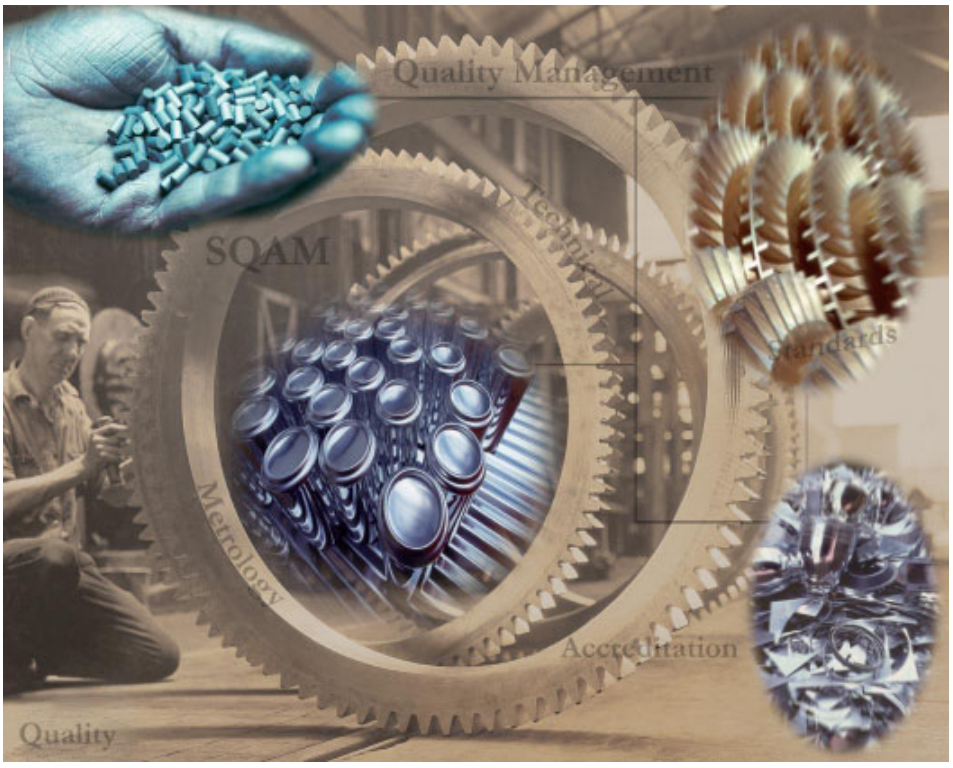
International Trade Centre
UNCTAD/WTO

Standards and Quality Management

ROAD MAP FOR QUALITY

Guidelines for the Review of the Standardization, Quality Management, Accreditation and Metrology (SQAM) Infrastructure at National Level



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Road Map For Quality

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INTERNATIONAL TRADE CENTRE UNCTAD/WTO
Road Map for Quality: Guidelines for the Review of the Standardization, Quality Management, Accreditation and Metrology (SQAM) Infrastructure at National Level.
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Guide providing a framework for assessing Standardization, Quality Management, Accreditation and Metrology (SQAM) infrastructure and identifying gaps in SQAM services to satisfy exporters' needs - discusses major elements of SQAM system and their attributes; provides assessment guidelines in form of questionnaire containing the questions as well as the evaluation criteria and comments.

Subject descriptors: **Conformity Assessment, Accreditation, Quality Management, Standardization, Metrology**.

English

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Foreword

One of the prerequisites for successful exporting is the ability to meet the technical requirements for the product being exported. In some cases, the exporter has to satisfy only the requirements laid down by the importer. In other cases, the exporter has also to meet mandatory requirements laid down by the authorities to, inter alia, protect the health and safety of consumers and the environment. In both cases, there is a need to demonstrate compliance of the product with the specified requirements. This demonstration of conformity should be acceptable to the buyer and to the regulatory authority.

A national infrastructure for Standardization, Quality Management, Accreditation and Metrology (SQAM) plays a fundamental role in ensuring the competitiveness of the export sector by providing conformity assessment services so that exporters can satisfy the requirements of buyers and regulators. An appropriate SQAM infrastructure should fulfil certain requirements. It should provide exporters with adequate information about technical regulations and standards promptly, and communicate impending changes to them. Conformity assessment certificates should be accessible at reasonable cost, delivered within a reasonable time and accepted in target markets. Consultancy services should be available to redesign or improve potential export products to align them with specifications in target markets.

Many developing countries and transition economies do not have a full-fledged SQAM infrastructure and need assistance for its improvement. This publication provides a framework for assessing the SQAM infrastructure and identifying the gaps in SQAM services to satisfy the needs of exporters. It can be used as a tool for needs assessment and for developing a road map for improving the SQAM infrastructure.

We hope that this publication will be of use to decision-makers in developing countries and transition economies who are considering establishing or strengthening their standards and conformity assessment infrastructure and to those carrying out needs assessment for SQAM to support their export development efforts.

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Executive Director
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Acronyms

A	
ANSI	American National Standards Institute
APEC	Asia-Pacific Economic Cooperation
APMP	Association of Proposal Management Professionals
API	American Petroleum Institute
ASQ	American Society for Quality
B	
BIPM	Bureau International des Poids et Mesures
BOBS	Botswana Bureau of Standards
C	
CGPM	Conférence Générale des Poids et Mesures
CIPM	Comité International des Poids et Mesures
D	
DGQ	Deutsche Gesellschaft für Qualität (German Society for Quality)
DIN	Deutsches Institut für Normung (German Institute for Standards)
E	
EEC	European Economic Council
EFQM	European Foundation for Quality Management
EN	European Norm
EU	European Union
EUROMET	European Collaboration in Measurement Standards
G – H	
GLP	Good Laboratory Practice
HACCP	Hazard Analysis Critical Control Point
I	
IAF	International Accreditation Forum
IATCA	International Auditor and Training Certification Association
ICSID	International Council of Societies of Industrial Design
IEC	International Electrotechnical Commission
IECEE	IEC System for Conformity Testing and Certification of Electrical Equipment
IIW	International Institute for Welding
ILAC	International Laboratory Accreditation Cooperation
IPPC	International Plant Protection Convention
IQA	Institute of Quality Assurance, UK
ISO	International Organization for Standardization
ITU	International Telecommunication Union

M

MAS-Q	Metrology, Accreditation, Standardization and Quality
MERCOSUR	El Mercado Común del Sur (Southern Common Market)
MLA	Multilateral Recognition Agreement/Arrangement
MoU	Memorandum of Understanding
MRA	Mutual Recognition Agreement/Arrangement
MSTQ	Metrology, Standards, Testing and Quality

N

NAFTA	North American Free Trade Agreement
NGO	Non-Governmental Organization
NMI	National Metrology Institute
NSB	National Standards Body

O - Q

OECD	Organization for Economic Co-operation and Development
OIML	Organization Internationale de Métrologie Légale
QMS	Quality Management System

S

SADC	Southern African Development Community
SADCMET	Southern African Development Community Cooperation in Measurement Traceability
SAE	Society of Automotive Engineers
SDO	Standards developing organization
SI	Système International d'Unités
SIM	Sistema Interamericano de Metrologia (Inter-American Metrology System)
SPS	Sanitary and phytosanitary (measures)
SQAM	Standardization, Quality Management, Accreditation and Metrology*

T

TBT	Technical barriers to trade
TQM	Total Quality Management

U

UN	United Nations
UN-ECE	UN Economic Commission for Europe

V - W

VDA	German Association of the Automotive Industry
WQC	World Quality Council
WTO	World Trade Organization

* Except in Annex B.

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Chapter I - Introduction

1. Historical Perspective

Since the earliest times, standardization has been part of human existence. It could be said that standardization started with creation. Nothing is more standard than an atom or a molecule, plants, animals and even human beings. It is difficult to say exactly when man began to use standards, at first unconsciously and, later, deliberately. An early reference to standardization is found on the statue of Gouda, the King of the Chaldeans. In the inscription, the sculptor extolled the fine characteristics of the ruler and praised him for the introduction of standards in the building industry.

An early account of building inspection is found on an Egyptian frieze in Thebes, dating from 1450 BC, which also illustrates brick-building instruments. Another early account dealing with sanctions that apply when standards were not upheld is found in The Code of Hammurabi of Babylon (2067 to 2025 BC) that promised death to builders of houses that collapsed on their inhabitants. Religious writings such as the Bible and the Koran include references to measurement standards as early as 1500 BC to ensure fair trade.

It was not only trade, and the need for specific qualities of merchandise, which demanded a need for uniformity. The fear of invasions, the desire of rulers to extend their power, and wars also contributed to standardization. Shih Huang Ti, who built the Great Wall of China to keep the Tartars out, was the founder of the Chinese Empire. He announced a uniform set of laws and a system of weights and measures for all the tribes in his empire, to settle differences which hampered trade. In the West, Charlemagne and William the Conqueror tried to set a uniform system of standards. None of these have survived.

The French Revolution in 1791 led to the establishment of the metric system. The French politician Talleyrand realized that a uniform system of weights and measures would enhance national unity. Based on earlier work by James Watt (Scotland) and Simon Stevin (Netherlands) his proposal for the introduction of a completely new measurement system, thereby abolishing all other systems in use, was adopted by the French Parliament and was subsequently implemented in 1800. France invited other countries including Britain and the USA to join in making the metric system into a universal system.

Credit for the present idea for standardization could be given to HJ Skelton, a steel merchant of London. Skelton wrote to the Times in 1895 that rolled steel girders from Germany and Belgium were imported by Britain because too much individualism was prevalent in Britain instead of pursuing collective action that would be economically advantageous. He bemoaned the fact that architects and engineers unnecessarily specified such diverse types of sectional material for a given work, that anything like economical and continuous production became impossible.

It was becoming clear that because of the fast pace of modern life, more uniformity was required – not only at national level but also internationally. As larger quantities and larger production lines of the same product became possible, production needed to be regulated. This leads to lower unit costs, efficient utilization of raw materials and labour in the production of an

article that meets the needs of the consumer. The consumer, on the other hand, is better informed and insists on higher standards of performance, safety, reliability and quality.

The existence of Standardization, Quality Management, Accreditation and Metrology (SQAM) is now taken for granted in the market place. It is unfortunately also true that it has not been pursued to its optimum logical consequence; witness as an example the various standards systems in the field of weights, measures and currencies. It seems also that it is not clearly understood that standardization does not aim at a uniform sameness, but that it is an attempt at reducing confusing proliferation and creating order in the interest of mankind and its environment.

Technological developments coupled with the greed of unscrupulous suppliers have as a result that unsafe or hazardous commodities are being supplied to the consumer. The increasing magnitude of this problem has resulted in governments imposing legally binding requirements on the supply of commodities to protect society. These technical regulations are based on the same elements the market place relies on, namely standards, quality, accreditation and metrology; be it in a legalistic rather than a voluntary way. The need for optimizing the concomitant institutional frameworks therefore becomes even more critical in order not to impede trade and to ensure an effective and efficient use of resources.

2. The value chain for standards, quality, accreditation and metrology

The SQAM[1] system is made up of many building blocks. These have developed over many years, are still developing, hence no definitive model for the effective and efficient implementation has yet been identified. It is also true, however, that from the performance of the various models in operation throughout the world, the relationships between the various activities and institutions at national and international level, some measures of what is working and what not is emerging. Understanding the value chain of the provision of commodities and services, and the points of intervention of standards, metrology, conformity assessment and accreditation, i.e. the SQAM system, will help in assessing the SQAM system operating within a country.

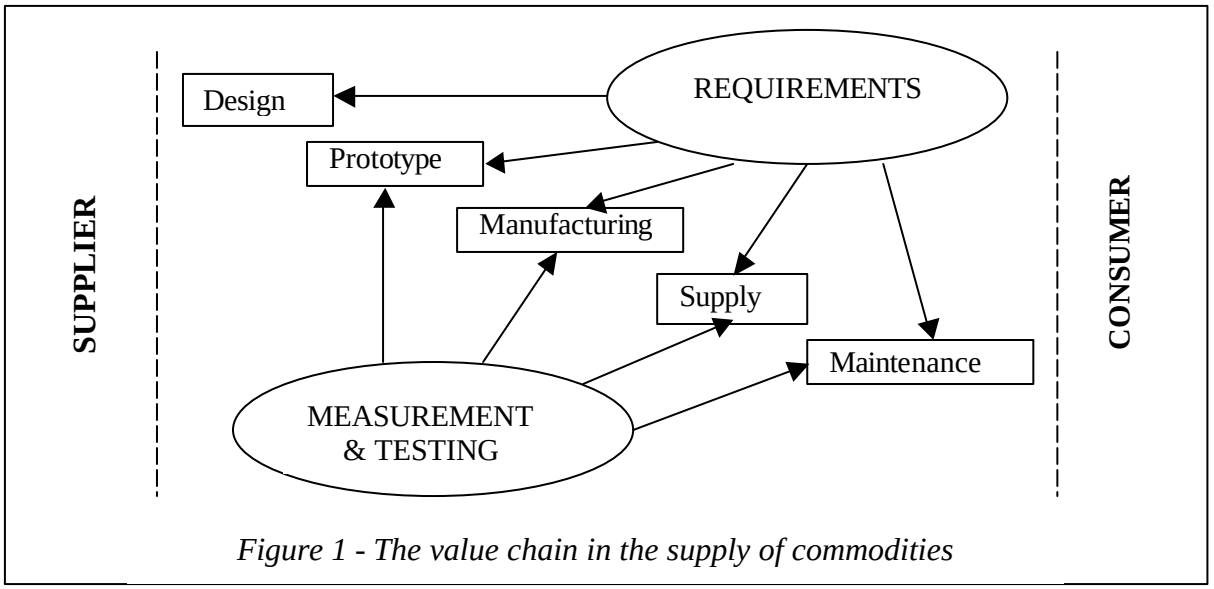


Figure 1 - The value chain in the supply of commodities

[1] There are also other abbreviations used for SQAM, like MSTQ (Metrology, Standards, Testing and Quality) or MAS-Q (Metrology, Accreditation, Standardization and Quality). There is no universal acceptance of any of these acronyms.

The value chain between the supplier and the consumer is shown in Figure 1. The consumer may determine the requirements for the desired product or service before purchasing, or the supplier can provide the requirements unilaterally or anything in between. In this situation the requirements are considered to be in the voluntary or non-regulatory domain. Over and above these voluntary requirements, governments also impose mandatory requirements for many types of products and services to ensure the safety and health of people and the environment. In this case the requirements are considered to be in the regulatory domain. In the non-regulated as well as the regulated case testing and measurement is required to demonstrate compliance with the requirements. The output of these activities is to provide assurance that a product meets customer expectations, in other words a quality product.

Accreditation is a support mechanism to engender trust in the workings of metrology and conformity assessment. Each of these SQAM activities or major elements will be expanded in the chapters following, thereby building the understanding of their specific role in the value chain, the way in which they are provided in the market place and the relationship between them. Institutional arrangements for the service providers will also be discussed, including the national, regional and international relationships. Figure 2 is similar to Figure 1, but uses the SQAM "jargon" instead.

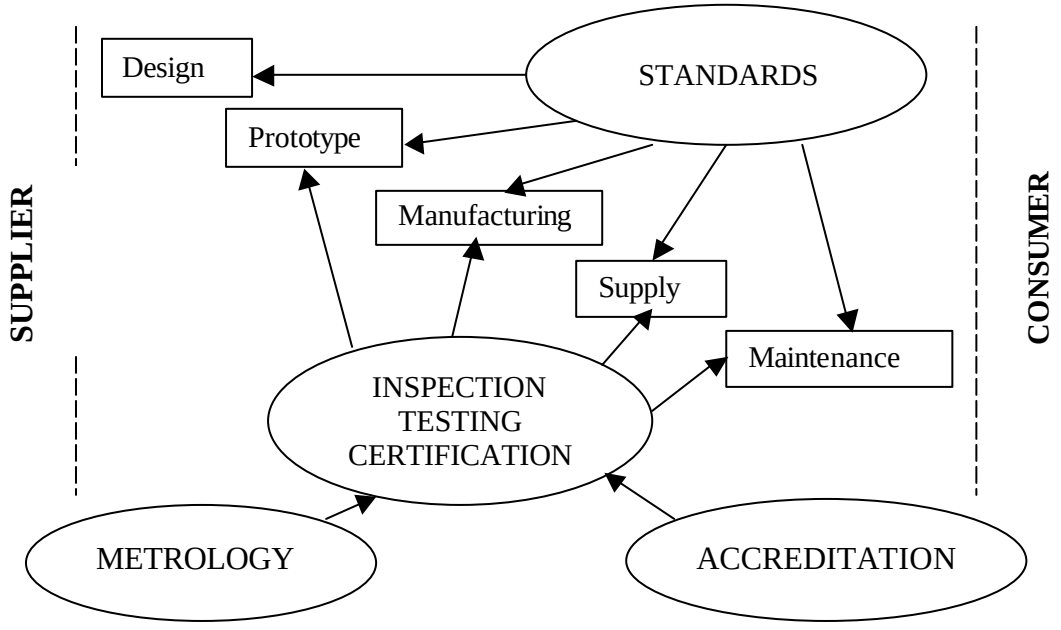


Figure 2 - Conformity assessment in the value chain of the supply of commodities

An inter-relationship exists between standards, metrology, testing, certification and accreditation as can be deduced from Figure 2 (as well as Figure 7 later on). These activities also take place at national, regional and international level. The relationship between the national, regional and international levels can be thought of as a hierarchy. However, not all the activities have the same type of hierarchy. Whereas Standards and Metrology have well developed national, regional and international structures, accreditation operates generally at the national and international level. Conformity assessment is very much a national phenomenon, with some regional structures that are beginning to be established, but very

little being available at international level. A more detailed discussion will be provided in the chapters following dealing with each of the activities. Formal definitions of the various terms used in this handbook are provided in Annex A.

3. Model SQAM systems

3.1. Regional and international arrangements

Due to trade and other pressures, SQAM institutions have increasingly been gravitating together at regional and international level in order to work more closely. The outcome of these liaisons has been a better understanding of the attributes of the SQAM system, as well as greater harmonization of metrology, standards and conformity assessment matters. The regional and international systems have also provided means of recognition of competence that goes far beyond national boundaries. Failure to become part of these regional and international organizations usually results in the non-acceptance of the outputs of the national system at international level. This has dire consequences for the industry of the country as well as creating major barriers to trade. The various regional and international organizations of note for each of the elements of the SQAM system are discussed in each of the chapters following. Table 1 provides an overview of the most important international organizations relating to the SQAM elements.

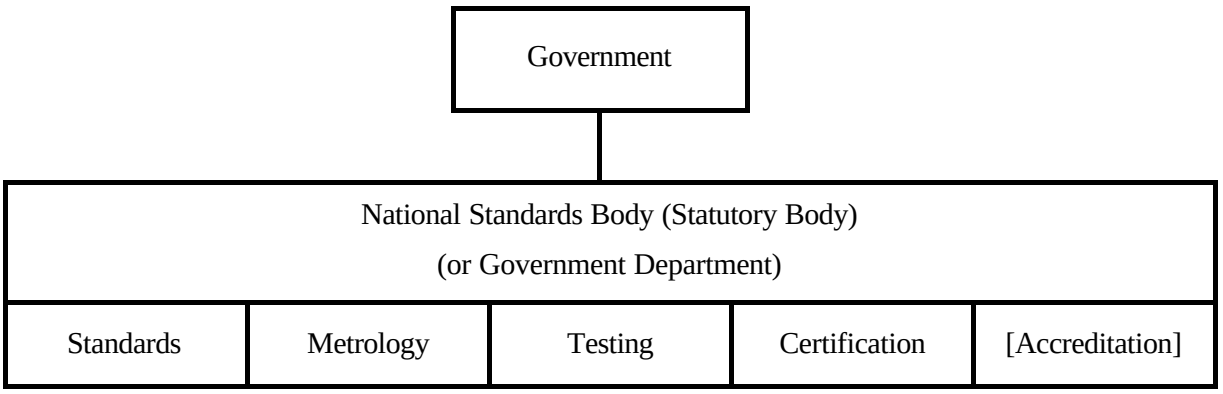
Table 1 - International SQAM organizations

SQAM element	International organization(s)
Metrology	Bureau International des Poids et Mesures (BIPM)
Legal Metrology	Organization Internationale de Métrologie Légale (OIML)
Standards	International Organization for Standardization (ISO) International Electrotechnical Commission (IEC) International Telecommunication Union (ITU) Codex Alimentarius Commission (CAC)
Accreditation	International Accreditation Forum (IAF) International Laboratory Accreditation Cooperation (ILAC)

3.2. National arrangements

The spectrum that will be encountered can vary from a totally integrated approach to totally decentralised individual organizations for each of the SQAM elements. Many of these arrangements can be effective and efficient, but some relationships give rise to problems, notably conflicts of interest. In the following diagrams a few of the more common arrangements are discussed.

3.2.1. Integrated Approach

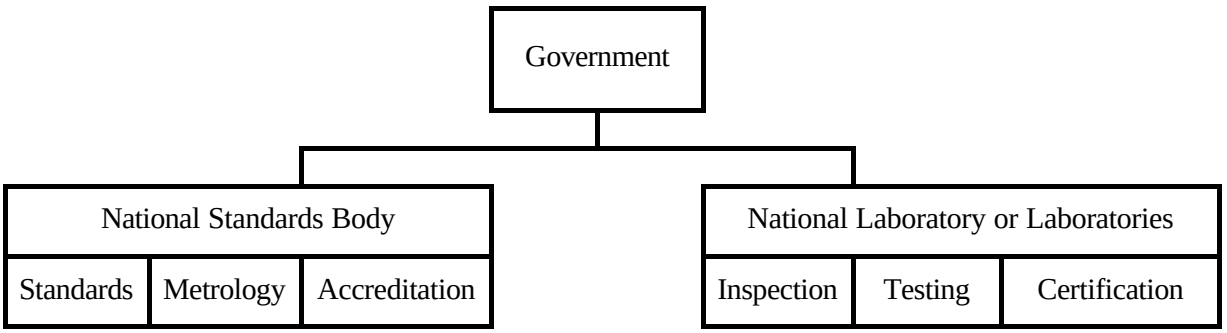


The integrated approach has been favoured for many years by especially the developing and transition economies, supported by members of the donor community that believed it to be the most effective way of setting up a viable MSTQ (Metrology, Standards, Testing and Quality) system. It is common to find standards, metrology, testing and certification within the same organization, less common to find accreditation. The reason for the absence is that accreditation is a fairly new element to be added to the MSTQ system, creating the new concept of SQAM (Standardization, Quality Management, Accreditation and Metrology), hence many countries with integrated systems have not yet established accreditation services, apart from the fact that they do not believe that it is needed as the organization has the monopoly anyway.

The integrated organization often enjoys legal protection against providers of similar services, i.e. they are the only recognised provider in the country by law. Inherent in this approach are a number of real problems, hence the approach has fallen from favour in recent times, especially where a more open trade policy is pursued.

The advantage of this approach is that the administrative support is shared by all the elements, it facilitates integration of relevant legislation and a common approach for all the SQAM elements and it makes optimum use of scarce resources (funding, personnel, equipment, buildings, etc.). The disadvantage is that if the organization enjoys legal protection against competition, then it is deemed to have a monopoly which is difficult to accept by trading partners, apart from the fact that it may violate WTO/TBT Agreement obligations. This lack of competition also quickly leads to lack of competence and inefficiencies. The inclusion of accreditation leads to a major conflict of interest with other laboratories, as well as its own laboratories.

3.2.2. Semi-integrated Approach

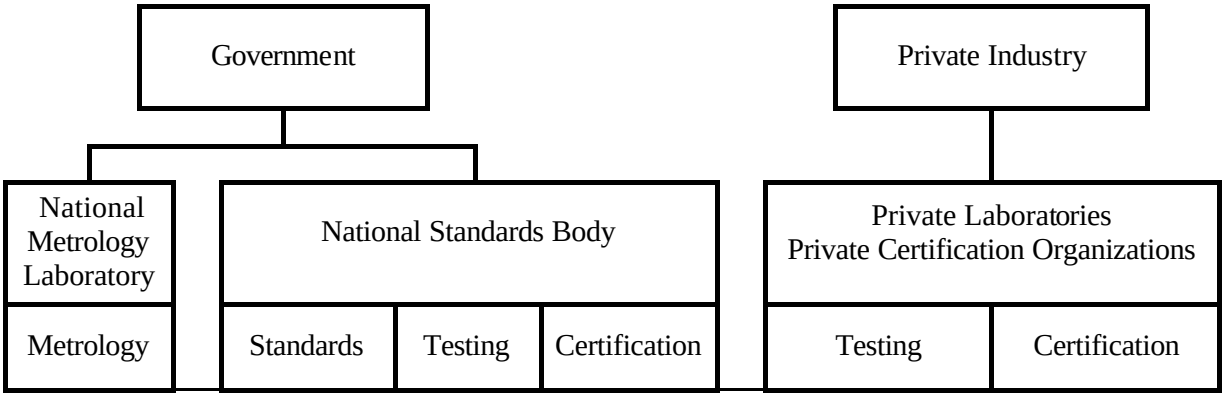


A large number of variations can be found under this heading. The elements of SQAM are still government departments or statutory bodies, but the various elements have been grouped in a more functional way. Two or more government organizations are now responsible for the whole SQAM infrastructure and not only one as is the case for the truly integrated approach. One example showing two organizations is given in the figure above, but other variations with three or four organizations are also possible.

The important part is that the organization responsible for accreditation should not be the same organization(s) that provide inspection, testing and certification services. Otherwise a conflict of interest would arise. This approach is gaining ground in that it has all the advantages of the Integrated Approach, but deals with some of the disadvantages.

The advantage is that administrative support is shared by some of the elements, a common approach to legislation and SQAM activities is facilitated and it engenders optimum use of scarce resources (funding, personnel, equipment, buildings, etc.). The disadvantage is similar to the Integrated Approach in that if the organizations enjoy legal protection against competition, then they are deemed to have a monopoly. The lack of competition similarly leads to lack of competence and inefficiencies.

3.2.3. Traditional Statutory Approach

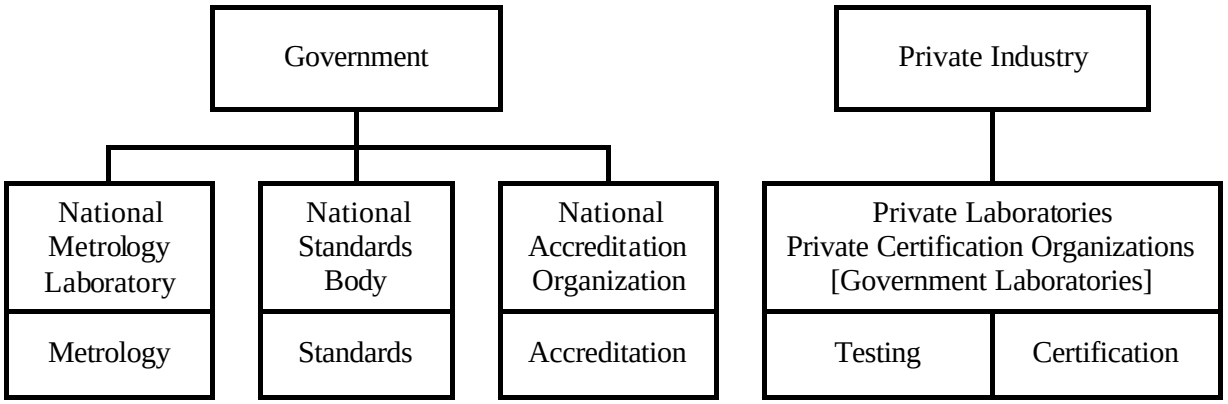


The Traditional Statutory Approach has long been the favoured approach in British sphere of influence. It has a number of advantages in that it provides a mechanism for the

government to set up and develop the infrastructure required to implement technical regulations as well as help industry in all standardization matters. In more recent times, as industry develops, governments relinquish their involvement in especially the testing and certification service provision and private industry has taken up that role. It is still a very good model to consider in the early stages of a SQAM system.

As can be seen in the diagram, accreditation does not feature in this approach from the 1920s, because it is a more recent addition to the SQAM landscape. Nothing however, prevents a country from establishing a third government organization to deal with accreditation in order to modernise the system.

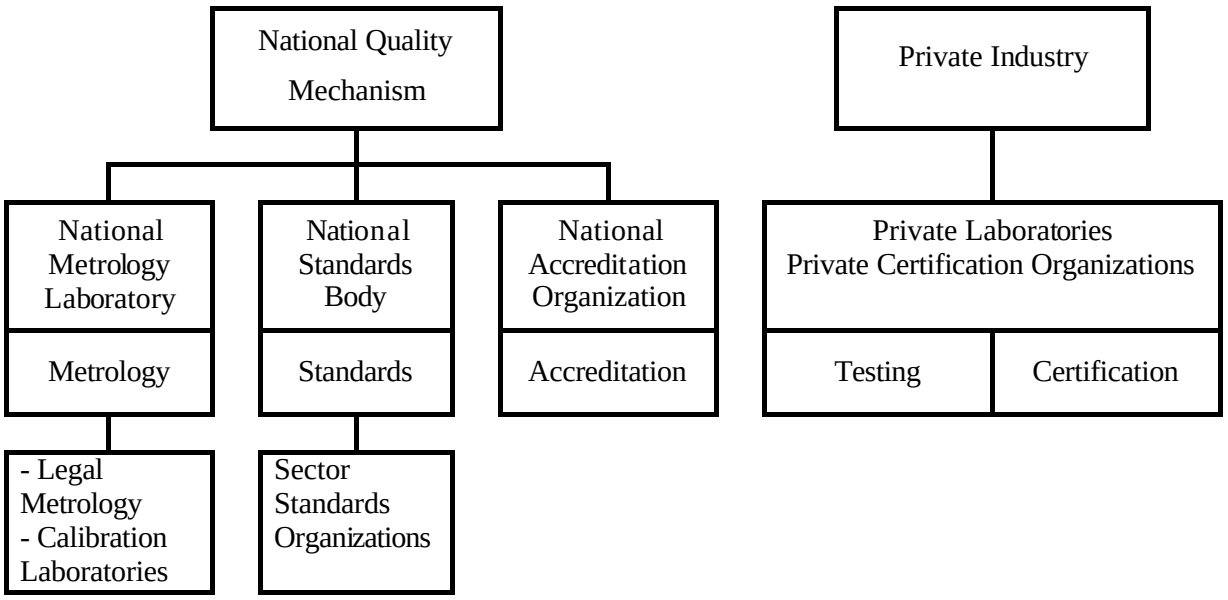
3.2.4. Separation of Statutory and Commercial SQAM activities



This approach, long favoured by continental Europe and the United States, envisages government involvement in those elements that would not be possible without some form of authority, but leave those elements that can be commercially exploited fully to private industry. This type of approach can be found in well developed economies, even the Traditional Statutory Model SQAM systems are tending to gravitate to this approach. It provides for a high level of competition, has safeguards to ensure a level playing field as regards technical competency, and is generally acceptable to most trading partners.

One variation that is still quite common, namely where Government Laboratories are still in existence, they operate in this environment as if they were private laboratories, e.g. they provide services against market related prices, they have to be accredited just as any private laboratory, and the client has the free choice to use either a private or a government laboratory. In some cases the standards and the accreditation function have been merged into the same government organization. This is quite acceptable as long as the conflict of interest between its own laboratories and others do not arise.

3.2.5. National Quality Mechanism



The logical but fairly recent development of the system shown in section 3.2.4 above raises the government involvement to the establishment of a national quality mechanism that coordinates the national metrology system, the national standards system and the national accreditation system, without being involved itself at the operational level. Testing and certification is mostly in the hands of private industry. The national quality mechanism ensures international recognition through accreditation and the national metrology institute.

Some industrial sectors may take responsibility for the development of national standards for their sector under the auspices and in full coordination with the NSB. The National Standards Body assumes responsibility for the "accreditation" of such private sector standards bodies, to ensure that they meet the international requirements such as those of the WTO/TBT Agreement. A small number of countries that have reviewed their SQAM systems recently seem to favour this approach. In this case the service delivery is mostly (with the exception of may be the national standards body and the national metrology laboratory) in the hands of private organizations, but the government can still guide the overall effectiveness of the system.

4. Assessment criteria and significance

Each of the major elements of the SQAM system (i.e. standards, metrology, accreditation, conformity assessment) is discussed in the chapters following. A general discussion on the attributes of each SQAM element precedes the assessment guideline as background. The assessment guideline is provided in the form of a questionnaire containing the questions as well as the evaluation criteria and comments. An indication is provided as to the significance of the attributes that make up the specific SQAM system element. Table 2 provides a key to the use of the decision making process for the significance of the attributes of each SQAM system element.

Table 2 - Significance indicators and how to use them	
Significance	**Comments**
Fundamental	The effective and efficient operation of this attribute is fundamental to the effectiveness of the SQAM element. The absence of this attribute is indicative that the SQAM system element is virtually ineffective.
Major	The effective operation of the attribute is essential for the SQAM system element functionality. The absence of this attribute indicates that the SQAM system element is not functioning optimally and will need major attention to become effective.
Important	The effective operation of the system is not compromised by the absence of this attribute. The SQAM system element would, however, be much more customer friendly, efficient and of major value to the country should the attribute be present. The absence of this attribute would also indicate that stakeholders would be inconvenienced, but that their needs could be satisfied from other quarters, e.g. other standards bodies.
RECOMMENDATION - If the attribute is only in part operational then an evaluation should be made to what extent it is operational. Due to the subjective nature of the assessment a numerical scale is not considered to be useful. A judgement on whether it is fully operational, just short of fully operational, half operational or even less than half operational could be considered if a meaningful report is to be provided.	

An extract about Export Quality Management and checklists regarding Export Quality Management is taken from ITC's "Secrets of Strategy Template"[2] is reproduced in Annex B and Annex C. The "Secrets of Strategy Template" is a process tool for national sectoral strategy-makers. The tool is available in the form of an interactive CD-ROM that covers the design process for a national export strategy. Beginning with guidelines for creating and managing the strategy development team, the Template leads the team through a comprehensive analysis of competitiveness issues cumulating in the preparation of a comprehensive strategy document that identifies export development priorities and elaborates action plans based on a realistic assessment of available resources. The Template comprises methodologies for strategy development at:

- The sector level (for both products and services); and
- The cross-sectoral level of support services as trade information, trade finance, quality management, competency development and export packaging.

[2] More information on the Template is available at www.intracen.org/execforum.

Chapter II - Technical regulations

1. Background

Consumers and society expect products and commodities in the market place to be safe and not to endanger their health. Society also increasingly expects products and commodities to be environmentally friendly. However, markets fail the consumer in that products and commodities are not always safe, are often hazardous to health, and are not environmentally friendly. Recent examples of such failures abound, e.g. the sale of red meat in Europe leading to mad cow disease, the sale of tyres in the USA on 4x4 vehicles that burst at medium speeds leading to fatal accidents, etc. Governments therefore must intervene in the market by demanding that such commodities meet certain minimum standards. Such mandatory standards are called technical regulations, e.g. standards that have been made mandatory through an appropriate legislative mechanism.

A similar situation exists in relation to indigenous plants and animals, and human health where these are endangered through the introduction of pesticides, alien plant material, illnesses, foreign bacteria and the like. Governments therefore implement measures to safeguard their plant and animal kingdom as well as human health against such calamities. These sort of measures are generally known as sanitary and phytosanitary (SPS) measures. The border between SPS measures and technical regulations is not always that clear, and the mechanisms to implement the measures are in many cases the same.

A further complication is that technical institutions dealing with the voluntary field of standards, metrology and conformity assessment are also involved in the implementation of technical regulations.

Modern technology is advancing at such a rapid pace that it becomes difficult for the authorities to keep up with the latest developments. Hence the implementation of technical regulations and SPS measures has become a very specialized field of government activity. Many of the tried and tested methods of the past are no longer effective or efficient. Among these are the time-honoured methods of writing detailed technical requirements into legislation itself, and maintaining a vast army of government inspectors who police the suppliers in the market place. Many economies of the world are grappling with this problem, and slowly a best practice methodology is emerging that involves an array of specialist agencies in both the public and private sectors. The government controls and guides all these activities through appropriate policies, strategies and overarching legislation.

At international and regional level these measures can and do lead to barriers to trade, hence the international community have for many years endeavoured to guide the introduction of such measures through agreements and treaties. The most notable of these agreements are the WTO Agreement on Technical Barriers to Trade and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

2. Relationship between technical regulations, standards and conformity assessment

2.1. General

The relationship between technical regulations, standards and conformity assessment can be deduced from the text of the relevant WTO/TBT Agreement[3]. This relationship is not clearly defined, because this could be construed as a framework that has to be followed by all WTO Member States. The reality is that especially the developed economies have a long history in the implementation of technical regulations, hence extensive systems, often very complex and steeped in history. They may be effective, but not necessarily efficient. To change such systems to comply with a definitive framework should it be provided in the WTO/TBT Agreement is very difficult and costly, without even having answered the question whether this is necessary.

On the other hand many developing economies do not have an effective technical regulation framework. Therefore developing economies can follow a "Greenfield"[4] approach to implement an effective and efficient technical regulation system. The text following describes the building blocks that have to be in place for an effective technical regulation system. The efficiency will be determined by factors that are covered mainly in the rest of the handbook chapters.

2.2. Definitions

To understand the relationship between standards and technical regulations the following definitions from the WTO Agreement on Technical Barriers to Trade need to be examined.

- *Technical regulation.* A document which lays down product characteristics or their related processes and production methods, including administrative provisions, with which compliance is mandatory. It may also cover terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.
- *Standard.* A document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products and their related processes or production methods, with which compliance is not mandatory. It may also cover terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

They are basically similar in content, but with two important differences. One, standards are voluntary in nature and technical regulations are compulsory by law. Two, technical regulations include administrative provisions, e.g. you are told how to implement them, whereas standards do not contain such provisions.

[3] **WTO Agreement on Technical Barriers to Trade**, Available on WTO website at www.wto.org.
[4] **Greenfield** is a term used to denote the development of a system or a factory on a pristine space.

2.3. Technical regulation framework

No definitive model for technical regulations has yet been agreed to at international or regional level, nor is one likely in the immediate future. The discussion below is therefore intended to provide a better understanding of the various building blocks (as shown in Figure 3) that have to be in place for the effective and efficient functioning of technical regulations. The actual methods in which these building blocks are implemented and linked at regional or national level will depend on the legal system, the available institutional framework, custom and practice and many other factors. Anecdotal experience suggests, however, that should one of these building blocks not be in place, then the effectiveness of the technical regulation is ultimately seriously compromised.

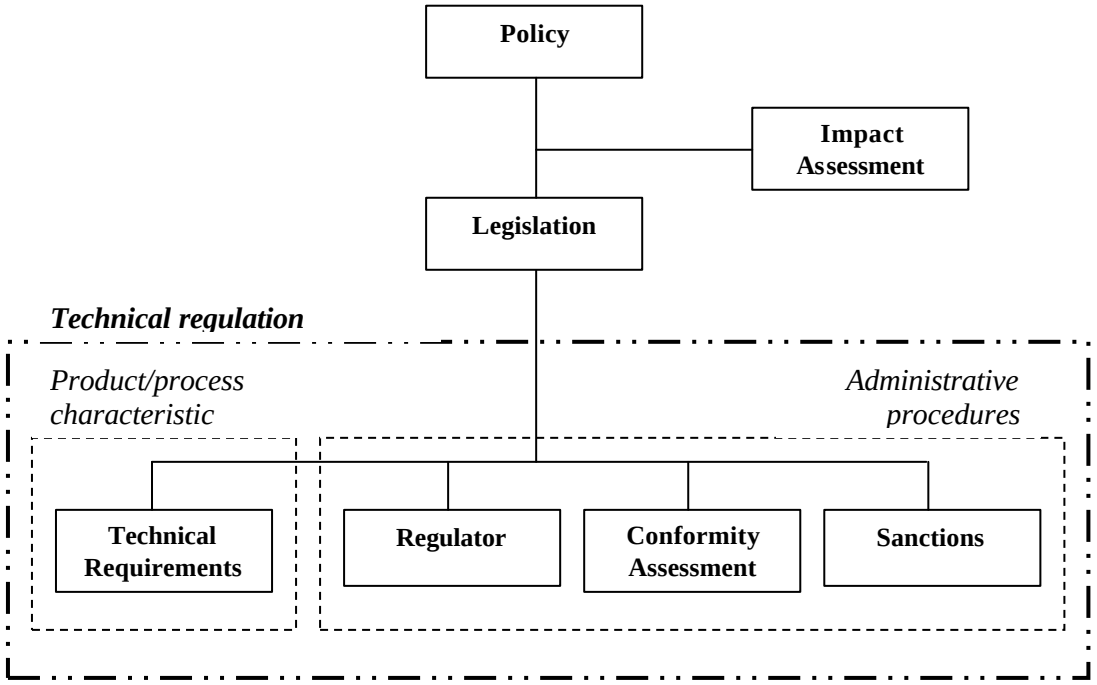


Figure 3 -Building blocks of a technical regulation framework

Usually the implementation of any technical regulation requires a ***policy*** decision on the part of government that there is a need to intervene in the market place, inter alia, to ensure the health and safety of the citizens or because there is a threat to the environment. The policy then leads to the development of ***legislation*** which is the instrument that governments have to give effect to their intended intervention.

It is considered good practice to conduct an ***impact assessment*** to evaluate the impact the envisaged technical regulation will have on trade, what the costs would be, whether all of society benefits or just a small part, and whether the required result cannot be achieved through less onerous means.

The actual technical regulation has two major components as indicated in the WTO/TBT Agreement, namely the ***product or process characteristics***, and the ***administrative procedures***. The WTO/TBT Agreement requires the product or process

characteristics (or ***technical requirements***) to be based on international standards, and there are many ways of achieving this objective. The most common are reference to standards, using standards under the "deemed to satisfy" rule or incorporation of the requirements in the legislative text. Standards are fully discussed in Chapter 3.

The administrative procedures require that a ***regulator*** be identified, i.e. the agency that will implement the technical regulation at national level, and institute sanctions should it be required. This is usually a government department or a regulator that has been established specifically for this purpose. The main criteria are that the agency should be appropriately empowered and that it should be shielded from unnecessary legal actions against it.

The ***conformity assessment*** proof provides the regulator with information on which decisions are made regarding the acceptability of the commodities in the market place. The conformity assessment evidence can be established by the regulator, it can be provided by the supplier or a competent independent service provider, the regulator may accept certificates unilaterally or there may even be government-to-government agreements in this regard, and hence many possibilities exist. Conformity assessment and the support elements metrology and accreditation are fully discussed in Chapters 4, 5 and 6 respectively.

And finally ***sanctions*** are required in the case where suppliers or products fail to meet the requirements of the technical regulations, and can range from administrative type of sanctions (e.g. removal of the commodities from the market place by the supplier) to court actions.

The relationships between these building blocks in particular have a major effect on trade and are usually the source of difficulties that are experienced. Unfortunately there are no definitive best practice models in existence. However, common sense, realities of the available institutional infrastructure and financial pressures are currently shaping the development of practical models, especially in developing countries that cannot afford the complex and costly systems of some of the developed countries.

3. Relationship between TBT measures and SPS measures

One of the major sources of confusion in the area of mandatory standards relates to the relationship between Technical Barriers to Trade (TBT) measures and Sanitary and Phytosanitary (SPS) measures as identified in the WTO Agreements. Sanitary measures relate to human or animal health, and phytosanitary measures are related to plant health. SPS measures include the protection of fish and wild fauna, forests and wild flora, but exclude the protection of the environment per se and animal welfare.

SPS measures are defined[5] as measures to be applied in four situations, namely

- For the protection of animal or plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms.
- For the protection of human or animal life or health arising from risks coming from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs.

[5] **Understanding the WTO Agreement on Sanitary and Phytosanitary Measures**, World Trade Organization, 1998. Available on WTO website at www.wto.org.

- For the protection of human life or health from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests.
- For the prevention or limitation of damage caused by the entry, establishment or spread of pests.

Any mandatory requirement not falling within these four situations can be safely assumed to be a technical regulation issue. It is therefore quite possible that a commodity may be subject to SPS measures as well as technical regulations.

NOTE - SPS measures will not be considered in this handbook.

4. The review of a Technical Regulation Infrastructure at national level

The questions in Table 3 are designed to provide a logical sequence in the evaluation of the technical regulation infrastructure of a country. The evaluation criteria should be read in conjunction with the preceding discussion in sections 1 to 3. The obligations of WTO Members with regard to the WTO/TBT and WTO/SPS Agreements have been taken into consideration as well.

Table 3 - Review questions for Technical Regulation Infrastructure

No	Question	Evaluation criteria / Comments	Significance
1	General implementation and administrative issues • Is the country a member of WTO or regional trading blocks? • Has the country formally notified WTO under Article 15.2[6] of the WTO/TBT Agreement regarding the provisions adopted at national level to implement the agreement?	If the country is a member of WTO, then it has a number of obligations to fulfil. The same would apply if it is a member of trading blocks such as EU, NAFTA, MERCOSUR, SADC, etc. All the trading blocks have agreements in place that deal with technical regulations and SPS measures similar to the WTO Agreements.	Fundamental
	• Has a Ministry been given overall responsibility for the WTO/TBT Agreement?	It is good practice to have a specific Ministry made responsible overall for the WTO/TBT Agreement. The implementation of the agreement is usually shared amongst a number of Ministries depending on their specific sector responsibilities.	Major
	• Have Ministries been given the responsibility to implement technical regulations and for which sectors are they responsible?	• If the various Ministries are not given specific responsibilities, then overlap can occur. • Ministries that are typically involved in the implementation of technical regulations include Trade and Industry	Major

[6] Each Member shall, promptly after the date on which the WTO Agreement enters into force for it, inform the Committee of measures in existence or taken to ensure the implementation and administration of this Agreement. Any changes of such measures thereafter shall also be notified to the Committee.

Table 3 - Review questions for Technical Regulation Infrastructure			
No	**Question**	**Evaluation criteria / Comments**	**Significance**
		(consumer goods, legal metrology), Labour (safety at work), Energy (supply of electric power), Mineral Affairs (supply of fuel), Communication (telephone and other telecommunication equipment), Environment (environmental regulations) and Transport (road and vehicle standards, rail safety).	
2	<u>International and regional representation</u> • If a member of WTO does the country actively take part in the deliberations of the WTO Committee on TBT in Geneva? • Does the country actively take part in deliberations at regional level (e.g. EU, NAFTA, MERCOSUR, SADC, etc.)?	The country delegates should attend all relevant meetings, otherwise the country cannot hope to influence proceedings and has to accept what other countries decide. This may ultimately prove to be very detrimental to its economy. The same applies to regional arrangements.	Fundamental
	• Does the country develop a national position on issues before the relevant meeting by soliciting input from all stakeholders?	It is also important that a national position be developed beforehand to be presented at such meetings. The views of authorities and industry are relevant in this regard. It is no use just to have delegates attend the meetings without proper briefings. • In this regard effective communication between the delegation in Geneva and the capital is absolutely essential.	Major
3	<u>Management of technical regulations</u> • Has a national policy been developed to guide Ministries in the implementation of technical regulations?	Due to the fact that the implementation of technical regulations is spread over a number of Ministries, it would be good practice to have a national policy in place to ensure that a common approach is followed by all. This is of particular importance in future trade negotiations. A lack of a cohesive approach is a major negative. Current trade negotiations are focussing on technical regulations and recognition agreements will be based on the knowledge of the technical regulation frameworks.	Major

Table 3 - Review questions for Technical Regulation Infrastructure			
No	**Question**	**Evaluation criteria / Comments**	**Significance**
	• Is overarching legislation in place that would regulate the implementation of technical regulations?	In some countries the national policy is given effect through legislation. Such legislation does not take away the responsibilities of the various Ministries, but does ensure that a common practice is followed.	Major
4	<u>Notification and information</u> • Has a Notification Authority been identified for TBT issues and has it been notified to WTO?	• A Notification Authority has to be set up that will ensure that the required day-to-day notifications regarding impending technical regulations are notified to the WTO Secretariat in accordance with the provisions of the agreement. • The Notification Authority is either the relevant Ministry or the Enquiry Point.	Fundamental
	• Has a National Enquiry Point been identified for TBT and has it been notified to WTO?	• The National Enquiry Point acts as a conduit for any enquiries regarding technical regulations, standards and conformity assessment requirements emanating from other WTO member states, and ensures that the appropriate responses are provided. • It is common to find the national standards body entrusted with the responsibility of the National Enquiry Point. • In smaller economies it may be useful to have the Enquiry Point and the Notification Authority provided by the national standards body.	Fundamental
5	<u>Transparency, consultations and notification issues</u> • Is the Notification Authority operational? • Are all impending technical regulations appropriately notified? • Is the National Enquiry Point operational? • What is the average response time to reply to enquiries from other Enquiry Points? • Are notifications of trading partners monitored for their relevance to the country's trade? • Does the Enquiry Point have Internet access? • Is information available	All the Ministries responsible for technical regulations must notify the WTO Secretariat regarding new and revised measures that are to be implemented at least 60 days before implementation. All the Ministries should use the Notification Authority to do so. • The Enquiry Point should have a system that is able to relay enquiries from other Enquiry Points to the relevant authority and should make sure that an appropriate response is forthcoming in the shortest time possible. • The Enquiry Point should also monitor the notifications of trading partners on the WTO website, evaluate their importance for the country and ensure that the information is disseminated to the relevant stakeholders in industry and government.	Major

Table 3 - Review questions for Technical Regulation Infrastructure			
No	**Question**	**Evaluation criteria / Comments**	**Significance**
	on any official documentation explaining the role of the Enquiry Point and the services it can render?	• The Enquiry Point should facilitate collating the responses from stakeholders regarding notifications of major trading partners; transmit the collated view to the country's representatives at WTO for further action. • The volume of notifications and enquiries in relation to the volume of trade in products is a good indication as to whether the Notification Authority and especially the Enquiry Point is actually functional. • The amount of information to be dealt with is so vast and time is of such importance that the Enquiry Point cannot work effectively without access to the Internet.	
6	<u>Technical regulation framework</u> • Does the implementation of technical regulations include the required building blocks?	• All the building blocks for the implementation of technical regulations have to be in place; otherwise the whole system will eventually fail to provide the required safeguards.	Major
	• Are the responsibilities of the various agencies (i.e. standards development organizations, regulators, conformity assessment service providers) involved in the implementation properly spelt out?	• If not, then at some time there will be confusion as to who is responsible, and the implementation of the technical regulation will not be effective.	Major
	• Are international and/or regional standards used as the basis for the implementation of technical regulations?	International standards should form the basis for the implementation of the various measures. The most efficient way would be to reference national standards that are based on international or regional standards. A very inefficient way is to repeat the text of standards in the legislation or regulations themselves. Technical requirements need to be updated continuously, which is more difficult to achieve with legislation and regulation than through standards that are reviewed at least every five years. The cost of developing the requirements is also largely transferred to the stakeholders rather than government paying for it.	Fundamental

Table 3 - Review questions for Technical Regulation Infrastructure			
No	**Question**	**Evaluation criteria / Comments**	**Significance**
	• Are appropriate measures in place to accept conformance assessment results from a variety of service providers in the public and private domain or is it a monopolistic system?	The regulator should be responsible for the approvals, market surveillance and imposition of sanctions. It is most inefficient for the regulator to be involved in the actual conformity assessment of products and services. That should be provided by independent service providers (public or in private) that have been appropriately accredited, and over whom the regulator has jurisdiction through the courts.	Major
	• Is every effort being made to accept approvals from trading partners as equivalent to own approvals or has everything to be retested?	• The regulator may decide to unilaterally accept conformity assessment results from foreign service providers, but then it should be clear that little redress is possible should things go wrong. • Bilateral and multilateral recognition agreements between trading partners regarding acceptance of conformity assessment results facilitate the implementation of technical regulations, and enhance trading opportunities.	Major
7	<u>Imported vs. local products</u> • Are imported products and local products dealt with in the same way in relation to technical regulations?	• One of the basic tenets of the WTO Agreements is that imported products should not be required to meet more onerous demands than local products. • This means that the technical regulations pertaining to any import inspection scheme should also be applicable to local production.	Fundamental

Chapter III - Standards

1. Definition and hierarchy

Many definitions have been developed for standards. Fundamentally these are the documents that contain the technical and other requirements that products and services have to comply with, either voluntary, through contract or by regulation. These requirements could include design, material, performance, manufacturing and testing requirements, including packaging and labelling. Specific definitions are referenced in Annex 1 at the end of this handbook. Standards can be stratified into the following hierarchy together with the standards developing organizations (SDOs) in descending range of applicability.

Table 4 - Types of Standards developed by "official" Standards Development Organizations

Level	Organizations (Examples)	Standards
International Standards	International Organization for Standardization	ISO
	International Electrotechnical Commission	IEC
	International Telecommunication Union	ITU
	Codex Alimentarius Commission	Codex Alimentarius
	International Plant Protection Convention	IPPC
Regional Standards	European Union	EN
	UN Economic Commission for Europe	UN-ECE
National Standards	Standards Australia	AS
	British Standards Institution	BS
	Deutsches Institut für Normung (Germany)	DIN
	American National Standards Institute	ANSI
	Botswana Bureau of Standards	BOBS

There is also a second, parallel body of standards developed by industry sectors, multinationals or even consortia within an industry. Some of these standards have attained international recognition due to the extent they are being used by the specific industrial sectors. Typical examples are shown in Table 5.

Table 5 - Examples of Standards developed by sectoral industry organizations	
Organization	**Standard**
American Petroleum Institute	API
SAE International	SAE
International Institute for Welding	IIW

2. Standards development process

One of the fundamental principles of standards development is that standards should be the result of a consultative process involving all interested parties in a consensus manner. Consensus is generally not seen as absolute unanimity, but rather general agreement combined with the absence of continued opposition from an important interested party. The process for development of standards is well defined in the ISO/IEC Directives[7] as well as in Annex 3 of the WTO Agreement on Technical Barriers to Trade[8]. The stages of the standards development process are illustrated in Table 6. Standards are a representation of the current state of technology, hence they need to be updated every once in a while to ensure their continuous applicability. Generally no more than five years should elapse before published standards are reviewed and either re-affirmed, revised or even withdrawn.

Table 6 - Typical stages in the development of standards		
No.	**Stage**	**Comments**
1	Project proposal	The SDO decides on the market relevance of the standard, agrees on a project plan to develop the standard and commits the necessary resources.
2	Technical Committee Drafts	A technical committee consisting of stakeholders and experts deliberates on the content of the standard. The work progresses through a number of drafting stages until the committee finalises the draft.
3	Comment stage	The committee draft is circulated to the full committee to solicit comments.
4	Draft Standard	The comments received during the previous stage are included in the work, and a draft standard is produced.
5	Public comment	The draft standard is circulated for public comment for a period of at least 60 days.
6	Approval and editing	The public comments are dealt with by the technical committee and edited for technical consistency and language. The final document is presented for approval to the SDO management.
7	Publication	The standard is published in a variety of ways, e.g. hard copy, electronic, CD-ROM, etc.
8	Five year review	As technology develops standards get out of date, and they have to be reviewed to confirm their continued relevance, to be revised or in some cases even withdrawn.

[7] **ISO/IEC Directives – Parts 1, 2 and 3**. 2001, International Organization for Standardization, Geneva.
[8] **WTO/TBT Agreement, Annex 3: Code of Good Practice for the Preparation, Adoption and Application of Standards.** World Trade Organization, Geneva. Available on WTO website at www.wto.org.

The standards can be country specific developments or can be based on regional or international standards with country specific deviations. The trend, however, is to adopt international standards (and in some specific cases regional standards) and publish them unchanged as national standards.

3. Publication and dissemination of standards

Standards are of no use if they are not easy to access or available. Most SDOs therefore maintain standards information centres that act as libraries for collections of their own and other national, regional and international standards. Interested parties make use of these standards information centres in the same way they would use a library. Standards are traditionally provided in hard copy, but as information technology advances standards are progressively being provided in various electronic formats, e.g. direct on-line, CD-ROM, 1.44 MB computer discs, etc. Many standards are published as collated documents that include all the standards related to a specific sector or topic, e.g. the building industry, the motor vehicle industry, etc.

Standards are considered intellectual property (i.e. enjoy copyright) by most of the SDOs and are offered for sale to generate funds for the SDO. In some cases private (local or international) standards publishing companies have taken over the publication of standards on behalf of the SDOs. The prices of standards vary considerably depending on the price policies of the SDOs. This is of particular interest in the case of national and regional standards that are adoptions of international standards. Customers can shop around for the best prices, or SDOs can bring the price down to make the standard more affordable in developing economies. Some SDOs, for example some UN Agencies such as the Codex Alimentarius Commission, provide their standards free of charge. As standards become more and more internationalized, SDOs will have to review their price policies very carefully not to lose a major source of income.

4. The review of a Standards Infrastructure at national level

The questions in Table 7 are designed to provide a logical sequence in the evaluation of the standards infrastructure of a country. The evaluation criteria should be read in conjunction with the preceding discussion in paragraphs 1 to 3.

Table 7 - Review questions for Standards

No	Question	Evaluation criteria/Comments	Significance
1	National Standards Body (NSB) • Does an organization or organizations exist that fulfil(s) the role of a national standards body (NSB)?	• Many countries have only one such organization that develops and publishes national standards. In some countries a number of organizations develop and publish national standards, but one of these should be designated the most representative of standardization in its country to facilitate membership of the international standardization organizations. In this case there should be a clearly defined relationship between the various organizations. • A system whereby the NSB accredits standards developing organizations in certain fields is acceptable, if it is deemed that they implement recognized standardization principles rigorously.	Fundamental
2	Organizational form • Is the NSB a part of government, a statutory body, or a private company?	• The answer to the first question depends to some extent on the legal system, the business culture and the extent of government regulation in society.	Important
	• Does the NSB operate in terms of an Act or other legal instrument? • If a legal instrument does not exist is there a formal agreement between the authorities and the NSB that identifies it as such?	• For smaller or developing economies it may be useful to have the NSB as a government department. However, as the manufacturing industry develops, a statutory body may be a better option. • If the NSB is a private organization, then it is imperative that a formal agreement exists between the government and the NSB to provide the NSB with the necessary political backing. • If the NSB does not enjoy this demonstrable support of the authorities it will find it extremely difficult to gain the required standing in business and society, especially in smaller and developing economies.	Fundamental

Table 7 - Review questions for Standards			
No	**Question**	**Evaluation criteria/Comments**	**Significance**
3	Governance • What do the governance structures of the NSB look like? • Does the NSB have a Council or Board of Directors that are independent of the senior management? • Are all stakeholders, e.g. authorities, business, science community, society, NGOs, etc on the Council or Board of Directors?	It is good governance practice (similar to any private company) to appoint a Council or Board to oversee the senior management and to provide strategic direction. The Council or Board should also have the final fiduciary responsibility. The members of the Council or Board should come from the stakeholders, namely government, industry and society should be represented to influence strategy and direction of the NSB. It is, however, not necessary that all the stakeholders be represented; it is more important that the Council or Board members be appointed for their expertise and experience in governance matters. • The Council or Board should include people that have a solid business and technology background as well as an understanding of the standards environment. The Council or Board should not be too large as to become unwieldy or too small in which case it can be dominated by one specific individual. Between 10 and 20 members can be considered as being optimum. • The head of the NSB should be a full member of the Council or Board, but should not hold key positions such as Chair or Vice- Chair. If the stakeholder group is fairly large, then consideration should be given to an Advisory Committee that reports to the Council or Board. The structure of the Advisory Committee should be such that all stakeholders have the possibility to be represented. The Advisory Committee provides recommendations on strategy and direction to the Council or Board.	Major
4	Funding mechanism • What is the mix between government funding, industry funding and sales of standards?	• There is no definitive model to fit all. The funding will however reflect government priorities and industry interest. Funding through a levy of sorts is not considered good practice for a number of reasons.	Important

Table 7 - Review questions for Standards			
No	**Question**	**Evaluation criteria/Comments**	**Significance**
	• Is the long term funding secured?	The long term sustainability of the funding is of major importance. Evidence especially in the form of long term commitments from government in the case of small and developing economies is important. • Total reliance on standards sales is a dangerous practice in view of international trends, e.g. electronic availability of standards on the Internet and harmonization of national standards with international standards is creating downward pressure on sales.	Fundamental
5	<u>International and regional relations</u> • Is the NSB a member of the major international standards organizations such as ISO and IEC? • If a regional standards body exists in the region, is the NSB a member?	• It is important that the NSB knows what is going on at international and regional levels to be able to disseminate the relevant standards information to all stakeholders.	Major
	• What is the level of involvement in the governance structures of ISO, IEC or the regional standards body?	Participation in governance structures of ISO, IEC and regional standards bodies is important to be able to help shape the strategy and future of these international organizations.	Major
	• What is the level of involvement in the international or regional standards development activities?	Participation in ISO and IEC Technical Committees should be commensurate with the level of industrial development of the country. Stakeholder representation at international and regional level under the auspices of the NSB is important.	Major
	• Does the standards body participate in international standardization activities?	Another important element is whether the NSB participates in regional and international technical committee work for those sectors important to the national industry, and does a feedback mechanism exist to facilitate such involvement. Mirror national technical committees should exist to facilitate effective international and regional participation.	Major
6	<u>Standards development process</u> • Is the standards development process defined?	• Standards development needs to take place in accordance with a formally defined process that should be based on ISO/IEC Directives.	Major

Table 7 - Review questions for Standards			
No	**Question**	**Evaluation criteria/Comments**	**Significance**
	• Does a process exist to determine market relevance of future standardization projects?	Standards development is a costly and lengthy process. It is therefore important for the NSB to carefully select the standards that should be developed. The standards should serve a demonstrable private industry, government or market need.	Important
	• Is the consensus building process part and parcel of the Technical Committee culture? • Does an effective mechanism exist whereby public comments on draft standards are solicited?	• Standards are by definition consensus documents, and the combined knowledge of the NSB staff to facilitate consensus amongst the stakeholders will be one of its major contributions to the process.	Major
	• Does an effective appeal mechanism exist?	• Consensus is not unanimity, but there may be an important dissenting opinion that has to be considered.	Major
	• Does a proper editing process exist to ensure technical consistency within the body of published standards including language?	• As standards are often called up in legislation, editing should check for the integrity of the standards within itself as well as with other national standards.	Major
	• Is the approval process independent from the development structures?	• To ensure that all the required steps in the development of a standard have been followed, it is considered good practice to split the approval process from the development process.	Important
	• Are appropriate controls in place to ensure that all standards development projects follow the defined process?	• Due to the fact that standards take a long time to develop, effective project control is essential for ensuring that the time to market is as short as possible.	Major
7	<u>International obligations</u> • Does the standards development process meet the requirements of Annex 3 of the WTO/TBT Agreement?	It is important that demonstrable evidence be available that the requirements of Annex 3 of the WTO/TBT Agreement are met. Many NSBs believe that they comply, but when assessed fall far short of the requirements. • If the country is a member of WTO, then the NSB is obliged to provide the future standards development work programme twice a year to the ISO/IEC Information Centre.	Fundamental

Table 7 - Review questions for Standards			
No	**Question**	**Evaluation criteria/Comments**	**Significance**
	• Is the national standards development process based on the ISO/IEC Directives?	It is good practice if the national standards development process is based on the ISO/IEC Directives. If this is so, the chances are good that the requirements of Annex 3 of the WTO/TBT Agreement will be complied with as well.	Major
8	Extent of standardization work What does the structure of the technical committees look like? Is there a clearly defined hierarchy? • Do sector committees, technical committees, sub-committees and work groups exist, and is the relationship between them clearly defined? • Does the number and structure of the committees reflect the needs of the government, industry and society?	Provides insight into the level of activity in the standards development domain. The activities should reflect the priorities of the country.	Major
9	Involvement of stakeholders • Who runs the Secretariats and Chairs of Committees?	• A "show" run only by the NSB to the exclusion of the input from stakeholders is not considered good practice. • The Chair of technical committees can be provided either by the NSB or preferably by industry or other stakeholders. • It is good practice for the NSB to retain the secretariat in order to ensure that proper project management is in place.	Major
	• What is the mix between adoption of international, regional and home-grown standards?	It should also answer the question whether these technical committees develop country specific standards, or whether they just overprint international standards. There should be a good reason to develop country specific standards; otherwise the trend for internationalization should be supported.	Major

Table 7 - Review questions for Standards			
No	**Question**	**Evaluation criteria/Comments**	**Significance**
10	Standards Information Centre • To what extent are international and regional standards available? • To what extent are national standards (own country and other important national standards) available?	The various collections of international, regional and national standards should be complete, up to date and properly catalogued. It is no use to have the standards sitting in piles and nobody can find them. The international standards should include ISO, IEC and Codex standards. The national collections should include those of the major trading partners. If the country is a member of a regional trading block then all the regional standards should also be available.	Major
	• Are standards available in hard copy, and various forms of electronic media? • Does the Standards Information Centre have access to the Internet? How fast can information be supplied? Immediately, or are days or weeks required?	A vast amount of standards information is available through the Internet. Lack of Internet access would therefore hamper the efficiency and effectiveness of the Standards Information Centre quite appreciably.	Important
	• Is the information centre easily accessible to the public?	Physical access to the standards information centre is very important. If it is difficult to get to the centre, then the stakeholders will not make use of the facility.	Important
11	Training and experience • What level of training is being provided on a continuous basis to the technical committee secretariats in standards development, project planning and management? • What level of training is provided for especially new chairpersons? • Is the training provided for the information officers in the standards information centre concomitant with the requirements of the work?	• Personnel should have the relevant tertiary education before they are trained in standards development processes. • Practical training and skills development programmes are important to hone the skills for the various specific jobs. • The training programmes should be "proper training" and not just ad hoc workshops.	Important
12	Trade negotiations • Is the NSB involved in trade talks of their governments at international and/or regional level?	• Due to the fact that standards are fundamental to any trade negotiations dealing with the acceptance or otherwise of the whole SQAM system, it is important that the NSB takes a meaningful part in such discussions.	Important

Chapter IV - Conformity assessment

1. Definitions and facets of conformity assessment

Conformity assessment is a collective term used to describe a whole host of activities that are designed to provide evidence that a commodity or a service meets the requirements of a given standard. Once the requirements for the delivery of the commodity or the service have been agreed to between the purchaser and the supplier, evidence has to be supplied that it meets the standard. The evidence can take many forms, can be provided by the supplier (the first party), by the purchaser (the second party), and can even be provided by an independent organization (the third party). Figure 4 illustrates the relationship between the market and conformity assessment service providers.

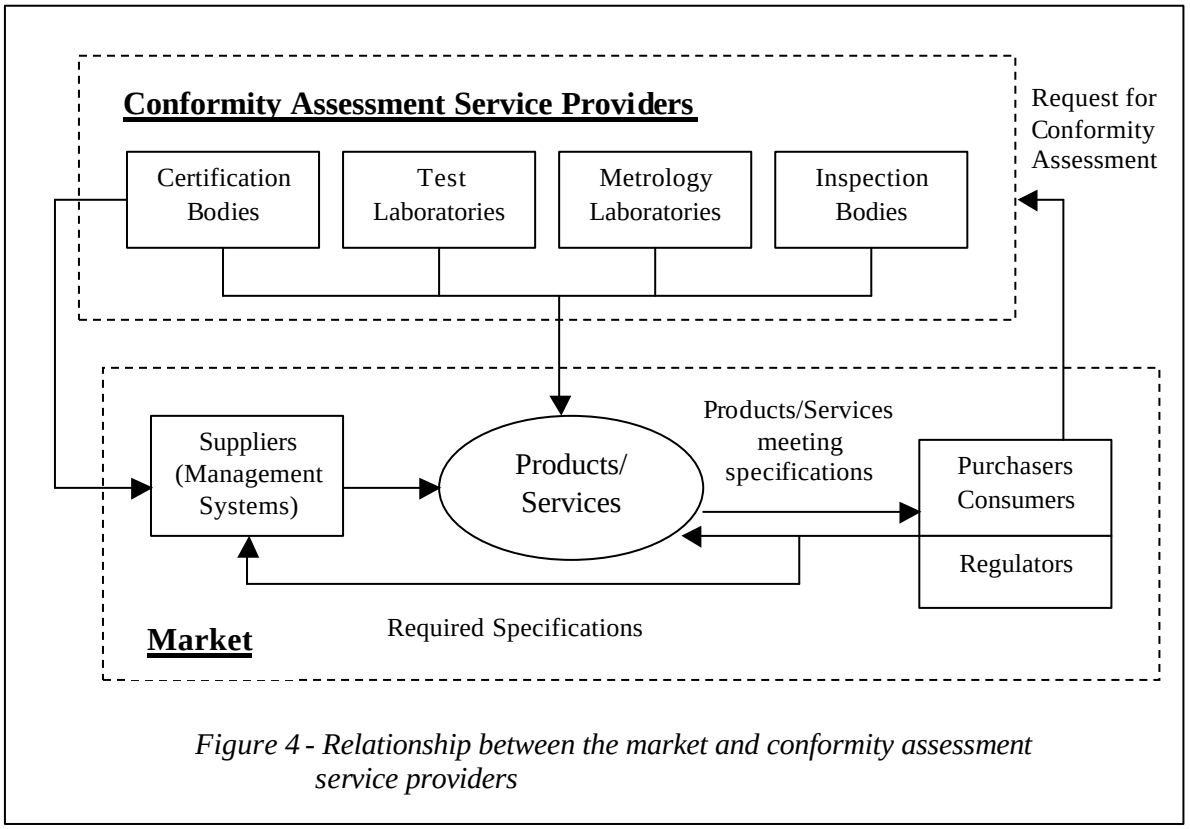


Figure 4 - Relationship between the market and conformity assessment service providers

Conformity assessment can consist of one or a combination of the following activities:

- Inspection;
- Testing;
- Metrology; and
- Certification

Each one of these activities has been developed into a specific discipline over many years, and each one is backed by statistics and technology. It is no longer a haphazard affair, or based solely on the skills of master technicians. It is important in the context of conformity assessment not to confuse testing with research type laboratory work. In this case

we are dealing with testing against very fixed requirements, whereas research type testing is dealing more with pushing the limits of the state of the art into new territories.

2. Conformity Assessment Elements

2.1. Inspection

The main purpose of inspection is to determine whether products meet the requirements of a given standard. One or more characteristics of a product are examined, measured or tested, and compared with the requirements. The inspection process can even extend to the product design or the manufacturing process. The product to be inspected may be a single product, it may be a representative sample from a whole production batch or consignment, or it may even be all the products of a consignment. Inspection is sometimes considered the forerunner of quality control and quality management. It is, however, still a very important element of conformity assessment.

The statistical approach to sampling as a prerequisite for inspection and testing has been developed to a fine art. Although inspection will be used primarily by the manufacturer to ensure consistency and compliance of the production with the requirements, specialised inspection agencies have developed over the years to satisfy a very specific market or regulatory demand. Typical examples of such specialised inspection agencies include:

Pre-shipment inspection. A third party inspection organization will be contracted by the importer to ensure that the product meets requirements before it is shipped. In this way costs associated with the disposition or return of non-conforming products are minimised.

Regulatory inspection. In the case of high risk products such as pressure vessels, a third party inspection agency would be required to verify the design of the pressure vessels, and to conduct in-process inspections during the manufacturing stages to ensure the integrity of the vessel. Such inspection bodies usually need to have official approval from the regulators.

Roadworthy inspection. In many economies, motor vehicles need to be inspected regularly to ensure that they remain roadworthy and do not become unsafe for use on public roads. Road worthy inspection agencies, suitably competent and acceptable to the authorities conduct such inspections.

In developing economies, such inspection agencies may have to be set up by the authorities. But as economies develop, the tendency is for the authorities to rely on inspection bodies in private industry. In all cases the competency and independence of the inspection bodies should be above reproach. Accreditation of such bodies therefore becomes an issue again. The standard that inspection bodies need to comply with is either ISO/IEC 17020[9] for inspection bodies, or national or regional derivatives of this international standard. Accreditation is dealt with more fully in Chapter 6.

[9] ISO/IEC 17020:1998, *General criteria for the operation of various bodies performing inspection*.

2.2 Testing

Testing can be considered as a technical operation that consists of the determination of one or more characteristics of a given product according to a specified biological, chemical, electrical, mechanical or other physical procedure. Testing in the context of conformity assessment is conducted against standards or test methods contained in standards. Testing is more often than not destructive in nature, in which case the product is no longer fit for use. Testing may also be non-destructive in nature. The test procedure should be such that it will provide repeatable results even when used at various times and in different locations or test laboratories.

In developing economies testing facilities are often initially set up by governments to help the fledgling industries, because the infrastructure for test laboratories is extremely expensive. The testing services are quite often subsidised to make them affordable to the fledgling industry. These "government" laboratories sometimes also start life as the testing facilities for technical regulations. As industry develops they set up their own in-house laboratories to provide better turn around times for testing, to use them to conduct their own product development work, and because of the confidential nature of testing.

In fully developed economies, most government testing laboratories are exclusively used for research and development or government work, and the private industry no longer has access to these laboratories for pure conformity assessment testing. This may also be the case for government laboratories set up specifically for the implementation of technical regulations (see Chapter 2). In developing and fully developed economies private organizations believe they can provide testing services as a business, and these can take over the role of conformity assessment in many cases.

The question of competency sooner or later needs to be answered. Government laboratories traditionally are considered to be above reproach, this place of eminence has been entrenched in legislation. Whether they in fact are competent has been successfully challenged in some cases. Even laboratories in private industry are challenged in this respect. Hence the need for an independent authoritative evaluation of the laboratory's competency is required, and accreditation is a common requirement in more recent times. Laboratories in both the public and private domain are subject to such demands. Accreditation is fully discussed in Chapter 6.

2.3. Certification

2.3.1. Product certification

The output of the test laboratory is usually a test report, and that of the inspection bodies an inspection report. The report will list the test or inspection results and compare them with the requirements. This is considered adequate evidence of compliance in some cases. Should the requirement be, however, that the quality or integrity of a whole batch or consignment of products be attested to, then a little more is required than just a test report.

If the consignment can be uniquely identified as coming from the same factory and that it has been manufactured under essentially the same conditions, then a sampling plan

can be devised in accordance with the risk associated with possible failure of the products, and the relevant number of products can then be inspected and/or tested. Should the sample meet the requirements of the standard, then a certificate can be issued that the whole consignment is deemed to comply with the relevant requirements.

It is also possible to evaluate the production process to ensure consistency of the production, test prototypes or take products directly from the production line and test them. Once the product and the production process have been shown to fulfil the relevant requirements, all subsequent production may be certified as deemed to comply. Such product certification services are rendered by certification organizations that undertake the required assessments; they either conduct the tests themselves or have them conducted under their supervision, and maintain a surveillance system on the manufacturers to ensure continuing compliance with all requirements.

The manufacturer is then allowed to put a specific mark on the product available in the market place to indicate to the consumer that the products comply. A large variety of mark-bearing consumer products indicate the extensive use of such schemes. This would be a classic product certification scheme. Many variations of these product certification schemes are in operation. Some of these product certification schemes are compulsory, e.g. are required in terms of technical regulations, but many are voluntary schemes. This means that the supplier believes that a certain market advantage is possible by voluntary participation on such a scheme.

Product certification bodies need to comply with ISO/IEC Guide 65[10].

2.3.2. System certification

The vast range of products on offer has in recent years led to the concept of management system certification schemes. The theory is that if a manufacturer's quality management system meets the relevant standards, then the consumer is assured of a quality product once the standard for the product has been agreed upon. The enormous growth of the ISO 9000 type certification scheme has been driven especially by the need of industry itself seeking assurance that their multitudes of suppliers provide quality components consistently. This system is less important in the consumer market, that still is concerned about the quality of a very specific product especially as far as safety and performance is concerned.

Assessment and audit is mostly associated with evaluating the quality, environmental or occupational safety and health management systems in accordance with well known standards such as ISO 9000, ISO 14000 and others. This is the more modern concept of inspection, where we plan for quality, design for quality, manufacture quality, inspect for quality, and deliver on time and within budget. Should something turn out wrong, adjustments are made to ensure consistent compliance with the standards, each time. The same applies to the influence we have on the environment and for safety and health in the workplace.

The management systems that ensure proper functioning of these systems can be assessed or audited against the requirements of internationally agreed standards. Once assessed and found to comply, a certificate is issued to attest to this fact. The assessment and

[10] ISO/IEC Guide 65:1996, *General requirements for bodies operating product certification systems*.

certification of management systems has developed into a big industry over the last fifteen years, with more than 560 000 ISO 9000 certificates having been issued by the end of 2002. Virtually no sector of industry has been exempted from these developments.

Once again questions regarding the competence of such certification organizations has arisen, and accreditation of such certification organizations is today common practice in most markets. Certification organizations need to comply with ISO/IEC Guides 62[11] and 66[12].

System certification schemes have been developed for a vast range of sectors even though the general schemes such as those based on ISO 9000 and ISO 14000 are by far the most prolific. Other system certification schemes are shown in Table 8.

Table 8 - System certification schemes

Sector	Standard	Comment
Occupational health and safety	OHSAS 18001:1999[13]	Can be integrated with ISO 9000 and ISO 14000 systems
Safety at sea	ISM Code:1994[14]	Mandatory for shipping companies and ships
Social accountability	SA 8000:2001[15]	Seeks to eliminate unfair and inhumane labour practices
Information security	ISO/IEC 17799:2000[16]	A systematic approach to managing sensitive company information
Food safety	HACCP[17]	Defines system requirements throughout the food chain for ensuring safety of food and can be integrated with ISO 9000
Eco-management and audit scheme	EEC Regulation No 1836/93[18]	To promote continuous improvement in environmental practices

2.4. General

[11] ISO/IEC Guide 62:1996, *General requirements for bodies operating assessment and certification/registration of quality systems.*
[12] ISO/IEC Guide 66:1999, *General requirements for bodies operating assessment and certification/registration of environmental management systems (EMS).*
[13] OHSAS 18001:1999 – *Specification for Occupational Health and Safety Management System*, Internet: www.osha-bs8800-ohsas-18001-health-and-safety.com.
[14] ISM Code 1994 - *International Safety Management Code for the Safe Operation of Ships and Pollution Prevention,* Internet: www.imo.org.
[15] SA 8000:2001 – Standard on *Social Accountability,* Internet: www.cepaa.org.
[16] ISO/IEC 17799:2000 – *Information technology -- Code of practice for information security management*, Internet: www.iso.org
[17] HACCP - *Hazard Analysis Critical Control Point,* Internet: www.codexalimentarius.net
[18] EEC Regulation No 1836/93, *COUNCIL REGULATION (EEC) No 1836/93 of 29 June 1993 allowing voluntary participation by companies in the industrial sector in a Community eco-management and audit scheme*, Internet: www.environmarket.com/document/emas/emasregulation.doc.

Product and system certification is well advanced in the non-regulatory market domain, e.g. mostly driven by contract conditions or perceived marketing advantages. A more recent development is that such product and system certification systems are accepted by the regulators to help them implement the technical regulations dealing with health and safety issues. The certification mark of the Bureau of Indian Standards (BIS) and others like it are well-known examples. In this case accreditation is of specific significance due to the fact that the regulators need assurance regarding the technical competency of the certification organizations. See Chapter 2 for more details on technical regulations.

3. International and Regional Organizations

Unlike standards, metrology and accreditation, conformity assessment is still very much a national phenomenon. Although it would be very efficient from the supplier's perspective to have the commodities tested once and accepted everywhere, this is still a dream. A number of international organizations are starting to develop schemes that provide a mechanism for the international acceptance of conformity assessment evidence. Most of them can be found in the regulatory domain, where international inter-governmental or standards organizations do enjoy market acceptance. Some examples include the OIML Certification Scheme for measuring equipment, the IEC Scheme for testing of electrical equipment for safety (IECEE) and others.

Steps have been taken for Mutual Recognition among certification bodies; one such group is the International Certification Network (IQNet), which consists mainly of non-profit certification bodies in various countries. IQNet members, who have signed the IQNet Multilateral Agreement, recognize the ISO 9001 and ISO 14001 certificates of all other members as equivalent to their own. Another group, the Independent International Organization for Certification (IIOC), is made up of international certification bodies, which operate worldwide. IIOC members have signed a memorandum of understanding to work towards the elimination of the need for multiple assessment.

4. The review of a Conformity Assessment Infrastructure at national level

Of all the structures discussed in this handbook, evaluating the conformity assessment infrastructure of a country is the most difficult. This is because the times are long gone that just government or official laboratories and certification organizations are involved. In most economies private as well as public laboratories and certification organizations can be found in many variations, sizes and competencies. At best it is possible to ask some general questions about the testing and certification environment. Table 9 below provides details on the questions, the evaluation criteria and the importance of the individual elements.

Table 9 - Review questions for Conformity Assessment			
No	**Question**	**Evaluation criteria**	**Significance**
1	Extent of laboratory services • What is the number and status of metrology laboratories, e.g. government and private industry? • What is the number, type and status of testing laboratories, e.g. government and private industry, technology sectors represented, etc?	A number of indicators (if available) can be used to provide a measure of judgement, be it largely subjective: The number of metrology and testing laboratories in the country. If the industry is well developed and diversified, then these numbers should be high as well. The ratio of government to private industry laboratories is an indication of its stage of development. Initially government usually has to provide a "kick-start" to the development of an appropriate metrology infrastructure. Later on private industry will set up laboratories that provide testing and metrology (i.e. calibration and measurement) services on demand and against payment as business grows. • The laboratories should be representative of the major industries and/or commodities that are supplied by the industry. • The laboratory landscape should also cover the scope of technical regulations that are in place in the country.	Major
	• Are any legal instruments in place for the control of testing and metrology laboratories?	Laboratories involved in the testing of commodities falling within the scope of technical regulations have to comply with legal requirements as contained in the administrative procedures of the regulations. These could include accreditation and jurisdictional issues, i.e. the laboratory should have a legal presence in the country. Other issues may deal with professional insurance and indemnity issues.	Major
2	Accreditation system (laboratories) • Does a relevant accreditation system exist for each of the categories of laboratories? • To what extent (e.g. percentage of laboratories accredited) have laboratories been accredited?	• If no accreditation system exists or there is no easy access to a foreign accreditation body, then the laboratory can considered not to be under control. • Without an effective and efficient accreditation system the technical competency of the laboratories cannot be demonstrated to trading partners, hence their results may not be accepted.	Major

Table 9 - Review questions for Conformity Assessment			
No	**Question**	**Evaluation criteria**	**Significance**
3	Inspection bodies • Do relevant inspection bodies exist for the various regulatory inspection functions? • Do inspection bodies exist that fulfil the pre-shipment inspection needs of customers?	• An assessment of the inspection bodies needed in terms of technical regulations is required, e.g. inspection bodies for pressure vessels, lifting equipment, lifts, road worthy inspections, etc. • These inspection bodies should be relatively independent from commercial pressures that could influence their judgement.	Important
4	Accreditation system (inspection bodies) • Does a relevant accreditation system exist for each of the categories of inspection bodies? • To what extent have the inspection bodies been accredited?	• If no accreditation system exists or there is no easy access to a foreign accreditation body, then the inspection body can considered not to be under control. • Without an effective and efficient accreditation system the technical competency of the inspection bodies cannot be demonstrated to trading partners, hence the results may not be accepted.	Major
5	Certification bodies • What is the number and status of certification bodies, e.g. government and private industry?	• Product and system certification is so much part and parcel of a modern economy that the absence of such bodies in the market place can be considered a major negative.	Major
	• What type of certification bodies are operating in the market, e.g. system, product, environmental, safety certification bodies, etc?	• Product and system certification is relevant for both the regulatory as well as the non-regulatory domain.	Important
	• Are any legal instruments in place for the control of certification bodies?	• The certification organizations in the regulatory domain would need some form of approval from the authorities. • Certification marks of the individual certification bodies should be protected by law, i.e. under trade marks legislation.	Major
6	Accreditation system (certification bodies) • Does a relevant accreditation system exist for each type of certification body? • To what extent have the certification bodies been accredited?	• If no accreditation system exists or there is no easy access to a foreign accreditation body, then the certification body can considered not to be under control. • Without an effective and efficient accreditation system the technical competency of the certification body cannot be demonstrated to trading partners, hence the results may not be accepted.	Major

Table 9 - Review questions for Conformity Assessment			
No	**Question**	**Evaluation criteria**	**Significance**
7	International and regional relations		
	• Are government to government recognition agreements in place regarding conformity assessment?	• These agreements at official level usually deal with the regulatory domain and can be of the bilateral type or the multilateral type (e.g. GLP, UN-ECE 1958 Agreement on Motor Vehicles and Components, etc.).	Important
	• Are institution to institution recognition agreements in place regarding conformity assessment?	• Market related arrangements have more to do with the market acceptance of the various certification organizations. • Product certification organizations are mostly limited to acceptance within national boundaries, whereas system certification organizations enjoy more international acceptance once they are appropriately accredited.	Important
	• Are there certification bodies members of IQNet?	• If a certificate is issued by a certification body member of IQNet, that certificate is recognized from all the other members, internationally.	Important
8	Training • To what extent does a training infrastructure for metrology and test laboratory personnel exist? • To what extent are these schemes related to similar schemes in other countries and trading blocks?	Two things are necessary to run proper laboratory services, instrumentation and trained people. If one is missing, the other is not of much use. • The proper running of certification and inspection schemes is absolutely dependent on the quality and the proficiency of the personnel involved. In many countries the government provides for the registration of training schemes as part of the national qualification framework. Where such a framework exists, the training schemes for metrology and test personnel should be part of it. • Such a competency training scheme should be appropriately recognised by the peer institutions at international level.	Major

Chapter V - Metrology

1. Definition

Metrology is the science of measurement. Measurements and metrology are essential to nearly all aspects of human endeavour, but are of specific significance in the SQAM system, especially for the provision of conformity assessment services. Metrology is fundamental to almost all inspection, testing and certification services whether in the voluntary or the regulatory domain. It is estimated that in most modern industries the cost bound up in taking measurements constitute 10-15% of production costs. Metrology is a collective term used in a broad sense. For the purposes of evaluating a metrology system or infrastructure it is important to distinguish between the following subgroups of metrology, namely:

General metrology (or *scientific metrology*)[19] is that part of metrology which deals with problems common to all metrological questions irrespective of the quantity measured. It touches on the general theoretical and practical problems related to units of measurement; the problems of errors in measurement; the problems of the metrological properties of measuring instruments.

Industrial metrology is used to describe typical metrological activities in industry, e.g. measurement in production and quality control. Typical issues are calibration procedures and calibration intervals, control of measurement processes, and the management of measuring equipment.

Legal metrology relates to mandatory technical requirements. A legal metrology service implements those requirements that would guarantee correct measurements in areas of public interest, such as trade, health, the environment and safety. The scope of legal metrology depends on national legislation, and may differ from country to country.

Due to the fundamental importance of metrology in society, governments generally accept the responsibility for the development and implementation of national metrology systems and the funding to maintain the national primary standards. The development of a metrology system should be the first priority for any government in the whole SQAM system that should function effectively and efficiently, because without metrology nothing else will work.

[19] Custody of national metrology standards is a task of scientific metrology usually entrusted to the national metrology institute.

2. Elements of a metrology system

2.1. Units of measurement

The starting point for any metrology system is the definition of the units of measurement. The only real international system, the *Système International d'Unités* (SI) evolved from the metric system, the system of measurement adopted with the signing of the *Convention du Mètre* by 17 countries in 1875. This recommended coherent system of units of measurements is today in use in more than 100 countries. It consists of seven base units and a number of derived units. The base units are the metre (length), the kilogram (mass), the second (time), the ampere (electric current), the kelvin (thermodynamic temperature), the mole (amount of substance) and the candela (luminous intensity).

There are still other units of measurement in use in some countries (e.g. the USA, Britain and Australia), notably the use of the inch, the foot and the mile (length), the pound (mass), the gallon (volume), and other non-SI units. Non-SI units are also used in special applications, e.g. navigation (nautical mile) and trade in crude oil (barrel). However, the SI system is extensively used in international trade, and it is the only one supported by an international treaty.

2.2. Measurement standards

Once a measurement unit has been defined, then a measurement standard (French: *étalon*) can be realised. A measurement standard is a material measure, measuring instrument, reference material or measuring system intended to define, realise, conserve or reproduce a unit or one or more values of a quantity to serve as a reference.

Whereas the measurement standard for the kilogram is still a unique artefact (a cylinder made from platinum-iridium alloy and kept at the International Bureau of Weights and Measures, the BIPM, in Sèvres near Paris), all other units are defined in terms of physical phenomena or natural constants. The metre for example is defined as the length of the path travelled by light in vacuum during a time interval of 1/299 792 458 of a second. The advantage of a natural constant is that it obviates the need to refer to artefacts, which can be altered or destroyed. Units based on natural constants can also be reproduced at any time, anywhere.

The definition of the SI unit is the basis of national realizations of the SI unit to assign values to the next lower level of standards, namely the reference standards at the National Metrology Institutes (NMIs), from where they are disseminated to the next national layer of measurement standards, usually the standards of accredited calibration or test laboratories as shown in Figure 5. An example of how the dissemination could work is as follows: The metre is realised by the wavelength from an iodine-stabilised helium-neon laser as the national primary standard, whereas the actual measuring device in industry may be a calliper that is calibrated against a gauge block whose length is determined by optical interferometry with reference to the national primary standard.

The NMI would develop and/or set up a piece of equipment that would realise the unit of measurement to the highest degree of measurement capability required. The leading NMIs

build their own equipment to probe the limits of measurement technology, whereas developing economies could be well served with the best measuring instruments that can be obtained commercially. It all depends on the best measurement capability required to service the industry and society of the country.

2.3. Traceability

Traceability is an unbroken chain of comparisons which shall make it certain that a measurement result or the value of a standard is related to references at a higher level, ending at the final level with a primary standard, or the international kilogram in the case of mass, all conducted with a known measure of uncertainty. The traceability chain is diagrammatically shown in Figure 5.

The primary function of the NMI is to provide the link, i.e. realisation of the international unit of measurement through the national primary standard to measuring equipment used in industry and commerce, in legal metrology, in aviation, in navigation, in law enforcement and in many other branches of society. The NMI would also be involved in international comparisons to ensure that its capability is comparable to that of other NMIs. This is to ensure that measurements anywhere in the world would be the same if repeated someplace else.

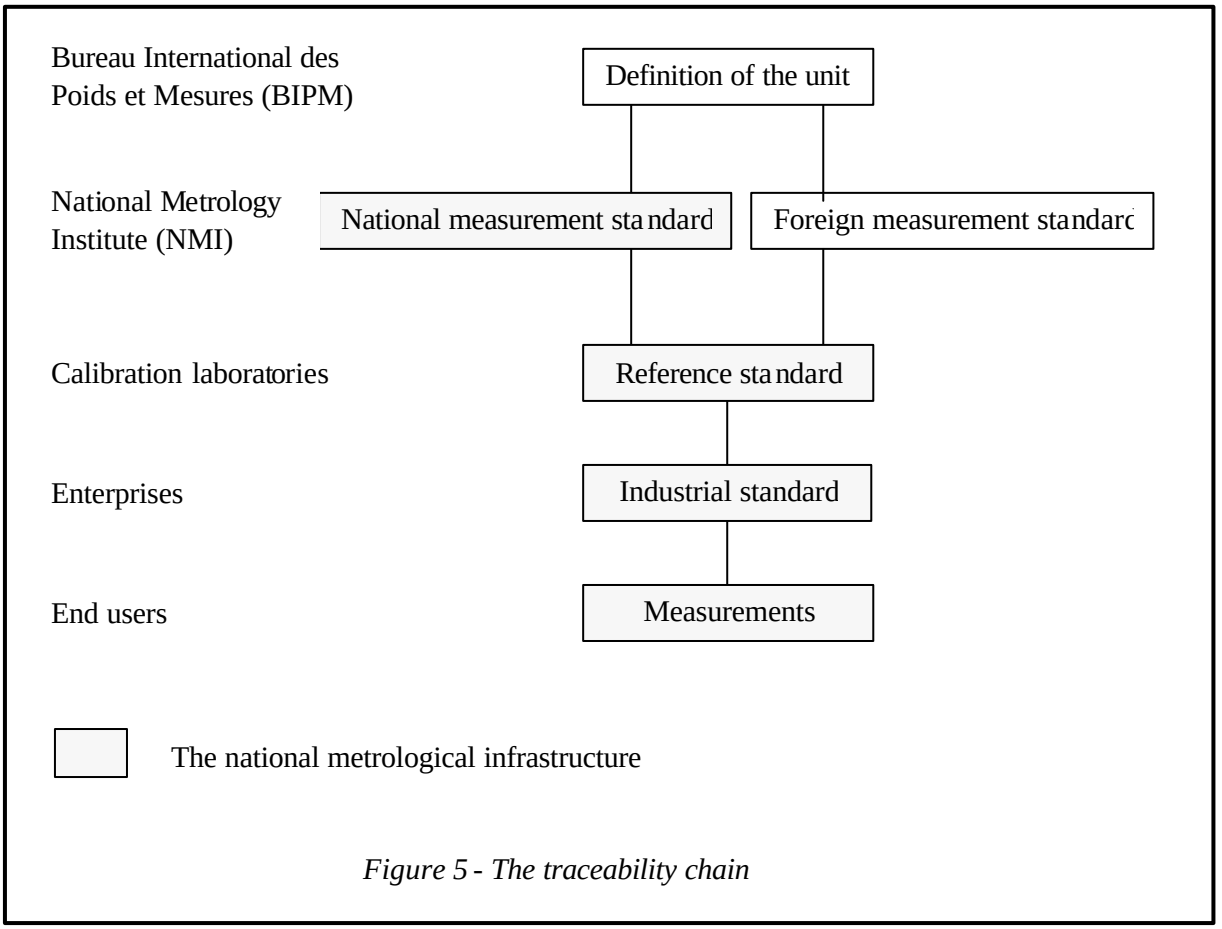


Figure 5 - The traceability chain

2.4. The CIPM Mutual Recognition Arrangement (CIPM MRA)

As a consequence of laboratory accreditation and international trade agreements a transparent and reliable system had to be put in place with respect to the consistency of the national measurement standards of countries that serve as the basis for measurement traceability and calibrations. These considerations have led to the creation of an international agreement under the umbrella of the *Convention du Mètre*. By 2002 this CIPM Mutual Recognition Arrangement (CIPM MRA) had been signed by 44 Member States and 9 Associates.

The objectives of the CIPM MRA are:

- To establish the degree of equivalence of national measurement standards maintained by the NMIs;
- To provide for the mutual recognition of calibration and measurement certificates issued by the NMIs;
- Thereby to provide governments and other parties with a secure technical foundation for wider agreements related to international trade, commerce and regulatory affairs.

The outcome of the CIPM MRA is published in the form of statements of the measurement capabilities of each NMI in a database maintained by BIPM. International recognition of claimed calibration and measurement capabilities (CMCs) of NMIs is conferred through publication of the capability in the MRA database and publicly available on the Internet[20]. CMCs are only published after an extensive regional and international peer review process, which ensures

- that the claims are consistent with the results of inter-laboratory comparisons between the NMIs, and
- that the NMI has an acceptable quality system (ISO/IEC 17025[21], or peer assessed to a standard at least equivalent to it) in place.

2.5. Inter-laboratory comparisons

As indicated in section 2.3, the various NMIs also need to ensure that their measurement capability is at par with that of their peers. The way in which this is evaluated is through inter-laboratory comparisons. A specific measurement standard will be sent to a number of laboratories, and each of the laboratories would determine the value of the measurement standard. One of the laboratories would be designated as the pilot laboratory and the results from all the laboratories would be statistically and metrologically evaluated by the pilot laboratory. From these results NMIs can deduce their calibration and measurement capability and the comparative results will form the basis for mutual recognition amongst the participating laboratories under the global MRA between NMIs.

Although technically sound, this procedure would take an inordinate amount of time if all the national measurement laboratories would be involved in the same international inter-comparison. To speed up the proceedings, the Consultative Committees of the International

[20] **BIPM.** Internet: www.bipm.fr.
[21] ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories*.

Committee of Weights and Measures (CIPM) arrange for international comparisons amongst a few leading laboratories from all the regions of the world. These participating laboratories then arrange an inter-laboratory comparison amongst the laboratories of the region itself. In this way many more laboratories can participate in a much shorter time. The practice is diagrammatically shown in Figure 6.

The regions referred to above are those covered by the Regional Metrology Organizations (RMOs) of major trading blocks or even continents. They are:

- The European Collaboration in Measurement Standards (EUROMET), http://www.euromet.ie/
- The Asia-Pacific Metrology Programme (APMP), http://www.nrlm.go.jp/apmp/
- The Metrology System of the Americas (SIM), http://www.ibpinet.com.br/sim/
- The Euro-Asian Cooperation of National Metrological Institutions (COOMET), http://www.coomet.org
- The Southern African Development Community (SADC) Cooperation in Measurement Traceability (SADCMET), http://www.sadc-sqam.org

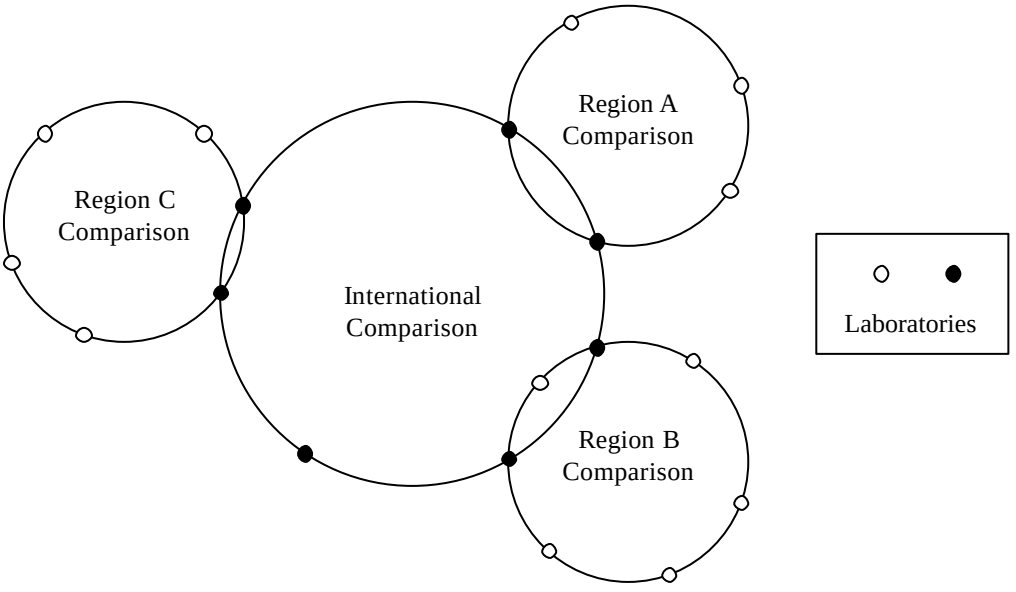


Figure 6 - Inter-laboratory comparisons

2.6. Calibration

Apart from the consequences of improper use, abuse or overload, the performance of measuring and test equipment inevitably changes with time anyway, as a consequence of the ageing of components, the environment to which it is exposed and normal wear and tear. The accuracy of the instrument therefore needs to be verified and corrected from time to time. To do this the value of a quantity measured by the instrument is compared with the value of the same quantity provided by a measurement standard. This procedure is called calibration.

Comparison with the measurement standard reveals whether the accuracy of the measuring equipment is within the tolerances specified by the manufacturer or prescribed error limits.

The user of the instrument is responsible for the calibration of the instrument. The measurement standards used for calibration should be traceable to the national measurement standards, which are traceable to the SI, thereby completing the chain of traceability. The national metrology institute (NMI), the accredited test and calibration laboratories and the legal metrology system form the national measurement system. National legislation for measurement units, measurement standards, legal metrology, accreditation and standardization should ensure that the national measurement system is consistent, coherent, easily accessible to users and that the roles of designated SQAM institutions are clearly defined.

2.7. Calibration laboratories

Any number of laboratories, private or public, in-house or independent, provide calibration services to industry, to law enforcement agencies, to business, etc. These laboratories should be competent to provide such services. The international standard that is used to verify the competency of calibration laboratories is ISO/IEC 17025. The competency is independently verified by an accreditation body as part of the national calibration system. For more information on accreditation see Chapter 6.

2.8. Verification

Measuring equipment, especially that in use in legal metrology (e.g. trade, health care, environmental protection, traffic surveillance, etc.) has to be examined, serviced, adjusted and re-calibrated from time to time to ensure that it still operates within the specified requirements. The interval when this should happen is legislated. To indicate that such measuring instruments are in fact subject to such a procedure and comply, they are appropriately marked and/or issued with a verification certificate. The organizations that conduct such verification services have to comply with requirements similar to calibration laboratories and in addition need to demonstrate competency to service and adjust the relevant measuring instruments as well.

3. International organizations

The two international organizations (other than accreditation organizations, see Chapter 6) active in the metrology field are described below.

3.1. Bureau International des Poids et Mesures (BIPM)

The *Convention du Metre*, the international treaty signed in Paris in 1875 by 17 States, resulted in the establishment of BIPM. The treaty currently has just over 50 members,

including the entire developed world. The BIPM's mandate is to provide the basis for a single, coherent system of measurements throughout the world, traceable to the International System of Units (SI). This task takes many forms, from direct dissemination of units (in the case of mass the BIPM maintains the international standard and all NMI measurements are traceably referenced/calibrated to this international standard) to coordination through international comparisons of national measurement standards (all the other international measurement standards such as length, electricity, radiometry and ionizing radiation). BIPM is also the custodian of the CIPM Mutual Recognition Arrangement administration and data base.

3.2. Organisation Internationale de Métrologie Légale (OIML)

OIML was established in 1955 as an intergovernmental body dedicated to the harmonisation of the national metrology regulations of its members. OIML has as its main tasks:

- Furnishing its members with international recommendations for establishing harmonised legal metrology schemes;
- Publishing OIML International Recommendations (i.e. standards) regarding the technical requirements for measuring instruments for use in legal metrology; and
- Implementation and maintenance of the OIML Certification Scheme and its central database, whereby instruments need only be tested once by a member country for approval by any other member country.

4. Legislation in the Metrology Field

4.1. National units and standards

National legislation should specify the legal units of measurement for the country and the areas where their application is mandatory, e.g. trade or official dealings. The SI units are the legal units in many countries. The legislation should further specify the national measuring standards, and stipulate measures for their conservation, the dissemination of units, and for ensuring their accuracy through comparison with international measurement standards. This implies that the legislation should also either establish a national metrology institute (NMI) or recognise an existing organization as the NMI of the country.

NOTE - In some countries the responsibility for the national measurement standards and the implementation of regulations pertaining to the use of measuring equipment for trade, health and law enforcement (see 4.2 below) is vested in one organization.

4.2. Legal metrology

Legal metrology legislation should cover the use of measuring instruments in areas of public interest such as trade (weighing instruments, measuring systems for liquids, electricity

meters, water meters, taxi meters, etc.), health care (clinical thermometers, blood pressure meters, etc.), environmental protection (gas chromatographs, atomic absorption spectrometers, etc.), traffic surveillance (breath analysers, vehicle emission measuring equipment, speed measuring equipment, weighing instruments, etc.) or safety at work (dosimeters, etc.). The national bureau of legal metrology (in earlier days known as weights and measures) is generally responsible for the implementation of regulations on the use of such equipment.

Legal metrology deals with such issues as

- Pattern approval of instruments against the technical standards, indicating that the instrument would be suitable for the designated use, providing reliable measurements over a specified verification period. Pattern approval would be required before a specific type of measurement instrument may be used for trade, law enforcement, etc.
- Control over the verification of instruments in use within the specified period. The user has to have the instruments recalibrated and reset (if necessary) to ensure continued reliable measurements. The verification can be carried out by the manufacturer, by a national verification service or other authorised organizations. In some countries especially in emerging economies, this service is even provided by the national bureau of legal metrology itself.
- Control over the pre-packaging of goods. Many goods are no longer weighed, counted or measured just prior to sale, but are pre-packaged before sale by the supplier. The purchaser has the right to receive the correct amount of goods in this case as well. Hence the national bureau of legal metrology should have a system in place that ensures that pre-packaged goods do in fact meet the relevant legal metrology requirements. Many different types of systems can be found, ranging from quantity certification schemes, to on-site inspections at regular intervals at suppliers and surveillance in the market place.

5. The review of a Metrology Infrastructure at national level

The questions in Table 10 are designed to provide a logical sequence in the evaluation of the metrology infrastructure of a country. The evaluation criteria should be read in conjunction with the preceding discussion in paragraphs 1 to 4.

Table 10 - Review questions for Metrology

No	Question	Evaluation criteria	Significance
1	National Metrology Bodies • Does a national institute exist that is responsible for the maintenance of national units of measurement and the related primary (measurement) standards?	• Metrology is the beginning of any SQAM infrastructure. Without metrology none of the other elements will be able to function effectively. This was true historically as well as today.	Fundamental

Table 10 - Review questions for Metrology			
No	**Question**	**Evaluation criteria**	**Significance**
	• Does an organization exist for the implementation of legal metrology requirements?	• The bodies responsible for the national units of measurement and legal metrology can be separate institutions, or the responsibility can be combined into one. • More developed economies often favour two separate organizations, due to a number of factors such as the split at international level, the nature of the technology, and the nature of the implementation mechanisms. • Scientific metrology requires a sound technology base, whereas legal metrology is more focused on regulation and administration.	Fundamental
2	<u>Legal instrument</u> • Does a National Units and Measurement Standards Act or similar legal instrument exist? • Does a Legal Metrology Act or similar legal instrument exist? • Are the national metrology institute and the national bureau for legal metrology a part of government or a statutory body?	• Due to the fact that national metrology bodies are also involved in technical regulations (i.e. they are the reference organization for the correctness of measurements used in technical regulations), it is important that they enjoy official backing, and also legal protection against spurious claims. This is especially important for the national bureau of legal metrology, less so for the national metrology institute.	Fundamental
	• If the national metrology institute is a private company, is there an agreement in place between the government and the institute?	• In exceptional cases the national metrology institute is not a statutory body but a private company. In this case an agreement needs to be in place between the government and the laboratory to provide it with official recognition and secure funding.	Fundamental

Table 10 - Review questions for Metrology			
No	**Question**	**Evaluation criteria**	**Significance**
3	Governance • Do the national metrology bodies have a Council or a Board that provides strategy and oversight of the management?	• The governance structure will depend on whether the bodies are stand-alone organizations or whether they are part of a bigger institution. Should they be part of a bigger institution such as the national standards body, the national research institution or a government division, then special measures will have to be taken to ensure that their activities enjoy the required prominence and that they do not disappear in the bigger picture. • If they are stand-alone organizations then it is good governance practice (similar to any private company) to appoint a Council or Board to oversee the senior management and to provide strategic direction. The Council or Board should also have the final fiduciary responsibility.	Major
	• Do the various interested authorities (e.g. government departments, scientific institutions, etc.) have representation in a meaningful way on the Council or Board of the national metrology institute?	• Some of the members of the Council or Board should come from the interested parties, namely government, and the metrology environment to influence strategy and direction of the bodies. It is, however, not necessary that all the stakeholders be represented; it is more important that the Council or Board members be appointed for their expertise and experience in governance matters. • The Council or Board should include people that have a solid business and technology background as well as an understanding of the metrology environment. • The Council or Board should not be too large as to become unwieldy or too small in which case it can be dominated by one specific individual. Between 10 and 20 members can be considered as being optimum. • The head of the metrology body should be a full member of the Council or Board, but should not hold key positions such as Chair or Vice Chair.	Major

Table 10 - Review questions for Metrology			
No	**Question**	**Evaluation criteria**	**Significance**
	• Does a mechanism such as an Advisory Body exist where all stakeholders can provide input into the strategic direction of the national metrology bodies?	• If the bodies are part of a bigger organization, or the stakeholder group is fairly large, then consideration should be given to an Advisory Committee. The structure of the Advisory Committee should be such that all stakeholders have the possibility to be represented. The Advisory Committee provides recommendations on strategy and direction to the Council or Board.	Important
4	<u>Funding mechanism</u> • What is the mix between government funding, industry funding (if any) and income form metrology activities?	• There is no definitive model to fit all. • National primary (measurement) standards and the national metrology institute are invariably funded by government, because their existence is vitally important for society and industry. Due to the scientific basis of the activity, it is virtually impossible to fund it from commercial income and the personnel needs to be free from commercial pressures in order to function optimally. • The answer to this question for the national bureau of legal metrology depends to some extent on the legal system, the business culture and the extent of government regulation in society. The pattern approval, and verification business can be structured in such a way that the user pays. Government funding is, however, required to try and minimise commercial pressures on the bureau for legal metrology.	Important
	• Is the long term funding secured?	• If the national metrology bodies do not enjoy this demonstrable long term financial support of the authorities they will find it extremely difficult to provide an effective and efficient link to the international community or to protect society against fraudulent transactions based on measurements. This is true for both developed and developing economies.	Fundamental

Table 10 - Review questions for Metrology			
No	**Question**	**Evaluation criteria**	**Significance**
5	National primary standards • Are the national primary standards clearly identified in a list with legislative backing? • Is the list complete, i.e. does it contain all the standards required by industry and the regulatory bodies?	• All the measurements required by industry as well as those required by the regulatory bodies for technical regulations and legal metrology need to be catered for.	Fundamental
	• Are the national primary standards, their accuracy class (or measurement capability) and calibration history in keeping with the requirements of industry and regulatory bodies?	• The level of accuracy (or measurement capability) of the national primary standards needs to be commensurate with the needs of the industry (e.g. the electronics industry requires a high level of accuracy regarding time and frequency, etc.) or the authorities (testing for pollutants, etc). • Developed economies, or economies with technologically advanced industries need national primary standards at the limit of what is technologically feasible. This means that such standards are usually developed by the national metrology institute itself, because they need to be better than the best that can be bought, which is what industry would have. • The national measurement standards should be compatible with and recognized by the main trading partners.	Major
6	Buildings and infrastructure • Do the required buildings and environmental control exist to house the national measurement standards?	• National primary standards can only be utilised to their full potential if the necessary laboratories and climate control exists. The lack of appropriate buildings and climate control can be considered as a major negative.	Fundamental
	• Does the required instrumentation exist to facilitate traceability to industry and other regulatory bodies?	• Having the national primary standards under proper access control is important. It is also very important that the relevant technical facilities exist to be able to compare the next level of measurement standards of industry and authorities to continue the traceability chain from the primary standards to the working standards in society.	Fundamental

Table 10 - Review questions for Metrology			
No	**Question**	**Evaluation criteria**	**Significance**
7	<u>CIPM Mutual Recognition Arrangement</u> • Does the national metrology institute participate in the CIPM Mutual Recognition Arrangement?	• The CIPM Mutual Recognition Arrangement is the primary international vehicle to ensure recognition of the national metrology system by trading partners and authorities. • Lack of participation in international or regional inter-laboratory comparisons places a big question mark over the true capability of the national measurement laboratory. • Lack of participation in the CIPM Mutual Recognition Arrangement has as a result that conformity assessment evidence emanating from within the country will not be accepted internationally. Hence products may be unacceptable as well.	Fundamental
	• Does the data of the national metrology institute appear on the BIPM website for comparison with those of other national metrology institutes?	• The national metrology institute should participate to the best level of its measurement capability, and not try to participate at a lower level.	Fundamental
	• Is the extent of participation in international or regional comparisons in keeping with the requirements of industry and the authorities?	• The laboratory should participate in all measurement fields and related subfields required by its industry and authorities, e.g. - Mass - Electricity and Magnetism - Length - Time and Frequency - Thermometry - Ionising Radiation and Radioactivity - Photometry and Radiometry - Flow - Acoustics, Ultrasound and Vibration - Amount and Substance	Fundamental
8	<u>International and regional liaison</u> • Is the country with its national metrology institute a member state of the Convention du Mètre or an associate of the General Conference of BIPM? • Is the national metrology institute a participating member of any regional metrology organization? • Is the country with its bureau of legal metrology a member of OIML?	• Due to the fact that metrology is about "connecting" with the international metrology community and gaining acceptance through demonstrable capabilities, the national metrology institute should be an active member of the relevant international and regional metrology organizations. • Only by actively participating in the relevant metrology organizations will the national metrology institute be able	Major

Table 10 - Review questions for Metrology			
No	**Question**	**Evaluation criteria**	**Significance**
	• Is the bureau of legal metrology a participating member of any relevant regional legal metrology organizations?	to effectively ensure recognition of the national metrology system at international and regional levels.	
9	National calibration service • Does a mechanism exist whereby measurement standards in industry and of the authorities can be traceably calibrated against the national primary (measurement) standards?	• Once the measurement capability *viz. a viz.* the international system has been established (CIPM Mutual Recognition Arrangement), then this capability has to be transferred to the industry and the authorities, otherwise it means absolutely nothing. • The national calibration system should be able to effectively provide for the calibration of all the various reference standards used in industry and by the authorities, in the voluntary as well as the regulatory domain.	Major
	• Is there a regional infrastructure where primary standards are available for calibration? • Is this service available at reasonable time and cost?	• In the absence of a national calibration service, the availability of such services at regional level could be the only possibility for the industries to have this service at reasonable time/cost.	Major
10	Legal metrology (Type approval of instruments) • Does a proper measuring instrument approval system exist before such instruments are used in the legal metrology domain?	• Any measuring instrument used in a service on behalf of the community in trade, health care, environmental protection, traffic surveillance or safety at work should be subject to legal metrology control.	Major
	• Are international standards used as the basis for such approvals?	• The standards used for the approval of such measuring instruments before they are allowed to be used should follow the recommendations of OIML and other relevant international organizations.	Major
	• Do competent laboratories exist to conduct tests on measuring equipment?	• Tests to determine whether measuring instruments comply with the relevant standards should be available either in the country itself, or a mechanism should exist to accept test reports from similar laboratories in other countries. • The OIML measuring equipment certification scheme could feature in the approval process.	Important
11	Verification system • Does a formal verification system for measurement instruments in the legal metrology domain exist?	• Once measuring instruments have been type approved and placed in service, they still need to be serviced and calibrated from time to time to ensure continued proper operation.	Major

Table 10 - Review questions for Metrology			
No	**Question**	**Evaluation criteria**	**Significance**
	• Is the verification system effective?	• The verification interval should be described in regulations or a similar legal instrument.	Major
	• Are inspections carried out in the market place to ensure that measuring equipment is in fact properly type approved and that the verification intervals are kept?	• The verification service can be provided by the bureau for legal metrology or it can also be delegated to verification companies in the private sector under the auspices of an accreditation/approval system. • Private verification companies need to demonstrably comply with defined requirements to ensure their technical competence and legal accountability. Accreditation to ISO/IEC 17025 with specific additions dealing with verification is a good way to establish the competency.	Major
12	Pre-packaged goods • Does a proper system for the control of pre-packaged goods exist?	• A pre-packaged goods system can take the form of metrology controls imposed on the packaging industry. • The controls could be in the form of regular inspections at packaging organizations.	Major
	• Does a certification scheme exist for quantities?	• The controls could be in the form of a quantity (volume, mass, etc.) certification scheme for the containers or the packaging material.	Important
13	Trade negotiations • Are the national measurement laboratory and the bureau for legal metrology involved in trade talks of their governments at international and/or regional level?	• Due to the fact that measurement capability and legal metrology are fundamental to any trade negotiations dealing with the acceptance or otherwise of the whole SQAM system, it is important that the national metrology institute and the bureau for legal metrology take a meaningful part in such discussions.	Important
14	Legal enforcement • Is the legal metrology system legally enforceable?	• A legal metrology system that is not legally enforced will fall into disuse eventually and will be of no value to society.	Major
	• Are contraventions of especially a legal metrology nature brought before the courts where administrative sanctions fail?	• Administrative sanctions are the first option, but should they not prove to be effective, recourse to the courts is necessary.	Major
15	Metrologists • Are the metrologists appropriately trained and experienced? • Is the number of metrologists	• The level of measurement is as much dependent on the people as it is on the instrumentation. • The number and disciplines of the	Fundamental

Table 10 - Review questions for Metrology			
No	**Question**	**Evaluation criteria**	**Significance**
	adequate for the metrology service that has to be rendered?	metrologists have to be commensurate with the fields of metrology, e.g. mass, time, length, etc. • The range will vary from scientists working at the limit of measurement physics and chemistry to technical staff and inspectors dealing with day-to-day legal metrology issues. • The number and remuneration of the metrologists should be such that long term sustainability is ensured.	

Chapter VI - Accreditation and MRAs

1. Definition

Accreditation is a formal recognition of competence to provide a specified service. From the point of view of conformity assessment, accreditation is applicable to service providers such as metrology laboratories, test laboratories, inspection bodies and certification organizations. The formal recognition follows an assessment of the specific service provided against the requirements of agreed standards. Accreditation adds value to conformity assessment service providers as well as to their management in a number of ways. It provides an assurance to the users of conformity assessment services that they are dealing with competent organizations, and it provides authorities with an assurance that the output of conformity assessment service providers can be trusted.

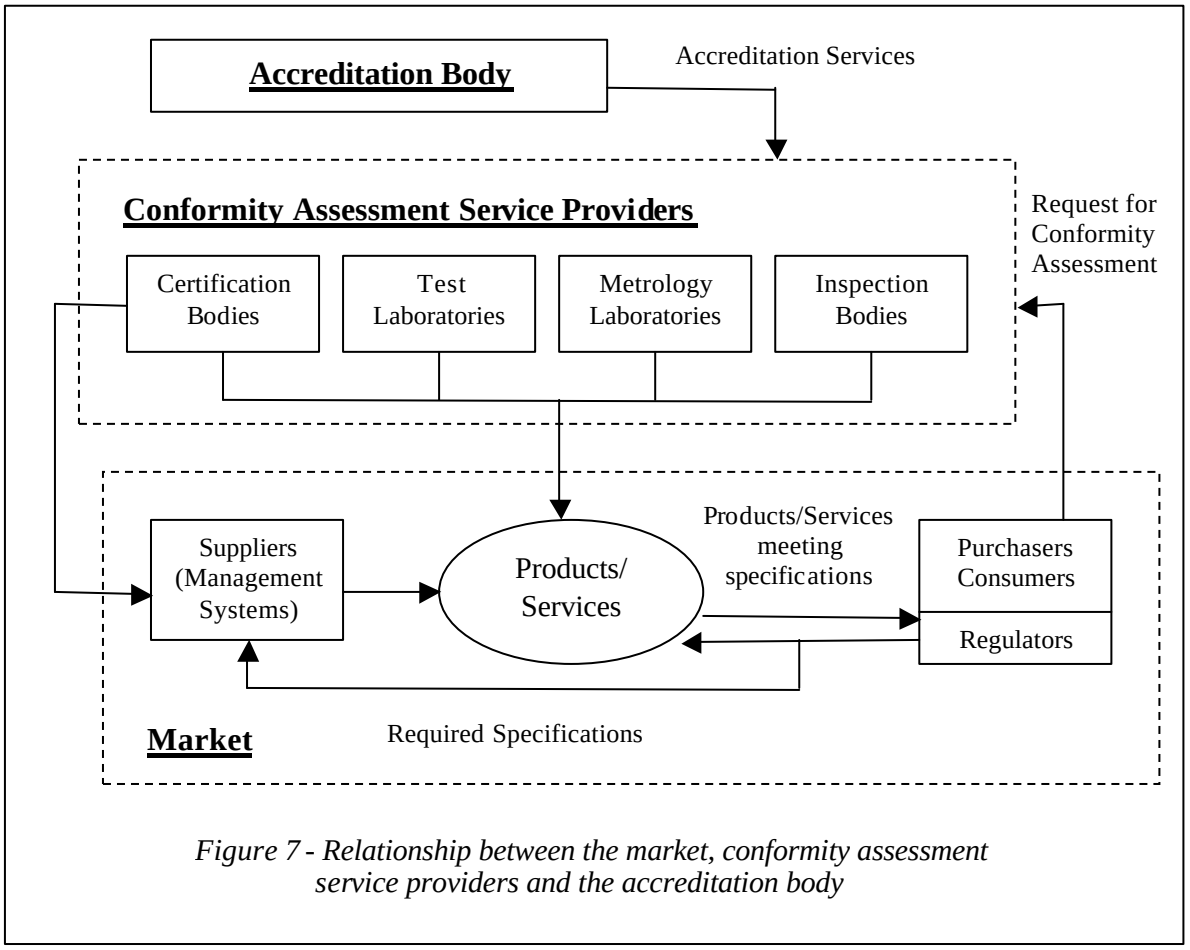


Figure 7 - Relationship between the market, conformity assessment service providers and the accreditation body

Due to the very nature of accreditation and its position in the conformity assessment value chain (see Figure 7), the reliance that authorities place on it, and the limited nature of the business, generally only one or two accreditation organizations are accepted by government at national level. In many cases this organization would have been established by government. Should the national accreditation organization not be a government department or a statutory body, then there should be an agreement in place between the

government and the accreditation organization to confer the appropriate status to such an organization.

2. International organizations

It is important that the accreditation of conformity assessment service providers be accepted by the market place not only at national level, but also internationally. Hence accreditation organizations have done their utmost in recent years to ensure that they conduct their affairs in a way that is acceptable to their peers. Two international organizations have emerged in this regard.

For laboratory accreditation bodies, the peak organization is the International Laboratory Accreditation Cooperation (ILAC). ILAC was established in 1978, first as an informal conference and , then in 1996, as a formal co-operation between laboratory accreditation bodies with participation of stakeholders and other interested parties. In January 2003 ILAC was incorporated in the Netherlands as a non-profit company. ILAC develops laboratory accreditation procedures and practices, it promotes laboratory accreditation as a mechanism to identify competent facilities and it is a forum for the recognition of competent test and calibration facilities world wide. It advocates the use of mutual recognition arrangements between accreditation bodies and maintains an ILAC Mutual Recognition Arrangement between its members.

Arrangements similar to those of ILAC exist for cooperation between bodies that accredit certification or registration bodies[22]. The International Accreditation Forum (IAF) was established in 1992 as a forum amongst accreditation bodies of certification organizations and was incorporated in the United States in 1998. IAF has as its objectives to support the establishment of emerging accreditation programmes, to facilitate the use of accreditation for building confidence in conformity assessment activities and to facilitate global trade with conformity assessment certificates. It operates the IAF Multilateral Recognition Arrangement (MLA) whose member accreditation bodies recognize the results of each other's accreditations as equivalent in accordance with ISO/IEC Guide 61[23] and ISO/IEC Guide 62.

3. Recognition Agreements and Arrangements

3.1. General

The most important mechanism to have certificates issued by conformity assessment bodies in one part of the world recognised by other parts of the world is through the recognition agreements or arrangement among accreditation bodies. These agreements or arrangements can be at a bilateral level (i.e. two bodies) or at a multilateral level (i.e. among a number of bodies). Bilateral agreements are easier to negotiate, but are very limiting in scope, whereas multilateral agreements are obviously more difficult to negotiate, but offer wider scope to the participating

[22] The term "registration" is commonly used in North America whereas "certification" is used in the rest of the world to give written assurance that management schemes conform to specified requirements (e.g. ISO 9000, ISO 14000, etc). In the case of product or process conformity, the use of the term "certification" is more universal.

[23] ISO/IEC Guide 61:1996, *General requirements for assessment and accreditation of certification/registration bodies*

organizations. These agreements can be dealt with at government or at institutional level. To differentiate between the two, the government to government agreements are now generally called Mutual Recognition Agreements (MRA) and those among the organizations in the voluntary domain Multilateral Recognition Arrangements (MLA).

Regional cooperation bodies have been set up to facilitate trade in specific trading blocks. Two such bodies are the Pacific Accreditation Cooperation (PAC) and the European cooperation for Accreditation (EA). Both PAC and EA as groups are part of the IAF MLA.

3.2. System accreditation

The MLA for the system certification domain as implemented by the International Accreditation Forum (IAF) includes a peer assessment on site against ISO/IEC Guide 61[24]. By August 2003 the IAF had 30 MLA Members. More information can be obtained from the IAF[25] itself.

3.3 Laboratory accreditation

ILAC operates a similar system to facilitate the recognition of laboratory reports at regional and international level. By August 2003 44 member bodies representing 35 economies were signatories to the ILAC Arrangement. More information can be obtained from the ILAC Secretariat[26].

4. Standards and Guides

A number of standards and guides are currently in use for the assessment of accreditation bodies and by accreditation bodies to assess conformity assessment service providers. A selection of the international standards and guides most commonly used is provided in Table 11.

Table 11 - Standards and Guides for accreditation, certification or registration

Applicable to	Standard	Title
Laboratories	ISO/IEC 17025:1999	General requirements for the competence of testing and calibration laboratories
Inspection bodies	ISO/IEC 17020:1998	General criteria for the operation of various bodies performing inspections
Product certification bodies	ISO/IEC Guide 28:1982	General rules for a model third-party certification system for products
	ISO/IEC Guide 65:1996	General requirements for bodies operating product certification schemes

[25] **International Accreditation Forum (IAF)**, Suite 1801, 2 Marcus Clarke Street, Canberra City ACT 2601, Australia, Email: adviser@accreditationforum.com, Internet: www.iaf.nu.
[26] **ILAC Secretariat**, c/o NATA, 7 Leeds Street, Rhodes NSW 2138, Australia, Tel: +61 2 9736 8222, Fax: +61 974 35311, Email: ilac@nata.asn.au, Internet: www.ilac.org.

Management system certification/registration bodies	ISO/IEC Guide 62:1996	General requirements for bodies operating assessment and certification/registration of quality systems.
	ISO/IEC Guide 66:1999	General requirements for bodies operating assessment and certification/registration of environmental management systems
Accreditation bodies	ISO/IEC Guide 61:1996	General requirements for bodies operating assessment and certification/registration of quality systems
	ISO/IEC TR 17010:1998	General requirements for bodies providing accreditation of inspection bodies
	ISO IEC Guide 58:1993	Calibration and testing laboratory accreditation systems – General requirements for operation and recognition

These documents are continuously being updated, and some of the Guides are being changed into International Standards. The latest status of these documents should be ascertained from either ISO or IEC.

5. Proven competence versus legislated competence

The objective of the accreditation process is to provide independent proof that a conformity assessment service provider is competent to conduct the calibrations, do the tests or certify commodities against stated norms. In years past, especially in the technical regulation domain, government laboratories have often been "recognised" through legislation. In this case the output of such laboratories was deemed to be correct in cases of dispute, for decision making purposes or in the eyes of the law. Whether the laboratories were actually competent was another issue. This type of arrangement, even though still very prevalent in many parts of the world, has been discredited on numerous occasions, and would not constitute good practice anymore.

Depending on the legal system in operation certain laboratories do need legal protection (e.g. they cannot be sued) otherwise they would not be able to operate at national level in the technical regulation domain. There is no problem with such legal protection provided that accreditation of such laboratories is also part of the arrangement. The National Metrology Institutes (NMIs) are dealt with somewhat differently. They are part of a different international recognition system more fully discussed in Chapter 5. But even the NMIs need to provide evidence of technical competency, and many are now being accredited to ISO/IEC 17025 as well.

6. The review of an Accreditation Infrastructure at national level

The questions in Table 12 are designed to provide a logical sequence in the evaluation of the accreditation infrastructure of a country. The evaluation criteria should be read in conjunction with the preceding discussion in sections 1 to 5.

Table 12 - Review questions for Accreditation			
No	**Question**	**Evaluation criteria**	**Significance**
1	National accreditation body		
	• Does a national accreditation body exist?	• Accreditation bodies are fairly new phenomena, but a very important one.	Fundamental
	• Is there a formal relationship between the accreditation body and the national measurement institute and the national standards body?	• The relationship between standards, metrology and accreditation should be such that no conflict of interest should arise.	Major
	• If a formal relationship does exist between the accreditation organization and the NMI and the national standards body, what is the nature of the relationship?	• The accreditation function and the standards function may be combined in one organization, but then it should not run any laboratories.	Major
	• If a national accreditation body does not exist, are arrangements in place to use an accreditation body from another country?	• Due to the nature of accreditation, small economies might not be in a position to warrant a national accreditation body, but then a formal arrangement needs to be in place for the acceptance of accreditation from bodies in other countries, be it a unilateral acceptance of the accreditation certificates.	Important
2	Legal instrument		
	• Does an Accreditation Act or other legal instrument exist? • Is the accreditation body a part of government, a statutory body or a private company?	• Due to the fact that accreditation bodies are also involved in technical regulations (i.e. they pass judgement on whether conformity assessment service providers are technically competent or not), it is important that they enjoy official backing, and also legal protection against spurious claims.	Fundamental
	• If the accreditation body is a private company, is there an agreement in place between the government and the body?	• The accreditation body need not be a statutory body; it can be a private company as well. In this case an official agreement needs to be in place between the government and the body to provide it with official backing.	Fundamental
3	Governance structure		
	• Does the accreditation body have a Council or Board that provides strategy and oversight of the management?	• It is good governance practice (similar to any private company) to appoint a Council or Board to oversee the senior management and to provide strategic direction. The Council or Board should also have the final fiduciary responsibility.	Major

Table 12 - Review questions for Accreditation			
No	**Question**	**Evaluation criteria**	**Significance**
	• Do the various interested parties (e.g. metrology laboratories, testing laboratories, certification bodies, etc.) have representation in a meaningful way on the Council or Board of the accreditation body?	• The members of the Council or Board should come from the interested parties, namely government, and the SQAM environment to influence strategy and direction of the accreditation body. It is, however, not necessary that all the stakeholders be represented; it is more important that the Council or Board members are appointed for their expertise and experience in governance matters. • The Council or Board should include people that have a solid business and technology background as well as an understanding of the accreditation environment. • The Council or Board should not be too large as to become unwieldy or too small in which case it can be dominated by one specific individual. Between 10 and 20 members can be considered as being optimum. • The head of the accreditation body should be a full member of the Council or Board, but should not hold key positions such as Chair or Vice-Chair.	Fundamental
	• Does a mechanism such as an Advisory Body exist where all stakeholders can provide input into the strategic direction of the accreditation body?	• If the stakeholder group is fairly large, then consideration should be given to an Advisory Committee that reports to the Council or Board. The structure of the Advisory Committee should be such that all stakeholders have the possibility to be represented. The Advisory Committee provides recommendations on strategy and direction to the Council or Board.	Major
4	<u>Funding mechanism</u> • What is the mix between government funding, industry funding (if any) and income from accreditation activities?	• There is no definitive model to fit all. • The funding will however reflect government priorities and industry interest.	Important

Table 12 - Review questions for Accreditation			
No	**Question**	**Evaluation criteria**	**Significance**
	• Is the long term funding secured?	• The long term sustainability of the funding is of major importance. Evidence especially in the form of long term commitments from government in the case of small and developing economies is important. • Total reliance on accreditation income (especially in small or developing economies) will not be adequate to provide long term sustainability.	Fundamental
5	<u>International and regional liaisons</u> • Is the accreditation body an active member of IAF and ILAC? • Is the accreditation body part of the Multilateral Recognition Arrangement (MLA) of these international bodies?	• Like all the bodies in the SQAM infrastructure, the accreditation body needs to "connect" to its peers in the international community. • The accreditation body can be a member of IAF without being part of the multilateral recognition arrangement (MLA) but it has to declare its intention to join the IAF MLA. Accreditation bodies have to be accepted as signatories to the ILAC Mutual Recognition Arrangement if they want to be Full Members of ILAC.	Major
	• Is the accreditation body a member of any regional accreditation arrangement?	• If there is a regional accreditation body/arrangement, it should be part of that.	Major
6	<u>Standards</u> • Does the accreditation body demonstrably meet the relevant standards for such bodies?	• Quite a number of standards and guidelines have been developed at international level by ISO/IEC, IAF and ILAC and others that accreditation bodies need to comply with in order to gain recognition. • These standards and guidelines deal with the management of the accreditation body itself as well as the way in which they go about accrediting the various conformity assessment service providers.	Major
	• Have peer reviews (by international teams) been conducted and what was the outcome of such reviews?	• A self declaration of conformity to these standards and guides is not considered to be adequate. Positive evidence of a peer review is considered a necessity. • Accreditation bodies do not have another body above them internationally that could oversee their activities. Hence they are assessed by their peers who usually come from the membership of IAF and ILAC.	Major

Table 12 - Review questions for Accreditation			
No	**Question**	**Evaluation criteria**	**Significance**
7	Extent of services provided • Which conformity assessment services are required by the industry and regulators of the country?	• The types of conformity assessment service providers vary tremendously depending on the industrial sector and the type of service provided. A number of sectors have developed their own specific type of conformity assessment schemes at international and even regional level. • The accreditation body has to ensure that its systems meet the requirements for each of the different sectors it wishes to accredit. • For each of the different sectors a different international recognition arrangement may exist.	Important
	• Which of these identified conformity assessment service providers can the accreditation body assess?	• Typical conformity assessment bodies to be accredited include: - Metrology laboratories - Test laboratories - System certification bodies (ISO 9000, ISO 14000, etc.) - Product certification bodies - Inspection bodies	Important
8	Recognition agreements • Has the accreditation organization concluded bilateral or multilateral recognition agreements for the relevant conformity assessment services it wishes to accredit? • Do formal agreements exist with other national accreditation bodies and what would be the extent of such agreements?	• It is important for the accreditation organization to facilitate acceptance of the conformity assessment regime of the country by its trading partners. • A few multilateral recognition arrangements exist at international level, e.g. IAF and ILAC. (These are dealt with in question 5 above). • Most of the other sectors require either bilateral or multilateral agreements with specific industry sector organizations (e.g. German automotive industry for VDA 6, American motor industry for QS 9000, etc.) or with specific political organizations (e.g. OECD for GLP, etc).	Major
	• Is the accreditation body involved in trade negotiations at national and/or regional level?	• It is important that the accreditation body participate in such negotiations as accreditation is an important vehicle for agreements for mutual recognition of conformity assessment certificates.	Important

Table 12 - Review questions for Accreditation			
No	**Question**	**Evaluation criteria**	**Significance**
9	Technical regulations • Do mechanisms exist whereby the accreditation body provides a service to the technical regulation environment?	• The modern tendency is to ensure technical competence of all the other players in the SQAM environment, whether of a regulatory nature or in the voluntary field through accreditation. • It follows therefore that the conformity assessment service providers in the regulatory domain should preferably be accredited before they are approved by the relevant regulators.	Major
	• What is the relationship at institutional level between the accreditation body and the government departments responsible for technical regulation implementation?	• This means, however, that the accreditation body should be independent of any pressures from these players.	Major
10	Training • Do formal training courses for assessment personnel exist? • What is the number of trained personnel that the accreditation body can call upon to conduct assessments either from their own ranks or from other independent organizations?	• The availability of trained personnel is important to gain acceptance of the accreditation system internationally and regionally. • Proper training courses should be provided on a continual basis, not only the ad hoc workshop. • Assessment personnel should maintain their skills through appropriate follow-up and continued experience.	Major

Chapter VII - Training, design and quality promotion

1. Training

The whole SQAM environment is a very technical environment. It owes as much of its success to the institutional frameworks, the technical infrastructure as it does to the technical and managerial skills of the people involved in the SQAM activities. Hence training is of vital importance for the implementation and continued effectiveness and efficiency of it all. The sections following will deal with the training and registration (where relevant) of the various disciplines in the SQAM environment.

1.1. Metrologists

Metrology is both a science and a technology. The national metrology institute (NMI) would usually require scientists such as physicists, chemists, and engineers with a strong academic background. The reason for this is the nature of the work of the NMI which is more of a scientific nature. The scientists and engineers would come from tertiary institutions such as Universities, and would develop their expertise through research and regular contact with their peers in other NMIs.

The national bureau of trade metrology would require technical staff dealing with day-to-day implementation of the legal metrology requirements. The level of metrology is quite a bit lower than what the case is for national primary standards. In addition much of the activities have to do with legal matters, administrative procedures, approvals and market surveillance. Therefore the psychological profile of metrologists in legal metrology is quite different from those dealing with the science of measurement. Technical Colleges are usually the source for metrologists in the legal metrology field.

There are no international organizations to harmonise the training and registration of metrologists in either of the two fields. But formal national structures should be in place especially for the legal metrology field.

1.2. System auditors

Quality and environmental system auditors for ISO 9000 and ISO 14000 have to comply with the requirements as set out in ISO 19011[27]. They normally receive training in auditing or assessment techniques after they have gained practical experience in a specific technical discipline. Training institutions providing system auditor training should also be seen to be competent and are therefore sometimes accredited to elements of ISO/IEC Guide 62[28] even though this standard does not address training institutions per se. In many countries training institutions have to register with the authorities as training institutions, and

[27] ISO 19011:2002, *Guidelines for quality and/or environmental management system auditing*.
[28] ISO/IEC Guide 62:1996, *General requirements for bodies operating assessment and certification/registration of quality systems*.

additional requirements may have to be fulfilled. System auditor training is provided by the certification organizations, by tertiary institutions and private training establishments. In many countries these institutions are members or are registered by an umbrella body.

Internationally, organizations which have in place, or are working towards the establishment of systems for the certification/registration of auditors and/or the approval of the provision of auditor training courses and which sign the MoU confirming their intention to join one of the MLAs can become a member of the International Auditor and Training Certification Association (IATCA)[29]. This is a self-regulating association, very much in the mould of IAF and ILAC. IATCA currently has 36 members that are signatories of the Memorandum of Understanding, and 6 QMS Auditor Certification Bodies are signatories of the Multilateral Recognition Agreement (MLA). Before an organization can become a signatory of the MLA, a peer evaluation on the management system, governance arrangements and practices is conducted against the IATCA requirements.

Any auditor trained and registered by any of these signatories of the MLA will be accepted in any of the other countries as equivalent to their own. This scheme is of fairly recent origin, and will no doubt grow in the years ahead. Up to date information should be sought from IATCA.

1.3. Laboratory assessors

Assessment of laboratories against the requirements of ISO/IEC 17025 is based on a management system component and a technical competency component. The management system component can be assessed by auditors trained in ISO 9000 or ISO 14000, but the technical competency has to be audited by technical experts. No international system of auditor training and registration has been set up yet. Many accreditation organizations do run training courses themselves either on their own or in conjunction with the system auditor training organizations to ensure that they have a pool of competent assessors they can call upon. These assessors would be technical experts in one or more of the test or calibration disciplines that the accreditation organization is competent to accredit.

2. Design and Quality Promotion

2.1. General

The question about promotion of quality in a broader sense is much like the chicken and egg as to what comes first? Should the authorities first ensure that the basic infrastructure for the more formal part of the SQAM system, e.g. metrology, standards, accreditation and conformity assessment is in place, or should it embark on a promotion campaign to ensure that industry and society is sensitised as to its importance before embarking on its establishment? Since the more pressing need for the country and its

[29] International Auditor Training and Certification Association (IATCA). Internet: www.iatca.com.

capacity for international trade are better served if the institutional framework is set up as quickly as possible, work should be started to inform and convince the authorities of the role and importance of the standardization infrastructure. Thereafter, promotion with stakeholders and further information of the authorities can be entertained.

It also depends on the philosophy of government in a given country, whether it is a more centralistic type of government that needs to control or guide all issues related to trade, or whether it leaves much of the "softer" side of the activities to industry and society as a whole, concentrating rather to provide the environment in which these can flourish. One will even find differences of opinion on this between the European or North American view and the view of the Far East Economies such as Korea, Japan and China. Developing economies would also be different to developed economies. There is therefore no definitive international model as to what is correct and good. The following sections can therefore only provide some tentative ideas.

2.2. Quality

Quality is a term that is used quite indiscriminately, and it means many different things to different people. For this reason quality is sometimes just defined as fitness for use. ISO gives the following definition for quality: "degree to which a set of inherent characteristics fulfils requirements"[30]. This concept is a universal concept, applicable to all products and services. Fitness for use is as judged by the consumer, not by the manufacturer, the supplier or the repair shop. But fitness for use is the result of a number of parameters, some of which are discussed below.

2.2.1. Product quality

Product quality can roughly be split into quality of identification of customer requirements, quality of design and quality of conformance and quality of product support, over and above other elements such as price, reliability, service, etc. It is interesting to note that promotion of quality has traditionally dealt with, and then has "jumped" to a higher level now dealing with the quality of the organization.

Quality of identification of customer requirements – Customer satisfaction is the customer's perception of the degree to which the customer's requirements have been fulfilled. Those requirements have to be identified through various market research activities. Customer's complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction. Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction[31].

Quality of design - Activity supported by a number of economies. Authorities have started to realise that product design can become a very powerful "ambassador" for all the good things a country stands for. Many economies therefore have a national design promotion body, funded by industry in the West, and by government in the East. Many developing economies have also realised that quality of design, and tapping into the vast potential of indigenous design, will enhance the acceptance of their products in the international and local markets.

[30] ISO 9000:2000: *Quality management systems – Fundamentals and vocabulary*
[31] Ibid.

These developing economies are therefore starting to pledge resources for the development of such design promotion bodies.

The activities of the national design promotion bodies would focus on sensitising society and industry on the merits of good product design through seminars and the like, supply of design information and especially through a national design award scheme. The design promotion body would also be involved in the education and training sector to facilitate the provision of good designers. Sometimes the national design promotion body would be the home of the society of professional designers in the country. Liaison and promotion at the international level is facilitated through the International Council of Societies of Industrial Design (ICSID), an international body established in 1957 to advance the discipline of industrial design at the international level. More information can be obtained from their website[32].

Quality of conformance has to do with product compliance with a given standard or design. This has traditionally been heavily promoted by national standards bodies, especially those that also run laboratories and product certification schemes. The quality control movement as well as the quality management system certification schemes are a direct result of this successful promotion campaign.

Quality of product support – The activities in this area, also called after-sales service, start with the salesmen who have to be aware of the distinguishing features, which make the product fit for use. Field service, like promptness, competence and integrity are indicators for the quality of product support. Customers having used the product might come with suggestions for modifications or improvements.

2.2.2. Quality of the organization

In order to become a player of note in the international market place, a perception of excellence has to be created. In the search for excellence, leading industries and some authorities have come to realise that more is needed than compliance with either product or system standards. A quality culture needs to be developed in industry and society culminating in a high measure of excellence in every endeavour of the country and in its society.

A national quality institute is a good vehicle to provide the required impetus to sensitise the society, industry and the authorities as to the importance of quality. The institute should also provide the infrastructure to run a national quality award, and should facilitate the training and development of personnel in quality matters. Typical national institutes in developed economies include ASQ in the USA, IQA in the UK and DGQ in Germany. In setting up quality promotion bodies, an attachment of an experienced person from a well-established quality promotion body as a mentor would save a tremendous amount of time and effort.

Well-known quality awards for organizations include the Malcolm Baldridge Award in the USA[33], (also of relevance in Canada and Mexico), the EFQM Award in Europe[34] and the Deming Prize in Japan[35]. An international organization, the World Quality Council (WQC),

[32] ICSID Secretariat, Erottajankatu 11 A 18, 00130 Helsinki, Finland. Internet: http://www.icsid.org, Tel: +358 9 696 22 90, Fax: +358 9 696 22 910.

[33] Malcolm Baldridge Award, USA, http://www.quality.nist.gov.
[34] The European Quality Award, http://www.efqm.org/model_awards/eqa/intro.htm.
[35] The Deming Prize, http://www.deming.org/demingprize.

has fairly recently been set up to foster the concepts of quality at international level. The Secretariat of the WQC is in London[36]. The World Quality Council may play a meaningful role in promoting excellence models in the future.

3. The review of the Training, Design and Quality Promotion infrastructure at national level

The questions in Table 14 are designed to provide a logical sequence in the evaluation of the SQAM training and promotion infrastructure of a country. The evaluation criteria should be read in conjunction with the preceding discussion in paragraphs 1 to 2.

Table 13 - Review questions for Training, Design and Quality Promotion

No	Question	Evaluation criteria	Significance
1	Legal instrument for design or quality promotion • Does a national policy document exist that deals with design promotion? • Does a national policy document exist that deals with quality promotion? • Are legal instruments in place that would facilitate design or quality promotion?	• Depending on the legal systems and custom and practice in the country, a policy document, White Paper or even legislation may be necessary to provide the framework and impetus for promoting design and quality. • Without such support from the authorities in developing economies the required promotional activities may not get off the ground.	Important
2	National Design Promotion Body • Does a national institute exist that is responsible for the promotion of product design?	• In developing economies that wish to facilitate the acceptance of their products in the international markets, good design needs to become part and parcel of their products. • Good design of products does not happen by itself; it needs to be a conscious effort on the part of the industry. • Industry does not necessarily know about this and needs to be sensitised regarding the economic value of good design.	Important

[36] World Quality Council, 1 Northumberland Av., Trafalgar Square, London WC 2N5BW, http://www.worldqualitycouncil.com

Table 13 - Review questions for Training, Design and Quality Promotion			
No	**Question**	**Evaluation criteria**	**Significance**
	• Does the design promotion body have the appropriate funding?	Design promotion is not an activity that brings results quickly. Successful design promotion bodies have track records that have been built up over many years. It is therefore important that the personnel should not have worries about the next pay cheque. Funding commitments from the authorities and the industry need to be long term. • For developing economies (or even economies with developing technologies) wishing to make an impact on international markets with their products, it will be incumbent on the authorities to fund the design promotion body for quite a number of years before industry will be willing to take up part of the funding.	Important
	• Does the design promotion body have the relevant programmes in place?	• Elements that would constitute an effective promotion activity include: - Seminars, workshops, etc.; - Provision of design information; - National design award schemes; - Facilitation of the training of designers at secondary and tertiary level.	Important
	• Is the design promotion body an active member of ICSID? • Is the design promotion body involved in regional design promotion activities?	The national design promotion body needs to be actively involved in international design promotion, in order to further the interests of the country it represents and to influence the direction of design in general. The same applies at the regional level.	Important
	• Are appropriate personnel available to really drive the design promotion programmes?	A very specific type of person is needed to successfully run a design promotion body. Such a person must be a marketer of note for the cause, the person should be very knowledgeable about the design discipline i.e. should be a designer, should be supported by first class administrative personnel, and be able to enthuse people with his/her vision.	Important

Table 13 - Review questions for Training, Design and Quality Promotion			
No	**Question**	**Evaluation criteria**	**Significance**
3	National Quality Promotion Body • Does a national institute exist that is responsible for the promotion of the quality concept?	• In economies that wish to facilitate the acceptance of their products in the international markets, the perception and real quality of their industries and practices need to become one of excellence. • Quality of products, actions and perceptions do not come by themselves. They have to instilled through appropriate programmes that aim to enhance the excellence of everything in the company. • Industry does not necessarily know about this and needs to be sensitised regarding the economic value of quality and excellence.	Important
	• Does the quality promotion body have the relevant programmes in place?	• Elements that would constitute an effective promotion activity include: - Seminars, workshops, etc.; - Provision of information; - National quality award schemes; - Facilitation of the training for quality at secondary and tertiary level.	Important
	• Does the quality promotion body have appropriate funding?	• Quality promotion is not an activity that brings results quickly. Successful quality promotion bodies have track records that have been built up over many years. It is therefore important that the personnel should not have worries about the next pay cheque. Funding commitments from the authorities and the industry need to be long term. • For developing economies (or even economies wishing to foster excellence) wishing to make an impact on international markets with their products, it will be incumbent on the authorities to fund the quality promotion body for quite a number of years before industry will be willing to take up all of the funding.	Important

Table 13 - Review questions for Training, Design and Quality Promotion			
No	**Question**	**Evaluation criteria**	**Significance**
	• Does the quality promotion body actively seek out liaison with other national quality promotion bodies? • Is the quality promotion body involved in regional quality promotion activities?	• The national quality promotion body needs to be actively involved in quality promotion at the international level, in order to further the interests of the country it represents. The same applies at the regional level.	Important
	• Are the appropriate personnel available to really drive the promotion programmes?	• A very specific type of person is needed to successfully run a quality promotion body. Such a person must be a marketer of note for the cause, the person should be very knowledgeable about the quality disciplines, should be ably supported by first class administrative personnel, and be able to enthuse people with their vision.	Important
4	<u>Auditor Training</u> • Is a national auditor training and registration scheme in operation?	• The whole system and to a large extent the product certification schemes required in the non-regulatory as well as the regulatory domain are dependent on the quality and integrity of the auditing personnel employed. • The country therefore needs a pool of trained auditors relevant to its needs.	Major
	• Does the auditor training meet the requirements of ISO 19011? • Is there a national body to oversee all the training providers?	• The training of auditors needs to meet international and local requirements.	Major
	• Is the national body a member of IATCA? • Is the national body a signatory to the Multilateral Recognition Arrangement of IATCA?	• Due to the importance of international acceptance of any certification schemes, the auditing personnel should also be trained and registered in accordance with internationally accepted practices and norms. • Membership of IATCA and becoming a signatory to the IATCA MLA is necessary for the long term acceptance of the system certification infrastructure internationally.	Major
5	<u>Consultants</u> • Are consultants in respect of the various disciplines, namely metrology, testing, quality and accreditation operating in the country?	• In any economy no company can afford to have all the expertise on staff any more. Therefore consultants are required from time to time to help with the development and implementation of new systems, including quality, metrology, testing, certification and accreditation.	Important

Annex A - Definitions

Only the terms considered to be the most essential for the overall understanding of the text are set out below. Definitions can be found in a number of sources and these definitions do vary slightly from source to source. The definitions chosen are those which seem to provide the greatest coherence among the various concepts.
For other definitions use can be made of ISO/IEC Guide 2, ISO 9000 or the Definitions published by BIPM, OIML, IAF and ILAC.

Accreditation. Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks (inspection, certification, testing).

ISO/IEC Guide 2

Calibration. Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.
NOTES

1. The result of a calibration permits either the assignment of values of measurands to the indications or the determination of corrections with respect to the indications.
2. A calibration may also determine other metrological properties such as the effect of influence quantities.
3. The result of a calibration may be recorded in a document, sometimes called a calibration certificate or a calibration report.

International Vocabulary of Basic and General Terms in Metrology

Certification. Procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements.

ISO/IEC Guide 2

Inspection. Examination of a product design, product, process or plant, and determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements.

ISO/IEC 17020

Standard. A document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products and their related processes or production methods, with which compliance is not mandatory. It may also cover terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

WTO/TBT Agreement

Standardization. Activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context.

ISO/IEC Guide 2

Technical regulation. A document which lays down product characteristics or their related processes or production methods, including administrative provisions, with which compliance is mandatory. It may also cover terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

WTO/TBT Agreement

Testing. A technical operation that consists of the determination of one or more characteristics of a given product, process or given service according to a specified procedure (physical, chemical, environmental, etc.).

ISO/IEC Guide 2

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

International Vocabulary of Terms in Legal Metrology

References:

ISO/IEC Guide 2:1996, *Standardization and related activities – General vocabulary. International Organization for Standardization.*

ISO/IEC 17020:1998, *General criteria for the operation of various types of bodies performing inspection, International Organization for Standardization.*

ISO 9000:2000, *Quality management systems – Fundamentals and vocabulary. International Organization for Standardization.*

International Vocabulary of Basic and General Terms in Metrology (1993). Prepared simultaneously in English and French by a joint working group of experts appointed by seven international organizations. International Organization for Standardization.

WTO Agreement on Technical Barriers to Trade. World Trade Organization.

Annex B - Extract about Export Quality Management from ITC's National Export Strategy Template

1 Put quality first

Meeting technical and quality requirements in the international market place is a tall order. But it is one that national export strategy must address.

Exporters must ensure that their products meet the *mandatory* technical specifications of the targeted market that have been established to protect consumers' health and safety and the environment. Exporters must also meet the "voluntary" quality and production standards specified by the prospective buyer.

First, the exporter has to obtain information about the mandatory technical regulations and standards applicable in the importing country. Second, the exporter must adapt his or her products to meet these requirements, plus the preferences of the buyer. Third, the exporter must be able to demonstrate to the regulatory authorities in the country of import and to a buyer that the products meet the relevant requirements. For each step the exporter needs assistance.

2 The SQAM system

To deliver this support, the national network must provide four core services, known collectively as the SQAM system. This covers:

- **Standardization:** the establishment of standards and the provision of information on standards, technical regulations and conformity assessment procedures
- **Quality Assurance (Conformity Assessment):** the certification of products to specifications and of quality management systems (such as ISO 9000)
- **Accreditation:** the formal recognition of certification and inspection bodies and of testing and calibration laboratories
- **Metrology:** the ensuring of traceability of measurements and accuracy of test results.

SQAM is complex. It's expensive and time-consuming. But the existence of SQAM infrastructure in the country is a fundamental aspect of ensuring the competitiveness of the export sector.

Nevertheless, it is an aspect that is not given sufficient attention by export strategy-makers in many developing and transition economies.

3 Developing SQAM infrastructure: First step

Given the investment involved, best practice suggests taking a step-by-step approach to building a national SQAM infrastructure.

The strategy-maker should, as a first step, work to provide a basic level of quality-related services to the export community. These should include:

• testing, calibration and inspection (conformity assessment) and measurement traceability services (metrology). These should be provided by the National Standards Body

and

• technical information services on issues relating to technical barriers to trade and sanitary and phytosanitary requirements. These should be obtained through the local National Enquiry Point.

4 Developing SQAM infrastructure: Second and third steps

The second step should focus on encouraging the private sector to provide a range of conformity assessment services. Where there is little interest among private-sector organizations to provide such services, the public sector bodies, such as the National Standards Body, should assume responsibility for the delivery of services to areas of national interest or such sectors.

The third and final step should involve the setting up of a national accreditation body whose certification is recognized in all foreign markets. As an interim measure, accreditation of local enterprises and conformity assessment bodies will have to be conducted by international organizations and certification bodies that have international accreditation.

5 The National Enquiry Point

The creation of a National Enquiry Point to provide information on national standards (to Enquiry Points in other countries) and to advise local exporters of international standards is a commitment of all WTO member countries.

The National Enquiry Point can make a major contribution to the national export effort and the efficient functioning of the Enquiry Point should, therefore, be a priority of the national trade support network.

Annex C– Extract of checklist about Quality Management from ITC's National Export Strategy Template

MODULE 4 Quality Management

Checklist 1: General Situation and Institutional Structure

	Question	Y=Yes/ N=No	Comment	Action Required
1.	Have the export quality requirements for priority product sectors and markets been identified?			
2.	Have the needs for technical information, conformity assessment and technical assistance been identified for exporters in these sectors?			
3.	Is an inventory of organizations providing SQAM services available?			
4.	Has an analysis been conducted to determine the gap between SQAM services available and those required by exporters?			

Checklist 1: General Situation and Institutional Structure

	Question	Y=Yes/ N=No	Comment	Action Required
5a.	Is there a National Quality Policy?			
5b.	Does the National Quality Policy have an export orientation?			
5c.	Is there a National Quality Council?			
5c.	If yes, does the Quality Council comprise all stakeholders? • Government • Consumers' associations • Exporters' associations • Manufacturers' associations • Quality organizations • Research organizations • Educational organizations			

MODULE 4 Quality Management

Checklist 2: Technical Information

	Question	Y=Yes/ N=No	Comment	Action Required
1.	Is information readily available to the export community on standards, technical regulations and conformity assessment procedures (TBT measures) and sanitary and phyto-sanitary measures (SPS measures)?			
2.	Is there a service to provide information about specific product sectors identified as being a priority?			

Checklist 2: Technical Information

Checklist 2: Technical Information

	Question	Y=Yes/ N=No	Comment	Action Required
3a.	Is there a service to undertake work to determine detailed requirements in selected markets?			
3b.	Is this service easily accessible?			
3c.	Is this service accessible at reasonable cost?			

MODULE 4 Quality Management

Checklist 3: Technical Regulations

	Question	Y=Yes/ Y=No	Comment	Action Required
1.	Is there a national inventory available of technical regulations affecting exports?	☐		
2.	Is there a mechanism where exporters are involved in decision making on technical regulations?	☐		
3.	Is an impact study done before implementation of technical regulations (e.g. impact on trade, cost effectiveness)?	☐		
4.	Is there a review mechanism to keep technical regulations up to date?	☐		

Checklist 3: Technical Regulations

Checklist 3: Technical Regulations

	Question	Y=Yes/ Y=No	Comment	Action Required
5.	Is there a mechanism for involving the business community in making comments on foreign notifications from WTO about TBT and SPS?			
6.	Are there national committees to deal with TBT and SPS issues?			
7.	Are issues of concern about problems faced by exporters raised at the WTO Committees on TBT and SPS?			

MODULE 4 Quality Management
Checklist 4: Standards

	Question	Y=Yes/ Y=No	Comment	Action Required
1.	Is there a body that coordinates standardization activity (e.g. NSB)?			
2.	Is there a National Codex Committee?			
3.	Is the country (and/or its relevant organizations) a member of relevant international SQAM bodies?			
4.	Is there a funding mechanism that provides adequate and long-term funds to the national standards body?			
5.	Does the NSB take an active part in preparing international standards?			

Checklist 4: Standards

Checklist 4: Standards

	Question	Y=Yes/ Y=No	Comment	Action Required
6.	In the process for development of national standards, does the NSB meet the requirements of the *Code of Good Practice* - Annex 3 of the WTO/TBT Agreement?	☐		
7.	Are there national technical committees for each of the priority export sectors?	☐		
8.	Does the export community participate in the national technical committees?	☐		
9.	Does the export community participate in international technical committees?	☐		

MODULE 4 Quality Management

Checklist 5: Quality Assurance (Conformity Assessment)

	Question	Y=Yes/ N=No	Comment	Action Required
1.	Does the country have services for testing, inspection and certification?			
2,	Do these services meet the needs of exporters?			
3.	Are these services available at an affordable cost?			
4.	Are the services delivered within a reasonable period of time?			
5.	Have these services the required technical competence?			
6.	Are the national conformity assessment bodies recognized in key international markets?			

Checklist 5: Quality Assurance (Conformity Assessment)

Checklist 5: Quality Assurance (Conformity Assessment)

	Question	Y=Yes/ N=No	Comment	Action Required
7.	Have some national conformity assessment bodies become "designated bodies" in the context of the WTO TBT Agreement?	☐		
8.	Is there a funding mechanism that provides adequate and long-term financing to national conformity assessment bodies?	☐		
9.	In the absence of national conformity assessment bodies, are the services of other, i.e. foreign certification bodies available?	☐		
10.	Are the services of foreign certification bodies available at reasonable cost?	☐		

MODULE 4 Quality Management

Checklist 6: Metrology

	Question	Y=Yes/ N=No	Comment	Action Required
1.	Are there measurement and calibration services available for the export sector (from private or public sector)?			
2.	Are these measurement and calibration bodies accredited to ISO/IEC 17025?			
3.	Are the measurement and calibration standards traceable to international standards?			
4.	Is the level of accuracy of measurement standards commensurate with the needs of the export community?			

Checklist 6: Metrology

	Question	Y=Yes/ N=No	Comment	Action Required
5.	Are the national measurement standards harmonized with those of trading partners (through intercomparison)?			
6.	If there are no measurement and calibration services available in the country, are such services available nearby?			
7.	Are measurement and calibration services available at affordable cost?			
8.	Are measurement and calibration services available within a reasonable time period?			

MODULE 4 Quality Management

Checklist 7: Accreditation and Multilateral/Mutual Recognition Agreements

	Question	Y=Yes/ N=No	Comment	Action Required
1.	Have the available conformity assessment bodies been accredited?			
2.	Is there demand for accredited conformity assessment services within the export community?			
3a.	Are there accreditation services available in the country?			
3b.	If there are no such services in the country, are there accreditation services easily accessible elsewhere?			
4.	Is there an accreditation body that fulfils: • ISO/IEC Guide 58 • ISO/IEC Guide 61 • ISO/IEC TR 17010			
5.	Is the national accreditation body a member of ILAC?			

Checklist 7: Accreditation and Multilateral Recognition Agreements

Checklist 7: Accreditation and Multilateral Recognition Agreements

	Question	Y=Yes/ N=No	Comment	Action Required
6.	Has the national accreditation body signed the ILAC Arrangement for mutual recognition?			
7.	Is the national accreditation body a member of IAF?			
8.	Has the national accreditation body signed the IAF Multilateral Recognition Arrangement?			
9.	Is there a funding mechanism that provides adequate and long-term funds to the national accreditation body?			
10.	Have Mutual Recognition Agreements (MRAs) been established with principal trading partners?			

MODULE 4 Quality Management
Checklist 8: Quality Promotion

	Question	Y=Yes/ N=No	Comment	Action Required
1.	Is a quality culture promoted by any national organization (e.g. chamber of commerce, trade promotion organization or quality association)?			
2.	Is there a mechanism for disseminating information to the export community on developments in quality management?			
3.	Are there special programmes to support the introduction /implementation of quality management systems within the export community?			
4.	Are there funds to subsidize the introduction / implementation of quality management systems in export firms?			

Checklist 8: Quality Promotion

Checklist 8: Quality Promotion

	Question	Y=Yes/ N=No	Comment	Action Required
5.	Is there a national programme to support quality improvement within the business sector as a whole?			
6.	Is there a national quality award?			
7.	Are there incentives for certifying products of export (e.g. tax exemptions)?			

MODULE 4 Quality Management

Checklist 9:Training & Consultantcy

	Question		Y=Yes / N=No	Comment	Action Required
1.	Are there training programmes available in the following areas?				
	• ISO 9000 • HACCP • ISO 14000 ISO/IEC 17025	• OHSAS 18000 • Testing and calibration • TQM • Continual improvement			
2.	Are these training programmes available at an affordable cost?				
3.	Are local consultants available for quality improvement?				
4.	Are auditors available for management systems?				
5.	Are there special programmes and funds to subsidize training for quality improvement?				
6.	Are the trainers and consultants registered for competence?				
7.	Is there strict demarcation between consultancy and certification (e.g. in the area of ISO 9000)?				
8.	Are quality aspects taken into account within vocational, technical and university curricula?				

ITC: Your Partner in Trade Development

The International Trade Centre (ITC) is the technical cooperation agency of the United Nations Conference on Trade and Develpoment (UNCTAD) and the World Trade Organization (WTO) for operational, enterprise-oriented aspects of trade development.

ITC supports developing and transition economies, and particularly their business sectors, in their efforts to realize their full potential for developing exports and improving import operations.

ITC works in six areas:

- Product and market development
- Development of trade support services
- Trade information
- Human resource development
- International purchasing and supply management
- Needs assessment, programme design for trade promotion

International Trade Centre
UNCTAD/WTO

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