Bureau International des Poids et Mesures

National Metrology Systems
Developing the institutional and legislative framework

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Bureau International des Poids et Mesures

This publication was developed jointly by the International Organization of Legal Metrology (OIML) and the International Bureau of Weights and Measures (BIPM) and is available on the websites of both organisations.

The content of both publications is identical except for the cover and the foreword.

Contents

Foreword

The **International Bureau of Weights and Measures (BIPM)** is the intergovernmental organisation through which States Parties to the Metre Convention act together on matters related to measurement science and measurement standards. Its mission is to work with the National Metrology Institutes of the participating states, the Regional Metrology Organisations and strategic partners world-wide, and to use its international and impartial status to promote and advance the global comparability of measurements for:

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

This publication was developed jointly by the International Organization of Legal Metrology (OIML) and the BIPM and is freely available on the websites of both organisations. The content of both publications is identical except for the cover and the foreword.

Additionally, the BIPM and the OIML participate in Joint Committees with other Institutions for the development of **Vocabularies** and **Guides** for metrology and measurement.

Part 1 – Introduction

This International Document, produced jointly by the International Organisation of Legal Metrology (OIML) and the International Bureau of Weights and Measures [1] (BIPM), gives advice to national authorities on the issues they should consider when producing policies aimed at developing their national metrology systems, setting up their 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 globalisation of trade and services in which such laws provide the basis for dealing with the appropriate national measurement-based requirements.

Many aspects of metrology are complex and cannot be understood without the use of technical terms, which are very precise in their meaning. Most of these 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] [1] or the *International Vocabulary of Terms in Legal Metrology (VIML)* [OIML V 1:2013] [2], which should be consulted if there is any doubt about the precise meaning intended. Where key terms are important for an understanding of the provisions in this Document, this is mentioned in a footnote.

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 specialist metrology institutions are often involved, metrology should still be seen as an integral part of an NQI.

For instance, there are metrology elements in all the various components of an NQI:

- the physical measurement standards on which traceability chains are built;
- the written standards that provide performance requirements for measuring instruments[2] 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[3]; and
- the management standards written for such conformity assessments, often applied through the process of accreditation[4].

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[1] *Bureau International des Poids et Mesures* in French.

[2] In this Document, the term "measuring instrument" covers measuring instruments in the sense of the VIM (device used for making measurements, alone or in conjunction with one or more supplementary devices - VIM, 3.1 [1]), as well as measuring systems (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 - VIM, 3.2 [1]), material measures (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 - VIM, 3.6 [1]) 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.

[3] There is no single widely accepted definition of market surveillance. For the purposes of this Document it is regarded as "activities carried out and actions taken by public authorities after a regulated measuring instrument or a prepackaged product subject to regulation has been placed on the market to ensure that the product complies with the applicable requirements set out in the relevant legislation." 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.

[4] ISO 17000:2004 [3], 5.6 defines accreditation as "third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks". National accreditation systems, in general, are voluntary systems which establish the competence and impartiality of calibration

The relationship between a national metrology system and the rest of the Quality Infrastructure is discussed further in 3.4.5.

Legislation will usually be an important part of how these policies and institutions are put in place and this 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 also be 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 divided into 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 in this Document also relate, and are applicable, to best internationally accepted metrology practice in the non-regulated sector.

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 recognised by the appropriate authorities.

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 *Benefit of legal metrology for the economy and society* [4]) 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.; and
- 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 relating 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[5], dissemination of units, and science-based policy advice.

Metrology facilitates fair trade through harmonised 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[6].

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 vehicle fuel, it is expected that one litre of vehicle fuel 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.

[5] VIM 5.1 [1] defines a measurement standard (or etalon) as a "realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference". For detailed examples, see VIM 5.1 [1].

[6] There are various definitions of verification. For the purposes of this Document, the definition used is in VIML 2.09 [2]: "conformity assessment procedure (other than type evaluation) which results in the affixing of a verification mark and/or issuing of a verification certificate".

- 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 rationalised 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.
- Research on measurement of new energy sources (such as biofuel, liquefied natural gas, etc.).

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 developments 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 organisations.

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.

There are significant risks in not having an efficient metrological structure.

Examples:

- Advances in technology and innovation are held back by an inefficient metrological infrastructure.
- The absence of metrological infrastructure reduces access to, and confidence in, accurate and reliable measurements and measuring instruments.
- Delays caused by inefficient metrological infrastructure increase risks such as disputation costs and stifle innovation.

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 terms in legal metrology* (VIML) [2] 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 particularly necessary when there is imbalance between buyers and sellers in terms of knowledge or resources. 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 prepackaged 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 organisations (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 therefore important 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 bodies responsible for metrology, standards and accreditation in the national interest work in a complementary way;
c) setting the national policy for the areas to be regulated and the regulatory techniques to be used;
d) setting the national policy on public funding for the provision of infrastructure and services to support legal metrology activities;
e) setting the national policy on engagement with international and regional metrology bodies;
f) setting the national policy on public funding for research and development of appropriate metrological controls and documentary standards for measuring instruments and prepackaged products (including international engagement)";
g) setting the national policy on public funding of research into new or better measurement techniques;
h) drafting metrology laws and regulations*;
i) developing and maintaining documentary standards;
j) maintaining national standards of measurement and disseminating the units;
k) maintaining and disseminating certified reference materials;
l) conducting research into and development of new or better measurement techniques;
m) conducting research into and development of appropriate metrological controls and documentary standards for measuring instruments and prepackaged products (including international engagement)*;
n) providing technical advice;
o) operating type approval [7] controls (including registration of instruments used for regulated purposes)*;
p) carrying out testing and evaluation for type approval control purposes*;
q) carrying out conformity to type[8] activities*;
r) verification of regulated instruments*;

[7] VIML 2.05 [2] defines type approval as a "decision of legal relevance, based on the review of the type evaluation report, that the type of a measuring instrument complies with the relevant statutory requirements and results in the issuance of the type approval certificate".

[8] OIML D 34 *Conformity to Type (CTT) - Pre-market conformity assessment of measuring instruments* [5] defines conformity to type (CTT) as a "conformity assessment procedure focused on the assessment of measuring instruments to give assurance that manufactured (or production) instruments meet the approved type".

s) in-service inspection of regulated instruments*;
t) inspections and controls for prepackaged products*;
u) other "post-market" surveillance of regulated instruments*;
v) calibration of measuring instruments[9];
w) testing of measuring instruments; and
x) 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 with standards, both the development of documentary standards (including international harmonisation and mandatory standards in the form of regulations) and the development and dissemination of physical standards of measurement. 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 the area of legal metrology is shown in Figure 1 and the relationship between scientific and industrial metrology activities is shown in Figure 2. It should be noted that in practice most legal metrology activities are themselves underpinned by activities described in Figure 2.

Tier 1 – Policy and legislation	
Responsibility for regulation policy (including regulatory compliance strategies) 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	
Development and international harmonisation of metrological controls, primarily through documentary 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 • Pre-market verification • Testing by authorised persons • Testing to support self-declaration	Verification • Initial verification on putting into use • Subsequent verification In-service inspections Inspection of pre-packaged products

Figure 1 – Legal metrology activities

[9] Calibration is defined in VIM 2.39 [1] as an "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".

Tier 1 – Scientific metrology - Development, maintenance and dissemination of 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 and development of new CRMs	
Tier 2 – "Industrial metrology"	
Service providers	**"In-house"**
Calibration laboratories	Calibration laboratories
Provision of reference materials	
Conformity assessment to support self-declaration	Testing for internal assurance
Advice to support innovation	In-house research
Contract testing	
Analytical services	
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

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

a) institutions, both public and private, carrying out metrology activities;
b) Policies to be carried out by those institutions, preferably brought together in a national metrology policy; and
c) 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 the government in charge of the national metrology policy, and of coordinating the actions of other parts of the government related to metrological issues. This can be arranged in a number of ways by the government. For clarity, in this Document we refer to this authority, however it is organised in practice, as the 'Central Government Authority'.

This authority should be responsible for

- consulting with the other parts of the government concerning 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 contact persons for metrology in other parts of Government, these contact persons being in charge of

- collecting information on the needs of the services of their part of the government in terms of measurement and metrology,
- collecting information about regulations made by their part of the government 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 their part of the government about the national metrology policy, the available technical and scientific support in metrology, the work of regional and international metrology organisations, 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)[10] framework. In some economies, 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[11], 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;

[10] See 4.2.2.3.

[11] See 4.2.2.

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 realising 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 tests) so as to avoid technical barriers to trade through participation at regional and international levels in the international recognition systems operated by ILAC[12] 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 organisations (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 organisation. These may include standards laboratories which are part of a university or other scientific institute or organisations 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 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 organisation 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" (DIs) within the meaning of the Arrangement. This does not necessarily indicate any national hierarchy. In all cases it is

[12] See 4.3.2

important that there are adequate arrangements for coordinating 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 recognised 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 organisation 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 organisation(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 organisation concerned as a provider of the specific national service. The designated status only applies to the role of the organisation 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 recognised within the CIPM MRA the laboratory must operate a quality management system complying with the appropriate international standards, namely ISO/IEC 17025 [6] (and if the laboratory produces reference materials, ISO 17034) [7]. 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 National 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,
- participating in the development and international harmonisation of metrological controls, mainly documentary standards, for measuring instruments and prepackaged products (for example, within OIML Technical Committees),

- 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, and
- 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 specialising 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 organisation, organisations or services depending on regional (provincial) or local elected authorities, or
- specialised bodies designated or licensed by local or central metrology authorities. Such designated or licensed bodies may be public or private.

Specialised 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 should be to

- implement the Law on Metrology through interactions with individual businesses,
- identify contraventions of the Law on Metrology and prosecute (or 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. In some cases it may be appropriate for local legal metrology authorities 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 decentralisation is essentially a matter of the political organisation of the country. This is considered further in Part 5 – .

Some 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 specialised laboratories;

- service for the maintenance of measuring equipment;
- accreditation of calibration and testing laboratories, accreditation of certification bodies and inspection bodies;
- consulting services; and
- third party experts to be consulted in the event of disputes.

The adequacy of provision of these services will be an important element in any national metrology policy (see 3.3). 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 metrological traceability in professional training,
- training metrology specialists at different levels of qualification for the industry and for specialised testing and calibration laboratories,
- supporting research and technological progress in metrology and establishing partnerships between specialised 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 Coordination and cooperation in the metrological infrastructure

There is a need for arrangements for cooperation and coordination in the metrological infrastructure for many reasons: 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. Coordination 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 coordinate 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. In doing so, it is important that the evaluation of the situation should include an economic analysis of the resources required for the operation of the national metrology system as proposed by the policy. 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 realisation of the units);
- support for research and development of appropriate metrological controls and documentary standards for measuring instruments and prepackaged products;
- general criteria for determining the scope of regulation for measuring instruments, prepackaged products and measurements;
- general policy on subcontracting tasks in legal metrology to bodies outside the administration - role of the state authorities;
- policies for the provision of infrastructure and services to support legal metrology activities, the development of calibration laboratories, training, etc.;
- engaging with the BIPM as a Member State[13] or as an Associate of the General Conference on Weights and Measures;
- engaging with the OIML as a Member State or as a Corresponding Member;
- becoming full or associate members of a relevant regional metrology or regional legal metrology organisation; and
- coordination with the national standards body and the national accreditation body, where these exist.

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 and 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 realisations 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 realisations maintained by another country. In either case regular comparison with standards held by the NMIs of other countries should be performed, utilising the infrastructure established for that purpose by the BIPM and Regional Metrology Organisations.

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

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

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 organisations and which do not normally enter into competition.

Accreditation systems are harmonised 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, organise this harmonisation 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 [8]).

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

In broad terms, metrological traceability to the SI is required for the application of any laws and regulations prescribing requirements on measurements, on prepackages and on measuring instruments. The VIM [1] defines metrological traceability as the "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"[14] and the detailed requirements to ensure that it is achieved are addressed in detail in ISO/IEC 17025 [6].

For legal metrology purposes, the metrological traceability chain should again be through an unbroken chain of calibrations, until the final verification (statement of conformity with the legal or regulatory requirement). However, as described in ISO/IEC 17025 [6], measurement standards that have reported information from a competent laboratory that includes only a statement of conformity to a specification (omitting the measurement results and associated uncertainties) are sometimes used to disseminate metrological traceability. This approach, in which the specification limits are imported as the source of uncertainty, is dependent upon:

- the use of an appropriate decision rule to establish conformity; and
- the specification limits subsequently being treated in a technically appropriate way in the uncertainty budget.

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

[14] For a detailed discussion of measurement uncertainty see OIML G 1-100:2008: *Evaluation of measurement data - Guide to the expression of uncertainty in measurement* (GUM) [12]

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 metrological 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 [9] and reaffirmed in 2018.

3.4.5 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 organisations (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.[15]

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

Several components of an NQI are intimately linked. These connections are illustrated in Figure 4.

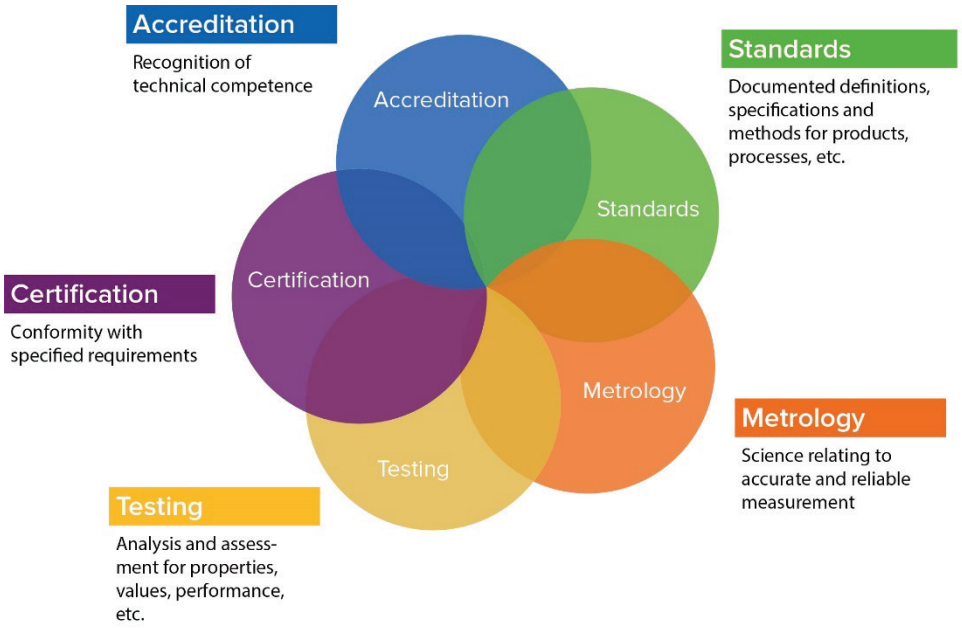

Figure 4 – Connections between components of a National Quality Infrastructure

[15] Taken from the DCMAS (now INetQI) definition adopted in July 2017. See 4.3.3 for a description of these bodies.

Although specialist metrology institutions are often involved, metrology does not function 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 measurement 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; and
- the management standards written for such conformity assessments, often applied through the process of accreditation.

The way in which metrology fits into a wider NQI is illustrated in Figure 5. There are several important points to note about this presentation:

- first, the shape and nature of standardisation, accreditation and metrology activities are very different;
- second, standardisation (the development of written standards for products and processes) is itself equivalent to what is described in 3.1 as a "Tier 1" activity – producing the standards which specify both performance requirements which can be assessed and the way in which assessments should be conducted;
- third, accreditation operates in a different dimension, allowing users of QI services to identify those conformity assessment and calibration providers in which they can have the most confidence;
- fourth, certification, inspection, testing and calibration which is undertaken without accreditation (e.g. because it is within a company or is part of official activities) are still regarded as part of the NQI; and
- finally, as already noted, metrology organisations may be involved in one way or another in most areas of QI.

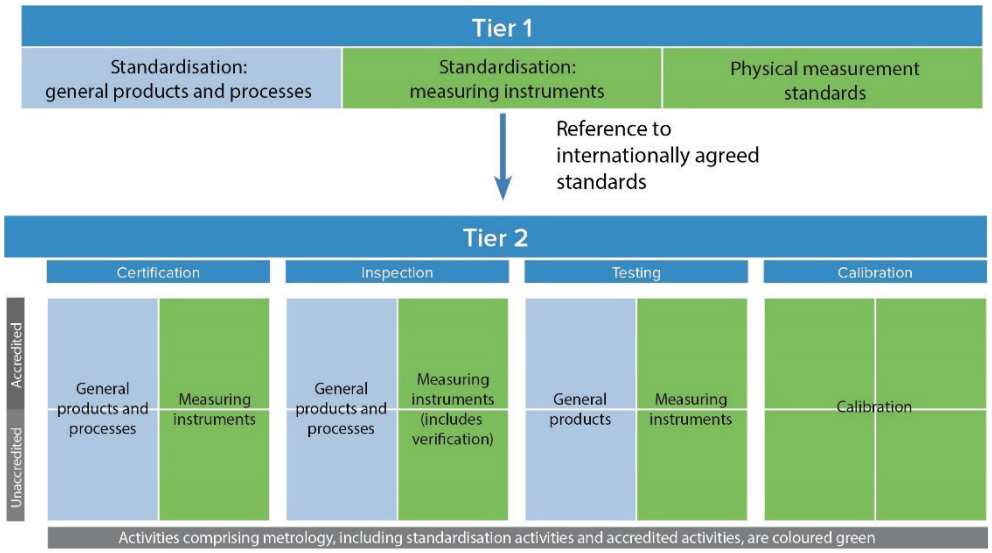

Figure 5 – Metrology as part of a National Quality Infrastructure

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

4.1 Need for compatibility between national and international metrological requirements

Each country has its own historical perspective on the development of metrological requirements. However, the Technical Barriers to Trade (TBT) Agreement (Article 2.4) [10], implemented within the World Trade Organization (WTO), provides for countries to base their national technical regulations on international documentary standards (norms) so as to harmonise 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 Organisation of Legal Metrology" [11]). In addition, Regional Metrology Organisations and Regional Legal Metrology Organisations are harmonising requirements throughout their member economies. The intent of these organisations is to facilitate trade and the exchange of measurement results and measuring instruments. Documents and Recommendations published by these organisations are a primary resource for structuring a national metrological infrastructure.

The international organisations 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 organisations

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) [9]. This was a development of a 2006 tripartite agreement among the BIPM, the OIML and ILAC. In the declaration the BIPM, the OIML, ILAC and ISO endorse recommendations related to

- use of the CIPM MRA and ILAC Arrangements,
- establishing measurement uncertainty in accordance with the principles set out in OIML G 1-100:2008: *Evaluation of measurement data - Guide to the expression of uncertainty in measurement (GUM)* [12],
- metrological traceability to the SI, and
- the use of the OIML-CS.

Adhering to these principles enables legislators, regulators and exporters/importers to take advantage of an international set of mutually supportive systems and thus reduce technical barriers to trade (TBTs). The declaration also contains brief statements on the roles of the various signatories that are also mentioned from 4.2.2 to 4.3.

4.2.2 The Metre Convention

The BIPM is the scientifically expert intergovernmental organisation [16] 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.

[16] Resolution 4 of the 26th General Conference on Weights and Measures (2018).

4.2.2.1 Mission and role of the BIPM

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

- scientific discovery and innovation,
- industrial manufacturing and international trade, and
- 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" [13], 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, and 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, and among other matters, discusses 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 follow 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 an 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:

CCAUV: 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 the 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 capabilities (CMCs) 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 [11] established the International Organisation of Legal Metrology (OIML) and provides the constitution for that organisation. The OIML is an intergovernmental treaty organisation whose membership includes Member States that participate actively in technical activities and Corresponding Members that join as observers.

The OIML promotes the global harmonisation 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 (BIML) 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 [11] and the structures of the 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 recognised, for all areas for which governments take responsibility, such as those which facilitate trade, establish mutual confidence and harmonise the level of consumer protection worldwide." (OIML B 15:2011 *OIML Strategy* [14]).

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 organisations and forums concerned with metrology, standardisation, testing, certification and accreditation,
- promotes and facilitates the exchange of knowledge and competencies within the legal metrology community worldwide, and
- 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 Organisation'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 B 6-1, *Directives for OIML Technical Work* [15].

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 Organisations (RLMOs) to meet and share information.

The OIML is an "international standard-setting body" in the sense of the World Trade Organisation's Technical Barriers to Trade (TBT) Agreement [10]. 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 downloaded from 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 harmonise 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, benefit from the OIML-CS as it provides 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 commits, in principle, the signatories to abide by the rules of the OIML-CS. OIML B 18 *Framework for the OIML Certification System (OIML-CS)* [16] establishes these rules whereby signatories voluntarily accept and utilise 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 [17] and Test Laboratories are required to demonstrate compliance with ISO/IEC 17025 [6]. 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 organisations

4.3.1 Standardisation

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 standardisation process has permeated quality management systems with a corresponding impact on the measurement process itself.

4.3.1.1 ISO

The **International Organization for Standardization (ISO)** is an independent, non-governmental international organisation of national standards bodies (members). Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

ISO publishes a range of standards that apply to the manufacture and testing of various products, and the provision of services. In many cases, calibration and testing form an integral part of the requirements of the standards. ISO harmonises its terminology with the VIM and frequently incorporates measurement-related clauses in these standards. As ISO is responsible, together with the International Electrotechnical Commission, (IEC), for ISO/IEC 17025 [6] it endorses the principle of traceable measurement to the SI.

4.3.1.2 IEC

The **International Electrotechnical Commission (IEC)** is a non-profit, non-governmental international standards organisation 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, magnetics 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).

4.3.1.3 JCGM

In 1997, the **Joint Committee for Guides in Metrology (JCGM)** was formed by the seven International Organisations that had prepared the original versions of OIML G 1-100:2008 *Evaluation of measurement data - Guide to the expression of uncertainty in measurement* (GUM) [12] and OIML V 2-200:2012 *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms* (VIM) [1].

The current membership of JCGM comprises eight organisations:

- The two intergovernmental organisations concerned with metrology, the BIPM and the OIML, since 1997;
- The two principal standardisation organisations, ISO and the IEC, since 1997;
- Three international unions, IFCC, IUPAC and IUPAP, since 1997; and
- One international accreditation organisation, ILAC, since 2005.

The JCGM operates through two working groups:

- JCGM-WG1, with responsibility for the GUM [12]; and
- JCGM-WG2, with responsibility for the VIM [1].

Various other international standards organisations 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

4.3.2.1 ILAC

The **International Laboratory Accreditation Cooperation (ILAC)** is the international organisation for accreditation bodies operating in accordance with ISO/IEC 17011 [8] and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025 [6]), testing laboratories (using ISO/IEC 17025 [6]), medical testing laboratories (using ISO 15189 [18]), inspection bodies (using ISO/IEC 17020 [20]) and proficiency testing providers (using ISO/IEC 17043 [19]) and reference material producers (using ISO 17034 [7]).

Accreditation bodies are established in many economies with the primary purpose of ensuring that conformity assessment bodies are subject to oversight by an authoritative body. Accreditation bodies that have been peer evaluated as competent sign regional and international arrangements to demonstrate their competence. These accreditation bodies then assess and accredit conformity assessment bodies to the relevant standards.

The primary purpose of ILAC is to establish an international arrangement between member accreditation bodies based on peer evaluation and mutual acceptance.

The ILAC Mutual Recognition Arrangement (ILAC MRA) provides significant technical underpinning to the calibration, testing, medical testing and inspection results and provision of proficiency testing programs of the accredited conformity assessment bodies that in turn delivers confidence in the acceptance of results.

In addition, the ILAC MRA enhances the acceptance of products across national borders. By removing the need for additional calibration, testing, medical testing and/or inspection of imports and exports, technical barriers to trade are reduced. In this way the ILAC MRA promotes international trade and the free-trade goal of "accredited once, accepted everywhere" can be realised.

Standards such as ISO/IEC 17025 [6] require metrological traceability of measurement results to primary realisations of the SI (often referred to as national measurement standards), or to other appropriate references where SI traceability is not, or not yet, possible.

4.3.2.2 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 the 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 recognised 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.

4.3.3 INetQI

The **International Network on Quality Infrastructure** (INetQI) is an initiative which seeks to bring together all specialised organisations that operate at the international level and that are active in promoting and implementing activities on metrology, accreditation, standardisation and conformity assessment as tools for sustainable economic development.

In 2002, a Joint Committee on coordination of assistance to Developing Countries in Metrology, Accreditation and Standardisation (JCDCMAS) was established by eight international organisations working in these fields. In 2005, this group was renamed as the DCMAS Network to reflect its role more accurately, and two more organisations joined the group.

In November 2018, responding to the challenges of globalisation and sustainable development, twelve international organisations involved with quality infrastructure, trade, and international development met in Geneva to enhance their cooperation in promoting the understanding, value and acceptance of the quality infrastructure and providing guidance and support for its effective implementation and integration worldwide. As a result, the International Network on Quality Infrastructure (INetQI) was born. The current membership is:

- BIPM Bureau International des Poids et Mesures / International Bureau of Weights and Measures
- IAF International Accreditation Forum
- IEC International Electrotechnical Commission
- IIOC Independent International Organisation for Certification
- ILAC International Laboratory Accreditation Cooperation
- IQNET International Certification Network
- ISO International Organisation for Standardization
- ITC International Trade Centre
- ITU International Telecommunications Union
- OIML International Organisation of Legal Metrology
- UNECE United Nations Commission for Europe
- UNIDO United Nations International Development Organization
- WBG World Bank Group
- WTO World Trade Organization

The Chair of the INetQI rotates annually amongst its member organisations.

4.4 Regional organisations

Regional bodies play an important part in the way in which all quality infrastructure organisations 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 others, legal metrology is addressed by dedicated regional bodies (see below). Within the 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, including participation in the operation of the CIPM MRA. The BIPM works closely with the RMOs primarily through the Joint Committee of the Regional Metrology Organisations and the BIPM (JCRB) on the operation of the CIPM MRA. In particular, RMOs carry out regional comparisons corresponding to the CIPM international comparisons, in order to establish and maintain quality oversight of participating institutes. Additionally, RMOs collaborate with the BIPM to organise capacity building and knowledge transfer activities for their members. Some RMOs, most notably EURAMET, run metrology research programmes. Participation in the RMOs is wider than in the BIPM (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 recognised 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 the 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 harmonisation 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 harmonisation in the region, thereby removing barriers to trade. RLMOs are independent of the OIML and of each other, although the OIML hosts an annual RLMO Round Table for exchange of information and views. They may also perform roles which are unique to their particular region – for instance WELMEC works with the European Commission to prepare guidance documents in order to ensure a coherent application of the measuring instruments directives.

In some cases, the same organisation performs the role of both Regional Metrology Organisation and Regional Legal Metrology Organisation. 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 the European Association of Metrology Institutes (EURAMET) and the RLMO is the European Cooperation in Legal Metrology (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).

4.5 Making the most of international and regional organisations

International mutual recognition of the measurement capability of a country 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) [10]. Countries should therefore be encouraged to take part in both the key international organisations (OIML, BIPM, ILAC) and the mutual recognition agreements or arrangements which they provide. The international and regional organisations 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 forums. However, both the BIPM and the 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 in a country facilitates participation in international organisations. In particular, central government must take the lead in coordinating international issues, including interfaces with other authorities. This is the case for instance with intergovernmental treaties (e.g. the Metre Convention and the OIML Convention [11]), including acceptance of other countries' measurement results. The relationships and engagement with the RMOs and RMLOs 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 for Weights and Measures (CIPM MRA).

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

Part 5 – Policy options for 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 governments 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 measurement-related fraud. It must be organised in a comprehensive and coherent policy, on the basis of a Law on Metrology.

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 standardisation activities, as well as the relevant international metrological organisations (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

The purpose of a national measurement system is to support activity across a country's economy. Therefore, the shape of that economy and the way it is expected to develop is crucial to decisions on the distribution of resources and the structures which should be the priorities for reform. Different areas of metrology are relevant to different sectors of industry, commerce, scientific research and innovation. The starting point for drawing up a national metrology policy should be an understanding of which of these sectors are the most important to the country's economy.

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 factors:

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 a 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, as well as benefitting 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 fulfilling that need:

a) enabling or directing public bodies such as the NMI to provide the testing and calibration services;
b) developing a private sector capable of providing these services (which may need to be accredited), ideally supported by the NMI; and
c) facilitating access to test and calibration services in other countries.

The right approach (or the right mixture of different approaches) will depend very much on the circumstances of each country.

Further guidance on identifying sectoral priorities when developing a national metrology system can be found in the PTB report *Steps towards a National Metrology System* (Eberhard Seiler) [21].

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 organisations 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 coordinating the activities of all these institutes, in particular as regards their input into the 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 their relevant facilities and expertise. It should be noted, however, that even in cases where a single institute deals with traditional physics and engineering, the extension of metrology into fields such as chemistry, medicine and food sometimes requires cooperation with 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 the others. It is important to have clarity as to whether the lead NMI will have the right to designate additional institutes, or whether this right is retained at a higher level of government. In addition, it should be clear what responsibility the NMI has for coordinating and/or representing the 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 organisation with services to the public. This has often required the introduction of more flexible accounting or management processes that are closer to the management models for the private sector than to those for administrative units in government.

Some governments have sought alternative models, in particular in "distributed" systems where there are a number of organisations with a different ownership or legal status, but where the majority of funding is still arranged to come from public sources.

In the few cases where the required expertise is wholly within an industrial or commercial organisation, 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 organisation concerned as a provider of the specific national service. The designated status only applies to the role of the organisation 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.

There are typically three forms of NMI:

1) a public institute owning and running its own laboratories;
2) a private institute operating under the authority of the government (with controls to safeguard fair competition and national security); and
3) a public agency coordinating public or private institutes.

The choice of the form largely depends on 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.

Before deciding on the form and arrangements of the NMI it is recommended that there should be a survey on the main capabilities existing in the country, in private, semi-public and public laboratories. An examination of the different options is also necessary, in particular whether to transfer some of these capabilities to a central institute or to a national network.

In all cases, however, the institutes must have (or be vested with) the legal capacity to enter into international agreements or arrangements on mutual acceptance and mutual recognition in their domain of competence. There should also be adequate safeguards of impartiality – in particular to ensure that where an NMI offers products or services in competitive markets this does not cause unfair competition. 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. Funding for NMIs should be based on the principles identified in 5.6.1.

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 specialising 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 and it is becoming increasingly important to share skills and competences between all areas of legal and scientific 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 national standards bodies and national accreditation bodies, where they exist. 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, is 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 coordination mechanisms (see 5.4).

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 decentralisation is essentially a matter of the political organisation of the country. In the Law on Metrology, it will be defined in accordance with the fundamental texts (Constitution), with the political and administrative organisation 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 specialised 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 options for delegation must be carefully studied considering the tasks that are being delegated and the respective advantages and disadvantages. In this study, factors to be considered include 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, and positive effects of competition on costs and efficiency.

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 cooperation and coordination 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 coordination

One approach is for all the issues of the national metrology policy at the central level (e.g. scientific, industrial and legal) to 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;

- organising or ensuring international representation of the national metrology bodies and system;
- facilitating 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 organisations and commitment in the work and recommendations of these organisations,
- 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 and other metrology services,
  - 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 one exists.

5.4.3 Coordination in legal metrology

Legal metrology includes five main activities:

- setting up legal requirements;
- participating in international engagement for harmonisation of technical requirements and compliance activities;
- conducting control/conformity assessment of regulated products and regulated activities;
- supervising regulated products and regulated activities; and
- providing the necessary infrastructure for correct measurements.

Coordination 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 LLMAs. Where there is a single central government authority this may be its responsibility and when the LLMAs are not directly under the control 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 LLMAs;
- instruments, measurement procedures and measurement results accepted by an LLMA are accepted by the other LLMAs;
- no deviating interpretations of laws and regulatory requirements should exist among LLMAs; the national authorities may ask an LLMA to revise its interpretation of the regulatory requirements when this interpretation appears to deviate from common interpretation;
- the LLMAs are represented in intergovernmental work and accept the agreements signed in the intergovernmental organisations.

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 need a forum to capture their input. One of the ways of doing this is for the responsible minister to set up a metrology board to operate as a consultancy body for metrology in the country. The stakeholders represented should include other parts of government, the NMI, legal metrology authorities, private providers of metrology services, industry and other users of instruments such as universities.

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 qualifications and assessments, and
- advise on functional matters of the board/council.

Notwithstanding the above, other solutions may also be appropriate to pursue the primary goal, which is the participation of all stakeholders in order to respond appropriately to trends and national needs in the field.

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:

- setting up of technology platforms (or networks) for collection and dissemination of expertise and experiences;
- stimulation of cooperation in research projects (themes) in which many stakeholders can take part;
- development/provision of rationales supporting harmonised standards for measurement and testing; and
- organisation 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 are 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; and
- use of authorised private sector bodies to undertake certain tasks.

It is important that changes to the legal framework fit with the country’s wider regulatory reform agenda. However, because legal metrology plays a vital role in delivering economic, health, safety and environmental protections and the benefits and risks of any regulatory reform proposals need to be carefully considered.

Written 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 have become more important. One of the first decisions for governments 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 verbatim text,
- 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, or
- 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 regulation. These are described in Figure 6. The approach adopted by a country will depend on its broader legal traditions and may vary between different areas of legal metrology.

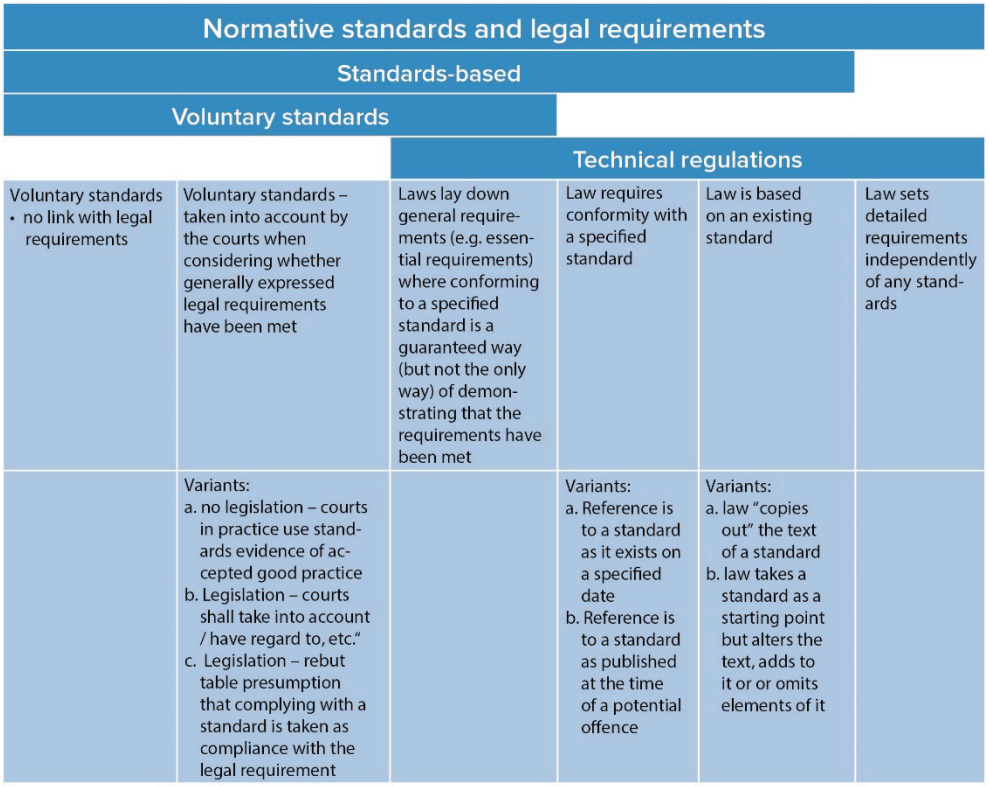

Figure 6 – Relationship between standards and technical regulations

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.

Governments also need 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 recognised and accepted processes;
- establishment of standards of weights or measures and standards of net contents (average or minimum fill requirements) for any packaged commodity; and
- establishment (if necessary) of requirements for unit pricing information.

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 7 shows the possible responses to infringements as the risk of the offence increases.

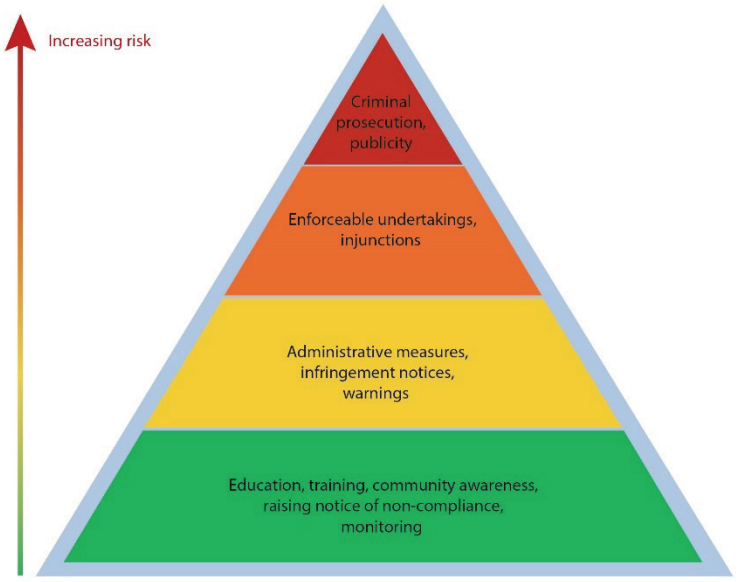

Figure 7 – Enforcement strategy as a function of risk

Ideally, the level of education and awareness-raising should be sufficient such that offences do not occur. When 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. For a company that offends repeatedly and regards any normal penalty as a necessary cost of business, an enforceable undertaking is a powerful tool to change the company's behaviour.

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

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 government agencies. The two areas where important policy decisions are required are the funding of NMI activities and the funding of legal metrology infrastructure.

5.6.1 National Metrology Institutes

The missions 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 NMIs must reflect these missions.

The establishment of the NMI, including the general operation of the laboratories, requires funding from the government on a sustainable 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 funding model for the NMI is to charge the direct costs and other associated costs for services such as delivering a particular calibration to a client.

Where the NMI is the main national provider, i.e. there is no secondary tier of commercial calibration laboratories, a higher proportion of costs is generally recovered. Care needs to be taken when the NMI has significant influence on mandating a service under a regulatory background. There is a risk that the NMI becomes dependent on the income from the mandated service. 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 for fear of loss of income, even when it is technically no longer necessary.

It is important to consider funding for research and development separately. Establishing national standards requires development work, because the standards inevitably need some support and improvement as technology moves forward if they are to remain current. In a small NMI it may be possible to manage this process through procurement, e.g. buying better equipment and/or having national standards calibrated by another NMI with appropriately low uncertainties. Nevertheless, all NMIs will need to undertake some level of development work and will require appropriate funding. This need becomes greater with the demand for increasing scope and quality of the services being offered. Some smaller NMIs may develop links with a local technical university, for example taking postgraduate students to help the development.

The decision on whether or not to engage in a funded advanced research programme in metrology will depend on national priorities, needs and available resources. Many NMIs function effectively without such a research programme, provided they are able to undertake the development of the national standards described above. However, at least in more developed economies, an advanced 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 or regional programmes. Research activities advance the existing standards, prepare the next generation of standards, and provide impact through the application areas of metrology. In general, 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 organisations.

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 forums, and for those with the technical capability, the CIPM's Consultative Committees. If the NMI has responsibility for legal metrology, then the activities of the OIML should be budgeted. Depending on the scope of the NMI, there may be many other scientific forums that are important to its work. At the most senior level, NMI directors will need funding to participate in the regional and international forums that shape and decide the metrology landscape.

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

5.6.2 Legal metrology infrastructure

Legal metrology infrastructure at the national level requires high-level policy-making, technical expertise on standards (primarily OIML Recommendations), and national support of the metrological control systems for measuring instruments, prepackaged products, transactions based on measurement, and measurement practices.

This national level infrastructure is needed to support some or all of the following activities:

- determining and prioritising the instruments and industry sectors that require metrological control;
- participating in international technical committees that develop and improve international model regulations (documentary standards);
- managing the adoption/adaption of international model regulations into national regulations;
- consulting and engaging with industry and consumers on regulatory standards, both at the international development stage and at the national adoption/adaption stage; and
- participating in international forums to advance international harmonisation and acceptance of test results.

A key objective of this infrastructure is to minimise technical barriers to trade and so it is considered important that all countries participate in international and regional legal metrology forums. Participation in OIML Technical Committees provides an opportunity to represent an economy's needs and interests in the development of international model regulations.

An integral part of this international and regional engagement is national consultation to seek the views and needs of industry and consumers.

Appropriate funding to support these activities is particularly important if national interests are to be adequately considered at the development stage of International Recommendations. Without such funding, there is a risk that International Recommendations will not meet national needs.

It will often be appropriate, however, for businesses to meet the direct costs of some legal metrology activities, through fees and charges. This may apply, 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 authorised 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:

- fees should be transparent - businesses should have a clear understand of the costs they will have to bear;
- 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 service;
- where authorised 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; and
- even where there is heavy reliance on 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 and the Law on Standardisation. The Law on Metrology should also consider international treaties such as the WTO/TBT Agreement [10][17], the WTO/SPS Agreement [22][18], the Metre Convention [23] and the OIML Convention [11]. 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 this Document. These Elements should be (re)worded taking into consideration the legislative drafting practice and the needs and the culture of the country, whilst maintaining their simplicity and clarity.

The criteria for (re)wording the Elements 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 a 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 government (staff needed for their enforcement, equipment, operating costs), costs for manufacturers and users of instruments, and expected benefits.

The obligations resulting from the OIML Convention [11] and from the WTO TBT Agreement [10] 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

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17 World Trade Organization - Agreement on Technical Barriers to Trade [10] (see https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm).

18 World Trade Organisation - Sanitary and Phytosanitary Agreement (WTO SPA) [22]. (see https://www.wto.org/english/tratop_e/sps_e/sps_e.htm).

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.

As noted in Part 1, it is important to be precise in the use of technical terms, particularly those which 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] [1] or the *International Vocabulary of Terms in Legal Metrology (VIML)* [OIML V 1:2013] [2]. When preparing a Law on Metrology, or other regulations, it is therefore 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.

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.

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

- globalisation of trade and services,
- technical developments, e.g. use of integrated measurement systems instead of discrete measuring 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 standardisation, etc. have to be taken into account.

6.3 Organisation 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 as "enabling legislation". This means that a Law on Metrology will address general and broader parameters that are not subject to frequent change such as administration, offences, rule setting powers and relevant definitions as well as responsibilities or obligations.

Specific requirements for organisations, procedures and measuring instruments should be laid down in legal documents such as decrees, circulars or by-laws. These may covers matters such as technical requirements or inspection frequencies which may change from time to time.

Binding regulations should be issued by the responsible ministry or the metrology authority. These regulations should comply with applicable OIML Recommendations, decisions of the Metre Convention and ISO/IEC standards.

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

An example of this is set out in Figure 8.

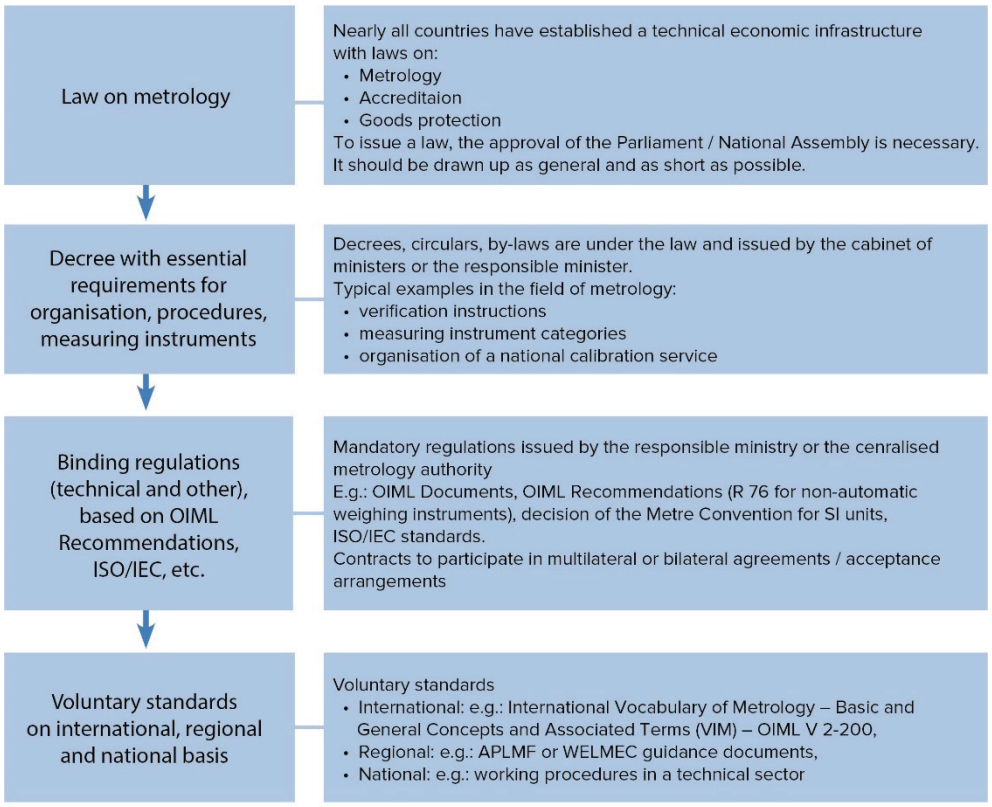

Figure 8 – Hierarchy of laws, decrees and standards

6.4 Legal units of measurement

A legal framework is required to specify which units of measurement are authorised to be used or made mandatory and for which applications. It is not necessary to include a full definition of the units in the law, as this is a scientific issue usually dealt with by international treaties or standards. Detailed definitions of the SI units are given by the SI Brochure [13] issued by the BIPM. Exceptional and customary units outside the SI 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 the 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 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 used as the basis for 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 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 [11] and with the WTO/TBT Agreement [10], 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 authorised 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 prepackers.

The regulatory requirements should take into account the equipment used for realising 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 recognise 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 measuring 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 6.5.

The instruments subject to these regulations should provide measurement results in the legal units defined in 6.4, 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 [10], 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 their conformity to other 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. subsequent verification, in service inspection and field surveillance), or are withdrawn from use if they do not meet the requirements, 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 certify the status of the conformity of the instruments with legal requirements (e.g. type approval or verification marking).

A measuring instrument 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 repaired or withdrawn 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 unauthorised 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 conformity assessment bodies to recognise instruments which conform with equivalent regulations in other countries. The regulations may allow conformity assessment bodies to enter into mutual acceptance or recognition arrangements and agreements with other countries, including the OIML Certification System (OIML-CS) [16].

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

The regulations may impose registration and other requirements for service agencies that install, adjust and maintain measuring instruments. The regulations should not conflict with other regulatory requirements applied to the agencies.

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

When measuring 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, possess for use or put into service for regulated applications, any measuring instrument subject to legal metrological control (see Element No. 16 of Annex A) unless the instrument bears the required control marks, sealing marks or audit certificates.

The owner of or the person/organisation responsible for a measuring instrument subject to legal metrology regulations is required to maintain the conformity of that instrument to legal requirements (including controls on accuracy) while it is in service. Use of the instrument should also comply with all operating instructions and maintenance requirements supplied by the manufacturer.

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 the OIML Certification System (OIML-CS) [16] covers a given category of measuring instrument, it is recommended that the national conformity assessment procedures for those instruments take the OIML-CS into account.

When conformity assessment procedures in another country comply with OIML Recommendations and Documents, the national conformity assessment procedures should take this into consideration.

Either the central government authority (see 3.2.1) or the legal metrology authorities (see 3.2.3) should decide whether an OIML-CS certificate or a foreign conformity assessment result is recognised to be as equivalent to the national conformity assessment. These authorities should also be in charge of the corresponding national conformity assessment procedures.

OIML Recommendations generally present recommended conformity assessment procedures applicable for Member States.

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.

A mix of appropriate market surveillance activities, carried out by enforcement authorities, can provide market confidence to those adopting good metrology practice. Manufacturers and prepackers gain assurance from surveillance activities carried out by enforcement authorities testing the robustness of systems and providing informed, impartial, technical feedback.

6.8 Legal framework – other provisions

It is necessary that the offences that arise from non-compliance with the obligations of the Law on Metrology are clearly listed, with corresponding penalties, in an appropriate law.

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

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, as a buyer, more than the represented quantity,
  - misrepresenting the quantity in any manner to mislead or 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 misrepresenting the price in any manner to mislead or 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 making 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 to have a clear statement of the responsibilities of those who use, keep, import, manufacture, repair, sell or rent measuring instruments or equipment intended for uses covered by the national legislation on metrology.

In addition it 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 businesses operate and societies are organised. 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); and
- 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 trend away from relying solely on verification towards using type approval controls and other conformity assessment procedures;
- globalisation and accompanying trade agreements mean that national legislation increasingly needs 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 digitisation 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; and
- 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 that may become apparent in the future), it is important that flexibility is built into the arrangements that are introduced. It is useful to consider five main areas:

- policy development;
- institutional structures;
- legislative arrangements;
- personnel training & development; and
- engagement with the public and society.

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 in which the different part of the metrology system work together. Where a metrology advisory board/council exists (see 0), this may be a suitable body to supervise or carry out the review. It is important that adequate resources are available to conduct the review. The publications of international and/or regional metrology organisations (see Part 4 –) may provide relevant information and research material.

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 should not prevent 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 a 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 organisations may again be helpful in this area.

7.8 Engagement with the public and society

As with many other areas of consumer protection regulation, consumers and other vulnerable groups, such as small traders, have an important part in play in safeguarding their own interests. New technology, including social media, has made it easier for consumers to share information and to check the accuracy of claims that traders make. These same developments make it possible for many forms of voluntary networks and institutions of society to play a more active role, and where appropriate, each country's law on metrology should facilitate this. However, these mechanisms can be effective only if consumers and other vulnerable groups are aware of both what their rights are and how to exercise those rights. Clear and easily

accessible means must be available to report problems to regulatory/enforcement authorities. Moreover, consumer confidence also requires that the authorities have the necessary powers and resources to act when they are informed about serious problems. It is desirable that public education and awareness policies are written in such a way that they reflect these considerations.

Part 8 – References

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[2] OIML V 1:2000: *International Vocabulary of Terms in Legal Metrology (VIML)*

[3] ISO 17000:2004 *Conformity assessment — Vocabulary and general principles*

[4] OIML E 2:2003: *Benefit of legal metrology for the economy and society*

[5] D 34 *Conformity to Type (CTT) - Pre-market conformity assessment of measuring instruments*

[6] ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*

[7] ISO 17034 *General requirements for the competence of reference material producers*

[8] ISO/IEC 17011 *Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies*

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

[10] WTO Agreement on Technical Barriers to Trade (TBT), January 1995

[11] OIML B 1:1968: *Convention establishing an International Organisation of Legal Metrology*, 1955

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[13] BIPM: *The International System of Units*, 9th Edition, 2019

[14] OIML B 15:2011 *OIML Strategy*

[15] OIML B 6-1 *Directives for OIML Technical Work*

[16] OIML B 18 *Framework for the OIML Certification System (OIML-CS)*

[17] ISO/IEC 17065 *Conformity assessment — Requirements for bodies certifying products, processes and services*

[18] ISO 15189 *Medical laboratories — Requirements for quality and competence*

[19] ISO 17043 *Conformity assessment — General requirements for proficiency testing*

[20] ISO/IEC 17020 *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

[21] PTB Report “Steps towards a National Metrology System” (Eberhard Seiler, April 2017)

[22] WTO SPA: World Trade Organisation - *Sanitary and Phytosanitary Agreement*

[23] The Metre Convention (Convention du Mètre), CIPM

Note: Other OIML International Documents, or documents issued by other International and Regional Metrology Organisations 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, if other legislation on matters such as consumer protection, conformity assessment or accreditation already exists, that legislation is adapted. 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 Standardisation, etc. and international treaties such as the WTO/TBT Agreement [10][19], the WTO/SPS Agreement [22][20], the Metre Convention [23], the OIML Convention [11], etc.

This Annex sets out a number of different "Elements" to be considered when developing or amending a Law on Metrology, drawing on the advice in Parts 1 to 7 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.

[19] World Trade Organization - Agreement on Technical Barriers to Trade [10] (see https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm).

[20] World Trade Organization - Sanitary and Phytosanitary Agreement (WTO SPA) [22]. (see https://www.wto.org/english/tratop_e/sps_e/sps_e.htm).

Element no. 2 (See 3.4.1 and 6.1)

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 [10] as well as other obligations deriving from regional treaties or agreements (these treaties should be quoted in the Law on Metrology).

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) [13],
- carrying out and/or coordinating 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) [13] 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 5.6)

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 into negotiations for international acceptance and recognitions in the scope of their activity.

Element no. 7 (See 3.2.7 and 5.4.1)

The government should 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 5.4.3)

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 0)

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 realisation 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 recognised 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 realisations 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 realisation of the International System of Units (SI) [13] and presented in compliance with the recommendations of the CGPM and the OIML, and with relevant international standards.

Element no. 12 (See 6.4)

The legal units of measurements should comprise the following:

- units of the "International System of Units" (SI) [13], adopted by the General Conference on 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 6.4)

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, the 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 organisation.

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 given in Element no. 11.

Element no. 16 (See 6.5)

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 6.5.1)

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 specialised bodies regarding the activity of the individuals or bodies who perform the measurements.

Element no. 18 (See 6.5.2)

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 recognise 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 (6.5.3)

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 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 recognising national or OIML certificates or test reports or affixed conformity markings.

Element no. 20 (See 6.6)

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 [10], with the exception of the obligation to notify proposed conformity assessment procedures.

Element no. 21 (See 6.7)

The central government authorities mentioned in Element 7 should be in charge of organising

- supervision and surveillance of the bodies to whom tasks have been assigned for the enforcement of the legal metrology regulations,
- market surveillance,
- surveillance of the use of regulated instruments, and
- 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 6.7)

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 6.8)

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 6.8)

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 6.8)

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 6.8)

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 6.8)

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 6.8)

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 6.8)

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 6.8)

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 6.8)

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 authorisations,
- 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 authorised by the proper authority.

Element no. 32 (See 6.8)

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 6.8)

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 6.6 and 4.1)

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 recognise 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 utilise in their work the results of international or foreign conformity assessment systems, providing that the level of confidence is recognised as equivalent to their own procedures.

Element no. 35 (See 5.5)

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 organisation responsible for the conformity.

Element no. 36 (See 6.1)

The organisation 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 6.5 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.

Reference to OIML V 2-200:2012 *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms* (VIM) [1] and to OIML V 1:2000 *International vocabulary of terms in legal metrology* (VIML) [2] 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 organisation 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 3.3 and Element no. 1.

Art. 4: National metrology infrastructure

See 3.2.

Art. 5: Organisation of metrology infrastructure

Information about institutions/organisations/authorised bodies performing metrology activities.

See 3.2, 5.3 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 0 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 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 3.2, 5.3 and 5.4 and Element no. 7.

Art. 9: Local legal metrology authorities (LLMA)

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

See 3.2.4 and 5.3.3.

Art. 10: Legal units of measurements

It is strongly recommended to use the units covered by the "International System of Units (SI)" [13], 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 6.4 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 realisations 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 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 realisations 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.

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 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 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 6.6 and Element no. 34.

Art. 15: Industrial metrology including calibration service

Organisation 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

Powers to make regulations specifying:

- instruments subject to control;
- 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, manufacturers, users

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

See 6.5.1 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 3.3.

Art. 20: Measuring instruments/systems in legal metrology

Powers to make regulations specifying procedures for:

- 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 6.5

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 6.5.3.

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 3.2.3), 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,
- 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;
- 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 6.7 and 6.8 and Elements nos. 21, 22, 23, 24, 25.

Art. 23: International agreements

Operating with foreign countries, recognition of certificates issued abroad.

See 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, and
- for actions at local level, by the local legal metrology authorities if appropriate (when the size of the country allows it, it may be decided that a central government 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 5.5.2.

Agents of the central government authorities and of the local legal 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 5.55.5 and Element no. 35.

Art. 26: Offences

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

See 6.8.

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.