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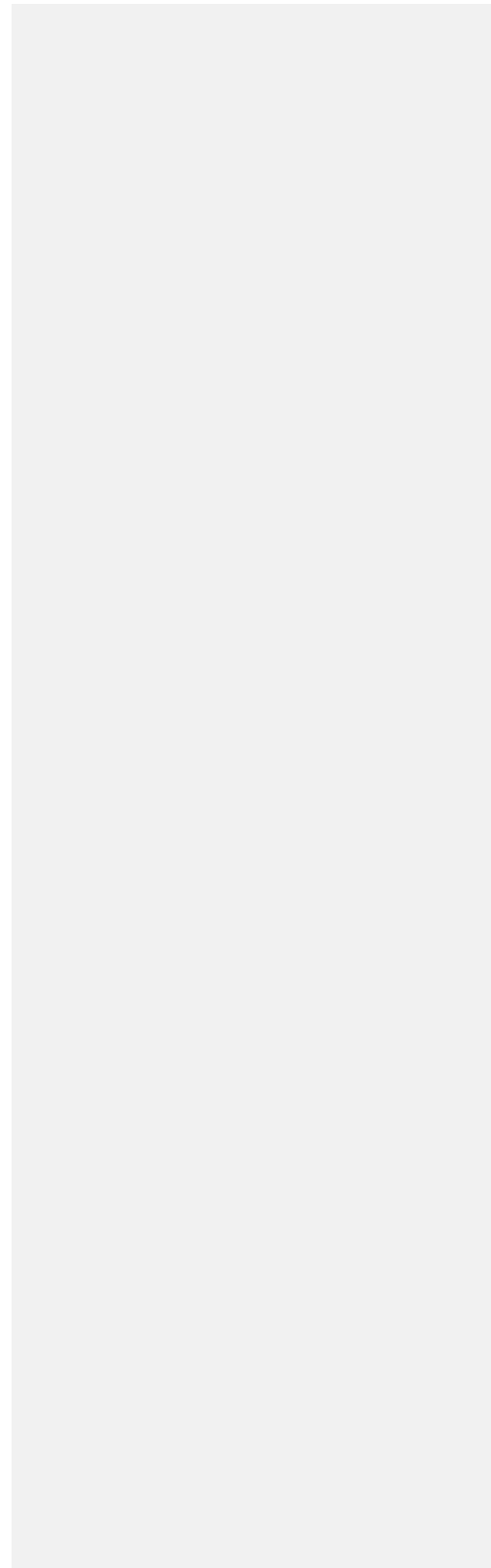
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National Metrology Systems
Developing the institutional and legislative framework

[titre en français]

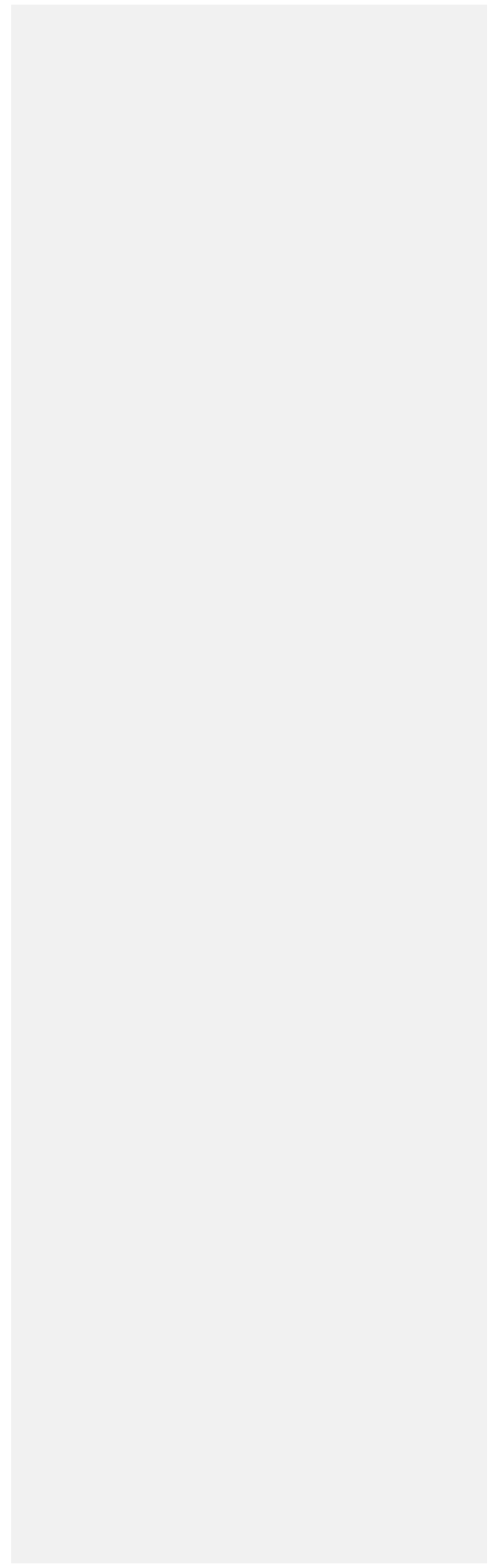


ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

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Foreword [Latest version to be used on publication]

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

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

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

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

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

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

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

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

This publication – reference OIML D 1, edition 2020 (E) – was developed by OIML and BIPM through a Project Group formed from the OIML's *Advisory Group on matters relating countries and economies with emerging metrology systems*. It was approved for final publication by the International Committee of Legal Metrology at its XXth meeting in [], in [] and supersedes the previous edition dated 2012.

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 International Document, produced jointly by the International Organization of Legal Metrology (OIML) and the Bureau International des Poids et Mesures (BIPM), gives advice to national authorities on the issues they should consider when producing policies aimed at developing the national metrology systems, setting up the institutions dealing with metrology within their jurisdictions and drawing up national laws related to metrology. The need for this 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.

A country's metrology system is a key part of its National Quality Infrastructure (NQI). Like a national metrology system, the wider quality infrastructure consists of both public and private institutions and the regulatory framework within which they operate. However, although there are often specialist metrology institutions involved, metrology should still be seen as an integral part of a National Quality Infrastructure. For instance, there are metrology elements in all the various components of an NQI:

- the physical measurements standards on which traceability chains are built;
- the written standards that guarantee the performance of measuring instruments or have measurement requirements within them;
- the various forms of conformity assessment that can be applied to measuring instruments or for other product quality purposes, including, certification, testing, inspection and market surveillance;
- the management standards written for such conformity assessments, often applied through the process of accreditation.

The relationship between a national metrology system and the rest of the Quality Infrastructure is discussed further in 3.5.

Legislation will usually be an important part of how these policies and institution are put in place and the Document provides both a checklist of the elements which should be considered when drawing up legislation (Annex A) and a Model Law which authorities may wish to use for this purpose (Annex B). The legislation used by authorities may either be one general law covering all legal aspects of metrology or separate laws, each related to a specific aspect of metrology. Relevant provisions may be also found in other laws or binding regulations, such as a regulation on legal units of measurement, legislation on metrological traceability, on measuring equipment (weights and measures act), etc., or provisions related to metrology and measurements in more general legislation such as laws on consumer protection or conformity assessment.

The authorities responsible for drawing up such laws are encouraged to select the appropriate Elements, examine their relevance 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", etc.

This Document is presented in eight parts:

- Part 1 – Introduction
- Part 2 – Explanation of the importance of metrology
- Part 3 – Consideration of the concept of a national metrology system and its place in a wider quality infrastructure
- Part 4 – Examination of the international aspects
- Part 5 – Examination of the role of government and discussion of the policy options available to national authorities
- Part 6 – Discussion of the options when legislating for metrology
- Part 7 – Developing a metrology system for the future
- Part 8 – References

While the priority for national authorities will be to address the regulated sector, many of these suggestions

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in this document also relate, and are applicable, to best internationally accepted metrology practice in the non-regulated sector.

Part 2 – The importance of metrology

2.1 What is metrology?

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

2.2 The scope of 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 reliable 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.

Metrology has a particular role to play 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 and virtually all countries provide such protections through their legal systems. Furthermore, since there is an increasingly global aspect to many of these areas involving measurement, countries need to take this global aspect into account as far as possible.

There are also other benefits for 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, and
- support of trade in measuring instruments.

2.3 The role of law

Laws and legal requirements interact with metrology in two main ways:

First, laws often provide the framework in which metrology in a country or economy operates - for instance, requiring the use of specific measurement units for certain purposes, establishing the authority of a National Metrology Institute, providing the basis for public funding of a national measurement system etc.

Second, many regulations relating to trade (e.g. consumer protection), health, safety and environmental protection set measurement-based requirements and indeed requirements for measuring instruments used for such purposes. **It is this second area which is most usually regarded as “Legal Metrology”.**

Where a country decides to cover all or most of these aspects through a general Law on Metrology it should be as compact and as simple as possible, while providing enough detail to address the country's policies involving measurement. It should provide sufficient 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 in a country's Law on Metrology.

2.4 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.

Examples:

Parts manufactured in one country fit into machines in another country;

A device tested and approved for use in one country may also be sold and used in another country, without duplication of testing;

A prepackage labelled "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. For instance, higher-precision manufacturing techniques require higher-precision measuring techniques in order to be able to control manufacturing and assembly processes, such as for mechanical micro- and nanostructures

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 litre of gasoline, it is expected that one litre 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 citizens, 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 such as 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 the reliability of medical measurements helps to better determine whether there is a real need for medical treatment. For example, a 10 % error in the determination of cholesterol levels

implies that 13 % of the population is not receiving treatment although they should, and 20 % would be unnecessarily exposed to this treatment, including its adverse side effects.

The continued refinement of methods aids in 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:

Atomic clock research helps to improve satellite navigation systems.

Electricity meters with (near) real-time data (smart meters) lead to greater efficiency through smart grids, and rationalized consumption with accessible energy usage data.

Improved reliability and/or sensitivity of sensors provides more accurate and adequate data for close control of industrial processes, thus increasing efficiency and reducing waste.

Support concerning the feasibility of research on the metering of new energy sources (such as biofuel, liquefied natural gas, etc.) is provided.

2.5 The need for an efficient metrological infrastructure

It is important that a country has an efficient and appropriately funded metrological infrastructure because no quantity can be correctly and consistently measured without metrology.

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.

Reliable and consistent measurement is an essential requirement for virtually all conformity assessment processes, including those which support health, safety and environmental objectives. It is also important for the international recognition of those measurements, which is an essential aspect within the world trading system. [Some activities undertaken by metrology bodies are themselves conformity assessment activities (e.g. verification, etc.).]

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.

2.6 The requirements of legal metrology

As noted in 2.3, law and legal requirements interact with metrology in two different ways and this is reflected in the definition of legal metrology included in the *International vocabulary of basic and general terms in metrology* (VIM) which describes legal metrology as the practice and the process of applying regulatory structure and enforcement to metrology.

For the purposes of this Document, “Legal Metrology” is taken to comprise all the activities for which legal requirements are prescribed on measurement. It thus includes prescribed units of measurement,

requirements on the use of measuring instruments or systems and methods of measurement, and activities 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, metrological traceability and treatment of measurement uncertainty ('decision rules'). It may apply to any quantity addressed by metrology.

This aspect of 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. which types of measurements and measuring instruments or systems are subject to legal requirements) will depend on those markets that are important to the economy, on the categories of users that the government considers necessary to protect, and on the ability of these users to protect themselves against abuse.

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.

Part 3 – The concept of a National Metrology System and its place in the wider National Quality Infrastructure

3.1 National metrology system –overview

A national metrology system is best understood as comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the metrology activities undertaken within a country or economy.

It is important therefore to begin with a clear understanding of the various metrology activities that need to be catered for. These include activities traditionally considered as falling into the areas of scientific metrology, industrial metrology and legal metrology but it should be noted that in practice there is substantial overlap between the activities in these three areas.

Activities that need to be catered for include:

- a) Setting the national policy on the structure and funding of public metrology institutions and the development of private metrology sectors;
- b) Setting metrology within the national policy for Quality Infrastructure so that the public good bodies responsible for metrology, standards and accreditation work in a complementary way*;
- c) Setting the national policy of the areas to be regulated and the regulatory techniques to be used;
- d) Setting the national policy on engagement with international and regional metrology bodies;
- e) Setting the national policy on public funding of research into new or better measurement techniques;
- f) Drafting metrology laws and regulations*;
- g) Maintaining and disseminating national measurement standards;
- h) Maintaining and disseminating certified reference materials;
- i) Conducting research into new or better measurement techniques;
- j) Providing technical advice;
- k) Operating Type Approval Controls (including registration of instruments used for regulated purposes)*;
- l) Carrying out testing and evaluation for Type Approval Control purposes*;
- m) Verification of regulated instruments*;
- n) In-service inspection of regulated instruments*;
- o) Other “post-market” surveillance of regulated instruments*;
- p) Calibration;
- q) Other testing of measuring instruments;
- r) Training and testing of metrologists.

Policy-making (i.e. activities a) to e) in the above list) is by definition the exclusive role of Governments, although it will usually be desirable to develop policies in consultation with the other bodies and companies providing metrology services and with the users of the metrology system.

With the other activities, it is helpful to distinguish between those activities that are mainly concerned with legal metrology (marked with an asterisk) and those which are mainly concerned with scientific and industrial metrology. In addition, it is possible to identify two tiers of activity, similar to the two tiers which can be identified in other parts of the Quality Infrastructure. The first tier is concerned essentially with the development and dissemination of standards, which in the context of metrology comprises both written standards (including mandatory standards in the form of regulations) and physical standards. The second

tier is concerned essentially with the application of those standards, in many cases involving various forms of conformity assessment.

The relationship between the various activities in these two areas is shown in the following diagrams (Figures 1 and 2):

Tier 1 – Policy and Legislation	
Responsibility for regulation policy	
Responsibility for legislation	
Responsibility for international representation in matters related to legal metrology (at the highest level)	
Advice on metrology legislation and on relevant standards	
Tier 2 – “Enforcement”	
Pre-market	Post-market
Type approval	Market surveillance (import and distribution)
Testing and evaluation for type approval	Testing for market surveillance
Conformity to Type <ul style="list-style-type: none"> • Pre-market verification • Testing by authorised persons • Testing to support self-declaration 	Verification <ul style="list-style-type: none"> • Initial verification on putting into use • Reverification In-service inspections

Commented [B1]: First line “Responsibility for regulation policy” – add “(including regulatory compliance strategies)”

Figure 1 – Legal metrology activities

Tier 1 – National standards	
Maintenance and dissemination of national measurement standards	
Maintenance and dissemination of certified reference materials	
Responsibility for international representation in matters related to scientific metrology (at the highest level)	
Research into new methods of measurement	
Tier 2 – “Industrial metrology”	
Service providers	“In-house”
Calibration laboratories	Calibration laboratories
Conformity assessment to support self-declaration	Testing for internal assurance
Advice to support innovation	In-house research
Contract testing	
Training of third parties	Internal Training

Figure 2 – Scientific and industrial metrology

For a national metrology system as a whole, Figure 3 illustrates the various components:

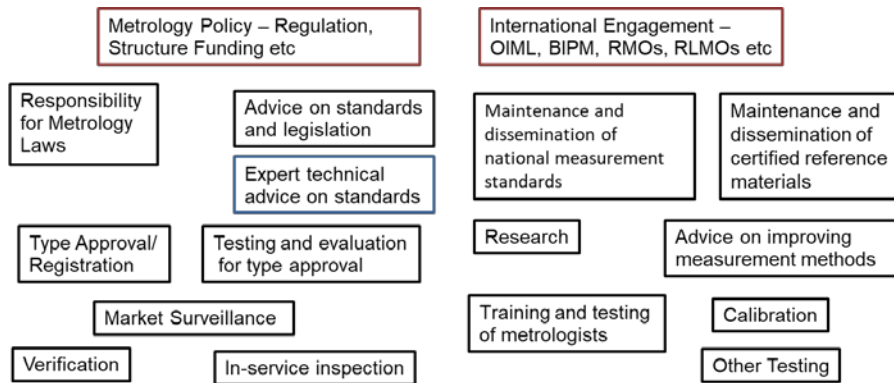


Figure 3 – Metrology activities

{An additional diagram – Figure 4 – will be discussed at the PG meeting on 12/13 March 2020}

As already noted, the concept of a national metrology system embraces:

- Institutions, both public and private, carrying out metrology activities
- Policies to be carried out by those institutions, preferably brought together in a national metrology policy, and
- Legal and regulatory frameworks

together with practices which support and enhance metrology activities.

3.2 Institutions

3.2.1 Central Government Authority

At the centre of a national metrology infrastructure there should be an authority in Government in charge of the national metrology policy, and of coordinating the actions of other departments related to metrological issues. This can be arranged in a number of ways by Government. For clarity, in this document we refer to this authority, however it is organized in practice, as the 'Central Government Authority'.

This authority should be responsible for

- consulting with the other Departments for the elaboration of the national metrology policy and reaching a consensus on this policy,
- ensuring that laws and regulations relating to metrology take account of and are in accordance with relevant international provisions relating to metrology,
- ensuring that the laws and regulations do not prevent the national bodies and authorities from entering into international agreements/arrangements, and
- ensuring that the national metrology policy is appropriately linked to a wider quality infrastructure policy.

Because metrology is relevant to a wide variety of Government activities, this authority 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, and

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.

3.2.2 National Metrology Institute (NMI)

An NMI has the responsibility of developing and maintaining national measurement standards and disseminating the SI units. To aid international recognition of national measurement standards and the associated measurement capabilities, NMIs participate in international comparisons of measurement standards under the CIPM MRA (Mutual Recognition Arrangement) framework. In some States, NMI functions are not restricted to a single entity. They may have a distributed system where a number of different metrology institutes develop and maintain national measurement standards in their own specialised fields and work collectively. Today, the NMIs of the industrialised countries serve as the national focus of measurement science, providing leadership to nationwide and worldwide scientific cooperation relating to metrology.

Collectively, and within the framework of the Metre Convention, the objectives of the metrology community worldwide are to ensure that:

1 Measurements are **accurate**

An expressed value can be as close to the true value as possible

2 Measurements are **stable**

Long-term trends can be detected by sufficient accurate measurements for decision-making

3 Measurements are **comparable**

Results from different laboratories can be brought together

4 Measurements are **coherent**

Results from different methods can be brought together.

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 and the NMI will be one of the main institutes in charge of developing this competence and other tasks assigned at the national level under a metrology policy.

It is the function of an NMI to be in charge of

establishing metrological 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 that are metrologically traceable to the SI via a foreign institute,

disseminating the units, which involves providing metrological traceability to the national references for calibration laboratories, that is the provision of calibration services either to a national network of (typically commercial) calibration laboratories, or in the smallest economies, directly to the users in industry and elsewhere,

participating in related international activities, e.g. comparisons,

ensuring the international recognition of calibrations (and thus test) so as to avoid technical barriers to trade through participation at regional and international level in the international recognition systems operated by ILAC and/or the BIPM,

carrying out development work on the improvement of national references,

where possible, undertaking research activities to prepare for the next generation of metrology standards,

providing the necessary advice and support to the government, industry, commerce and the public on metrological issues,

providing a sound metrological basis for the national accreditation scheme, including the provision of experts for assessments,

providing expertise through national, regional or international standards developing organizations (i.e. for documentary standards) to ensure appropriate treatment of measurement issues.

The NMI will also be the most suitable means for government to provide the public with an independent and impartial source of advice about the validity, credibility and reliability of metrological information. It ought to have the expertise needed for this advice, but will need to be appropriately funded by the government to accomplish this.

Ideally a country will establish a single national institute covering all of its needs. However, for a variety of reasons this may not always be practical, in which case NMI functions may be carried out by more than one organization. These may include standards laboratories which are part of a university or other scientific institute or organizations having a different ownership or legal status. This can occur, for instance when countries have traditionally distributed responsibility for different quantities/units among different institutes or when metrology encompasses activities outside the traditional physics and engineering base and moves into the fields such as chemistry, medicine, food, etc. Furthermore, whilst there are considerable advantages in having all of the country's primary capability in a single institute, a distributed organization allows small or developing countries to make use of the existing competencies and capabilities. However, participation in the international recognition system (the CIPM MRA) requires a degree of national coordination. For the purposes of the CIPM MRA one institute is typically appointed as the National Metrology Institute for the country, with the others acting as "Designated Institutes" within the meaning of the Arrangement. This does not necessarily indicate any national hierarchy. In all cases it is important that there are adequate arrangements for co-ordinating the activities of these institutes, in particular as regards their input into BIPM's work, either by a principal institute or by an agency.

NMIs are nearly always entirely within the public sector, although other models do exist. Recent policies have recognized the benefits of giving NMIs, even in the public sector, a degree of management freedom that is appropriate for the efficient and effective running of a research-based organization with services to the public. The issues which this raises are discussed in 5.3.1.

Where the required expertise is wholly within an industrial or commercial organization(s), governments typically 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 that country (care is needed to avoid confusion between the use of the term 'designated' at national level, and the very specific meaning within the CIPM MRA). 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" NMI.

An NMI may thus 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; or
- a public agency coordinating public or private institutes.

In all cases, the institutes should be impartial. Special attention must also be paid to the sustainability of the NMIs, and appropriate financial resources must be provided for their long term stability. This is best achieved when NMI funding respects 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.

In practice most Governments arrange matters so that the majority of NMI funding comes from public sources.

For an NMI (or DI) calibration and measurement capabilities to be recognized within the CIPM MRA the laboratory must operate a quality management system complying with the appropriate international standards, namely ISO/IEC 17025 (and if the laboratory produces reference materials, ISO 17034). Accreditation of NMI measurement services is not required by the CIPM MRA, though many NMIs are accredited. The decision to accredit or not rests with the NMI (or their governing ministries).

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.

Small countries may wish to consider setting up a regional infrastructure with one or more neighbouring countries.

3.2.3 Legal Metrology Authorities

In addition it is necessary to make arrangements for national authorities or institutes to carry out a variety of legal metrology activities, such as studying technical specifications for legal metrology, issuing type approvals and providing technical coordination and support to other legal metrology bodies.

At the national level, it is necessary to have provision for

- providing the necessary advice and support to the government, industry, commerce and the public on legal metrology issues,
- 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 in legal metrology for other bodies in charge of legal metrology activities.

In many countries some or all of these functions are carried out by the NMI. In other jurisdictions, such activities may be distributed among several institutes or authorities specializing in different fields under an appropriate coordination.

In all cases, however, it is highly recommended to develop the synergies between scientific and legal metrology activities. This is considered further in Part 5 – .

3.2.4 Local legal metrology authorities

Many legal metrology activities require implementation at a local level. This may be the responsibility of

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

specialized bodies designated or licensed by local or central metrology authorities. Such designated or licensed bodies may be public or private.

Specialized bodies may be considered where there is a need for testing, assessing the conformity of, and marking for conformity either measuring instruments or prepackages.

The mission of local legal metrology authority (LLMA) should be to

- implement the Law on Metrology through interactions with individual businesses,
- identify contraventions of the Law on Metrology and prosecute (refer to prosecuting authorities),
- direct and implement the legal control of the instruments,
- 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 on Metrology and regulations promulgated by the Central Government Authority,
- accept for use, and mark, such measuring instruments that are found to be correct, and
- 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 should remove from service and may seize any weights and measures found to be incorrect that are not capable of being rendered correct.

In some cases it may be appropriate for LLMA's to have a role in supporting the development of the metrology infrastructure.

The question of which activities should be performed by national authorities and which are appropriate for decentralization is essentially a matter of the political organization of the country. This is considered further in Part 5 – .

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

3.2.5 Private sector providers of metrology services to industry and to the economy

In the same way as the economy and industry need infrastructures such as road, railways, ports, airports, banks, etc., metrological services to industry and to the economy are essential for ensuring economically sustainable development. In some cases services below the national laboratory level may be provided by public authorities or institutes but in many countries these services are supplied by the private sector.

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;
- third party experts to be consulted in case of disputes.

The adequacy of provision of these services will be an important element in any national metrology policy (see 3.3) should address these needs. Actions of the State may be required to support these structures.

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

The competence of metrologists in all parts of the National Metrology System, including metrologists working in manufacturing and other parts of the economy, has a major impact on the effectiveness of the system. A national metrology infrastructure therefore needs the 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 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, and
- regular and effective engagement by national experts in the appropriate international metrology fora, which will also help ensure that knowledge disseminated within the country is up to date and of the highest calibre.

The national metrology policy (see 3.3) should address these needs. Actions of the State may be required to support these structures.

3.2.7 Co-ordination and co-operation in the metrological infrastructure

The range and complexity of the metrology activities undertaken in a modern economy, the diversity of areas and sectors involved, the number of institutions and bodies which participate in the national metrology systems and the variety of Government interests affected mean that effective arrangements for co-operation and co-ordination are required. Co-ordination is also needed with the other key elements of the Quality Infrastructure, that is the National Standards Body and the National Accreditation Body. This may include arrangements to oversee the implementation of the national metrology policy (see 3.3), to co-ordinate the activities of the various parts of the national measurement system, to secure liaison between central and local authorities, and to engage stakeholders (e.g. a Metrology Advisory Board/Council). These matters are further considered in 5.4.

3.3 National Metrology Policy

Developing a National Metrology Policy should be the responsibility of a lead government department. It should begin with the preparation, in cooperation with all other departments of a report on the status of metrology in the country and should take the form of 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 the academy of science, and/or international experts.

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);
- the number of institutes performing NMI functions and the way responsibilities are allocated;
- development of the effort for 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 a Member State of the OIML and a full member of the BIPM, or Corresponding / Associate Member;

becoming full or associate members of a relevant regional metrology or regional legal metrology organization;

coordination with the national standards body and the national accreditation body.

3.4 Legal and Regulatory Frameworks

3.4.1 Legal requirements – general

As noted in 2.3, laws and legal requirements interact with metrology in two distinct ways, first in providing the framework in which metrology in a country or economy operates and second through regulations relating to trade, health, safety and environmental protection which set measurement-based requirements and indeed requirements for measuring instruments used for such purposes. For the purposes of a National Measurement System this can be approached as a single legal corpus, comprising all the laws and regulations that have provisions related to metrology.

The content of this legal corpus is discussed further in Part 6 – and Annexes A & B.

3.4.2 System of national measurement standards and dissemination of legal units

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

National standards may be primary realizations of the definition of units. However if the very best uncertainties are not needed, many countries choose to hold national standards that are not primary. Such national standards need to be metrologically traceable, through a calibration under the CIPM MRA, to the primary realizations maintained by another country. In either case regular comparison with standards held by the NMIs of other countries should be performed, utilizing the infrastructure established for that purpose by the BIPM and Regional Metrology Organizations.

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

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

Small countries may wish to consider setting up a regional infrastructure with one or more neighbouring countries.

3.4.3 A 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 non-profit 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 the 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 the 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 it 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 an NMI, but which are in charge of the implementation of legal metrology activities.

3.4.4 Metrological traceability

Metrological traceability to the SI (see definition in Annex C) is required for the application of any laws and regulations prescribing requirements on measurements, on prepackages and on measuring instruments,.

Rules for expressing the results of measurements should comply with the recommendations of the BIPM and the OIML, and relevant international standards.

To establish whether foreign national standards meet the necessary requirements for metrological 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 regarding traceability requirements. Where metrological traceability cannot be established via the KCDB the Central Government Authority 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. This approach is supported by the Joint Declaration on Metrological Traceability adopted by BIPM, OIML, ILAC and ISO in 2011 and reaffirmed in 2018.

3.5 The place of a metrology system in a wider national quality infrastructure

A country's metrology system is a key part of its National Quality infrastructure (NQI). A Quality Infrastructure in this context should be understood as the system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes, which rely on metrology, standardisation, accreditation, conformity assessment, and market surveillance.¹

The "infrastructure" thus includes both public and private institutions and the regulatory framework within

¹ Taken from the DCMAS (now INetQI) definition adopted in July 2017

which they operate.

A well-functioning quality infrastructure is required for the effective operation of domestic markets, and its international recognition is important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing. It is essential to a modern approach to regulation because of the role which standards can play in supporting technical regulation and because of the role that both voluntary and mandatory conformity assessment plays in ensuring that regulations are effective. This is particularly significant in regulations on trade-related activities, consumer protection, etc. For this reason most countries have established a national quality infrastructure.

Although there are often specialist metrology institutions involved, metrology should not be seen as a separate part of a National Quality Infrastructure. On the contrary, there are metrology elements in all the various components of an NQI:

- the physical measurements standards and capability on which traceability chains are built;
- the written standards that guarantee the performance of measuring instruments;
- the various forms of conformity assessment that can be applied to measuring instruments, including calibration, certification, testing, inspection and market surveillance;
- the management standards written for such conformity assessments, often applied through the process of accreditation.

The way in which metrology touches every part of an NQI is illustrated in Figure 5.

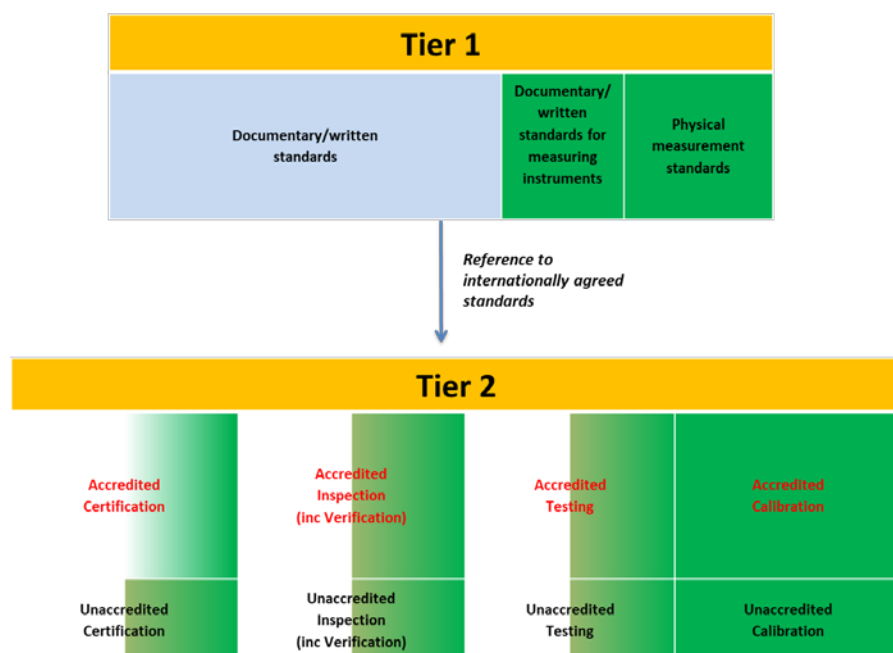


Figure 5 – Metrology as part of a National Quality Infrastructure

[alternatives to this diagram are still under discussion]

The fact that changes to an approach to metrology can be reflected in so many parts of an NQI, and that metrology is usually delivered through long-established specialist institutions, means that reform of a country's metrology systems is often a good starting point for the modernisation of the whole of the Quality

Infrastructure.

In addition to the importance of an NQI to regulation, it can also facilitate market and consumer driven responses to quality problems. For instance, consumers often use quality marks from product certifiers as a guide when making purchasing decisions. In addition, their attention is drawn to the area in a negative way when failures of standardisation become apparent, for example, when technical equipment cannot be connected abroad.

Part 4 – International aspects

Commented [B2]: This has been moved to the beginning of the current Part 5.

4.1 Need for compatibility between national and international metrological requirements

Each nation has its own historical perspective on the development of metrological requirements. However, the Technical Barriers to Trade (TBT) Agreement (Article 2.4), implemented within the World Trade Organization (WTO), makes it 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.

4.2 International metrology organizations

4.2.1 Introduction

In November 2018, the BIPM, the OIML, ILAC and ISO reaffirmed a joint declaration on metrological traceability (with minor updates from the original, signed in 2011). This was a development of a 2006 tripartite agreement among BIPM, the OIML and ILAC. The declaration sets out agreed principles to be followed in order to achieve metrological traceability of measurements; this element is one of several that establish international confidence in the equivalence of measurements. These principles enable legislators, regulators and exporters/importers to take advantage of an international set of mutually supportive systems that demonstrate equivalence of measurements and can therefore significantly reduce technical barriers to trade (TBTs) that might result from lack of equivalence. The declaration also contains brief statements on the roles of the various signatories that may be read in conjunction with the descriptions of the organizations in the remainder of this chapter.

4.2.2 The Metre Convention

The BIPM is the intergovernmental organisation established by the Metre Convention, through which Member States act together on matters related to measurement science and measurement standards. The BIPM operates under the exclusive supervision of the International Committee for Weights and Measures (CIPM) which itself comes under the authority of the General Conference on Weights and Measures (CGPM) and reports to it on the work accomplished by the BIPM.

4.2.2.1 Mission and role of the BIPM

The mission of the BIPM is to work with the NMIs of its Member States², the RMOs and strategic partners worldwide and to use its international and impartial status to promote and advance the global comparability

² The official term is "States Parties to the Metre Convention"; the term "Member States" is its synonym and used for easy reference.

of measurements for:

- Scientific discovery and innovation,
- Industrial manufacturing and international trade,
- Improving the quality of life and sustaining the global environment.

The BIPM, under the responsibility of the International Committee for Weights and Measures (CIPM) publishes the “SI brochure”, which is an essential reference document for the application and correct use of the SI units.

4.2.2.2 General Conference on Weights and Measures (CGPM)

The CGPM is the plenary organ of the BIPM, which consists of the delegates of all the contracting Governments. Associates of the CGPM have the right to participate in meetings of the CGPM as non-voting observers. The General Conference receives the report of the CIPM on work accomplished; it discusses and examines the arrangements required to ensure the propagation and improvement of the SI; it endorses the results of new fundamental metrological determinations and various scientific resolutions of international scope; and it decides all major issues concerning the organisation and development of the BIPM, including the dotation of the BIPM. The CGPM meets in Paris, usually once every four years.

4.2.2.3 International Committee for Weights and Measures (CIPM)

The CIPM is the organ that exerts the exclusive direction and supervision of the BIPM. It is placed under the authority of the CGPM. It is composed of 18 members, each of a different nationality. The CIPM meets once or twice a year to, among other matters, discuss reports presented by its Consultative Committees, oversee the progress of the decisions of the CGPM and the BIPM Work Programme, take decisions on various issues, and follows them up. A “bureau” of the CIPM is set up as a restricted collegial organ of the CIPM, composed of the President, the Secretary and two Vice-Presidents, and supported by the Director of the BIPM.

4.2.2.4 CIPM Consultative Committees (CCs)

The CIPM is aided by a series of Consultative Committees. The objectives of the CCs are:

- to progress the state-of-the-art by providing a global forum for NMIs to exchange information about the state of the art and best practices,
- to define new possibilities for metrology to have impact on global measurement challenges by facilitating dialogue between the NMIs and new and established stakeholders, and
- to demonstrate and improve the global comparability of measurements, particularly by working with the RMOs in the context of the CIPM MRA to:
 - plan, execute and monitor KCs, and
 - support the process of CMC review.

The ten Consultative Committees of the CIPM are:

- CCAUUV: Consultative Committee for Acoustics, Ultrasound and Vibration
- CCEM: Consultative Committee for Electricity and Magnetism
- CCL: Consultative Committee for Length
- CCM: Consultative Committee for Mass and Related Quantities
- CCPR: Consultative Committee for Photometry and Radiometry
- CCQM: Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology
- CCRI: Consultative Committee for Ionizing Radiation
- CCT: Consultative Committee for Thermometry
- CCTF: Consultative Committee for Time and Frequency

CCU: Consultative Committee for Units

Each CC is supported by a number of Working Groups.

4.2.2.5 Activities of the BIPM

Full details of the activities run under the Metre Convention can be found on the website hosted by BIPM, but notably include custodianship of the SI, coordination of the CIPM MRA, the creation of the world timescale Universal Coordinated Time (UTC), piloting of many scientific comparisons (for which it has its own laboratories), promoting the SI through international liaison activities, supporting the CCs, and operating a number of joint committees. In recent years the mission has been supported by capacity building and knowledge transfer activities.

The CIPM Mutual Recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes (known as the CIPM Mutual Recognition Arrangement, or CIPM MRA) is the framework through which NMIs:

- demonstrate the international equivalence of their measurement standards, and
- accept the calibration and measurement certificates they issue.

The outcomes are:

- recognised degrees of equivalence between national standards, and
- peer-reviewed, approved and therefore internationally recognised CMCs of the participating institutes,

The outcomes are publicly available from the CIPM MRA database, known as the KCDB, maintained by the BIPM.

The CIPM MRA responds to the need for an open, transparent and comprehensive scheme to give users reliable quantitative information on the comparability of national metrology services and to provide the technical basis for wider agreements negotiated for international trade, commerce and regulatory affairs.

4.2.3 The OIML Convention

The OIML Convention established the International Organization of Legal Metrology (OIML) and provides the constitution for that organization. The International Organization of Legal Metrology (OIML) is an intergovernmental treaty organization whose membership includes Member States that participate actively in technical activities and Corresponding Members that join the OIML as observers.

The OIML promotes the global harmonization of legal metrology laws and procedures and provides its members with guidance with respect to their national legislation, including the principle that measurements used for trade and regulatory purposes should be made using measurement standards that are legally traceable to the SI. It has developed a worldwide technical infrastructure that provides its members with metrological guidelines for the alignment of national requirements concerning the manufacture and use of regulated measuring instruments. This infrastructure supports the legal traceability of measurements used in regulated activities such as trade, traffic control, healthcare, and monitoring of the environment.

4.2.3.1 Structures (International Conference on Legal Metrology, CIML and BIML)

The International Conference on Legal Metrology is the highest decision-making body in the OIML. It is composed of representatives of the Member States. In principle, each delegation should include a representative of the national legal metrology authority of each Member State.

The International Committee of Legal Metrology (CIML) is the working body of the Conference. It comprises one representative from each OIML Member State. These representatives are designated by their country's government and are must be serving officials in the department responsible for legal metrology in that Member State, or have active official functions in this field.

The International Bureau of Legal Metrology is the secretariat of the OIML, and is located in Paris. It ensures the organisation and operation of the Conference and the CIML, and is responsible for implementing their decisions. It also coordinates and supervises the technical work of the OIML and publishes all OIML publications.

The OIML website contains details of the Convention and the structures of OIML.

4.2.3.2 Mission and role of the OIML

“The mission of the OIML is to enable economies to put in place effective legal metrology infrastructures that are mutually compatible and internationally recognized, for all areas for which governments take responsibility, such as those which facilitate trade, establish mutual confidence and harmonize the level of consumer protection worldwide.” (OIML Strategy, 2011)

In implementing its mission, the OIML:

- Develops model regulations, standards and related documents for use by legal metrology authorities and industry;
- Provides mutual recognition systems which reduce trade barriers and costs in a global market;
- Represents the interests of the legal metrology community within international organizations and forums concerned with metrology, standardization, testing, certification and accreditation;
- Promotes and facilitates the exchange of knowledge and competencies within the legal metrology community worldwide;
- Cooperates with other metrology bodies to raise awareness of the contribution that a sound legal metrology infrastructure can make to a modern economy.

4.2.3.3 OIML technical work

Project Groups (PG) within the OIML's Technical Committees (TC) and Subcommittees (SC) develop the Organization's technical publications. There are eighteen TCs, each with a number of subcommittees and project groups. The details of the structure and rules for operation are contained in OIML document B 6-1, Directives for OIML Technical Work.

4.2.3.4 Activities

The principal activities of the OIML are the writing of technical standards and the promotion of the acceptance of type evaluation test reports in order to avoid duplication of approval testing. In addition, the OIML runs seminars and training sessions, and supports expert studies and reports. It provides an annual “round table” forum for Regional Legal Metrology Organizations (RLMOs) to meet and share information.

The OIML is an “international standard-setting body” in the sense of the World Trade Organization's Technical Barriers to Trade (TBT) Agreement. OIML publications should therefore be applied, when appropriate, by all signatories of the TBT Agreement when developing technical regulations, in application of Article 2.4 of that Agreement:

“Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.”

OIML publications may be accessed on the OIML website. These publications comprise Recommendations (R), Documents (D), Vocabularies (V), Basic Publications (B), Expert Reports (E), Guides (G) and Seminar Reports (S). OIML Recommendations are standards in the form of model regulations intended to be incorporated into the laws of Member States. Thus, they can only be recommendations to Member States.

4.2.3.5 Mutual Confidence and the OIML Certification System (OIML-CS)

The OIML-CS is a system for issuing, registering and using OIML Certificates and their associated OIML type evaluation/test reports for types of measuring instruments (including families of measuring instruments, modules, or families of modules), based on the requirements of OIML Recommendations.

It is a single Certification System comprising two Schemes: Scheme A and Scheme B.

The aim of the OIML-CS is to facilitate, accelerate and harmonize the work of national and regional bodies that are responsible for type evaluation and approval of measuring instruments subject to legal metrological control. In the same way, instrument manufacturers, who are required to obtain type approval in some countries in which they wish to sell their products, should benefit from the OIML-CS as it will provide evidence that their instrument type complies with the requirements of the relevant OIML Recommendation(s).

It is a voluntary system and OIML Member States and Corresponding Members are free to participate. Participating in the OIML-CS and signing an OIML-CS Declaration will commit, in principle, the signatories to abide by the rules of the OIML-CS. OIML B 18 Framework for the OIML Certification System (OIML-CS) establishes these rules whereby signatories voluntarily accept and utilize OIML type evaluation and test reports, when associated with an OIML Certificate issued by an OIML Issuing Authority, for type approval or recognition in their national or regional metrological controls.

The requirements for the participation of OIML Issuing Authorities and their associated Test Laboratories in Scheme A or Scheme B are the same, but the method of demonstrating compliance is different. OIML Issuing Authorities are required to demonstrate compliance with ISO/IEC 17065 and Test Laboratories are required to demonstrate compliance with ISO/IEC 17025. For participation in Scheme B, it is sufficient to demonstrate compliance on the basis of "self-declaration" with additional supporting evidence. However, for participation in Scheme A, compliance must be demonstrated by accreditation or peer assessment.

4.3 Other international quality infrastructure organizations

4.3.1 Standardization

Written standards and measurements have complementary roles in technology and manufacturing. Standards contain specifications for a particular physical quantity to be measured; these specifications are necessary in order to apply the most cost-effective measurement technology. Furthermore, the standardization process has permeated quality management systems with a corresponding impact on the measurement process itself.

ISO

The International Organization for Standardization (ISO) is the largest international publisher of voluntary standards and is responsible for the publication of a range of written standards and guides that apply to the manufacture and testing of various products. The range of standards is vast, covering such areas as quality management, environmental management, energy management, food safety, information security and occupational health and safety, among many others. Of particular importance to metrology are the following:

ISO 9000 family of standards for quality management and quality assurance;

ISO 14000 family of environmental management standards which can be implemented in any type of organization in either public or private sectors;

ISO/IEC 17000 specifies general terms and definitions relating to conformity assessment, including the accreditation of conformity assessment bodies, and to the use of conformity assessment to facilitate trade;

ISO/IEC 17011 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies;

ISO/IEC 17020 Conformity assessment – Requirements for the operation of various types of bodies

Commented [PM3]: This section has been taken virtually verbatim from APMP/APLMF Guide 1 and probably needs considerable updating. It may also contain too much detail. This will be covered in consultations with INetQI colleagues

performing inspection;

ISO/IEC 17021 contains principles and requirements for the competence, consistency and impartiality of bodies providing audit and certification of all types of management systems;

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories is the main ISO standard used by testing and calibration laboratories. ISO/IEC 17025 is used in peer reviews (e.g. in the framework of the OIML MAA and the CIPM MRA), by accreditation bodies and other organizations in order to assure technical competence of laboratories.

ISO/IEC 17040:2005 Conformity assessment – General Requirements for peer assessment of conformity assessment bodies and accreditation bodies. (*Note* See also OIML V2-200:2012, 2.44)

ISO/IEC 17065 Conformity assessment – Requirements for bodies certifying products, processes and services;

ISO/DIS 17034 specifies general requirements in accordance with which a reference material producer has to demonstrate that it operates if it is to be recognized as competent to carry out the production of reference materials. It is intended for use by reference material producers in the development and implementation of their management system for quality, administrative and technical operations. Reference material customers, regulatory authorities and accreditation bodies may also use it in confirming and recognizing the competence of reference material producers;

ISO Guide 68 Arrangements for the recognition and acceptance of conformity assessment results.

IEC

The **International Electrotechnical Commission** (IEC) is a non-profit, non-governmental international standards organization that prepares and publishes its International Standards for all electrical, electronic and related technologies – collectively known as “electrotechnology”. IEC standards cover a vast range of technologies from power generation, transmission and distribution to home appliances and office equipment, semiconductors, fibre optics, batteries, solar energy, nanotechnology and marine energy, as well as many others. The IEC also manages four global conformity assessment systems that certify whether equipment, systems or components conform to its International Standards.

The IEC charter embraces all electrotechnologies, including energy production and distribution, electronics, magnetism and electromagnetics, electroacoustics, multimedia, telecommunication and medical technology, as well as associated general disciplines such as terminology and symbols, electromagnetic compatibility (by its Advisory Committee on Electromagnetic Compatibility, ACEC), measurement and performance, dependability, design and development, safety, and the environment. The IEC cooperates closely with ISO and the International Telecommunication Union (ITU).

JCGM

In 1997, the **Joint Committee for Guides in Metrology** (JCGM) was formed by the seven International Organizations that had prepared the original versions of the *Guide to the expression of uncertainty in measurement (GUM)* and the *International vocabulary of basic and general terms in metrology (VIM)*.

The current membership of JCGM comprises eight organizations:

The two intergovernmental organizations concerned with metrology, BIPM and the OIML, since 1997;

The two principal standardization organizations, ISO and the IEC, since 1997;

Three international unions, IFCC, IUPAC and IUPAP, since 1997; and

One international accreditation organization, ILAC, since 2005.

The JCGM operates through two working groups:

JCGM-WG1, with responsibility for the GUM, and

JCGM-WG2, with responsibility for the VIM.

Various other international standards organizations exist in special areas, for example:

CISPR – International Special Committee on Radio Interference. This is an offshoot of the IEC that writes standards for radio interference and compatibility.

CODEX Alimentarius or the food code has become the global reference point for consumers, food producers and processors, national food control agencies and the international food trade. The code has had an enormous impact on the approach of food producers and processors, as well as on the awareness of the end users – the consumers. Its influence extends to every continent, and its contribution to the protection of public health and fair practices in the food trade is immeasurable. CODEX was founded in 1958.

4.3.2 Accreditation

ILAC

The **International Laboratory Accreditation Cooperation** (ILAC) aims to promote the mutual recognition of test and calibration certificates issued by laboratories accredited by national accreditation bodies in accordance with internationally accepted standards for technical competence. ILAC members are peer evaluated and become signatories to the ILAC Mutual Recognition Arrangement (MRA). The ultimate aim of the Arrangement is enhanced international acceptance by industry as well as by governments of the tests and calibrations of accredited laboratories. Standards such as ISO/IEC 17025 require metrological traceability of measurement results to primary realizations of the SI (often referred to as national measurement standards), while in other, similar standards, traceability should either be to the SI or to other agreed international references where SI traceability is not, or not yet, possible.

IAF

The **International Accreditation Forum** (IAF) is the world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment. Its mission is to develop a single worldwide programme of conformity assessment that reduces risk for businesses and their customers by assuring them that accredited certificates may be relied upon. Accreditation assures users of the competence and impartiality of the body accredited. The primary purpose of IAF is to establish a **Multilateral Recognition Arrangement** (MLA) among its accreditation body members in order to contribute to the freedom of world trade by eliminating technical barriers.

The MLA allows the accreditations and certificates that are issued by the certification/registration bodies that, in turn, are accredited by members of the MLA to be recognized by the other members of the MLA. The objective is that the MLA will cover all accreditation bodies in all countries in the world, thus eliminating the need for suppliers of products or services to be certified in each country where they sell their products or services (i.e., certified once, accepted everywhere). Membership in the MLA is based on peer evaluation of each applicant for membership and continued surveillance of each member to ensure and confirm that all the members of the MLA operate their accreditation programs and implement the MLA Guidelines consistently and in an equivalent way.

4.4 Regional organisations

Regional bodies play an important part in the way in which all quality infrastructure organizations operate. Regional Metrology Organisations (RMOs) are regional associations of NMIs, and in some but not all regions include legal metrology with their remit. In the remainder this is addressed by dedicated regional bodies (see below). Within BIPM context, RMOs work to improve regional metrological capability by sharing expertise and exchanging technical services among Member laboratories. They have a wide range of activities, with perhaps the most important role in scientific metrology being their participation in the operation of the CIPM MRA. The BIPM works closely with the RMOs primarily through the Joint Committee of the Regional Metrology Organizations and the BIPM (JCRB) on the operation of the CIPM MRA. In particular, RMOs carry out regional comparisons corresponding to the CIPM international comparisons, establish and maintain quality oversight of participating institutes. Additionally, RMOs collaborate with the BIPM to organise capacity building and knowledge transfer activities for their

Commented [PM4]: This section is based on what is in APMP/APLMF Guide 1. The descriptions of what an RMO and an RMLO do are based on the way APMP and APLMF are described so they need to be looked at carefully.

members. Some RMOs, most notably EURAMET, run metrology research programmes. The RMO membership is wider than the BIPM membership (particularly in Africa), and thus countries with very limited metrological capacity in that region are also able to benefit from the “transfer down” of metrological knowledge.

RMOs recognized by the CIPM for the purpose of the CIPM MRA are able to support worldwide mutual recognition of measurement standards and of calibration and measurement certificates. In this way they promote the development of a regional measurement infrastructure that facilitates international trade, improves industrial efficiency and competitiveness, ensures equity in the marketplace, and enhances the quality of life and the environment.

Within OIML, Regional Legal Metrology Organisations (RLMOs) are groupings of legal metrology authorities whose objectives are the development of legal metrological infrastructure and promotion of free and open trade in the region through the harmonization and removal of technical or administrative barriers to trade. They perform a range of functions, to promote the coordination and integrity of legal metrology activities and services in order to achieve greater harmony of measurement and testing within their region, to build mutual confidence among their members. A major activity of some RLMOs is training to improve infrastructure, skills and knowledge in legal metrology/trade measurement and to promote harmonization in the region, thereby removing barriers to trade.

Within the standardization fields, similar regional organisations provide for:

- Strengthening the international standardization programmes of IEC and ISO and improving the ability of standards organizations in the region to participate in these programmes effectively;
- Improving the quality and capacity of standardization in economies of the region;
- Supporting free trade within the region and with economies in other regions;
- Supporting improvement of economic efficiency and development of the region through the promotion of standardization; and
- Interacting with other bodies that represent elements of the standardization technical infrastructure, as well as industry, consumers and government.

As regards accreditation, there are regional organizations that provide for cooperation among bodies in the region that accredit testing and calibration laboratories and, increasingly, inspection bodies and reference material producers, and provide other related services. They provide a forum for the exchange of information among members on accreditation and related issues, with the aim of continual improvement of accreditation services offered in the region and facilitate the acceptance by governments and industry in each economy of reports and certificates from accredited facilities. Other regional organizations bring together accreditation bodies and other interested parties whose objective is to facilitate trade and commerce among economies in the region with the ultimate objective of creating of a global system that grants international recognition for certification or registration of management systems, products, services, personnel and other programmes of conformity assessment.

In some cases, the same organization performs the role of both Regional Metrology Organization and Regional Legal Metrology Organization. These are:

- Intra-Africa Metrology System (AFRIMETS)
- Euro-Asian Cooperation of National Metrological Institutions (COOMET)
- Gulf Association for Metrology (GULFMET)
- Inter-American Metrology System (SIM).

Within Europe and the Asia-Pacific Region, there are separate RMOs and RLMOs. In Europe, the RMO is the European Association of Metrology Institutes (EURAMET) and the RLMO is (WELMEC). The RMO for the Asia-Pacific region is the Asia Pacific Metrology Programme (APMP) and the RLMO is the Asia-Pacific Legal Metrology Forum (APLMF).

Commented [PM5]: This section has been included because it is in Guide 1, but it seems too detailed for a metrology document. Views from colleagues in INetQI will be sought on how it should be edited.

4.5 Making the most of international and regional organisations

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 therefore be encouraged to take part in both the key International Organizations (OIML, BIPM, ILAC) and the mutual recognition agreements or arrangements which they provide. The international and regional organizations are also a valuable source of information and support to countries which are seeking to develop their metrology systems.

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. However, both BIPM and OIML offer opportunities for participation at a level below full membership (“Associate” and “Corresponding Member” respectively) for those countries and economies that are not yet in a position to take on all the responsibilities of full membership.

It is also important that the institutional and legal framework facilitates participation in international organisations. In particular Central Government needs to take the lead in coordinating issues in relation to metrology which imply interfaces with overseas authorities and overseas economies. This is the case for instance with intergovernmental treaties (e.g. the Metre Convention and the 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.

NMIs should be enabled and 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 should also be enabled and encouraged to enter into international agreements establishing the equivalence of the legal metrology systems and controls in the participating countries. This should include participation in international legal metrology conformity assessment systems.

Part 5 – Policy options facing Governments

5.1 What is the role of government?

Governments are responsible for

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

The role of the government in metrology is to provide society with the necessary means to establish confidence in measurement results. The involvement of Governments is particularly important 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 legal framework 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 legal framework should take this global aspect into account as far as possible.

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 an authority within central government to coordinate metrology policy and activities in the country. This authority will 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 BIPM). The structure of the metrology system and of the legal metrology system should be adapted to the specific circumstances of the country (e.g. size, economy, scientific and technological infrastructure, etc.).

When taking strategic decisions on the shape and size of a national metrology system, and in particular in drawing up a national metrology policy, there are several different areas to consider. In particular it is necessary to address:

- sectoral priorities,
- institutional options,
- coordination options,
- regulation and enforcement policy options, and
- funding options.

5.2 Sectoral priorities

Since the purpose of a national measurement system is to support activity across the economy, the shape of that economy and the way it is expected to develop should be the main determinant of where resources are directed and which institutions should be the priorities for reform. Different areas of metrology are relevant to different sectors of industry and commerce, and to scientific research and innovation. When a national metrology policy is drawn up the starting point should be an understanding of which of these sectors is the most important.

In deciding on the resources to be applied to different areas of metrology it is also important to have a strategy which balances building on areas of strength, particularly those of international significance, and areas of weakness, particularly those relevant to sectors whose international competitiveness is vital.

In determining which sectors should be priorities, governments may wish to take account of the following:

- a) Many economic sectors, especially those which may be important sources of exports, are very dependent on metrology for their ability to compete in export markets. Extractive industries and bulk agricultural products, for instance, need good quality weighing infrastructure. Industrial products, especially components which will be assembled elsewhere, require world-class industrial metrology if they are to be competitive
- b) Many products, for instance food and agricultural goods, have to meet demanding regulatory requirements in export markets.
- c) A key source of added value, in particular in food products, is the ability to package goods prior to export. This requires a modern legal framework for prepackages, enforced to acceptable international standards, so that the exported products are readily accepted all over the world.
- d) Perceptions of consumer protection can be important when attracting international tourists. Good consumer protection can therefore be an important part of a country's tourism strategy, quite apart from the benefits to the domestic population.

Once the priority sectors have been identified, the attention should be focused on the parts of the National Quality Infrastructure which are most important to those sectors. This is likely to require action in the standards and accreditation fields as well as in the metrology system itself.

Where metrology is important to a priority sector, one of the first requirements is to ensure that the sector has access to good quality test and calibration services. Broadly speaking there are three options for meeting that need:

- a) Enabling or directing public bodies such as the NMI to provide those services
- b) Developing a domestic commercial test and calibration sector capable of providing those services (which may need to be accredited), ideally supported by the NMI
- c) Facilitating access to test and calibration services in other countries

Which is the right approach (or which is the right mix over time) will depend very much on the circumstances of each country.

Further guidance on identifying sectoral focus when developing national metrology system priorities can be found in the PTB report *Steps towards a National Metrology System* (Eberhard Seiler).

5.3 Institutional options

5.3.1 Questions relating to NMIs

As noted in 3.2.2, a country will often designate a single National Metrology Institute, but in some cases NMI functions may be carried out by one or more organizations constituting what are in effect "distributed" systems.

If it is decided to form a single national institute, this institute should be in charge of all "NMI functions". Where more than one institute carries out "NMI functions", it is important that there are adequate arrangements for co-ordinating the activities of all these institutes, in particular as regards their input into

BIPM's work.

The choice between establishing a single NMI or more “distributed” systems, depends to a large extent on the history of the institutions and where the relevant facilities and expertise is located. It should be noted, however that even in cases where a single institute deals with traditional physics and engineering the move of metrology into fields such as chemistry, medicine, food etc. there is sometimes a need to bring in other institutes.

Where a distributed system is adopted, it should be recalled that in the system of international recognition (CIPM MRA) coordinated by the BIPM one institute signs on behalf of all others. It is important to have clarity as to whether the lead NMI will have the right to designate additional laboratories, or whether that right is retained at a higher level of Government, and the degree to which the NMI has responsibility for coordinating and or representing any other designated institutes in terms of their international role.

There is also a policy question of how independent of Government NMIs should be. Traditionally, NMIs were nearly always entirely within the public sector. However, more recent policies in some countries have attempted to give NMIs 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, governments have sought alternative models, in particular in “distributed” systems where there is a number of other organizations with a different ownership or legal status, but have in all cases arranged matters so that the majority of funding of the institutes comes from public sources.

In the few 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 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” NMI.

The choices between 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); and a public agency coordinating public or private institutes will be determined to a large extent by the existing structures and institutions in place, the fields of metrology that the national metrology policy is aiming to develop and the constitutional and legislative traditions of the country.

It is recommended that before deciding on the form of the NMI arrangements there should be a survey on the main capabilities existing in the country, in private, semi-public and public laboratories and an examination of the different options, in particular whether to transfer some of these capabilities to a central institute or to include and federate them in a national network.

In all cases, however, 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. There also need to be adequate safeguards of impartiality. In addition special attention must be paid to the sustainability of the NMIs, and appropriate financial resources must be provided for their long term stability and their funding should 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.

5.3.2 Relationship between metrology bodies

In many countries some or all of the national level legal metrology functions are carried out by the NMI. In other jurisdictions, such activities may be distributed among several institutes or authorities specializing in different fields under an appropriate coordination.

In all cases, however, 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;

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.

5.3.3 Relationship between metrology bodies and other Quality Infrastructure bodies

Because of the importance of metrology within the wider Quality infrastructure, it is necessary to be clear on how the various metrology bodies interact with key institutions such as the National Standards Body and the National Accreditation Body [In some countries the National Standards Body may also be given responsibility for some metrology functions. In some countries there may be no National Accreditation Body at all or its scope may be limited. In all cases, however the NMI is likely to be an important source of expertise when the performance of laboratories, notably calibration laboratories, are being assessed. There is no single preferred model for dividing responsibilities between QI bodies, but the more bodies that are involved the more important it is that there are good co-ordination mechanisms (see 5.4), especially if the bodies report to different parts of Government.

5.3.4 Relationship of national legal metrology authorities and local legal metrology authorities

The question of which activities should be performed by national authorities and which are appropriate for decentralization is essentially a matter 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.).

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

5.3.5 Involvement of the private/commercial sector

While as a minimum national government should establish and manage the national metrology policy, maintain an appropriate metrology infrastructure and also define 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 with sufficient competencies exist outside the public administration, the tasks of the public administration may be limited to overseeing the activities.

In those countries in which public administration bodies have the necessary technical competencies, the metrology policy could include the development of infrastructures 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 such 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.).

5.4 Coordination options

As noted in 3.2.7, the range and complexity of the metrology activities undertaken in a modern economy, the diversity of areas and sectors involved, the number of institutions and bodies which participate in the national metrology systems and the variety of Government interests affected mean that effective arrangements for co-operation and co-ordination are required. It would be inconsistent and inadvisable for different central bodies to be in charge of different aspects of the metrology policy without coordination.

5.4.1 Central government co-ordination

One approach is for 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. Activities that need to be undertaken at the Central Government level include:

- 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, and ensuring that this is updated periodically;
- elaborating and formulating the national metrology policy that has to be endorsed by the government;
- fitting the national metrology policy within the wider national quality infrastructure policy;
- coordinating the actions of the various ministries related to metrological issues, in order to ensure consistency;
- issuing legal metrology regulations;
- organizing or ensuring international representation of the national metrology bodies and system;
- to facilitate international recognition of the national metrology bodies and system;
- supervising the national bodies to which technical tasks are delegated; and
- providing appropriate information to the public about the national metrology system.

5.4.2 Implementation of national metrology policy

It will usually be desirable to 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, and

areas in which metrological regulations should be developed or coordinated,

distribution of tasks between the public and the private sectors, and

financial resources that the State should allocate to the support of metrology.

This role may be performed by either a Central Government authority or a Metrology Advisory Board/Council where they exist.

5.4.3 Coordination in legal metrology

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.

Co-ordination among legal metrology authorities is thus important in order to ensure uniform application of the law, especially where there are several enforcement authorities such as LLMA. Where there is a single central government authority this may be its responsibility and when the LLMA are not directly under the authority of this authority, the law should include provisions to direct this coordination.

Examples of such provisions could be the following:

certifications issued by the national authorities are accepted by the LLMA;

instruments, measurement procedures and measurement results accepted by an LLMA are accepted by the other LLMA;

no deviating requirements or interpretations of requirements should exist between LLMA; national authorities may ask an LLMA to revise its interpretation of the regulatory requirements when this interpretation appears to deviate from common interpretation;

the LLMA are represented in intergovernmental work and accept the agreements signed in the intergovernmental organizations.

5.4.4 Involvement of stakeholders - Metrology Advisory Board/Council

The very large number of stakeholders who rely on the national metrology system in order to do their own work makes it important that there is a forum to capture their input. A good way of doing this is for the Minister in charge to set up a Metrology Board to operate as a consultancy body for metrology in the country. The stakeholders represented should include other government Departments, the NMI, Legal Metrology Authorities, private providers of metrology services, industry and other users of instruments, universities, etc.

The Metrology Board/Council may

advise on identifying the metrological needs in the country,

propose the priorities in investments,

propose scientific and training activities,

advise on professional clarification in e.g. assessments, and
advise on functional matters.

Stakeholder involvement is particularly important in legal metrology which should not merely be regarded as a one way enforcement issue. The infrastructure should provide for interaction between the stakeholders (government, industry and testing and measurement laboratories, users/consumers).

Especially for evaluating 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; and
- organization of meetings/conferences to which all stakeholders are encouraged to contribute.

5.5 Regulatory and enforcement options

5.5.1 Regulatory policy

Weights and measures used in trade was one of the first areas which governments attempted to regulate and legal metrology remains an important part of most regulatory systems, especially when areas of health, safety and environmental protection is taken into account. In many countries weights and measures have been in the forefront of regulatory innovations such as:

- Focus on measuring instruments used rather than the underlying transaction or activity;
- Standards-based regulation;
- Dedicated inspectorates;
- Use of innovative conformity assessment procedures;
- Risk-based or intelligence driven enforcement;
- Use of authorized private sector bodies to undertake certain tasks.

It is important that when changes to the legal framework are made, they fit with the country's wider regulatory reform agenda. At the same time, legal metrology plays a vital role in delivering economic, health, safety and environmental protections and it will rarely be appropriate to set the total removal of the legal framework as a policy goal.

Standards have long played a key role in legal metrology and this has grown (and continues to grow) as international standards (such as OIML Recommendations). One of first decisions governments need to make is how such standards are to be incorporated or referenced in their legal framework. Adoption of a standard's provisions may occur in several different ways including

- inclusion of the verbatim text in the regulations,
- inclusion of identical requirements, but not identical text, or
- inclusion of compatible but not identical requirements.

cross-reference to a specific edition of a standard

compliance with the standard as a guaranteed but not compulsory way of complying with a generally expressed requirement,

compliance with a standard used as evidence of generally accepted practices

In practice there is a spectrum of options between purely voluntary standards and various forms of technical

Commented [PM6]: The original text in the 2012 edition only covered part of the standards - technical regulation spectrum and the order was illogical. It has been expanded to take into account the full spectrum.

regulation. These are described in Figure 6. Which approach a country adopts will depend on its broader legal traditions and may vary between different areas of legal metrology.

Standards-based					
Voluntary standards					
		Technical Regulation			
Voluntary standards - No link with legal requirements	Voluntary standards - taken into account by the courts when considering whether generally expressed legal requirements have been met	Law lays down general requirements (eg essential requirements) where conforming to a specified standard is a guaranteed way (but not the only way) of demonstrating that the requirements have been met	Law requires conformity with a specified standard	Law is based on an existing standard	Law sets detailed requirements independently of any standards
	Variants: a. No legislation - courts in practice use standards as evidence of accepted good practice b. Legislation- "courts shall take into account/have regard to etc" c. Legislation - rebuttable presumption that complying with a standard is taken as compliance with the legal requirement		Variants: a) Reference is to a standards as it exists on a specified date b) Reference is to a standards as published at the time of a potential offence	Variants: Some laws may "copy out" the text of a standards; others may take the standard as a starting point but alter the text, add to it or omit elements of it to varying degrees	

Figure 6 – Relationship between standards and technical regulations

Another key decision is which of the various legal metrology "tools" should be used in any area of regulation. Traditionally, most of the emphasis was placed on verification of instruments when they were put into use. However, consideration should be given to additional tools such as type approval controls, pre-market verification, pre-market surveillance, market surveillance in the distribution chain and intelligence-based inspections which can enhance the effectiveness of regulatory controls.

Government also needs to take responsibility for ensuring consistency of regulations and their application. Central government authorities 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 rules 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; and

exemption from the provisions of the Law on Metrology or any regulations subsequently made when appropriate to the maintenance of good commercial practices, etc.

5.5.2 Enforcement strategies

The choices of the legal metrology techniques discussed in 5.5.1 will to a large extent determine the enforcement approach adopted. However, in all cases there will be an opportunity to develop a risk-based approach to enforcement wherein the enforcement response is proportional to the severity of the offence and the likelihood of its recurrence. Figure 6 shows the possible responses to infringements as the severity of the offence increases.



Figure 7 – Enforcement strategy as a function of risk

Ideally, the level of education and awareness-raising should be sufficient such that offences do not occur. Where they do occur, depending on the circumstances, it may be appropriate to issue several warnings before a financial penalty is imposed. For serious offences, it may be necessary to seek a court injunction in order to stop the offending behaviour. Where a company is a repeat offender and has sufficient resources to regard any normal penalty as a cost of doing business, an enforceable undertaking is a powerful tool to change the company's behaviour.

Typically, the penalties associated with any further transgressions (i.e. ignoring the directions of a supreme court) are much more severe than are usual in trade-measurement legislation.

Commented [PM7]: This text is taken from section 7.8 of APLMF/APMP Guide 1.

5.6 Funding the metrological infrastructure

All metrology systems are inherently complex, involving both activities that can readily be funded on a commercial basis and activities that can only effectively be undertaken by the State. The two areas where important policy decisions are required are the funding of NMI activities and the funding of legal metrology enforcement.

5.6.1 National Metrology Institutes

The missions and tasks of NMIs 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.

The establishment of the laboratories and overall general operation of the NMI requires funding from government on an ongoing basis. This funding must cover the work necessary to purchase, maintain and update equipment, establish and maintain the national standards and gain their international acceptance through the comparisons activities (within the framework of the CIPM MRA). Where international aid is sought to help establish the NMI, it is important that the national funding to maintain the NMI is properly

put in place, otherwise the original investment will be wasted.

The most common model is for the NMI to charge the direct cost of service delivery, that is to say to charge the labour and other costs associated with delivering a particular calibration to a client.

Where the NMI is directly providing a high volume of services (for example where no commercial calibration sector exists), a higher proportion of costs are generally recovered. Care needs to be taken when the NMI has significant influence on mandating the need for a service via regulatory or other control. The risk that the NMI becomes dependent on the income from a service it has mandated has to be managed. It does not serve the economy well if that dependency reaches the point where the NMI (or its funding Ministry) is reluctant to cease the service because of loss of income, even when it is technically no longer necessary.

It is important to consider research and development funding separately. Establishing national standards requires development work, and the standards inevitably need some support as technology moves forward if they are to remain current. In a small NMI it may be possible to manage much of this process through procurement (i.e. buying better equipment, having national standards calibrated by an NMI with appropriately low uncertainties etc.). Nevertheless all NMIs will need to undertake some level of development work, and will require funding to do so. This need becomes more pronounced with the increasing breadth and sophistication of the services being offered. Some smaller NMIs develop links with a local technical university, for example taking postgraduate students to help undertake development projects if they do not have the in house expertise.

The decision on whether or not to engage in a funded metrology research programme will depend on national priorities, needs and available resources. Many NMIs function effectively without such a programme, provided they are able to undertake the development work described above. However, at least in more developed economies, having a research capability significantly increases the impact of the NMI. National funding for a research programme may come directly from government as part of the core funding for the NMI mission, or from wider national programmes. Research activities advance the existing standards, prepare the next generation of standards and look at increasing impact through the application areas of metrology. As a generalization a research programme helps the NMI to attract a higher quality of staff, which in turn increases the NMI's ability to advise clients and represent the NMI in the international community. In some countries and in some regions there may be wider sources of research funds available, usually on a competitive basis. They should always be seen as complementary to national funding. Increasingly research is undertaken collaboratively with other NMIs, universities and research organizations.

Irrespective of whether an NMI has a research programme or not, its staff will need to participate in the RMO technical committees, and other scientific fora, including for those that have the capability, the activities of the CIPM Consultative Committees. If the NMI has responsibility for legal metrology, then, as for scientific metrology participation at regional level, and in the activities of the OIML should be budgeted. Depending on the scope of the NMI there may be many other scientific fora that are important to its work. At the most senior level NMI Directors will need funding to participate in the regional and international fora that shape and decide the metrology landscape, and the activities that flow from them.

Finally, it should be recognized that in an NMI, the greatest asset is its staff. It takes considerable time, training and experience to maintain and develop national standards and deliver high quality services at a national level.

5.6.2 Legal metrology enforcement

It will often be appropriate for the businesses to meet the direct costs of some legal metrology activities, through fees and charges. This may be the case, for instance where requirements involve applications for permissions (such as type approval) or where the business derives broader benefits of assurance, such as testing or verification. The scope for applying fees and charges will depend to a large extent on the regulatory and enforcement policy choices that have been made (see 5.5). In particular, where private bodies have been authorized to carry out some legal metrology tasks, businesses will be expected to pay the fees those bodies charge.

Important points to bear in mind when setting fees and charges are:

- a) Fees should be transparent - businesses should have a clear understand of the costs they will have to bear
- b) Fees should reflect the actual cost of the legal metrology activity involved – they should not be used to subsidise other activities of the legal metrology authorities, in particular the provision of commercial services
- c) Where authorized private bodies are carrying out legal metrology tasks they may wish to set their fees competitively – in that case the authorities should consider whether they should be informed of the fee structures and indeed whether to require advance approval by the authorities
- d) Even where there is heavy reliance and enforcement provisions where the costs fall on businesses, there will be a need for some additional market surveillance activities, such as intelligence-based inspections. Legal metrology budgets should be set accordingly.

Part 6 – Legislating for metrology

6.1 General considerations when developing a Metrology Law

A Law on Metrology should take into account other national laws such as the Law on Consumer Protection, the Law on Accreditation, the Law on Standardization, etc. and international treaties such as the WTO/TBT Agreement¹, the WTO/SPS Agreement², the Metre Convention, the OIML Convention, etc. It should reflect the government's responsibility for

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

Annex B sets out a possible Model Law, which provides the preferred structure and the minimum points which should be included in a Law on Metrology. It is built on 36 Elements that have been identified in Parts 1 to 5 of this Document. These Elements 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.

The criteria used include

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

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 in 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, and
- 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 the regulation to be correctly enforced. The scope can then be progressively extended as additional resources become available.

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

The obligations resulting from the OIML Treaty and from the WTO TBT Agreement (obligation to use OIML Recommendations as far as possible, and encouragement 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, meaning that the national legislation must be strictly identical to the regional legislation,
- of optional application, meaning that the national legislation may be of different scope or have different requirement levels but must be compatible with the regional legislation, or
- of voluntary application, allowing each Member State to consider its application.

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

- of direct application, meaning that the provisions of this legislation are applicable in the countries without transcription in the national laws, or
- of indirect application, meaning 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 into consideration the obligations of their Members towards the OIML and the Metre Convention.

6.2 One metrology law or different frameworks for different areas of regulation?

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 to 5. One new point is that 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. Different aspects of this activity are described by various technical terms such as market surveillance, inspection, conformity assessment, investigation and others (see 6.7 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, and
- supervision of the metrology system on a regional or international basis.

Nevertheless, a Law on Metrology is always a national affair. In Europe even with binding European Directives for the member countries, the individual 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),
- the needs of the national economy, and
- the involvement of private bodies or not, etc.

Other laws such as a law on accreditation, a law on standardization, etc. have to be taken into account.

6.3 Organization of metrological infrastructure by a suitable order of laws, decrees and standards

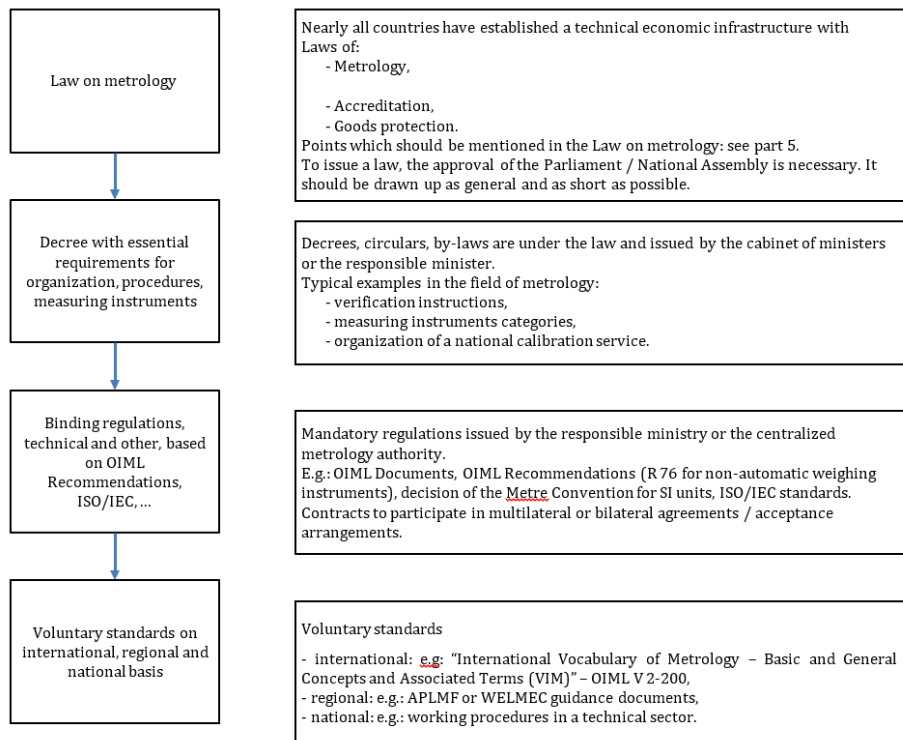
It is recommended that a “Law on Metrology” be developed in such a manner that it is considered “enabling legislation”. A Law on Metrology could address broader parameters that are not subject to change such as administration, offences, rule setting powers, relevant definitions as well as responsibilities 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 such as decrees, by-laws, circulars, etc. where ministries are responsible for their issuance. Also binding regulations based on OIML Recommendations and on the Metre Convention should be approved by the responsible ministry

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

An example of this is set out below



6.4 Legal units of measurement

A legal framework is required to specify which units of measurement are authorized to be used or made mandatory and for which applications. 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.

In addition it is necessary to specify when use of units other than legal units is permitted.

6.5 Legal metrology

Regulations on measurements, on prepackages and on measuring instruments are required 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 ought, when applicable, to be compatible with the OIML Recommendations 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.

6.5.1 Regulations on measurements

Depending on the areas it is wished to control, regulations may be required 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 no. 16.

These regulations need to 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 should be expressed in legal units as defined in 6.4. and should be traceable as required in 3.4.4.

These regulations may specify, when necessary, a measurement method, and may require the use of instruments subject to legal control in application of 6.5.3. When necessary, they should 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.

6.5.2 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 should be based on OIML

Recommendations as far as possible.

These regulations should prescribe that the nominal quantity of product in prepackages be labelled on them and expressed in legal units as defined in 6.4. 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 should 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 should 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 packers.

The regulatory requirements should 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 should 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 should be traceable to the SI as described in 3.4.4.

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.

6.5.3 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 8.5.

The instruments subject to these regulations should provide measurement results in the legal units defined in 8.4, and the measurement results should be traceable as prescribed in 3.4.4.

These regulations should 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 should be based on OIML Recommendations as far as possible.

These regulations should 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 should 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), or are withdrawn from use, and

to ensure that instruments are correctly installed, used and operated under the defined correct conditions (e.g. environmental).

These regulations should 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 should be marked as rejected (and/or should have its verification marks removed) and should either 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 regulations 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 should 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). The owner's use of the instrument must conform with the manufacturer's operating instructions and maintenance requirements.

6.6 Conformity assessment framework

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 into service,
 at the stage of repair of an instrument, before putting it back into service, and
 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.

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

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 either the central government authority mentioned in 3.2.1 or the legal metrology authorities (see 3.2.3).

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.

OIML Recommendations generally present possible conformity assessment procedures.

6.7 Surveillance framework

In addition to the legal metrology procedures and to the supervision and coordination of the activities carried out by the bodies appointed for specific legal metrology tasks (see 6.6), a general surveillance must be exerted by the enforcement authorities. Enforcement is an essential component of legal metrology and must be carried out by or on behalf of the State.

The surveillance is composed of

- surveillance of bodies or persons to which obligations are made by the regulations,
- market surveillance,
- surveillance of the use of instruments, and
- surveillance of the correct use of units of measurement.

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;
- prohibition on tampering with instruments;
- obligation to submit instruments to regulatory verification when required; and
- obligation to have instruments maintained when required.

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.

6.8 Legal framework – other provisions

In all the various regulations which form part of the national metrology system, and in particular its legal metrology components, it is necessary that to 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.

These should be proportionate and as far as possible consistent across the various areas of regulation. This consistency is most easily achieved if they are contained in a general Law on Metrology, if there is one.

In specifying offences it is necessary to consider a number of different offences:

General offences, such as

- selling, offering, or exposing for sale a quantity less than the quantity represented, as prescribed in regulations (which may account for statistical variation),
- taking more than the represented quantity when, as the buyer, he/she furnishes the weight or measure by means of which the quantity is determined,
- representing the quantity in any manner calculated or intending to mislead or in any way deceive another person,
- misrepresenting the price of any commodity or service sold, offered, exposed, or advertised for sale by quantity (weight, measure, or count/number), or representing the price in any manner calculated or intended to mislead or in any way deceive a person,
- misrepresenting measurements of quality of products used to determine the price or grade of the product,
- failing to register when registration is required,
- not complying with obligations to keep records, or not make them available to legal metrology officials,
- not complying with corrective actions requested/instructed by legal metrology officials,
- hindering or obstructing any legal metrology official in the performance of their duties,
- affixing fake or undue conformity marking or verification marks, and
- impersonating a legal metrology official.

Offences related to measurements provided in advertisements or other public communications

Offences related to the use of legal units

Offences related to regulations on measurements

Offences related to regulations on prepackages

Offences related to measuring instruments for which legal control is required

It is also desirable for there to be a clear statement of the responsibilities of those who use or keep measuring equipment covered by national metrology legislation and those who import, manufacture, repair, sell or hire measuring equipment intended for uses covered by the national legislation on metrology.

In addition is necessary to make provisions for enforcement powers.

Considerations to be addressed when drawing up provisions on enforcement powers, offences and penalties and the responsibilities and duties of both official and businesses are discussed further in the Model Law in Annex B.

Part 7 – Developing a metrology system for the future

7.1 Responding to a changing world

The economies and societies which national metrology systems support are constantly changing and developing. Accordingly, metrology systems also need to change and adapt if they are to meet the needs of the economy and the society in which they operate. Technological change in particular presents new challenges for metrology systems, changing the products which need to be measured and the ways in which business operates and societies are organized. At the same time, however, technological change can provide new ways in which metrology systems can function, introducing new opportunities for operating more efficiently and effectively.

Recent examples of the technological changes to which metrology systems have had to respond include:

- the change from mechanical measuring instruments to electronic devices and later the addition of software tools,

- the change from single measuring instruments to measurement systems

- the change from static measurements to dynamic measurements (e.g. smart meters)

- The increased complexity of fraud.

In addition, there have been important contemporary developments in the way in which metrology, in particular legal metrology, is practiced:

- developments in information technology mean that it is now possible to use databases to track measuring instruments from the time they are placed on the market until they reach their end of life;

- there has been a switch of emphasis away from relying solely on verification to using type approval controls and other conformity assessment procedures;

- globalization and accompanying trade agreements mean that national legislation needs increasingly to follow regional/international legislation; and

- reducing international transaction costs has encouraged wider recognition of test results from other countries/regions.

7.2 Future developments

The future is inherently difficult to predict. However, some future trends are already apparent:

- the move to an increasingly paperless world, including reduced use of paper money;

- continued introduction of digitization in all areas;

- redefinition of the SI is likely to lead to increased availability of intrinsic standards;

- the “internet of things” will lead to increased size and complexity in measuring systems, with a proliferation of sensors;

- artificial intelligence will become an increasingly important feature in the software of measuring instruments.

It is clear that in the future the way in which calibration and verification is performed will have to adapt to meet these developments.

7.3 Implications for metrology policy and metrology systems

If metrology systems are to be responsive to these changes, and others yet to become apparent, it is important that flexibility is built into the arrangements that are introduced. It is useful to consider four main areas:

- Policy development;

Institutional structures;
Legislative arrangements;
Personnel training & development.

7.4 Policy development

The design of a metrology system and the production of a national metrology policy cannot be a “one off” exercise. Provision should be made for a regular review (for instance, every five years) both of the national policy and the way the way in which the different part of the metrology system work together. Where a Metrology Advisory Board/Council exists (see 5.4.4), this may be a suitable body to supervise or carry out the review. It is important that there are adequate resources available to conduct the review. The publications of international and/or regional metrology organizations (see Part 4 –) may provide relevant information and research.

7.5 Institutional structures

The various institutions operating within the metrology system, both public and private bodies, are likely to change their shape and activities. It is important that issues such as funding do not stand in the way of otherwise desirable developments. Where public and private bodies are operating in the same area there should be robust arrangements for managing conflicts of interest.

7.6 Legislative arrangements

In most countries, it can be difficult and time-consuming to change top-level laws such as a Law on Metrology. If such top-level laws contain detailed provisions drafted on the basis of current policies and structures, this can prevent the metrology system adapting quickly to new circumstances. The approach advocated in Part 6 – and in Annexes A and B therefore recommends that the law on metrology should be short and general, with details set out in by-laws or other regulations.

7.7 Personnel training and development

Both technological change and the introduction of new work methods require metrologists in all parts of the metrology community to develop their skills and competences in order to keep up-to-date. Both training and continuing professional development are therefore vital throughout the metrology system (see 3.2.6). The publications of international and/or regional metrology organizations may again be helpful in this area.

Part 8 – 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 2-200:2012: International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM), 3rd Edition 2007, corrected version
- [4] OIML V 1:2000: 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

Joint Declaration on Metrological Traceability adopted by BIPM, OIML, ILAC and ISO in 2011 and reaffirmed in 2018.

PTB report “Steps towards a National Metrology System” (Eberhard Seiler, April 2017)

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

Annex A – Elements of a Legal Framework for Metrology

PRELIMINARY NOTE

This purpose of this Annex and the accompanying Annex B is to identify all 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 the latter 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.

Any Law on Metrology should take into account other national laws such as the Law on Consumer Protection, the Law on Accreditation, the Law on Standardization, etc. and international treaties such as the WTO/TBT Agreement³, the WTO/SPS Agreement⁴, the Metre Convention, the OIML Convention, etc.

This Annex sets out a number of different “Elements” to be considered for inclusion in a Law on Metrology, drawing on the advice in Parts 1 to 9 of this Document. It can be considered a “checklist” of the matters which should be considered when developing a legal framework for metrology. The Elements 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.

For countries which are introducing a Law on Metrology for the first time and which want more explicit guidance on the shape of the legislation they might adopt, Annex B provides a Model Law which covers all these elements. These may be used directly for writing articles of the law, or may be reflected upon for developing similar but not verbatim text.

Element no. 1 (See 3.2.1)

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

Commented [B9]: Cross-references in this annex will be updated before publication.

Element no. 2 (See 3.4.1 and 8.1)

The Government should make appropriate regulations in application of the Law on Metrology, in order to define

- those measurements and measuring instruments that are 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.

These laws and regulations should 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 should be quoted in the Law on Metrology).

³ World Trade Organization - Agreement on Technical Barriers to Trade.

⁴ World Trade Organisation - Sanitary and Phytosanitary Agreement.

Element no. 3 (See 3.2.2 and 3.2.3)

The Government should designate the institute or institutes in charge of

- keeping and maintaining the national measurement standards and providing metrological traceability to the International System of Units (SI),
- carrying out and/or coordinating the research work in metrology, and
- 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.

Element no. 4 (See 3.4.2)

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

Element no. 5 (See 3.4.3)

The regulations adopted in application of the Law on Metrology may require that implementing bodies in charge of certain tasks be appropriately accredited.

Element no. 6 (See 3.2.2 and 7.6)

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

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

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

Commented [PM10]: This needs to be reconsidered in the light of the changes to 7.6

Element no. 7 (See 3.2.7 and 7.4.1)

The Government should [may?] designate the Central Government authorities to be in charge of

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

Element no. 8 (See 3.2.4 and 7.4.3)

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

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

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

Element no. 9 (See 7.4.4)

The Government should set up an advisory board/council for metrology, to address, as a minimum, legal metrology.

Element no. 10 (See 3.4.4)

For the application of any laws and regulations prescribing requirements on measurements, on prepackages and on measuring instruments, metrological traceability to the realization of the SI should 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 internationally 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, or when the cost of maintaining primary realizations of standards is not supportable or needed.

Element no. 11 (See 3.4.4)

Certified calibration results, test results and measurement results established by the national institutes in the scope of their designation should be metrologically 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.

Element no. 12 (See 8.4)

The legal units of measurements should comprise 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,

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 should be periodically reviewed to ensure their continued relevance.

Element no. 13 (See 8.4)

The use of units other than legal units should not be 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.

Element no. 14 (See 3.2.2)

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.

Element no. 15 (See 3.2.2)

The national metrology institutes defined in Element no. 3 should 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.

Element no. 16 (See 8.5)

Regulations made by the Government in application of Element no. 2 should 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.

Element no. 17 (See 8.5.1)

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 should 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.

Element no. 18 (See 8.5.2)

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 should take account of OIML Recommendations 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 should 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. 19 (8.5.3)

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 should bear a conformity marking.

These regulations should take account of OIML Recommendations and of the international standards and should 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 should 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.

Element no. 20 (See 8.6)

- 1 The Central Government authorities mentioned in Element 7 may appoint bodies to perform tasks pertaining to conformity assessment, verification, or inspection in application of the legal metrology regulations. These bodies should be competent and impartial. They should perform their tasks in a non-discriminatory manner.
- 2 Appropriate accreditations are an acceptable way to show competence and impartiality.
- 3 The bodies appointed in application of this Element should 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.

Element no. 21 (See 8.7)

The Central Government authorities mentioned in Element 7 should 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 definition in Annex C),
- the surveillance of the use of regulated instruments, and
- the surveillance of obligations resulting from the regulations mentioned in Elements nos. 2, 12, 13, 17, 18, and 19.

The division of responsibilities between the Central Government authorities and the Local Legal Metrology Authorities for carrying out these activities should be laid down in the Legal Metrology Regulations made in application of Element no. 19.

Element no. 22 (See 8.7)

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.

Element no. 23 (See 8.8)

Persons in charge of enforcing the provisions of the Law on Metrology (inspectors) should 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,
- and
- 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.

Element no. 24 (See 8.8)

The legal metrology officials (inspectors) mentioned in Element no. 23, upon presentation of their credentials and in order to perform their duties, should 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, programmed, monitored, kept or used. Also, the officials should have the right to access where prepackages are, or may be filled, labelled, kept or offered for sale.

Element no. 25 (See 8.8)

The legal metrology officials (inspectors) mentioned in Element no. 23 should 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 also stop-sale, hold, and removal orders with respect to any packaged commodities or bulk commodities kept, offered, or exposed for sale.

They should 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).

Element no. 26 (See 8.8)

It should 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 intended 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, and
- impersonate a legal metrology official.

Element no. 27 (See 8.8)

It should be an offence to

- refuse or fail to provide justifications of the measurement results provided in advertisements (or other public communications), and
- provide false or misleading measurement results in advertisements (or other public communications).

Element no. 28 (See 8.8)

It should 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.

Element no. 29 (See 8.8)

It should be an offence to

- not perform the legally required measurements and document them when required,
- not fulfil the metrological (including traceability) requirements prescribed in application of Element no. 17, or
- perform measurements with instruments other than those prescribed.

Element no. 30 (See 8.8)

It should 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.

Element no. 31 (See 8.8)

It should 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 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, or
- remove any tag, seal, or mark from any weight or measure or measuring instrument without being duly authorized by the proper authority.

Element no. 32 (See 8.8)

Persons, (i.e. individuals, partnerships, corporations, companies, societies, associations, etc.) that use or keep measuring equipment covered by national metrology legislation should be 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 should be liable for having the required metrological controls performed on the instruments or installations which are the subject of their activities.

Element no. 33 (See 8.8)

Whenever there is 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 should 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 is 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 should be a presumption that such a measuring instrument is regularly used for its intended purpose.

Element no. 34 (See 8.6 and 6.1)

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

The Central Metrology Authority may decide to recognize international or foreign certification systems when they appear to give equivalent confidence.

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

Element no. 35 (See 7.5)

- 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 should be performed on demand of the individual or organization responsible for the conformity.

Element no. 36 (See 8.1)

The organization of a national metrological infrastructure should contain

- a Law on metrology, a Law on accreditation, etc.,
- legal documents such as decrees, by-laws, etc.,
- binding regulations, and
- voluntary written standards.

Annex B – Model Law on Metrology

This Annex is intended for countries which are introducing a Law on Metrology for the first time and which want more explicit guidance on the shape of the legislation they might adopt. It presents a Model Law which covers all the elements identified in Annex A. The various articles may be used directly for writing articles of the law, or may be reflected upon for developing similar but not verbatim text.

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

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

See 8.5 and Element no. 16 for legal metrology

Art. 2: Terms and definitions

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

See Annex C.

Reference to OIML V 2-200:2012 *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms* (VIM) and to OIML V 1:2000 *International vocabulary of terms in legal metrology* (VIML) is strongly recommended.

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”.

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; and
- mutual recognition of test results or certificates.

See Part 3.3 and Element no. 1.

Art. 4: National metrology infrastructure

See Part 3.2.

Art. 5: Organization of metrology infrastructure

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

See Parts 3.2, 7.3 and Elements nos. 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 7.4.4 and Element no. 9.

Art. 7: Transparent availability of measurement results

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

See Part 3.2.2 and Elements nos. 14 and 15.

Art. 8: Central Government Authorities 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 at central government level.

See Parts 3.2, 7.3 and 7.4 and Element no. 7.

Commented [PM11]: Revised to bring into line with revisions in 3.2 etc

Art. 9: Local Legal Metrology Authorities (LLMA)

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

See Parts 3.2.4 and 7.3.3.

Art. 10: Legal units of measurements

It is strongly recommended to use the units covered by the “International System of Units (SI)”, although in some cases units not covered by SI and customary units may be specified by the Central Government.

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 8.4 and Elements nos. 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 3.4.2 and Element no. 4.

Art. 12: Metrological 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 metrological 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. In some special cases, it is not yet technically possible to establish metrological traceability to the SI. In these circumstances metrological traceability should be to an appropriate reference, e.g.: certified values of certified reference materials provided by a competent producer or to reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use.

Commented [AH12]: When we revised ISO/IEC 17025, after a very long discussion, we moved from using the term 'traceability' to always spelling it out and thus using 'metrological traceability' recognising there are other common uses in Government and law for the term traceability (country of origin for example). I propose we do the same, accepting that it is a little clumsy. I may not have caught every use.

Commented [AH13]: Consistent with ISO/IEC 17025:2017

To establish whether foreign national standards meet the necessary requirements for metrological 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 metrological traceability cannot be established via the KCDB the Central Government 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 3.4.4 and Elements nos. 10, 11.

Art. 13: Calibration/testing laboratories

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

See Part 3.2.5.

Art. 14: Conformity assessment of measuring instruments

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

See Part 8.6 and Element no. 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 no. 11.

Art. 16: Legally controlled measuring instruments

- regulations;
- applications including list of measuring instruments belonging to the field of legal metrology;
- special items such as precious metals;
- marking;
- stamps, seals;
- responsibility and powers; and

liability of persons and corporate bodies.

Details should be laid down in decrees.

See Element no. 2.

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

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

See Part 8.6.1 and Element no. 17.

Art. 18: Regulations on prepackages

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

See Element no. 18.

Art. 19: Regulations on areas of special government interest

Normally where the item of interest is an important area for the country's trade, production or wealth, etc.

See Part 3.3.

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; and

database of verified instruments.

See Part 8.5

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 8.5.3.

Art. 22: Inspection/supervision/surveillance

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

In addition to the legal metrology procedures and to the supervision and coordination of the activities carried out by the bodies appointed for specific legal metrology tasks (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 3.1.13), and
- surveillance of the correct use of units of measurement.

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;

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.

See Parts 8.7 and 8.8 and Elements nos. 21, 22, 23, 24, 25.

Art. 23: International agreements

Operating with foreign countries, recognition of certificates issued abroad.

See Parts 3.2 and 3.3 and Elements 6, 11, 19, 20.

Art. 24: Enforcement

The enforcement of the regulations taken in application of the Law on Metrology shall be placed under the responsibility of a designated Central Government Authority and should be carried out:

- for actions at national level, by the Central Government Authorities;
- 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 Government Authorities 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;

removal from service;
seizure;
civil penalty (Administrative monetary penalty, name and shame); and
prosecution.

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

Art. 25: Fees, financial provisions

See Part 7.5 and Element no. 35.

Art. 26: Offences

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

See Part 8.8.

See Elements nos. 26, 27, 28, 29, 30, 31.

Art. 27: Fines and penalties

Fines and penalties should be severe enough in order to prevent repetition of the offence. Publication of offenders could be a useful means (“name and shame” approach).

Art. 28: Coming into force, transition period

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

Annex C – Terminology

Definitions

The purpose of this annex is to explain terms used in this Document, where this is important for an understanding of their provisions. All but a small number are defined in the *International Vocabulary of Metrology - Basic and General Concepts and Associated Terms* (VIM) [JCGM200:2012; OIML V 2-200:2012; ISO/IEC Guide 99:2007] or the *International Vocabulary of Terms in Legal Metrology* (VIML) [OIML V 1:2013].

When preparing a Law on Metrology, or other regulations, it is recommended that terms other than those defined in the VIM, VIML or relevant ISO/IEC publications should be avoided and the definitions used should be those found in the VIM, VIML or this Document. OIML V 2).

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.

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

~~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.~~

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

Commented [PM14]: This Annex contains the various definitions which appear in section 3.1 of the 2012 Edition of D 1, but they have been rearranged into alphabetical order. Most are exactly as they appear in the 2012 edition, but the definition of "market surveillance" has been updated to reflect the analysis which appears in OIML D 34

Commented [PM15]: Deleted because the phrase "legal control of measuring instruments" does not appear in the Document. ("Legal metrological control" is used 4 times and is defined later in the Annex; "Legal control" appears 22 times, but is defined in the VIML)

secondary legislation (for example named decree, decision or regulation).

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

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, and
- legal metrological expertise.

Market surveillance

activities carried out and actions taken by public authorities after a regulated measuring instrument or a prepackaged product subject to harmonised regulation has been placed on the market to ensure that the product complies with the applicable requirements set out in the relevant legislation.

Note: Activities carried out to ensure that a compliant measuring instrument has been properly adjusted and is being used correctly while in service are not themselves market surveillance, but they may be regarded as market surveillance if they are carried out by persons who can identify a non-compliant product and initiate further market surveillance checks.

Commented [PM16]: This is a new definition, based on the text in Annex 7 of OIML D 34.

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

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 µΩ.
- 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 the 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 the 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.

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 and the correct use of units of measurement.~~~~*Note 2* For achieving these purposes, means and methods such as market surveillance and quality management may be utilized.~~**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

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.~~**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~~**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.~~**Verification of a measuring instrument****Commented [PM17]:** Propose to delete, as “metrological supervision” appears only once in the present Document and is not being used in a very technical way.**Commented [PM18]:** Propose to delete, as “surveillance of the use of instruments” appears only twice in the present Document and is not being used in a very technical way.**Commented [PM19]:** Propose to delete, as “type of a measuring instrument” does not appear in the present Document.**Commented [PM20]:** Propose to delete, as “type evaluation of measuring instruments” does not appear in the present Document.**Commented [PM21]:** Propose to delete, as “verification of a measuring instrument” does not appear in the present Document.

~~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~~

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