



# Standards, Metrology and Conformity Assessment: Tools to Facilitate Trade and Market Access

A Publication of the Mozambique National Institute of Standards and Quality

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# FOWARD



Quality is a pre-requisite for Mozambique's economic success, as well as for any organization engaged in the provision of goods and services. It is well recognized that standards, technical regulations and over burdening testing and certification requirements (Technical Barriers to Trade) can be impediments to domestic production, international trade, foreign investment, consumer protection and economic growth. Mozambique's domestic industry needs to demonstrate that they are capable of producing high quality, safe goods and services for domestic and foreign markets. This demonstration is best implemented through

a National Quality Infrastructure (NQI), which is guided by the country's National Quality Policy.

For Mozambique to compete and succeed in today's regional and global market: traders, producers and suppliers must not only find a buyer, but they must also ensure that their products meet the importing country's safety requirements, as well as the customers' expectations. This includes providing credible proof of this.

To facilitate trade and industrial growth as well as protection of health and public safety, the Government must develop and implement an effective strategic plan (National Quality Infrastructure) that is transparent, meets the needs of domestic industry and is fully compliant with the country's international and regional trade agreements, such as the WTO Agreement on Technical Barriers to Trade, the Sanitary Phytosanitary Agreement and the TBT provisions contained in the SADC Trade Protocol.

A National Quality Infrastructure is one method breaking down technical barriers to trade. Building a NQI will enable Mozambican enterprises to meet the demands of a multilateral trading system and to provide credible proof that their products conform to international standards, technical regulations and conformity assessment requirements. This is extremely important for both business and regulatory authorities. This is a complex challenge that has to be met in several organizational dimensions including the public and private sectors, academia, trade associations, and other stakeholders. Private sector involvement is crucial to the overall success of a national quality program; they are the ultimate beneficiaries of such a program. A properly developed and implemented NQI will minimize the duplication of re-testing and recertification requirements and eliminate non-tariff barriers to trade and market access delays.

This handbook on Standards, Metrology, Conformity Assessment, Tools to Facilitate Trade and Market Access is the first work in this field in Mozambique. We hope it improves your understanding of the basic concepts of metrology, standardization and conformity assessment. I wish to thank and appreciate the hard work of INNOQ staff and the SPEED+ project in developing this handbook.

Wishing you good luck and success,

Alfredo Sitoe

**Director General** 

Instituto Nacional de Normalização e Qualidade (INNOQ)

# **PREFACE & ACKNOWLEDGMENTS**



The Mozambique National Institute for Standards and Quality together with the U.S. Agency for International Development SPEED + project have jointly developed this handbook to create awareness and the importance of Standards, Metrology and Conformity Assessment as they relate to trade facilitation and economic growth in Mozambique.

#### **Technical Development**

The handbook reflects basic concepts developed by regional and international organizations including ISO, IEC, ASTM, the WTO, the World Bank, Codex, BIPM, ILAC, IAF, ITC, NIST, ANSI, SIM, and many others. Over the years, special versions of the handbook have been published in co-operation with the United States Agency for International Development (USAID) and the National Standards and Metrology institutes of Afghanistan, Laos, Myanmar and Vietnam. Previous versions have been printed in English, Dari and Vietnamese and now in Portuguese.

Much of the material presented in the handbook concerning regional and international organizations was obtained from their web sites or other published information.

## **Technical Review**

As the primary developer of this handbook, I want to thank the following individuals who provided direction, guidance and technical support in the development of the original and current version of the handbook; their contribution is noted with thanks and appreciation.

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Thank you all, Edward Nemeroff Senior Technical Advisor U.S. Agency for International Development SPEED + project ednemeroff@cs.com

# **GLOSSARY OF ACRONYMS**

AB	Accreditation Body		
ANSI	American National Standards Institute		
APEC	Asia Pacific Economic Cooperation		
APLAC	Asia Pacific Laboratory Accreditation Cooperation		
APMP	Asia Pacific Metrology Program		
ARSO	African Regional Organization for Standardization		
ASTM	American Society for Testing Materials International		
ASEAN	Association of South-East Asian Nations		
BIPM	Bureau International des Poids et Measures		
CA	Conformity Assessment		
CAB	Conformity Assessment Body		
CAC	Codex Alimetarius Commission		
CAC-MASQ	Central Asian Cooperation on MAS-Q		
CASCO	Committee on Conformity Assessment at ISO		
CE Marking	European mark of conformity		
CEN	European Committee for Standardization		
CENELEC	European Committee for Electrotechnical Standardization		
CEOC	International Confederation of Inspection & Certification Organizations		
CGPM	Conference Generale des et Poids		
COOMET	Euro-Asian Cooperation of National Metrological Institutes		
CRM	Certified Reference Material		
DEVCO	Committee on Developing Country's (ISO)		
EA	European Cooperation for Accreditation		
EASC	The Interstate Council for Standardization, Metrology and Certification		
EC	European Commission		
EMS	Environmental Management System		
EOQ	European Organization for Quality		
EOTC	European Organization for Conformity Assessment		
ETSI	European Telecommunications Standards Institute		
EU	European Union		
EUROLAB	Associations of Measurement, Testing and Analytical Laboratories		
EURAMET	European Association of Metrology Institutes		
FAO	Food and Agriculture Organization		
GATT	General Agreement on Tariffs and Trade		
GUM	Guide to the Expression of Uncertainty in Measurement		
HACCP	Hazard Analysis Critical Control Point		
IAAC	InterAmerican Accreditation Cooperation		
IAF	International Accreditation Forum		
IEC	International Electrotechnical Commission		
ILAC	International Laboratory Accreditation Cooperation		
IMEKO	IMEKO International Measurement Confederation		
IRCA	IRCA International Register of Certified Auditors		
ISO	International Organization for Standardization		

ІТС	International Trade Centre		
ITU	International Telecommunications Union		
JCDCMAS	Joint Committee on Coordination of Technical Assistance on Metrology,		
	Accreditation and Standardization		
JCRB	Joint Committee of the Regional Metrology Organizations and the BIPM		
MAS-Q	Metrology, Accreditation and Standards = Quality		
MLA	Multilateral Mutual Recognition Arrangement		
MRA	Mutual Recognition Arrangement		
MSTQ	Metrology Standards, Testing and Quality		
NACLA	The National Cooperation for Laboratory Accreditation		
NAFTA	North American Free Trade Agreement		
NATA	National Association of Testing Authorities		
NQI	National Quality Infrastructure		
NCSLI	National Conference of Standards Laboratories International		
NMI	National Metrology Institute		
NORAMET	North American Cooperation in Metrology		
NSB	National Standards Body		
NVLAP	National Voluntary Laboratory Accreditation Program(USA)		
OIML	International Organization for Legal Metrology		
PAC	Pacific Accreditation Cooperation		
QMS	Quality Management System		
RMO	Regional Metrology Organization		
SADCA	Southern African Development Community Accreditation		
SADCMEL	SADC Cooperation in Legal Metrology		
SADCMET	South-African Development Community Cooperation in Measurement		
SANAS	Traceability South-African National Accreditation System		
SI	International System of Units		
SIM	Inter-American Metrology System		
SoA	Scope of Accreditation		
SPS	•		
	Agreement on the Application of Sanitary and Phytosanitary Measures		
SQAM TBT	Standards, Quality, Accreditation and Metrology Technical Barriers to Trade		
TQM	Total Quality Management		
UILI	International Union of Independent Laboratories		
UNIDO	United Nations Industrial Development Organization		
USAID	United States Agency for International Development		
VIM	International Vocabulary of Basic and General Terms in Metrology		
WECC	Western European Calibration Cooperation		
WELAC	Western European Laboratory Accreditation Cooperation		
WELMEC	European Cooperation in Legal Metrology		
WEMC	Western European Metrology Club		
WSSN	World Standards Service Network		
WTO	World Trade Organization		

# **GLOSSARY OF TECHNICAL TERMS IN SIMPLE LANGUAGE**

Accreditation	Accreditation is the internationally accepted procedure that recognizes the competence of testing and calibration laboratories, product certification bodies system certification body's inspection bodies and other activities. Accreditation schemes minimize the duplication of re-testing and re-certification reduces cost and eliminates non-tariff barriers to trade and market access delays.	
Calibration	<b>Calibration</b> refers to a written process of verification that an instrument is within its designated accuracy. This is usually accomplished by formal comparison with a measurement standard of higher accuracy that is traceable to national or international measurement standards.	
Certification	Based on the results from accredited laboratory and the specifications from a documentary standard, certification is the operation intended to assure the conformity of products, services, etc. by means of technical evaluation consisting of the proper combinations of defined operations.	
Conformity Assessment	Conformity assessment procedures are technical activities such as testing, verification, inspection, certification, and accreditation, which confirm that products or processes fulfill the requirements as defined in technical regulations and standards.	
Inspection	Inspection in its simplest form, it is a verification of the quantity and/or weight of traded goods, or if it occurs at a border, verification can consist of examining import/export documents with a visual check of the cargo on the basis on professional judgment.	
Legal Metrology	Legal metrology is the practice and the process of applying regulatory structure and enforcement to metrology a credible measurement system is vital for trade in any society. All measurements related to trade and consumer protection come under legal metrology.	
Metrology	Metrology is the science of measurement. No testing would be possible unless the characteristics of the product or service in question can be measured in a way, which compares them against a physical or chemical reference of known value. Therefore, adequate methods for measuring the properties of products and services are fundamental to the quality assessment process.	
Mutual Recognition Arrangement	Mutual Recognition Arrangements (MRA's or MLA's) are formal non- Government agreements between parties whereby they agree to recognize the results of each other's testing, inspection, certification, or accreditation. MRA's are an important step towards reducing the multiple conformity assessment that products, services, systems, processes and materials may need to undergo, especially when they are traded across borders.	
National Metrology Institute	A National Metrology Institute (NMI) is an institute designated by national decision to develop and maintain national measurement standards for one or more quantities.	

Product certification	Product certification may consist of initial testing of a product combine with assessment of a quality management system. This may be followed by surveillance that takes into account the supplier's quality management system and testing of samples from the factory or the market. Other produc certification schemes comprise of initial testing and surveillance, while so others rely on the testing of a sample product - this is known as type testing	
Quality Management System Certification	The most well known examples are the certification of quality management systems and environmental management systems as conforming, respectively, to ISO 9001 and ISO 14000 standards. More than 1,000,000 organizations worldwide have been certified to an ISO 9000 family of standards.	
Standard (Document)	A standard is a document that describes the important features of a product, service or system and, the essential requirements that it must meet. Compliance is voluntary.	
Standard (Measuring)	An instrument, reference material, or measuring system intended to define or reproduce one or more values of a quantity to serve as a reference.	
TBT Agreement	The World Trade Organizations Agreement on Technical Barriers to Trade (TBT) aims to reduce impediments to trade resulting from differences between national regulations, standards, and conformity assessment procedures.	
Technical Barrier to Trade	TBT's are non-tariff barriers that generally result from the preparation adoption, and application of different technical regulations and conformity assessment procedures.	
Technical Regulation	A technical regulation is a document issued by a government that details product characteristics, production methods, and administrative provisions, with which compliance is mandatory.	

# **INTRODUCTION AND EXECUTIVE SUMMARY**

The intention of this handbook is to provide the reader with a basic overview of the importance of a national quality infrastructure that includes metrology, accreditation, standardization and conformity assessment procedures as tools to enhancing trade facilitation, market access and export competitiveness.

The handbook includes a basic introduction to trade facilitation and the NQI concept, the WTO TBT and SPS Agreements, metrology, standards, and conformity assessment. Readers will find that the handbook is a source of practical information including an introduction to the major regional and international technical organizations that support trade facilitation and promote market competitiveness. Each technical section of the handbook contains a list and description of reference material offered by the WTO, national, regional and international NQI organizations, etc. Hyperlinks are available that will take the reader directly to a copy of the material or the website of the organization that offers the information. We hope that this handbook will provide the reader with a source of valuable information and a basic understanding of national quality infrastructure concepts.

Note: Websites listed in the handbook can be accessed by simply clicking on the appropriate link. In addition, copies of most reference material described in each section of the handbook can be accessed by opening the appropriate section folders contained on the wafer drive. The handbook is divided into five major sections:

**Prior to the Introductory Section, there** are a list acronyms and abbreviations commonly associated with the TBT Agreement and an NQI. This is followed by a glossary of TBT and related technical terms in plain language.

**The Introductory Section** is an overview of the importance of an NQI as it relates to trade facilitation and the TBT Agreement.

**Section One** addresses technical barriers to trade with the focus on understanding the fundamentals, background, structure, and content of the TBT and SPS Agreements and member obligations.

**Section Two** describes documentary standards and technical regulations, the evolution, recognition, their need, and voluntary standards and mandatory technical regulations. The role of standards and technical regulations in international trade, international and regional standards organizations, and the standards development process are also detailed.

**Section Three** is metrology, the science of measurement, its history, the international system of metrological units, the different categories of metrology, the vocabulary of metrology and regional and international metrology organizations are described.

**Section Four** is conformity assessment, the international accepted procedure for determining compliance to standards and technical regulations. The concept of mutual recognition and the principles of conformity assessment are detailed as well as an introduction to regional and international conformity assessment organizations.

Section Five describes the NQI system in Mozambique.

Section Six-Summary

# The importance of establishing a National Quality Infrastructure

For Mozambique, understanding the link between a National Quality infrastructure, global trade, and export competitiveness is at the forefront of trade policy. The removal of non-tariff barriers to trade and implementing a regulatory system that includes a national quality infrastructure system that is WTO compliant and accepted internationally has become a central political task for Mozambique and many developing and transitional economies. In seeking to expand international trade, it is virtually impossible to underestimate the importance of adopting and implementing international recognized and accepted NQI practices. These activities provide a vital link to global trade, market access and export competitiveness as they contribute to consumer confidence in product safety, quality, health and the environment.

One of the main challenges facing the international trading system is the diverse conformity assessment practices and standards used in different countries and some regional organizations. Unless trading partners adhere to similar or equivalent procedures and requirements, and recognize each other's test and certification results, then the costly problem of discriminatory, non-transparent, and unnecessary obstacles to trade will persist.

Conformity assessment is the internationally recognized procedure for demonstrating that specified requirements relating to a product, process, system, person or body are fulfilled, thus determining compliance. Conformity assessment activities include testing, inspection, certification, labeling, and accreditation. These procedures offer practical solutions to many developing countries. Developing countries and countries making the transition from a centralized to a market economy make up some three quarters of the members of the World Trade Organization (WTO). For them, standards and conformity assessment are an important source of technological expertise for developing their economy and raising their capability to export and compete on global markets.

As a trade facilitation body, the WTO emphasizes through its various agreements the importance of ensuring that countries' regulations do not create unnecessary barriers to international trade. Despite its emphasis on ensuring that no unnecessary barriers to trade be created through technical regulations, the TBT Agreement recognizes that countries have the right to establish protection for human, animal, or plant life, or the protection of health and the environment. The substantive provisions under the TBT agreement can be grouped into four sometimes-interrelated areas.

These groups of obligations include:

- • Granting treatment to imports of a country that is not less favorable than that granted to local production (national treatment) or to imports of another country (most favored nation status);
- • Encouragement of members to rely on international standards :
- • Transparency in the development, application, and implementation of standards, conformity assessment procedures and technical regulations; and
- • Procedural requirements related to notification to the WTO of TBT-related

#### matters

The TBT Agreement requires that conformity assessment procedures be prepared, adopted, and applied to grant access for suppliers of like products originating in the territories of other Members [signatories to the agreement] under conditions no less favorable than those accorded to suppliers of like products of national origin or originating in any other country.

The Agreement also requires that such procedures not be prepared, adopted, or applied with a view to or with the effect of creating unnecessary obstacles to global trade. Ideally, a properly conducted conformity assessment program benefits, not hinders the free flow of goods into the marketplace.

The TBT Agreement distinguishes between standards and technical regulations. The difference between a standard and a technical regulation lies in compliance. While standards are voluntary, technical regulations are mandatory and have the force of law.

Standards are agreed procedures, systems and methods, etc. that producers voluntarily meet to show that their products achieve a stated level of quality and or performance. When a standard or part of a standard is used in regulations, they effectively become technical regulations, thus their use becomes a mandatory requirement that local goods and imports must meet.

Accreditation (a conformity assessment activity) is the internationally accepted system that recognizes the competence of testing and calibration laboratories, product certification bodies, quality system certification bodies and inspection bodies. Accreditation establishes assurance of the quality of test data recognizes the competence of conformity assessment bodies and provides discipline that is internationally accepted. This minimizes duplication of re-testing and re-certification reduces cost and eliminates non-tariff barriers to trade and market access delays.

Mutual recognition of accreditation and certification systems facilitates access to international markets; provides the technical underpinning to international trade by promoting cross-border stakeholder confidence and acceptance of accredited test data and certified results. The present international concept and goal is "Certified Once, Accepted Everywhere". This is made possible through a network of mutual recognition arrangements (MRA or MLA) among international accreditation bodies.







In 2017, there were 164 members of the WTO and some 20 countries that have formally stated their intention to accede to the World Trade Organization. In doing so, they have

committed to complying with the WTO's, Technical Barriers to Trade Agreement and the Agreement on Sanitary and Phytosanitary Measures. Compliance to these two agreements is mandatory as well as compliance to the "Code of Good Practice" (ANNEX 3 of the TBT Agreement) which establishes the principles for the preparation, adoption, and application of standards.

National Standardizing bodies that have accepted or withdrawn from this Code shall notify this fact to the ISO/IEC Information Centre in Geneva. The notification shall include the name and address of the body concerned and the scope of its current and expected standardization activities.

# A NATIONAL QUALITY INFRASTRUCTURE

All Countries could use a National Quality Infrastructure (NQI) in order to realize the benefits that will be gained from being a member of the WTO, compliance to the WTO TBT and SPS Agreements are necessary. A National Quality infrastructure is the very effective first step in meeting the requirements of the TBT Agreement.

# What is a National quality Infrastructure?

There have been several approaches to establishing an NQI, but there is no one best model or international best practice that meets the needs of all countries. There has been no single internationally acceptable definition of National Quality Infrastructure -that is until:

VIENNA, 30 June 2017 – 1The United Nations Industrial Development Organization (UNIDO) hosted the annual meeting of the Network on Metrology, Accreditation and Standardization for Developing Countries in which a QI definition of QI was developed. The meeting focused on quality infrastructure as a pillar supporting competitiveness, trade and sustainable development. Standards, metrology, conformity assessment services and accreditation are instrumental to achieving Sustainable Development Goals (SDGs).

The key outcome of the meeting was the adoption of a common definition of "quality infrastructure (QI)".

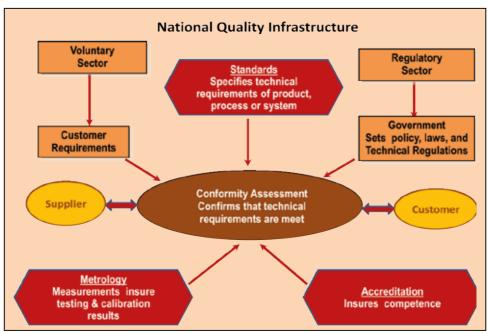
"The system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes.

The quality infrastructure is required for the effective operation of domestic markets, and its international recognition is important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing. It relies on: metrology, standardization, accreditation, conformity

<sup>&</sup>lt;sup>1</sup> The following organizations participated in the meeting: International Bureau of Weights and Measures (BIPM), International Accreditation Forum (IAF), International Electrotechnical Commission (IEC), International Laboratory Accreditation Forum (ILAC), International Standards Organization (ISO), International Trade Centre (ITC), International Telecommunication Union (ITU), International Organizations of Legal Metrology (OIML), United Nations Economic Cooperation for Europe (UNECE) and UNIDO; as well as, the World Bank.

#### assessment, and market surveillance."

The WTO TBT Agreement states clearly that Central Governments Bodies shall ensure acceptance of conformity assessment procedures based on adequate technical competence and verified compliance through accreditation. This requirement cannot be fulfilled without having an internationally recognized quality infrastructure in place.



# The Main Components of a Quality Infrastructure

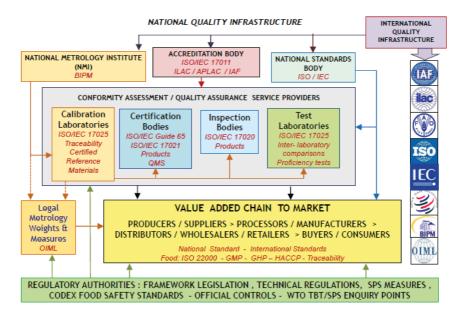
Metrology, standards and conformity assessment are three separate but interdependent and interlinked "pillars" of knowledge and are essential to develop a quality infrastructure that enables sustainable development that can lead to full participation in international trade and to satisfy the technical requirements of the multilateral trading system. When considering the role, structure, and functions of the National Standards and Metrology institute it is essential to understand how these three pillars fit together.

METROLOGY	
	<ul> <li>Metrology is the science of measurement and includes the functions required to ensure internationally recognized traceability of measurement and calibration of measuring instruments. Metrology can be classified as follows: <ul> <li>Scientific metrology</li> <li>Legal metrology</li> <li>Industrial metrology</li> </ul> </li> </ul>
STANDARD	
	A document that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context Standards are used as the basis for creating technical regulations.
CONFORMITY	
ASSESSMENT	
	Conformity assessment is the internationally recognized procedure for demonstrating that specific requirements relating to a product, process, system person or body are fulfilled, thus determining compliance with the requirements as defined in technical regulations and standards. The following are conformity assessment activities:
ACCREDITATION	Accreditation is the internationally recognized conformity assessment activity, by which an authoritative body provides formal recognition that a body or person is competent to carry out a specific task. This is always carried out by an independent third party.

These activities provide a vital link to global trade, market access and export competitiveness as they contribute to consumer confidence in product safety, quality, health and the environment. Metrology, standards, accreditation and conformity assessment are vital to products and product processes; although consumers are not always aware of it.

To improve export potential, producers must meet the requirements of the target markets in terms of quality, safety, reliability, environmental compatibility and hygiene and they must be able to provide credible proof of this. This is even more true for agricultural products. A prerequisite is the existence of a quality infrastructure that meets international standards and that monitors the production chains and furnishes the proof required. If this infrastructure is not in place or if it is underdeveloped, the lack of acceptable proof such as a product certification report issued without citing the international standard of the product characteristics and the conformity assessment method used to determine conformance can constitute a different technical barrier to overcome.

# **DEVELOPING A NATIONAL QUALITY STRATEGY**



# All countries need an adequate national quality infrastructure

Source: Physikalisch-Technische Bundesanstalt (PTB).

In order to realize the benefits that will be gained from being a member of the WTO, compliance to the WTO TBT and SPS Agreements is required. To meet these conditions, a NQI system is the most effective mechanism in place in order to comply adequately with these Agreements. In many developing countries and transitional economies, the

national metrology and standards institutes were and are in many cases providers of all NQI services. The emphasis was and in many cases still is on control and supervision. These organizations are regulatory and enforcement bodies. This situation creates a series of conflicts of interest and creates unnecessary barriers to trade.

Experience suggests that there is a logical path for developing a NQI. The best start is that the government develops and approves a quality policy providing details of the quality infrastructure components and their relevant responsibilities. This would facilitate a proper division of work. The quality policy should also detail the relationship of the quality infrastructure with the country's technical regulations.

# The Governmental Role in building a successful National Quality Infrastructure

The NQI program should consist of a set of parallel paths describing the technical and regulatory aspects.

1. <u>Technical</u>

To Develop and implement a unified national quality infrastructure that strengthens and aligns the technological base of the national metrology, standards, and conformity assessment organizations to a level that will be accepted by the international NQI community.

#### 2. Legal and Regulatory

There are several constraints to the successful NQI program, including overly restrictive legal and regulatory issues, conflicts of interest, political interference and lack of harmonization with international best practice. The legal framework should establish transparent, independent institutions within a national structure that can work with international/regional organizations such as the WTO. The Government's basic role in developing and implementing a National Quality Policy and Infrastructure should include:

In the Area of Standardization: To support the development and growth of a market driven system based on a harmonized, voluntary consensus standards for products, processes, and services.

In the Area of Scientific Metrology: To realize, maintain and disseminate the national measurement units that are traceable to the International System. (SI)

<u>In the Area of Legal Metrology</u>: To develop and implement a weights and measures program in order to ensure, in a regulatory manner, the appropriate quality and credibility of measurements related to official controls, trade, health, safety and the environment

In the Area of Conformity Assessment: To ensure that conformity assessment bodies are competent, impartial and work with integrity and that they are accredited in accordance with international standards and best practice.

In the Area of Accreditation: To provide technical and financial support for the development of an accreditation system that is based on international requirements.

<u>In the Area of Mutual Recognition</u>: To enter into international and regional mutual recognition arrangements with trading partners and international standards, metrology and accreditation bodies.

In the Area of Technical Regulations: To use international standards as the basis for developing technical regulations and to ensure that technical regulations promote trade by not including unnecessary barriers to trade without compromising public health, safety, and the environment.

# TRADE FACILIATION

# **Understanding the TBT Agreement**





WORLD TRADE ORGANIZATION

The World Trade Organization (WTO) is the international organization dealing with the rules of trade between nations. Its main function is to ensure that trade flows

as smoothly, predictably and freely as possible. At the heart of the WTO are its Agreements, negotiated and signed by the bulk of the world's trading partners. These Agreements provide the legal ground rules for international trade. They are essentially contracts, binding governments to keep their trade policies within agreed limits.

The WTO was established in 1994 as the result of the Uruguay Round of trade talks with the goal:

#### To promote world trade by:

- Improving the GATT rules for trade in goods;
- Bringing the trade in services under international discipline;
- Adopting uniform international standards for the protection of intellectual property rights.

#### To promote trade in goods by:

- Removing unnecessary technical barriers to trade;
- Bring trade in textiles and clothing under GATT rules

# From the Tokyo Round, to the Standards Code to the WTO TBT Agreement

The provisions of the GATT 1947 contained only a general reference to technical regulations and standards in Articles III, XI and XX and the Standards Code. A GATT working group, set up to evaluate the impact of non-tariff barriers in international trade, concluded that technical barriers were the largest category of non-tariff measures faced by exporters. After years of negotiations at the end of the Tokyo Round in 1979, 32 GATT Contracting Parties signed the Agreement on Technical Barriers to Trade (TBT). The Agreement laid down the rules for preparation, adoption and application of technical regulations, standards and conformity assessment procedures. The new WTO Agreement on Technical Barriers to Trade, or TBT Agreement, has strengthened and clarified the provisions of the Tokyo Round Standards Code. The TBT Agreement, negotiated during the Uruguay Round is an integral part of the WTO Agreement.



The <u>Agreement on Technical Barriers to Trade</u> is one of the 29 individual legal texts of the WTO Agreement. It obliges Members to ensure that technical regulations, voluntary standards, and conformity assessment procedures do not create unnecessary obstacles to trade. Although it is difficult to give a precise estimate of the impact on international trade of the need to comply with different foreign technical regulations and standards, it certainly involves significant costs for producers and exporters.

In general, these costs arise from the translation of foreign regulations, hiring of technical experts to explain foreign regulations, and more importantly adjustment of production facilities to comply with the foreign requirements. In addition, there is the need to prove that the exported product meets the foreign regulations.

The high costs involved may discourage manufacturers from trying to market their products abroad. In the absence of international disciplines, a risk exists that technical regulations and standards could be adopted and applied solely to protect domestic industries.

As the major world trade facilitation body, the WTO emphasizes through its various agreements the importance of ensuring that countries' regulations do not create unnecessary barriers to international trade. Despite its emphasis on ensuring that no unnecessary barriers to trade be created through technical regulations, the TBT Agreement recognizes that countries have the right to establish an adequate level of protection for human, animal, or plant life, or the protection of health and the environment. These are called legitimate objectives. The substantive provisions under the Agreement can be grouped into four sometimes-interrelated areas.

# These groups of obligations are summarized below:

- • Granting treatment to imports of a country that is not less favorable than that granted to local production (national treatment) or to imports of another country (most favored nation status);
- • Encouragement of members to rely on international standards :
- • Transparency in the development, application, and implementation of standards and technical regulations; and
- • Procedural requirements related to notification to the WTO of TBT-related matters

The Code of Good Practice (Annex 3) of the TBT Agreement extends these principles to standards.

# So Why the TBT Agreement?

In recent years, the number of technical regulations and standards adopted by countries has grown significantly. Increased regulatory policy can be seen as the result of higher standards of living worldwide, which have boosted consumers' demand for safe and high-quality products, and of growing problems of water, air and soil pollution which have encouraged modern societies to explore environmentally-friendly products.

Countries sometimes try to protect domestic industries while requiring open trade for their exports. The TBT Agreement aims to prevent this practice and incorporates the following: Basic rules:

- • Equal treatment for domestic and foreign products
- • Regulations may not limit trade unnecessarily
- • Import ban with no scientific evidence. Members shall ensure that technical regulations are applied only to the extent to protect human, animal or plant life or health and is based on scientific principles
- • Import ban imposed on goods by a given process. Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics
- • Import ban based on a technically meaningless standard where technical regulations are required and relevant international standards exist, members shall use them.
- • Import ban by means of a packaging/labeling regulation. Members shall ensure the technical regulations are not prepared, adopted, or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

# Technical Regulations, Standards and the TBT Agreement

Technical regulations and standards set out specific characteristics of a product, such as its size, shape, design, functions and performance, or the way it is labeled or packaged before it is put on sale. In certain cases, the way a product is produced can affect these characteristics, and it may then prove more appropriate to draft technical regulations and standards in terms of a <u>product's process and production methods</u> rather than its characteristics *per se*. The TBT Agreement makes allowance for both approaches in the way it defines technical regulations and standards (Annex 1).

Note: The TBT Agreement states that if technical regulations are required and relevant international standards exist or their publication is imminent, then Members shall use them as a basis for their technical regulations.

# **Conformity Assessment Procedures**

Conformity assessment procedures are technical procedures, such as testing, verification, inspection, accreditation, and certification, which confirm that products fulfill the requirements laid down in regulations and standards. Generally, manufactures, exporters bear the cost, if any, of these procedures. Non-transparent and discriminatory conformity assessment procedures can become effective protectionist tools.

#### **Divergent Regulations — costs for exporters - Loss of Economies of Scale**

If a firm must adjust its production facilities to comply with diverse technical requirements in individual markets, production costs per unit are likely to increase. This imposes handicap particularly on small and medium enterprises.

# **Conformity Assessment Costs**

Compliance with technical regulations generally needs to be confirmed. This may be done through testing, certification or inspection by laboratories or certification bodies, usually at the company's expense.

# **Information Costs**

These include the costs of evaluating the technical impact of foreign regulations, translating, and disseminating product information, training of experts, etc.

# **Surprise Costs**

Exporters are normally at a disadvantage i.e.: domestic firms, in terms of adjustments costs, if confronted with new regulations.

# The TBT Agreement – Main Structure and Content

#### The TBT Agreement is made up of four sections

The main Section contains 15 separate articles:

- ✓ General Provisions
- ✓ Preparation, Adoption and Application of Technical Regulations
- ✓ Preparation, Adoption and Application of Standards
- ✓ Procedures for Assessment of Conformity
- ✓ Recognition of Conformity Assessment
- ✓ International and Regional Conformity Assessment Systems

Three Annexes follow this:

- ✓ Annex 1: Terms and their Definitions for the Purpose of this Agreement
- ✓ Annex 2: Technical Expert Groups
- ✓ Annex 3: The Code of Good Practice for the Preparation, Adoption and Application of Standards

# **General Principles**

The TBT agreement contains two (2) basic principles:

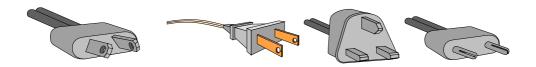
<u>Basic Principle 1</u>: Equal treatment for domestic and foreign products from member's countries. This is the most fundamental principle of free trade

Basic Principle 2: Regulations and measures may not limit trade unnecessarily.

The TBT Agreement recognizes that sometimes a barrier to trade may be necessary; but every attempt should be made to limit such barriers both in extent and in duration.

# What are the Sources of Technical Barriers to Trade?

Differences in standards and Technical Regulations from one country to another can be used as Technical Barriers to Trade.



TBT's generally result from the improper preparation, adoption, and application of different technical regulations and conformity assessment procedures. If a producer in country A wants to export to country B, the producer will be obliged to satisfy the technical requirements that apply in country B, with all the financial consequences this entails. Differences between one country and another in technical regulations and conformity assessment procedures may have legitimate origins such as differences in local tastes or levels of income, as well as geographical or other factors. For example, countries with areas prone to earthquakes might have stricter requirements for building construction materials; others, facing serious air-pollution problems might want to impose lower tolerable levels of automobile emissions, there are also dietary issues.

# **TBT Provisions on Technical Regulations**

The TBT Agreement establishes the rules for the Creation, Publication, and Application of Technical Regulations.

The TBT Agreement recognizes the existence of legitimate divergences of preference, income, geographical and other factors between countries. For these reasons, the Agreement accords to Members a degree of flexibility in the preparation, adoption and application of their national technical regulations. The Preamble to the Agreement states "no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal, and plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate". However, Members' regulatory flexibility is limited by the requirement that technical regulations "are not prepared, adopted, or applied with a view to, or with the effect of, creating unnecessary obstacles to trade". (TBT Article 2.2).

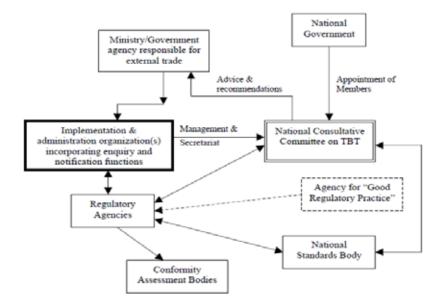
## Avoidance of Unnecessary Obstacles to Trade

For a government, avoiding unnecessary obstacles to trade means that when it is preparing a technical regulation to achieve a certain policy objective - whether protection of human health, safety, the environment, etc. - the regulations shall not be more trade-restrictive than necessary to fulfill the legitimate objective. According to the TBT Agreement, specifying, whenever appropriate, product regulations in terms of performance rather than design or descriptive characteristics will also help in avoiding unnecessary obstacles to international trade (See Article 2.8). For example, a technical regulation on fire-resistant doors should require that the door successfully pass all the necessary tests on fire resistance. Thus it could specify, "The door must be fire resistant with a 30-minute burn through time"; it should not specify how the product must be made, e.g., that "the door must be made of steel, one inch thick".

#### When is a Technical Regulation an Unnecessary Obstacle to Trade?

Unnecessary obstacles to trade can result when a regulation is more restrictive than necessary to achieve a given policy objective, or when it does not fulfill a legitimate objective. A regulation is more restrictive than necessary when the objective pursued can be achieved through alternative measures, which have less trade-restricting effects, taking account of the risks non-fulfillment of the objective would create. Elements that Members can use for risk assessment are available technical and scientific information, technology, or end-uses of the products. Article 2.2 of the Agreement specifies that legitimate objectives include national security requirements, prevention of deceptive practices, protection of human health or safety, protection of animal and plant life or health, or the environment.

Some countries have formed a National Commission or Committee for the Preparation, Adoption and Application of Technical Regulations, here is one example.



#### **TBT Provisions on Conformity Assessment Procedures**

The obligation to avoid unnecessary obstacles to trade applies also to conformity assessment procedures. An unnecessary obstacle to trade could result from stricter or more time-consuming procedures than are necessary to assess that a product complies with the domestic laws and regulations of the importing country. For instance, information requirements should be no greater than needed, and the setting of facilities to carry out conformity assessment, and the selection of samples should not create unnecessary inconvenience to the agents

#### Non-discrimination and National Treatment - Technical Regulations

Like many other WTO Agreements, the TBT Agreement includes Most Favored Nation (MFN) and National Treatment obligations (NT). Article 2.1 of the Agreement states that "in respect of their technical regulations, products imported from the territory of any Member be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country".

# **Conformity Assessment Procedures**

The MFN and national treatment provisions also apply to conformity assessment procedures. Procedures for conformity assessment shall be applied to products imported from other WTO Members "in a manner no less favorable then that accorded to like products of national origin and to like products originating in any other country" (See Article 5.1.1). This means that imported products must be treated equally with respect

to any fees charged to assess their conformity with regulations. Similarly, Members must respect the confidentiality of information about the results of conformity assessment procedures for imported products in the same way as for domestic products so that commercial interests are protected.

## Harmonization - Producers' Benefits

The arguments for harmonization of technical regulations and standards are well known. Interoperability is necessary for the connection and compatibility of parts of products, i.e. telecommunications equipment or car parts. Lack of technical compatibility might otherwise generate barriers to international trade. For example, television sets suitable for the US market could not be sold in Europe due to divergences in color broadcasting formats (NTSC vs. PAL or SECAM). The costs of designing, manufacturing, the same product in various configurations may be high.

# **Consumers' Benefits**

Technical harmonization may increase consumer welfare. Within a harmonized regulatory environment, competition ensures that consumers have a wide and economically attractive choice of products. This presupposes, however, that harmonized standards do not go beyond fulfilling their legitimate regulatory objective, i.e. that they do not stifle innovation or otherwise discourage producers from introducing new products or product variants.

# Harmonization and Key International Organizations for Harmonization

For many years, technical experts have worked towards the international harmonization of standards. The TBT Agreement encourages Members to use existing international standards for the basis of their national regulations, or for parts of them, unless "their use would be ineffective or inappropriate" to fulfill a given policy objective. This may be the case, for example, "because of fundamental climatic and geographical factors or fundamental technological problems" (See Article 2.4 of the TBT Agreement).

As explained previously, technical regulations in accordance with relevant international standards are rebuttable presumed "not to create an unnecessary obstacle to international trade". Similar provisions apply to conformity assessment procedures: international guides or recommendations issued by international standardizing bodies, or the relevant parts of them, are to be used for national procedures for conformity assessment unless they are "inappropriate for the Members concerned for, inter alia, such reasons as national security requirements, prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or protection of the environment; fundamental climatic or other geographical factors; fundamental technological or infrastructural problems."

# **Participation in International Standardizing Bodies**

Widespread participation in international standardizing organizations can ensure that international standards reflect country-specific production and trade interests. The TBT Agreement encourages Members to participate, within the limits of their resources, in the work of international bodies for the preparation of standards (See TBT Article 2.6) and guides or recommendations for conformity assessment procedures (See TBT Article 5.5).

## **Special and Differential Treatment**

Implementing and enforcing international standards may require technical and financial resources beyond the capabilities of developing countries. The TBT Agreement eases the impact of certain provisions whose full application would not be compatible with developing country Members' development, financial and trade needs. Moreover, in view of their particular technological and socio-economic conditions, developing country Members may adopt technical regulations, standards or test methods aimed at preserving indigenous technologies and production methods and processes compatible with their development needs. Finally, developing country Members may request international standardizing bodies to examine the possibility of, and if practicable, prepare international standards for products of special trade interest to them.

## What is Equivalence?

The process leading to the preparation of an international standard can be lengthy and costly. Reaching consensus on technical details can take several years. The time gap between the adoption of an international standard and its implementation by national regulators can also be significant. For these reasons, negotiators introduced in the TBT Agreement a complementary approach to technical harmonization, known as equivalence. Technical barriers to international trade could be eliminated if Members accept that technical regulations different from their own fulfill the same policy objectives even if through different means.

#### **How Does Equivalence Work?**

Let us assume that country A, wishing to protect its environment from high automotive emission levels, requires that automobiles be equipped with a catalytic converter. In country B, the same objective is achieved through the use of diesel engines in motor vehicles. Since environmental concerns are identical in the two countries — to reduce the levels of pollutants in the air — A and B can agree that their technical regulations are essentially equivalent. Thus, if automotive manufacturers in country A want to export to B, they will not be obliged to satisfy country B's requirement to fit diesel engines, and vice versa. This will eliminate the costs of adjusting production facilities to fulfill foreign regulations.

#### **Mutual Recognition, Costs of Multiple Testing**

As explained previously, demonstrating compliance with technical regulations may impede international trade. In particular, if products are to be exported to multiple markets, multiple testing may be required.

Manufacturers can have difficulties in securing approval for their products on foreign markets, for instance because testing experts disagrees on optimal testing procedures, from bureaucratic inertia, or even from manipulation of the testing process by protectionist groups. Whatever the reason might be, such diversity of procedures and methods significantly increases the costs of producers who sell in multiple markets.

## What is Mutual Recognition of Conformity Assessment Procedures?

One of the main difficulties exporters face is the costly redundant testing or certification. These costs would be drastically reduced if a product could be tested once and the testing/ certification results be accepted in all markets. This is made possible through a growing network of mutual recognition arrangements (MRAs) among regulators and international accreditation bodies.

#### **How Does Mutual Recognition Work?**

In practice, countries, would agree to accept the results of one another's conformity assessment procedures, although these procedures might differ. Accreditation bodies agree to accept conformity assessment results issued by conformity assessment bodies that are accredited by signatory AB to an arrangement. This minimizes duplication of retesting and re-certification reduces cost and eliminates non-tariff barriers to trade and market access delays.

#### **Mutual Recognition and the TBT Agreement**

Article 6.3 of the TBT Agreement strongly encourages WTO Members to enter into negotiations with other Members for the mutual acceptance of conformity assessment results. The presence of a high degree of confidence in testing and certification bodies is, in fact, a prerequisite for the good functioning of an MRA. Article 6.1 of the TBT Agreement points out that compliance, such as when verified by accreditation by conformity assessment bodies with relevant guides or recommendations issued by international standardizing bodies can be regarded as an indication of adequate technical competence.

#### Transparency - Notifications -The WTO Notification System

Under the TBT Agreement, each member of the WTO has obligations relating to "transparency". In essence, the word transparency in the context of the WTO is used to signify one of the fundamental principles of its agreements: the aim to achieve a greater degree of clarity, predictability and information about trade policies, rules and regulations of Members. The WTO defines transparency as the "Degree to which trade policies and practices, and the process by which they are established, are open and predictable"

The Agreement on Technical Barriers to Trade contains several provisions related to

transparency. For example, it stipulates that Members shall notify other WTO Members of their draft technical regulations and conformity assessment procedures and allow a reasonable time to make comments on them. It also provides that Members shall publish their TBT measures. It contains obligations related to the establishment and operation of TBT Enquiry Points. In addition, standardizing bodies have to notify their acceptance of the Code of Good Practice.

Transparency can be looked at as the process whereby the creation, terms, and application of technical regulations, standards, measures and conformity assessment procedures are made public, and opportunities are provided for the public (including other Members) to comment on proposed technical regulations, measures, standards and conformity assessment procedures.

Members must notify when two conditions apply:

- (1) whenever a relevant international standard or guide or recommendation does not exist, or the technical content of a proposed or adopted technical regulation or procedure is not in accordance with the technical content of relevant international standards or guides of recommendations; and
- (2) If the technical regulation or conformity assessment procedure may have a significant effect on the trade of other Members (Articles 2.9 and 5.6). Draft regulations should be notified to the WTO Secretariat, if possible sixty days prior to their formal adoption to allow time for other Members to make comments. Regulations can also be notified ex-post whenever urgent problems of safety, health, environment protection arise (Articles 2.10 and 5.7). Local Governments at the level directly below central government are required to notify technical regulations and conformity assessment procedures which have not been previously notified by their central government authorities (Article 3.2 and 7.2).

As a complement to the obligation to notify, each WTO Member must set up a national enquiry point. This acts as a focal point where other WTO Members can request, obtain information and documentation on a Member's technical regulations, standards and test procedures, whether impending or adopted, as well as on participation in bilateral or multilateral standard-related agreements, regional standardizing bodies and conformity assessment systems (TBT- Article 10).

#### Statements on the Implementation and Administration of the Agreement

Each WTO Member must, promptly after the Agreement enters into force, notify Members of the measures in existence or taken to ensure the implementation and administration of the Agreement and of any subsequent changes to them (Article 15.2). This written statement has to include, *inter alia*, all relevant laws, regulations, administrative orders, etc., to ensure that the provisions of the Agreement are applied; the names of the publications where draft and final technical regulations, standards and conformity assessment procedures are published; the expected length of time for the comments presentation of written on technical regulations, standards or conformity assessment procedures; and the name and

address of the enquiry points established under Article 10.

# **Bilateral or Multilateral Agreements**

Under Article 10.7, a Member who has reached an agreement with any other country or countries on issues related to technical regulations, standards or conformity assessment procedures, which may have a significant effect on trade, must notify other Members through the WTO Secretariat of the products to be covered by the agreement, and provide a brief description of the agreement.

# The Code of Good Practice

The Code of Good Practice for the <u>Preparation, Adoption and Application of Standards</u> lays down disciplines in respect of central government, local government, non-governmental and regional standardizing bodies developing voluntary standards.

The Code is open for acceptance by any of these standardizing bodies.

Central government standardizing bodies must accept and comply with the provisions of the Code. A standardizing body wishing to adhere to, or withdraw from, the Code has to notify its acceptance of, or withdrawal from, the Code using the appropriate notification format (paragraph C of the Code).

	ISO IEC Information Centre
	International Organization for Standardization
	Case postale 56
	CH-1211 GENEVA 20
	Switzerland
	NOTIFICATION
	F THE WTO THT CODE OF GOOD PRACTICE
(Notification of accepta	nce of the WTO THT Code of Good Practice)
Country (or regional arrangement):	
Name of standardizing body:	
Address of standardizing body:	
Telephone: Te	lefas:
E-mail:	
Type of standardizing body:	
Scope of current and expected standa	rdiration activities:
The above indicated standardizing body	phendby notifies its acceptance of the Code of Good Practice relication of Standards presented in Amer. 3 to the WTO
for the Proparation, Adoption and Ap Arreement on Technical Barriers to Tra	
Agreement on seconical Barriers to Tra	<u>w</u> .
(Name)(Signature)(Date)	
(Taba)	

Standardizing bodies that have accepted the Code must notify at least twice a year of their standards and where details of this plan can be obtained (paragraph J). Notifications have to be sent either directly to the ISO/IEC Information Centre in Geneva, or through the national member of ISO/IEC or, through the relevant national member or international affiliate of ISONET.

# Understanding The Code of Good Practice - Why a Code of Good Practice?

Governmental or non-governmental standardizing bodies can prepare product standards. The Code of Good Practice provides disciplines, including those related to transparency, for the preparation, adoption, and application of standards by central government, local government, non-governmental and regional standardizing bodies.

# Who Can Accept the Code?

The Code is open for acceptance to any standardizing body, whether central government, local government, or non-governmental and regional standardizing bodies.

The "Code of Good Practice" states: where international standards exist or their completion is imminent, the standardizing body shall use them, or the relevant parts of them, as a basis for the standards it develops, except where such international standards or relevant parts would be ineffective or inappropriate, for instance, because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems.

It also aims at the harmonization of standards, encouraging standardizing bodies to play as full a part as resources allow in the preparation of international standards by the relevant international body.

Members of the TBT Agreement are responsible for the acceptance and compliance with the Code of Good Practice by their central government standardizing bodies. Furthermore, they are required to take such reasonable measures as may be available to them to ensure also that local government and non-governmental standardizing bodies within their territories, and regional standardizing bodies of which they are members, accept and comply with the Code.

# **Enquiry Point and Notification Authority**

As an integral part to the obligation of transparency, each WTO Member must set up a national enquiry point and notification authority. The EP/NA acts as a focal point where other WTO Members can request and obtain information and documentation on a Member's technical regulations, standards and test procedures, whether impending or adopted, as well as on participation in bilateral or multilateral standard-related agreements, regional standardizing bodies, and conformity assessment systems (Article 10). Enquiry points are generally governmental agencies, but the relevant functions can also be assigned to private agencies. However, notifications must be made by the government entity. The obligation to set up enquiry points is particularly important for developing countries. On the one hand, it is the first step by a developing country Member towards implementation of the TBT Agreement. On the other, developing countries can acquire information from other Members' enquiry points on foreign regulations and standards affecting products in which they have a trade interest.

# The Committee on Technical Barriers to Trade

Finally, transparency is also ensured through the existence of a TBT Committee. This allows WTO Members the possibility of consulting on any matters relating to the operation of the Agreement or the furtherance of its objectives. The Committee holds on average two to three meetings a year and, if necessary, can establish working parties to carry out specific functions.

# Technical Assistance - Who Has the Right to Technical Assistance?

Any Member, and especially developing country Members, can request technical assistance from other Members or from the WTO Secretariat, on terms and conditions to be agreed by the Members concerned (See Article 11). Requests for technical assistance received from least-developed Members have priority.

# What Type of Assistance?

The coverage of technical assistance ranges from the preparation of technical regulations

and the establishment of national standardizing bodies to the participation in international standardizing bodies and the steps to be taken by developing country Members to gain access to regional international conformity assessment systems. Technical assistance can help firms in developing country Members to manufacture products in accordance with the technical requirements existing in an importing country, thus ensuring that the products are accepted on the importing Member's market.

# The Agreement on the Application of Sanitary and Phytosanitary Measures

#### **Introduction to SPS measures**

The SPS Agreement entered into force with the establishment of the World Trade Organization on 1 January 1995. It concerns the application of food safety, animal, and plant health regulations. The Agreement sets out the basic rules for food safety, animal, and plant health standards. It allows countries to set their own standards. However, it also says regulations must be based on science. They should be applied only to the extent necessary to protect human, animal or plant life or health. In addition, they should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.

Member countries are encouraged to use international standards, guidelines and recommendations where they exist. However, members may use measures that result in higher standards if there is scientific justification. They can also set higher standards based on appropriate assessment of risks so long as the approach is consistent, not arbitrary. The agreement still allows countries to use different standards and different methods of inspecting products.

#### From TBT to SPS

During the Uruguay Round, agricultural negotiations strove to lower barriers that countries used to protect their domestic markets. Some countries feared, however, that the elimination of agriculture-specific non-tariff measures and the tariff reductions would be circumvented by disguised protectionist measures in the form of sanitary or phytosanitary regulations. This concern provided a major driving force which led negotiators to create a separate Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement"), in parallel with the major agricultural trade negotiations.

The SPS and Agriculture Agreements are complementary. Both are in fact are serviced by the same Division. Although the TBT and SPS are complementary, they differ in their design.

# How do they differ?

<u>The SPS Agreement</u>: Applies only to measures directly affecting health of humans, animals and plants;

The TBT Agreement: Applies to every kind of measure for whatever purpose, including the

protection of health.

## TBT and SPS: Why two Agreements?

- ✓ Both the TBT and SPS Agreements aim at preventing unfair trade barriers.
- ✓ A measure that limits trade can be seen as a TBT measure (with a general goal) or an SPS measure with the specific goal of protecting health.
- ✓ If the goal is general, then the measure is evaluated under the somewhat stricter, less discretionary rules of TBT.
- ✓ Only measures specifically addressing a limited range of health problems will be evaluated under less rigorous SPS rules.
- ✓ By splitting barriers to trade into these two categories, the WTO could achieve international consensus that non-health measures should be subject to high level of scrutiny; without this two-tier system, the level of scrutiny for all measures might have been at the lower level applied to health-protection measures.

## **The SPS Agreement -Definitions**

- ✓ "Sanitary" means concerning health
- ✓ "Phytosanitary" means concerning health of plants
- ✓ "Sanitary and Phytosanitary measures" means (broadly) <u>any measure designed</u> <u>to protect</u>:
- ✓ Animals or plants from pest and disease;
- ✓ Humans and animals from food-borne risks;
- $\checkmark$  Humans from pests and from animal or plant borne disease

# The SPS Measures and Trade Barriers

- ✓ SPS adopts the same basic approach as TBT
- ✓ The main rules are:
- ✓ SPS measures may not impose unfair restrictions on trade
- ✓ Measures may not discriminate between domestic and non-domestic procedures or among members
- ✓ Measures should be based on accepted international standards if they exist Codex Alimentarius
- ✓ Publication must be prompt and access –via the enquire point easy
- ✓ Inspection procedures must be quick and fair. Domestic products should no advantage over imported products.

# The SPS Agreement typically deals with:

Additives in food or drink

- ✓ Contaminants in food or drink
- ✓ Poisonous substances in food or drink
- ✓ Residues of veterinary drugs or pesticides in food or drink
- ✓ Certification: food safety, animal or plant health
- ✓ Processing methods with implications for food safety
- ✓ Labelling requirements directly related to food safety
- ✓ Plant/animal quarantine
- ✓ Declaring areas free from pests or disease
- ✓ Preventing disease or pests spreading to a country
- ✓ Other sanitary requirements for imports

# The TBT Agreement typically deals with:

- ✓ Regulations for electrical appliances
- ✓ Regulations for cordless phones, radio equipment etc.
- ✓ Textiles and garments labelling
- ✓ Testing vehicles and accessories
- ✓ Regulations for ships and ship equipment
- ✓ Safety regulations for toys
- ✓ Labelling of food, drink and drugs
- ✓ Packaging requirements for fresh food
- ✓ Packaging and labelling for dangerous chemicals and toxic substances

# **TBT REFERENCE INFORMATION VIA HYPERLINKS**

WORLD TRADE The following TBT related material may be downloaded free of charge via the Internet.

#### From the World Trade Organization at www.wto.org

#### **Official TBT documents**

#### http://www.wto.org/english/tratop\_e/tbt\_e/tbt\_e.htm

- The TBT <u>Agreement</u>
- <u>Technical explanation of WTO Agreement on Technical Barriers to Trade</u>
- Understanding the TBT Agreement a more technical explanation
- National enquiry points by country in alphabetical order
- • Notifications of mutual recognition agreements
- Notifications submitted by Members on technical regulations and conformity assessment procedures
- • Notifications related to the Code of Good Practice for the Preparation, Adoption and Application of Standards
- • Annual lists of standardizing bodies that have accepted the Code of Good Practice
- • Working documents of the TBT Committee

- • What are Technical Barriers to Trade?
- • Sign up to receive TBT notifications by e-mail
- • Technical Assistance related to Technical Barriers to Trade
- • General documents of the TBT Agreement in relation to Technical Assistance
  - Transparency provisions of the TBT Agreement
  - Databases on TBT-related technical assistance
  - The TBT Committee
  - Harmonization
  - Transparency
- • TBT Work shop presentations
  - Workshop on Different Approaches to Conformity Assessment
  - TBT workshop on supplier's declaration of conformity
  - TBT Workshop on Statements on the Implementation and Administration of the Agreement under Article 15.2
  - TBT Learning Event on Labeling

# **Other free WTO publications**

- • Future of the WTO
- The World Trade Organization: understanding the WTO
- • GATS- Fact and Fiction
- • The WTO in Brief
- • 10 benefits of the WTO trading system
- • 10 common misunderstandings about the WTO

The following information is available free of charge via the Internet

- • The Agreement on Technical Barriers to Trade (TBT)
- • List of National Enquiry Points <u>by country</u>
- • The contribution of international standards and conformity assessment
- Standardizing bodies having accepted the WTO TBT Code of Good Practice
- • Obtaining the WTO-TBT Standards Code Directory
- • The WTO Agreement on the Application of Sanitary and Phytosanitary Measures
- • The WTO General Agreement on Trade Services (GATS)
- • The WTO Committee on Trade and Environment (CTE)



The International Trade Centre

# (ITC) for a slight fee. www.intracen.org

Export Quality Management: An Answer Book for and Medium-Sized Exporters

- • International Trade Rules: An Answer Book on the WTO Agreements
- • Business Guide to the World Trading System
- Export Quality Management Resource Material for Training Activities
- • Influencing and Meeting International Standards: Challenges for Developing Countries.
- ISO 22000 Food Safety Management Systems : A easy to-use Checklist for Small business
- •• Trade in Information Technology Products and the WTO Agreements: Manual for Procedures and Guidance Notes for the Implementation of the WTO Technical Barriers to Trade.

#### The WTO – TBT Agreement – A Power Point Presentation



A slide presentation-training course, an introduction to the TBT Agreement and conformity assessment. To access this presentation, see the TBT folder on the Wafer Drive.

# SPS REFERENCE INFORMATION & HYPERLINK TO THE WTO



From the World Trade Organization at www.wto.org Official SPS documents

- Introduction to WTO rules on sanitary and phytosanitary measures Links to part of the agriculture section of the WTO guide "Understanding the WTO"
- <u>"Understanding the SPS Agreement" (text only</u>)A more technical introduction
- Interactive course: <u>How to apply the transparency provisions of the SPS</u> <u>Agreement</u>
- The mandate Browse or download the text of the SPS Agreement from the legal texts gateway
- Review of the operation and implementation of the Agreement of the application of sanitary and phytosanitary measures. <u>Committee Report of the Second</u> <u>Review adopted in 2005</u>

- Interactive course: SPS Handbook
- New mentoring system available for national notification authorities and enquiry points
- • Download the SPS notification formats <u>here</u>.
- Down load Handbook: How to apply the transparency provisions of the SPS Agreement
- A practical guide for member governments' officials on how to notify measures to the WTO, establish an enquiry point, and respond to enquiries. Download in <u>MS Word</u> (74 pages, 357KB, opens in a new window) or <u>pdf format</u> > <u>Interactive</u> <u>course</u>: SPS Handbook

Section



# **STANDARDS & TECHNICAL REGULATIONS**

Standards provide a vital link to global trade, market access and export competitiveness. In expanding trade, in particular, standards and technical regulations are essential for market access. Standards (voluntary) and technical regulations (mandatory) define what goods and services can and cannot be exchanged, and outline procedures under which such exchanges are and are not permissible. Without standards we could not implement the TBT Agreement, there might not even be a TBT Agreement.

# The Evolution and Recognition of the Need for Standards

## King John's Magna Carta in the year 1215



"There shall be standard measures of wine, ale and corn throughout the Kingdom. There shall also be a standard width of dyed cloth, Weights are to be standardised similarly"

# In ancient civilizations



- Standardized calendar
- Standards in construction and transportation
  - Standardized signs for writing words and numbers
- Unified weights and measures for trade and construction

# After the industrial revolution



- Standards and measures for interchangeable production
  - Standards for interoperability (i.e.: Railway gauge)
- • Rationalization through standardization and variety reduction

• •

Safety standards (pressure vessels, gas and electric appliances)

Standards are important, but they vary from country to country. Having different standards can make life difficult for produces and exporters. If standards are set arbitrarily, they could be used as an excuse for protectionism. Standards can become obstacles to trade.

However, they are also necessary for a range of reasons, from environmental protection, safety, national security to consumer protection. Manufacturers, exporters and importers need to know what are the latest standards being used in their markets.

The term Standard as defined in ISO/IEC Guide 2:2004 Standardization and related activities -- General vocabulary:

"A standard is a document, established by consensus and approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context"

#### **Explanatory note**

Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of the TBT Agreement, standards are defined as voluntary and technical regulations are defined as mandatory.

When a standard is declared mandatory, it becomes a Technical Regulation.

## The TBT Agreement defines a standard as a;

"Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with **which compliance is not mandatory**. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method."

## The TBT Agreement defines a technical regulation as a:

"Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively **with terminology**, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method."

#### Technical Regulations, Standards and the TBT Agreement

Technical regulations and standards set out specific characteristics of a product, such as its size, shape, design, functions and performance, or the way it is labeled or packaged before it is put on the market. In certain cases, the way a product is manufactured can

affect these characteristics, and it may then prove more appropriate to draft technical regulations and standards in terms of a product's process and production methods rather than its characteristics *per se*. The TBT Agreement makes allowance for both approaches in the way it defines technical regulations and standards (Annex 1).

Note: The TBT Agreement states that if technical regulations are required and relevant international standards exist or their publication is imminent, then Members shall use them as a basis for their technical regulations.

# The Difference Between Standards and Technical Regulations

The difference between a standard and a technical regulation lies in compliance. While conformity with standards is voluntary, technical regulations are by nature mandatory and have the force of law. They have different implications for international trade. If an imported product does not fulfill the requirements of a technical regulation, it will not be allowed to enter the market. In case of standards, non-complying imported products will be allowed in the market, but then their market share may be affected if consumers' prefer products that meet local standards such as quality or color standards for textiles and clothing.

## **Technical Regulations vs. Standards**

# **Technical Regulations**

Are <u>Mandatory</u> and form part of legislation. Are the responsibilities of the <u>Government</u>. They address: <u>Product Characteristics</u> and <u>Administrative Procedures.</u>

## **Standards**

Are <u>Voluntary</u> in nature

Can be developed by a <u>variety of bodies</u> in the public or private sector. Contain only product characteristics, or

technical requirements.

Are developed in a stakeholder inclusive consensus process. Note: In a free market economy, the majority of standards are voluntary (>90%). When referencing the TBT Agreement, standards are always voluntary and technical regulations are mandatory.

# The Creation, Publication and Enforcement of Technical Regulations

The TBT establishes the procedures for:

- • The creation of technical regulations
- • The publication of technical regulations
- • The demonstration of compliance with technical regulations

The creation

The primary procedures for creation include the following:



• • Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

• Assurance that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favorable than that accorded to like products of national origin and to like products originating in any other country.

- • A technical regulation must be based on technical and scientific information
- A technical regulation must use international standards as their basis if they exist or their publication is imminent.
- • A technical regulation must address a legitimate objective
- A technical regulation may only restrict trade as far is necessary to achieve a legitimate objective.

# The Publication



The primary procedures for publication include the following:

• • Transparency is the primary goal – companies wishing to enter into a market must be able to find out what regulations their products must meet.

• • The enquiry point must be able to disseminate information concerning technical regulations.

• Technical Regulations must be published promptly, but they must be phased in giving manufactures and other Members time to comply.

# **The Enforcement**



The enforcement of technical regulations is called conformity assessment. The primary rules of conformity assessment include the following: To provide the importing country with an adequate degree of confidence. Procedures must be efficient and contain no hidden obstacles. Discrimination is not allowed.

# **Legitimate Objectivities**

A basic principle for the creation of technical regulations is that they must be based on "legitimate objectives.'

Legitimate objectives are defined in the TBT Agreement for the:

- Protection of human safety or health
- Protection of animal and plant life or health
- Protection of the environment
- Prevention of deceptive practices
- National security requirements

# Note: Quality is not considered a legitimate objective



## **Protection of Human Safety or Health**

The largest number of technical regulations and standards are aimed at protecting human safety or health. Numerous examples can be given. National regulations that require that motor vehicles be equipped with seat belts to minimize injury in the event of road accidents, or those

electrical sockets be designed in a way that protect users from electric shocks, fall under this first category. A common example of regulations whose objective is the protection of human health is labeling of cigarettes to indicate that they are harmful to health.



#### **Protection of Animal and Plant Life or Health**

Regulations that protect animal and plant life or health are very common. They are intended to ensure that animal or plant species endangered by water, air, and soil pollution do not become extinct. Some countries require that endangered species of fish reach a certain length before they can be caught.



#### **Protection of the Environment**

Increased environmental concerns among consumers, due to rising levels of air, water and soil pollution, have led many governments to adopt regulations aimed at protecting the environment. Regulations of this type cover for example, the re-cycling of paper and plastic products, and levels of motor vehicle emissions.



#### **Prevention of Deceptive Practices**

Most regulations aim to protect consumers through information, mainly in the form of labeling requirements. Other regulations include classification and definition, packaging requirements, and measurements (size, weight etc.), to avoid deceptive practices.

# **Other Objectives**

Other objectives of regulations are quality, technical harmonization, or simply trade facilitation. Quality regulations — e.g. those requiring that vegetables and fruits reach a certain size to be marketable — are very common in certain developed countries. Regulations aimed at harmonizing certain sectors, for example that of telecommunications and terminal equipment, are widespread in economically integrated areas such as the European Union and North American Free Trade Agreement (NAFTA).

There are many organizations that produce International Standards such as ISO, IEC, ,ASTM, ITU and CODEX.

## Standards can be broadly sub-divided into numerous categories

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Standards can be differentiated based on purpose. A basic standard has a broad ranging effect in a particular field.

• <u>Terminology standards</u> (or standardized nomenclature) define words permitting representatives of an industry or parties to a transaction to use a common, clearly understood language.

• <u>Test and measurement standards</u> define the methods to be used to assess the performance or other characteristics of a product or process.

- <u>Product standards</u> establish qualities or requirements for a product (or related group of products) to assure that it will serve its purpose effectively.
- <u>Process standards</u> specify requirements to be met by a process, such as an assembly line operation, in order to function effectively.
- <u>Service standards</u>, such as for repairing an automobile, establishes requirements to be met in order to achieve the designated purpose effectively.
- <u>Interface standards</u>, such as the point of connection between a telephone and a computer terminal, are concerned with the compatibility of products.

• <u>Standards on data</u> to be provided contain lists of characteristics for which values or other data are to be stated for specifying the product, process or service.

# Standards may also be classified by the intended user group.

#### Some examples:

- • Company /private standards are meant for use by a single industrial organization and are usually are developed internally.
- International standards are developed and promulgated by non-government organizations that comply with the WTO/TBT principles for the development of international standards..
- Harmonized standards can be either an attempt by a country to make its standard compatible with an international, regional or other standard or it can be an agreement by two or more nations on the content and application of a standard, the latter of which tends to be mandatory.
- • Industry standards are developed and promulgated by an industry for materials and products related to that industry.
- • Government standards are developed and promulgated by Federal, State, and local agencies to address needs or applications peculiar to their missions and functions.

## Another distinction among standards is the manner in which they specify requirements.

- Performance standards describe how a product is supposed to function. A performance standard for a water pipe might set requirements for the pressure per square inch that a pipe must withstand, along with a test method to determine if a specimen meets the requirement.
- • Design standards define characteristics or how the product is to be built. The specification that a pipe is made of a given gage of copper would characterize a design standard.
- Government agencies are encouraged to write technical regulations and standards in terms of performance, rather than design characteristics.

## How are International Standards developed?

International standards are developed according to the following basic principles:

- • Consensus, the views of all interests are taken into account:
- • Manufacturers, vendors and users, consumer groups, testing laboratories, governments, engineering professions and research organizations.
- • Industry-wide Global solutions to satisfy industries and customers worldwide.
- • Voluntary International standardization is market-driven and therefore based on voluntary involvement of all interests in the market place.

# The main phases in ISO's standards development process<sup>2</sup>



The need for a standard is usually expressed by an industry sector, which communicates its need to the national member body. Once the need for an appropriate standards development organization. It is now also possible to publish interim documents at different stages in the standardization process.

Most standards require periodic revision. Several factors combine to render a standard out of date: technological evolution, new methods and materials, new quality and safety requirements. To take account of these factors, SDOs generally recommend a defined period for review. On occasion, it is necessary to revise a standard earlier.

## How standards are developed

The first step in developing a new international standard as recommended by ISO is to research whether there is an existing standard in the area identified through contact with trade

associations, government agencies, or other standards developing organizations (SDOs). Duplication of effort and parallel standardization activities cause marketplace confusion and drain the resources of stakeholders participating in the standards development process. If you are aware of a technical committee that appears to be able to cover the scope of the proposed activity, contact the SDO liaison. If you are unable to identify a committee that covers the scope of the proposed activity, contact someone at the SDO with responsibility for new activities. Next, it is necessary to identify and contact key stakeholders to ensure that there is agreement that the standards area identified has market relevance for the industry and stakeholders are committed to participate on the project.

If the initial research indicates the area of interest is ripe for standardization, it is time to issue a formal request to consider formation of a new task group or subcommittee to the appropriate SDO or technical committee. The SDO staff will be able to provide information about the structure of the committee, the process by which a standard is developed, and answer any other specific questions.

Once approval to proceed with the creation of a new standard is given by the subcommittee, a task group will be formed to develop a first draft. It is appropriate for the proponent to be active, and possibly even chair the task group. The chair of the new task group needs to be familiar with the SDO's standards development tools. Available tools include templates and guides to form and style. Each technical committee is divided into multiple subcommittees that address specific subjects or areas within the scope of the technical committee. Task groups are organized to complete a single specific project such as the development of a new standard, the revision of an existing standard, or the coordination

of an inter-laboratory study to obtain supporting data for a precision statement.

The completed draft standard should be forwarded to the chair of the subcommittee with jurisdiction over the new activity for transmission for formal balloting. A standard must gain several levels of approval before becoming an official international standard.

At each level, voting requirements are enforced to ensure fairness. When a draft standard has been reviewed and accepted at all levels, the draft becomes an international standard and is published.

# **Choosing standards based on merit**

International standards are the cornerstones of a liberalized trading system. When used as the basis for technical regulations and developed according to principles recommended by the WTO Committee on Technical Barriers to Trade, they are less likely to create unnecessary barriers to trade. International standards can also increase efficiency, enhance the quality of life, and transfer technology from developed to developing countries.

The TBT Agreement delegates certain responsibilities to international standards:

- (1) they must function effectively and appropriately;
- (2) they must fulfill legitimate objectives; and;
- (3) they must be relevant. In this context, relevance is associated with regulatory and market needs, as well as scientific and technological developments.

In the global market, relevance is associated with a standard's ability to solve real problems in real time.

A standard's relevance is arguably related to the extent to which it is used. Technology that originates in standards developing organizations domiciled in the United States is used in countless measure by WTO members in the efficient production and testing of good in international trade, and in technical regulations. The widespread application of these standards is plainly evident from the most cursory examination of the technical regulations of member countries; and it is clear that an ample supply of effective, relevant international standards has been produced by a network of standards developing organizations, i.e., standards used in regulation, trade, and in building the capacity of developing countries around the world emanate from multiple sources. Multiple sources of international standards are especially useful to WTO members. They provide regulators with choice and flexibility while reducing the need to base technical regulations on national standards. One of the most important features of the U.S.-based standardization system is that it is open to every nationality; its technical committees abound with experts from around the globe. No less important is its commitment to the TBT principles for the development of international standards and the Code of Good Practice.

# Frequently asked questions about standards and technical regulations

- • Where do I find information on technical regulations for specific countries?
- • Where can I find information on standards

• • How can I keep up to date on developments in the field of Standards and Technical Regulations?

The Agreement on Technical Barriers to Trade requires each WTO Member to identify a National Enquiry Point on standards, technical regulations and conformity assessment and to notify its contact details to the WTO Secretariat in Geneva. Each enquiry point is responsible for ensuring that any enquiry on national and even subnational technical regulations is adequately answered. Each WTO Member must inform the WTO Secretariat of any draft technical regulation within its territory. The WTO Secretariat then makes this information available to all WTO Members. By making these requirements, the WTO TBT Committee tries to ensure that the TBT Agreement system of technical regulations is open and transparent. A number of options are available:

Mozambique has set up a national enquiry point within INNOQ. You can request your national enquiry point to forward your request for information to its counterpart in the country to which you wish to export. You can also address your query direct to the enquiry point abroad. If your country is not a WTO Member, you can still contact the national enquiry point in your target market. Even though national enquiry points are not obliged to respond to enquiries from non-WTO Members, they will rarely refuse to do so. It becomes a little bit more difficult to obtain information if your target market does not have a national enquiry point. You will have to deal with other official sources (such as embassies and departments of trade or commerce) either in your country or abroad. Should all of the above fail, you can conduct a search in your target market. It can be a frustrating task to find your way through the bureaucracies; obtaining the help of a local partner will ease your way through the maze.

## Where can I get information about standards?

The first step is to contact the national standards body (NSB) in your country, which will generally have a standards information center. NSBs keep a collection of their own standards, and they will frequently have collections of national, regional and international standards from bodies such as the American National Standards institute (ANSI), ASTM International (ASTM), British Standards Institution (BSI) and the Association française de normalization (AFNOR, French Standards Association). At the information centers, you should be able to consult catalogues of standards from various standards bodies. An NSB will be able to sell you its own standards and it will be licensed to sell the standards of other bodies. If it does not have the standard you require, you can ask it to be ordered. Standards are generally not distributed free, there are some exceptions. Codex Alimentarius standards, for example, can be downloaded free from www.codexalimentarius.net). They are often priced in relation to their length. I.e.: number of pages. Standards can also be purchased via the internet. You can use the Internet to search for and acquire standards.

# How can I keep informed of developments of Standards and Technical Regulations?

Contact your country's national standards body (NSB) for information on standards that they are developing that could affect you. Your NSB may also be able to inform you about international standards being created by international standards bodies such as ISO, IEC, ITU, ASTM and regional Standards organizations.

All WTO Members are subject to the Agreement on Technical Barriers to Trade, which obliges them to ensure that technical regulations, voluntary standards and conformity assessment procedures do not create unnecessary obstacles to trade. Annex 3 of the Agreement contains a Code of Good Practice for the Preparation, Adoption and Application of Standards. All central government standardizing bodies in member countries must comply with this Code.

WTO Members also need to take reasonable measures to ensure that their subnational and regional standardizing bodies, which may be governmental or non-governmental, accept the Code. The Code requires all standardizing bodies that have accepted its terms to publish their work programs at least once every six months. Work programs contain the standardizing body's name and address, and give details of new standards that are under preparation and those that were adopted in the preceding period. A standard is considered to be 'under preparation' from the moment a decision is taken to develop it and until it has been adopted. The work programs of many standardizing bodies are available at no cost from those bodies.

#### **Technical Regulations**

According to the TBT Agreement, countries must publish notifications of proposals of new technical regulations or amendments to existing regulations before the final versions are published. The purpose of a notification is to allow interested parties (usually trading partners whose trade will be affected by the regulation) to comment on the draft regulation, and for the requisite changes to be made. Members have 60 days from the date of publication of the notification to respond. Notifications are sent to the WTO Secretariat in Geneva, which circulates them to all Members and posts them on the WTO website (from which they can be downloaded freely). Notifications go to the diplomatic missions in Geneva, after which they are theoretically sent on to the countries' national enquiry points on TBT. Individual enterprises or industry associations should contact their national enquiry point and request it to forward notifications of interest to them. They should send their comments back to the enquiry point within the required time, to allow their governments to defend their interests by responding to the notifications at the WTO. Developing countries can request the WTO Secretariat to inform them of notifications on topics of particular interest to them, but very few actually use this service.

#### **Food Standards**

The CODEX Alimentarius Commission was created in 1963 by the Food and Agricultural

Organization of the United Nations and World Health Organization to develop food standards, guidelines, and related texts such as codes of practice under the Joint FAO/ WHO Food Standards Program. The main purposes of this Program are protecting health of consumers ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. CODEX is a single contact point for internationally recognized food safety programs.

Internationally, regional organizations have established a harmonized system of standards and technical regulations for member countries in their particular region. Listed below are examples of such systems. Internationally, regional organizations have established a harmonized system of standards and technical regulations for member countries of their particular region. Here is the European approach.

# Approaches to Technical Regulations by Region

# The African Approach to Standards and Technical Regulations



# African Organization for Standardization Facilitating inter-African and Global Trade through harmonized Standards and Conformity Assessment Procedures

#### www.arso-oran.org

The African Organization for Standardization, formerly the African Regional Organization for Standardization (ARSO) traces its genesis to the unfolding events and the prevailing mood of the African socio-political and economic Pan-Africanism of the 1970s and the culmination of which at a Conference held at the historic and important city of Accra, Ghana.

The idea of a continental standardization body had received considerable impetus from the buoyant and optimistic mood that characterized the post-independence period in most of Africa. The mood then, under the Organization of African Unity (OAU), was one of pan-African solidarity and collective self-reliance born of a shared destiny with standardization viewed as a guidepost of the destiny and bedrock of African Economic Integration Agenda and a route to linking up of the fresh Africa's economy with the rest of the world and to deliver the African Common Market for economic prosperity of the continent.

## ASRO Strategic Framework 2012 – 2017

The ARSO Strategic framework outlines the fundamental purpose for the existence of the Organization as expressed in the Mission Statement and serves as a guiding principle for the operations of the Organization for the next five years. The Vision statement, project is strategically what ARSO plans to accomplish in the period outlined and provides operational direction of ARSO.

The Goals and objectives which are specific, measurable and result oriented statements of what the organization intends to accomplish in the next five years has been spelt out. The strategies and activities present the preferred course of action that ARSO will undertake in order to achieve the objectives. The activities are accompanied by performance indicators, which are criteria by which the achievements of the objectives will be measured.

The Key Strategic Objectives of ARSO within the ARSO Strategic Framework 2012 – 2017 are:

Strategic Objective 1: Establish a standards harmonization system that supports a sound regulatory framework

**Strategic Objective 2:** Disseminate harmonized standards and guidelines to support intra, inter African and international trade and industrialization

**Strategic Objective 3:** Strengthening ARSO work-management capabilities for the sustainability of the Organisation

**Strategic Objective 4:** Promoting maximum and effective participation of Members and other stakeholders.



# Southern African Development Community Cooperation in Measurement Traceability

# http://www.sadcmet.org

#### **Objectives of SADCMET**

The SADC Cooperation in Measurement Traceability coordinate metrology activities and services in the Region, in order to provide regional calibration and testing services, including regulatory bodies, with readily available traceability to the SI units of measurement, through legally defined and regionally and internationally recognized national measurement standards.

Its major objectives are to:

- Promote closer collaboration amongst its members in their own work on measurement standards within the present decentralized regional metrology structure
- 2. Improve existing national measurement standards and facilities and make them accessible to all members
- 3. Ensure that new national measurement standards and facilities developed in the context of SADCMET collaborations are accessible to all members
- 4. Contribute to the formulation of and participate in intra and inter-regional systems to maintain the continued traceability of the national measurement standards of the SADC Member states to the SI units of measurement
- 5. Encourage the harmonization of legislation relating to national measurement standards.

#### **Aims of SADCMET**

- Promote closer collaboration amongst its Members in their work on measurement standards within the present decentralized regional metrology structure.
- Improve existing national measurement standards and facilities and make them accessible to all Members.
- • Ensure that new national measurement standards and facilities developed in the context of SADCMET collaborations are accessible to all Members.
- • Contribute to the formulation of and participate in intra- and inter-regional systems

to maintain the continued traceability of the National Measurement Standards of the Member States to the SI units of measurement.

• • Encourage the harmonization of legislation relating to National Measurement Standards.

## The United States Approach to Standards and Technical Regulations



The U.S.-based standardization system produces many international standards that do not exist elsewhere. It produces standards and test methods that are unique and standards that have given rise and safety to many of civilization's best endeavors, from the construction of basic infrastructures to the exploration of

space. These standards have become so deeply rooted in the texture of the world's economies that their absence or the lack of ongoing revisions to their technology would destabilize large areas of international trade and significantly reduce the quality of life on this planet.

Standardization activities in the United States are broad, complex, and decentralized. Private and public sector volunteers participate in the work on such activities with funding provided by themselves or their employers, not by U.S. Government subsidy. In the consensus process, no single organization is permitted to control the process, which is industry-led, even when Government representatives participate.

For the most part, standards in the United States are developed by the private sector based on a consensus process in which the developmental committees consider many points of view. Some standards in technological areas which are subject to rapid change (such as in electronics and information technology) may be developed by industry consortia.

## Key Concepts of the US Standards system

The United States Standards Strategy affirms that the U.S. is committed to a sectorbased approach to voluntary standardization activities, both domestically and globally. It establishes a standardization framework that is built upon the traditional strengths of the U.S. system - such as consensus, openness, due process and transparency. These vital concepts ensure a system that is open to all interested parties, transparent, and based on broad participation by a diverse group of affected parties. A complete list of globally accepted principles for standards development can be found in the <u>U.S. Standards</u> <u>strategy</u>.

Who develops standards in the U.S.?

Hundreds of private organizations in the United States develop standards. Standards Developing Organizations (SDO) differs greatly in size, membership, number of standards produced, and scope of work. General categories of SDO include:

<u>• Professional Societies</u> whose members seek to advance their professions
 - but which also develop standards

- <u>• Testing and certifying organizations</u> produce their own standards and may also use those of other organizations
- • Organizations that only develop standards
- • Industry Consortia sometimes referred to as Standards Setting Organizations (SSO)

No single U.S. government organization oversees the voluntary standards development process in the United States. As directed by the <u>National</u> <u>Technology Transfer and Advancement Act</u>, NIST brings together federal agencies as well as state and local governments to achieve greater reliance on voluntary standards and decreased dependence on in-house standards.

In particular, NIST works closely with the with ASTM International and the American National Standards Institute (ANSI), ANSI is a federation of standards developers, government, industry, consumers, and other stakeholders. ANSI is the U.S. Member Body to the International Organization for Standardization and sponsors the U.S. National Committee for International Electrotechnical Commission (IEC) and serves to coordinate U.S. private sector standards development activities. NIST and ANSI have signed a Memorandum of Understanding recognizing the NIST and ANSI roles in strengthening the national voluntary consensus standards system.

The NIST and ANSI collaboration performs a vital coordinating role for the entire standards community, ensuring that U.S. interests are adequately represented in international standards arenas, thus enhancing U.S. competitiveness in global markets. Because the U.S. standards system is diverse and decentralized, a comprehensive list of all bodies that develop standards in the United States does not exist. However, several resources do offer a substantive snapshot of the community: List of many U.S.-based <u>standards developers</u> and <u>consortia</u> (via NIST) is available.

As a Member of the World Trade Organization and signatory to the Technical Barriers to Trade (TBT) Agreement, the U.S. is required to base technical regulations and conformity assessment procedures on relevant international standards, guides and recommendations, except where they would be inappropriate or ineffective in meeting a legitimate objective. The TBT Agreement also strongly discourages standardizing bodies from developing standards when international standards already exist.

The TBT Agreement does not, however, designate specific standardizing bodies as "international." Instead, in its **2000 Decision on the Principles for the Development of International Standards, Guides and Recommendations** (2000 Committee Decision), the TBT Committee adopted a set of six principles for developing international standards. The Decision is designed to clarify the concept of "international standard" and to advance objectives such as greater harmonization of technical requirements across markets.

The six principles are: (1) openness; (2) transparency; (3) impartiality and consensus; (4) relevance and effectiveness; (5) coherence; and (6) the development dimension.

It is the policy of the U.S. government to use the term "international standard" to refer to those standards developed in conformity with the 2000 Committee Decision principles.

For a list of voluntary consensus standards, government unique standards, private industry standards, and international standards referenced in the Code of Federal Regulations (CFR) and those used by U.S. Federal Government Agencies in their procurement activities, visit the <u>Standards Incorporated by Reference</u> database on <u>www.Standards.gov.</u>

## The American National Standards Institute



# https://www.ansi.org/\_

ANSI is a private sector, non-profit organization founded in 1918 by five Standards Development Organizations (SDOs) and three U.S. Government agencies. The Institute is composed of more than 700 company members; 30

government agencies; 20 institutions; and 260 professional, technical, trade, labor, and commercial organizations. Unlike the SDOs mentioned above, ANSI itself does not develop standards. Rather, it functions as a central coordinating body for its member organizations, which in turn develop standards on a decentralized, consensus basis. ANSI also provides procedures for standards bodies to follow in managing the consensus standards development process in a fair and open manner.

Standards developing organizations whose procedures comply with the requirements of the <u>ANSI Essential Requirements</u> may apply to ANSI for accreditation. The Institute approves standards submitted by accredited SDO, designating them as American National Standards (ANS), indicating that they have followed the essential due process and consensus criteria defined by the ANSI Essential Requirements. However, regardless of the accreditation status of an SDO, standards only become ANS when submitted to ANSI for approval as ANS. At last count, ANSI had accredited approximately 240 SDOs and listed more than 11,000 standards as American National Standards.

The American National Standards Institute (ANSI) has served in its capacity as administrator and coordinator of the United States private sector voluntary standardization system for more than 100 years. While ANSI fills an important domestic role, the Institute also represents the U.S. in various international forums. ANSI is the U.S. member body to the International Organization for Standardization (ISO) and, through the U.S. National Committee, to the International Electrotechnical Commission (IEC). ANSI administers the international secretariat to the Joint Technical Committee (JTC-1) of ISO and IEC, which develops standards in information technology and is the U.S. member body to the Pacific Area Standards Congress (PASC), the Pan American Standards Commission (COPANT), and the Pacific Accreditation Cooperation (PAC). As the U.S. representative to these bodies, ANSI convenes delegations, approves delegation members, and appoints technical groups with a broad spectrum of experts to represent the United States in deliberations of relevant international policy boards, individual technical committees, and working groups.

ANSI further engages the international standards community through various regional and bilateral relationships and outreach programs. The Institute actively coordinates with regional organizations such as the European Standards Organizations (ESOs) and the African Organization for Standardization (ARSO) as well as other NSBs like the Standardization Administration for China (SAC) and the Bureau for Indian Standards (BIS). ANSI implements multiple capacity-building programs across the globe including the USAID Standards Alliance.

## **USAID Standards Alliance**



Created by USAID in 2012, the Standards Alliance is a funding facility designed to provide capacity building assistance to developing countries, specifically related to implementation of the World Trade Organization (WTO) Technical Barriers to

Trade (TBT) Agreement.

The Standards Alliance (SA) provides technical and financial resources to advance reforms that help businesses participate in the global trading system while building the capacity of developing countries to implement the WTO Agreement on Technical Barriers to Trade (TBT). A U.S.-sponsored technical assistance facility, the SA works with government authorities to design and provide technical assistance and training based on international standards and best practice.

The main objectives of the program included:

- • Increased understanding of WTO TBT principles
- Implementation of the Code of Good Practice for the Preparation, Adoption and Application of Standards
- • Improved transparency in the development and/or modification of technical regulations
- • More robust and transparent engagement with the private sector in standards development and use

In May 2013, USAID and ANSI entered into a partnership to coordinate experts from the U.S. standardization system in the delivery of training and other technical assistance to interested countries.

The Standards Alliance is a public-private partnership between the American National Standards Institute (ANSI) and USAID designed to assist developing countries in effectively implementing their commitments under the WTO's Technical Barriers to Trade (TBT) agreement. The program began in May 2013 when USAID and ANSI entered into a partnership, which will coordinate private-sector subject matter experts from ANSI member organizations in the delivery of training and other technical assistance to interested Standards Alliance countries.

The ANSI-USAID agreement covers a planned 5-year initiative, funded 50% by USAID and 50% by ANSI and other private sector partners.

During the first year of the Standards Alliance, ANSI and USAID selected ten countries/regions for engagement and ANSI conducted initial assessments with each partner, establishing individual work plans for each country/region. In the program's third year, five additional countries were added to support the expansion of the Obama Administration's Trade Africa initiative.

## U.S. Interfaces with the International Standards System

Both the U.S. Government and private sector participate in international standards development in a variety of ways, including private, voluntary organizations whose membership is on a national body basis; through treaty organizations (governments are members); through professional and technical organizations whose membership is on an individual or organizational basis, and through consortia, whose membership is typically company and industry-based. For example, ISO and IEC are non-governmental international organizations consisting of national member bodies. ISO is made up of the national standards bodies of full-member countries. IEC is made up of national committees from individual countries. ISO currently has over 250 technical committees with a wide variety of scopes; IEC committees, primarily on electrotechnical issues. ISO and IEC have one joint committee, JTC-1, which focuses on information technology and its application. Standards developed by ISO and IEC do not, however, cover all areas of technology or application. Standards developed by other standards developing organizations also are used globally. For example, standards developed by organizations such as ASTM International, the American Society of Mechanical Engineers (ASME), the American Petroleum Institute (API), the Society of Automotive Engineers (SAE), and others are used around the globe to meet specific sector needs, including materials standards, boiler and pressure vessel codes, and specifications for piping and fuels.

## The European Approach to Technical Regulations



The formation of the single market in Europe, one in which there is a free flow of goods, has as one of its objectives, the elimination of barriers to trade between the Member State countries. Differences between national laws, standards, and conformity assessment procedures made trade between the countries difficult, contentious,

and expensive. In order to eliminate these barriers, a new legislative technique, and strategy was instituted. The new approach was designed to envelop, or "harmonize," the health, safety, and environmental requirements of Member States into one Europeanwide legislative package. The result of this new approach to lawmaking, or "harmonization," was a new set of laws that emanated from the European Commission in Brussels, Belgium. They are called the New Approach Directives. In each case, one new approach directive replaced existing legislation with the same scope in the fifteen member nations. Member States were required to adopt the new harmonized laws.

"New Approach" <u>Directives</u> (or Community Law) set out the essential requirements, on safety for example, written in general terms which must be met before products may enter the market in the European Community. European harmonized standards provide the detailed technical information enabling manufacturers to meet these essential requirements. The directives also explain how manufacturers are able to demonstrate conformity with the essential requirements. Products which meet the essential requirements are to display the <u>CE marking</u>, as described in the particular directive, which means that the products can be sold anywhere in the Community. Note: Some Directives do not require CE Marking.

Note: Many countries outside of the EU that have significant trade with the EU have begun to adopt and implement the New Approach Directives as national Technical Regulations. This concept eliminates the need for developing countries to create their own new technical regulations and standards as well as simplifies trade facilitation between the developing country and EU member states.



# EU New Approach Standardization in the Internal Market

Reference of directive/ regulation	Subject of directive/ regulation	Info about directive/ regulation	Info on European standards	Harmonized standards cited in the Official Journal
2000/9/EC	<b>Cableway installations</b>			
(EC) 1907/2006	Chemical substances (REACH)	Þ		Þ
89/106/EEC	Construction products (CPD)	•	•	•
(EU) 305/2011	Construction products (CPR)		ł	Þ
(EC) 1223/2009	Cosmetics			
92/42/EEC	Ecodesign – hot-water boilers	Þ		Þ
2010/30/EU	Ecodesign and energy labelling	•	-	•
2009/125/EC	Ecodesign and energy labelling	Þ	-	Þ
(EC) 1221/2009	Eco-management and audit scheme (EMAS)		-	

2014/30/EU	E l e c t r o m a g n e t i c compatibility (EMC)	Þ	-	Þ
2014/34/EU	Equipment for explosive atmospheres (ATEX)	•	-	•
2014/28/EU	Explosives for civil uses		-	
2009/142/EC	Gas appliances (GAD)	•	•	•
2014/28/EU	Inspection of pesticide application equipment	Þ	-	•
2014/33/EU	Lifts	•	-	
2014/35/EU	Low Voltage (LVD)		-	
2006/42/EC	Machinery (MD)	•		
2014/32/EU	Measuring instruments (MID)	Þ	-	•
93/42/EEC	Medical devices (MDD)	•	•	
90/385/EEC	Medical devices: active implantable	Þ	Þ	•
98/79/EC	Medical devices: in vitro diagnostic	•	•	•
(EC) 765/2008	New legislative framework (NLF)	Þ	-	Þ
2014/31/EU	Non-automatic weighing instruments (NAWI)	•	-	•
94/62/EC	Packaging and packaging waste	Þ	Þ	Þ
89/686/EEC	Personal protective equipment (PPE)	•	•	•
2014/68/EU	Pressure equipment (PED)	Þ	-	2
2013/29/EU	Pyrotechnic articles		-	
2014/53/EU	Radio and telecommunications terminal equipment (RTTE)	Þ	-	Þ
2008/57/EC	Rail system: interoperability	•	•	•
2013/53/EU	Recreational craft		-	
2011/65/EU	Restriction of the use of certain hazardous substances (RoHS)	•	-	•

2014/29/EU	Simple Pressure Vessels	-	
2009/48/EC	Toys safety		

#### Additional Useful information

Please click on one of the links below if you require more information.

<u>Harmonized standards</u>: lists of references of harmonized standards published in the Official Journal of the European Union

#### CE marking: guidance

#### **Notified bodies**

The information contained in the above summary lists is a compilation of the references of standards, which have been published in the Official Journal of the European Union.

The directives cover a very wide range of product areas. It should be noted: The New Approach Directive do not cover food, these are covered in the old approach. The majority of the New Approach Directive requires that a manufacturer have a CE mark their product. CE marking requirements vary from Directive to Directive. Third party testing, systems assessment can be mandatory, but sometimes the manufacturer's unverified claim is all that is required. However, if you claim your product complies and it does not, you may be prosecuted. Having independent testing and assessments carried out is the safest way for manufacturers to proceed, whether this is mandatory or not.

Where a Directive requires products and/or systems to be independently tested, certified, or inspected, this must be done by a "Notified Body" or "Competent Body". A Notified Body is an organization that has been nominated by a member Government and Notified by the European Commission. The primary role of a Notified Body is to provide services for conformity assessment on the conditions set out in the New Approach Directives in support of CE marking.

# **STANDARDS REFERENCE INFORMATION**

# International & Regional Standards Organizations

# International

ISO	International organization for Standardization	www <u>.iso.org</u>
IEC	International Electrotechnical Commission	www.iec.ch
ASTM	ASTM International	www.astm.org
ITU	International Telecommunication Union	<u>www.itu.int/net</u>
CODEX	Codex Alimententarius Commission	<u>www.codexalimentarius.</u> <u>net</u>

# Regional

Africa	ARSO	African Regional Organization for Standardization	www.arso-oran.org
Americas	COPANT	Pan American Standards Commission	www.copant.org
Arab states	AIDMO	Arab Industrial Development and Mining Organization	www.arifonet.org.ma
Asia and Pacific	ACCSQ	ASEAN Consultative Committee for Standards and Quality	http://www.asean.org/ accsq-working-group- on-standards-and- technical-regulations- wg3-standards- harmonization-and- technical-regulations/
	PASC	Pacific Area Standards Congress	http://www.pascnet.org

CIS	EASC	Euro Asian Council for Standardization, Metrology and Certification	www.easc.org
Europe	CEN	Comité Européen de Normalisation	www.cen.eu
	CENELEC	Comité Européen de Normalisation Electrotechnique	www.cenelec.org
	ETSI	European Telecommunications Standards Institute	<u>www.etsi.org</u>



International Organization for Standardization

## The International Organization for Standardization

#### www.iso.org

ISO is the world's largest (over 20,500 standards) developer and publisher of International Standards. ISO is a network of the national standards institutes of 162 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.



While there is a great deal of standards related information available free of charge through the ISO web site, it should be noted that all standards and guides are available for sale and can be purchased via the Internet from the ISO Store. ISO gives you the option of downloading ISO standards as electronic files in Adobe Acrobat PDF format that you can store on your computer, making them available at your desktop instantly. Buying ISO

standards as PDF files is subject to the conditions of the License Agreement. The <u>License</u> <u>Agreement</u> protects ISO copyright and users are only allowed to print one hardcopy from each downloaded PDF file.

ISO through the activities of DEVCO, (ISO Committee on developing country matters) have been providing assistance to developing countries for nearly fifty years. The web site highlights the numerous ways in which <u>ISO helps developing countries</u> to participate in international standardization activities. Technical assistance is a pivotal element of DEVCO's work, and training is recognized as one of the key components. Users will find information covering the broad spectrum of DEVCO's technical assistance activities and details of ISO's training services. In addition to information on relevant publications, the publications and resources page gives links to download or obtain the individual documents.

Examples of technical assistance include Seminars, Workshops, Training courses, Trainingof-trainers programs, Fellowships, Training materials, and reference publications, including e learning.

# The International Electrotechnical Commission (IEC)



#### www.iec.ch

The IEC is the global organization that prepares and publishes international Standards for all electrical, electronic, and related technologies. The IEC promotes, through its members, international cooperation on all questions of electrotechnical standardization and related matters, such

as the assessment of conformity to standards, in the fields of electricity, electronics, and related technologies. Copies of IEC standards can be purchased online from their web store for a fee. IEC standards cover a vast range of technologies from power generation, transmission, and distribution to home appliances and office equipment, semiconductors, fiber optics, batteries, flat panel displays and solar energy, to mention just a few. Wherever you find electricity and electronics, you find the IEC supporting safety and performance, the environment, electrical energy efficiency and renewable energies.

The IEC website contains *"Electropedia: The World's Online Electrotechnical Vocabulary"* If you're looking for an electronic or electrical term and its definition? Electropedia is the world's leading online electrical and electronic database containing more than 20, 000 terms and definitions in English and French. Electropedia is also known as the International Electrotechnical Vocabulary online.

#### **ASTM International**



#### www.ASTM.org

ASTM International, originally known as the American Society for Testing and Materials (ASTM), was formed over a century ago. ASTM International is a globally recognized leader in the development and delivery of voluntary consensus standards. Today, <u>over 13,000 ASTM standards</u> are used around the world to improve product quality, enhance

health and safety, strengthen market access and trade, and build consumer confidence. ASTM International is one of the largest voluntary standards development organizations in the world-a trusted source for technical standards for materials, products, systems, and services. Known for their high technical quality and market relevancy, ASTM International standards have an important role in the information infrastructure that guides design, manufacturing and trade in the global economy. Standards developed at ASTM are the work of over 30,000 ASTM members. These technical experts represent producers, users, consumers, government and academia from over 140 countries.

Today, ASTM International and the global construction industry have enjoyed a long and enduring partnership marked by progress and innovation in the building of homes, offices

and other facilities worldwide. This relationship dates back to the founding of ASTM, as many of the Society's earliest technical committees and standards were driven by construction-related needs.

## The International Telecommunications Union



#### http://www.itu.int

ITU is the leading United Nations agency for information and communication technologies. As the global focal point for governments and the private sector, ITU's role in helping

the world communicate spans, three core sectors: radio communication, standardization and development. ITU also organizes TELECOM events and was the lead organizing agency of the World Summit on the Information Society. ITU is based in Geneva, Switzerland, and its membership includes 191 Member States and more than 700 Sector Members and Associates. ITU's standards-making efforts are its best-known — and oldest activity. Working at the world's fastest changing industry, today's Telecommunication Standardization Sector (ITU-T) continues to evolve, adopting streamlined working methods and more flexible, collaborative approaches designed to meet the needs of increasingly complex markets. ITU publishes over 4,500 titles in printed form, CD-Rom and online, these are available via the ITU Bookstore for a nominal fee.

#### **CODEX Alimentarius Commission**

#### www.codexalimentarius.net

FAO/ WHO Food Standards



The Codex Alimentarius Commission is an intergovernmental body with over 170 members, within the framework of the Joint Food Standards Program established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), with the purpose of protecting the health of consumers and ensuring fair practices in the food trade. CODEX Alimentarius (Latin, meaning Food Law or Code) is the result of the Commission's work: a collection of internationally adopted food standards, guidelines, codes of practice and other recommendations. Through the CODEX website, users may download many of these documents free of charge, including: Procedural Manuals, recommended practices and standards.

# **Regional Standards Organizations**



## ASEAN Consultative Committee on Standards and Quality

<u>http://www.asean.org/accsq-working-group-on-standards-and-technical-regulations-wg3-standards-harmonization-and-technical-regulations/</u>

The Consultative Committee on Standards and Quality (ACCSQ) is a committee within the Association of Southeast Asian Nations and was established to facilitate trade in the region. Recognizing the contribution of standards and conformity assessment, these two "pillars" to facilitate and liberalize trade and investment in the region, ASEAN through the ASEAN Consultative Committee on Standards and Quality (ACCSQ) has endeavored to harmonize national standards with international standards and implement mutual recognition arrangements on conformity assessment to achieve its end-goal of "One Standard, One Test, Accepted Everywhere".

All Member Countries have accomplished the harmonization of standards for the 20 priority products and 81 standards for Safety and EMC. New areas for harmonization are currently being identified. Priority for harmonization will be given to those standards used in technical regulations in Member Countries. A complete work program of ASEAN Consultative committee on Standards and quality is available on through this website.

## The New Approach for European Standardization

#### www.newapproach.eu



European standards are available from CEN Members (in the general area) and from CENELEC Members (in the electrotechnical area). The National Members of CEN and CENELEC are responsible for selling European Standards. ETSI offers the possibility to download European telecommunication standards free of charge via its web site.

The New Approach and European standardization have contributed significantly to the development of the Single Market. The success of the European standardization system, in removing technical barriers to trade within EU Member States, has played a vital role in ensuring the free movement of goods between Member States.

This Web site has been realized to increase the visibility of New Approach Standardization in Europe and to provide information on the standardization process. This site provides access to information on standards and routes into the standardization process, irrespective of which of the three European Standards Organizations is responsible for the standards applicable to the products.

Via the web site: <u>www.eotc.be/newapproach</u>, a series of downloadable publications is

available free of charge that addresses the "The New Approach to technical harmonization and standardization - Harmonized Standards".



# Pan-American Standards Commission (COPANT)

#### http://www.copant.org

The Pan American Standards Commission, better known by its Spanish acronym COPANT, is a private, non-profit association that promotes standardization and related activities for its member's bodies of the

Americas region. The object of COPANT shall be to promote the development of technical standardization and related activities in its member countries with the aim of promoting their commercial, industrial, scientific and technological development in benefit of the economic and commercial integration and the exchange of goods and services, while facilitating cooperation in the intellectual, scientific, economic and social spheres. On this website, you will find up-to-date information on the Pan-American Standards Commission (COPANT), the Regional Standardization Body of the Americas. The site provides access to information on the activities of the Commission and is a dynamic tool for the exchange of documents and views. In addition, through the site, direct contact with COPANT can be maintained. A complete list of COPANT regional standards is available to be downloaded from this website.



# Euro Asian Interstate Council for Standardization, Metrology, and Certification (EASC) www.easc.org.

The Interstate Council for Standardization, Metrology, and Certification of the Commonwealth of Independence States (CIS) is the CIS Intergovernmental body for formulation and carrying out of coordinated policy in the field of standardization, metrology, and certification.

Members of the EASC are the national metrology and standards institutes of the former Soviet Union. The Interstate Council was created in accordance with the "Agreement on realization of coherent policy in the field of standardization, metrology and certification of the 13 of March 1992. The Agreement was established to coordinate the work in the field of standardization, metrology and certification and to define the main directions of the interstate standardization, metrology, certification and accreditation in stated fields of activities. It should be noted: all downloadable documents are available in Russian language only.



#### **Pacific Area Standards Congress (PASC)**

#### http://www.pascnet.org

In 1972, standards body representatives from Pacific Rim countries met in Honolulu USA to plan for a program leading to the development of a voluntary, independent organization the area national standards organizations. In 1973, the first meeting, which was named the PACIFIC AREA STANDARDS CONGRESS (PASC), was held in Honolulu. The members of PASC have adopted a number of important resolutions concerning international standardization, the work of ISO and IEC, and communication and interrelationships among PASC members. PASC is concerned not only with standards preparation but also with conformance to standards.



# Asia Pacific Economic Cooperation Sub-Committee on Standards and Conformance

#### http://www.apec.org/Groups/Committee-on Trade-and-Investment/Sub-Committee-on-Standards-and- Conformance.aspx

The Sub-Committee on Standards and Conformance (SCSC) assists the Committee on Trade and Investment to achieve the standards and conformance related components of APEC's trade and investment liberalization and facilitation agenda. This agenda includes the reduction of negative effects on trade and investment flows caused by differing standards and conformance arrangements in the region. The agenda also involves developing open regionalism and market-driven economic interdependence through a number of activities including encouraging alignment of APEC Member Economies' standards with international standards and liaison with international standards organizations. Ultimately, more closely harmonized standards and conformance will improve the efficiency of production and facilitate the conduct of international trade, resulting in more rapid trade flows, reduced costs, and greater integration of production networks in the region. The SCSC was established in 1994 and contributes to trade and investment liberalization and facilitation through technical areas of standards and conformance.



# **CARICOM Regional Organization for Standards and Quality**

#### http://www.crosq.org

CROSQ, the CARICOM Regional Organization for Standards and Quality, was established in 2003 by a Caribbean Common Market CARICOM) Community treaty as an Intergovernmental Organization and the regional center for promoting efficiency and competitive production in

trade and services, through the process of standardization and the verification of quality. Located in Bridgetown, Barbados, CROSQ is the successor to the Caribbean Common Market Standards Council (CCMSC), and supports the CARICOM mandate in the expansion of intra-regional and extra-regional export of goods and services. CROSQ is mandated to represent the interest of the region in international and hemispheric standards work, to promote the harmonization of metrology systems and standards, and to increase the pace of standards development in the region, as it facilitates the resolution of CARICOM trade disputes where standards are involved.

# HYPERLINKS FOR STANDARDS & TECHNICAL REGULATIONS

# **Books, Manuals and Compact Disks**

The following reference information is available from the sources listed below:



## Standards and Global Trade –A Voice of Africa

Produced by the World Bank, the publication contains over 400 pages of case studies and surveys conducted in Africa on standards and trade facilitation. The book may obtained by contacting the Office of the publisher, World Bank, 1818 H Street NW Washington DC 20433 USA or e-mail pubrights@worldbank.org

ASTM Standardization News is the official bimonthly magazine of ASTM International. It provides news of ASTM's latest work in international standardization, columns about how to develop standards in ASTM, interviews with industry and standardization professionals and features showing how ASTM International standards benefit governments, industries, consumers and global trade.



**ASTM International eNews** To supplement the bimonthly publication of Standardization News, ASTM International publishes eNews, a monthly e-mail newsletter. The newsletter provides quick links to timely news stories about ASTM International and its technical committees, interesting tidbits about ASTM standards, information on upcoming ASTM meetings and symposia, and links to new ASTM publications. – www.astm.org

The following information is available free of charge via the Internet from ASTM International at <u>www.astm.org</u>

Fact Sheet on ASTM International's Compliance with the WTO Principles for the Development of International Standards

http://www.astm.org/GLOBAL/images/intl\_standards1.pdf

Letter from U.S. Trade Representative to the World Trade Organization concerning international standards developing organizations

## http://www.astm.org/GLOBAL/images/SFX193B.pdf

ASTM International's Memorandum of Understanding Program with National Standards

Bodies <u>http://www.astm.org/GLOBAL/index.html</u>

#### Choosing Standards Based on Merit www.astm.org/choosingstandards



#### Standards & Competitiveness: Coordinating for Results

Produced by the US Department of Commerce, the document addresses "Removing Standards-Related Trade Barriers Through Effective Collaboration" as part of the Department of Commerce Standards Initiative

The U.S. standards system is highly decentralized and naturally partitioned into industrial sectors that are supported by numerous

independent, private-sector standards development organizations (SDOs)—currently more than 450 such organizations, with at least 150 more consortia. Approximately 20 SDOs develop about 80 percent of U.S. standards. A copy of this report is available on the USB wafer drive.

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# The Agreement on Technical Barriers to Trade –Agreement on the Application of Sanitary and Phytosanitary Measures

Produced by the International Trade Centre, this document is part of a workshop on the subject. For additional information contact ITC at 54-56 rue de Montbrillant, 1202 Geneva, Switzerland. E-Mail <u>itcreg@intracen.</u> org. Internet <u>www.intracen.org</u>

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#### Export Quality Management -An answer book for SME's

This book is produced by the International Trade Centre and the PTB; this document is part of a workshop on the subject. For additional information contact ITC at 54-56 rue de Montbrillant, 1202 Geneva, Switzerland . A free PDF of this publication is available on ITC's website at: www.intracen.org/publications



# An overview of the US Approach to Standards, Conformity Assessment and Metrology.

Produced by the US National Institute of Standards and Technology, this CD contains information on international, regional and national MAS-Q systems. Additional information is available from NIST, Standards Services Division at www.

NIST.gov



# Quality Systems and Standards for a Competitive Edge

Produced by the World Bank and written by Guasch JL, Racine JL, Sánchez I and Diop M., this 324-page publication reviews the economic impact and effect of quality, standards, and conformity assessment. Many examples are provided. For permission to photocopy or reprint any part of this work, please send a request with complete information to the Copyright Clearance Center Inc., 222 Rosewood Drive, Danvers, MA 01923, USA; fax: 978-750-4470; Internet: www.copyright.com.



#### **Understanding the Codex Alimentarius**

The Codex Alimentarius, or the food code, has become the global reference point for consumers, food producers and processors, national food control agencies and the international food trade. Published by the Codex Alimentarius Commission, this 47-page document addresses the Codex system and how it works. A copy of the complete document is in the standards folder on the wafer drive.



#### ISO FOCUS – the ISO Magazine

Published in English, French and Spanish, six times per year, *ISO focus* is your gateway to International Standards. Whether a multinational enterprise faced with major decisions or a small business looking for ideas, ISO focus seeks to provide both the kind of overviews that strategic planners need and the little details that can make a big difference. A subscription is available from ISO –for additional information contact ISO at www. iso.org



#### **STANDARDS** – a Power Point Presentation

A practical approach to standards including the history, writing, and the use in international trade. A copy of the complete document is in the standards folder on the Wafer Drive.

#### **National Standards Strategy for the United States**



#### www.ansi.org Or www.nist.gov

Produced by the American National Standards Institute and the National Institute of Standards and Technology, this 16-page document describes the US approach to Standards. Voluntary consensus standards

for products, processes and services are at the foundation of the U.S. economy and society. The United States has a tradition of developing and using voluntary standards to support the needs of our citizens and the competitiveness of U.S. industry. The American National Standards Institute (ANSI), the coordinator of the U.S. standards system, has brought together public and private sector interests to make this happen.



However, the system is facing new challenges. Increasing global concern for health, safety and the protection of the environment combined with dramatic increases in world trade and competition from other countries have altered the standards landscape. At the national level, the U.S. Congress has directed federal agencies to rely on voluntary consensus standards where compatible with their mission, raising the importance of national standardization processes for both the market and society. This document is available from ANSI and or NIST at or a copy of the complete document is in the standards folder on the Wafer Drive.



#### The Economic Value of Standardization

#### www.scc.ca

Produced by the Standards Council of Canada, this 40-page report examines the impact of standardization on the Canadian economy. The study involved a review of the standards-oriented economics literature, an empirical analysis of the impact of the collection of standards on Canadian labor productivity, a series of interviews with Canadian

leaders, and two case studies on the benefits of selected aspects of standardization. The report is available from the SCC web site or a copy of the complete document is in the standards folder on the Wafer Drive.



## The WTO Agreements Series - Technical Barriers to Trade

The book provides a brief overview of the background, purpose and scope of the TBT Agreement as well as the types of measures it covers. It sets out the key principles of the Agreement, and discusses how these have been addressed in recent disputes brought under the TBT Agreement. It describes the mandate, role and work of the TBT Committee, and considers how TBT-related matters have arisen in the Doha Round negotiations. Full copy available on the USB wafer Drive.



# **METROLOGY** – The Science of Measurement

It has been stated that the basic necessity of a trading system is metrology. Without the ability to determine length, weight (mass), volume, time and temperature, even the simplest of transactions would be open to ab trade would be impossible and legislation aimed at protecting the health and

No technical standards could exist for products, there are the standards or measurement of their performance against requirements. That or metrology system is therefore the first step in economic developer trade.





## Let us not forget:

What cannot be measured cannot be manufacture

What cannot be measured cannot be tested!

#### What cannot be measured cannot be certified!

Globally there is an increased understanding of the importance of metrology to the economy and to society as a whole. Accurate measurement forms the backbone of technical regulations, documentary standards and legal metrology, thus it is the prerequisite for free and fair trade nationally and internationally. In every institute, company, or organization, concepts such as safety, security, efficiency, reliability and precision are of paramount importance in designing systems, which provide guarantees of product quality. Accurate and widely accepted measurements are important in ensuring that market transactions can take place and that consumers can feel confident that the goods they buy are of the quantity and quality they except. Importantly for developing countries, accurate and internationally accepted measurements allow market access for food and commodity exports. Accurate and precise measurements curb the buyer's tendency to want more and the seller's tendency to give less.

Technology innovation depends on accurate measurements. New ideas and products can only be implemented if reliable measurement systems are in place. At the social level, protection of the environment requires that pollutants be precisely monitored. Patients receiving medical treatment need confidence in their test results and the dosage of treatment, even that the ingredients of the drugs they take have been measured properly. Similarly, industrial and commercial standards such as those introduced by ISO create a demand for measurement. Case studies have shown that there is a strong relationship between the adoption of international standards and the extent of trade in measurement and testing equipment, and these studies prove that a good metrology system ultimately contributes to the GDP of a country.

**Metrology is the Science of Measurement.** A study of history shows that the economic progress and growth of a nation is directly related to their progress in implementing and maintaining a unified national measurement system. Many decisions in life are based on measurements. Measurements influence and are an integral part of our daily lives, a fact that we often forget. Almost everything we buy is purchased by weight, length, volume, or measure: a kilogram of meat, a liter of gas, a meter of clothing.

In a conversation, one might ask:

- • What is the temperature today?
- • What time is it?
- • How tall are you?
- • How much does it weigh?
- • How fast is my automobile traveling?
- • How far is it to the next town?

All of these assume an accurate unit of measurement.

A Quote from William Thomson, Lord Kelvin 1824 – 1907



"When you can measure what you are speaking about, you know something about it. However, when you cannot measure it, your knowledge is of a meager and unsatisfactory kind. It may be the beginning of knowledge, but you have scarcely advanced to the stage of science."

## A Brief History of Metrology

The need for accurate measurements is evident throughout history and important steps for international metrology were the establishment of internationally agreed measurement units and standards and the methodology to enable recognition of the measurement standards of National Metrology Institutes and Designated Institutes around the world.

## The Royal Egyptian Cubit



One of the earliest records of precise measurement is from Egypt. The Egyptians studied the science of geometry to assist them in the construction of the great pyramids and temples. It is believed that about 3000 years BC, the Egyptian unit of length came in being. The "Royal Egyptian Cubit" was decreed to be equal to the length of the forearm from the bent elbow to the tip of the extended muddle finger plus the width of the palm of the hand of the Pharaoh or king ruling at that time.

The "Royal Cubit Master <sup>3</sup>was carved out of a block of granite to endure for all times. Workers engaged in building tombs, temples, pyramids, etc. were supplied with cubits made of wood or granite. The Royal Architect or Foreman of the construction site was responsible for maintaining & transferring the unit of length to workers instruments. They were required to bring back their cubit sticks at each full moon to be compared to the Royal Cubit Master. Failure to do so was punishable by death. Though the punishment prescribed was severe, the Egyptians had anticipated the spirit of the present day system of legal metrology, standards, traceability and calibration recall and penalties for non-compliance.

With this standardization and uniformity of length, the Egyptians achieved surprising accuracy. Thousands of workers were engaged in building the Great Pyramid of Giza. With the use of cubit sticks, they achieved an accuracy of 0.05%. This is roughly 756 feet or 9,069.4 inches, they were within 4 1/2 inches of the desired result.

Also in Egypt, scales were used to weigh precious metals and gems. Later, when coins began to be used as elements of trade, they were simply pieces of gold or silver, stamped with their weight. They gave birth to a monetary system that spread throughout the Mediterranean area. The way we measure time is based on the sexagesimal system developed in Mesopotamia, and our calendar is derived from the original 365 days Egyptian calendar.

<sup>&</sup>lt;sup>3</sup> The Story of the Egyptian cubit and the Papyrus shown above were presented to Ed Nemeroff, NCSL International, VP International Division, by Professor, Dr. Mohamed El-Fiki, President of the Egyptian National Institute for Standards during the US - Egypt Bilateral Workshop on Metrology, Standards & Conformity Assessment, held in Alexandria Egypt..

## The Unit of mass (weight)



Seeds, grains, and stones were used as weights.

The grain was the earliest unit of mass (weight) and is the smallest unit in the apothecary, avoirdupois, Tower, and troy systems. The early unit was a grain of wheat or barleycorn used to weigh the precious metals silver and gold. Larger units preserved in stone standards were developed that were used as both units of mass and of monetary currency. The pound was derived from the mina used by ancient civilizations. A smaller unit was the shekel, and a larger unit was the talent. The magnitude of these units varied from place to place. The Babylonians and Sumerians had a system in which there were 60 shekels in a mina and 60 minas in a talent. The Roman talent consisted of 100 libra (pound) which were smaller in magnitude than the mina. The troy pound (~373.2 g) used in England and the United States for monetary purposes, like the Roman pound, was divided into 12 ounces, but the Roman uncia (ounce) was smaller. The carat is a unit for measuring gemstones that had its origin in the carob seed, which later was standardized at 1/144 ounce and then 0.2 gram.

Goods of commerce were originally traded by number or volume. When weighing of goods began, units of mass based on a volume of grain or water were developed. For example, the talent in some places was approximately equal to the mass of one cubic foot of water. Was this a coincidence or by design? The diverse magnitudes of units having the same name, which still appear today in our dry and liquid measures, could have arisen from the various commodities traded. The larger avoirdupois pound for goods of commerce might have been based on volume of water, which has a higher <u>bulk density</u> than grain.

#### 1875 - Meter Convention – The creation of BIPM



The Convention of the Metre (*Convention du Mètre*) is a treaty that created the International Bureau of Weights and Measures (<u>BIPM</u>), an intergovernmental organization under the authority of the General Conference on Weights and Measures (<u>CGPM</u>) and the supervision of the International Committee for Weights and Measures (<u>CIPM</u>). The BIPM acts in matters of world metrology, particularly concerning the demand for

measurement standards of ever-increasing accuracy, range and diversity, and the need to

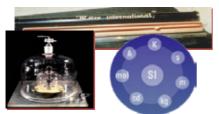
demonstrate equivalence between national measurement standards.



The Convention was signed in Paris in 1875 by representatives of seventeen nations. As well as founding the BIPM and laying down the way in which the activities of the BIPM should be financed and managed, the Metre Convention established a permanent organizational structure for member governments to act in common accord on all matters relating to units of measurement.

The Convention, modified slightly in 1921, remains the basis of international agreement on units of measurement. As of 2015, there are 57 Member States of the BIPM, and <u>40 Associates of the General Conference</u>.

## The Metre Convention and the International System of Units (SI)



The 11th General Conference on Weights and Measures (1960) adopted the name *Système International d'Unités* (International System of Units, international abbreviation SI), for the recommended practical system of units of measurement.

The 11th CGPM laid down rules for the prefixes,

the derived units, and other matters. The **base units** are a choice of seven well-defined units that by convention are regarded as dimensionally independent: the metre, the kilogram, the second, the ampere, the kelvin, the mole, and the candela. **Derived units** are those formed by combining base units according to the algebraic relations linking the corresponding quantities. The names and symbols of some of the units thus formed can be replaced by special names and symbols, which can themselves be used to form expressions and symbols of other derived units. The SI is not static but evolves to match the world's increasingly demanding requirements for measurement

#### **Future revision of the SI**



At its 25th meeting (November 2014) the CGPM adopted a Resolution on the future revision of the International System of Units. This Resolution built on the CGPM's previous Resolution (2011), which took note of the CIPM's intention to propose a revision of the SI and set out a detailed roadmap towards the future changes.

In the revised SI four of the SI base units - namely the

<u>kilogkilogram</u>, the <u>ampere</u>, the <u>kelvin</u> and the <u>mole</u> – will be redefined in terms of constants; the new definitions will be based on fixed numerical values of the Planck constant (*h*), the elementary charge (*e*), the Boltzmann constant ( $k_{\rm B}$ ), and the Avogadro constant ( $N_{\rm A}$ ), respectively. Further, the definitions of all seven base units of the SI will also be uniformly expressed using the <u>explicit-constant formulation</u>, and specific <u>mises</u> <u>en pratique</u> will be drawn up to explain the realization of the definitions of each of the base units in a practical way.

#### The Original Units of the Metric System



On March 19, 1791, a report was presented to the Academie Royale des Sciences of Paris by a Committee made up of Messes. Borda, Lagrange, Laplace and Condorcet. It was entitled "On the choice of a unit of measurement" and began as follows

"The idea referring all measurements to a unit of length taken from nature was seized upon by mathematicians as soon as

the existence of such a unit and the possibility of determining it became known. They saw it as the only way to exclude all that was arbitrary from a system of measurement and to conserve it unchanged, so that no event or revolution in the world could cast uncertainty upon it. They felt that with such a system, belonging exclusively to one nation, one could hope that it would be adopted by all.

#### The International System of Units

The name Système International d'Unités (SI) was adopted in 1960 for the recommended practical system of units of measurement. The SI is a system of units founded on older metric systems and adopted by the General Conference on Weights and Measures (CGPM), the highest international authority on units. The SI consists of seven base units, metre (length), kilogram (weight), second (time), ampere (electric current), kelvin (thermodynamic temperature), mole (amount of substance) and candela (luminous intensity) that are independent of one another. These base units can be combined to create derived units defining new quantities. e.g. Volt, Watt, Newton, Pascal, and joule. The base and derived units form the coherent SI units. Recognizing the need to work towards internationally agreed measurement standards, in 1875 governments from 17 countries worldwide signed this treaty and agreed to create and finance a permanent, scientific institute, the Bureau International des Poids et Mesures (BIPM) as the center for coordination of world measurement. The Comité International des Poids et Mesures (CIPM) was established to oversee the BIPM and today there are 51 Member States of the Metre Convention, and 23 Associate States and Economies of the General Conference.

<u>e</u> - The Unit of length	Symbol = m
The metre is the length of the parts of the parts of a second.	bath travelled by light in vacuum during a time interval of 1/299
info.: <u>SI brochure</u>   practical realiz	zation   evolution of the definition   CCL
am- The Unit of weight	Symbol = kg
The kilogram is the unit of mass kilogram.	s; it is equal to the mass of the international prototype of the
More info.: <u>SI brochure</u>   <u>practi</u> <u>CCM</u>	ical realization   the name "kilogram"   work at the BIPM
<mark>d</mark> – The unit of Time	Symbol = S
	9 192 631 770 periods of the radiation corresponding to the perfine levels of the ground state of the caesium 133 atom.
More info.: <u>SI brochure</u>   <u>pract</u>	tical realization   work at the BIPM   CCTF
<u>re</u> - The Unit of Electricity	Symbol = A
of infinite length, of negligible c	irrent which, if maintained in two straight parallel conductors circular cross-section, and placed 1 m apart in vacuum, would ctors a force equal to $2 \times 10^{-7}$ newton per metre of length.
More info.: <u>SI brochure</u>   practic	cal realization   work at the BIPM   CCEM
	· · · · · · · · · · · · · · · · · · ·
- The unit of Temperature	Symbol = K
	Symbol = K amic temperature, is the fraction 1/273.16 of the thermodyn
The kelvin, unit of thermodyna	Symbol = K amic temperature, is the fraction 1/273.16 of the thermodyn of water.
The kelvin, unit of thermodyna temperature of the triple point More info.: <u>SI brochure</u>   practica	Symbol = K amic temperature, is the fraction 1/273.16 of the thermodyn of water.
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The kelvin, unit of thermodyna temperature of the triple point More info.: <u>SI brochure</u>   <u>practica</u> <u>The Unit of Substance</u> The mole is the amount of s there are atoms in 0.012 kild When the mole is used, the ions, electrons, other particl	Symbol = K         amic temperature, is the fraction 1/273.16 of the thermodyn         of water.         al realization   history   CCT         Symbol = mol         substance of a system, which contains, as many elementary en ogram of carbon 12.         e elementary entities must be specified and may be atoms, modeles, or specified groups of such particles.

## **Metrology: the Science of Measurement**

Depending on the field of application, metrology can be sub-divided as:

- • Scientific Metrology
- Legal Metrology
- • Industrial Metrology.

#### **Scientific Metrology**



Scientific Metrology in the field of national measurement standards is of primary importance for any country, since it is the prerequisite for the development of other branches of metrology as well as new technologies, and for the development of the society as a whole. The basic tasks of a national metrology institute is to which this field is entrusted throughout the world is the realization and keeping of the national measurement standards and conducting of the necessary research and development tasks

related to special measuring needs of individual sectors. The results of this work is assurance of measurement traceability to the SI and knowledge transfer or expert assistance in performing the most sophisticated or important measurements for a wide range of users.

#### Scientific metrology covers three main tasks:

- The definition of internationally accepted units of measurement
- The realization and dissemination of units of measurement by scientific methods and
- The establishment of traceability chains in documenting the accuracy of a measurement.

## Legal Metrology



According to the International Organization of Legal Metrology (OIML) "Legal metrology is the legislative, administrative and technical procedures established by, or by reference to public authorities, and implemented so their behalf in order to specify and to insure in a regulatory of contractual man, the appropriate quality and credibility of measurements related to official controls, trade, health, safety and the environment."

Most commercial transactions are based on weight, volume, length, or count of products bought and sold. Packaged goods are purchased at the supermarket, people buy delicatessen items over price computing scales, gasoline and diesel fuel are purchased through pumps. Gasoline and diesel fuel must meet prescribed quality or octane standards. , scanners are used at checkout stands in retail stores to look up prices of products identified by bar codes, farmers sell grain, produce, and livestock over scales, grain prices are adjusted up or down based upon quality measurements. This is legal metrology.

In short, legal metrology is the practice and the process of applying regulatory structure and enforcement to metrology a credible measurement system is vital for trade in any society. All measurements related to trade and consumer protection come under the forum of legal metrology, specifically in the area of weights and measures.

Trade and economic development is a fundamental human activity, and it operates on the principle of fair exchange of products between two parties, which may be persons or organizations.

Legal metrology ensures that all measurements made for the purpose of exchanging products as part of trade are fair and credible. Example: "Getting what you pay for" a kilogram of meat, a liter of gas, a meter of cloth. Those measuring devices which themselves are legally controlled, such as gas pump meters, taxi meters, household electricity meters, scales in the marketplace are a major part of legal metrology. In addition, devices, which may be used for law enforcement, such as breath analyzers, or in medical applications, such as blood pressure monitors or clinical thermometers would fall under the category of legal metrology.

## **Industrial Metrology**



The function of industrial metrology is mainly the proper calibration and control of measuring equipment used in a manufacturing process. The purpose here is to guarantee that the products, produced comply with required standards. The equipment is controlled at set time intervals in such a way that the uncertainty of the measurements is known. Calibration is carried out against certified equipment,

with a known valid relation to standards such as, a national reference standard.

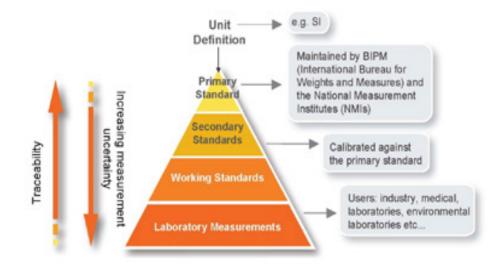
## The Role of a National Metrology Institute

A National Metrology Institute is an organization designated by governmental decision to develop and maintain and disseminate the national measurement system based on the international system of units (SI). Some countries operate a centralized metrology organization with one NMI. In some countries, the NMI may outsource the maintenance of specific standards to other government agencies or another competent in country laboratory without these having the status of a NMI. Other countries operate a decentralized organization with a multiplicity of institutes, all having the status of a NMI. An NMI represents the country internationally in relation to the national metrology institutes of other countries, in relation to the Regional Metrology Organizations (RMO) and to the BIPM. The NMIs are the backbone of the international metrology system. Many NMIs undertake primary realizations of the metrological base units and derived units at the highest achievable international level, whilst some NMIs hold national standards which are traceable to other NMIs.

#### **Traceability of Measurement**

Traceability is an unbroken chain of calibrations, all having stated uncertainties. This ensures that a measurement result or the value of the standard is related to references at a higher level, ending at the final level with a primary standard or realization of the definition of a measurement unit. A calibration laboratory establishes traceability of its own measurement standards and instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to the SI units may be achieved by reference to <u>national</u> measurement standards. <u>National</u> measurement standards may be primary standards, which are realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. All test equipment requiring calibrations should be repeated at appropriate intervals. For any individual instrument, it is the responsibility of the laboratory to determine the appropriate calibration regime based on its application, construction, and drift history,

#### **The Traceability Chain**



## The Importance of Mutual Recognition of Measurements

Mutual Recognition of Measurements plays an important role in reducing technical barriers to trade, thus, facilitating global trade. This is emphasized by the **Bureau International des Poids et Mesures (BIPM)** in their following statement;

"Reliability of the international measurement system is enhanced through continual effort by the world's national metrology institutes (NMS) to base measurements and measurement uncertainties on universally accepted units, normally those of the International System of Units (SI). It is important for individual nations, through their NMS, to compare national measurements and establish their mutual equivalence, not only in an effort to enhance measurement capabilities, but also as a means to reduce technical barriers to international trade. The extent to which an NMI can secure the mutual equivalence of national measurement standards and calibration capabilities, within known uncertainties, is thus a contributing factor to its nation's ability to engage in global trade. Historically, mutual equivalence has been determined through an NMS's participation in bilateral agreements, or in regional multilateral agreements and organizations (ROMs). In October 1999, however, the importance of metrological equivalence was extended to a fully international spectrum with the signing of an arrangement for the Mutual recognition of national measurement standards and of calibration and measurement capability (Comics) issued by national metrology institutes, under the auspices of the Comité International des Poids et Mesures (CIPM), and coordinated by the Bureau International des Poids et Mesures (BIPM). Known as the Mutual Recognition Arrangement (MRA), it provides for the formal recognition of national measurement standards and calibration capabilities, and is expected to become the basis for wider agreements related to trade and commerce (e.g., WTO)."

## Calibration

A basic tool in ensuring the traceability of a measurement is the calibration of measuring instruments. Calibration involves determining the metrological characteristics of an instrument. This is achieved by a direct comparison to a higher accuracy know standard. A calibration certificate or test report is issued. Based on this information, a user can decide whether the instrument is fit for the application.

## **Measurement Standard**

A measurement standard (etalon/artifact) is a material measure, measuring instrument, reference material or measuring system intended to define, realize, conserve, or reproduce a unit or one or more values of a quantity to serve as a reference.

A National Measurement Institute (NMI) that develops, maintains and disseminates national measurement standards at the highest level appropriate to national needs, and develops and transfers new measurement technology to domestic users and a national authority responsible for overseeing legislation relating to measurement and its application in everyday commerce.

## **Primary Measurement Standard**

A standard is designated or widely acknowledged as having the highest metrological quantities and whose value is accepted without reference to other standards of the same quantity.

## **Secondary Measurement Standard**

A standard whose value is assigned by comparison with a primary standard of the same quantity.

#### **Working Measurement Standard**

A standard that is used routinely for the calibration of equipment and measuring instruments in general use, having less accuracy than secondary measurement standards.

#### **International and Regional Metrology Organizations**

#### International

BIPM	Bureau International des et Poids Measures	www.bipm.org	
OIML	International Organization of Legal Metrology	www.oiml.org	
IMEKO	International Measurement Confederation	www.imeko.org	
NCSLI	NCSL International	www.ncsli.org	
JCDCMAS	Joint Committee on Coordination of Assistance to Developing Countries in Metrology, Accreditation and Standardization	istance to Developing ntries in Metrology, ic/icdemas/	

#### Regional

Africa	AFRIMETS	Inter-Africa Metrology System	http://www. afrimets.org/ SitePages/Home. aspx
	SADCMET	South-African National Development Community Cooperation in Measurement Traceability	www.sadcmet. org
The Americas	SIM	InterAmerican Metrology System, sub-regions: ANDIMET, CAMET, CARMET, NORAMET and SURAMET	http:// <u>www</u> .sim- metrologia.org. br/

Asia and Pacific	APMP APLMF	Asia Pacific Metrology Program The Asia-Pacific Legal Metrology Forum	www.apmpweb. org www.aplmf.org
Former USSR	COOMET	Euro-Asian Cooperation of National Metrological Institutions	www.coomet.org
	EASC	The Interstate Council for Standardization, Metrology and Certification	www. <u>easc</u> .org.by
Europe	EURAMET	European Association of National Metrology Institutes	<u>www.euramet.</u> org
	WELMEC	European Cooperation in Legal Metrology	www.welmec.org
	WEMC	Western European Metrology Club	N/A

#### **Bureau International des Poids et Measures (BIPM)**



#### www.bipm.org

The task of the BIPM is to ensure worldwide uniformity of measurements and their traceability to the International System of Units (SI). It does this \*with the authority of the

Convention of the Metre, a diplomatic treaty between fifty-one nations, and it operates through a series of Consultative Committees, whose members are the national metrology laboratories of the Member States of the Convention, and through its own laboratory work. The BIPM is an intergovernmental organization established by the Metre Convention, through which Member States act together on matters related to measurement science and measurement standards. The mission of the BIPM is to ensure and promote the global comparability of measurements, including providing a coherent international system of units for:

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

The unique role of the BIPM is based on its international and impartial character enabling it:

- To coordinate the realization and improvement of the worldwide measurement system to ensure it delivers accurate and comparable measurement results.
- To undertake selected scientific and technical activities that are more efficiently carried out in its own laboratories on behalf of Member States.

 To promote the importance of metrology to science, industry and society, in particular through collaboration with other intergovernmental organizations and international bodies and in international forums.

## International Organization of Legal Metrology (OIML)



#### www.oiml.org

The International Organization of Legal Metrology (OIML) is an intergovernmental treaty organization whose membership includes <u>Member States</u>, countries that participate actively in technical activities, and <u>Corresponding Members</u>, countries that join the OIML as

observers. It was established in 1955 (see the <u>Convention</u>) in order to promote the global harmonization of legal metrology procedures. Since that time, the OIML has developed a worldwide technical structure that provides it's Members with metrological guidelines for the elaboration of national and regional requirements concerning the manufacture and use of measuring figures, instruments for legal metrology applications. According to 2007, World Bank OIML Members cover in total an astounding 86 % of the world's population and 96 % of its economy.

#### **NCSL International (NCSLI)**



#### www.ncsli.org

NCSLI is the world's premier technical organization dedicated to the field of metrology, and conformity assessment. It was formed in 1961 to promote cooperative efforts for solving the common problems faced by measurement laboratories. Today, NCSL International has

over 1200 Member Organizations from academic, scientific, industrial, and commercial and government facilities around the world. The mission of NCSL International is to advance technical and managerial excellence in the field of Metrology, Measurement Standards, Conformity Assessment, Instrument Calibration, as well as Test and Measurement through voluntary activities aimed at improving product and service quality, productivity, and the competitiveness of Member Organizations in the international marketplace.

Annually, NCSL International holds a *Workshop and Symposium* that includes over 100 presentations on measurement issues, such as traceability, quality, uncertainties, procedures, new and improved standards, etc., as well as training tutorials and committee meetings.

NCSL International has developed an extensive library of technical and management publications as well as training videos to educate members about international standards, laboratory procedures, measurement practices and available metrology services and seminars. Some of the publications available through NCSL International include:

- Recommended Practices (RPs)
- Recommended Intrinsic/Derived Standards Practices (RISPs)

- Training Video Tapes
- Calibration Laboratory Manager's Guidebook
- "MEASURE," The Journal of Measurement Science, a metrology scientific and technical journal
- Training Information Directory
- "METROLOGIST NCSLI" International Quarterly Magazine.

## Intra-Africa Metrology System



#### http://www.afrimets.org/SitePages/Home.aspx

To harmonize metrology activities in Africa, the intra-Africa metrology system (AFRIMETS) was established, based on the Regional Metrology Organization (RMO)

of the Americas, SIM (Sistema Interamericano de Metrologia). Assembly meeting was held in July 2007 at the premises of the NEPAD. The MOU was finalized and signed by 5 sub-regional metrology organizations (SRMOs), namely SADCMET, EAMET, CAMET (later changed to CEMACMET), SOAMET and MAGMET, representing 37 countries in Southern, Eastern, Central, Western and North Western Africa. In addition, Nigeria and Cote d'Ivoire have signed on as individual (Ordinary) members.

# South-African National Development Community Cooperation in Measurement Traceability



## www.sadcmet.org

The SADC Cooperation in Measurement Traceability coordinate metrology activities and services in the Region, in

order to provide regional calibration and testing services, including regulatory bodies, with readily available traceability to the SI units of measurement, through legally defined and regionally and internationally recognized national measurement standards.

## Inter-American Metrology System (SIM)



#### http://www.sim-metrologia.org.br/

The Inter-American Metrology System, SIM is the regional organization for metrology in the Western Hemisphere, and consists of the national metrology institutes from 34 member nations represented at the Organization of American States, which acts as its Executive Secretariat.

SIM coordinates its functions based on an organization of five (5) sub-regions that corresponds to the five (5) main economic and commercial groups in the region. These metrology groups are: NORAMET (North America), CAMET (Central America), CARIMET

(the Caribbean), ANDIMET (Andean Group), and SURAMET (South America).

## **Euro-Asian Cooperation of National Metrological Institutions**



#### www.coomet.org

COOMET is the regional organization originally establishing cooperation of state metrology institutes of countries of Central and Eastern Europe. It was founded in June, 1991 and renamed in *"Euro-Asian cooperation of state metrology institutions"* in

May, 2000. COOMET is open for any metrology institutions from other regions to join as the associate members.

Now the members of COOMET are the metrology institutions from Belarus, Bulgaria, Georgia, Germany (associate member), Kazakhstan, Kyrgyzstan, DPR of Korea (associate member), Cuba (associate member), Lithuania, Moldova, Russia, Romania, Slovakia, Uzbekistan and Ukraine.

The basic activity of COOMET is the cooperation in measurement standards of physical quantities, legal metrology, accreditation and quality management systems, information and training.

## **EuroAsain Interstate Council for Standardization, Metrology and Certification** (EASC) www.easc.org.



The Interstate Council for Standardization, Metrology and Certification of the Commonwealth of Independence States (CIS) is the CIS Intergovernmental body for formulation and carrying out of coordinated policy in the field of standardization, metrology and certification. The Interstate Council for Standardization, Metrology and Certification of the Commonwealth of Independence States (CIS) is the CIS Intergovernmental body for formulation and carrying out of coordinated

policy in the field of standardization, metrology and certification. Members of the EASC are the national metrology and standards institutes of the former Soviet Union.

## **European Cooperation in Legal Metrology (WELMEC)**



#### www.welmec.org/info.asp

WELMEC is the European Cooperation in Legal Metrology, founded in June 1990. When it was founded, the acronym WELMEC stood for Western European Legal Metrology Cooperation. However, today WELMEC extends beyond

Western Europe and includes representatives from Central and Eastern Europe. The principal aim of WELMEC is to establish a harmonized and consistent approach to European legal metrology. WELMEC is concerned with the establishment, maintenance, and improvement

of channels of communication between its members and associate members and aims to develop mutual confidence through participation in common activities. WELMEC offers a series of guides on legal metrology; these can be accessed on their website.

## **European Association of National Metrology Institutes**



#### www.euramet.org

The European Association of National Metrology Institutes (EURAMET) is the Regional Metrology Organization (RMO) for Europe. European metrology was coordinated successfully over

almost 20 years by EUROMET, a collaboration based on a Memorandum of Understanding, but the new challenges facing European metrology, and in particular the higher level of integration necessary to manage the multi-million-euro European Metrology Research Program (EMRP), required a legal entity, which could enter into contractual obligations on behalf of its members. EURAMET i.e.: was therefore established as an association of public utility under German law on 11 January 2007. Its members are the European National Metrology Institutes (NMIs). As well as running the EMRP, EURAMET continues to coordinate the cooperation between the European NMIs in support of the CIPM MRA. It organizes regional inter-comparisons between NMIs and validates their Calibration and Measurement Capabilities.

#### The Asia Pacific Metrology Program



#### www.apmpweb.org

The Asia Pacific Metrology Program (APMP) is primarily responsible for developing international recognition of the measurement capabilities of the regions national and territorial measurement laboratories. APMP has been operating in the Asia-Pacific since its inception as a Commonwealth

Science Council initiative in 1977. As such, it is the oldest continually operating metrological grouping in the world. The Program grew out of a need by participating members to develop their metrological capability. It was based on a true collaborative spirit of mutual assistance and sharing of expertise and information, and this remains one of the major strengths of APMP to this day. The APMP membership has a diverse range of skills and capabilities and these are being developed to support the needs of individual economies. As of June 2006, the Full member consists of thirty-two (32) organizations from twenty-one (21) economies, and the five (5) organizations from five (5) economies are the Associate members.

## The Asia-Pacific Legal Metrology Forum (APLMF)



#### www.aplmf.org

The Asia-Pacific Legal Metrology Forum (APLMF) is a grouping of legal metrology authorities in the Asia-Pacific Economic Cooperation (APEC)

and other economies on the Pacific Rim. The objective is the development of legal metrology and the promotion of free and open trade in the region through the harmonization and removal of technical or administrative barriers to trade in the field of legal metrology. In November 1994, the Asia-Pacific Legal Metrology Forum (APLMF) was established with 14 member economies from the Asia-Pacific Economic Cooperation (APEC) region, and they were Australia, Canada, People's Republic of China, Indonesia, Japan, Republic of Korea, Malaysia, New Zealand, Papua New Guinea, Philippines, Singapore, Chinese Taipei, Thailand and USA.

## HYPERLINKS FOR METROLOGY REFERENCE INFORMATION

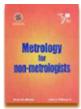
## **Books, Publications and Compact Disks**



Inter-American Metrology System (SIM)

#### www.sim-metrologia.org.br

This 139-page book is available from the SIM web site in pdf format free of charge – a copy of the complete document is in the metrology folder on the Wafer drive



## Metrology for Non-Metrologist Inter-American Metrology System (SIM)

#### www.sim-metrologia.org.br

This 128-page book is available from the SIM web site in pdf format –free of charge – a copy of the complete document is in the metrology folder on the Wafer Drive



## Metrology -- in short 3rd Edition -

#### www.euramet.org/index.php?id=mis

This 3<sup>rd</sup> edition is to increase the awareness of metrology and to establish a common metrological frame of reference. This 84 page book is available from the EURAMET website and may be downloaded free of charge. EURAMET also publishes a series of calibration guides, which are intended

to improve harmonization in the calibration of measuring instruments.



## The International System of Units (BIPM)

http://www.bipm.org/en/publications/si-brochure/

This brochure is the reference for all those who wish to use the SI correctly. It contains the official definitions of the base units of the SI, and all the decisions of the CIPM and CGPM related to the SI, its formalism and use. The text is viewable on line and the brochure can be downloaded free of

charge in PDF format.



## Metrologia -BIPM

## www.bipm.org/en/metrologia/

Metrologia is an international journal dealing with the scientific aspects of metrology. Annual subscriptions may be purchased via the web site. The BIPM publishes, in addition to scientific articles by members of staff, which appear in the open literature, the official reports of the CGPM, CIPM and Consultative Committees, the SI brochure entitled *Le Système* 

International d'Unités, and the journal Metrologia. Also published are a wide range of scientific Reports and Monographs, most written by members of the BIPM staff. Individual copies of BIPM publications may be obtained on request.



## The International Bureau of Weights and Measures

#### www.bipm.org

This 44-page brochure is an introduction to the BIPM's work provides an overview of its activities and responsibilities in the physical and chemical metrology. It also provides a glimpse into a vast and economically essential endeavor upon which we all depend. This brochure is available from BIPM

free of charge.



## **NCSL International**

## www.ncsli.org

NCSL International "MEASURE" The Journal of Measurement Science, a metrology scientific and technical journal. The journal's primary audience is centered on calibration laboratory personnel, from laboratory managers, engineers and technicians –This journal is available free of charge to all

members of NCSLI or may be purchased from NCSLI- information is available on the NCSLI Website.



## **NCSL International**

## www.ncsli.org

## NCSL International 'Metrologist' magazine

NCSL International's publication focusing on people, networking, and members. Magazine features include Learning and Development,

Educator's Corner, Education Outreach, Scholarship Promotion, Lab Tours, Accreditation and Publication Reviews and Summaries. This publication is available free of charge to all members of NCSLI or may be purchased from NCSLI - information available on the NCSLI website.



#### **NCSL International**

#### www.ncsli.org

Laboratory Management Publications Recommended Practice Publications

These documents are a series of how- to publications, guides, and procedures.

## Examples:

- Calibration Laboratory Manager's Guidebook
- NCSL Glossary of Metrology-Related Terms
- Calibration Procedures
- Test Reports and calibration certificates
- Laboratory Design
- Laboratory Environment
- Measurement Uncertainty
- Calibration Control Specifications
- Documentation Guidelines and more
- These documents are available from NCSLI via the website.

# WorkPlace Training

## **Precision Measurement Training**

**Computer based – interactive training** 

## www.wptraining.com



Workplace Training offers a series of computer

based interactive training courses. Their goal is to improve measurement quality by increasing the calibration knowledge infrastructure in developing countries. All of the following courses come with complete testing and documentation in the form of a Certificate of Competency.

Course subjects include the following:

## **Precision Measurement Series**

- Introduction to Measurement and Calibration
- Precision Electrical Measurement
- Precision Dimensional Measurement
- Precision Pressure Measurement
- Precision Flow Measurement
- Precision Mass Measurement
- Precision Temperature Measurement
- Measurement Uncertainty



## CAL LAB – The International Journal of Metrology

## www.callabmag.com

This quarterly published magazine is a resource of current metrology information; it contains technical articles, calendar of metrology events, industry and research news, new products and services. To obtain a subscription visit Cal Labs web site.



# AN INTRODUCTION TO THE BUREAU INTERNATIONAL DES POIDS MEASURES (BIPM)

A Power Point Presentation- covering The <u>Metre Convention</u> and the <u>SI</u>, the international metrology system & Metrology and society – a copy of the complete document is in the metrology folder on the wafer Drive.



# AN ASSESSMENT OF THE UNITED STATES MEASUREMENT SYSTEM (USMS)

**Produced by the US National Institute of Standards and** Technology, this 54 page publication addresses the measurement barriers to accelerate innovation is available from NIST in hard copy or on a CD. A copy of the complete document is in the metrology folder on the wafer drive.



# INTERNATIONAL VOCABULARY OF METROLOGY – BASIC AND GENERAL CONCEPTS AND ASSOCIATED TERMS (www.bipm.org)

This 104 page document is a terminological dictionary which contains designations and definitions from one or more specific subject fields" (ISO 1087-1:2000, 3.7.2). The present Vocabulary pertains to metrology, the "science of measurement and its application". It also covers the basic principles governing quantities and units. The field of quantities and units

could be treated in many different ways. Clause 1 of this Vocabulary is one such treatment, and is based on the principles laid down in the various parts of ISO 31, *Quantities and units,* currently being replaced by ISO 80000 and IEC 80000 series *Quantities and units,* and in the SI Brochure, *The International System of Units* (published by the BIPM). This document is available free of charge from the BIPM web site.



# THE INTERNATIONAL VOCABULARY OF TERMS IN LEGAL METROLOGY (VIML)

#### www.oiml.org

The International Vocabulary of Terms in Legal Metrology (VIML) is the result of work on the harmonization of terminology used in the field of legal metrology. The need to harmonize metrological terminology worldwide resulted in the identification of general concepts, which

form the basic terminology common to various technical disciplines. Seven International Organizations (BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML) thus jointly prepared the International Vocabulary of Basic and General Terms in Metrology. This document can be downloaded from the OIML website free of charge.



## THE LITTLE BIG BOOK OF METROLOGY

Produced by the UK's National Physical Laboratory (NPL), this 145-page book looks at metrology, the branch of science that deals measurement. The little book contains a brief history of measurement, the SI units, measurement uncertainty and traceability and more. The book is available for a small fee from NPL –e-mail <u>enquiry@npl.co.uk</u>.



#### A NATIONAL QUALITY INFRASTRUCTURE

This 136 page book published by the Organization of American States(OAS) in cooperation with the Inter-American Metrology System and the PTB is a guide for SME's to the steps that have to be followed in order for their products to fulfill the quality requirements demanded by international markets





#### **PRECISION: THE MEASURE OF ALL THINGS**

This DVD is published by the BBC –the Open University Worldwide -Marcus du Sautoy shows how precision measurement has helped to define and advance civilization. It has taken us from Stone Age Skymaps to the exploration of outer space. Packed with cutting-edge science and jaw-dropping examples from the modern world, this is a journey from sundials to time lords and lasers. Three programs each 60 minutes long cover Time and Distance. Mass and Moles. Light,. For additional

information to obtain a copy visit www.ouw.co.uk

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-	T. Marrie

# A CONCISE SUMMARY OF THE INTERNATIONAL SYSTEM OF UNITS

This four (4)-page summary of the SI System was prepared by the Bureau International Des Poids Measures (BIPM) is an excellent introduction to the international units of measurement. A copy of the brochure is available in the metrology section of the attached Wafer Drive.



## JOURNAL OF RESEARCH OF NIST

The Journal of Research of NIST reports NIST research and development in metrology and related fields of physical science, engineering, applied mathematics, statistics, biotechnology, information technology – for additional visit www.nist.gov

## **CONFORMITY ASSESSMENT**



#### An Internationally Recognized Procedure

The international Standard ISO/IEC 17000, Conformity assessment—Vocabulary and general principles, defines conformity assessment as the "demonstration that specified requirements relating to a product, process, system, person or body are fulfilled."

Conformity assessment procedures provide a means of ensuring that the products, services, or systems produced or operated have the required characteristics, and that these characteristics are consistent from product to product, service to service, or system to system. Conformity assessment includes: sampling and testing; inspection; certification; accreditation and management system assessment. Accreditation evaluates and recognizes the competence of bodies conducting these activities. A specific conformity assessment process may include one or more of these conformity assessment activities. While each of these activities is a distinct operation, they are closely interrelated. In addition, standards are interwoven into all aspects of these activities and can have a major impact on the outcome of a conformity assessment process. Conformity assessment activities form a vital link between standards (which define necessary characteristics or requirements for products) and the products themselves. Together standards and conformity assessment activities influence almost every aspect of life.

The purpose of conformity assessment is to provide confidence for users that requirements applicable to products, services, and systems have been met. Such confidence, in turn, directly contributes to the market acceptance of those products, services, and systems. Such user confidence can be achieved through cooperation among conformity assessment bodies and/or accreditation bodies, resulting in mutual recognition and promotion of each participant's work across borders.

## A Simple Guide to Understanding Conformity Assessment

## Why is conformity assessment so important?

Today, many products require testing for conformance with specifications or compliance

with safety or other regulations before they can be put on many markets. Even simple products may require supporting technical documentation that includes test data. It is not always practical for these activities to be carried out by suppliers and customers, and so often specialized third parties get involved. In addition, national legislation may require such testing to be carried out by independent bodies, particularly when the products concerned have health or environmental implications. In fact, conformity assessment has become an important component of world trade and is most often carried out by specialist organizations, such as inspection and certification bodies and testing laboratories.

The purpose of conformity assessment is to provide confidence for users that requirements applicable to products, services, and systems have been met. Such confidence, in turn, directly contributes to the market acceptance of those products, services, and systems. Such user confidence can be achieved through cooperation among conformity assessment bodies and/or accreditation bodies, resulting in mutual recognition and promotion of each participant's work across borders

- a) What is it? Conformity assessment is a process that verifies whether products, services, materials, processes, systems and personnel measure up to the requirements of standards, regulations or other specifications.
- b) Why is it important? Conformity assessment is important to suppliers, consumers, and regulators. It enables conscientious producers to distinguish their products from those made by disreputable ones. It provides consumers a means on which to rely in selecting products in the marketplace. In addition, it permits governments to determine compliance with the regulations for which they are responsible in protecting the public health and safety.
- c) Why is its importance increasing? Nations in the Asia-Pacific, the Americas, and Europe are entering into regional trade pacts to implement practices that facilitate trade. The World Trade Organization fosters international trade based on, among others, conformity assessment practices that balance regulated public protection and heightened industrial competition.
- d) Who benefits? Conformity assessment benefits manufacturers, service providers, users, consumers, and regulators and supports sustainable development.
- e) What activities are included? Conformity assessment may consist of any one of, some of, or all of the following: sampling and testing; inspection; certification; management system assessment (including HACCP and food safety management) and accreditation of the competence of those activities. A specific conformity assessment process may include one or more of these conformity assessment activities.
- f) What about mutual recognition? Conformity to and assessment based on, International Standards provide confidence and facilitate access to world markets. A mutual recognition agreement/arrangement minimizes duplication of re-testing and re-certification reduces cost and eliminates non-tariff barriers to

trade and market access delays.

- g) Why accreditation? With the large number of conformity assessment bodies, some may want to distinguish themselves from their competitors by having an impartial evaluation of their competence based upon internationally recognized criteria. Becoming accredited will improve their credibility. Accredited conformity assessment organizations can be expected to achieve at least a minimal level of performance with greater consistency in the services they offer and uniformity in the results they produce. Hence, accreditation allows for the recognition of the equivalence of services provided by competing organizations.
- h) How does it improve trade facilitation? When trading partners adhere to similar or equivalent conformity assessment procedures and requirements, or recognize each other's conformity assessment results, then the costly problem of discriminatory, non-transparent and unnecessary obstacles to trade will disappear.

Before going further, it is important to understand the various terms and definitions that are associated with conformity assessment. The definitions listed below are based on the international standard: ISO/IEC 17000 Conformity assessment — Vocabulary and general principles.

**Accreditation** -Third party attestation related to a conformity assessment body conveying a formal demonstration of its competence to carry out specific conformity assessment tasks. (These tasks include sampling and testing, inspection, certification and registration.)

**Certification** -Third party attestation related to products, processes, or persons that conveys assurance that specified requirements have been demonstrated.

**First, Second and Third Party** -The first party is generally the person or organization that provides the object, such as the supplier. The second party is usually a person or organization that has a user interest in the product, such as the customer. The third party is a person or body that is recognized as being independent of the person or organization that provides the object, as well as the user or customer of the object.

**Inspection** -Examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements

**Recognition** -Procedure used to provide formal notice that an accreditation body is competent to carry out specific tasks. These tasks include accreditation of testing laboratories and inspection, certification and registration bodies. A governmental recognition system is a set of one or more procedures used by a Federal agency to provide recognition.

Sampling – A provision of a sample of the object of conformity assessment according to a procedure

**Supplier's Declaration** - Procedure by which a first party or supplier conveys assurance that the object of conformity fulfils specified requirements

**Test** -Technical operation that consists of the determination of one or more characteristics of a given product, material, equipment, organism, person's qualification, physical phenomenon, process or service according to a specified technical procedure (test method).

**Testing** - Determination of one or more characteristics of an object of conformity according to a specified technical procedure (test method). Action of carrying out one or more tests.

**Test Method** - Specified technical procedure for performing a test.

In describing the importance of conformity assessment in the Global economy, ISO/IEC Standard 17011: 2004 Conformity Assessment - General requirements for accreditation bodies accrediting conformity assessment bodies' states:

"In the regulatory sector, government authorities implement laws covering the approval of products and services for reasons of safety, health, environmental protection, fraud prevention, or market fairness. In the voluntary sector, many lines of industry have within an economy as well as globally, set up systems for conformity assessment and approval, aimed at achieving a minimum technical level, enabling comparability, and also ensuring competition on equal terms.

A prerequisite for trade on equal terms is that any product or service, accepted formally in one economy, must also be free to circulate in other economies without having to undergo extensive re-testing, re-inspection, re-certification, etc. This should be the case regardless of whether the product or service falls wholly or partly under the regulatory sector."

ISO and other authoritative bodies state that conformity assessment includes:

"All activities concerned with determining directly or indirectly that relevant requirements in standards or regulations are fulfilled. Conformity assessment procedures provide a means of ensuring that the products, services, or systems produced or operated have the required characteristics, and that these characteristics are consistent from product to product, service to service, or system to system. Conformity assessment includes sampling and testing; inspection; certification; quality management system assessment (including HACCP and food safety management) and certification; and accreditation of the competence of those activities and recognition of an accreditation program's capability. A specific conformity assessment process may include one or more of these conformity assessment activities. While each of these activities is a distinct operation, they are closely interrelated. In addition, standards are interwoven into all aspects of these activities and can have a major impact on the outcome of a conformity assessment process. Conformity assessment activities form a vital link between standards (which define necessary characteristics or requirements for products) and the products themselves."

The Standards Council of Canada in its "National Conformity Assessment Principles for Canada" provides a more readily accessible description of conformity assessment"

"Examples of conformity assessment are all around us, every day, making our lives a little better, providing assurance that the products we use won't harm us, that their components will work and that manufacturers are effectively managing the impact of their activities on health, safety and the environment, and that services are being delivered in a consistent fashion. In essence, <u>conformity assessment</u> is the practice of determining whether a product, service or system meets the requirements of a particular standard. The "<u>standard</u>" being the document that describes the important features of that product, service, or system and, the essential requirements that it must meet. Internationally conformity assessment serves to reassure users and provide them with confidence in the integrity of products, services or systems. Conformity assessment helps ensure that products, services and systems meet the requirements of standards for consistency, compatibility, effectiveness, and safety. It is thus that standards and conformity assessment go hand-in-hand. Together they affect virtually every aspect of society and are vital to preserving and enhancing our quality of life.

Despite the simplicity of the definitions provided above, there are actually many facets and diverse activities that make up a national conformity assessment system. These activities include verifying the capabilities of those organizations that offer conformity assessment services, interacting with relevant international bodies, contributing to the reduction of potential barriers to trade and participating in the promotion of public health and safety.

## **Conformity Assessment and Trade Facilitation**

Harmonizing conformity assessment procedures around the world has far-reaching benefits for international trade in general. Agreements among nations or regions on the mutual acceptability of requirements, assessment methods, inspection or test results, etc., can all help to reduce or remove technical barriers to trade. These are procedures or requirements relating to importation and market access that vary from country to country and may bar a foreign product from entering a country.

The World Trade Organization's Agreement on Technical Barriers to Trade was established

to ensure that technical regulations and standards, and the procedures for assessing conformity with them, do not create unnecessary obstacles to international trade. The World Trade Organization has increasingly recognized that technical barriers to trade are one of the main hindrances to the free flow of goods and services.

The WTO TBT Agreement promotes the recognition of others' conformity assessment results as a way of reducing barriers to trade. It emphasizes that confidence in the continued reliability of conformity assessment results is a prerequisite to recognition of assessments.

The Agreement says that verifiable compliance thru accreditation for example with International Standards or Guides for the operation of testing, inspection and certification bodies is considered as an indication of adequate technical competence. Many of the relevant standards and guides are ISO/IEC publications produced under the auspices of CASCO, the ISO committee on conformity assessment.

ISO and the World Trade Organization work increasingly closely to ensure that the above benefits are realized. The importance of the International Standards and Guides on conformity assessment developed by CASCO to removing technical barriers to trade and facilitating the flow of goods and services is recognized by the World Trade Organization.

A practical example of trade facilitation is where a country exporting cheese to another country accompanies the product with a test report on, amongst other criteria, the fat content, to enable the importing country to classify the cheese according to its regulations on fat content. The importing country may accept the test report of the importing country with no qualifications based on its level of confidence in the conformity assessment procedures used and in place within the exporting country requires the product to be completely retested in the imported country. This would add time and cost to the whole process.

## The Principal Components of Conformity Assessment

## Certification

Certification is when a third party gives written assurance that a product (including services), process, personnel, organization or system conforms to specific requirements.

## **Product Certification.**

Many variants exist. For example, product certification may consist of initial testing of a product combined with assessment of its supplier's quality management system. This may be followed up by surveillance that takes into account the supplier's quality management system, plus testing of samples from the factory and/or the open market. Other product certification schemes comprise initial testing and surveillance testing, while still others rely on the testing of a sample product - this is known as type testing.

## Accreditation

Accreditation is a conformity assessment activity that is the internationally accepted system that recognizes the competence of testing and calibration laboratories, product certification bodies, management system certification bodies and inspection bodies. Accreditation establishes assurance of the quality of test data and provides assurance of the competence and independence of the conformity assessment . This minimizes duplication of re-testing and re-certification reduces cost and eliminates non-tariff barriers to trade and market access delays.

ISO/IEC 17000 Conformity Assessment — Vocabulary and General Principles defines accreditation as: "third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks". Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

Accreditation is carried out for testing and calibration laboratories, inspection bodies, product certification bodies and management system certification bodies. In some countries, accreditation is a legal requirement for conformity assessment bodies. ISO/ IEC 17011 establishes the general requirements for accreditation bodies accrediting conformity assessment bodies.

#### Testing

Testing is perhaps the most common form of conformity assessment. It can include activities like measurement and calibration.

#### Inspection

With the growth of world trade and increasing trade liberalization - as well as the rapid development of new manufacturing and distribution technologies - have come hundreds of third-party national and multinational inspection bodies. Inspection Bodies examine a huge range of products, materials, processes, work procedures, and services, in the private as well as the public sector; the overall aim is to reduce risk to the buyer, owner, user or consumer of the item being inspected.

The general requirements for the operation of various types of inspection bodies is described in the International Standard ISO/IEC 17020 General criteria for the operation of various types of bodies performing inspection.

Although metrology is not generally considered a conformity assessment activity, we could not have conformity assessment without metrology. We could not have laboratory accreditation, testing, product certification, etc.

## **Quality Management System Certification**

The most well known example of certification and the most popular standard in the world is ISO 9001. There are more than 1,138,000, organizations in 170 counties that have been

certified to ISO 9001. This standard as become the global benchmark for quality systems (QMS). The standard is a framework for providing assurance about the supplier's ability to satisfy quality requirements and ISO 9001 certification is often a market requirement for suppliers to participate in supply chains or to bid for procurement contracts. It is also widely used as a marketing argument by companies selling goods or services to consumers.

It should be noted that ISO itself does not perform the certification of quality management systems or issue certificates of conformity to these standards or any other standard. QMS certification is carried out independently of ISO by more than 800 certification bodies active internationally.

## Management System Standards<sup>4</sup>

In addition to the ISO 9000 family of QMS standards, ISO also producers a series of Management Systems standards.

ISO management system standards provide a model to follow when setting up and operating a management system. Like all our standards, they are the result of international, expert consensus and therefore offer the benefit of global management experience and good practice. These standards can be applied to any organization, large or small, whatever the product or service and regardless of the sector of activity.

## What is a Management System?

A management system describes the set of procedures an organization needs to follow in order to meet its objectives. In some small organizations, there may not be an official system, just "our way of doing things" that is mostly kept in the heads of the staff. But the larger the organization, the more likely that procedures need to be recorded to ensure everyone is clear on who does what. This process of systemizing how things are done is known as a management system.

To view additional information on the following Management systems, simply click on the specific photographs below:



ISO 50001 – Energy Management



ISO 14000 family -**Environmental Management** 

<sup>&</sup>lt;sup>4</sup> The information listed about Management Systems Standards is taken directly from the ISO web site, for additional information please click on the various photographs -this will take you to the specific ISO web site.



ISO 9000 family - Quality Management



ISO 22000- Food Safety Management



ISO/IEC 27001 – Information

Security Management



ISO 20121- Sustainable Events

Management

The experts of the many ISO Working Groups have developed PowerPoint presentations to highlight the main elements of the documents and show the differences with the former versions. The slides can be used by anyone doing a presentation or simply to learn about the new standard.

**ISO/TS 22003**, Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems. <u>PowerPoint</u> <u>presentation</u>

**ISO/IEC 17067**, Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes **PowerPoint presentation** 

**ISO/IEC 17020**, Conformity assessment - Requirements for the operation of various types of bodies performing inspection. <u>PowerPoint presentation</u>

**ISO/IEC 17065**, Conformity assessment - Requirements for bodies certifying products, processes and services. <u>PowerPoint presentation</u>

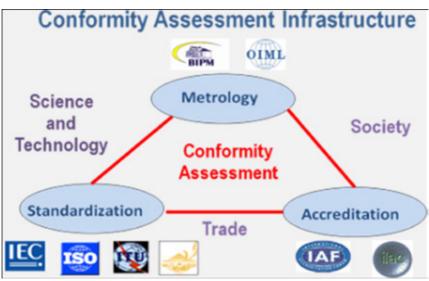
**ISO/IEC 17024,** Conformity assessment - General requirements for bodies operating certification of persons. <u>PowerPoint presentation</u>

**ISO/IEC 17021-1**, Conformity assessment - Requirements for bodies providing audit and certification of management systems - Part 1: Requirements. <u>PowerPoint presentation</u>

# Who is qualified to perform certification that will be accepted internationally without redundant testing and certification?

Certification bodies that have been accredited by an accreditation body are qualified to perform internationally accepted certification. Another option for recognizing certification bodies is through bilateral trade agreements. Accreditation is granted to the certification body as recognition that it meets and continues to meet international accepted criteria.

These criteria cover independence and technical competence and the capability of the staff to assess products or manufacturers in specific areas to a consistent level of quality. Accreditation and certification require one hundred percent compliance to the appropriate international standard and full compliance to rules and procedures established by the International Accreditation governing bodies, (i.e., the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC).



## A Conformity Assessment Model

## **ISO and Conformity Assessment**

Within ISO, CASCO the Committee on Conformity Assessment is responsible for developing both International Standards and Guides produced as joint ISO/IEC publications covering the various aspects of conformity assessment activities and the organizations that carry them out. CASCO is ISO's policy development committee on conformity assessment, reporting to the ISO Council. CASCO, as it is commonly referred to, was established in 1970 to study means of conformity assessment, prepare documents concerning the practice and operation of conformity assessment, and to promote their use.

CASCO comprises representatives from ISO members (national standards bodies), from the technical committees that develop ISO Standards, and from other international organizations. ISO/CASCO develops its documents jointly with the International Electrotechnical Commission (IEC).

Nine international organizations are liaison members of ISO/CASCO:

- The Bureau International des Poids et Mesures (BIPM)
- The International Accreditation Forum (IAF),
- The International Federation of Standards Users (IFAN)
- The International Federation of Inspection Agencies (IFIA),
- The International Certification Network (IQNet)
- The International Laboratory Accreditation Cooperation (ILAC)
- The International Personnel Certification Association (IPC)
- The Organisation Internationale de Métrologie Légale (OIML) and
- The International Union of Independent Laboratories (UILI).

CASCO Guides and Standards (click on the below to see summary of the standard guide)

#### ISO/IEC Guide 23:1982

Methods of indicating conformity with standards for third-party certification systems

#### ISO Guide 27:1983

Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity

#### ISO/IEC Guide 60:2004

Conformity assessment -- Code of good practice

#### ISO/IEC Guide 68:2002

Arrangements for the recognition and acceptance of conformity assessment results

#### ISO/IEC 17000:2004

Conformity assessment -- Vocabulary and general principles

#### ISO/IEC 17007:2009

Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment

#### ISO/IEC 17011:2017

Conformity assessment -- Requirements for accreditation bodies accrediting conformity assessment bodies

#### ISO/IEC 17020:2012

Conformity assessment -- Requirements for the operation of various types of bodies performing inspection

#### ISO/IEC 17021-1:2015

Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements

#### ISO/IEC 17021-2:2016

Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 2: Competence requirements for auditing and certification of environmental management systems

#### ISO/IEC 17021-3:2017

Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 3: Competence requirements for auditing and certification of quality management systems

#### ISO/IEC TS 17021-4:2013

Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 4: Competence requirements for auditing and certification of event sustainability management systems

#### ISO/IEC TS 17021-5:2014

Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 5: Competence requirements for auditing and certification of asset management systems

#### ISO/IEC TS 17021-6:2014

Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 6: Competence requirements for auditing and certification of business continuity management systems

#### ISO/IEC TS 17021-7:2014

Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 7: Competence requirements for auditing and certification of road traffic safety management systems

#### ISO/IEC TS 17021-9:2016

Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 9: Competence requirements for auditing and certification of anti-bribery management systems

#### ISO/IEC TS 17023:2013

Conformity assessment -- Guidelines for determining the duration of management system certification audits

#### ISO/IEC 17024:2012

Conformity assessment -- General requirements for bodies operating certification of persons

#### ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories

#### ISO/IEC TR 17026:2015

Conformity assessment -- Example of a certification scheme for tangible products

#### ISO/IEC TS 17027:2014

Conformity assessment -- Vocabulary related to competence of persons used for certification of persons

#### ISO/IEC TR 17028:2017

Conformity assessment -- Guidelines and examples of a certification scheme for services

#### ISO/IEC 17030:2003

Conformity assessment -- General requirements for third-party marks of conformity

#### ISO 17034:2016

General requirements for the competence of reference material producers

#### ISO/IEC 17040:2005

Conformity assessment -- General requirements for peer assessment of conformity assessment bodies and accreditation bodies

#### ISO/IEC 17043:2010

Conformity assessment -- General requirements for proficiency testing

#### ISO/IEC 17050-1:2004

Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements

#### ISO/IEC 17050-2:2004

Conformity assessment -- Supplier's declaration of conformity -- Part 2: Supporting documentation

#### ISO/IEC 17065:2012

Conformity assessment -- Requirements for bodies certifying products, processes and services

#### ISO/IEC 17067:2013

Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes



# The WTO-TBT provisions on conformity assessment procedures

The obligation to avoid unnecessary obstacles to trade applies also to conformity assessment procedures. An unnecessary obstacle to trade could result from stricter or more time-consuming procedures than are necessary to assess that a product complies with the domestic regulations of the importing country. Example, information requirements should be no greater than needed, and the sitting of facilities to carry

out conformity assessment, and the selection of samples should not create unnecessary inconvenience to the agents (Articles 5.2.3 and 5.2.6).

# The TBT Agreement states that:

- Conformity assessment procedures are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.
- Members shall ensure that results of conformity assessment procedures of other Members are accepted, even when those procedures differ from their own, provided those procedures offer an assurance of conformity with applicable technical regulations.
- Conformity Assessment procedures shall not be more strict or be applied more strictly than is necessary.
- To give the importing member country adequate confidence that products conform, taking account of the risks non-conformity would create.
- The Most Favored Nation and national treatment provisions also apply to conformity assessment procedures. Procedures for conformity assessment shall be applied to products imported from other WTO Members "in a manner no less favorable then that accorded to like products of national origin and to like products originating in any other country" (Article 5.1.1). This means that imported products must be treated equally with respect to any fees charged to assess their conformity with regulations. Similarly, Members must respect the confidentiality of information about the results of conformity assessment procedures for imported products in the same way as for domestic products so that commercial interests are protected.
- In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant guides or recommendations issued by international standardizing bodies exist or their completion is imminent, Members shall ensure that central government bodies use them, or the relevant parts of them, as a basis for their conformity assessment procedures, except where, as duly explained upon request, such guides or recommendations or relevant parts are inappropriate for the Members concerned, for, *inter alia*, such reasons as: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological or infrastructural problems.

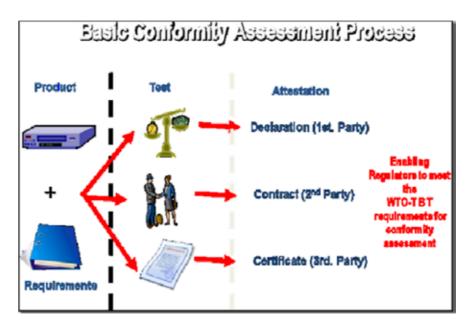
- With a view to harmonizing conformity assessment procedures on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of guides and recommendations for conformity assessment procedures.
- Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures.

# **Verifying Conformity**

There are three methods of verifying conformity that are recognized and accepted internationally. These are generally known as first, second and third party assessment.

- First party/self-assessment usually carried out by the supplier in the form
  of a supplier's self-declaration of conformity, this is widely used in commercial
  transactions. Integrity and reliability of the conformity assessment process is
  ensured mainly through a supplier's need to defend their brand reputation in
  competitive markets; liability legislation and provisions against false advertising
  etc. may impose additional disciplines. The procedures generally prove time,
  cost efficient, and do not require a producer to disclose information that may be
  considered commercially sensitive.
- <u>Second party assessment usually carried out by the buyer</u> within a manufacturer's premises through inspectors commissioned by customers. This tends to provide a more reliable indication, in particular in technically complex areas, of a product being manufactured in accordance with specified requirements.
- Third party assessment Usually carried out by an independent persons or bodies,

This is generally considered the strictest and best approach to conformity assessment. Third parties may be involved at all stages of ensuring compliance, individually or combined, of the verification process.



# **Regulatory – Market Requirements for Product Certification and Inspection**

With the growth of world trade and increasing trade liberalization as well as the rapid development of new manufacturing and distribution technologies, <u>hundreds of third-party national and multinational inspection bodies have been created</u>. These organizations examine a huge range of products, materials, installations, plants, processes, work procedures and services, in the private as well as the public sector, and report on such parameters as quality, fitness for use and continuing safety in operation.

# **Marks of Conformity**

Marks of conformity play a major role in consumer safety and international trade. Before 1990, product certification was fundamentally concerned with consumer safety. Products that display an authorized certification mark label indicated that they have passed certain safety, health, and environmental standards. Officials and consumers considered the mark a sign that the product was safe to use and that the interests of the consumer are protected. Marks on products or on information documents about products, processes, or services take many forms. It is important to distinguish between, on the one hand, those that identifies or describes products, processes or services and their characteristics, and, on the other hand, those that indicate compliance with a specification, code of practice, management system or product or service standard. The latter group is normally based on conformity assessment by an independent certification, accreditation or inspection body, or placed on the product by the supplier through self-declaration of compliance. Some examples not based on conformity assessment include the trademarks or brand names

of the supplier, nutritional labeling, safety or handling warnings, claims of the absence of particular ingredients (often related to some eco-labeling programs, or alerts to dietsensitive consumers), or details on the method of production. While it is possible for some of these labeling claims to be verified by conformity assessment, such labeling is usually done without a formal, structured conformity assessment process

Marks can convey powerful messages about a product or service, but do all users understand the messages?

- Does a mark attest to the safety of a particular product, or its impact on the environment, or its durability and performance?
- Does a mark represent a claim that the product or service supplier operates under a management system complying with particular standards or codes of practice?
- Who owns the mark appearing on a product or accompanying a service?
- Does it belong to the supplier or an independent conformity assessment body?
- Why do some products have many different marks?
- •
- Will the marks provide access for a product or service to a particular market, or will it result in acceptance of the product or service by a regulatory body?
- Where can a consumer find out more about the significance of a particular mark?
- Who is liable if a marked product fails?

# What a Conformity Mark Is?

- Manufacturer's apply and submit products for testing on a voluntary basis.
- The "Mark" indicates that the manufacturer has undergone all assessment procedures required for the product.
- Products that meet the essential technical requirements outlined by the appropriate certifying body are presumed to conform to the requirements of the defined standards.
- It indicates conformity to legal requirements.

# What a Product Conformity is Not?

• It is not intended to imply quality

# **General Requirements**

In order to obtain a conformity mark for a product, the manufacturer may be required to undergo a comprehensive product-testing program. Samples of the product are tested to national or internationally recognized safety standards and must be reasonably free from foreseeable risk of fire, electric shock, and related hazards. The certification body periodically and unannounced may visit each manufacturer's production facility to counter check that the products continue to meet product safety requirements. Even after the initial product, evaluation the certification body will check samples of the product repeatedly.

A product conformity Mark is not intended to include detailed technical information on the product, but there must be enough information to enable the inspector to trace the product back to the manufacturer or the authorized representative established in the exporting country. This detailed information should appear not next to the safety mark, but rather on the declaration (certificate) of conformity. This is sometimes known as the manufacturers declaration, which the manufacturer or authorized representative or importer must be able to provide at any time, along with the products technical file.

# The declaration of conformity must contain at a minimum the following:

- Product identification model, serial number, etc.
- Names and numbers of the standards used to verify compliance
- Name of independent testing laboratory authorized to perform conformity assessment.
- Signature of manufacturer or authorized representative
- The manufacturer's name and address.

Note: For CE Marking, the European Directives complied with, must be listed.

# **Brief Description of Product Certification Mark Organizations & Systems**



**United States Underwriters Laboratories Inc.** (UL) is an independent product safety certification organization that has been testing products and writing Standards for Safety for over a century. UL evaluates more than 19,000 types of products, components, materials and systems annually with 21 billion UL Marks appearing on 72,000 manufacturers' products each year.

UL's worldwide family of companies and network of service providers includes 62 laboratory, testing and certification facilities serving customers in 99 countries. UL is an architect of U.S. and Canada safety systems, having developed more than 1,200 safety standards, and actively participating in national and international standards development. UL is a National Certification Body (NCB) in the CB Scheme of the International Electrotechnical Commission's System (IEC) for Conformity Testing to Standards for Safety of Electrical Equipment (IECEE). This means that UL can assist in obtaining national certification in over 30 countries throughout the world. Under the CB Scheme UL can evaluate the laboratories information technology and business equipment to IEC 950, Medical devices to IEC 601, Laboratory and measuring equipment to IEC 1010 and issue a CB Test Certificate and CB Test Report that can be used to obtain national certifications in participating countries.



**Canada - The Canadian Standards Association (CSA)** is Canada's largest standards development and certification organization. An independent, non-government, not for profit association with headquarters in Toronto, CSA operates through a network of offices and partners across North America and

around the world. Established in 1919, CSA has long proven its leadership on matters of safety, performance and quality through the development of consensus standards as well as certification testing and registration services.

The CSA certification mark<u>is</u> recognized around the world as a symbol of safety and integrity. Now appearing on more than one billion products sold annually, the CSA mark indicates that a product or system has been evaluated under a formal system which includes examination, testing and inspection, and that it complies with applicable standards.

**The European Union** – The letters "CE" are the abbreviation of French phrase "Conformité Européene" which literately means "European Conformity". The term initially used was "CE Mark" and it was officially replaced by "CE Marking" in 1993. "CE Marking" is now used in all EU official

documents. CE Marking on a product is a manufacturer's declaration that the product complies with the regulations of the relevant European health, safety, and environmental protection legislation.

In return for fulfilling the CE-markings requirements, the manufacturer or its agents gets the opportunity to cover the entire European market using only one approval procedure for the topics covered in the various directives. The member states of the EC cannot refuse any product that has been CE-marked. CE Marking is the main tool employed in harmonizing European product standards.

The Mark is an important sales factor for any company entering the European market. Ideally, harmonization of standards is expected to reduce Technical Barriers to Trade (TBT) as manufacturers worldwide are required to meet a single standard, rather than make costly changes to a product to meet a variety of different national standards. The harmonization of standards is also expected to boost trade within the EU and with major trading partners outside Europe.

- a. CE Marking on a product is a manufacturer's declaration that the product complies with the laws of the relevant European health, safety and environmental protection legislations, in practice by many of the so-called Product Directives.
- b. Product Directives contains the "essential requirements" and/or "performance levels" and "Harmonized Standards" to which the products must conform. Harmonized Standards are the technical specifications (European Standards or Harmonization Documents) which are established by several European standards agencies such as CEN and CENELEC, etc.
- c. A CE marked product may be legally placed on the EU market.-
- d. CE Marking on a product ensures the free movement of the product within the EFTA & European Union (EU) single market.

e. Absence of CE Marking on a product permits the withdrawal of the nonconforming products by customs and enforcement/vigilance authorities.

Japanese Industrial Standard: In Japan, industrial standardization is promoted at the national, industry association, and company levels. Japanese Industrial Standards are voluntary national standards for industrial and mineral products. Various industry associations also establish voluntary standards for their specific needs. Many companies have a set of company standards some of which were adopted from JIS and or industry association standards.

One means of promoting industrial standardization is the JIS marking system. The JIS marking system is a voluntary certification system. Some 900 items with JIS product standards are designated for JIS marking. Factories manufacturing products that satisfy JIS are permitted to affix the JIS mark on their products if their company standards and practices of quality control are judged by the relevant minister to guarantee continuous production of products satisfying JIS.

The aims of JIS and the JIS marking system are to improve the quality of products, rationalize production, ensure fair and simplified trade, etc., through the establishment and dissemination of appropriate and rational standards. Some 8,200 JIS have been established for these purposes, and some 16,000 permissions (or approvals in the case of foreign factories) have been given to affix the JIS mark on their products.

In 1985, the government decided to internationalize Japan's economy and society (Action Program for Improved Market Access) to maintain the free trade system. One of the most important areas of the Action Program was related to standards and certification. The Action Program included ensuring transparency in the standards formulation process, and accepting foreign test data as much as possible under the existing certification systems. To facilitate exports to Japan, and in line with the 6<sup>th</sup> Long – Range Plan for the Promotion of Industrial Standardization, it was decided that foreign test data could be used for approving foreign factories under the JIS marking system.



**Denmark - DEMKO** was founded in 1928 by the Danish government with the brief to test the safety of electrical products before they were marketed and sold in Denmark. As Underwriters Laboratories Inc.'s (UL's) major subsidiary, DEMKO is part of the world's largest independent, product safety-testing authority.

In Denmark today, DEMKO is still the National Body for testing of electrical products to the appropriate European or International safety standards. Although, since 1978, electrical products need no longer be affixed with the D-Mark in order to be sold in Denmark, many Danish manufacturers and importers continue to choose to have DEMKO test and affix D-Marks to their products for reasons of consumer safety and European Product Liability legislation.

The D-Mark also provides international traders and exporters with fast access to the marks for other countries without further re-testing through DEMKO's full participation in the IECEE CB Scheme. DEMKO fully supports all categories of the global CB Scheme for the

mutual acceptance of test results between signatory countries, avoiding the need for multiple tests to obtain other safety marks world-wide. Thus, one set of tests at DEMKO to IEC Standards, with national differences, results in all international certifications required by clients. We call this - global trade facilitation!



**China - CCEE (China Commission for Conformity Certification of Electrical Equipment)** The China Commission for Conformity Certification of Electrical Equipment issues the CCEE Mark, also known as the Great Wall Mark. CCEE is a non-profit impartial organization established in 1984, to provide safety

certification for electrical products. The organization is made up of experts and representatives from various governmental agencies in China. CCEE is authorized by the China State Bureau of Quality and Technical Supervision as the Chinese National Certification Body (NCB) and is the Chinese representative in the CB Scheme. The CB Scheme was established by the International Electro-technical Committee for Conformity Testing to standards for Electrical Equipment (IECEE) and allows for mutual acceptance of test reports among participating safety organizations in certain product categories. The new Safety Mark is called CCC and replaced the previous CCIB and CCEE mark. The new system went into effect on May 1st, 2002 and grants existing CCIB and CCEE mark approved products at 12 months conversion period.



**United Kingdom – Kitemark** The Kitemark is the UK's most recognized product certification mark. It is visible proof that a product conforms to a published specification. When a product displays the Kite mark, the purchaser can be more confident that the product will be safe and fit for its intended purpose. Research shows that the more discerning purchasers will specifically look for the Kite mark

when choosing between products. In fact, 60% of UK customers are willing to pay a price premium for the peace of mind. The Kitemark<sup>®</sup> scheme can be developed using a publicly available specification. This specification can either be a BS, EN, ISO or a Trade Association specification. Based on this specification, BSI produces the formal scheme protocol that forms the backbone of the certification. Kitemark<sup>®</sup> schemes have been running since 1902 and now cover a wide variety of products and services, from electrical contractors to double glazed windows and from printed circuit boards to cattle tags.



Mexico - NOM In 1992, two new federal laws applicable to both domestic and imported products were implemented. The first law specifies consumer protection requirements, revising the system of Mexican standards. The second contains a set of regulations defining two new classes of standards - NOM, the Official Mexican Standards (Normas Oficiales Mexicanas) and

NM, additional Mexican Standards (Normas Mexicanas). For certain, specified classes of products, compliance to NOM is compulsory while compliance to NM is voluntary.



**Malaysia** –**SIRIM Mark** - The certification body in Malaysia, SIRIM QAS Sdn. Bhd. has achieved wide recognition nationally and internationally. The company provides a comprehensive range of certification, inspection and testing services that conforms to international standards and guides. Product Certification is offered to manufacturer who wishes to have its product certified to the requirements of a Malaysian or International Standard. Participation in this scheme is voluntary for most products. However, government regulatory authorities may require mandatory certification for certain products.

After successful application, the applicant is given a license to mark the certified product with the "MS" certification mark. However, for most regulated products, it is mandatory to affix the SIRIM labels on the products. The presence of the Label attests that the product meets quality requirements of the specified standard or specification. It also provides consumer an assurance of performance, safety and reliability as well as it demonstrates an effective system for production processes.



**Nordic Countries** - The Mark tells that the countries involved have uniform product standards. The license for the Nordic Mark may be applied for at each country's own certification organization. One application and one test laboratory's report on the compliance with the standard provide for the use of Swedish, Norwegian, Danish and

Finnish certification marks.



**Sweden -SIS Mark** - A product with an SIS label is type-approved and meets the production requirements given in the standard. The procedure of commenting on the degree, to which the product satisfies the standard, and carrying out a follow-up check, is often called certification. This gives the

buyer assurance that the product meets certain requirements and makes it easier for the seller to market the product.



**The IEC System** - For Conformity Testing to Standards for Safety of Electrical Equipment (referred to as the IECEE) is based on the use of specific IEC standards for electrical equipment. The CB Scheme is applicable to electrical equipment within the scope of IEC standards for safety, accepted for use in the IECEE. The Scheme becomes operative for such standards as soon as at

least three Member Bodies of the CCB, or the National Certification Bodies (NCBs) which they represent, have declared their recognition of CB Test Certificates.



**The European Committee for Standardization** – Keymark The CEN Certification Board controls conformity assessment issues, notably the CEN/CENELEC European Mark of conformity to European Standards. The Keymark, the single, pan-European safety mark for household appliances available to manufactures worldwide for access to Europe's appliance markets.

# **Certification and Accreditation**

# What is certification?

<u>Official definition</u> "A procedure by which a third party gives <u>written assurance</u> that a product, process, personnel, organization or service conforms to <u>specific requirements</u>.

#### What is Accreditation?

Accreditation is an internationally accepted system that recognizes the competence of testing and calibration laboratories, product certification bodies, quality management system certification bodies and inspection bodies.

Note: Accreditation" is a term which in the ISO 9001 context is sometimes wrongly used as a synonym for certification.

<u>Official definition</u> "A Procedure by which an <u>authoritative body</u> gives <u>formal recognition</u> that a body or person is competent to carry out a <u>specific task"</u>.

In accreditation, the specific task is defined a "Scope of Accreditation"

The Scope of Accreditation clearly establishes and identifies what the certification body is accredited to perform. The certification body cannot claim that they can provide accredited certification to anything that they are not accredited to perform.

# The Two Spheres of Accreditation



# **Certification and Accreditation**

In the context of ISO 9001 or ISO 14000, quality management systems, "certification" refers to the issuing of written assurance (the certificate) by an independent external body that it has audited a management system and verified that it conforms to the requirements specified in the standard.

In the ISO 9001 or ISO 14000 context, the difference between certification and registration is not significant and both are acceptable for general use. **"Certification" is the term most widely used** worldwide, although **registration** was sometimes used **in North America**, and the two are used interchangeably.

On the contrary, using **"accreditation"** as an interchangeable alternative for certification or registration is a mistake, because it **means something different**.

In the ISO 9001 or ISO 14000 context, accreditation refers to the **formal recognition** by a specialized body – an accreditation body – **that a certification body is competent** to carry out ISO 9001 or ISO 14000 certification in specified business sectors.

In simple terms, accreditation is like certification of the certification body. Certificates issued by accredited certification bodies may be perceived on the market as having **increased credibility**.

In the publication, "Laboratory Accreditation in Developing Economies" prepared by the United Nations Industrial Development Organization the following differences between accreditation and certification was cited:

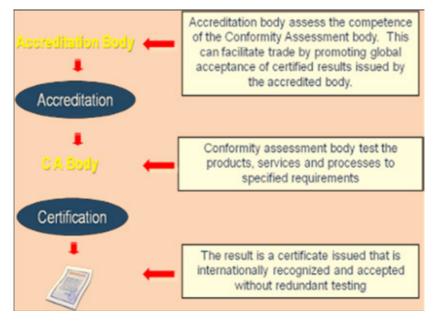
# Management System Certification

- Means compliance with a standard or specification (e.g. system or product standards)
- Use management system auditors who are certified by an independent body meeting international agreed criteria
- May be general in the scope of recognition
- Consider the total business

# Accreditation

- Is the recognition of specific competence and its scope is normally highly specific
- Evaluates people, skills and knowledge
- Users assessors who are recognized specialist in their fields
- Evaluates the supporting management system for a specific activity
- Involves practical tests as appropriate (proficiency testing and measurement audits)

# The Relationship between Certification and Accreditation





# The Recognition and Acceptance of Conformity Assessment

Mutual recognition of accreditation and certification systems facilitates access to international markets; provides the technical underpinning to international trade by promoting cross-border stakeholder confidence and acceptance of accredited test data and certified results. The present international concept is "Certified Once, Accepted Everywhere". This is made possible through a network of mutual recognition arrangements or agreements among international accreditation bodies. Accreditation is a

valuable and neutral tool that facilitates trade by enabling organizations to independently demonstrate their competence in an internationally acceptable manner. The accreditation community is structured at both the regional and international level. At the international level, the main organizations are the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF). These organizations together with the International Standards Organization (ISO) and the International Electrotechnical Organization I(EC) promote the use and acceptance of international standards and conformity assessment activities as part of national trade policies. The primary objective of conformity assessment is to give its users confidence that requirements applicable to products, services, systems, processes and materials have been met. One of the reasons why internationally traded goods and services are subject to repeated conformity

assessment controls is a lack of confidence by users of conformity assessment in one country regarding the competence of bodies carrying out conformity assessment activities in other countries.

# **International and Regional Accreditation Bodies**

#### International

ILAC	International Laboratory Accreditation Cooperation		
IAF	International Accreditation Forum	www.iaf.nu	

Regional

Africa	SADCA	Southern African Development Community Accreditation	www.sadca.org
	AFRAC	African Accreditation Cooperation	<u>http://www.</u> intra-afrac.com/
Americas	IAAC	InterAmerican Accreditation Cooperation	www.iaac.org. mx/English/ Index.php
Asia and Pacific	APLAC	Asia Pacific Laboratory Accreditation Cooperation	www.ianz.govt. nz/aplac
	PAC	Pacific Accreditation Cooperation	www.apec-pac. org
Europe	EA	European Cooperation for Accreditation	http://www. european- ccreditation.org/





# An Introduction to the International Laboratory Accreditation Cooperation (ILAC)

The International Laboratory Accreditation Cooperation is an international cooperation of laboratory and inspection accreditation bodies. ILAC first started as a conference in 1977 with the aim of developing international cooperation for facilitating trade by promotion

of the acceptance of accredited test and calibration results.

#### ILAC provides a focus for:

- Developing and harmonizing laboratory and inspection accreditation practices.
- Promoting laboratory and inspection accreditation to industry, governments, regulators and consumers.
- Assisting and supporting developing accreditation systems.
- Global recognition of laboratories and inspection facilities via the ILAC Arrangement, thus facilitating acceptance of test, inspection, and calibration data accompanying goods across national borders.

ILAC was formalized as cooperation in 1996 when 44 national bodies signed a Memorandum of Understanding (MOU) in Amsterdam. This MOU provided the basis for the further development of the Cooperation and the eventual establishment of a multilateral recognition agreement between ILAC member bodies.

The arrangement came into effect on 31 January 2001. The ILAC Arrangement provides

significant technical underpinning to international trade. The key to the Arrangement is the developing global network of accredited testing and calibration laboratories that are assessed and recognized as being competent by ILAC Arrangement signatory accreditation bodies. The signatories have, in turn, been peer-reviewed and shown to meet ILAC's criteria for competence. Now that the ILAC Arrangement is in place, governments can take advantage of it to further develop or enhance trade agreements. The ultimate aim is increased use and acceptance by industry as well as government of the results from accredited laboratories, including results from laboratories in other countries. In this way, the free-trade goal of product tested once and accepted everywhere can be realized.

Over 40 laboratory accreditation bodies have signed the multi-lateral, mutual recognition arrangement (the ILAC Arrangement) to promote the acceptance of accredited test and calibration data. This ILAC Arrangement provides significant technical underpinning to international trade.

As part of its global approach, ILAC also provides advice and assistance to countries that are in the process of developing their own laboratory accreditation systems. These developing systems are able to participate in ILAC as associate members, and access the resources of ILAC's more established members.

# How does the ILAC Mutual Recognition Arrangement Work?

This arrangement is based on the results of an intensive evaluation of each body carried out by peers and in accordance with the relevant rules and procedures contained in several ILAC publications. Each accreditation body signatory to the Arrangement agrees to abide by its terms and conditions and by the ILAC evaluation procedures and shall:

- Maintain conformance with the current version of ISO/IEC 17011, related ILAC guidance documents, and a few, but important, supplementary requirements, and
- Ensure that all accredited laboratories comply with ISO/IEC 17025 or ISO 15189 (for medical testing laboratories) and related ILAC policy and guidance documents.

The ILAC Arrangement builds upon existing or developing regional arrangements established around the world. The bodies participating in these regional arrangements are responsible for maintaining the necessary confidence in accreditation bodies from their region that are signatories to the ILAC Arrangement. Each recognized Regional Cooperation Body must abide by the procedures defined in ILAC requirements documents. The European cooperation for Accreditation (EA), the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the Inter-American Accreditation Cooperation (IAAC) are the current ILAC-recognized regions with acceptable mutual recognition arrangements (MRAs) and evaluation procedures. The Southern African Development Community in Accreditation (SADCA) is currently developing their MRA evaluation processes before requesting recognition and approval by ILAC. Regions being developed in other parts of the world are in their infancy, with one such region, the Central Asian Cooperation on Metrology Accreditation and Quality (CAC-MAS-Q) having recently joined ILAC. Accreditation bodies that cannot be affiliated with a recognized region may apply directly to ILAC for evaluation

and recognition.

The evaluation of an accreditation body to establish its qualifications to be a signatory involves a team of peers (generally senior staff of experienced accreditation bodies). Evaluations include time spent at the headquarters office of the applicant body to determine compliance with ISO/IEC 17011. Additionally, the evaluators witness the performance of the applicant's assessors during actual assessments/reassessments to determine if the laboratories are in compliance with ISO/IEC 17025 or ISO 15189 (for medical testing laboratories) and that, there is sufficient depth of examination to determine competence.



# An Introduction to the International Accreditation Forum (IAF)

The IAF is the world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of management systems, products, services,

personnel and other similar programs of conformity assessment. Its primary function is to develop a single worldwide program of conformity assessment which reduces risk for business and its customers by assuring them that accredited certificates may be relied upon. Accreditation assures users of the competence and impartiality of the body accredited.

The mission of IAF is to develop a single worldwide program of conformity assessment, which reduces risk for business and its customers by assuring them that accredited certificates may be relied upon. Accreditation assures users of the competence and impartiality of the body accredited. IAF members accredit certification or registration bodies that issue certificates attesting that an organization's management, products or personnel comply with a specified standard (called conformity assessment).

The primary purpose of IAF is two-fold. Firstly, to ensure that its accreditation body members only accredit bodies that are competent to do the work they undertake and are not subject to conflicts of interest. The second purpose of the IAF is to establish mutual recognition arrangements, known as Multilateral Recognition Arrangements (MLA), between its accreditation body members who reduce risk to business and its customers by ensuring that an accredited certificate may be relied upon anywhere in the world. The MLA contributes to the freedom of world trade by eliminating technical barriers to trade. IAF works to find the most effective way of achieving a single system that will allow companies with an accredited conformity assessment certificate in one part of the world, to have that certificate recognized elsewhere in the world. The objective of the MLA is that it will cover all accreditation bodies in all countries in the world, thus eliminating the need for suppliers of products or services to be certified in each country where they sell their products or services. Certified once - accepted everywhere.

# IAF has programs to:

Develop guidance, rules and procedures for the operation of accreditation, certification / registration and mutual recognition programs resulting in "Certified once, accepted

everywhere"

- Ensure that all accreditation body members operate to the highest standards of competence and probity, and only accredit bodies that have demonstrated that they are competent and impartial.
- Harmonize accreditation procedures and their implementation based on international standards and guides, and IAF guidance on their application.
- Develop guidance, rules and procedures for the operation of specific sector conformity assessment schemes to meet the needs of specific industries.
- Develop guidance, rules and procedures for the operation of compliance programs to satisfy regulatory or government requirements.
- Exchange information between accreditation bodies.
- Cooperate in the training of assessors and other personnel.
- Contribute to the work of ISO and other relevant international bodies.
- Liaise with the regional groups of accreditation bodies.
- Liaise with other relevant bodies such as ILAC, ISO and industry groups.
- Assist emerging accreditation bodies in low and medium income economies.

# IAF Multilateral Recognition Arrangement (MLA)

One purpose of the IAF MLA is to provide users in countries with accreditation bodies, that are IAF MLA members, assurance that equivalent certification/registration bodies in other countries operate to the same standard as those in their own country. International experts subject IAF MLA members to rigorous operational evaluations before and during their MLA membership to ensure that the high standards of the IAF are maintained.

Accreditations granted by IAF Multilateral Recognition Arrangement (MLA) accreditation body members are recognized worldwide based on their equivalent accreditation programs, therefore reducing costs and adding value to industry and consumers. Certificates in the fields of management systems, products, services, personnel and other similar programs of conformity assessment issued by bodies accredited by IAF MLA members are therefore relied upon in international trade. Without international standards, technical barriers to trade would result in increased costs for importers and consumers, reduced competition and different standards of a product or service.

#### **MLA Signatories**

IAF has granted Special Recognition to three Regional Accreditation Groups, the European co-operation for Accreditation (EA) the Inter Ammerican Accreditation cooperation (IAAC) and the Pacific Accreditation Cooperation (PAC), on the basis of the acceptance of the mutual recognition arrangements established within these organizations. Membership of the IAF MLA is recognized as being satisfied by membership of either the EA MLA the IAAC MLA and the PAC MLA and IAF members who are also signatories of these regional MLAs

are automatically accepted into the IAF MLA

## **International Best Practices – Conformity Assessment**

There is no one national conformity assessment system that is considered the best practice, but there are significant similarities in many national systems, which are based on a common set of principles aimed at facilitating trade. Beyond the trade sphere, standards and conformity assessment contribute to the basic infrastructure that underpins society. The health and safety of a nations citizens, environmental protection and good regulatory practice, are all supported by conformity assessment activities.

The following appear to be some of the basic principles that are utilized internationally:

- Conformity Assessment contributes to safeguarding public health, the environment.
- Conformity Assessment is based on international standards, agreements and protocols without undue national bias.
- Conformity Assessment upholds the WTO Agreement on Technical Barriers to Trade (TBT) and, avoids creating unnecessary obstacles to trade.
- Information regarding Conformity Assessment (CA) requirements, accreditation
  procedures, and results are made publicly available. Activities are conducted with
  due regard to confidentiality while ensuring full disclosure of CA results to regulatory
  authorities as required.
- Conformity Assessment is inherently voluntary. However, marketplace demands and/ or government regulation may mandate specific CA requirements.
- Conformity Assessment operates in an explicit, credible, and transparent manner and is accessible, equitable, and fair in its treatment of all users.

# The following are some of the major conformity assessment similarities used globally:

- Using qualified inspectors, auditors, and assessors. Technical competence, qualifications and integrity of inspectors, auditors, and assessors is a major requirement of implementing a successful conformity assessment system. Most inspectors and auditors have special training, experience, and international recognized credentials. The International Register of Certificated Auditors (IRCA) is the world's original and largest international certification body for auditors/ inspectors. Located in the United Kingdom, IRCA has certified more than 11,500 auditors/inspectors in over 105 countries. IRCA offers certification programs that recognize the competence of auditors/inspectors who audit quality, environmental, occupational health and safety, software development, information security and food safety management systems. IRCA also offers a wide range of training courses.
- WTO, and EU Compliance. Economies that have officially stated their intention to accede to the World Trade Organization (WTO) or the European Union (EU), and those who have already completed the accession process, have had to develop

new or revise laws governing mandatory inspection and certification to bring them into compliance with the with the WTO TBT Agreement and the SPS Agreement.

- Inspection and certification bodies use harmonized international standards, procedures and guides. The most commonly used standard for inspection bodies is ISO/IEC 17020 "General criteria for the operation of various types of bodies performing inspection".
- Laboratory Testing Activities. In order to ensure acceptability of test results performed by testing and calibration laboratories internationally, it is essential that the international standard determining the competence of the laboratories, i.e., ISO/IE: 17025, is implemented. Many countries have formally adopted this standard as a national standard, e.g., USA, Canada, Mexico, and EU members.
- Authoritative Agencies. The government agency normally responsibility for inspection and enforcement of conformity is determined by a mutual agreement between agencies and is usually based on the agencies primary responsibility. For example, agricultural products would be the responsibility of the Ministry of Agriculture; medical devices and drugs would be under the Ministry of Health; and aircraft, automobiles, etc. would be under the Ministry of Transportation. There are instances where there appears to be overlapping authority, and in these few cases, it is important that the agencies resolve who has the ultimate and sole authority.
- Adopting International Standards and Procedures. There is a major trend for developing countries and those translational economies to adopt international standards rather than developing their own standards.

#### **CONFORMITY ASSESSMENT REFERENCE INFORMATION**



# International Laboratory Accreditation Cooperation (ILAC) www.ilac.org

The International Laboratory Accreditation Cooperation is an international cooperation of laboratory and inspection accreditation bodies. ILAC produces a series of publication, all of which can be viewed and downloaded

via their website. Listed below a sample of the types of publications that are available.

- **Brochures** In addition to English, several of these documents, promoting laboratory accreditation, are available in Chinese, Japanese, Russian, French, and Spanish.
- Information Series (I Series) Information documents providing background or reference information on a range of topics.
- **Guidance Series (G Series)** For laboratories and accreditation bodies. These guidance documents provide information on the interpretation of accreditation criteria for

specific applications.

- **Procedural Series (P Series)** Procedural and policy publications for ILAC's operation, which form part of the criteria for ILAC MRA evaluations.
- Secretariat Series (S Series) Publications of the Secretariat, including the Rules, the Strategic Plan, Handling Complaints etc.
- ILAC-IAF Joint Publications (A Series) Publications jointly prepared by ILAC and IAF.



# International Accreditation Forum (IAF)

# www.iaf.nu

The International Accreditation Forum, Inc. (IAF) is the world association of Conformity Assessment Accreditation Bodies and

other bodies interested in conformity assessment in the fields of quality management systems, products, services, personnel. IAF produces a series of publication, all of which can be viewed and downloaded via their website. Listed below is a sample of the types of publications that are available.



# The South African National Accreditation System (SANAS)

# www.sanas.co.za/

The South African National Accreditation System (SANAS) is recognized by the South African Government as the single National Accreditation Body that gives formal recognition that Laboratories, Certification Bodies, Inspection Bodies, Proficiency Testing Scheme Providers and Good Laboratory Practice (GLP) test facilities are competent to carry out specific tasks.

SANAS is responsible for the accreditation of Certification bodies to ISO/IEC Guide 62 and 66 (and the IAF interpretation thereof), and laboratories (testing and calibration) to ISO/ IEC 17025. Inspection Bodies are accredited to ISO/IEC 17020 standards. GLP facilities are inspected for compliance to OECD GLP principles.



# Southern African Development Community Accreditation (SADAC)

#### www.sadca.org

SADCA, as the regional accreditation structure of SQAM (Standardization, Quality Assurance, Accreditation, and Metrology) was tasked with defining a suitable accreditation infrastructure, enabling organizations in the SADC Member States to access

accreditation services from internationally recognized National Accreditation Bodies within their countries, or to from a regional accreditation service, SADCAS.

The SADC Cooperation facilitates the creation of a pool of internationally acceptable

accredited laboratories and certification bodies (for personnel, products and systems, including quality and environmental management systems) in the Region, and provides Member States with accreditation as a tool for the removal of TBTs in both the voluntary and regulatory areas.



# African Accreditation Cooperation (AFRAC)

The African Accreditation Cooperation (AFRAC) is a cooperation of accreditation bodies, sub-regional accreditation cooperation's and stakeholders whose

objective is to facilitate trade and contribute to the protection of health, safety and the environment, in Africa and thereby improve Africa's competitiveness.

AFRAC was established in 2010 following 3 years of extensive consultative preparatory work including the development of its bylaws and project document. AFRAC held its first general assembly in September 2010 in Cairo Egypt, attended by representatives of the African Union, NEPAD, Regional Economic Co-operations, Accreditation Bodies in Africa and ILAC, IAF, EA, IAAC and APLAC and government representatives and other stakeholders.



#### Asia Pacific Laboratory Accreditation Cooperation (APLAC)

#### www.aplac.org

APLAC is a regional cooperation among accreditation bodies in the Asia Pacific region. Initially these accreditation bodies accredited testing and calibration laboratories. Increasingly, however, they now also

accredit inspection bodies, reference material producers, and other related services.

Part of APLAC's role is to provide a forum for the exchange of information among its members on accreditation and related issues, with the aim of continual improvement of accreditation services offered in the region. Through the APLAC, Mutual Recognition Arrangement (MRA) APLAC facilitates the acceptance by governments and industry in each economy of reports and certificates from facilities accredited by signatories to the MRA. APLAC is an ILAC-recognized region and most signatories to the APLAC MRA are also Members of ILAC (signatories to the global ILAC Arrangement). As a Specialist Regional Body recognized by the Asia Pacific Economic Cooperation (APEC) Sub-Committee on Standards and Conference (SCSC), APLAC supports the trade facilitation and related activities of APEC.



# The Pacific Accreditation Cooperation (PAC) www.apec-pac.org

The Pacific Accreditation Cooperation (PAC) is an association of accreditation bodies and other interested parties whose objective is

to facilitate trade and commerce among economies in the Asia Pacific region.

Its ultimate objective is the creation of a global system that grants international recognition of certification or registration of management systems, products, services, personnel and other programs of conformity assessment. The PAC promotes the international acceptance of accreditations granted by its accreditation body members, based on the equivalence of their accreditation programs.

The PAC operates within the framework of the International Accreditation Forum (IAF) and in cooperation with other regional groups of accreditation bodies around the world.

# PAC has programs to:

- Harmonize accreditation procedures and their implementation based on international standards and guides and IAF guidance on their application.
- Exchange information between accreditation bodies.
- Cooperate in the training of assessors and other personnel.
- Contribute to the work of ISO and other relevant bodies.
- Liaise with the IAF and the other regional groups of accreditation bodies and with other relevant bodies.

# The InterAmerican Accreditation Cooperation (IAAC)

# http://www.iaac.org.mx/English/Index.php

The InterAmerican Accreditation Cooperation is an association of accreditation bodies and other organizations interested in conformity assessment in the Americas. IAAC's mission is to promote cooperation among accreditation bodies and interested parties in the Americas, aiming at the development of conformity assessment structures to achieve the improvement of products, processes, and services

- IAAC plays a key role in the accreditation and conformity assessment infrastructure of the Americas by:
- Evaluating and recognizing the competence of accreditation bodies in the Americas, which, in turn, evaluate and recognize the competence of certification, registration and inspection bodies, and of testing and calibration laboratories that operate in the continent.
- Providing the institutional infrastructure required for the existence of multilateral recognition arrangements among accreditation bodies of the Americas.
- Developing the technical and institutional capabilities needed to create and operate a modern, reliable and efficient conformity assessment system in the Americas.
- Providing a forum in which consensus among regional accreditation bodies may be reached on important matters related to accreditation and conformity assessment issues.
- Facilitating cooperation among member bodies.

# The European Cooperation for Accreditation

# http://www.european-accreditation.org/

The European Co-operation for Accreditation was established in 1997 as a result from the merger of EAC, European Accreditation of Certification, and EAL, European Cooperation for Accreditation of Laboratories. EA is the European network of nationally recognized accreditation bodies based in the European geographical area.

In compliance with the European Commission's policy, EA members:

- Operate in complete independence from commercial motivations.
- Are authoritative and impartial bodies.
- Are not involved in conformity activities for which they accredit other bodies.
- Can demonstrate a high level of competence through participation in the EA peer evaluation system.

The EA missions are:

- To ensure transparency of the operations (including assessments) and results of its members.
- To ensure common interpretation of the standards they use.
- To manage a peer evaluation system, consistent with the international practice EA as a region is a member of ILAC and IAF.
- To support and promote mutual recognition and acceptance of accredited conformity assessment services and results.

# HYPERLINK FOR CONFORMITY ASSESSMENT INFORMATION

# **Books, Publications and Compact Disks**



# **ISO and Conformity Assessment**

The four-page guide is published by ISO addresses:

- Why conformity assessment matters
- Who benefits from conformity assessment
- How ISO's work overcomes trade barriers
- What conformity assessment activities cover
- Conformity assessment and sustainability

This brochure is available free of charge and maybe downloaded from the ISO website www.iso.org



# National Conformity Assessment Principles for the United States

#### www.ansi.org/ncap

This 12-page document is published by the American National Standards Institute. The National Conformity Assessment Principles for the United States articulates the principles for U.S. conformity assessment activities that will allow consumers, buyers, sellers, regulators and other

interested parties to have confidence in the processes of providing conformity assessment, while avoiding the creation of unnecessary barriers to trade. An electronic version of this text is available online.



# ISO Guide to Good Practice - www.iso.org

This document was developed by ISO to assist regulators and market surveillance authorities. It is especially intended for developing regions, to design market surveillance systems that conform to modern good practice criteria and that make the best use of the "CASCO Toolbox" of International Standards and other deliverables that have been developed to support good regulatory practice. Click on the picture to view the document



# **ISO Document on Conformity Assessment for Standards writers** - Do's and don'ts – <u>www.ISO.org</u>

This document provides guidance to ISO technical committees and subcommittees on the drafting of documents specifying conformity assessment arrangements. A copy of this document is available from the ISO website free of charge.



# ISO - Building trust - The Conformity Assessment Toolbox

A comprehensive, user-friendly handbook covering all aspects of conformity assessment and its role in international trade, and will be useful for business managers, regulators and consumer representatives. It is the latest in a series of joint publications issued by ISO and UNIDO.

A copy of this document can be downloaded from; http://www. iso.org/iso/publication\_item.html?pid=PUB100230

# ILAC Promotional Brochures - <u>www.llac.org</u>

ILAC has created a series of promotional materials to promote awareness and understanding of accreditation all of which can be downloaded from the their web-site.



The series includes brochures on:

- The ILAC MRA
- Accredited Laboratories, Inspection Bodies and Reference Material Producers
- Specifying Accreditation

In addition ILAC offers a series of documents that are available for download

- <u>Guidance Documents (G Series)</u>
- Policy Documents (P Series)
- Rules Documents (R Series)
- Joint ILAC / IAF Documents (A Series)



# IAF Reference Documents and guides

IAF publishes a series of documents and guides for the use of accreditation bodies when accrediting certification/registration bodies to assure that they also operate their programs in a consistent and equivalent manner. IAF Guidance documents are not intended to establish, interpret, subtract from or add to the requirements of any ISO/IEC Guide but simply to assure consistent application of those Guides.

**Copies of all published IAF documents and Guides are listed below.** -These Publications are available and can be downloaded free of charge for their IAF web-site website, simply click on the highlighted document title below. The publications section provides information on IAF publications and Auditing Practices Groups. The publications include:

<u>Policy Documents (PL Series</u>): IAF Policy documents set out the policies, including governance requirements that IAF members are expected to follow as well as statements of the IAF viewpoint on current issues.

<u>Multilateral Recognition Arrangement (MLA) Documents - (ML Series</u>): The primary purpose of IAF is to establish Multilateral Recognition Arrangements (MLA) between its accreditation body members in order to contribute to the freedom of world trade by eliminating technical barriers to trade.

<u>IAF Guidance Documents (GD Series</u>): IAF also publishes Guidance for the use of accreditation bodies when accrediting certification/registration bodies to assure that they also operate their programs in a consistent and equivalent manner.

<u>IAF Informative Documents (ID Series</u>): IAF Informative Documents reflect the consensus of IAF members on this subject and are intended to support the consistent application of requirements.

<u>IAF Mandatory Documents (MD Series</u>): IAF publishes Mandatory Documents which are required to be used by accreditation bodies when accrediting certification/registration bodies to assure that they operate their programs in a consistent and equivalent manner.

<u>Procedures Documents (PR Series</u>): IAF Procedures documents lay down the procedures to be followed in implementing the IAF program, spelling out the procedures and processes which must be followed in order to satisfy the IAF Objectives, Certificate of Incorporation and Bylaws.

<u>IAF-ILAC Joint Publications (A Series)</u>: Joint IAF and ILAC documents used for the evaluation of regions, unaffiliated bodies and inspection bodies.

<u>Accreditation Auditing Practices Group (AAPG) Documents</u>: The AAPG has prepared a number of papers and presentations on accreditation auditing practices, against the International Standards and Guides produced by ISO/CASCO.

ISO 9001 Auditing Practices Group (APG) Documents: The APG has prepared a number of papers and presentations on auditing QMSs.

<u>Documents for General Information</u>: This page contains a number of IAF documents which are made available publicly for information to assist people interested in understanding IAF and its operations.

<u>Promotional Documents</u>: A range of resource materials promoting accreditation and accredited certification will be added to this page as they become available. These are for use by IAF members, their accredited certification bodies and other stakeholders interested in accreditation.



#### National Conformity Assessment Principles for Canada

#### www.scc.ca

Published by the Standards Council of Canada, this 12-page brochure focuses on the national benefits of standards and conformity assessment working together towards a better quality of life. Included in this document is a brief overview of the Canadian system, a list of the principles upon which it is founded and some of the most commonly used terms. For a copy of this brochure

contact, SCC or a copy of the complete document is in the conformity assessment folder on the Wafer Drive.

# THE MOZANBIQUE NATIONAL QUALITY INFRASTRUCTURE

# The Instituto Nacional de Normalização e Qualidade

Law Decree 02/93 of the Council of Ministers, under the Ministry of Industry and Energy, established the Instituto Nacional de Normalização e Qualidade (INNOQ) on 24 March 1993. INNOQ is judicially and administratively an autonomous body that has been operating under the Ministry of Industry and Trade (MIC) since 2000, and acts as the recognized central body responsible for defining and implementing quality policy and for coordinating all standardization and quality activities at national level.

Section

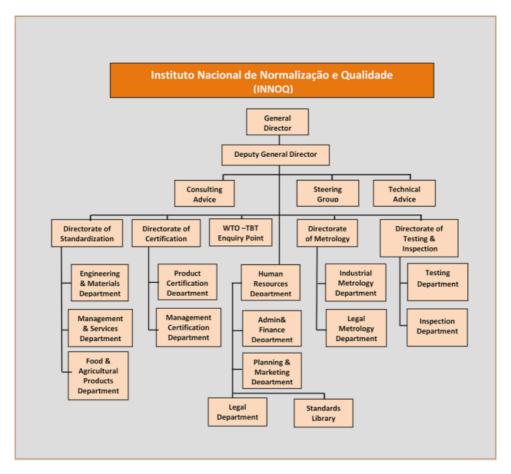


INNOQ was created with the main objective of promoting and coordinating the National Policy of Quality through the implementation of activities of Standardization, metrology, certification and quality management aimed at the development of the national economy.

INNOQ is a multi-disciplinary organization that conducts scientific and technological research and development activities, and is also responsible for the coordination of the Mozambique National Quality Infrastructure (NQI) for the industrial, economic and social development of the nation in order to improve the standard of living of the people of Mozambique.

The main functions of INNOQ include the development of national standards, maintaining the country's national measurement (metrology) system and to provide traceability of measure to the international system of units and disseminate this to the private sector and other government organizations via calibration services. INNOQ conducts Certification, Inspection and Legal Metrology activities. INNOQ's mission includes the aim to improve the conditions of industry, protect consumers and the environment, increase and facilitate domestic and international trade in order to improve the standard of living and strengthen the overall economy of the country.

INNOQ's technical Directorates are shown in the following chart; these are supported by a number of administrative, legal, marketing and training Departments.



# **ABOUT US**



#### The Stanvrds Directorate

The Standards Directorate develops Mozambique National Voluntary Standards (NM), adopts regional and international standards as National Standards and makes them available for Mozambique industry, government and other stakeholders. The Standards Directorate's primary functions include raising awareness and promoting the

importance of standards and the removal of technical barriers to trade and coordinating

and implementing the Mozambique National Quality Infrastructure as tools to improve market access, to transfer technology and to encourage good business practices and sustainable.

The Standards Directorate is the national standards body of the Republic of Mozambique with a view to accomplishing the following goals of standardization:

- increasing the safety level of products and processes,
- protecting human health and lives and environmental protection,
- promoting the quality of products, processes and services,
- improving production efficiency and safety and
- removing technical barriers to trade.
- The INNNOQ Standards Directorate is active member of the:
- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- SADCSTAN
- ASTM International

# The Role and Services of the Standards Directorate



The Standard Directorate is the source for stakeholders to obtain copies of National and international standards, simply contact us,

• The Standards Directorate provides information to Mozambique businesses and other government organizations on standards and related conformity assessment issues,

• INNOQ maintains a specialized library containing national and international standards and technical regulations, which business and government organizations can use to search data on standards and other documents in the field of standardization.

The specialized library stores and maintains a collection of standards and other normative documents with the accompanying catalogues, periodicals and databases, which you can use to search data on standards and other documents in the field of standardization. Users can get, free of charge, an insight into the standards library holdings, access to all available information, use of computers and professional assistance of the Library's staff in defining their requirements and searching.

The Library is open to the public – Monday to Friday 7:30 AM to 03:30 PM By appointment, please contact:

• Telephone: 258-213-44-600

- Fax: 258-213-44-610
- Address: Av. De Moçambique, Parcela 7168/D17 Bairro do Zimpelo Maputo, Mozambique To purchase standards, phone: 258-213-44-600

# TBT ENQUIRY POINT AND NOTIFICATION AUTHORITY

INNOQ has been appointed as the Enquiry Point and Notification Authority for the <u>World</u> <u>Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT)</u>

INNOQ is the Mozambique World Trade Organization's Technical Barriers to Trade Enquiry Point. The TBT Enquiry Point was established to provide assistance, collect and provide advisory services on receiving and responding to enquiries from domestic and foreign countries on standardizations, technical regulations and conformity assessment procedures that are used for products that are sold in Mozambique and technical regulations for products that are exported or imported to or from other WTO member countries.

# Functions of the National Enquiry Point (NEP)

- Notify WTO secretariat of the proposed Mozambique standards, technical regulations and conformity assessment procedures which may affect international trade;
- Handle all enquiries on standards, technical regulations and conformity assessment procedures concerned with TBT agreement form other WTO members
- Download notifications from WTO secretariat on technical regulations and conformity assessment procedures adopted or proposed by other WTO members
- Request information for interested parties in Mozambique from foreign enquiry points
- Provide foreign enquiry points upon request with copies of documents related to Mozambique notifications

# **Benefits of the NEP/Notification Authority**

The business community will benefit from the NEP/Notification Authority in the following manner:

- Identify standards, technical regulations and conformity assessment procedures applicable to products in target markets
- Improve competitiveness in local markets
- Give opportunity to comment on technical regulations that may affect trade
- Promote trade facilitation by providing national exporters and importers with information on technical requirements from WTO member countries

#### **INFORMATION RESOURCES AT THE NEP**

The Mozambique National Enquiry Point maintains a collection of standards, technical regulations and laws and related documents issued by international standards organizations, such as the International Organization for standardization (ISO), the International Electrotechnical Commission (IEC), the Food and Agriculture Organization (FAO) and World Health Organization (WHO), the International Organization for Legal Metrology (OIML), ASTM International (ASTM).

As the focal point of National Enquiry Point of Mozambique, INNOQ is enhancing and application of standards, technical regulations and conformity assessment procedures in line with the requirement of the World Trade Organization (WTO) agreement on Technical Barrier to trade with the cooperation of trade related ministries. INNOQ is fulfilling the tasks of the National Enquiry Point as regards the information exchange procedures and distribution of related documents required by respective WTO Agreements in regard to drafts of obligatory regulations and measures which could possibly create on obstacle to international trade and performing following activities:

- Any technical regulations adopted or proposed within its territory
- Any standards adopted or proposed within its territory
- Any conformity assessment procedures, or proposed conformity assessment procedures, which are operated within its
- The membership and participation of the Member, or of relevant central or local government bodies within its territory, in international and regional standardizing bodies and conformity assessment systems

More detailed information Can be obtained from Method of Enquiry: Enquiries should be submitted to the Enquiry Point by downloading from INNOQ's Website <u>www.INNOQ.gov.</u> <u>mz</u> or by fax at: 258-213-3344-610 or mail.

The enquiry point should provide answers in writing within 30 days of receiving the enquiry forms (according to the date shown on the post or the time the fax is received). Under special circumstances, it may give its answers and reasons for the delay in writing in 45 days.

#### The Mozambique Metrology Directorate

The Mozambique Metrology Directorate is the organization designated by law to develop, maintain and disseminate the national measurement standards of Mozambique to industry and Government. This is to ensure uniformity of measurement and their traceability to the international System on Units (SI) throughout the country.

#### **Mission and Vision of the Metrology Directorate**

To promote and support an integrated national measurement system that insures that measurements made in Mozambique are accurate, reliable and will be recognized by the international metrology community.

# The Role and Functions of the Metrology Directorate



- Provides calibration services to industry and other Government organizations;
- Establishing the national measurement system of units and participation in international metrology activities;
- Establishing and maintaining traceability of measurement to the SI;
- Disseminating the legal units of measurements to all sectors in the country;
- Providing education, training and consultancy in metrology to all stakeholders. INNOQ has the responsibility of maintaining the nation's measurements standards and to disseminate them through calibrations services to industry and government laboratories.

The Metrology Directorate has the basic equipment and instrumentation to serve as the highest order National Measurement Standards. Currently, the Metrology Directorate conducts measurement and calibration services for Mass, Temperature, Pressure, Dimensional, Electrical and Volume.

The mass, (weight) temperature, electrical, pressure and volume laboratories have been accredited in accordance the international standard ISO/IEC 17025 by the Portuguese Institute of Accreditation (IPAC), which is a signature to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement. This Arrangement minimizes the duplication of re-testing and re-certification, this reduces cost and eliminates non-tariff barriers to trade and market access delays, thus the accredited calibrations performed by the Metrology Directorate are recognized regionally and internationally.





The Metrology Directorate provides a host of verification and calibration services to industry and other stakeholders to insure that measurements made in factories are accurate and are traceable to our national measurement system.

INNOQ's Legal Metrology Unit's primary function is to insure that measurements related to trade, specifically in the area of weights and measures are accurate and fair. Carrying out this function, the Legal Metrology Unit conducts inspection and verification of measuring instruments in the market place and in its laboratories for:

- Verification od scales in the market place
- Verification of petroleum pumps
- Verification of Water supply meters
- Verification of the volume of petroleum tanker trucks
- Verification of the weight of Pre-Packaged goods in the market place

The regulated measurements include the fundamental trade measurements to ensure consumer protection and a level playing field for manufacturers who produce prepackaged goods and other measureable products, which will promote competition and fair trade.

#### The Mozambique Certification Directorate

The Certification Directorate performs certification of "Quality Management Systems" such as ISO 9001 and certification of products. Certification is a process by which the INNOQ evaluates whether given system or product complies with applicable standards

#### or regulations.

Benefits of Certification

- Customer's would know at a glance that your quality is acceptable and consistent;
- Increases consumer confidence in the product;
- Provides protection against competition from sub-standard products;
- Products would have less difficulty in getting accepted into new and foreign markets;
- ◆ Reduces the need for repetitive and uncoordinated testing activities by individual purchasers.

# **INNOQ Quality Management System Certification**

INNOQ has been accredited by the Portuguese Institute of Accreditation (IPAC) to perform ISO 9001 Quality Management System certification in Mozambique. IPAC is a signature of the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA). The purpose of the arrangement is to ensure mutual recognition of accredited certification between signatories to the MLA, and subsequently acceptance of accredited certification in many markets based on one accreditation.

Accreditations granted by IAF MLA signatories are recognized worldwide based on their equivalent accreditation programs, therefore reducing costs and adding value to business and consumers.

- A quality management system is a way of defining how an organization can meet the requirements of its customers and other stakeholders affected by its work.
- ISO 9001 is based on the idea of continual improvement.
- It does not specify what the objectives relating to "quality" or "meeting customer needs" should be, but requires organizations to define these objectives themselves and continually improve their processes in order to reach them.

The INNOQ certification team is ready to assist your organization through the certification process. INNOQ certification highlights and differentiates the company, its products and services from other competitors, as well as add value to the brand and facilitate introduction of new products on the market. Technically, ensures compliance, quality and safety, raising the level of products and services, reducing waist and improving the management of the production process.

The certification process is not complicated and any company can get it, demonstrate and ensure, through documents that your system and the production process is controlled and that their products are being manufactured in accordance to the rules.

# Why choose INNOQ to certify your organization of company?

**Experience:** INNOQ is an institution with a deep knowledge of the Mozambican market and that offers lower operating costs and extremely competitive prices. INNOQ has certified Mozambique organization's and private company's management system.

National Presence: We are present in Maputo and have focal points in all the provinces

through the Single Service counters (BAUs). Our national network allows our customers to benefit from a dual advantage: experience combined with knowledge of local situations and realities.

**Business knowledge:** Our success is based on a work focused on creating value to your business: more than 20 qualified auditors with the aim to provide certification services that create value to your business.

Contact us -see our website for additional information www.innoq.gov.mz

# **CERTIFICATION OF PRODUCTS**



Product certification is the way which INNOQ ensures that a product complies with the requirements specified in a standard or regulation. The certification of products can use various certification systems, as defined by international standards and conformity assessment organizations. INNOQ carries out certification of products according to several international and regional certification systems.



# Advantages of product certification

Product certification allows manufacturers to demonstrate a credible and impartial manner the quality, reliability, safety and performance of their products to the extent that;

- improves market acceptance;
- Makes the difference vis-à-vis competitors;
- Increases competitiveness through reducing the cost of non-quality;
- Facilitates access to new markets;
- Allows to show compliance with regulatory requirements;
- Supports users and consumers in their purchasing decisions.

#### The Testing and Inspection Directorate

This direction was established for carry out tests laboratory necessary for the supporting of certification and inspection of products in the scope of national production, as well as of imports.

Already operating in the quality control of fortified food imports in the light of food fortification with micronutrients regulation.

The functions of this direction extend to:

• Carry out laboratory tests necessary for the continuation of INNOQ activities;

- promote and coordinate inter-laboratory studies to improve the reproducibility and reliability of the tests carried out;
- Perform and participate in the study and development of new methods of analysis a;
- develop plans and projects for research and experimentation;
- to promote the acceptance of test data from other national and international laboratories;
- Inspect the compliance of INNOQ certified products in the market;
- Verify the conformity of the betting marks with products on the market, with established legal requirements;
- inspect, by designation, the conformity of products for which certification is required by technical regulations;
- Evaluate the maintenance of the technical aspects prescribed in the technical norms and regulations for which the certification was granted;
- Provide Inspection services in different fields in voluntary scope.

# **INNOQ's Training Department**

Currently, with globalization, organizations are faced with many challenges from technological evolution, expansion to new markets that leads to the need to keep updated, recycle knowledge and skills enhancing the developer and image of the organization. It is in this context that the INNOQ promotes vocational training in all provinces of the country directed at State institutions and the private sector, according to the needs required by the market in the areas of Metrology, certification, standardization, that allow the forming exercise with efficiency, effectiveness and success to your employment.

The INNOQ has trainers with more than 20 years of experience in matters related to quality, being the only institution in Mozambique that develops technical standards and operates in the area of Legal Metrology. INNOQ has a portfolio of renowned clients such as CFM, Aeroportos de Moçambique, Emose, Petromoc, CEDCIF, Gapi, EDM, Mozambican Society, Igepe Chairman, and other organizations and individuals.

# **Specialized Training Courses offered**

- Management systems: ISO 9001, NM ISO 14001, ISO/IEC 17025, OHSAS 18001, NM ISO 50001
- Metrology: metrology technique, verification and calibration of measuring instruments;
- Calibration and metrology training can help you and your staff become more knowledgeable in a wide variety of disciplines. Our instructors are experts who work in electrical calibration, temperature calibration, pressure and flow calibration, and who really want to help you learn the foundation and techniques of metrology that you can put to immediate use in your workplace.
- Standards and Technical Regulations.

See our website for a complete listing of training courses offered <u>formacao@innoq.gov.mz</u> or contact us at formacao@gmail.com

# **Location of Training**

At INNOQ's modern training facility located in the neighborhood of Zimpeto, or at customer sites, other provinces, districts and municipalities throughout Mozambique.

## **Course Registration**

Registrations can be carried out on the premises of INNOQ, located on AV. de Moçambique, neighborhood of Zimpeto, or by email address: <u>formacao@innoq.gov.mz</u> or formacao@

gmail.com

# **SUMMARY**

As stated in the introduction of this handbook, trade is the crucial driver for economic growth in developing countries and economies in transition; today it is virtually impossible to underestimate the importance of metrology, accreditation, standards, certification, and quality (NQI) in the development of economic policies. Understanding



the link between global trade, NQI and export competitiveness is at the forefront of trade policy. The removal of non-tariff barriers to trade and implementing a NQI system that is World Trade Organization (WTO) compliant and recognized internationally has become a central political task for many developing and transitional economies.

# **Countries must have an adequate National Quality Infrastructure in place.**



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