results and measuring instruments established in other countries. The relationships and engagement with the Regional Metrology Organization and Regional Legal Metrology Organization are also of prime importance. The CMA may delegate responsibility for specific interactions in relation to metrology with overseas authorities and overseas economies to national bodies, such as the national institutions as appropriate.

3.2.4.5 *Local Metrology Authorities (LMAs)*

Implementation at local level will be the responsibility of LMAs, which can be:

- Local offices of the ministries;
- Services of states in a federal organization, organizations or services depending on regional (provincial) or local elected authorities.

Smaller countries may not need local metrology authorities and the implementation may then be taken care of by the national authorities.

Testing, assessing the conformity of, marking for conformity the measuring instruments and prepackages, may be carried out by specialized bodies designated or licensed by the local metrology authorities. Such designated or licensed bodies may be public or private.

The missions of the LMAs should be to:

- implement the Law on Metrology in the field,
- identify contraventions of the law on metrology and prosecute (refer to prosecuting authorities),
- direct and implement the legal control of the instruments,
- support the development of the metrology infrastructure;
- conduct surveillance inspections and verifications on the sale of goods including prepackages and instruments or supervise these functions when carried out by designated or licensed bodies to ensure compliance with the law in metrology and regulations promulgated by the CMA.
- accept for use, and mark, such measuring instruments that are found to be correct;
- reject and order to be corrected, replaced, or removed those measuring instruments that are found to be incorrect. Measuring instruments that have been rejected must not be used unless

they have been corrected and have passed the re-verification when required, and may be seized if this has not been done within any time that might be specified, or if used or disposed of in a manner not specifically authorized. The head legal metrology official or designated agents shall remove from service and may seize the weights and measures found to be incorrect that are not capable of being rendered correct.

3.2.4.6 *Coordination of the LMAs*

The coordination of the LMAs is an essential responsibility of the CMA in order to assure uniform application of the law. When the LMAs are not directly under the authority of the CMA, the law should include provisions to direct this coordination.

Examples of such provisions could be the following:

- Certifications issued by the CMA are accepted by the LMA;
- Instruments, measurement procedures and measurement results accepted by an LMA are accepted by the other LMAs;
- No deviating requirements or interpretations of requirements should exist between LMAs; the CMA may ask an LMA to revise its interpretation of the regulatory requirements when this interpretation appears to deviate from common interpretation;
- The LMAs are represented in intergovernmental work and accept the agreements signed in the intergovernmental organizations.

Element 8

If applicable, the Government shall designate Local Metrology Authorities to be in charge of

- contribution at local level to the implementation of the national metrology policy,
- the enforcement of the legal metrology regulations at local level.

The enforcement of the legal metrology regulations by the local authorities shall be coordinated by the Central Metrology Authority.

3.2.4.7 *Metrology Advisory Board/Council*

The Minister in charge shall set up a Metrology Board which operates as a consultancy body for metrology in the country. The stakeholders should be represented, e.g. the government, CMA, LMA, NLMI, NMI, industry, user of instruments, universities, etc.

The metrology Board/Council should:

- advise on identifying the metrology needs in the country,
- propose the priorities in investments,
- propose scientific and training activities,
- professional clarification in e.g. assessments,
- advise on functional matters.

Element 9

The Government shall install an advisory board/council for metrology, to address, as a minimum, legal metrology.

3.3 Metrological traceability

For the application of any laws and regulations prescribing requirements on measurements, on prepackages and on measuring instruments, traceability to SI (see definition 3.1.2) shall be required.

Element no. 10

For the application of any laws and regulations prescribing requirements on measurements, on prepackages and on measuring instruments, traceability to the realization of the SI shall be required and may be obtained:

- either through the system of national measurement standards and certified reference materials defined in Element no. 4;
- or through traceability to recognized national measurement standards or certified reference materials of other countries when the uncertainty level of the system of national measurement standards is not sufficient or when this system does not cover the considered quantity.

Rules for expressing the results of measurements shall comply with the recommendations of the Metre Convention and the OIML, and relevant international standards.

To establish whether foreign national standards meet the necessary requirements for traceability, reference may be made to the CIPM MRA. Under the CIPM MRA information is available in the Key Comparison Database (KCDB), which is the publicly available database operated by the BIPM for that purpose. Inclusion in the KCDB provides a presumption of compliance with regard to traceability requirements. Where traceability cannot be established via the KCDB the CMA should establish the appropriate mechanism so that regulators have access to appropriate advice on whether alternative solutions are acceptable. Normally such advice would be provided by the NMI.

Element no. 11

Certified calibration results, test results and measurement results established by the national institutes in the scope of their designation shall be traceable to the realization of the International System of Units (SI) and presented in compliance with the recommendations of the CGPM and the OIML, and with relevant international standards

3.4 Legal units of measurement**3.4.1 Legal units**

The law needs to specify for which applications, which units of measurement are authorized to be used or made mandatory. It is not pertinent to include in the law a full definition of the units, as this is a scientific issue which does not need to be voted on. The definition of legal units may refer to international treaties or standards. Detailed definitions of the SI units may be given by referring to standards. Exceptions, units outside the SI and customary units should be defined in a governmental decision rather than in the law.

It should be noted that the definition of the multiples and submultiples of the SI units and their notation is part of the SI system.

Element no. 12

The legal units of measurements are the following:

- units of the "International System of Units" (SI), adopted by the General Conference of Weights and Measures and recommended by the OIML for legal purposes;
- units used for quantities that are not covered by the SI, as specified by a decree of the Government; and
- customary units as decided by the Government.

Customary units may include specific units for particular applications, required:

- by the necessities of international trade; or
- for specific uses such as air or maritime navigation, health care, or military applications; or
- for safety reasons.

When customary units are adopted, their use shall be periodically reviewed to ensure their continued relevance.

3.4.2 Use of units other than legal units**Element no. 13**

The use of units other than legal units is not allowed in trade, commercial transactions, documentation and advertisements for products and services, publications, or training, with the following exceptions:

- documentation of and references to products produced and services carried out prior to the obligation of the units concerned;
- mentioning non legal units in a historical perspective in publications and training; and
- documents and publications which are intended for users in countries having different systems of units.

The use of units other than legal units may be accepted in applications for which international Conventions, Agreements or Treaties prescribe those specific units.

3.5 Transparency of metrological information**Element no. 14**

Those responsible for publishing or transmitting measurement results to the public may be required to provide justifications as to the relevance and reliability of these measurement results.

Individuals and other interested parties may have access to any measurement result issued on the initiative of the government or transmitted to the government, and related to health, public safety, environment and economics, as long as the communication of this information does not cause an undue prejudice to an individual or to a company or other organization.

The government should provide the public with an independent and impartial source of advice about the validity, credibility and reliability of metrological information. The national metrological infrastructure, defined in 3.2.2, shall provide the expertise needed for this advice, and shall be appropriately funded by the government to accomplish this.

Element no. 15

The national metrology institutes defined in Element no. 3 shall be a source of independent and impartial expertise on questions related to the validity, credibility and reliability of metrological information mentioned in Element no. 11.

3.6 Legal metrology

Regulations on measurements, on prepackages and on measuring instruments, as described in this Chapter, may be made in order to:

- protect the interests of individuals and enterprises;
- protect national interests;
- protect public health and safety, including in relation to the environment and medical services; and
- ensure fair trade and level playing fields to promote trade.

These regulations shall, when applicable, be compatible with the International Recommendations of the OIML and make use of their requirements. Other relevant OIML Publications should also be considered.

The conformity assessment procedures required by these regulations should, when applicable, be compatible with the conformity assessment systems set up by the OIML, and, if appropriate, make use of them.

Element no. 16

Regulations made by the Government in application of Element no. 2 shall aim at:

- protecting the interests of individuals and enterprises;
- protecting national interests;
- protecting public health and safety, including in relation to the environment and medical services; and
- meeting the requirements of international trade.

3.6.1 Regulations on measurements

Regulations may be made to:

- define measurement units to be used in legal transactions for various methods of sale;
- prescribe that certain measurements are to be the basis of transactions or law enforcement activities, and
- define the list of measurements subject to legal metrological requirements for the purposes listed in Element 16.

These regulations shall define the metrological requirements (ordinarily including the required measurement uncertainty) and the legal control and supervision provisions applicable to these measurements in order to ensure confidence in the measurement results.

The results of measurements covered by the regulations mentioned in this section shall be expressed in legal units as defined in 3.4.1 and shall be traceable as required in 3.3.

These regulations may specify, when necessary, a measurement method, and may require the use of instruments subject to legal control in application of 3.6.3. When necessary they shall specify the criteria for the choice of instruments such as accuracy class, measurement range, scale division, etc.

When necessary and for specific applications, these regulations may:

- define requirements applicable to the individuals or bodies who perform the measurements;
- require records of the measurement operations to be available to the legal metrology officials;
- require the issuing of certificates for the result of these measurements;
- require records of the traceability of measurement results to be available to the legal metrology officials; and
- define controls to be applied by legal metrology officials or by specialized bodies regarding the activity of the individuals or bodies who perform the measurements.

Element no. 17

Regulations may be made by the Government to define quantities to be referred to in legal transactions for various methods of sale, to prescribe that certain measurements are to be the basis of transactions or law enforcement activities, and to define the list of measurements subject to legal metrological requirements for the purposes listed in Element no. 2.

These regulations shall define the metrological requirements (including the required measurement uncertainty) and the legal control and supervision provisions applicable to these measurements in order to ensure confidence in the measurement results.

When necessary and for specific applications, these regulations may define requirements applicable to the individuals or bodies who perform the measurements and define controls to be applied by legal metrology officials or by specialized bodies regarding the activity of the individuals or bodies who perform the measurements.

3.6.2 Regulations on prepackages

Regulations may be made to set up metrological requirements and legal control provisions applicable to the quantity of product in prepackages offered or presented for sale or sold. In accordance with the OIML Convention and with the WTO/TBT Agreement, these regulations shall be based on the International Recommendations of the OIML as far as possible.

These regulations shall prescribe that the nominal quantity of product in prepackages be labeled on them and is expressed in legal units mentioned in 3.4.1. They may prescribe the authorized values of the nominal quantity of product in prepackages (standard pack sizes), and/or they may require that unit pricing information be provided at the point of sale.

These regulations shall specify the tolerable deficiency of individual prepackages from their nominal value, and requirements for the conformity assessment of prepackages including statistical methods when necessary.

These regulations shall specify the requirements to which the quantity of product in prepackages is subjected to determine acceptance or rejection, including sampling plans, test procedures and statistical methods and other appropriate guidance for legal metrology officials and prepackers.

The regulatory requirements shall take into account the equipment used for realizing and controlling the prepackages, such as measuring container bottles, checkweighers, etc.

These regulations may define the marks which indicate the conformity (compliance) of the prepackages to the regulatory requirements.

These regulations may require manufacturers and importers of prepackages to be registered by the authorities. They may require importers to notify the authorities of importation(s) to facilitate inspections.

These regulations may prescribe that records of the control operations performed by the manufacturer or importer shall be available to the legal metrology officials. They may prescribe that a quality system be applied by the manufacturer or importer of the prepackages when appropriate.

These regulations may define the procedures and criteria for the legal control exerted by legal metrology officials on prepackages and on the sellers, packers, manufacturers and importers of prepackages.

All measurement results involving measuring instruments and measurement standards used for the controls prescribed in application of these regulations shall be traceable to the SI as described in 3.3.

These regulations may allow enforcement authorities to recognize the conformity to the national provisions of prepackages which bear marks of conformity affixed under the legal metrology regulations of other countries or under conformity marking systems set up by international bodies.

Element no. 18

Regulations may be made by the Government to set up metrological requirements and legal control provisions applicable to the quantity of product in prepackages offered or presented for sale or sold.

These regulations shall take account of the Recommendations of the OIML and of the international standards related to prepackages and should as far as possible take into account international systems for the certification of prepackages or for acceptance and/or recognition of prepackage control.

These regulations shall allow enforcement authorities to recognize the conformity to the national provisions of prepackages which bear marks of conformity affixed under the legal metrology regulations of other countries or under conformity marking systems set up by international bodies.

3.6.3 Regulations on instruments and their use

Regulations should be made to define the list of measuring instrument categories subject to legal control for the purposes listed in 3.6.

The instruments subject to these regulations shall provide measurement results in the legal units defined in 3.4, and the measurement results shall be traceable as prescribed in 3.3.

These regulations shall specify the required metrological performance and technical requirements applicable to instruments in these categories.

In accordance with the OIML Convention and, when applicable, the WTO/TBT Agreement, these regulations shall be based on the International Recommendations of the OIML as far as possible.

These regulations shall set up legal control, including supervision, of these instruments. The purpose of this legal control is to ensure that instruments are fit for their intended use, meet and maintain the necessary metrological performance requirements and provide adequate protection against misuse, incorrect interpretations of results and fraud. The regulations shall include the appropriate control and supervision procedures:

- to assess the initial conformity of instruments to legal requirements, at the stage of design (e.g. type evaluation);
- to assess, at the stage of manufacturing, the conformity of instruments to type (when applicable) and the conformity of instruments produced to the legal requirements (e.g. initial verification);
- to ensure that instruments in service maintain their required metrological properties under expected conditions of use and with age (e.g., reverification, in service inspection and field surveillance (see 3.1.12, Note 2), or are withdrawn from use; and
- to ensure that instruments are correctly installed and used and operated under the defined correct conditions (e.g. environmental).

These regulations shall specify the markings and inscriptions which attest to the status of the conformity of the instruments with legal requirements (e.g. type approval marking, verification marking, etc.).

Measuring equipment that no longer conforms to the legal requirements shall be marked as rejected (and/or shall have its verification marks removed) and shall be made to conform, repaired, withdrawn from the market, decommissioned, or removed from use.

In the event of infringements, equipment may be seized pending a decision of the legal authorities, or its further use may be prevented by appropriate means.

To prevent unauthorized adjustments or interventions, the regulations may restrict access to certain parts or functions of the instruments (including software). This access may be required to be physically protected by sealing (or protection of access to the software) defined by the regulations. Alternatively or in addition, the regulations may require that the instruments adequately detect and record any access to these parts or functions.

These regulations may allow the bodies in charge of conformity assessment activities to recognize conformity to the national provisions of instruments that have been recognized to conform with equivalent regulations in other countries. They may allow the bodies in charge of conformity assessment activities to enter into mutual acceptance or recognition arrangements and agreements with other countries with the goal of recognizing national or OIML Certificates or test reports or affixed conformity markings.

These regulations may allow the acceptance and utilization in legal metrology controls, of test or verification results issued in other countries.

The regulations may impose registration requirements and establish requirements for service persons and service agencies that install, adjust and maintain measuring instruments (provided that the regulations do not conflict with other regulatory agency requirements).

These regulation may set verification periods within which measuring instruments must be re-verified.

When instruments are offered for sale, sold, or placed on the market for use subject to legal metrology requirements, the seller must inform the buyer about the legal requirements/status, and offer instruments suitable for the intended use.

No person shall use, have in their possession for use or put into service for applications as stated in Element no. 16, any instrument subject to legal metrological control unless this instrument bears the required control marks and the sealing marks or audit requirements mentioned above.

The owner of or the person/organization responsible for a measuring instrument subject to legal metrology regulations that is in service is required to maintain the conformity of that instrument to legal requirements (including accuracy and including the execution of required legal controls). Owner's use of the instrument must conform with the manufacturer's operating instructions and maintenance requirements.

Element no. 19

Regulations may be made by the Government to set up metrological requirements and legal control provisions applicable to measuring instruments that are used for the applications listed in Element no. 16. Measuring instruments that comply with pertinent requirements and have passed the applicable legal control shall bear a conformity marking.

These regulations shall take account of the Recommendations of the OIML and of the international standards and shall as far as possible take into account international systems for the certification of measuring instruments or for acceptance and/or recognition of evaluation results of measuring instruments.

They shall allow the bodies in charge of conformity assessment activities to enter into mutual acceptance or recognition arrangements and agreements with other countries with the goal of recognizing national or OIML Certificates or test reports or affixed conformity markings.

3.7 Application of the law

3.7.1 Enforcement - General

The enforcement of the regulations taken in application of the law on metrology shall be placed under the responsibility of the Central Metrology Authority and should be carried out:

- for actions at national level, by the Central Metrology Authority,
- for actions at local level, by the Local Metrology Authorities if appropriate (when the size of the country allows it, it may be decided that the Central Metrology Authority will carry out the whole enforcement activities).

Technical tasks necessary for the enforcement of these regulations may be delegated to designated bodies (for example testing or assessing instruments), see 3.7.2 below.

Agents of the Central Metrology Authority and of the Local Metrology Authorities must be duly legally empowered for the enforcement activities that are incumbent on them.

Enforcement may be developed to address the following, escalating options:

- Education;
- Warning;
- Seizure;
- Removal from service;
- Civil penalty (Administrative monetary penalty, name and shame);
- Prosecution.

Some of this could be addressed in legislation, regulation or via policy.

3.7.2 Bodies participating in the application of the law

Element no. 20

- 1 The Central Metrology Authority may appoint bodies to perform tasks pertaining to conformity assessment, verification, or inspection in application of the legal metrology regulations. These bodies shall be competent and impartial. They shall perform their tasks in a non discriminatory manner.
Appropriate accreditations are an acceptable way to show competence and impartiality.
- 2 The bodies appointed in application of this Element shall comply with the relevant parts of Articles 5 and 6 of the WTO/TBT Agreement, with the exception of the obligation to notify proposed conformity assessment procedures.

3.7.3 Surveillance

In addition to the legal metrology procedures and to the supervision and coordination of the activities carried out by the bodies appointed for specific tasks of legal metrology (see 3.7.1), a general surveillance must be exerted by the enforcement authorities.

The surveillance is composed of:

- Surveillance of bodies or persons to which obligations are made by the regulations,
- Market surveillance (see 3.1.12),
- Surveillance of the use of instruments (see 3.1.14).

The purpose of the surveillance of bodies or persons involved in legal metrology activities is to detect non compliances of these persons or bodies with their obligations, for example:

- obligation to put on the market only instruments complying with the regulation when applicable,
- obligation to give notice of installation or repair of measuring instruments when this is required,
- obligation to affix legal marks on instruments and prohibit the removal of required marks
obligation to use measuring instruments according to the regulatory conditions when required,
- prohibit tampering with instruments,

- obligation to submit instruments to regulatory verification when required,
- obligation to have instruments maintained when required,
- etc.

Enforcement must be carried out by or on behalf of the State. It is an essential component of legal metrology.

All the persons subject to regulations under the law on metrology have the obligation to allow enforcement authorities to carry out their surveillance tasks and to provide them with relevant information upon request.

Element no. 21

The Central Metrology Authority shall be in charge of organizing:

- the supervision and surveillance of the bodies to whom tasks have been assigned for the enforcement of the legal metrology regulations,
- the market surveillance (see 3.1.12),
- the surveillance of the use of regulated instruments,
- the surveillance of obligations resulting from the regulations mentioned in elements no. 2, 12, 13, 17, 18, 19.

The division of responsibilities between the Central Metrology Authority and the Local Metrology Authorities, of carrying out these activities shall be laid down in the Legal Metrology Regulations made in application of element 19.

Element no. 22

All the persons subject to regulations under the law on metrology have the obligation to allow enforcement authorities to carry out surveillance tasks and to provide them with relevant information upon request.

3.7.4 Powers of official agents

Element no. 23

Persons in charge of enforcing the provisions of the law on metrology (inspectors) shall be appropriately appointed..

They should be empowered to:

- request the information required in application of Element no. 14;
- exert the legal control on prepackages mentioned in Element no. 18;
- request information with respect to obligations made by the law on metrology to manufacturers, importers, installers, repairers and users of measuring instruments and producers and packers of prepackages, subject to legal control;
- perform inspections on measuring instruments subject to legal control;
- affix rejection marks and/or remove conformity marking in application of Element no. 19;
- perform surveillance on the bodies appointed in application of Element no. 20.

Their findings concerning offences enumerated in 3.8.1 may be transmitted to the administrative or prosecution authorities for further action.

3.7.5 Powers of official agents - right of access

Element no. 24

The legal metrology officials (inspectors) mentioned in Element no. 23, upon presentation of their credentials and in order to discharge their duties, shall have the right of access (within national constitutional requirements) to all industrial establishments or commercial premises or vehicles, where measuring equipment subject to legal control is, or may be installed, kept or used. Also, the officials should have the right to access where prepackages are, or may be filled, labeled, kept or offered for sale.

3.7.6 Powers of official agents - actions

Element no. 25

The legal metrology officials (inspectors) mentioned in Element no. 23 shall be empowered according to the national judicial procedures to issue stop-use, hold, and removal orders with respect to any measuring instruments subject to legal control; and stop sale, hold, and removal orders with respect to any packaged commodities or bulk commodities kept, offered, or exposed for sale.

They shall be empowered according to the national judicial procedures to seize, for use as evidence, without formal warrant, any measuring instrument, package, or commodity found to be used, retained, offered, or exposed for sale or sold in violation of the legal metrology requirements.

They may be empowered to issue non-judicial monetary penalties (civil penalties).

3.8 Offences

The list of offences that result from the non observance of the obligations of the law on metrology should be written, and corresponding penalties should be defined in the penal law or in the law on metrology.

The following offences are suggested.

3.8.1 General

Element no. 26

It shall be an offence to:

- Sell, offer, or expose for sale a quantity less than the quantity represented, as prescribed in regulations (which may account for statistical variation);
- Take more than the represented quantity when, as the buyer, he/she furnishes the weight or measure by means of which the quantity is determined;
- Represent the quantity in any manner calculated or intending to mislead or in any way deceive another person;
- Misrepresent the price of any commodity or service sold, offered, exposed, or advertised for sale by quantity (weight, measure, or count/number), or represent the price in any manner calculated or tending to mislead or in any way deceive a person;
- Misrepresent measurements of quality of products used to determine the price or grade of the product;
- Fail to register when registration is required;
- Not comply with obligations to keep records, or not make them available to legal metrology officials;
- Not comply with corrective actions requested/instructed by legal metrology officials;
- Hinder or obstruct any legal metrology official in the performance of their duties;
- Affix fake or undue conformity marking or verification marks
- Impersonate a legal metrology official.

3.8.2 Related to measurements provided in advertisements or other public communications

Element no. 27

It shall be an offence to:

- Refuse or fail to provide justifications of the measurement results provided in advertisements (or other public communications);
- Provide false or misleading measurement results in advertisements (or other public communications).

3.8.3 Related to the use of legal units

Element no. 28

It shall be an offence to:

- Use other units and symbols than those defined in application of Element no. 12, for the applications defined in Element no. 13.

3.8.4 Related to regulations on measurements

Element no. 29

It shall be an offence to:

- Not perform the legally required measurements and document them when required;
- Not fulfill the metrological (including traceability) requirements prescribed in application of Element no. 17;

- Perform measurements with instruments other than those prescribed.

3.8.5 Related to regulations on prepackages

Element no. 30

It shall be an offence to:

- Sell or offer for sale any prepackage which does not satisfy the requirements of the regulations referred to in Element no. 18.

3.8.6 Related to measuring instruments for which legal control is required

Element no. 31

It shall be an offence to:

- Offer for sale (place on the market), sell or install instruments which do not comply with the legal requirements for the intended use;
- Use instruments (for other than personal use) which have not been submitted to the legal control;
- Use instruments without conforming to their prescribed conditions of use;
- Repair or install regulated instruments without required authorizations;
- Affix false conformity markings or affix conformity markings illegally on measuring instruments;
- Bias measuring instruments to yield an inaccurate result;
- Remove any tag, seal, or mark from any weight or measure or measuring instrument without being duly authorized by the proper authority.

3.9 Responsibilities and duties

3.9.1 General

Element no. 32

In the following, "person" refers to both natural and legal persons (individuals, partnerships, corporations, companies, societies, associations, etc.).

Persons that use or keep measuring equipment covered by national metrology legislation are responsible for having the required metrological controls performed on the measuring equipment which they use or keep.

Persons importing, manufacturing, repairing, selling or hiring measuring equipment intended for uses covered by the national legislation on metrology, are liable for having the required metrological controls performed on the instruments or installations which are the subject of their activities.

3.9.2 Presumption of responsibility

Element no. 33

Whenever there shall exist a weight or measure, measuring instrument or prepackage in or around any place in which or from which buying or selling is commonly carried out, there shall be a presumption that such a weight or measure, measuring instrument or prepackage is regularly used for the business purposes of that place. Whenever there shall exist a measuring instrument subject to legal metrological control used for health, safety or application of environmental regulation in or about any place in which or from which measurements are commonly carried out, there shall be a presumption that such a measuring instrument is regularly used for its intended purpose.

3.10 Conformity assessment procedures

The enforcement of the regulations generally requires the use of appropriate conformity assessment procedures. Conformity assessment procedures may be required:

- at the stage of the design of a type of instrument (see definition of a type),
- at the stage of the production of instruments or prepackages, before placing them on the market,
- at the stage of installing and putting an instrument in service,
- at the stage of repair of an instrument, before putting it back in service,
- during the lifetime of the instrument in use.

Applicable conformity assessment procedures should be defined by an appropriate legal document, in application of the law on metrology (see 3.2.2.2 above).

It is recommended that these conformity assessment procedures be defined according to the guidance given in the publications of the OIML.

When an OIML certification system has been developed, it is recommended that the national conformity assessment procedures take this OIML system into account.

When conformity assessment procedures in another country comply with OIML Documents and Recommendations, and when they refer to OIML requirements, the national conformity assessment procedures should take them into consideration for acceptance or recognition.

The decision to recognize OIML certification systems or foreign conformity assessments as equivalent to the national regulatory conformity assessment should belong to the national legal metrology authority (CMA or NLMI).

The decision to accept and utilize the results of OIML certification systems or foreign conformity assessments in the process of national conformity assessment should belong to the bodies in charge of the corresponding national conformity assessment procedures.

Element no. 34

The conformity assessment procedures defined in application of the regulations shall comply as far as possible with the procedures described in the OIML publications.

The central metrology authority may decide upon the recognition of international or foreign certification systems when they appear to give equivalent confidence.

The bodies in charge of conformity assessment tasks may decide upon the acceptance and utilization in their work, of results of international or foreign conformity assessment systems, providing that the level of confidence is recognized as equivalent to their own procedures.

OIML Recommendations generally present possible conformity assessment procedures.

3.11 Financial provisions

Element no. 35

- 1 The metrological work carried out by the legal metrology authorities may give rise to the levying of official fees for services rendered. A financial regulation may fix the procedures to be followed, the operations for which fees have to be paid and the amount of these fees.
- 2 Fees collected for services rendered may be used for facilities and personnel employed in carrying out established duties.
- 3 The conformity assessment and verification tasks carried out by the bodies mentioned in Element no. 17 shall be performed on demand of the individual or organization responsible for the conformity.

These bodies may be required to inform the authorities of their fee structure. These fee structures may require the approval of the Authority.

The applicant shall bear the costs and/or applicable fees of these tasks.

Part 4 Proposal for regulations in metrology

After defining the national strategy for the metrology system it has to be decided whether the Law on Metrology should cover all areas of metrology with the establishment of a calibration service, etc, or only legal metrology with a nationwide system of verification/conformity assessment bodies.

New developments are described in Parts 2 and 3. One new point is of holding manufacturers of measuring instruments and users responsible for complying with legal requirements as in the past. This approach of ensuring the marketing of legal measuring instruments and correct measurements needs an effective and efficient system of supervision activities. Different aspects of this activity are described by various technical terms such as market surveillance, inspection, conformity assessment, investigation and others (see Part 3.7.3 and OIML Document D 16).

The revisions of a Law on Metrology and mandatory requirements (decrees, binding regulations) should reflect the new developments of

- globalization of trade and services,
- technical developments, e.g. use of measurement systems instead of instruments,
- use of various conformity assessment procedures for verification,
- supervision of the metrology system on a regional or international basis.

Nevertheless, a Law on Metrology is always a national task. In Europe with binding directives for the member countries, the national Laws on metrology are nevertheless all different.

This is because each law has to reflect:

- the culture and history of the country,
- the political system (e.g. central or federal),
- needs of the national economy,
- involvement of private bodies or not, etc.

Other laws like Law on Accreditation, Law on Standardization ... have to be taken into account.

4.1 Proposal to organize a metrological infrastructure by a suitable order of laws, decrees and standards

It is proposed that a “law on metrology” be developed in such a manner that it is considered “enabling legislation”. A law on metrology could address broader parameters that are not subject to change such as administration, offences, rule setting powers, relevant definitions as well as responsibilities or obligations.

More specific matters (technical requirements, inspection frequencies) could be addressed in other instruments such as regulations, specifications, etc.

More detailed regulations for organizations, procedures and technical requirements should be laid down in legal documents like decrees, by-laws, circulars, etc. where ministries and the CMA are responsible for their issuance. Also binding regulations based on OIML-Recommendations, Metre Convention should be approved by the responsible ministry or the CMA.

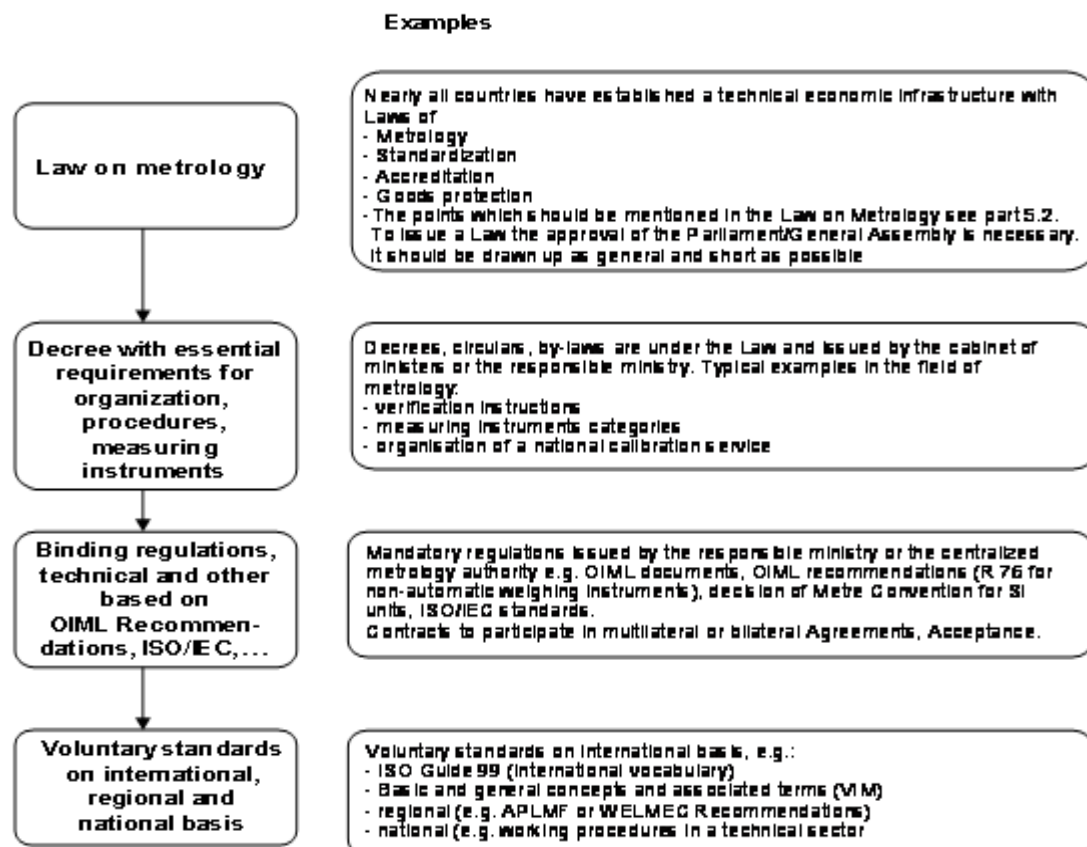
The lowest level in this hierarchy is voluntary standards on an international, regional or national basis.

Element no. 36

The organisation of a national metrological infrastructure should contain

- Law on metrology, Law on accreditation, ... ,
- legal documents like decrees, by-laws, ... ,
- binding regulations,
- voluntary written standards .

4.2 Examples of Order



Part 5 Proposal for the structure of a Law on Metrology

A Law on Metrology should take into account other national laws like Law on Consumer Protection, Law on Accreditation, Law on Standardization ... and international treaties of the country such as WTO/TBT Agreement¹, WTO/SPS Agreement², Metre Convention, OIML Convention, etc.

The government is responsible for

- protecting the citizens,
- guaranteeing free trade with fair measurements,
- supporting industry and services with a metrological infrastructure.

The elements of Part 3 should be (re)worded taking into consideration the legislative drafting practice of the country, the needs, the culture, etc., whilst maintaining their simplicity and clarity.

This Part provides the minimum points which should be dealt with in a Law on Metrology.

The criteria used include:

- obligation by the law of what is mandatory, what is forbidden,
- enforcement practices,
- necessary sanctions,
- notifications,
- status of public bodies participating in the infrastructure.

The preferred structure and the minimum points are as follows.

5.1. Structure of a Law on Metrology

Art. 1: Scope/aim/subject of the Law

Field of applications: to provide the legal base and empowerments for detailed binding regulations in decrees, ordinances ...

See 3.2, element 16 for legal metrology

This law regulates ...

Art. 2: Terms and definitions

Only main and important definitions should be mentioned for the understanding of the law.

See Part 3.1

¹ World Trade Organization - Agreement on Technical Barriers to Trade.
² World Trade Organization - Sanitary and Phytosanitary Agreement.

Reference to the International Vocabulary on Metrology (VIM) and to the OIML International Vocabulary on Legal Metrology (VIML) is useful.

A sentence should be included in the law such as “For terms and definitions not mentioned here the definitions given in the VIM or VIML, respectively, shall apply”, how to deal with this and

“Metrology...”

“Legal Metrology”

“Legal document”

Art. 3. *National strategy and policy*

The national strategy and policy should be clearly stated, e.g.:

- consumer protection, environmental protection,
- official measurements,
- support of national industry including consultancy on technical regulations,
- fair trade,
- international recognition,
- statement on the organization of the infrastructure, including advisory board with representatives of all stakeholders,
- statement on the competence of laboratories on responsible persons,
- education and/or training in metrology,
- mutual recognition of test results or certificates.

See Part 3.2, element 1.

Art. 4: *National metrology infrastructure*

See Part 3.2.2

Art. 5: *Organization of metrology infrastructure*

Information about institutions/organizations/authorized bodies performing metrology activities.

See Part 3.2.2, elements 1 and 2

Art. 6: *Metrology Advisory Board/Council*

Setting up a National Metrology Council composed of qualified personnel to advise the government on metrology issues should be considered.

See Part 3.2.4.7, element 9.

Art. 7: *Transparent availability of measurement results*

Results should be available to legal bodies and individuals having a justified interest.

See Part 3.5, elements 14 and 15

“Measurement results perform...”

Art. 8: *Centralized metrology authority (CMA) including a national metrology institute*

All issues of the national metrology policy and a metrology council at the central level (e.g. scientific, industrial and legal metrology) should be managed or coordinated by one single central authority.

See Part 3.2.4.3 element 7

Art. 9: *Local metrology authorities (LMA)*

Responsibilities and organization of LMAs should be mentioned under this article.

See Part 3.2.4.5

Also local metrology authorities (LMA) should be mentioned.

Art. 10: *Legal units of measurements*

It is recommended to use the units covered by the “International System of Units (SI)”. Units not covered by SI and customary units may be specified by the CMA..

A number of quantities are not covered by the SI (colorimetry, biology, medicine, etc.). They are expressed in units which are not SI units.

See Part 3.4, elements 12, 13.

Art. 11: *National measurement standards and reference materials*

A country should set up national measurement standards according to its needs. When relevant, these national measurement standards will be primary realizations of the SI units (or a copy of the international prototype of the kilogram), and in other cases, the national measurement standards may just be secondary measurement standards traceable to primary measurement standards of another country.

See Part 3.2.2.4, element 4

Art. 12: *Traceability of measurement results*

In the interests of free trade and the avoidance of issues that might be perceived by other countries or the WTO as technical barriers to trade, national requirements for traceability should be written carefully. Ideally traceability should always be specified as conforming to the SI system, through realizations of the appropriate units and quantities at the NMI or at other countries’ NMIs, rather than specifically to the NMI.

To establish whether foreign national standards meet the necessary requirements for traceability reference may be made of the CIPM MRA. Under the CIPM MRA information is available in the

KCDB, which is the publicly available database operated by the BIPM for that purpose. Inclusion in the KCDB provides a presumption of compliance with regard to traceability requirements. Where traceability cannot be established via the KCDB the CMA should establish the appropriate mechanism so that regulators have access to appropriate advice on whether alternative solutions are acceptable. Normally such advice would be provided by the NMI.

See Part 3.3, elements 10, 11

Art. 13: *Calibration/testing laboratories*

For quantities whose traceability can be easily obtained by the users and by calibration laboratories directly to national standards of another country, and when the traceability provided by this direct reference is acceptable to the national accreditation scheme, a national measurement standard may not be necessary.

See Part 3.2.2.7

Art. 14: *Conformity assessment of measuring instruments*

Requirements, procedures of conformity assessment, records of conformance marking, documentary should be mentioned here. Details may be fixed in mandatory regulations.

See Part 3.10, element 34

Art. 15: *Industrial metrology including calibration service*

Organization of a national calibration service, if applicable and not already addressed in a separate Law on accreditation.

See element 11

Art. 16: *Legally controlled measuring instruments*

- regulations,
- applications including list of measuring instruments belonging to the field of legal metrology,
- special items like precious metals,
- marking,
- stamps, seals,
- responsibility and powers,
- liability of persons and corporate bodies.

Details should be laid down in decrees ...

See element 2

Art. 17: *Regulations on measurements, responsibilities of authorities, manufacturer, user*

Confidence in measurement results requires statement of uncertainty, environmental conditions, proof of traceability, etc.

See Part 3. 6.1, element 17

Art. 18: *Regulations on prepackages*

If applicable, i.e. in case that the chapter on prepackages will be included in the Law on metrology. Essential information on items like marking, unit price, etc. shall be given.

See element 18

Art. 19: *Regulations on precious materials (e.g. gold, gemstones) or regulations on gambling or voting machines, if applicable*

See Part 3.2.1

Art. 20: *Measuring instruments/systems in legal metrology*

- conformity assessment of instruments(type approval, initial and subsequent verification)
- market surveillance
- withdrawal from use
- bodies in legal metrology
- database of verified instruments

See Part 3.6

Details should be laid down in decrees,...

Art. 21: *Placing measuring instrument on the market*

Scope, requirements, conformity assessment procedures, use of instruments (responsibility of manufacturer, owner/user)

See Part 3.6.3

Art. 22: *Inspection/supervision/surveillance*

This is the task of governmental bodies or on behalf of the government.

See Part 3.7, elements 21, 22, 23, 24, 25

Art. 23: *International agreements*

Operating with foreign countries, recognition of certificates issued abroad.

See Part 3.2, element 6, 11, 19, 20

Art. 24: Enforcement

Enforcement of the regulations.

See Part 3.7.1

Art. 25: Fees, financial provisions

See element 35

Art. 26: Offences

The paragraphs must be explicitly mentioned, the non-observance of which will be penalized.

See Part 3.8

See elements 26, 27, 28, 29, 30, 31

Art. 27: Fines and penalties

Fines and penalties should be severe enough in order to prevent repetition. Publication of offenders could be a useful means ("name and shame" approaches).

Art. 28: Coming into force, transition period

The transition period should be long enough to avoid unacceptable high financial losses and/or to allow for adequate adaptation to the new regulations.

Part 6 References

- [1] WTO Agreement on Technical Barriers to Trade (TBT), January 1995
- [2] OIML B 1:1968: Convention establishing an International Organization of Legal Metrology, 1955
- [3] OIML V 2-200:2010: International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM), 3rd Edition 2007, corrected version
- [4] OIML V 1:201x: International Vocabulary of Terms in Legal Metrology (VIML)
- [5] BIPM: The International System of Units, 8th Edition, 2006
- [6] OIML D 2:2007, Legal Units of Measurement
- [7] OIML G 1-100:2008: Evaluation of measurement data - Guide to the expression of uncertainty in measurement (GUM)
- [8] OIML E 2: 2003: Benefit of Legal Metrology for the Economy and Society.
- [9] OIML D 16:2011: Principles of assurance of metrological control.

Other OIML documents or Documents issued by other International and Regional Metrology Organizations may be of great importance