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# Standards, Metrology, Conformity Assessment and The TBT Agreement

**A Desk Top Reference Handbook**



*STAR – Vietnam*  
**Support for Trade Acceleration**



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## FOREWORD

Trade is crucial for economic growth in developing countries. However, to expand international trade, countries cannot underestimate the importance of adopting and implementing international recognized and accepted metrology, accreditation, standardization, and quality (MAS-Q) 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.

Globalization of trade and investment via multilateral institutions such as the World Trade Organization (WTO) as well as through regional and bilateral trade agreements that promulgate rules governing non-tariff trade barriers.

One of the main challenges facing the international trading system is the variation in certification, testing, inspection practices, and standards used by different countries. Unless trade partners use similar or equivalent standards and conformity assessment procedures and recognize each other's certification results, 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, and accreditation. Developing countries and countries in transition from a centralized to a market-oriented economy make up three quarters the WTO membership. For these members and those who wish to accede to the WTO and or the European Union, standards and conformity assessment is an important source of technological knowledge for developing their economy and raising their capability to export and compete in global markets.

Mutual recognition of accreditation and certification activities facilitates access to international markets and provides the technical underpinning to international trade by promoting cross-border stakeholder confidence and acceptance of accredited test data and certified results. This is made possible through a network of mutual recognition arrangements (MRAs) among international accreditation bodies.

The importance of standards and conformity assessment in both domestic and international trade was prominently noted in the 1994 Agreement on Technical Barriers to Trade (TBT Agreement). The agreement recognizes that harmonized standards and conformity assessment procedures can expedite or seriously hinder the free flow of goods in international commerce. 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 trade.

If on the one hand the use of international standards is a major requirement to accede to the WTO, on the other hand the transposition of European directives is part of the agenda to assist the national legislators committed to enter the EU Community Treaty. An opportunity to enter a single economic space, where goods, services, capital and labor can circulate freely, providing a foundation for prosperity and innovative instruments to remove barriers to trade.

Edward Nemeroff  
Senior MAS-Q Technical Advisor  
STAR Vietnam Project

## PREFACE & ACKNOWLEDGMENTS

The Vietnamese Directorate for Standard and Quality (STAMEQ) of the Ministry of Science and Technology (MOST) has requested technical assistance from the U.S. Agency for International Development (USAID) funded Support for Trade Acceleration (STAR) project to develop a handbook on metrology, standards, conformity assessment, and the TBT Agreement. This handbook is the result of that request.

The handbook reflects basic concepts developed by numerous national, regional, and international MAS-Q organizations such as ISO, IEC, the WTO, the World Bank, Codex, BIPM, ILAC, IAF, ITC, NIST, ANSI, SIM, and many others.

### Technical Development

This handbook was prepared and published by the co-operation between USAID funded STAR Vietnam Project, implemented by Development Alternatives Inc. (DAI) and Directorate for Standard and Quality of Vietnam (STAMEQ). Mr. Ed Nemeroff, Senior MAS-Q Technical Advisor and Consultant developed the parts of the handbook which relate to international experiences and practices on Technical Barrier to Trade Agreement (TBT Agreement), standards, metrology, conformity assessment (from part 1 to part 4 of the handbook). Mr. Le Quoc Bao, Director of the TBT Vietnam Office developed part 5 of the Handbook, which relates to standard, metrology, quality activities and the implementation of TBT Agreement in Vietnam.

### Direction, Guidance and Administrative Support

Mr. Dan Rathbun, Project Director, Mr. Phan Vinh Quang, Deputy Project Director, and Ms. Tran Thi Huong Giang, Legal Program Officer of the USAID STAR Vietnam Project provided guidance, comment, and administrative support for the production of this handbook.

Dr. Vu Van Dien, Deputy Director General of STAMEQ provided comment for this handbook.

This Handbook also benefited greatly from the guidance and support provided by Mr. David Brunell, Economic Growth Office Manager, of the USAID Mission in Hanoi.

### Technical Review

The following international experts participated in the technical review of this handbook, their contribution is noted with thanks and appreciation.

- ✓ Dr. Seton Bennett-Deputy Director, National Physical Laboratory (NPL)
- ✓ Dr. B. Stephen Carpenter-Director Office of International and Academic Affairs, National Institute of Standards and Technology, (NIST) (retired)
- ✓ Dr. Charles Ehrlich-National Institute of Standards and Technology, (NIST) Weights and Measures Division
- ✓ Professor, Dr. Mauricio Frota. Catholic University of Rio de Janeiro, Past President, Brazilian Metrology Society
- ✓ Mr. Paul Hanssen-President Workplace Training.
- ✓ Ms. Carol Hockert –President NCSL International (NCSLI)
- ✓ Dr. Charles Motzko, - President, C. A. MOTZKO & ASSOCIATES

- ✓ Dr. Richard Pettit-Editor NCSLI Measure Magazine, Sandia National Laboratories (retired)
- ✓ Mr. John Owen-Secretary, International Accreditation Forum (IAF)
- ✓ Ms. Dianna Rodrigues- Director, Antigua and Barbuda Bureau of Standards, Vice-Chairman CROSQ/Immediate Past President, Inter-American Metrology System (SIM)
- ✓ Mr. Peter Unger-President, American Association for Laboratory Accreditation(A2LA), Vice Chair, International Laboratory Accreditation Cooperation (ILAC)
- ✓ Dr. Svetlana Zhanaidarova-First Secretary, Central Asian Cooperation for MAS-Q (CAC MAS-Q)

The designations employed and the presentation of the material in this document does not imply the expression of any opinion whatsoever on the part of the United States Agency for International Development.

For questions concerning permission to copy and or translate this handbook in part or whole, contact:

Mr. Dan Rathbun, Project Director, STAR Vietnam  
 53 Quang Trung Street, 4th Floor, Hanoi, Socialist Republic of Vietnam  
 Tel. (84-4)3944-7391 Fax: (84-4)944-7390  
[www.starvietnam.org](http://www.starvietnam.org)

or

Mr. Edward Nemeroff,  
 MAS-Q Consulting  
 4255 SW Mallard Creek Trail  
 Palm City, Florida 34990  
 Telephone: 772-475-4176  
 e-mail: [ednemeroff@live.com](mailto:ednemeroff@live.com)

or

Mr. Le Quoc Bao  
 Director of TBT Vietnam Office  
 8 Hoang Quoc Viet Street, Hanoi, Vietnam  
 Telephone: (84-4)-37911599  
 Email: [quocbao@tbtvn.org](mailto:quocbao@tbtvn.org)

## 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 Mesures
CA	Conformity Assessment
CAB	Conformity Assessment Body
CAC	Codex Alimentarius Commission
CAC-MAS-Q	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 Institutions
CRM	Certified Reference Material
DEVCO	Committee on Developing Country Matters at 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	International Measurement Confederation
IRCA	International Register of Certified Auditors
ISO	International Organization for Standardization
ITC	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, 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
NCB	National Certification Body
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
OIML	International Organization for Legal Metrology
PAC	Pacific Accreditation Cooperation
QMS	Quality Management System
RMO	Regional Metrology Organization
SADCA	Southern African Development Community Accreditation
SADC MEL	SADC Cooperation in Legal Metrology
SADC MET	South-African Development Community Cooperation in Measurement Traceability
SANAS	South-African National Accreditation System
SI	International System of Units
SIM	InterAmerican Metrology System
SoA	Scope of Accreditation
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
SQAM	Standards, Quality, Accreditation and Metrology
TBT	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 PLAIN LANGUAGE

<b>Accreditation</b>	Accreditation is the internationally accepted procedure that recognizes the competence of testing and calibration laboratories, product certification bodies, quality system certification bodies and inspection bodies. Accreditation schemes minimize the duplication of re-testing and re-certification, reduces cost and eliminates non-tariff barriers to trade and market access delays.
<b>Calibration</b>	<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 that is traceable to national or international standards.
<b>Certification</b>	Based on the results from accredited laboratory or body 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.
<b>Conformity Assessment</b>	Conformity assessment procedures are technical activities such as testing, verification, inspection, certification, and accreditation, which confirms that products or processes fulfill the requirements laid down in regulations and standards.
<b>Inspection</b>	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.
<b>Legal Metrology</b>	The entirety of the legislative, administrative, and technical procedures established by, or by reference to public authorities, and implemented on their behalf in order to specify and to ensure, in a regulatory or contractual manner, the appropriate quality and credibility of measurements related to official controls, trade, health, safety, and the environment.
<b>Metrology</b>	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 physical or chemical reference of known values. Therefore, adequate methods for measuring the properties of products and services are fundamental to the quality assessment process.
<b>Mutual Recognition Arrangement</b>	Mutual Recognition Arrangements (MRA's or MLA's) are formal 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.
<b>National Metrology Institute</b>	A National Metrology Institute (NMI) is an institute designated by national decision to develop and maintain national measurement standards for one or more quantities.
<b>Product certification</b>	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 and 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.
<b>Quality Management System Certification</b>	The most well known examples are the certification of quality management systems and environmental management systems as conforming, respectively, to ISO 9000 and ISO 14000 standards. More than 560,000 organizations worldwide have been certified to an ISO 9000 and/or ISO 14000 standards
<b>Standard (Document)</b>	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.
<b>Standard (Measurement)</b>	An instrument, reference material, or measuring system intended to define or reproduce one or more values of a quantity to serve as a reference.
<b>TBT Agreement</b>	The World Trade Organizations Agreement on Technical Barriers to Trade (TBT) - sometimes referred to as the Standards Code - aims to reduce impediments to trade resulting from differences between national regulations, standards, and conformity assessment procedures.
<b>Technical Barrier to Trade</b>	Technical barriers to trade are non-tariff barriers that generally result from the preparation, adoption, and application of different technical regulations and conformity assessment procedures.
<b>Technical Regulation</b>	A technical regulation is a document issued by an authorized body that details product characteristics, production methods, including administrative provisions, compliance is mandatory.
<b>Testing</b>	Prior to making a product or service available for consummation, it needs to be tested to assure its compliance with specifications contained in the documentary standard detailing its quality.
<b>Traceability of Measurement</b>	The result of a measurement or the value of a standard that can be related to stated references, usually national or international measurement standards through an unbroken chain of comparisons; all having stated uncertainties.

## INTRODUCTION AND EXECUTIVE SUMMARY

The purpose of this handbook is to provide the reader with a general overview of the importance of metrology, accreditation, standardization (MAS-Q) as a tool to enhancing trade facilitation, market access and export competitiveness in accordance with the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement.

The handbook includes a basic introduction to the TBT agreement, 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 MAS-Q 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 and international MAS-Q organization, etc. A Hyperlink is available that will take the reader directly to a copy of the material or 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 the TBT agreement and MAS-Q concepts.

Note: Websites listed in the handbook can be accessed by simply clicking on the appropriate link. In addition, copies of reference material described in each section can be accessed by opening the section folders contained on the CD.

The handbook is divided into several sections:

**Prior to the Introductory Section** there is a list acronyms and abbreviations commonly associated with the TBT Agreement and MAS-Q. This is followed by a glossary of TBT and MAS-Q technical terms in plain language.

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

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

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

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

**Section Five** looks at the MAS-Q system in Vietnam; Vietnam became a member of the WTO in 2007, this section describes the countries commitment and obligations as it moves to integrate into the world's economy.

**Section Six** summaries the importance of MAS-Q as it relates to global trade.

## Handbook overview

For developing countries, understanding the link between global trade, MAS-Q 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 MAS-Q system that is WTO compliant and accepted internationally has become a central political task for 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 MAS-Q 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. Unless trading partners adhere to similar or equivalent procedures and requirements, and recognize each other's test 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, all that is the formal process that establishes trust. 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 International Organization for Standardization's (ISO) membership and similar numbers for 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.

## The TBT Agreement

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 barrier 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 agreement can be grouped into four sometimes-interrelated areas.

These groups of obligations are:

- Granting treatment to imports of a country that is no less favorable than that granted to local production (national treatment) or imports of other countries (most favored national treatment);
- Encouragement of members to rely on harmonized standards (reliance 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 TBT Agreement requires that conformity assessment procedures be prepared, adopted, and applied so as 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. Standards are agreed upon procedures, systems and methods, etc. that producers voluntarily meet to show that their products achieve a stated level of quality and or performance. When standards are adopted or used in regulations, they are termed technical regulations thus their use becomes mandatory requirements 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 and provides discipline and a sense of professionalism 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 (MRAs) among international accreditation bodies.

#### **The Code of Good Practice (Annex 3 of the TBT Agreement)**

The “Code of Good Practice” which establishes the principles for the preparation, adoption, and application of standards is open to acceptance by any standardizing body within the territory of a Member of the WTO, whether a central government body, a local government body, or a non-governmental body; to any governmental regional standardizing body one or more members of which are Members of the WTO; and to any non-governmental regional standardizing body one or more members of which are situated within the territory of a Member of the WTO.

Standards bodies that have accepted and are complying with the “Code’ are required to notify the ISO/IEC Information Center in Geneva of their acceptance. The obligations of Members with respect to compliance by their standardizing bodies concerning the provisions of the “Code of Good Practice” apply irrespective of whether or not the standardizing body has accepted the Code.

There are presently 153 members of the WTO and some 30 countries/separate Customs territories 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 (SPS). Compliance to these two agreements is mandatory as well as the acceptance of the WTO/ISO “Code of Good Practice” The TBT Agreement

also establishes the rules for the creation, publication, and enforcement of technical regulations.

### **All countries need an adequate MAS-Q infrastructure**

In order to realize the benefits that will be gained from being a member of the WTO, compliance to the WTO Agreement on Technical Barriers to Trade and the Application of Sanitary and Phytosanitary Measures, are necessary. To meet these conditions, a MAS-Q system must be 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 MAS-Q services, thus no competitors and the system (infrastructure) is in conflict with international principles of conformity assessment, thus eliminating their chances to achieve mutual recognition of accreditation and certification activities. 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.

The government's basic role concerning MAS-Q should include:

- In the area of Standardization: To support the development and growth of a market driven system based on a system of harmonized, voluntary consensus standards for products, processes, and services.
- In the area of Metrology: To realize, maintain and disseminate the national measurement units that are traceable to the International System (SI) of units.
- In the area of legal metrology: To develop and implement a weights and measures program that can ensure uniformity of measurement and support quantity measurements within the legal framework of the country.
- 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 mutual recognition: To enter into MAS-Q mutual recognition agreements with trading partners and international accreditation bodies.
- In the area of technical regulations: To use international standards as a template for developing technical regulations and to ensure that technical regulations promote trade by removing unnecessary barriers to trade without compromising public health and safety of the citizens of their country.
- In the area of infrastructure development: To ensure that adequate technical and financial resources are available for the implementation of a sound and internationally compliant MAS-Q system.

A successful MAS-Q program requires that nations develop standards and conformity assessment practices to ensure confidently and competently that products, processes, and services are developed and implemented according to the best international practices. The vast majority of the responsibility for confirming this is normally with the national metrology and standards institutes of the world.

The program should consist of a set of two parallel paths describing the technical and legal (regulatory) aspects.

1. Technical To Develop and implement a unified national MAS-Q 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 MAS-Q community.
2. Legal (regulatory) To strengthen the legal framework and harmonization process of national MAS-Q laws, standards, regulations, and policies to be consistent with international requirements.

## SECTION 1. TECHNICAL BARRIERS TO TRADE

### **1.1 Understanding the TBT Agreement**

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

### **1.1.2 From the Tokyo Round, 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. 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 Standards Code, as the Agreement was called, 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.

### **1.1.3 The Agreement on Technical Barriers to Trade 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 adjustment of production facilities to comply with the 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 barrier 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. 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.

#### **1.1.4 All Countries Need an Adequate MAS-Q Infrastructure**

In order to realize the benefits that will be gained from being a member of the WTO, members must comply with TBT Agreement and the Agreement on The Application of Sanitary and Phytosanitary Measures; In order to achieve this, countries must have an adequate MAS-Q infrastructure in place. In many developing countries and transitional economies, the national metrology and standards institutes were and in many cases still are providers of all MAS-Q functions. This restricts private sector competition and the system (infrastructure) is in conflict with international principles of conformity assessment, thus eliminating their chances to achieve mutual recognition of conformity assessment activities. These government organizations being regulatory and enforcement bodies creates a series of conflicts of interest and creates unnecessary barriers to trade.

A successful national MAS-Q program requires that nations develop technical standards and practices that ensure confidently and competently that products, processes, and services are developed and implemented according to the best international practices.

#### **1.1.5 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.

### **1.1.6 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 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.

### **1.1.7 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, exporters bear the cost, if any, of these procedures. Non-transparent and discriminatory conformity assessment procedures can become effective protectionist tools.

### **1.1.8 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 ie: domestic firms, in terms of adjustments costs, if confronted with new regulations.

**1.2 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*

**1.2.1 General Principles**

The TBT agreement contains two (2) basic principles:

Basic Principle 1: *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.

**1.2.2 What are the Sources of Technical Barriers to Trade?**

TBT's generally result from the 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 products; others, facing serious air-pollution problems might want to impose lower tolerable levels of automobile emissions, there are also dietary issues.

**1.2.3 TBT Provisions on Technical Regulations**

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

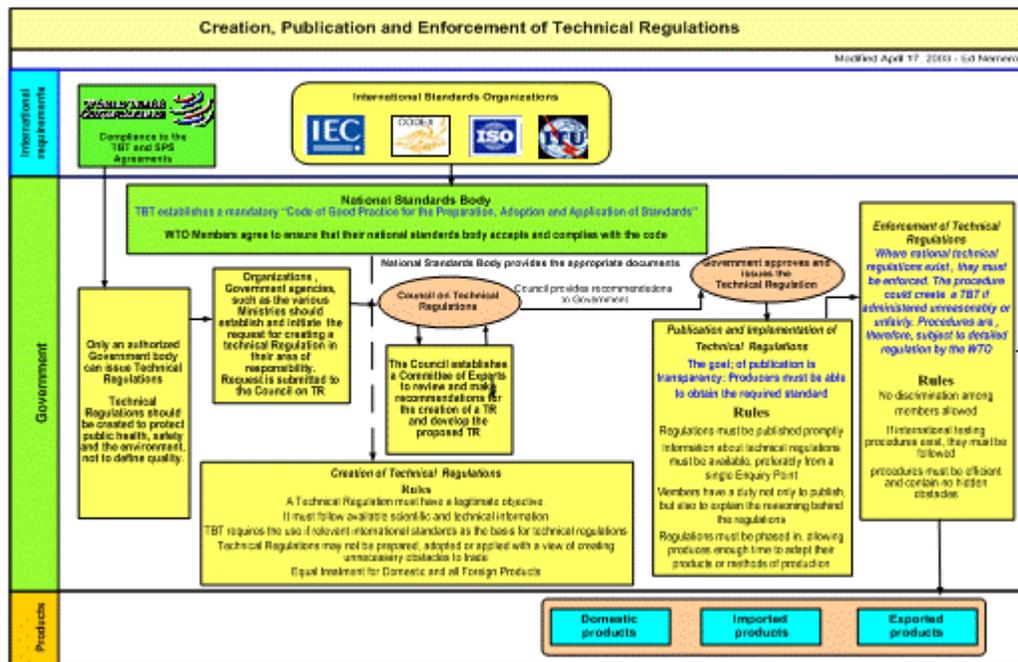
The TBT Agreement takes into account the existence of legitimate divergences of preference, income, geographical and other factors between countries. For these reasons, the Agreement accords to Members a high degree of flexibility in the preparation, adoption and application of their national technical 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”. (See Article 2.2).

#### **1.2.4 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 negotiations 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”.

#### **1.2.5 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.



### 1.2.6 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 (See Articles 5.2.3 and 5.2.6).

### 1.2.7 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 than 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.

## 1.2.8 Harmonization

### Producers' benefits

The arguments for harmonization of technical regulations 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.

## 1.2.9 Harmonization and Key International Organizations for Harmonization

For many years, technical experts have worked towards the international harmonization of standards. An important role in these efforts is played by the International Standardization Organization, the International Electrotechnical Commission (IEC), and the International Telecommunication Union (ITU). Their activities have had major impact on trade, especially for industrial products. Example, ISO has developed more than 16,500 international standards covering almost all technical fields.

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).

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”

## 1.2.10 Participation in International Standardizing Bodies

Widespread participation in international standardizing bodies 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 Article 2.6) and guides or recommendations for conformity assessment procedures (See Article 5.5).

### **1.2.11 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 (See Article 12.4). 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.

### **1.2.12 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. This approach, based on the European Community's 1985 "new approach" to standardization and regulators.

#### **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.

### **1.2.13 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 disagree 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, or accreditation bodies would agree to accept the results of one another's conformity assessment procedures, although these procedures might differ. This minimizes duplication of re-testing 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 by conformity assessment bodies with relevant guides or recommendations issued by international standardizing bodies can be regarded as an indication of adequate technical competence.

**1.2.14 Transparency - Notifications****Technical regulations 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).

**1.2.15 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 presentation of written comments on technical regulations, standards or conformity assessment procedures; and the name and address of the enquiry points established under Article 10.

**1.2.16 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.

### **1.2.17 Code of Good Practice**

The Code of Good Practice for the Preparation, Adoption and Application of Standards 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). Standardizing bodies that have accepted the Code must notify at least twice a year the existence of their work program, and where details of this program can be obtained (paragraph J). Notifications have to be sent either directly to the ISO/IEC Information Centre in Geneva, or to the national member of ISO/IEC or, preferably, to 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, including the ISO and Codex Alimentarius.

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.

### **1.2.18 Enquiry Points**

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 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 (See Article 10). Enquiry points are generally governmental agencies, but the relevant functions can also be

assigned to private agencies. 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.

### **1.2.19 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.

### **1.2.20 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.

## **1.3 THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES (SPS)**

### **Introduction and Definition of SPS measures**

The **Agreement on the Application of Sanitary and Phytosanitary 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 on the Application of Sanitary and Phytosanitary Measures** 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. And 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 which 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.

### 1.3.1 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 serviced by the same Division within the WTO Secretariat, i.e. the Agriculture and Commodities Division.

Although the TBT and SPS are complementary, they differ in their design.

#### **How do they differ?**

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

The TBT Agreements: 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) any measure designed to protect:
  - Animals or plants from pest and disease;
  - Humans and animals from food-borne risks;
  - 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
- ✓ Quality requirements for fresh food
- ✓ Packaging requirements for fresh food
- ✓ Packaging and labelling for dangerous chemicals and toxic substances

## 1.4 TBT REFERENCE INFORMATION AND HYPERLINK

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



From the World Trade Organization at [www.wto.org](http://www.wto.org)

### Official TBT documents

[http://www.wto.org/english/tratop\\_e/tbt\\_e/tbt\\_e.htm](http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm)

- The Agreement on Technical Barriers to Trade
- Technical explanation of WTO Agreement on Technical Barriers to Trade
- 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
  - WTO Manual on technical cooperation and training
  - 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

In addition, the WTO offers a series of publications for sale through the WTO on-line bookstore



### 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 CD

**TBT REFERENCE INFORMATION AND HYPERLINK**

**From the International Organization for Standards (ISO) [www.iso.org](http://www.iso.org)**

The following information is available free of charge via the Internet

- The Agreement on Technical Barriers to Trade (TBT)
- List of National Enquiry Points by country
- 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)



**International Trade Centre**  
UNCTAD/WTO

**From the International Trade Centre (ITC) for a slight fee. [www.intracen.org](http://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.
- International Standard-Setting Organizations and Country Reports on TBT and SPS
- 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

Note: The above publications are available from the ITC e-shop/Publications & Products. In addition, the ITC web site contains other WTO information of interest. The following publications and others are available free of charge.

- Road Map for Quality: Guidelines for the Review of the Standardization Accreditation, Metrology (SQAM) Infrastructure at National Level.
- Improving and maintaining Market Access through Standards and Conformity assessment.

## 1.5 SPS REFERENCE INFORMATION AND HYPERLINK TO THE WTO

The following SPS related material may be downloaded free of charge via the Internet.

**From the World Trade Organization at [www.wto.org](http://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"

"Understanding the SPS Agreement" (text only)

A more technical introduction

Interactive course: [Agreement on Sanitary and Phytosanitary Measures \(SPS\)](#)

Interactive course: [How to apply the transparency provisions of the SPS Agreement](#)

The mandate Browse or download the text of the SPS Agreement from the [legal texts gateway](#)

WTO Agreements series: SPS

Find decisions of WTO bodies concerning the SPS Agreement in the [Analytical Index](#) — Guide to WTO Law and Practice

Review of the operation and implementation of the Agreement of the application of sanitary and phytosanitary measures. [Committee Report of the Second Review adopted in 2005](#) (MS Word format; opens a new window).

Interactive course: SPS Handbook

[Links to member governments' SPS websites](#)

[New mentoring system available for national notification authorities and enquiry points](#)

Download the SPS notification formats [here](#).

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 [MS Word](#) (74 pages, 357KB, opens in a new window) or [pdf format](#) (74 pages, 278KB, opens in a new window). Published September 2002.

> [Interactive course: SPS Handbook](#)

## SECTION 2. 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.

### 2.1 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 (ie: 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 producers 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.

#### **2.1.1 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.”*

#### **2.1.2 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 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.

#### **2.1.3 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 Mandatory and form part of legislation.  
 Are the responsibility of the Government.  
 They address:  
Product Characteristics  
 and  
Administrative Procedures.

**Standards**  
 Are Voluntary in nature  
 Can be developed by a variety of bodies 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.

### 2.1.4 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 enforcement of 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 as 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 a adequate degree of confidence of compliance with its regulations
- If international conformity assessment procedures exist, they must be used.
- Procedures must be efficient and contain no hidden obstacles to trade
- Discrimination is not allowed

### 2.1.5 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 adopted to aim 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 that 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 include regulations 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 recycling of paper and plastic products, and levels of motor vehicle emissions.



## Prevention of Deceptive Practices



Most of these 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.

### 2.1.6 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).

The leading organizations that produce International Standards are ISO, IEC, ITU and CODEX. The scope of ISO covers standardization in all fields except electrical and electronic engineering, which are the responsibility of the IEC; telecommunications are covered by the ITU. The three organizations have a strong collaboration on standardization in the field of information technology. CODEX covers food and food safety.

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



Standards can be differentiated based on purpose. A basic standard has a broad ranging effect in a particular field, such as a standard for metal, which affects a range of products from cars down to screws.

- Terminology standards (or standardized nomenclature) define words permitting representatives of an industry or parties to a transaction to use a common, clearly understood language.
- Test and measurement standards define the methods to be used to assess the performance or other characteristics of a product or process.
- Product standards establish qualities or requirements for a product (or related group of products) to assure that it will serve its purpose effectively.
- Process standards specify requirements to be met by a process, such as an assembly line operation, in order to function effectively.
- Service standards, such as for repairing an automobile, establishes requirements to be met in order to achieve the designated purpose effectively.
- Interface standards, such as the point of connection between a telephone and a computer terminal, are concerned with the compatibility of products.
- Standards on data to be provided contain lists of characteristics for which values or other data are to be stated for specifying the product, process or service.

#### 2.1.7.1 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 developed internally.

- International standards are developed and promulgated by international governmental and non-governmental organizations, such as ISO, IEC, ITU.
- 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.

#### **2.1.7.2 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.

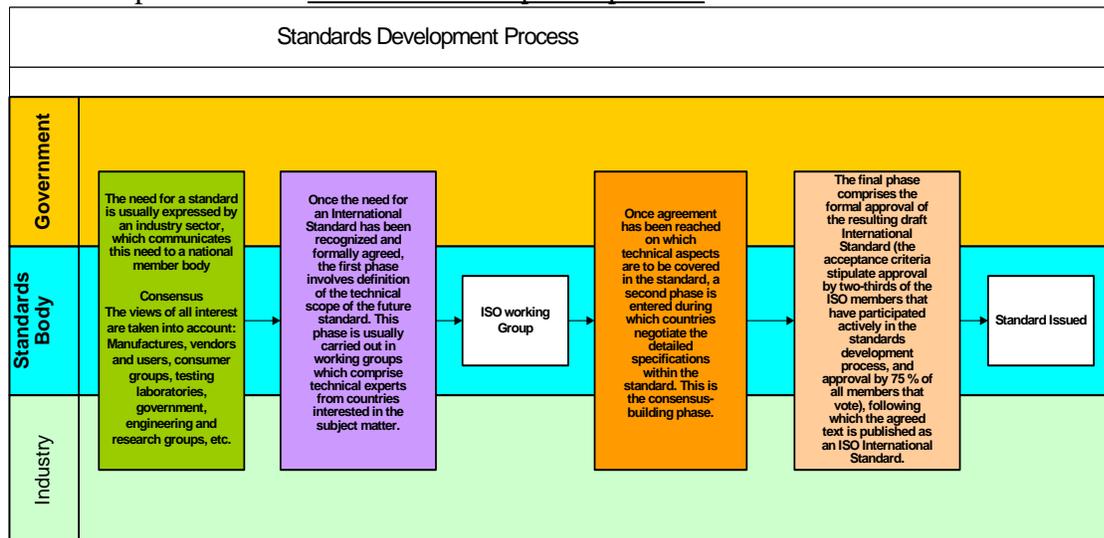
It is clear, then, that standards cover a broad range of types and serve a wide variety of purposes.

#### **2.1.7.3 How are International Standards developed?**

ISO standards and other 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 the standards development process



The need for a standard is usually expressed by an industry sector, which communicates its need to a national member body. The latter proposes the new work item to ISO as a whole. Once the need for an International Standard has been recognized and formally agreed, the first phase involves definition of the technical scope of the future standard. This phase is usually carried out in working groups that comprise technical experts from countries interested in the subject matter.

Once agreement has been reached on which technical aspects are to be covered in the standard, a second phase is entered during which countries negotiate the detailed specifications within the standard. This is the consensus-building phase. The final phase comprises the formal approval of the resulting draft International Standard (the acceptance criteria stipulate approval by two-thirds of the ISO members that have participated actively in the standards development process, and approval by 75 % of all members that vote), following which the agreed text is published as an ISO International Standard.

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, ISO has established the general rule that all ISO standards should be reviewed at intervals of not more than three years. On occasion, it is necessary to revise a standard earlier.

To date, ISO's work has resulted in some 16,500 International Standards, A list of all ISO standards appears in their catalog on the ISO Web site.

### 2.1.8 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.

### 2.1.9 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 European-wide 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" Directives (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 CE marking, 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 have 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.

<b>New Approach directives (directives providing for CE marking)</b>		
<b><i>Text of directive and amendments</i></b>	<b><i>Consolidated version of directive</i></b>	<b><i>Subject (short title of directive)</i></b> <b><i>Lists of references of harmonized standards and general information</i></b>
<u>2006/95/EC</u>		<u>Low Voltage</u>
<u>87/404/EEC</u> <u>90/488/EEC</u> <u>93/68/EEC</u>	<u>87/404/EEC</u>	<u>Simple Pressure Vessels</u>
<u>88/378/EEC</u> <u>93/68/EEC</u>	<u>88/378/EEC</u>	<u>Safety of toys</u>
<u>89/106/EEC</u> <u>93/68/EEC</u>	<u>89/106/EEC</u>	<u>Construction products</u>
<u>89/336/EEC</u> <u>92/31/EC</u> <u>93/68/EEC</u> <u>2004/108/EC</u>	<u>89/336/EEC</u>	<u>Electromagnetic compatibility (EMC)</u>
<u>98/37/EC</u> <u>98/79/EC</u> <u>2006/42/EC</u>	<u>98/37/EC</u>	<u>Machinery</u>
<u>89/686/EEC</u> <u>93/68/EEC</u> <u>93/95/EEC</u> <u>96/58/EC</u>	<u>89/686/EEC</u>	<u>Personal protective equipment (PPE)</u>
<u>90/384/EEC</u> <u>93/68/EEC</u>	<u>90/384/EEC</u>	<u>Non-automatic weighing instruments</u>
<u>90/385/EEC</u> <u>93/42/EEC</u> <u>93/68/EEC</u> <u>2007/47/EC</u>	<u>90/385/EEC</u>	<u>Active implantable medical devices</u>
<u>90/396/EEC</u> <u>93/68/EEC</u>	<u>90/396/EEC</u>	<u>Appliances burning gaseous fuels</u>
<u>92/42/EEC</u> <u>93/68/EEC</u> <u>2004/8/EC</u> <u>2005/32/EC</u>	<u>92/42/EEC</u>	<u>Efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels</u>
<u>93/15/EEC</u>		<u>Explosives for civil uses</u>

<u>93/42/EEC</u> <u>98/79/EC</u> <u>2000/70/EC</u> <u>2001/104/EC</u> <u>2007/47/EC</u>	<u>93/42/EEC</u>	<u>Medical devices</u>
<u>94/9/EC</u>		<u>Equipment explosive atmospheres (ATEX)</u>
<u>94/25/EC</u> <u>2003/44/EC</u>	<u>94/25/EC</u>	<u>Recreational craft</u>
<u>95/16/EC</u>		<u>Lifts</u>
<u>97/23/EC</u>		<u>Pressure equipment</u>
<u>98/79/EC</u>		<u>In vitro diagnostic medical devices</u>
<u>1999/5/EC</u>		<u>Radio Equipment and Telecommunications Terminal Equipment and the Mutual Recognition of their Conformity</u>
<u>2000/9/EC</u>		<u>Cableway installations designed to carry persons</u>
<u>2004/22/EC</u>		<u>Measuring instruments</u>

**Directives based on the principles of the New Approach or the Global Approach, but which do not provide for CE marking**

<b>Text of directive and amendments</b>	<b>Consolidated version of directive</b>	<b>Subject (short title of directive)</b> <b>Lists of references of harmonized standards and general information</b>
<u>94/62/EC</u> <u>2005/20/EC</u>	<u>94/62/EC</u>	<u>Packaging and packaging waste</u>
<u>96/48/EC</u> <u>2004/50/EC</u>	<u>96/48/EC</u>	<u>Interoperability of trans-European high-speed rail system</u>
<u>96/98/EC</u> <u>2002/84/EC</u>	<u>96/98/EC</u>	<u>Marine equipment</u>
<u>2001/16/EC</u> <u>2004/50/EC</u>	<u>2001/16/EC</u>	<u>Interoperability of trans-European conventional rail system</u>

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.

### **2.1.10 ASEAN Cooperation on Standards and Conformity Assessment -A program to Facilitate Trade In South East Asia**

Conformity Assessment of products or services generates results that determine their marketability. A supplier may not be able to sell a product or service because the results of a conformity assessment process such as testing and certification are not accepted by the prospective buyer or by regulatory authorities in the target market. This does not necessarily mean that the product or services have failed to meet a certain standard. Thus, more than standards themselves, it is often the duplicative testing procedures arising from different systems of conformity assessment in various countries have become serious barriers to trade.

Recognizing the contribution of 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.

Work on Mutual Recognition Arrangements (MRAs) has been accelerated. Mutual Recognition Arrangement for Electrical and Electronic was signed by the ASEAN Economic Ministers on 5 April 2002 in Bangkok, Thailand. To date, ten member countries have notified their participation either in acceptance of test report and/or product certification. Member countries have also agreed to work toward harmonization of regulatory regimes in electrical and electronic sector by 2010.

The Agreement on ASEAN Harmonized Cosmetic Regulatory Scheme was signed by the ASEAN Economic Ministers on 2 September 2003 in Phnom Penh. The first part of the Agreement is an MRA under which signatories are to recognize the product registration approval of any signatory in accordance with agreed rules and procedures. The second part is the ASEAN Cosmetic Directive, which lays down the requirements for cosmetic products to comply with all signatory countries.

For Pharmaceuticals, efforts to develop harmonization schemes of pharmaceutical regulations in ASEAN to facilitate trade in pharmaceuticals continued. An ASEAN

Common Technical Dossiers (ATCD), covering administrative data, quality, safety and efficacy and an ASEAN Common Technical Requirements (ATCRs), covering quality, safety and efficacy have been developed. The ACTD is the part of marketing authorization application dossier that is common to all ASEAN member countries while the ATCR is the set of written materials, intended to guide applicant(s) to prepare application dossiers in a way that is consistent with the expectations of all ASEAN Drug Regulatory Authorities. Series of guidelines for the implementation of the ATCR are being finalized.

The ASEAN Standards and Quality Bulletin is regularly published with a view to ensure dissemination of information and promote transparency on standards, technical regulations and conformity assessment procedures in ASEAN member countries.



### **Harmonization of Standards in ASEAN**

In 1997, 20 products were identified as a priority for standards harmonization in ASEAN by the AFTA Council. In recognition of clause 2.4 of the WTO Agreement on Technical Barriers to Trade, the harmonization of the priority products was carried out based on 59 ISO, IEC and ITU International Standards. The harmonization for the 20 priority products were completed in 2003.

To supplement this was the initiative in 1999 to harmonize standards on the electrical safety aspects of electrical products and on the subject of Electromagnetic Compatibility (EMC). 71 Safety and 10 EMC were identified and all Member Countries had completed this harmonization of these identified standards in July 2004.

### **Basic Principles of Harmonization**

During this harmonization exercise, the national standards bodies in ASEAN or similar bodies would need to adopt the International Standards, based on the requirements of ISO/IEC Guide 21, as their national standards. In the event they do not adopt any of the identified International Standards as their national standards, they would then accept the direct use of these International Standards.

For the list of ASEAN harmonized standards, please click here  
<http://www.aseansec.org/15564.htm>

### **2.1.11 PACIFIC AREA STANDARDS CONGRESS**

<http://www.pascnet.org/>

In 1972, standards body representatives from a number of Pacific Rim countries met in Honolulu, Hawaii, USA, to plan for and suggest a program leading to the development of a voluntary, independent organization of Pacific area national standards organizations. In 1973, the first meeting of the organization, which was named the PACIFIC AREA STANDARDS CONGRESS (PASC), was held in Honolulu.

The members of PASC have adopted by consensus 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.

### **Objectives of PASC**

- ✓ To exchange information and views between national standards bodies and among organizations interested in standardization and conformance and initiate necessary actions to help ensure that international standardization activities are properly coordinated on a consensus basis to meet world needs and foster international trade and commerce
- ✓ To provide a geographically convenient forum for the countries and territories of the Pacific area to develop recommendations for communication to the international standards bodies, particularly ISO and IEC
- ✓ To form a consultative liaison with International and Regional standards bodies to help them meet world needs in standardization through communication of recommendations of PASC members
- ✓ To provide a central site for papers and reports on related subjects which further the objectives of PASC
- ✓ To work with the Asia Pacific Economic Cooperation (APEC), relevant APEC Specialist Regional Bodies (SRBs), and multilateral agencies to support economic and technical infrastructure development and free trade in the region. This may extend to seeking financial assistance from those bodies. In this capacity, PASC serves as the APEC Specialist Regional Body for Standards
- ✓ To actively promote the benefits of standardization and conformance in the region to governments, industry and consumers
- ✓ To provide a source of information for members on standards and conformance issues in the region and globally and to promote the region at the international level
- ✓ To have members promote PASC and its activities within their countries
- ✓ To promote the benefits of PASC membership to other National Standards Bodies (NSBs)
- ✓ To determine the policy and technical standardization priorities of members and establish mechanisms to address items of greatest common interest to PASC
- ✓ To consider evolving strategic issues in international standardization and examine possible changes in the current international structures, approaches and organizations that may be necessary to meet future requirements
- ✓ To ensure that members contribute sufficient resources to allow for effective and efficient achievement of PASC's objectives
- ✓ To support and promote adherence to the provisions of relevant WTO Agreements, including the Agreement on Technical Barriers to Trade (TBT) and the Agreement on Sanitary and Phytosanitary Measures (SPS), among PASC member countries

### 2.1.12 The US Standards System

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. The U.S. marketplace is demand-driven, as is standards development in the United States. Individual standards typically are developed in response to specific concerns and constituent issues expressed by both industry and government. Public, formal standards development in the United States began more than 100 years ago as a private-sector enterprise, with strong government participation and support. Without any central responsibility, authority, or overly burdensome interference from government, a wide variety of U.S. voluntary standards activities have proceeded very successfully along sector-specific lines for over a century. Although U.S. decisions about standards authority and responsibilities were not made deliberately with a view to providing support for U.S. efforts in international trade, they work well to support the domestic and international goals of health, safety, and protection of the environment as well as specification of products, processes, and systems.

The American National Standards Institute (ANSI) a private-sector, non-profit organization founded in 1918 by several SDOs and U.S. Government representatives, 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 clearinghouse and 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, and it accredits U.S. domiciled SDOs that comply with the procedures. It also approves standards submitted by accredited SDOs, designating them as American National Standards, (ANS) indicating that they have followed the essential due process and consensus criteria defined by ANSI. However, regardless of the accreditation status of an SDO, standards only become American National Standards (ANS) when submitted to ANSI for approval as ANS. At last count, ANSI had accredited approximately 200 SDOs and listed about 10,000 of their standards as ANS in which Commerce may enhance or expand its activities on standards-related issues are recommended.

ANSI coordinates the development of ANS by accrediting standards development organizations (SDOs) to develop and publish ANS. ANSI works through its accredited standards development process to avoid overlap and duplication in proposed standards. Accreditation by ANSI signifies that the procedures used by the standards body in connection with the development of ANS meet the Institute's essential requirements for openness, balance, consensus, and due process.

ANSI is also 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) and to the Pan American Standards Commission (COPANT). 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.

### **The Role of the U.S. Government in Standards**

While the U.S. Government does not operate or finance a U.S. national standards body, individual agencies do participate actively in the development of voluntary consensus standards. Additionally, the Government also is directly concerned with setting and implementing standards through legislation, regulation, or contractual obligations for sale to government purchasers. In specific cases, agencies develop mandatory standards as part of technical regulations (e.g., automotive, aviation, consumer products). Public Law 104-113, the National Technology Transfer and Advancement Act of 1995, directs Federal agencies to use voluntary consensus standards to carry out policy objectives or activities determined by the agencies and departments, except when impracticable. Office of Management and Budget (OMB) Circular A119 guides agencies in this effort. Agencies also are directed to participate in the activities of voluntary consensus bodies to aid them in carrying out their standards-related responsibilities. Finally, the Act directs NIST to coordinate Federal, State, and local technical standards and conformity assessment activities with those of the private sector in order to reduce duplication and complexity.

From a policy perspective, and in keeping with Article 4.1 of the World Trade Organization's Technical Barriers to Trade (WTO TBT) Agreement, the U.S. Government also must ensure that central government standardizing bodies accept and comply with the Code of Good Practice.

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

Both the U.S. Government and private sector participate in international standards development in a variety of ways: through 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 185 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.

## 2.2 STANDARDS REFERENCE INFORMATION

### 2.2.1 International & Regional Standardization Organizations

#### International

ISO	International organization for Standardization	<a href="http://www.iso.org">www.iso.org</a>
CODEX	Codex Alimentarius Commission	<a href="http://www.codexalimentarius.net">www.codexalimentarius.net</a>
IEC	International Electrotechnical Commission	<a href="http://www.iec.ch">www.iec.ch</a>
ITU	International Telecommunication Union	<a href="http://www.itu.int/net">www.itu.int/net</a>

#### Regional

<b>Africa</b>	ARSO	African Regional Organization for Standardization	<a href="http://www.arso-oran.org">www.arso-oran.org</a>
<b>Americas</b>	COPANT	Pan American Standards Commission	<a href="http://www.copant.org">www.copant.org</a>
<b>Arab states</b>	AIDMO	Arab Industrial Development and Mining Organization	<a href="http://www.arifonet.org.ma">www.arifonet.org.ma</a>
<b>Asia and Pacific</b>	ACCSQ	ASEAN Consultative Committee for Standards and Quality	<a href="http://www.aseansec.org">www.aseansec.org</a>
	PASC	Pacific Area Standards Congress	<a href="http://www.pascnet.org">http://www.pascnet.org</a>
<b>CIS</b>	EASC	Euro Asian Council for Standardization, Metrology and Certification	<a href="http://www.easc.org">www.easc.org</a>
	CAC-MASQ	Central Asian Cooperation on MAS-Q	N/A
<b>Europe</b>	CEN	Comité Européen de Normalisation	<a href="http://www.cen.eu">www.cen.eu</a>
	CENELEC	Comité Européen de Normalisation Electrotechnique	<a href="http://www.cenelec.org">www.cenelec.org</a>
	ETSI	European Telecommunications Standards Institute	<a href="http://www.etsi.org">www.etsi.org</a>





## **The International Organization for Standardization** **[www.iso.org](http://www.iso.org)**

ISO is the world's largest (over 17,000 standards) developer and publisher of International Standards. ISO is a network of the national standards institutes of 157 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 License Agreement 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 ISO helps developing countries 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, Training-of-trainers programs, Fellowships, Training materials and reference publications, including e learning.



## **The International Electrotechnical Commission (IEC)** **[www.iec.ch](http://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 organized by subject area, with equivalent terms in German, Spanish and Swedish. Electropedia is also known as the International Electrotechnical Vocabulary online.



### **The International Telecommunications Union (ITU)**

**<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.

### **The World Standards Services Network (WSSN) [www.wssn.net](http://www.wssn.net)**



The WSSN is a network of web sites of worldwide standards Organizations. Through the web sites of its members, WSSN provides information on international, regional and national standardization and related activities and services. Many web sites of national, regional and international standards bodies linked to the WSSN allow you to search for, buy, and download standards on-line. Even if they do not have the complete standards on-line, you should be able to consult on-line catalogues and then contact your own NSB, or, failing that, an NSB in another country, or the Original standards-development organization to buy a hard copy of the standard you want.

FAO/WHO Food Standards

## **CODEX** alimentarius

### **CODEX Alimentarius Commission - [www.codexalimentarius.net](http://www.codexalimentarius.net)**

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
- Strategic Plan for 2008-2013
- List of official standards and copies of the standards



### **ASTM International**

[www.ASTM.org](http://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 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 120 countries. Participation in ASTM International is open to all with a material interest, anywhere in the world.

### **Regional Standards Organizations**



### **ASEAN Consultative Committee on Standards and Quality (ACCSQ)**

[www.aseansec.org](http://www.aseansec.org)

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 and European standardization**

[www.newapproach.eu](http://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: [www.eotc.be/newapproach](http://www.eotc.be/newapproach), 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. Also, 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.



## African Organization for Standardization (ARSO)

[www.arsso-oran.org](http://www.arsso-oran.org)

ARSO is an African inter-governmental standardization agency comprising national standards bodies (NSBs) of African countries. ARSO was established on 10 January 1977 by the Organization of African Unity (OAU) and the United Nations Economic Commission for Africa (UNECA). The responsibility of ARSO is the coordination of standardization in Africa in collaboration with various socio-economic stakeholders within and outside the continent.

The responsibility of ARSO is the coordination of standardization in Africa in collaboration with various socio-economic stakeholders within and outside the continent. ARSO's mission is to facilitate intra-African and global trade by promoting quality through co-ordination and harmonization of standards and conformity assessment in Africa.

Via the website, users may download in pdf format, free of charge the ARSO Standardization-Activities-Model Challenging The Challenges of Technical Barriers to Trade (TBT).

This document details the:

- Evolution of African Standardization Roadmap
- Harmonization of African member States/Socioeconomic sub-regional standards as African Standards (ARS)
- ARS are meant to reduce TBT, improve beyond-the border trade and facilitate market integration.



## Euro Asian Interstate Council for Standardization, Metrology, and Certification (EASC)

[www.easc.org](http://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 " (here and later in the text - the Agreement) to coordinate the works 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.



## Central Asian Cooperation on Metrology, Accreditation, Standardization and Quality (CAC-MAS-Q)

**Note: no website available at this time**

In July 2003, the (CAC-MAS-Q) was formally established with the assistance of international experts and facilitated by USAID's MAS-Q team in the region. This

organization was established at the request of the Gosstandards in the region to address MAS-Q issues that affected Central Asia.

Members of the cooperation are the four National metrology and standards institutes of Kazakhstan, Kyrgyzstan, Tajikistan, and Uzbekistan. As part of the CAC activities, a series of MAS-Q technical committees were formed. The main goal of the CAC is to promote harmonization of standards and conformity assessment procedures in the region and to become signatures of the ILAC and IAF MRA and MLA.

One of the primary goals of the CAC-MAS-Q was to align the National Metrology and Standards Institutes in the region to a level that will be internationally recognized, accepted and compliant with the WTO's, TBT and SPS Agreements and other international norms. The Afghanistan National Institute requested participation in the organization. This was unanimously approved by the executive committee.



### **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 (APEC SCSC)**

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 centre for promoting efficiency and competitive production in trade and services, through the process of standardization and the verification of quality.

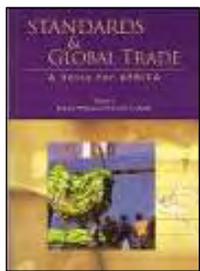
Located in Bridgetown, Barbados, CROSQ is the successor to the Caribbean Common Market Standards Council (CCMSC), and supports the CARICOM mandate in the expansion of intra-regional and extra-regional export of goods and services. CROSQ is mandated to represent the interest of the region in international 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.

In the execution of its mandate, CROSQ would serve as the Regional Accreditation Body, and as an enquiry, notification and information point for World Trade Organization (WTO) related matters on behalf of Member States, and would provide international representation for Member States on Standards related matters.

## 2.3 HYPERLINK FOR STANDARDS & TECHNICAL REGULATION REFERENCE INFORMATION

### Books, Manuals and Compact Disk

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 be obtained by contacting the Office of the publisher, World Bank, 1818 H Street NW Washington DC 20433 USA or e-mail [pubrights@worldbank.org](mailto:pubrights@worldbank.org)



#### The New and Global Approach

Produced by the European Commission, this multimedia CD interactive learning tool addresses the New Approach Directives and their compliance including conformity assessment. The CD is available free of charge from the EOTC at [www.eotc.be](http://www.eotc.be) or CEN at [www.cenorm.be](http://www.cenorm.be)



#### International Standards –Desk Reference

Written by Amy Zukerman and published by the American Management Association. This publication contains over 300 pages and addresses international and regional standards systems, quality and conformity assessment practices. Information on obtaining this book and its cost please contact AMACOM, a Division of the American Management Association 1601 Broadway, New York 10019, USA.



#### 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 [itcreg@intracen.org](mailto:itcreg@intracen.org). Internet [www.intracen.org](http://www.intracen.org)



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

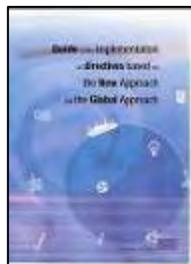
This 230-page book is produced by the International Trade Centre; this document is part of a workshop on the subject. For additional information contact ITC at 54-56 rue de Montbrillant, 1202 Geneva, Switzerland. e-Mail [itcreg@intracen.org](mailto:itcreg@intracen.org). Internet [www.intracen.org](http://www.intracen.org)



### **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](http://www.NIST.gov)



### **Guide to the Implementation of directives based on the NEW Approach and Global Approach**

Produced by the European Commission, this 118-page document can be downloaded in all 11 official EU languages at [www.europa.eu.int/comm/enterprise/newapproach/newapproach.htm](http://www.europa.eu.int/comm/enterprise/newapproach/newapproach.htm) or access the English version on the standards folder on the CD.

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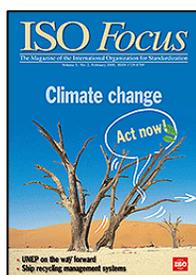
### **Quality Systems and Standards for a Competitive Edge**

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; telephone: 978-750-8400; fax: 978-750-4470; Internet: [www.copyright.com](http://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 CD.



### **ISO FOCUS – the ISO Magazine**

Available from ISO, this magazine features news and views on ISO's contribution to economic growth, environmental integrity, and societal equity through standards for technology dissemination, global interoperability, testing and conformity assessment, quality, health, safety, security and the environment. A subscription is available from ISO –for additional information contact ISO at [www.iso.org](http://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 CD.



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

[www.ansi.org](http://www.ansi.org) or [www.nist.gov](http://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.

But 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 CD.

### **The Economic Value of Standardization**

[www.scc.ca](http://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 CD..

## SECTION 3. METROLOGY

### 3.1 Metrology and Trade

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 expect. Importantly for developing countries, accurate and internationally accepted measurements allow market access for food and commodity exports. Accurate and precise measurements curbs the buyer's tendency to want more and the seller's tendency to give less.

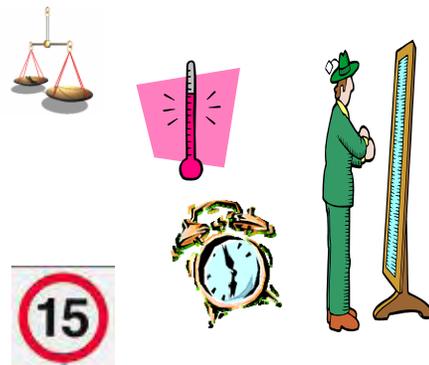
Technology innovation depends on accurate measurements. New ideas and products often can only be implemented if reliable measurement systems are in place. At the social level, protection of the environment requires that pollutants are precisely monitored. Patients receiving medical treatment need confidence 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 the International Organization for Standardization (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.

**3.1.1 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 cloth, and a dozen eggs.

In daily conversations, 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. But 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.”*

### **3.1.2 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 SI is built in such a way that only one unit is used for each kind of quantity. This makes the total number of units less and the system becomes easier to learn and use.



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

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.1960 - SI units Established

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, joule. The base and derived units form the coherent SI units.

### 3.1.3 The seven base units of the SI:

↙ <u>metre</u> –The unit of length	Symbol=m
------------------------------------	----------

The metre is the length of the path travelled by light in vacuum during a time interval of  $1/299\,792\,458$  of a second.

↙ <u>kilogram</u> –The unit of weight (Mass)	Symbol=Kg
--	-----------

The kilogram is the unit of mass; it is equal to the mass of the international prototype of the kilogram.

↙ <u>second</u> – The unit of time	Symbol=S
------------------------------------	----------

The second is the duration of  $9\,192\,631\,770$  periods of the radiation corresponding to the transition between the two hyperfine levels of the ground state of the cesium 133 atom.

↙ <u>ampere</u> –The unit of electricity	Symbol=A
--	----------

The ampere is that constant current which, if maintained in two straight parallel conductors of infinite length, of negligible circular cross-section, and placed 1 m apart in vacuum, would produce between these conductors a force equal to  $2 \times 10^{-7}$  Newton per meter of length.

↙ <u>kelvin</u> –The unit of temperature	Symbol=K
--	----------

The Kelvin, unit of thermodynamic temperature, is the fraction  $1/273.16$  of the thermodynamic temperature of the triple point of water.

↙ <u>mole</u> – The unit of the amount of substance	Symbol=Mol
---	------------

The mole is the amount of substance of a system which contains as many elementary entities as there are atoms in 0.012 kilogram of carbon 12.

↙ <u>candela</u> –The unit intensity of light	Symbol= Cd
---	------------

The candela is the luminous intensity, in a given direction, of a source that emits monochromatic radiation of frequency  $540 \times 10^{12}$  hertz and that has a radiant intensity in that direction of  $1/683$  watt per steradian.

History tells us that archeological finds show that very ancient civilizations had well-defined concepts of weighing and measuring. Trade, land division, and taxation, among others, must have required very soon the uniformity of measurements.

### 3.1.4 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 into 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 middle finger plus the width of the palm of the hand of the Pharaoh or King ruling at that time.

#### *The Royal Egyptian Cubit Papyrus*



#### *The Royal Egyptian Cubit Master*



The "Royal Cubit Master"<sup>(1)</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. Through the use of cubit sticks, they achieved an accuracy of 0.05%. In 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.

(1) *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 in June.1996.*

### 3.1.5 Metrology

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

- Scientific Metrology
- Legal Metrology
- Industrial Metrology.

#### 3.1.5.1 Scientific Metrology

Scientific Metrology in the field of national measurement standards is of primary importance for any state, 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 institution - 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 of units of measurement by scientific methods and
- The establishment of traceability chains in documenting the accuracy of a measurement.

#### 3.1.5.2 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.”*

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.

### 3.1.5.3 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.

### 3.1.6 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 (NMIs) 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 NMIs, 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 NMI’s participation in bilateral agreements, or in regional multilateral agreements and organizations (RMOs). 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 (CMCs) 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).”*

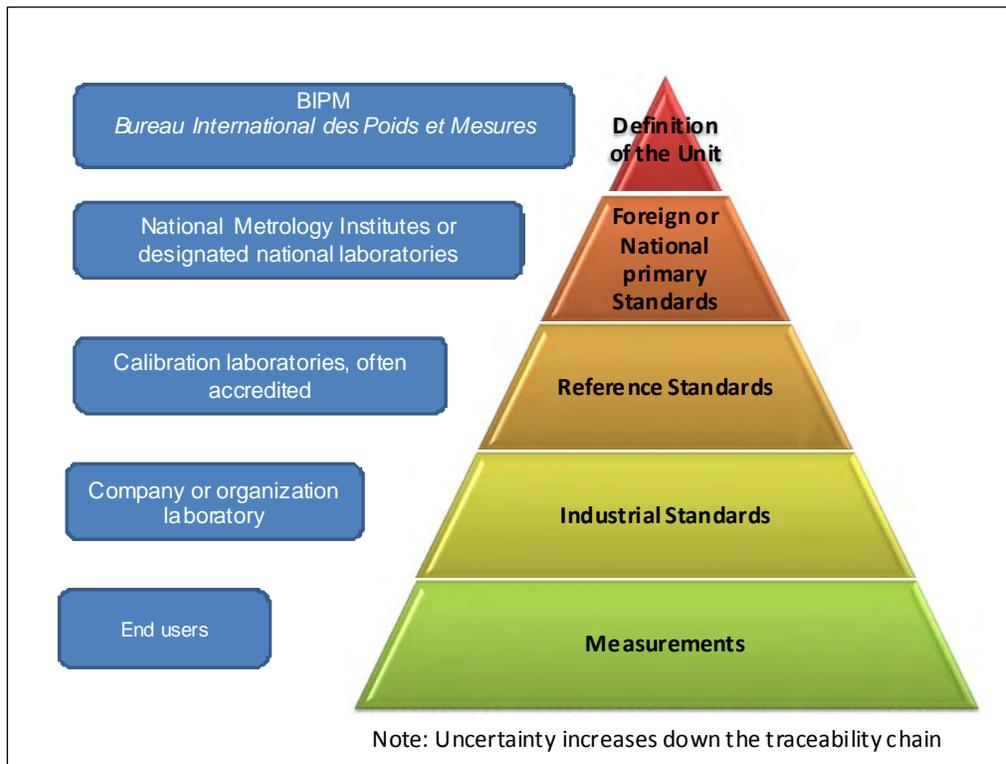
### 3.1.7 Metrology Vocabulary

Fundamental metrology has no international definition, but it signifies the highest level of accuracy within a given field. Fundamental metrology may therefore be described as scientific metrology, supplemented by those parts of legal and industrial metrology that require scientific competence.

#### 3.1.7.1 Traceability of Measurement

A traceability chain 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.

## The Traceability Chain



### 3.1.7.2 Calibration

A basic tool in ensuring the traceability of a measurement is measuring instrument calibration. This calibration involves determining the metrological characteristics of an instrument. It is achieved by means of a direct comparison against known standards. A calibration certificate or test report is issued and (in most cases) a sticker is attached. Based on this information a user can decide whether the instrument is fit for the application in question.

#### The importance of having instruments calibrated

- a. To ensure readings from an instrument are consistent with other measurements.
- b. To determine the measurement uncertainty of the instrument.
- c. To establish the reliability of the instrument that it can be trusted.

By calibrating an instrument, it is possible to obtain the following:

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

### **3.1.7.3 Measurement Standards**

A measurement standard or 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 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 Standard**

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

#### **Reference Standard**

A standard, generally having the highest metrological quantity available at a given location, from which measurements made there are derived.

#### **Working Standard**

A standard that is used routinely to calibrate or check material measures, measuring instruments or reference materials.

#### **Transfer Standard**

A standard used as an intermediary to compare standards.

### 3.2 METROLOGY REFERENCE INFORMATION

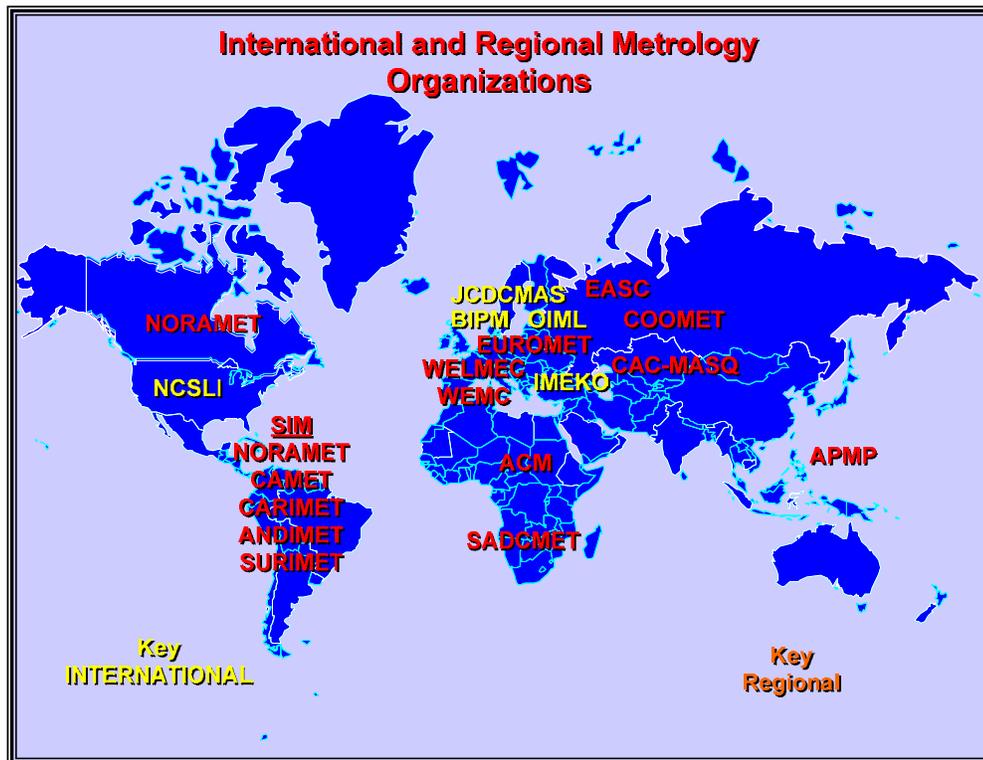
#### *International and Regional Metrology Organizations*

##### *International*

BIPM	Bureau International des et Poids Measures	<a href="http://www.bipm.org">www.bipm.org</a>
OIML	International Organization of Legal Metrology	<a href="http://www.oiml.org">www.oiml.org</a>
IMEKO	International Measurement Confederation	<a href="http://www.imeko.org">www.imeko.org</a>
NCSLI	NCSL International	<a href="http://www.ncsli.org">www.ncsli.org</a>
JCDCMAS	Joint Committee on Coordination of Assistance to Developing Countries in Metrology, Accreditation and Standardization	<a href="http://www.bipm.org/en/committees/jc/jcdcmas/">www.bipm.org/en/committees/jc/jcdcmas/</a>

##### *Regional*

<i>Africa</i>	AFRIMETS	Inter-Africa Metrology System	<a href="http://www.afrimets.org">www.afrimets.org</a>
	SADCMET	South-African National Development Community Cooperation in Measurement Traceability	<a href="http://www.sadcmets.org">www.sadcmets.org</a>
<i>The Americas</i>	SIM	InterAmerican Metrology System, sub-regions: ANDIMET, CAMET, CARMET, NORAMET and SURAMET	<a href="http://www.sim-inmetro.org.br">www.sim-inmetro.org.br</a>
<i>Asia and Pacific</i>	APMP	Asia Pacific Metrology Program	<a href="http://www.apmp207.com">www.apmp207.com</a>
	APLMF	The Asia-Pacific Legal Metrology Forum	<a href="http://www.aplmf.org">www.aplmf.org</a>
<i>CIS</i>	CAC-MAS-Q	Central Asian Cooperation on MAS-Q	N/A
	COOMET	Euro-Asian Cooperation of National Metrological Institutions	<a href="http://www.coomet.org">www.coomet.org</a>
	EASC	The Interstate Council for Standardization, Metrology and Certification	<a href="http://www.easc.org">www.easc.org</a>
<i>Europe</i>	EURAMET	European Association of National Metrology Institutes	<a href="http://www.euramet.org">www.euramet.org</a>
	WELMEC	European Cooperation in Legal Metrology	<a href="http://www.welmec.org">www.welmec.org</a>
	WEMC	Western European Metrology Club	N/A



### Bureau International des Poids et Mesures (BIPM)

[www.bipm.org](http://www.bipm.org)

The task of the BIPM is to ensure world-wide 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 carries out measurement-related research. It takes part in, and organizes, international comparisons of national measurement standards, and it carries out calibrations for Member States. The BIPM publishes, in addition to scientific articles by members of their 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.



### International Organization of Legal Metrology (OIML)

[www.oiml.org](http://www.oiml.org)

The International Organization of Legal Metrology (OIML) is an intergovernmental treaty organization whose membership includes Member States, countries which participate actively in technical activities, and Corresponding Members, countries which join the OIML as observers. It was established in 1955 in order to promote the global harmonization of legal metrology procedures. Since that time, the OIML has developed a worldwide technical structure that provides its Members with metrological guidelines for the elaboration of national

and regional requirements concerning the manufacture and use of measuring instruments for legal metrology applications.

The OIML encourages the participation of developing countries at all levels of its work. Specific activities in support of developing countries are currently organized by the OIML's *Permanent Working Group on Developing Countries* (PWGDC).



### **International Measurement Confederation (IMEKO)**

[www.oiml.org](http://www.oiml.org)

IMEKO is a non-governmental federation of 37 Member Organizations individually concerned with the advancement of measurement technology. Its fundamental objectives are the promotion of international interchange of scientific and technical information in the field of measurement and instrumentation and the enhancement of international co-operation among scientists and engineers from research and industry. Founded in 1958, the Confederation has consultative status with UNESCO and UNIDO, and is one of the five Sister Federations within FIACC, 5 International Associations coordinating Committee.



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

[www.ncsli.org](http://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, 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



**Joint Committee for the coordination of technical assistance to Developing Countries in Metrology, Accreditation and Standardization. - [www.jcdcmas.org](http://www.jcdcmas.org)**

A newly formed organization, the JCDCMAS seeks to bring together all specialist organizations operating at a global level that are active in promoting MAS (metrology, accreditation, and standardization) as a tool for sustainable economic development. Members of the JCDCMAS are BIPM, IAF, IEC, ILAC, ISO, ITC, ITU, OIML and UNIDO. The JCDCMAS recognized the fact that in many developing countries the MAS-Q infrastructure is incomplete or at inception and prevents those economies from attaining their full potential. Click on the JCDCMAS logo to see a copy of the background paper on the formation and activities of the Joint Committee on co-ordination of assistance to Developing Countries in Metrology, Accreditation and Standardization (JCDCMAS).



**AFRIMETS**  
Inter-Africa Metrology System  
Sistema Intercontinental de Metrologia

**Intra-Africa metrology system**  
[www.afriments.org](http://www.afriments.org)

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).

The first AFRIMETS workshop, held in March 2006, was attended by delegates from more than 25 African countries and representatives from APMP, SIM, EUROMET, the BIPM and other interested parties such as ECOWAS, COMESA, the African Committee of Metrology (CAFMET), the South African National Accreditation System (SANAS), the Bureau of Standards (SABS) and the National laboratory Association of South Africa (NLA). A draft MOU was prepared and a second workshop was held in September 2006. The first General 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 SADC MET, 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. It is expected that Egypt and Ethiopia will sign during 2008.



**South-African National Development Community  
Cooperation in Measurement Traceability**  
[www.sadcmnet.org](http://www.sadcmnet.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)**

[www.sim-metrologia.org.br](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](http://www.coomet.org)

COOMET is the regional organization originally establishing co-operation 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.



### **Central Asian Cooperation on Metrology, Accreditation, Standardization and Quality (CAC-MAS-Q)**

**Note: no website available at this time**

In July 2003, the (CAC-MAS-Q) was formally established with the assistance of international experts and facilitated by USAID's MAS-Q team in the region. This organization was established at the request of the Gosstandards in the region to address MAS-Q issues that affected Central Asia.

Members of the cooperation are the four National metrology and standards institutes of Kazakhstan, Kyrgyzstan, Tajikistan and Uzbekistan. As part of the CAC activities, a series of MAS-Q technical committees were formed. The main goal of the CAC is to promote harmonization of standards, acceptance of certification and accreditation procedures within the region and to become signatories of the ILAC and IAF Mutual Recognition Arrangements.

## **EuroAsain Interstate Council for Standardization, Metrology and Certification (EASC)**

[www.easc.org](http://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](http://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](http://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 ie.: 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 (APMP)**

[www.apmpweb.org/](http://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)**

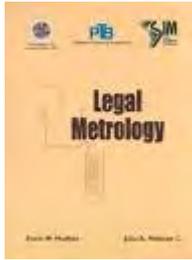
[www.aplmf.org/index.shtml](http://www.aplmf.org/index.shtml)

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. Now the membership expanded to 20 full member economies and 6 corresponding economies as of November 2007.

### 3.3 HYPERLINK FOR METROLOGY REFERENCE INFORMATION

#### Books, Publications and Compact Disk

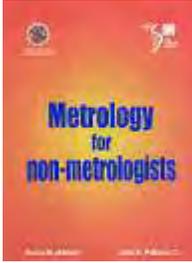


#### Legal Metrology

Inter-American Metrology System (SIM)

[www.sim-metrologia.org.br](http://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 CD.

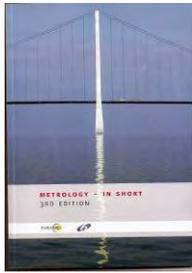


#### Metrology for Non-Metrologist

Inter-American Metrology System (SIM)

[www.sim-metrologia.org.br](http://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 CD.



#### Metrology –in short 3<sup>rd</sup> Edition

[www.euramet.org/index.php?id=mis](http://www.euramet.org/index.php?id=mis)

The main purpose of 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..



#### INFOSIM MAGAZINE

Inter-American Metrology System (SIM)

[www.redhucyt.oas.org/SIM/publications/sm\\_inf\\_magazine.html](http://www.redhucyt.oas.org/SIM/publications/sm_inf_magazine.html)

INFOSIM is a publication coordinated by The Inter-American Metrology System and sponsored by the Organization of American States (OAS). Copies of this magazine can be downloaded via the website.



#### The International System of Units (BIPM)

[www.bipm.org/en/si/si\\_brochure/general.html](http://www.bipm.org/en/si/si_brochure/general.html)

This brochure is the essential 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 brochure is periodically updated after detailed discussion by the Consultative Committee for Units. The text is viewable on line and the brochure can also be downloaded free of charge in PDF format.



### **Quantities and Units**

Published by ISO

[www.iso.org/iso/publications](http://www.iso.org/iso/publications)

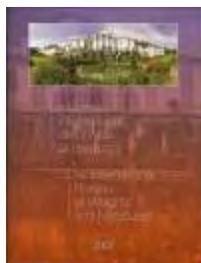
SI units and recommendations for the use of their multiples and of certain other units, general principles concerning quantities, units and symbols. Individual standards dealing with quantities in space and time, periodic phenomena, mechanics, heat, electricity and magnetism, electromagnetic radiation, chemistry, molecular physics, nuclear physics, etc. This publication is available from the ISO website for a fee.



### **Metrologia -BIPM**

[www.bipm.org/en/metrologia](http://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 Intentional Bureau of Weights and Measures**

[www.bipm.org](http://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.



### **NSCL International**

[www.ncsli.org](http://www.ncsli.org)

**NSCL 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.

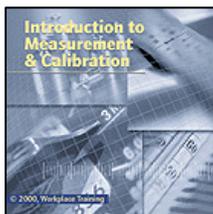


### **NSCL International**

[www.ncsli.org](http://www.ncsli.org)

#### **NSCL International's "Metrologist" magazine**

NSCL 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.



## Precision Measurement Training Computer based – interactive training



<http://www.wptraining.com/index.htm/>

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

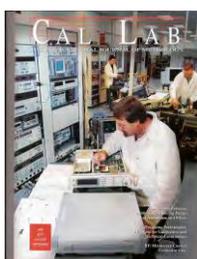
### **Level II Titles**

- Dimensional: Surface Texture, Roundness, Hardness
- Acoustics and Vibration
- Time and Frequency
- AC/DC Metrology
- Microwave Principles
- Test Equipment Operation and Calibration
- Metrology Applications for Engineers and Scientists

### **ISO/IEC 17025 Compliance**

- Uncertainty Management
- Introduction to 17025 for Technicians
- Audit/Assessment to 17025
- Proficiency Testing

For additional courses, visit Workplace training web site



## **CAL LAB – The International Journal of Metrology**

[www.callabmag.com](http://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.



**NCSL International**  
<http://www.ncsli.org/>  
**Laboratory Management Publications**  
**Recommended Practice Publications**

These CD's contain a series of how- to publications, guides, and procedures.

Examples:

Calibration Laboratory Manager's Guidebook

NCSL Glossary of Metrology-Related Terms

Catalog of Intrinsic and Derived Standards

Acronym List

Calibration Procedures

Test Reports and calibration certificates

Laboratory Design

Laboratory Environment

Measurement Uncertainty

Calibration Control Specifications

Documentation Guidelines and more

These CD's are available free of charge to all NCSLI members, or may be purchased from NCSLI via the website.

**List of National Metrology Institutes**

From the following websites, a complete list of worldwide National Metrology Institutes may be viewed.

**From the US National Institute of Standards and Technology**

[www.nist.gov/oiaa/national.htm](http://www.nist.gov/oiaa/national.htm)

**From the BIPM**

[www.bipm.org/en/practical\\_info/useful\\_links/nmi.html](http://www.bipm.org/en/practical_info/useful_links/nmi.html)

National metrology institutes of Member States of the Metre Convention and Associate States and Economies of the CGPM, institutes designated in the CIPM MRA, and other institutes.



**METROLOGY IN OUR DAILY LIVES – A Power Point Presentation- By the US NIST**

A slide presentation highlighting the importance of metrology on international trade and its impact on our daily lives. A copy of the complete document is in the metrology folder on the CD.



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

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



## 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 CD.



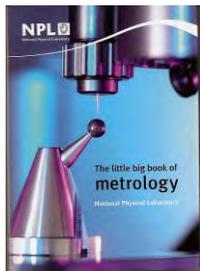
## INTERNATIONAL VOCABULARY OF METROLOGY – BASIC AND GENERAL CONCEPTS AND ASSOCIATED TERMS (KNOWN AS THE VIM)

[www.bipm.org](http://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

This 3rd edition cancels and replaces the 2nd edition, 1993. This 3rd edition is also published as ISO Guide 99 by ISO (ISO/IEC Guide 99-12:2007 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms, VIM).



## 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 [enquiry@npl.co.uk](mailto:enquiry@npl.co.uk).



## 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. A copy of this book may be obtained from OAS contact [oharasic@oas.org](mailto:oharasic@oas.org)

## SECTION 4. CONFORMITY ASSESSMENT

### 4.1 An internationally recognized procedure

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 plays a critical role in sustainable development and trade. In developing countries conformity, assessment activities are generally less developed than their industrialized counterparts.

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.

In describing the importance of testing, certification and accreditation in the global economy, ISO/IEC Standard 17011: 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, conformity assessment is the practice of determining whether a product, service or system meets the requirements of a particular standard. The “standard” 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 with International Standards or Guides for the operation of accreditation, 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. The alternative would be where there is no level of confidence and the importing country requires the product to be completely retested in the imported country. This would add time and cost to the whole process.

#### **4.1.1 The Principal Components of Conformity Assessment**

##### **4.1.1.1 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.

Quality Management system certification is the most well known example of certification. There are more than 951,486 organizations in 175 countries have been certified to ISO 9001 standard. It should be noted that ISO itself does not assess the conformity of quality management systems. ISO does not issue certificates of conformity to these standards or any other standard. QMS certification is carried out independently of ISO by more than 800 certification or registration bodies active internationally.

##### **4.1.1.2 Accreditation**

Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

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 carried out for testing and calibration laboratories, inspection bodies, product certification bodies and Quality 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.

#### **4.1.1.3 Testing**

Testing is perhaps the most common form of conformity assessment. It can include activities like measurement and calibration. It is the main technique used in product certification.

#### **4.1.1.4 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 17020:1998, General criteria for the operation of various types of bodies performing inspection.

#### **Note:**

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.

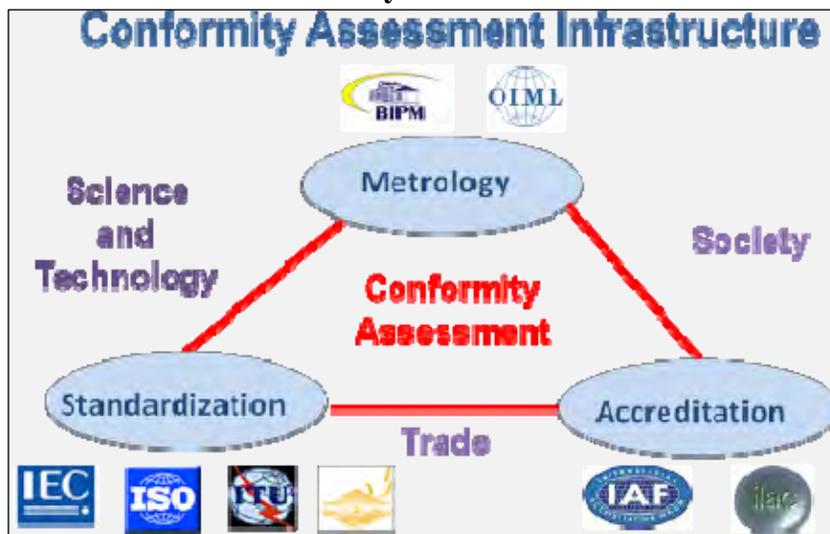
Accreditation is a conformity assessment activity and is the internationally accepted system that recognizes the competence of testing and calibration laboratories, product certification bodies, quality system certification bodies and inspection bodies. Accreditation establishes assurance of the quality of test data and provides discipline and a sense of professionalism 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.

#### **4.1.2 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 integrity 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, (ie, the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC).

### 4.1.3 Conformity Assessment brings together the disciplines needed to insure compliance

A Conformity Assessment Model



### 4.1.4 A Simple Guide to Understanding Conformity Assessment

This is a brief statement on the subject of conformity assessment intended for the reader who wishes to have an elementary introduction to its concepts.

- a) **What is it?** Conformity assessment is a process whereby verifying 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. And it permits governments to enforce 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; 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.

- 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 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.

i) **How conformity assessment works**

Conformity assessment activities can be characterized as:

**First party** - this is the technical term used when conformity assessment to a standard, specification or regulation is carried out by the supplier organization itself. In other words, it is a self-assessment. This is known as a supplier's declaration of conformity.

**Second party** - this is defined as the conformity assessment activity which is performed by the customer of the organization. For example the manufacturer would allow his customer to do an assessment of the product against the requirements.

**Third party** - this is defined as the conformity assessment activity that is performed by a body that is independent of the organization that provides the product and is not a user of the product. An example of this would be when an independent certification body certifies that another organization complies with ISO 9001 and issues it with a certificate to this effect.

Very often the decision to use one type of conformity assessment above another will depend on a number of factors, one of which is the level of risk associated with the product/service and the customer's requirements.

We can therefore say that conformity assessment is a series of three functions (functional approach) that satisfy a need or a demand for demonstration that specified requirements are fulfilled. These three functions are:

1. Selection
2. Determination
3. Review and attestation

Such determination adds credibility to claims that specified requirements are fulfilled, giving users greater confidence in such claims. ISO standards are used as the specified requirements.

Conformity assessment may be applied to products which includes services, process and systems for example management systems.

Note: ISO publishes a Development Manual 2 on Conformity Assessment; it should be consulted by the reader who wishes to go beyond this introduction. Development Manual 2 not only introduces interested parties to the basic concepts, but also indicates which detailed international guides and technical documents should be referred to for full information on each concept.

#### **4.1.5 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) and the European Committee for Standardization (CEN).

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).

**4.1.6** CASCO has produced International Standards and Guides pertaining to conformity assessment practices, and the organizations and accreditation bodies that use them.

- Vocabulary and general principles of conformity assessment
- The development of technical specifications suitable for use in conformity assessment
- Code of good practice for conformity assessment
- Operation of testing and calibration laboratories and activities
- Proficiency testing by inter-laboratory comparisons
- Inspection bodies and activities
- Supplier's declaration of conformity (SDoC)

- Product certification bodies and activities
- Management system audit and certification bodies and activities
- Personnel certification bodies and activities
- Marks of conformity
- Accreditation
- Peer assessment
- Mutual recognition of conformity assessment results.

### Detailed List of ISO Conformity Assessment Guides and Standards

<u>ISO/IEC Guide 7:1994</u> Guidelines for drafting of standards suitable for use for conformity assessment
<u>ISO/IEC Guide 23:1982</u> Methods of indicating conformity with standards for third-party certification systems
<u>ISO Guide 27:1983</u> Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
<u>ISO/IEC Guide 28:2004</u> Conformity assessment -- Guidance on a third-party certification system for products
<u>ISO/IEC Guide 43-1:1997</u> Proficiency testing by inter-laboratory comparisons -- Part 1: Development and operation of proficiency testing schemes
<u>ISO/IEC Guide 43-2:1997</u> Proficiency testing by inter-laboratory comparisons -- Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies
<u>ISO/IEC Guide 53:2005</u> Conformity assessment -- Guidance on the use of an organization's quality management system in product certification
<u>ISO/IEC Guide 60:2004</u> Conformity assessment -- Code of good practice
<u>ISO/IEC Guide 65:1996</u> General requirements for bodies operating product certification systems
<u>ISO/IEC Guide 67:2004</u> Conformity assessment -- Fundamentals of product certification
<u>ISO/IEC Guide 68:2002</u> Arrangements for the recognition and acceptance of conformity assessment results
<u>ISO/IEC 17000:2004</u> Conformity assessment -- Vocabulary and general principles
<u>ISO/PAS 17001:2005</u> Conformity assessment -- Impartiality -- Principles and requirements
<u>ISO/PAS 17002:2004</u> Conformity assessment -- Confidentiality -- Principles and requirements
<u>ISO/PAS 17003:2004</u> Conformity assessment -- Complaints and appeals -- Principles and requirements
<u>ISO/PAS 17004:2005</u> Conformity assessment -- Disclosure of information -- Principles and requirements

## Detailed List of ISO Conformity Assessment Guides and Standards

### ISO/IEC 17011:2004

Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies

### ISO/IEC 17020:1998

General criteria for the operation of various types of bodies performing inspection

### ISO/IEC 17021:2006

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

### ISO/IEC 17024:2003

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

### ISO/IEC 17025:2005

General requirements for the competence of testing and calibration laboratories

### ISO/IEC 17025:2005/Cor1:2006

### ISO/IEC 17030:2003

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

### ISO/IEC 17040:2005

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

### 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

### 4.1.7 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 siting 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).

### 4.1.8 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 than 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 (Articles 5.2.4 and 5.2.5).
- 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.

#### 4.1.9 Verifying Conformity

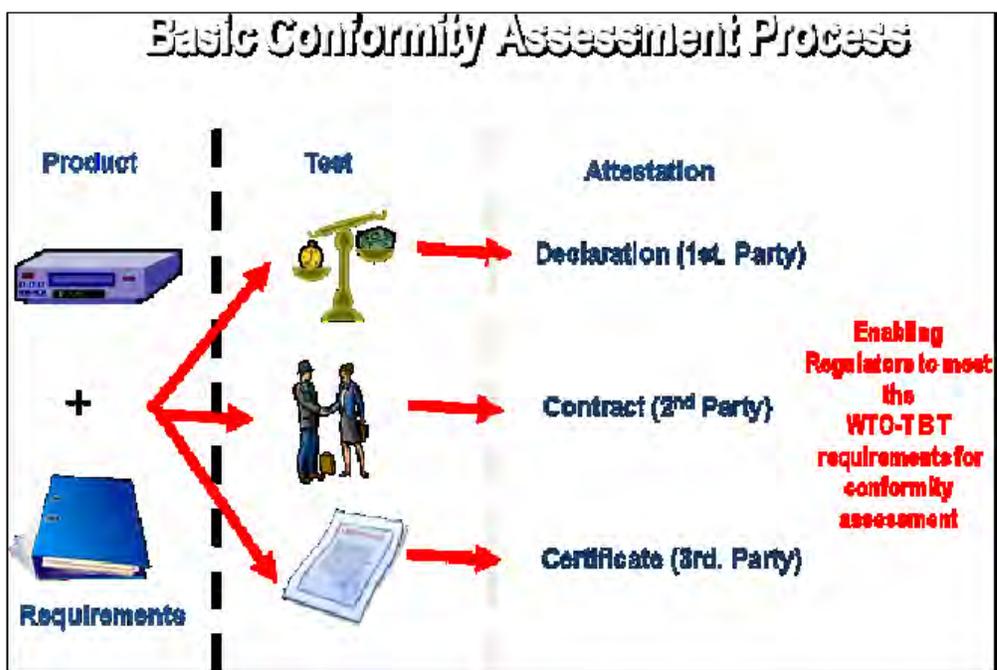
There are three methods of verifying conformity that are recognized and accepted internationally. These are generally known as first, second and third party assessment.

- **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.
- **Second party assessment** Usually carried out by the buyer - 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.

#### 4.1.10 Regulatory – Market Requirements for Product Certification



With the growth of world trade and increasing trade liberalization as well as the rapid development of new manufacturing and distribution technologies, *hundreds of third-party national and multinational inspection bodies have been created*. 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.

#### 4.1.11 Conformity Assessment Services.

The tables below provide an overview of functions and/or responsibilities related to different conformity bodies that provide conformity assessment services.

<b>There are two ISO/IEC documents that impact all conformity assessment bodies:</b>	
ISO/IEC 17000:2004 - Conformity assessment — Vocabulary and general principles	
ISO/IEC Guide 2:2004 - Standardization and related activities — General vocabulary	
Comment: These two documents define the international vocabulary, terminology, definitions, general rules and procedures that all conformity assessment bodies are obligated to follow.	

<b>Primary Function of the Conformity Assessment Body</b>	
Testing laboratory	<ul style="list-style-type: none"> <li>✓ Testing of products as received <i>e.g. testing of packaging and food additives in canned sardines</i></li> <li>✓ Not necessarily operated by third party. Testing can be carried out by the first party or the second party. Reporting the test results as received.</li> </ul>
Inspection body	<ul style="list-style-type: none"> <li>✓ Inspection of products according to the requirements <i>e.g. inspection of contaminants in canned sardines (tin shall not be more than 150 mg/kg and mercury not more than 0.2 mg/kg)</i> or In-service inspection <i>e.g. inspection of boilers</i></li> <li>✓ Not necessarily operated by third party. Inspection can be carried out by the first party or the second party. Reporting or certifying the inspection results according to the requirements on the basis of professional judgment.</li> </ul>
Product Certification Body	<ul style="list-style-type: none"> <li>✓ Certifying compliance of products according to the standards <i>e.g. certifying that all lots of canned sardines comply with CODEX.</i></li> <li>✓ Normally operated by third party.</li> </ul>
Accreditation Body	<ul style="list-style-type: none"> <li>✓ Authoritative body that performs accreditation. This is third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.</li> </ul>

<b>Certificates, Reports, Licenses Issued by the Conformity Assessment Body</b>	
Testing laboratory	The laboratory issues a test report stating their findings as to compliance to conformity, (ie: the product meets or does not meet the minimum requirements) certificates are not normally provided.
Inspection body	The inspection report and or inspection certificate can be issued, they shall include all the results of examinations and the determination of conformity made from these results as well as all information needed to understand and interpret them.

Product Certification Body	<p>The certification body will issue to the supplier of the product formal certification documents such as a letter or certificate signed by an officer who has been assigned such responsibility. The documents shall contain the following,</p> <p>The name and address of the supplier whose products are subject to certification;</p> <p>The scope of the certification granting, including as appropriate,</p> <ul style="list-style-type: none"> <li>✓ The products certified, which may be identified by type or range of products,</li> <li>✓ The product standards or other normative documents to which the product or product type is certified,</li> <li>✓ The applicable certification system;</li> </ul> <p>The effective date of certification, and the term of the certification if applicable.</p>
Accreditation Body	<p>The accreditation body will issue a certificate to the laboratory or the certification body that has meet all the requirements of the appropriate standard. As part of the certificate, a “Scope of Accreditation” (SoA) is supplied. This SoA clearly defines what functions the laboratory or certification body is accredited to perform. The laboratory or certification body cannot claim that they are accredited to perform any activities that are not listed on the SoA.</p>

Name, logo or Mark of the conformity Assessment Body	
Testing laboratory	The name, logo or mark of the testing laboratory is shown on the test report or certificate.
Inspection body	The name, logo or mark of the inspection body is shown on the inspection report or inspection certificate. Marking to show that the products have passed the inspection can be put on the lot which has been subject to inspection only.
Product certification body	A legally registered certification mark should be applied or issued under the procedures of a 3 <sup>rd</sup> party certification system for a product or service which is in conformity with specific standards or other technical specifications. Ie; CE, UL, CSA, etc.
Accreditation Body	The name and or logo of the accreditation body are shown on the accreditation report.

#### 4.1.12 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 diet-sensitive 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

How aware are consumers of marks of conformity assessments and should they be at all concerned about their use?

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 Certification Mark is Not?**

- It is not intended to imply quality

#### **General Requirements**

In order to obtain a conformity mark for a product, the manufacturer is 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.

#### 4.1.13 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 is 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 literally 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 non-conforming 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** 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 worldwide. 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® 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® 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.



**Finland SFS Mark** - The SFS Mark can be used to prove the compliance of products, work performances and services with requirements. The SFS Mark also indicates the continual monitoring of the quality of products and services. Besides the manufacturer's own quality activities a so-called third party regularly controls the manufacturer's quality activities as well as inspects the products through spot checks. The SFS Mark on a product acts as a guarantee that the product fulfils the requirements set in the SFS and/or EN standards concerning 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.

#### 4.1.14 Certification and Accreditation

##### What is certification?

Official definition “A procedure by which a third party gives written assurance that a product, process, personnel, organization or service conforms to specific requirements.”

##### 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.

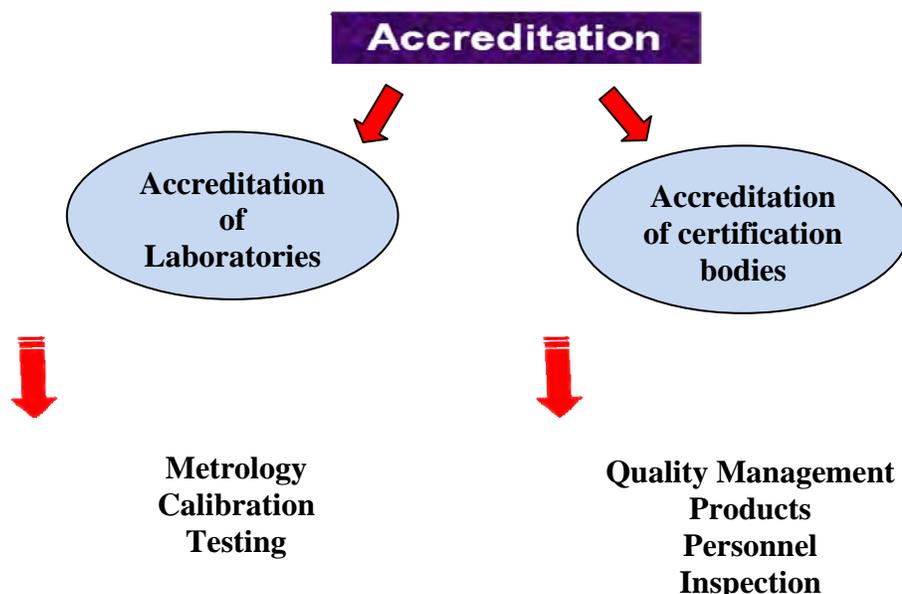
Note: Accreditation" is a term which in the ISO 9000 context is sometimes wrongly used as a synonym for certification.

Official definition “A Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out a specific task”.

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 (authorized) to perform. The certification body cannot claim that they can provide accredited certification to anything that they are not accredited to perform.

##### Two different spheres of accreditation



##### **Certification, Registration and Accreditation**

In the context of ISO 9001:2000 or ISO 14001:2004, 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.

“**Registration**” means that the auditing body then records the certification in its client register. So, the organization’s management system has been both certified and registered.

Therefore, in the ISO 9001:2000 or ISO 14001:2004 context, the difference between the two terms is not significant and both are acceptable for general use.

“Certification” is the term most widely used worldwide, although registration is often preferred 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 9001:2000 or ISO 14001:2004 context, accreditation refers to the formal recognition by a specialized body – an accreditation body – that a certification body is competent to carry out ISO 9001:2000 or ISO 14001:2004 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 were cited:

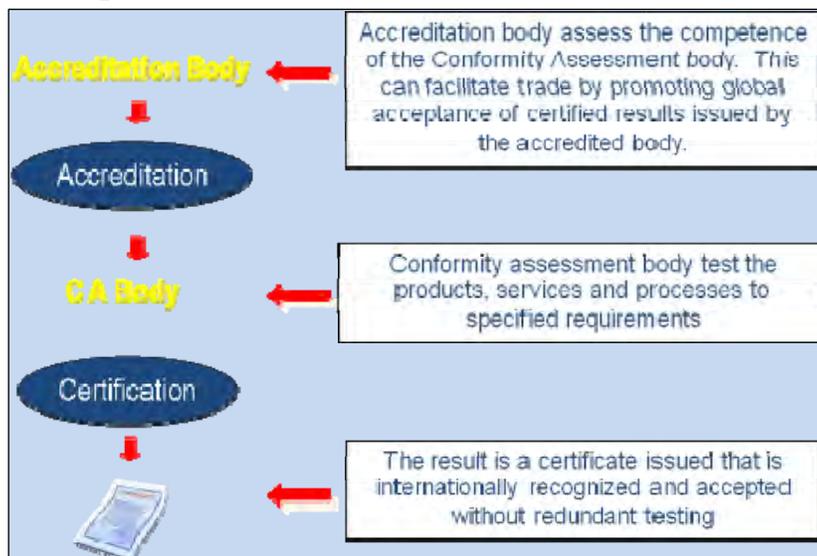
**Certification**

- 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**

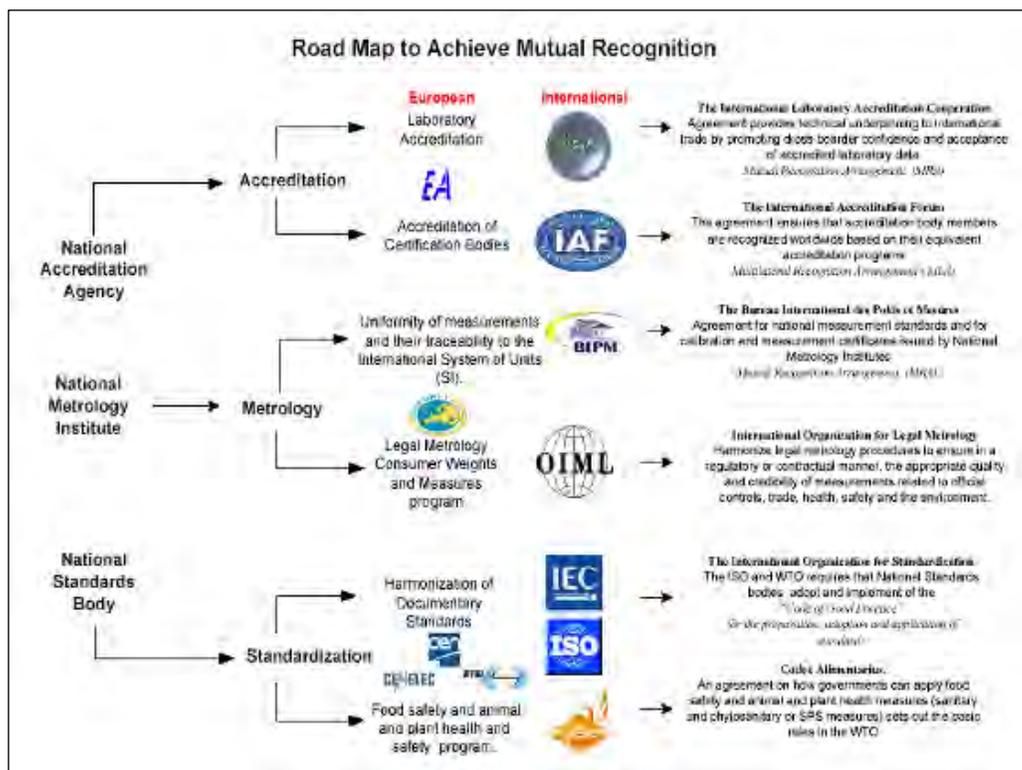


#### 4.1.15 The Recognition and Acceptance of Conformity Assessment

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 (IEC) 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.



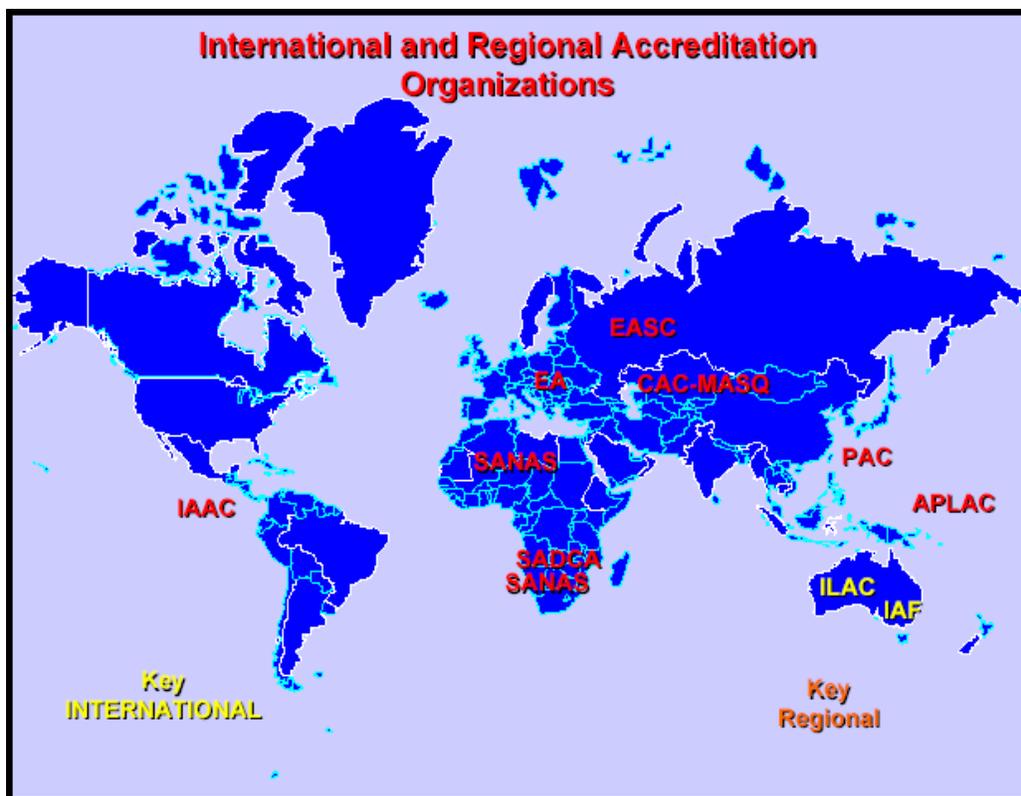
**International**

ILAC	International Laboratory Accreditation Cooperation	<a href="http://www.ilac.org">www.ilac.org</a>
IAF	International Accreditation Forum	<a href="http://www.iaf.nu">www.iaf.nu</a>

**Regional**

<i>Africa</i>	SADCA	Southern African Development Community Accreditation	<a href="http://www.sadca.org">www.sadca.org</a>
	SANAS	South-African National Accreditation System	<a href="http://www.sanas.za">www.sanas.za</a>
<i>Americas</i>	IAAC	InterAmerican Accreditation Cooperation	<a href="http://www.iaac.org">www.iaac.org</a>
<i>Asia and Pacific</i>	APLAC	Asia Pacific Laboratory Accreditation Cooperation	<a href="http://www.ianz.govt.nz/aplac">www.ianz.govt.nz/aplac</a>
	PAC	Pacific Accreditation Cooperation	<a href="http://www.apec-pac.org">www.apec-pac.org</a>
<i>CIS</i>	CAC-MAS-Q	Central Asian Cooperation on MAS-Q	Not available
<i>Europe</i>	EA	European Cooperation for Accreditation	<a href="http://www.eupopen-accreditation.org">www.eupopen-accreditation.org</a>
	JCDCMAS	Joint Committee on Coordination of Technical Assistance on Metrology, Accreditation and Standardization	<a href="http://www.bipm.org/en/committees/jc/jcdcmas/">www.bipm.org/en/committees/jc/jcdcmas/</a>
	WELAC	Western European Laboratory Accreditation Cooperation	Not available
<i>Other</i>	IQ-NET	The International Certification Network	<a href="http://www.iqnet-certification.com">www.iqnet-certification.com</a>

**International and Regional Conformity Assessment Bodies**





## 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 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 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 management systems, products, services, personnel, and other similar programs of conformity assessment.

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 two Regional Accreditation Groups, the European co-operation for Accreditation (EA) 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 or the PAC MLA and IAF members who are also signatories of these regional MLAs are automatically accepted into the IAF MLA. Special Recognition was granted to the InterAmerican Accreditation Cooperation (IAAC) for the Quality Management Systems (QMS) MLA at the IAF Annual Meetings held in Cancun, Mexico in November 2006.

The number of IAF MLA Signatories at November 2007 is as follows:

- IAF QMS MLA: 3 Regional Accreditation Groups (EA, PAC & IAAC) and 39 Accreditation Bodies
- IAF EMS MLA: 2 Regional Accreditation Groups (EA & PAC) and 36 Accreditation Bodies
- IAF Product MLA: 2 Regional Accreditation Groups (EA & PAC) and 28 Accreditation Bodies

#### **4.1.16 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 in many countries

- 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 in many countries:**

- **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 Agreement on Technical Barriers to Trade (TBT Agreement) and the Agreement on the Application of Sanitary and Phytosanitary Measures (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.

## 4.2 CONFORMITY ASSESSMENT REFERENCE INFORMATION



### International Laboratory Accreditation Cooperation (ILAC)

[www.ilac.org](http://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](http://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.

- **Guidance Documents (GD Series)**  
Guidance documents for the use by accreditation bodies when accrediting certification/registration bodies to assure that they also operate their programs in a consistent and equivalent manner.
- **Mandatory Documents (MD Series)**  
Documents which are required to be used by accreditation bodies when accrediting certification/registration bodies to assure that they operate the programs in a consistent and equivalent manner.
- **Multilateral Recognition Arrangement Documents (ML Series)**  
The primary purpose of IAF is to establish MLAs between its accreditation body members to contribute to the freedom of world trade by eliminating technical barriers to trade.
- **Procedures Documents (PR Series)**  
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.

- **Multilateral Recognition Arrangement Documents (ML Series)**

The primary purpose of IAF is to establish MLAs between its accreditation body members to contribute to the freedom of world trade by eliminating TBT's.

- **Procedures Documents (PR Series)**

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.



### **The South African National Accreditation System (SANAS)**

[www.sanas.co.za](http://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, 65 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](http://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.



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

[www.aplac.org](http://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](http://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 International Code Council (ICC)**

[www.iccsafe.org](http://www.iccsafe.org)

The International Code Council, a nonprofit membership association dedicated to building safety and fire prevention, develops the codes used to construct residential and commercial buildings, including homes and schools. Most U.S. cities, counties and states in the U.S. and several economies worldwide that adopt codes choose the International Codes developed by the International Code Council. The organizations that comprise the International Code Council include its subsidiaries, International Accreditation Service (IAS) and ICC Evaluation Service (ICC-ES). The ICC family of companies offers technical, educational and informational products and services, internationally recognized laboratory and inspection body accreditation services and product evaluation in support of the International Codes, with more than 400 qualified staff members at 16 offices throughout the United States and in Latin America. Some of the products and services readily available to code users include:

- Code application assistance
- Educational programs
- Certification programs
- Technical handbooks and workbooks
- Plan reviews
- Automated products

- Monthly magazines and newsletters
- Publication of proposed code changes
- Training and Informational videos
- Accreditation of laboratories, inspection bodies and product certifiers through IAS, an ILAC-recognized independent subsidiary
- Product evaluation through ICC-ES, an ANSI recognized independent product certification agency

The ICC has developed and made available an impressive inventory of International Codes, including:

- International Building Code®
- International Energy Conservation Code®
- International Code Council Electrical Code Administrative Provisions ®
- International Existing Building Code®
- International Fire Code®
- International Fuel Gas Code®
- International Mechanical Code®

ICC Performance Code™

- International Plumbing Code®
- International Private Sewage Disposal Code®
- International Property Maintenance Code®
- International Residential Code®
- International Urban-Wildland Interface Code™
- International Zoning Code®

ICC codes are comprehensive and coordinated with each other to provide the appropriate package for adoption and use in the 21st Century.



**The InterAmerican Accreditation Cooperation (IAAC)**  
[www.iaac.org.mx](http://www.iaac.org.mx)

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**  
[www.european-accreditation.org](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.



**The International Certification Network**  
[www.iqnet-certification.com](http://www.iqnet-certification.com)

IQNet is a provider of management system certification. It is composed of more than 35 certification bodies. IQNet partners have certified more than 200, 000 companies in 150 countries. They can appoint more than 10.000 auditors and 5,000 experts, auditing in more than 30 different languages. IQNet has a unique mix of competence, multicultural and multilingual capability and professional knowledge to operate in all organizations. Equivalence of the certification activities is assured by periodic assessments of each IQNet partner based on international guides and standards. The training of auditors is conducted on national and international levels. The international reputation and high competence makes IQNet a reliable partner. IQNet is involved in international standardization, certification and accreditation organizations.

Note: IQNet system differs from the typical MRA-MLA approach to mutual recognition established by ILAC and IAF. IQNet recognition is between certification bodies that are certified by IQNet.

## 4.3 HYPERLINK FOR CONFORMITY ASSSSMENT REFERENCE INFORMATION & HYPERLINKS

### Books, Publications and Compact Disks

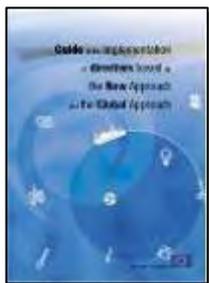


#### ISO and Conformity Assessment

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](http://www.iso.org)

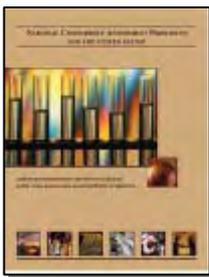


#### Guide to the implementation of directives based on The New Approach and the Global Approach

This 118-page document published by the European Union addresses the concept of the New Approach and the Global Approach and how to meet the EU requirements.

This document is available on the Internet and can be downloaded in all 11 official EU languages from the Europa server at the following address:

<http://europa.eu.int/comm/enterprise/newapproach/newapproach.htm>



#### National Conformity Assessment Principles For The United States

[www.ansi.org/ncap](http://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.



#### Certified Once Accepted Everywhere

[www.iaf.nu](http://www.iaf.nu)

This six-page brochure is published by the International Accreditation Forum (IAF). The concept and advantages of mutual recognition as it related to trade facilitation is described. A copy of this document may be downloaded free of charge from the IAF website .



## Laboratory Accreditation in Developing Economies

[www.ilac.org](http://www.ilac.org)

This 82-page handbook produced by ILAC and the United Nations Industrial Development Organization. This publication discusses the reasons why an accreditation body might be established and provides some background into its essential operational requirements. It then outlines the international and regional organizations that exist and the pathway to participation in the ILAC Arrangement while the role of UNIDO and the process of Pre-pee Evaluation is discussed. For a

copy of this handbook contact UNIDO or ILAC.

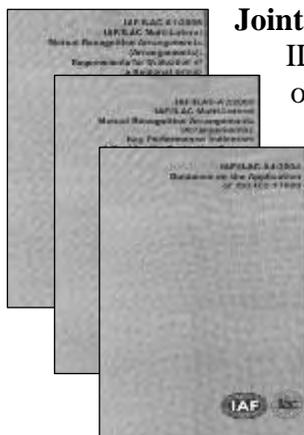


## The Role of Testing and Laboratory Accreditation in International Trade

[www.ilac.org](http://www.ilac.org)

This 28-page document produced by ILAC discusses the use of international systems for the accreditation of laboratories as an effective means of reducing technical barriers to trade. Sections 1 to 4 cover the international trading environment and the importance of valid test reports in trade. Section 5 deals in greater depth with the issues involved in ensuring that test results meet trading

requirements. This document is designed as background for officials and others dealing with trade policy matters and for technical personnel interested in how test results can affect trade. A copy of this document is available free of charge from the ILAC website.



## Joint ILAC- IAF Publications

ILAC and IAF have produced a series of publication that focus on Conformity Assessment. These publications can be downloaded via the websites of ILAC and IAF free of charge.

[www.ilac.org/ilaciafjoint.html](http://www.ilac.org/ilaciafjoint.html)

**IAF/ILAC MRAs: Requirements for Evaluation of a Regional Group** This document provides ILAC and IAF with requirements or criteria for evaluating Regional Groups for the purpose of recognition.

**IAF/ILAC MRAs: Requirements for Evaluation of a Single Accreditation Body.** This document provides ILAC and IAF with a procedure for evaluating single Accreditation Bodies for the purpose of qualifying them to sign applicable multi-lateral mutual recognition Arrangement(s).

**IAF/ILAC MRAs: Key Performance Indicators A tool for the Evaluation Process.** This document provides a tool for the evaluation process to allow an evaluated accreditation body to present information about how it addresses thirteen topics important to its performance, to focus the evaluation agenda on important topics, and to provide a framework to present this information in an evaluation report.

**IAF/ILAC Guidance on the Application of ISO/IEC 17020** This guidance will form the basis of mutual recognition arrangements between accreditation bodies, and is considered necessary for the consistent application of ISO/IEC Standard 17020.



### ILAC Brochures

<http://www.ilac.org/Brochuredownloads.html/>

ILAC publishes a series of resource materials brochures promoting laboratory accreditation. These are for use by ILAC members, their accredited laboratories and other stakeholders interested in accreditation. These brochures may be downloaded free of charge via the ILAC website.

- Why use an accredited laboratory ?
- Why become an accredited lab ?
- How does using an accredited lab benefit government and regulators
- The advantages of being an accredited laboratory
- Laboratory Accreditation or ISO 9001 Certification



### ILAC Guidance Series

<http://www.ilac.org/guidanceseries.html/>

ILAC publishes a series of conformity assessment guidance brochures. These guidance documents provide information on the interpretation of accreditation criteria for specific applications. These guidance, guidelines may be downloaded free of charge via the ILAC website at:

- ILAC G3:1994 Guidelines for Training Courses for Assessors
- ILAC G8:1996 Guidelines on Assessment and Reporting of Compliance with Specification
- ILAC G9:2005 Guidelines for the Selection and Use of Reference Materials
- ILAC G10:1996 Harmonized Procedures for Surveillance & Reassessment of Accredited Laboratories
- ILAC G11:07/2006 ILAC Guidelines on Qualifications & Competence of Assessors and Technical Experts
- ILAC G12:2000 Guidelines for the Requirements for the Competence of Reference Materials Producers
- ILAC G17:2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025
- ILAC G13:08/2007 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes
- ILAC G18:2002 The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing
- ILAC G19:2002 Guidelines for Forensic Science Laboratories
- ILAC G20:2002 Guidelines on Grading of Non-conformities
- ILAC G21:2002 Cross Frontier Accreditation - Principles for Avoiding Duplication
- ILAC G22:2004 Use of Proficiency Testing as a Tool for Accreditation in Testing
- ILAC G24:2007 Guidelines for the determination of calibration intervals of measuring instruments



### ILAC Procedural Series

ILAC publishes a series of Procedural and policy publications for ILAC's operation, which form part of the criteria for ILAC MRA evaluations. These procedural documents may be downloaded free of charge via the ILAC website.

<http://www.ilac.org/procseries.html/>

- ILAC P1:07/2007 ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies By ILAC-recognized Regional Cooperation's
- ILAC P2:2003 ILAC Mutual Recognition Arrangement (Arrangement): Procedures for Evaluation of Regional Cooperation Bodies for the Purpose of Recognition.
- ILAC P3:07/2007 ILAC Mutual Recognition Arrangement (Arrangement): Procedures for Evaluation of Unaffiliated Bodies for the Purpose of Recognition
- ILAC P5:04/2007 ILAC Mutual Recognition Arrangement (Arrangement)
- ILAC P8:07/2006 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories
- ILAC P9:2005 ILAC Policy for Participation in National and International Proficiency Testing Activities.
- ILAC P10:2002 ILAC Policy on Traceability of Measurement Results
- ILAC P11:2004 Monitoring Performance of ILAC Evaluators
- ILAC P12:2005 Harmonization of ILAC Work with the Regions ILAC Mutual Recognition Arrangement (Arrangement): Terms of Reference and Composition of the Arrangement Management Committee



### Marks of Conformity Assessment

[www.iso.org](http://www.iso.org)

This 12-page document published by ISO, addresses current practices in the use of marks of conformity assessment, including marks of conformity and logos. The paper describes features of marks currently in use and their significance. It also identifies areas where future guidance on use of marks may lead to greater understanding of the meaning of different marks and their relevance to end users of products and services. This document is available on

the ISO website. free of charge.



### IAF Guidance Documents (GD Series)

<http://www.iaf.nu/>

IAF 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. 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 Guidance to the application of ISO/IEC Guides are available from the IAF website/

- IAF GD 1:2003 Guidance on the Application of ISO/IEC Guide 61:1996
- IAF GD 3:2003 Guidance on Cross Frontier Accreditation
- IAF GD 5:2006 Guidance on ISO/IEC Guide 65:1996
- Summary of Changes for IAF GD 5:2006 Issue 3
- IAF GD 6:2006 Guidance on the Application of ISO/IEC Guide 66:1999
- Summary of Changes for IAF GD 6:2006 Issue 4
- IAF GD 7:2006 Transition Plan for Accredited Certification from AM/WDI to ASRP
- IAF GD 24:2004 Guidance on the Application of ISO/IEC 17024:2003.
- IAF Guidance in the Application of ISO9001:2000
- IAF Guidance on Guide 65:1996



### IAF Mandatory Documents (MD Series)

[www.iaf.nu/](http://www.iaf.nu/)

IAF publishes Mandatory Documents, which are required to be used by accreditation bodies when accrediting certification bodies to assure that they operate their programs in a consistent and equivalent manner. IAF Mandatory documents are not intended to establish, interpret, subtract from or add to the requirements of any ISO/IEC Guide or Standard, but simply to assure consistent application of those Guides or Standards.

Copies of all published IAF mandatory documents are available from the IAF website.  
IAF MD 1:2007 Certification of Multiple Sites Based on Sampling

- IAF MD 2:2007 Transfer of Accredited Certification of Management Systems
- IAF MD 3:2008 Advanced Surveillance and Recertification Procedures (ASRP)



### Multilateral Recognition Arrangement Documents (ML Series)

[www.iaf.nu](http://www.iaf.nu)

The purpose of the MLA is to allow accreditations and the certificates issued by certification bodies accredited by members of the MLA to be recognized by the other members of the MLA. The objective is that the MLA will cover all accreditation bodies in all countries in the world, thus eliminating the need for suppliers of products or services to be certified in each country where they sell their products or services (certified once – accepted everywhere).

Copies of all published IAF MRA documents are available from the IAF website

- IAF ML 1:2003 Procedure for Exchange of Documentation among IAF MLA Accreditation Bodies
- IAF ML 2:2004 General Principles on Use of the IAF MLA Mark
- IAF ML 3:2004 IAF Procedure on Responding to Inquiries on Multilateral Recognition Arrangement (MLA) Signatory Equivalence
- IAF ML 4:2005 MLA Policies and Procedures
- IAF The Multilateral Recognition Arrangement
- IAF MLA - Procedure for Identification of Equivalence of Accreditations
- IAF Guidance on Completing Peer Evaluation Reports for the IAF Multilateral Recognition Arrangement



### **A Strategic Approach To The Quality Assurance Challenge SQAM Systems -*The Need for Accreditation***

[www.intracen.org](http://www.intracen.org)

This 5-page report published by the International Trade Centre focuses on the importance of quality and standards for the export competitiveness of Least Developed Countries.

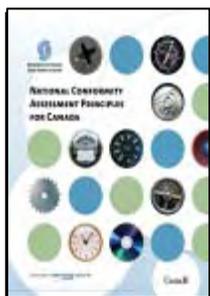
A second document **A Strategic Approach To The Quality Assurance Challenge Model SQAM Systems**. This 13 page report is an excerpt of the “Road Map for Quality – Guidelines for the Review of Standardization, Quality Management, Accreditation and Metrology (SQAM) Infrastructure at National”, which was originally published in 2004 as part of the ITC’s Standards and Quality Management series. Both of these documents are available from ITC.



### **ILAC News**

[www.ilac.org/ilac\\_news.html%20](http://www.ilac.org/ilac_news.html%20)

ILAV News is a publication of the International Laboratory Accreditation Cooperation. ILAC publishes this newsletter twice annually. For a copy of the latest ILAC News and recent past issues please visit their web site.



### **National Conformity Assessment Principles for Canada**

[www.scc.ca](http://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 CD

## SECTION 5. METROLOGY, STANDARDS, CONFORMITY ASSESSMENT AND THE TBT AGREEMENT IN VIETNAM

### 5.1 Vietnam's TBT Commitment and Implementation

#### 5.1.1 Vietnam's TBT Commitment

The Report of the Working Party on Vietnam's accession to WTO referred; inter alia, Vietnam's TBT current status and its commitment to implement the WTO/TBT Agreement from the date of becoming a WTO member.

The main paragraphs of part on "Technical barriers to trade, standards and certification" in Report of the Working Party are quoted as follows:

289. *The representative of Viet Nam said that a State administration body - the Directorate for Standards and Quality (STAMEQ), which consisted of standardization, metrology, quality management, and conformity assessments organizations and which reported to the Ministry of Science and Technology - was responsible for advising the Government on issues related to standardization, metrology and quality management, and representing Viet Nam in international standardization fora. STAMEQ had been designated as Viet Nam's central contact point for standards, technical regulations and conformity assessment issues, and Viet Nam's TBT Notification Authority and Enquiry Point pursuant to Decision No. 356/2003/QD-BKHCN of 25 March 2003 of the Ministry of Science and Technology. He confirmed that the enquiry point would be fully operational as from the date of accession. He provided initial information on technical barriers to trade in document WT/ACC/VNM/3/Add.1, Annex 5.*

290. *The main tasks of STAMEQ included preparation of rules and regulations on standardization, metrology and quality control for approval by the competent authorities; supervision and control of the implementation of approved rules and regulations; to organize and guide activities relating to standardization, metrology and quality control; to formulate national standards; to perform quality system certification, product certification and accreditation of testing and calibration laboratories, quality inspection bodies and quality certification bodies; to implement State supervision of quality requirements related to goods; to keep the national measurement standards; to organize and guide activities of verification, calibration, and certification of measuring instruments and patterns; to conduct studies on standardization, metrology and quality control; to participate in international cooperation on standardization, metrology and quality control; and to provide information and training on these subjects. Asked to clarify the respective roles of STAMEQ and the Ministry of Science and Technology, he said that unlike the Ministry of Science and Technology, STAMEQ did not have the power to issue legal documents. STAMEQ developed TBT policies and submitted them to the Ministry or the Government for approval. In addition to its policy-making role, STAMEQ had a technical role (testing, certification, inspection). Responding to concerns about the ability of STAMEQ to function independently and impartially as an accreditation body, the representative of Viet Nam said that the accreditation and certification services of STAMEQ were entirely separate from a financial, professional, and legal point of view. STAMEQ's role was to ensure conformity with Vietnamese laws and international standards and recommendations. He added that his Government was considering establishing a National Accreditation Council as an effort towards reorganizing STAMEQ. The Decision establishing the National Accreditation Council would be provided to the Working Party once promulgated.*

291. The legal framework for standardization, metrology and quality control consisted of the Ordinance on Metrology No. 16/1999/PL-UBTVQH10 of 6 October 1999, the Ordinance on Goods Quality No. 18/1999/PL-UBTVQH10 of 24 December 1999, the Ordinance on Consumer Rights Protection No. 13/1999/PL-UBTVQH10 of 27 April 1999, the Ordinance on Food Safety and Hygiene No. 12/2003/PL-UBTVQH11 of 26 July 2003, issued by the National Assembly Standing Committee, and other related regulations such as Decrees or Decisions issued by the Government or Prime Minister, including Decision No. 444/2005/QĐ-TTg of 26 May 2005 approving the scheme of implementation of the TBT Agreement, and inter-Ministerial or Ministerial Circulars and/or Decisions issued by ministries or Ministers to guide the implementation of the Ordinance on Metrology and the Ordinance on Goods Quality. However, a framework law on Standards and Technical Regulations had been adopted in June 2006, which covered all standard-related issues previously contained in the various legal documents, including the Ordinances on Measurement, Goods Quality, Food Safety and Hygiene, Plant Protection, Veterinary, and Consumer Protection. This framework Law focused on issues such as the development and application of standards, conformity assessment procedures, as well as technical regulations.

292. The main ministries involved in standards, technical regulations and conformity assessment procedures were the Ministries of Science and Technology; Industry; Fisheries; Health; Trade; Agriculture and Rural Development; Post and Telematics; Resources and Environment; Transport; and Construction. Asked to define the term "quality" more precisely, he said that the term should be understood in a broad sense. The Ordinance on Goods Quality governed the State administration of quality through technical regulations with the aim to protect human health, safety, the environment and other legitimate objectives as indicated in the TBT Agreement.

294. Draft standards were prepared by technical committees (90 technical committees and 42 sub-committees had been established to date). These committees and sub-committees had been established by STAMEQ and were organized and expected to operate in accordance with the guidelines of the International Standardization Organization (ISO). To facilitate the collection of comments, STAMEQ posted at the beginning of each year an annual work programme on the Internet (<http://www.vsc.org.vn>). This programme was revised in the second part of the year, generally during the third quarter, and re-posted. The programme included information about the title of the proposed standards and technical regulations, the name of the technical committee in charge, and the form of adoption. Interested parties could request copies of draft standards for consideration and comment. He added that a schedule of development would be considered and added to the programme.

295. Concerning technical regulations, the Law on the Promulgation of Legal Documents stipulated that for regulations issued by the Government, the Government would assign a drafting body to establish drafting committees. The drafting committees consisted of the relevant agencies and organizations, experts and scientists. Pursuant to the Law on Standards and Technical Regulations, ministries, ministerial level bodies and provincial-level People's Committees that issued technical regulations, developed them in cooperation with the relevant State management agencies, scientific and technological organizations, enterprises, consumers, experts and other relevant agencies. Reviews of existing regulations were carried out on an annual basis by each

government agency involved. Draft technical regulations were - subject to their nature and content - submitted to the relevant bodies, organizations and individuals for comment. Notices of proposed technical regulations were, for that purpose, published in the Appendix of the Official Gazette by decision of the competent State bodies (Article 5.4 of Government Decree No. 104/2004/ND-CP of 23 March 2004 on the Official Gazette of Viet Nam and Circular No. 04/2005/TT-VPCP of 21 March 2005 guiding the implementation of the Decree). Representatives of stakeholders could participate in the drafting process by taking part in the drafting committees or by submitting comments on proposed technical regulations when these were published in the media. He said further that his Government was considering publishing draft laws and regulations, including technical regulations, in the electronic Official Gazette. He added that the issue of ensuring quality and integrity in the development of legal documents was provided for in the Law on the Enactment of Legal Normative Documents. In response to a question, he noted that the Law on Standards and Technical Regulations provided for a period of six months between adoption and implementation of a technical regulation – except in very special cases such as national security – which he considered to be in line with TBT rules. He added that a network of TBT notification bodies and enquiry points had been established in the concerned ministries and local authorities by Prime Minister's Decision No. 114/2005/QĐ-TTg of 26 May 2005. The network would support the central TBT notification body to fulfil the obligation of notifying proposed technical regulations to WTO Members through the Secretariat.

296. All standards were voluntary unless specifically indicated in the relevant regulation. Among the 5,800 national standards listed in the Viet Nam Standards Catalogue in 2004, 231 were mandatory. Mandatory requirements aimed at protecting the environment or human, animal or plant life or health, or at preventing deceptive practices or national security. Requested to provide a list of the mandatory requirements /technical regulations applicable in Viet Nam, he referred Members to the internet homepage of STAMEQ (<http://www.tcvn.gov.vn>). Providing an example, he noted that on 24 December 1999, the Standing Committee of the National Assembly had adopted Ordinance No. 18/1999/PL-UBTVQH10 which stipulated that goods related to food, safety, sanitary, human health, environment, and other goods specified by laws and regulations, were obliged to be in conformity with Viet Nam's national standards. The Ordinance had entered into force on 1 July 2000, superseding an Ordinance on Goods Quality of 27 December 1990. The Ordinance stipulated that both domestic and imported goods could be subject to either quality inspection – the list of goods would be determined by the Government - or quality certification, to be determined by Ministers. Both methods were being developed and revised on the basis of ISO Guides. Quality certification to establish conformity with Viet Nam's standards was mostly carried out on a voluntary basis. Conformity assurance procedures were laid down in Decree No. 179/2004/ND-CP of 21 October 2004 guiding the implementation of the 1999 Ordinance on Goods Quality.

298. The representative of Viet Nam stated that the Ordinance on Goods Quality stipulated that the Government should issue a list of goods subject to mandatory quality inspection. The most recent list had been published in Prime Minister's Decision No. 50/2006/QĐ TTg of 10 March 2006. He added that mandatory

registration of product quality had been abolished in early 2001. Inspection procedures for imported and exported goods had been simplified by moving towards a system of type testing. The requirement to inspect each individual consignment could be waived for companies with a proven track record of quality (i.e., when conformity with relevant standards and/or technical regulations had been demonstrated several times for the same goods). The principle of simplified inspection procedures applicable to imported and exported goods had been approved by the Minister of Science and Technology in Decision No. 1091/1999/QĐ-BKHCMNT of 22 June 1999. The detailed conditions under which simplified inspection procedures could be applied were specified in regulations issued by the Directorate for Standards and Quality and line management ministries for each type of good. Complaints against decisions by the authorities responsible for conformity assessment or quality inspection procedures were resolved in accordance with Viet Nam's Ordinance on Claim and Denouncement. In response to a Member who enquired why line government agencies had to be involved in the inspection for quality/conformity testing of imported goods, he said that government agencies had set up and operated testing facilities to support enterprises, in particular small and medium-sized enterprises, many of which did not have testing facilities and were not able to test the quality and conformity of import products. He noted that these testing facilities were financially independent.

301. Asked whether and how Viet Nam accepted the results of conformity assessment procedures in other Members, as foreseen under Article 6.1 of the TBT Agreement, and whether Viet Nam recognized test data and/or certification conducted by bodies outside of Viet Nam, he said that Viet Nam provided many forms of acceptance of testing results or certification undertaken by foreign organizations. In most cases, test results and certifications undertaken by foreign organizations were accepted by the sellers and buyers. For goods subject to quality inspection and certification, testing and certification results were accepted under, for example, (i) bilateral and multilateral mutual recognition agreements to which Viet Nam and exporting countries were parties; (ii) unilateral acceptance by Viet Nam of foreign laboratories or certifying organizations; and (iii) import quality inspection. Viet Nam's unilateral acceptance of foreign laboratories or certifying organizations was based on the criteria of the ASEAN and APEC mutual recognition agreements and guidelines. Testing results of foreign laboratories accredited by foreign accreditation bodies were automatically accepted in Viet Nam if both Viet Nam and the foreign country were signatories of APLAC and ILAC MRAs. He confirmed that the CE mark could be recognized as a standards conformity stamp provided Viet Nam and the exporting country had signed a mutual recognition agreement on conformity assessment results.

303. The representative of Viet Nam confirmed that Viet Nam would comply with all the obligations under the TBT Agreement from the date of accession without recourse to any transitional period. Further, for the purpose of greater transparency and predictability, he confirmed that Viet Nam would issue measures that specifically set out Articles 2.1, 2.2, 5.1, 5.2, 5.4 and Annex 1.1 of the TBT Agreement. The Working Party took note of these commitments.”

Main points in Vietnam's TBT commitment are focused on the efforts to comply with all obligations under the TBT Agreement from the date of accession and reach the greater transparency and predictability for technical regulations and conformity assessment procedures issued by governmental agencies.

In order to realize this commitment, even during process of negotiation Vietnam has revised its TBT legal system for the purpose to make the system in compliance to main principles stipulated in the TBT Agreement such as non-discriminatory (MFN and NT), non trade-restriction, transparency...Furthermore, some institutional agencies were set up to deal with the effective implementation of TBT commitment such as TBT Vietnam notification and enquiry point, TBT Vietnam Network...

Readers can find more detail information on Vietnam's TBT implementation as bellows.

#### 5.1.2 Vietnam's TBT implementation

##### 5.1.2.1 Compliance of Vietnam's TBT legal system to WTO/TBT

**Vietnam's TBT related legal system (laws and regulations) consist of three levels as follows:**

- the highest level includes fundamental laws issued by the National Assembly or ordinances issued by the Standing Committee of the National Assembly;
- the intermediate level includes decrees issued by the Government, decisions, directions issued by the Prime Minister; decisions, circulars or directions issued by Ministers and Heads of ministerial-level agencies;
- The local level includes decisions or directions issued by the chairmen of people's committees in provinces or belonging-to-central-government cities.

(i) Legal documents by the National Assembly and the Standing Committee of the National Assembly which include, inter alias, technical regulations, are as bellows:

- Law on Trade 2006;
- Law on Construction 2003;
- Law on Environmental Protection 2005;
- Law on Public Health Care 1989;
- Law on Standards and Technical Regulations – 2006;
- Ordinance on Metrology – 1999;
- Law on Products and Goods Quality – 2007;
- Ordinance on Consumer Rights Protection – 1999;
- Ordinance on Consumer Protection 1999;
- Ordinance on Food Safety and Hygiene - 2003;
- Ordinance on Veterinary 2004;
- Ordinance on Plant Protection 2001.

Three last ordinances (namely, Ordinance on Food Safety and Hygiene – 2003, Ordinance on Veterinary 2004 and Ordinance on Plant Protection 2001) mainly concern SPS measures. But some aspects of these legal documents are related to TBT measures such as standards developments, labeling, quality systems...

(ii) Legal documents by the Government and Prime Minister on standards and conformance issues include:

- Decrees of the Government guiding the above mentioned legal documents by the Assembly and the Standing Committee of the National Assembly;

- Decisions and Directives of Prime Minister on the list of products/goods subject to quality inspection/control; on labeling of goods on domestic market; on metrological units and standards...

There are some key legal documents issued by the Governments and the Prime Minister:

- The Government Decree No. 179/2004/ND-CP of October 21, 2004 providing for State Management over Product and Goods Quality;
- The Government Decree No. 65/2001/ND-CP of Sept 28, 2001 on system of legal metrological units of the Socialist Republic of Vietnam;
- The Government Decree No. 126/2005/ND-CP of October 10, 2005 on the administrative punishments of violations in the field of product quality and measurement;
- The Government Decree No. 89/2006/ND-CP of August 30, 2006 on the labeling of goods;
- The Prime Minister Decision No 50/2006/QD-TTg of March 10, 2006 on the List of goods subject to quality inspection;
- The Prime Minister Decision No 444/2005/QD-TTg of May 26, 2005 on the approval of The Scheme of implementation and operation of TBT Agreement (see Annex 1);
- The Prime Minister Decision No 114/2005/QD-TTg of May 26, 2005 on establishment of, and issuance of Statute of organization and operation of Vietnam Network of Notification Authorities and Enquiry Points on TBT (see Annex 2);
- The Government Decree No. 127/2007/ND-CP of August 1, 2007 regulating the implementation in details of some provisions of Law on Standards and Technical Regulations.

(iii) Technical regulations (decisions, circulars, or directions) by Ministers, Heads of ministerial-level organizations.

These documents count for the largest part in Technical Regulation System of Vietnam. There are 12 ministries are involved in issuing technical regulations: Ministry of Science and Technology, Ministry of Trade, Ministry of Industry (two these ministries were merged in called as Ministry of Industry and Trade), Ministry of Construction, Ministry of Post and Telematics (this ministry was renamed as Ministry of Information and Communication), Ministry of Transport, Ministry of Health, Ministry of Culture and Information (this ministry was renamed as Ministry of Culture Sport and Tourism), Ministry of Natural Resources and Environment, Ministry of Labor, Invalid and Social Affairs, Ministry of Agriculture and Rural Development, Ministry of Fishery (this ministry was merged into Ministry of Agriculture and Rural Development).

There are some key technical regulations issued by ministerial-level authorities:

*Declaration, certification of conformity of products/goods with standards and technical regulations:*

The Decision No. 24/2007/QD-BKHCHN by Minister of Science and Technology of September 28, 2007 on issuing Regulation on Certification and Declaration of

conformity with standards and technical regulations. According to this Regulation, certification and declaration of conformity with standards and technical regulation have two types: voluntary and mandatory.

**State Quality inspection:**

- The Decision No. 1091/1999/QD-BKHCNMT by Minister of Science Technology and Environment of June 22, 1999 promulgating the Regulation on the State Control of Import-export Goods Quality.

***Accreditation of Testing/Calibration, Certification and Inspection Bodies:***

- The Decision No. 26/2007/QD-BKHCN by Minister of Science and Technology of October 31, 2007 issuing “Regulation on Organization and Operation of Accreditation Body”

***Mutual Recognition***

- The Circular No. 27/2007/TT-BKHCN by Minister of Science and Technology of October 31, 2007 guiding the conclusion and implementation of Mutual Recognition Agreements and Arrangements on conformity assessment results.

***Labeling***

- The Circular No. 09/2007/QD-BKHCN by Minister of Science and Technology of April 06, 2007 guiding some provisions of Decree No. 89/2006/QD-CP by the Government of August 30, 2007 on labeling of goods.

***Implementation of TBT Agreement and Operation of National TBT Office and TBT Network:***

- Decision No. 116/QD-TDC of March 1, 2006 by the Directorate for Standards and Quality (STAMEQ) on Statute of organization and operation of TBT VIETNAM;
- The Decision No. 07/2006/QD-BKHCN by Minister of Science and Technology of March 20, 2006 on organization and operation of TBT Inter-ministerial Committee;
- The Decision No. 09/2006/QD-BKHCN by Minister of Science and Technology of May 4, 2006, issuing Regulation on Procedures of Notification and Enquiry by TBT Network;
- The Decision No. 16/2006/QD-BKHCN by Minister of Science and Technology of August 23, 2006 and the Decision No. 05/2007/QD-BKHCN by Minister of Science and Technology of March 30, 2007 on realization of the Scheme of TBT Agreement implementation (approved by Prime Minister).
- The Circular No. 23/2007/TT-BKHCN by Minister of Science and Technology of September 28, 2007 guiding the preparation, appraisal and promulgation of technical regulations.

**Development and Application of Standards**

- The Circular No. 21/2007/TT-BKHCN by Minister of Science and Technology of September 28, 2007 guiding the Preparation and Application of Standards.
- The Decision No. 22/2007/TT-BKHCN by Minister of Science and Technology of September 28, 2007 issuing “Regulation on Organization and Operation of National Standards Committee”

(iv). Legal documents by the Provincial Committees on standards and conformance issues include decisions and directives for the purpose to guide higher level legal documents or

regulate specific aspects in local territory.

In fact, in Vietnam the Provincial (governmental) Committees rarely issue TBT related legal documents. They concentrate on the implementation of legal documents by central governmental agencies. This practice is different from some other WTO Members such as US where state governments play the important role in legislature.

Vietnam's Law on Standards and Technical Regulations was approved by the National Assembly promptly before Vietnam becoming a Member of WTO. This Law became a key legal document in interpretation of basic principles of TBT Agreement in Vietnam.

The Law states: "Standardization activities must ensure non-discrimination as to the origin of goods, products and services..., must not cause unnecessary obstacles to the production, trade and commercial activities; and must secure transparency."

"The development of standards and technical regulations must be based on scientific and technological achievements, practical experiences, present needs and tendency of social-economic development; use of international, regional standards as wide a basis as possible for development of standards and technical regulations, except where such standards are inappropriate to Vietnam's climatic, geographical, technological and technical factors or except where they have negative impact on the national benefit; give priority to the development of requirements in relation to the utility of products, goods and services; the development of requirements of a descriptive nature or as to the detailed design shall be limited; secure uniformity of the system of standards and the system for technical regulations of Vietnam."

"Standards and technical regulations must satisfy requirements on safety; national security; human hygiene and health; legitimate rights and benefits of relevant parties; and the protection of animals, plant and the environment." "The development of standards must secure the involvement and agreement between related parties and that the standards shall secure improvement of productivity, quality and socio-economic efficiency; and improvement of competitive capacity of products and services in the domestic and international markets; and reasonable use of natural resources."

Vietnam's technical regulations system has been developed mainly based on Vietnam national standards, international standards (ISO, IEC, CODEX, ITU..., regional standards (previous ST SEV, EN) and foreign standards (ASTM, AS, BS...)/technical regulations.

As main source for technical regulations, Vietnam's national standards system covers nearly 6000 TCVNs of which 25% adopted international, regional and foreign standards (mainly international ones). This level will be reached up to 35%-40% in 2010 as planned. High level of harmonization with international standards, recommendations and guidelines will facilitate trade with other WTO members.

In the light of definition of TBT Agreement, all standards in Vietnam will be applied on voluntary basis. A standard or a part thereof will be mandatory if it is covered in a technical regulation by a competent authority. Transparency provisions of Law on Standards and Technical Regulations on standards development are similar to provisions specified in Annex 3 of TBT Agreement on Code of Good Practice of Application, Adoption and Application of Standards. Relating to transparency of technical regulations development, Law on Standards and Technical Regulations stipulated that:

- A master plan or work program for the preparation of technical regulations shall be prepared by the approving technical regulations agency in cooperation with Ministry of Science and Technology. They shall be publicized for comment before approval.
- The approving technical regulations agency shall adopt and publish a master plan and work program of the preparation of technical regulations no later 30 days since the date of approval.
- Agencies, organizations, individuals have rights to participate in the preparation of technical regulations through the following ways, but not limited to:
  - Proposing and making comments on the master plans and work programs for preparation of technical regulations;
  - Drafting of technical regulation in order to propose to the approving technical regulations agency for consideration and approval;
  - Taking part in drafting technical regulation upon allocation of the approving technical regulation agency;
  - Providing comments on draft technical regulations.

All State management agencies, scientific and technological organizations, enterprises, professional organizations, consumers and experts can involve in the preparation of the national technical regulations and the approving national technical regulations agency have a responsibility to organize the collection of comments from the relevant organizations and individuals; provide workshop(s) with participation of the concerned parties for commenting draft technical regulation.

The period of time for comment on draft technical regulation is at least 60 days, except in urgent cases of health, safety, environment or national security, this period may be shortened by decision of the approving national technical regulations agency. The enforcement of technical regulations as stated in Law is at least 6 months from the date of publication, except for cases of national security, safety, health or environment. In those cases this period may be shortened by decision of the approving technical regulation agency.

#### 5.1.2.2 TBT Institutions

##### (i) TBT Vietnam Inter-ministerial Committee

On 26 May 2005, Prime Minister has promulgated Decision No 444/QĐ-TTg on the Scheme of the implementation of the TBT Agreement TBT in Vietnam. Decision has, inter alia, established TBT Vietnam Inter-ministerial Committee in order to enhance the coordination of the relevant agencies in the country in implementation of the TBT Agreement. The Committee has such main function and responsibilities as bellows:

- Advising Minister of Science and Technology and other relevant governmental agencies on measures to comply with obligations under the TBT Agreement in Vietnam, in particular in regard of implementation and administration of the Agreement.
- Proposing measures to protect national interest in preparation and application of technical regulations and conformity assessment procedures, in harmonization national standards with international standards and participation in standardization and conformity for advising the relevant agencies in settlement of TBT disputes, if any.

The representatives from 13 Ministries and governmental agencies are members of Committee. STAMEQ serves as an executive body and TBT Vietnam is a secretary member for the Committee.

Ministries and governmental agencies are members of TBT Inter-ministerial Committee as follows:

- Ministry of Science and Technology (one of leaders of this Ministry is a chair of Committee and one of leaders of STAMEQ is vice-chair of Committee);
- Ministry of Industry and Trade;
- Ministry of Transport;
- Ministry of Health;
- Ministry of Resources and Environment;
- Ministry of Information and Communication;
- Ministry of Construction;
- Ministry of Agriculture and Rural Development;
- Ministry of Finance;
- Ministry of Justice;
- Ministry of Labor, Invalid and Social Affairs;
- Ministry of Culture Sport and Tourism;
- Government Office.

As usual, TBT Inter-ministerial Committee will meet two times per year, except unofficial or extraordinary cases. The decisions are made by the consensus principle.

For more information of TBT Inter-ministerial Committee, please contact TBT Vietnam Office or visit TBT Portal at [www.tbvtvn.org](http://www.tbvtvn.org).

(ii) TBT Vietnam Network (see the Prime Minister Decision in Annex 2)

This Network was established by Prime Minister Decision No 114/2005/QĐ-TTg of 26 May 2005, in order to better deal with obligation of transparency under the TBT Agreement. Network consists of TBT Vietnam and 72 other TBT points in 9 TBT related ministries and 63 localities in the country (before 1 Aug., 2008 there was 64 localities having TBT Points, but from 1 Aug., 2008 Ha Noi and Ha Tay were merged in one and called as Ha Noi) Besides function of notifying proposed technical regulations and conformity assessment procedures affecting trade, Network will be also TBT information provider to assist exporters to better access regional and world market by avoiding TBT barriers, if any. For more information on activity of TBT points in TBT Network, please see TBT Portal of TBT Vietnam Office at [www.tbvtvn.org](http://www.tbvtvn.org), where you can read general information of TBT Network and also visit many TBT points websites attached to Portal. Contact details of all TBT points throughout the country are as given in Annex 3 attached hereafter.

**(iii) TBT Vietnam Office**

# TBT VIETNAM

VIETNAM WTO/TBT NOTIFICATION AUTHORITY AND ENQUIRY POINT

As a body responsible for TBT issues in Ministry of Science and Technology, STAMEQ has the TBT Vietnam Office (in short, TBT Vietnam) in its structure. TBT Vietnam serves as National TBT notification authority and National TBT enquiry point. Such organizational structure could help TBT Vietnam to deal with transparency obligation under the TBT Agreement efficiently and simply.

Besides, TBT Vietnam also takes part in some other activities such as TBT negotiation, education, and training.

TBT Vietnam acts as the secretary of TBT Vietnam Inter-ministerial Committee and the central point of TBT Vietnam Network. TBT Vietnam Portal is a hub of TBT information flows in Vietnam. These information flows include, inter alia, the followings:

- Information received from WTO and its Members on proposed technical regulations, standards and conformity assessment procedures that may cause the unnecessary obstacles to international trade;
- Information of the trends and events of TBT in WTO and related fora;
- Information of TBT issues and events in Vietnam;
- Information of the implementation of TBT Agreement in Vietnam;
- Information of other TBT related issues in Vietnam and overseas.

The tools and services provided by the Portal may include as below:

- Free downloading the available data and information in Portal;
- Receiving TBT notifications of other WTO Members on proposed technical regulations and conformity assessment procedures through users' registered email;
- Send enquiries and receive answers on TBT and related issues in Vietnam and in other WTO Members;
- Take part in TBT forum;
- Other consultancy services.

The Portal has links to many websites of TBT Points in ministries and local provinces throughout the country; TBT websites of other WTO members; websites of foreign, regional and international standardizing bodies and conformity assessment systems. The Portal will be an address where all agencies and stakeholders can trust in seeking information of TBT and TBT related issues which could help overcome the technical barriers to facilitate trade and protect consumer's interests as well. Having any further information of this Portal, please visit [www.tbvtvn.org](http://www.tbvtvn.org).

Recently, TBT Vietnam has focus its efforts to strengthen TBT Network; to develop more value-added services such as close cooperation with business associations by cooperation agreements or provision of TBT information in other WTO members markets to Vietnamese stakeholders by TBT Vietnam *Thong bao* Database (learned from *Notify US*).

There are some publications on TBT issues which were prepared by TBT Vietnam itself or in cooperation with sponsoring bodies.



This Handbook on the TBT Agreement published by the WTO to guide the implementation of TBT obligations by the Members. It is a good reference for everyone who likes to understand TBT issues in light of WTO point of view. It is especially valuable for people who work in TBT Network such as notification authorities and/or enquiry points. It was translated by TBT Vietnam Office under the permission of WTO. Vietnamese version is available in TBT Portal [www.tbvtvn.org](http://www.tbvtvn.org).



This book is published by the Technical Assistance Program of the Republic of France and Vietnam's National Committee of International Economic Cooperation (NCIEC). The book consists of some important reports on TBT issues for Vietnamese audience, which quoted from the original the WTO and Technical Barriers to Trade edited by Spencer Henson and Fohn S. Wilson. Vietnamese translation was done by experts of STAMEQ. Vietnamese version is available at TBT Vietnam Office.



This book is published by TBT Vietnam Office. It consists of information of WTO dispute settlement for a decade, in particular regarding TBT. Besides, the book also draws a procedure un which Vietnam could deal with such disputes in the future, if any. The book is available at TBT Vietnam Office.



This book is prepared by effort of MUTRAP II (a Project of EU to assist Vietnam in trade facilitation) and experts of TBT and SPS Vietnam Offices. It covers a range of TBT ad SPS issues; and serves as a reference for people who deal with transparency obligations under the TBT and SPS Agreements.

The book published by MUTRAP II is available at TBT and SPS Vietnam Offices



This handbook is published by TBT Vietnam Office. It contains information of TBT Vietnam Inter-ministerial Committee and Network in Vietnam, their function and operation and how they deal with advisory work to implement all obligations required by the TBT Agreement and especially transparency obligation.

The book is available at TBT Vietnam Office

## 5.2 Vietnam's MAS-Q Institutions

### 5.2.1 The Ministry of Science and Technology



In Vietnam, Ministry of Science and Technology is assigned by the Government as a central contact point for the implementation of TBT Agreement.

This Ministry took part in negotiation of Vietnam's accession to WTO in regard of TBT issues. In cooperation with other relevant agencies, it draws the Action plan to implement the TBT Agreement as required by the Working Party. After WTO accession, the Ministry continues its function as central contact point in implementation of WTO/TBT commitment in WTO and other related fora such as ASEAN, APEC, ASEM and bilateral relations as well.

As assigned by Prime Minister, the Ministry has a responsibility of leading the TBT Vietnam Inter-ministerial Committee. Draft technical regulations by this Ministry will be posted in its website [www.most.gov.vn](http://www.most.gov.vn) for comment.

#### (ii) Directorate for Standards and Quality- STAMEQ

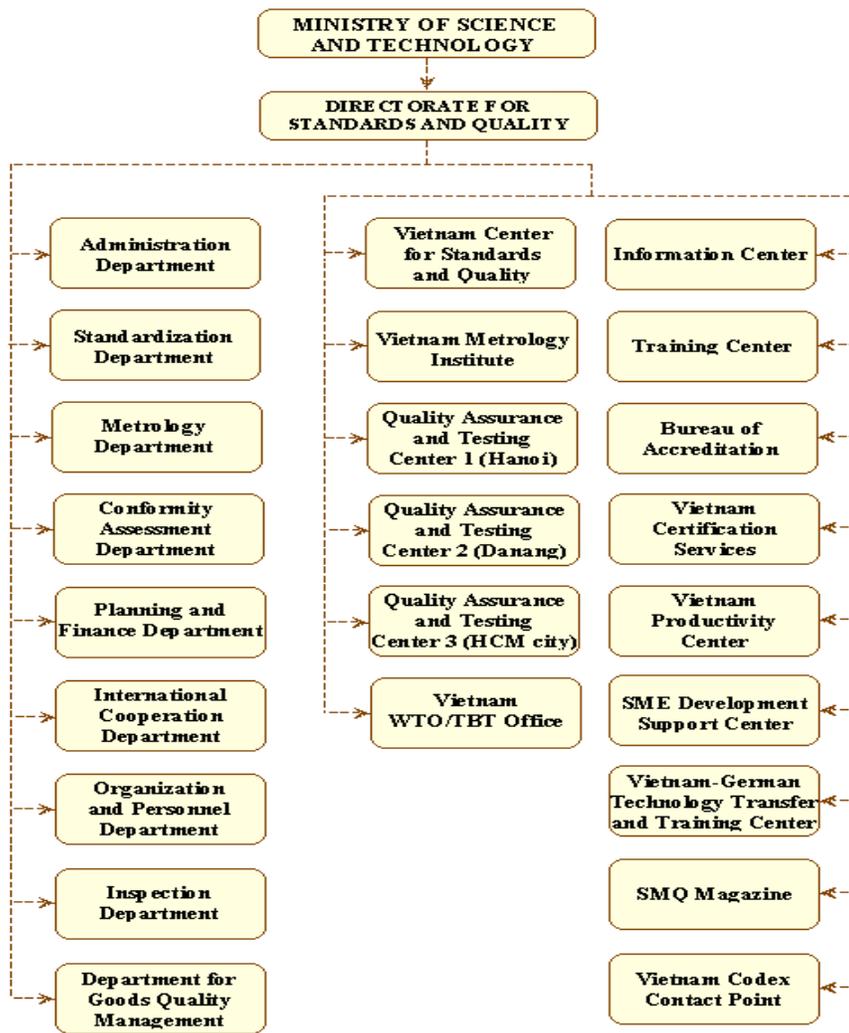


The Directorate for Standards and Quality (STAMEQ) - a Governmental Body under Ministry of Science and Technology, is responsible to standardization, metrology, quality, productivity as well TBT issues before the Ministry.

STAMEQ has long process of development with different names: the Institute for Standardization and Metrology from 1962, the Department for Quality Control of Products and Merchandises since 1971, the State Department for Standards, Metrology and Quality since 1979, the General Department for Standards, Metrology and Quality since 1984 and Directorate for Standards and Quality-STAMEQ since 1995 up to now.

In 1999, the President of Vietnam promulgated an Ordinance on Metrology, an Ordinance on Good Quality and an Ordinance on the protection of Consumers' interests which promote the development of standardization, metrology and **quality** control activities, in keeping with the Government's Renovation Policy. STAMEQ is the national standards body of Vietnam and has been a member of ISO since 1977 with short name TCVN valid until this day. STAMEQ consists of six directly-belong-to departments and 16 other financial-independent subsidiaries with total staff of more than 1,200 employees (see the Organizational structure of STAMEQ).

## The Organizational structure of STAMEQ



STAMEQ is also guiding activities of more 20 agencies in charge of Standards, Metrology and Quality (SMQ) in line ministries, branches, and 63 provinces and cities under the central government.

STAMEQ has main functions as follows:

- To set out policy in the fields of standardization, metrology and quality management in the country;
- To carry out activities in the fields of standardization, metrology, quality management and productivity in benefit of Vietnam's economy and society;
- To represent Viet Nam in international and regional standards, conformity and productivity fora.

### STAMEQ's Regulatory Activity

In Vietnam, system of technical regulations consists of:

- National Technical Regulations, symbolized as QCVN;
- Local Technical Regulations, symbolized as QCDP.

National technical regulations are prepared and approved by Ministers, Heads of ministerial-level agencies within the scope of their management sectors and areas authorized by the Government. Local technical regulations are prepared and approved by People's Committee of a province or city under central within their territory appointed by the Government. As usual, local technical regulations are not contradicted to the relevant national technical regulations. In most cases, they will detail the relevant national technical regulations in order to meet local requirements in term of specific geographical, climatic and socio-economical factors.

Avoiding the possible contradiction among national and local technical regulations, there is the appraisal work carried out by the relevant ministries for draft local technical regulations. STAMEQ will prepare draft regulations to set out detail procedures in preparation, appraisal, approval and application of technical regulations for consideration and promulgation by the competent authorities. Besides, STAMEQ carries out the appraisal work for those draft local technical regulations covered by the scope of Ministry of Science and Technology.

STAMEQ's standardization activity

From 1<sup>st</sup> Jan., 2007 Vietnam's system of standards consists of two categories:

- National standards, symbolized as TCVN; and
- Organization's standards, symbolized as TCCS.

Draft national standards may be developed or proposed by many organizations including all line ministries and other related organizations. Ministry of Science and Technology has power to appraise all draft national standards and adopt those meeting the requirements of a national standard. Organization's standards are developed and implemented in full power of any organization. The State agencies do not interfere process of development of TCCSs. As a national standards body, STAMEQ only issues a good practice to guide organizations how to develop and apply a TCCS to meet the legal requirements, if any.

STAMEQ's National Standards development is performed mainly by Vietnam Standards and Quality Center

### **Vietnam Standards and Quality Center**



This Center (VSQC), under STAMEQ, has responsibilities as follows:

- To take part in development of draft technical regulations; carry out research on standardization, quality and bar-coding policy and works;
- To organize national standards (TCVN) development activity;
- As Vietnam's contact point, to take part in international standards development;
- As a member of GS 1, to carry out bar-coding activity in Vietnam;
- To organize activity of Vietnam's Quality Award and International and Regional Quality Awards in Vietnam.

Technical committees for national standards preparation

VSQC is the secretary of all *Technical committees for national standards preparation* established by Ministry of Science and Technology for each standardization field.

Members of technical committees for national standards consist of representatives of government agencies, scientific and technological organizations, associations, and enterprises, other concerned organizations, consumers, and experts. Up to now, 93 technical committees for national standards were established (see List of Technical Committees in Annex attached hereafter).

The names the mentioned above Committees and steps of standards development thereof are similar of ISO Technical Committees. The period of time for public commenting draft national standards is at least 60 days from date of notification, except for urgent cases of health, safety, environment or national security this period could be shortened. This fully meets requirements of the Annex 3, TBT Agreement.

STAMEQ is now preparing conditions to accept the Code of Good Practice in accordance with Annex 3 of TBT Agreement regarding preparation, adoption and application of standards by the end of this year in order to fulfill Vietnam's commitment of WTO accession. Up to now, more than 6000 TCVN were developed and more than 30%, among them have adopted the relevant international and regional standards.



#### ***The Vietnam Quality Award***

The Vietnam Quality Award (VQA) was established in August 1995 by the Ministry of Sciences, Technology and Environment. The VQA aims at encouraging production business and service organizations to improve quality of their activities for higher competitiveness on the domestic and overseas markets. The VQA is annually presented to organizations with outstanding quality achievements, positive impacts on the society and good business performance. This is the National Award with criteria consulted from other countries' Awards that have reached international standard. Selection process is laborious and scientific, from local level to central level, in concerned Ministries and Branches. Enterprises can participate only in International Award if they have been awarded with Vietnamese Quality Award.

For more information, please contact:

*Vietnam Standards and Quality Centre*

*Address: 8 Hoang Quoc Viet, Cau Giay, Hanoi-Vietnam*

*Phone: +84-4 -37564407*

*Email: info@vsqc.org.vn*

*www.vsqc.org.vn*

### STAMEQ's Metrology Activities

This field of STAMEQ's activity is performed by Vietnam's Metrology Institute (VMI) and in Quatest 1, 2 and 3 as well.

#### Vietnam's Metrology Institute



Vietnam Metrology Institute (VMI) has the functions:

- To establish, maintain and custody national measurement standards;
- To ensure traceability of measurement standards to SI system;
- To develop measurement and evaluation technology for industries; design, produce and supply measurement standards, instruments, calibration means;
- To calibrate the measurement standards and instruments;
- To set up and carrying out the metrological assurance program for industries;
- To represent Vietnam in international and regional metrology organizations.

VMI has 10 measurement laboratories, all of which are accredited by VILAS (Vietnam Laboratory Accreditation System)

- Laboratory of Length
- Laboratory of Mass
- Laboratory of Volume & Flow
- Laboratory of Physical-Chemical Parameters & Reference Materials
- Laboratory of Force & Hardness
- Laboratory of Pressure
- Laboratory of Electricity
- Laboratory of Electromagnetic
- Laboratory of Time & Frequency
- Laboratory of Temperature

STAMEQ (VMI) is member in the following international and regional measurement bodies:

- Asia Pacific Metrology Program (APMP);
- International Organization of Legal Metrology (OIML);
- Asia Pacific Legal Metrology Forum (APLMF);
- Conférence Generale des Poids et Mesures (CGPM) ;

STAMEQ (VMI) has cooperation agreements with national measurement institutes as follows:

- National Institute of Standards and Technology-USA (NIST);
- National Measurement Laboratory-Australia (NML);
- Metrology Standards Laboratory-New Zealand (MSL);
- Physikalisch - Technische Bundesanstalt -Germany (PTB);
- Korea Research Institute of Standards and Science (KRISS);
- National Metrology Institute of Japan (NMIJ);
- National Institute of Metrology-China (NIM).

For more information, please contact: *Vietnam's Metrology Institute*  
*Address: 8 Hoang Quoc Viet Cau Giay Hanoi Vietnam*

Phone: +84-4-38361872

Fax: +84-4-37564260

www.vmi.gov.vn

## VMI Measurement Standards and Accuracy

Parameters	Units	Standards	Accuracy
<b>1. Mechanical</b>			
Length	m	He-Ne Stabilized Laser	$2 \times 10^{-9}$
Angle	rad	24 Sided & 36 Sided Polygon	0,5"
Mass	kg	Standard weight 1 kg	$2 \times 10^{-8}$
Volume	m <sup>3</sup>	Standard Flasks & Vessels	$2 \times 10^{-4}$
Flow	m <sup>3</sup> /h	Standard of water flow (3 , 200) m <sup>3</sup> /h	$2 \times 10^{-3}$
Density	kg/m <sup>3</sup>	Glass Hydrometers (650 , 2000) kg/m <sup>3</sup>	0,2
Viscosity	m <sup>2</sup> /s	Ubbelohde Viscosimeters	$10^{-3}$
Moisture	%	Vacuum Oven	0,1%
pH	pH	pHmet (2 , 9) pH	0,001
Force	N	Standard of Mass and Local Gravitation Acceleration	$3 \times 10^{-4}$
Hardness	HR, HB, HV	Standard Hardness Machine HNG-250	0,3 HRC 1,2%
Pressure	Pa	Dead Weight Piston Gauge up to 100 MPa	đến $1 \times 10^{-5}$
<b>2. Electrical</b>			
DC Voltage	V	Fluke 732B Voltage	$2 \times 10^{-6}$
AC Voltage	V	HP 3458A; Fluke 5720A (f ≤ 100 kHz; U = 0,1 1000 V)	$5 \times 10^{-5}$
DC Resistance	Ω	Standard Resistors ( 1 ÷ 10 <sup>6</sup> )Ω	$3 \times 10^{-6}$
Power & Energy	W-Wh	C 1-2 5A - 240 V 3 x ( 3 ÷ 480 ) V; 3 x ( 1 mA ÷ 120 A ) KOM 200.	$5 \times 10^{-5}$  $1 \times 10^{-4}$
Capacitance	F	Standard Capacitors	$2 \times 10^{-4}$
Inductance	H	Standard Inductors	$5 \times 10^{-4}$
HF Voltage	V	Complex Device Digital Voltmeter D7075 Power meter NRS BN 2414 CAC Standard Fluke 5790A f < 30 MHz; U = 0.1 ÷ 3 )V	$5 \times 10^{-3}$  100 ppm
HF Power	W	Digital power meter HP - E4418B 10MHz ÷ GHz, 100pW ÷ 100mW	$5 \times 10^{-3}$
Level	dB	Level Meter	0,1 dB
Attenuation	dB	Standard Attenuators	0,5 dB
<b>3. Time &amp; Frequency</b>			
Time interval	s	Electronic counter HP 53132A	$1,5 \times 10^{-10}$
Frequency	Hz	Cesium beam Frequency Standard HP 5071 A	$2 \times 10^{-12}$
<b>4. Temperature</b>			
	K	Fixed points and standard platinum resistance thermometer	
		Triple point of water 0.01 °C	1 mK
		Freezing point of Tin 231.928 °C	2 mK
		Freezing point of Zinc 419.527 °C	3 mK

## STAMEQ's Conformity Assessment Activities

STAMEQ has a wide range of conformity assessment activity. This includes accreditation, certification, and testing.

### Accreditation activity

This activity is carried out by Bureau of Accreditation (BOA) of STAMEQ

### Bureau of Accreditation



BoA was established in 1995 with mission and work programs as below:

Mission:

- To strive for the objective of one certificate/testing and calibration report accepted worldwide;
- To provide confidence for customers, regulators in the market to the conformity assessment bodies (CABs);
- To comply with international standards.

BoA Accreditation programs include Laboratories, Certification Bodies and Inspection Bodies.

The Vietnam Laboratory Accreditation Scheme (VILAS) by BoA is aimed at:

- Recognizing the competence of laboratories in testing and calibration
- Facilitating the recognition of testing/calibration results between laboratories
- Integrating the laboratory accreditation activities of Vietnam with those of other countries in the region.

STAMEQ is a member of such international and regional accreditation bodies such as:

- ILAC (International Laboratory Accreditation Cooperation),
- APLAC (Asia Pacific Laboratory Accreditation Cooperation) and
- PAC (Pacific Accreditation Cooperation).

STAMEQ is also signatory to ILAC and APLAC MRAs for VILAS and VIAS schemes, PAC MRAs for VICAS scheme.

Boa has accredited more than 300 laboratories in conformity with international standards.

For more information, please contact:

**Bureau of Accreditation**

**Address: 8 Hoang Quoc Viet - Cau Giay - Hanoi-Vietnam**

**Tel: +84-4-37 911 552**

**Fax: +84-4-37 911 551**

**E-mail: [vpcongnhan@boa.gov.vn](mailto:vpcongnhan@boa.gov.vn)**

### Certification activity

Certification is carried out by different subsidiaries of STAMEQ (Quacert, Quatest 1, 2 and 3; and some other Centers) of which Quacert is one of leading certification bodies in STAMEQ and Vietnam as well.

### Vietnam Certification Center (Quacert)



The Center supports Vietnamese enterprises and other stakeholders in the process of international integration of quality by ensuring the consistence and compliance with national and international standards and practices through product and system certifications.

Quacert is evaluated and recognized by [JAS-ANZ](#) Joint Accreditation System of Australia and New Zealand) and a member of the International Accreditation Forum [IAF](#).

Quacert has taken part in conformity assessment activities of ACCSQ in ASEAN and SCSC in APEC; and linkage between certification and customers' business efficiency;

QUACERT provides such services as:

- Product certification to Vietnamese standards (TCVN), foreign standards (JIS, ASTM, GOST, GB...), regional standards (EN, CEN,) and international standards (ISO, IEC);
  - Management System Certification in accordance with international Standards
  - Quality Management System Certification – ISO 9001
  - Environmental Management System Certification ISO 14001
  - Occupational & Health Safety Management System OHSAS 18001
  - Hazards Analysis and Critical Control Point HACCP
  - Good Manufacturing Practices GMP
  - Quality Management System in specific industries such as ISO/TS 29001 for the Petroleum, Petrochemical and Natural gas industries
  - Information Security Management System ISMS
  - Training activities to assist customer achieve excellent business system through process efficiency;
  - Provision of business management solutions applying information technology (IT) for enterprises.

For more information, please contact:

**Vietnam Certification Centre - QUACERT**

*Address: 8 Hoang Quoc Viet, Cau Giay, Hanoi -Vietnam*

*Tel: +84-4)-37.561.025 - 7.565.483*

*Fax: +84-4-37.563.188*

**Email: [Quacert@quacert.gov.vn](mailto:Quacert@quacert.gov.vn)**

**<http://www.quacert.gov.vn/>**

## STAMEQ's Testing Activity

This STAMEQ's activity is performed at Quality Assurance and Testing Centers 1, 2 and 3 (in short Quatest 1, 2 and 3 which are located in North, Central and South of Vietnam, respectively).

Testing facilities of STAMEQ Quatest 1, 2 and 3 have a widest range of testing field in Vietnam with high-performance testing equipment and in many cases serve the arbitration purpose.

### The Quality Assurance and Testing Center 1



The Quality Assurance and Testing Center 1 (Quatest 1) belong to the Directorate for Standards and Quality, under Ministry of Science and Technology. The main functions of Quatest 1 as follows:

- Verification the quality of import-export goods;
- Inspection the technical conditions of equipment, technologies and commodities' quality;
- Testing quality of products, commodities, also on-site testing;
- Verification and calibrating measurers;
- Repairing and maintaining measurers;
- Instructing and consulting; establishing and application of the Quality Management System (QMS) in accordance with International Standards ISO 9001, ISO 14000, ISO/IEC 17025, etc.

Quatest 1 has 06 testing Labs, namely:

- Mechanical - NDT
- Electric - Electronic
- Light Industry
- Chemical, Microbiological and food
- Environment chemical
- Petroleum and Oils

Quatest 1 Mechanical & Non-Destructive Testing Laboratory (accredited, VILAS 148) has the following testing fields:

- Testing physical Mechanics, microstructure, quality of coating, metal parts, soldering sticks, welds, etc. according to TCVN, ISO, BS, JIS, ASTM, etc.
- Testing physic-mechanical natures of different products, building materials (bricks, tiles, concrete, wood, roofing, precast members, porcelain, isolated glass) according to TCVN, ISO, BS, JIS, ASTM, etc.
- Analyzing chemical component of steel and low alloy steel (G, G-Ni), manganiferous steel, usual cast iron, spherical cast iron, pure aluminium, low alloy aluminium (siliceous aluminium, siliceous-coppery aluminium) , pure copper, alloy-copper according to ASTM E-415-95.
- Verification in undestroyed conditions with the devices of ultrasound, X-ray, magnetic, endosmosis; Measuring and defining the interior and external defectiveness

of metal such as welds of boiler, pipeline, bridges and locks, cranes, building structure, etc. Appreciating welds' quality according to TCVN, ISO, ASME, BS, JIS, EN.

- Verification and appreciating the quality of materials, metal parts (iron, steel, aluminium, etc), wood, bricks, tiles, concrete, roofing, etc.
- Verification and appreciating the quality of welds.
- Verification and appreciating the accordance with standards (TCVN, ISO, BS, JIS, ASTM, etc.) or/and technical requirements of investor or consultative company.

***Quatest 1 Electric-Electronic Testing Laboratory (accredited in compliance with ISO/IEC 17025, VILAS ).***

The Laboratory is equipped with modern equipment from the State's Projects and International Cooperation Programs such as UNDP, KOICA (Korea). With technical qualification and a rank of skilled technicians, the Laboratory is able to test various produces such as: Household electric and electronic appliances; Wires and Cables; Magnetic wires; circuit Breakers; Insulation material; Transformers, electric machines; Other Electric accessories. The methods for testing are based on the TCVNs or/and International Standards such as IEC, ASTM, etc.

***Quatest 1 Food-Chemical and Microbiological Laboratory (accredited in compliance with ISO/IEC 17025, VILAS 21)***

The Laboratory's Testing fields:

- Methods of chemistry, physic-chemistry, and microbiology are applied.
- Test Items: Food and Agricultural products, cosmetics, water, products from fermentation process biochemistry, aseptic medical device, Safety Toy, customer's goods.
- Testing methods are applied: TCVN, ISO, CODEX, FAO/FNP, IUPAC, AOAC, AOCS, OIV, NF, EPA, etc.

***Quatest 1 Environmental Testing Laboratory (accredited in compliance with ISO/IEC 17025, VILAS 30) has the following services:***

- Assessing environmental impacts;
- Analyzing environment's quality including air, water, soil, sediment.
- Analyzing residual amount of pesticide and organic compounds such as: chlorophenols, PCBs, PAHs, etc. are existing in soil, water, sediment, creatures.
- Analyzing heavy metals.
- Surveying and analyzing environmental factors and indexes.
- Consultancy works to deal with pollution issues.
- Training on the environmental chemistry's testing.

For more information, please contact:

*Quatest 1*

*Tel: (84-4) 7564188*

*Fax: (84-4) 8361199*

*E-mail: [quatest1@fpt.vn](mailto:quatest1@fpt.vn)*

*<http://www.quatest1.com.vn/>*

### The Quality Assurance and Testing Centre 3

## QUALITY ASSURANCE & TESTING CENTER 3

The Quality Assurance and Testing Centre 3 (QUATEST 3) is a government-own scientific - technical organization under Directorate for Standards and Quality - Ministry of Science and Technology. Quatest 3 main functions are the followings:

- Inspection, assessment on quality, safety, hygiene of products, commodities, services and construction site-works.
- Verification, calibration and validation of measuring equipment.
- Testing for quality, safety and hygiene of products.
- Product certification in conformity with standards and technical regulations.
- Inspection on the quality of construction site-works and industrial safety.
- Examination and evaluation technology status.
- Assessment of environmental effects and environmental requirements.
- Research, development and supplying metrology standards.
- Training and consulting on standardization, metrology, quality and productivity.
- Providing of information on standards, metrology and quality.

In order to fulfill the above mentioned functions, QUATEST 3 provides services as bellow:

- Quality inspection, testing and evaluation of controlled commodities as designated by government authorities;
- Verification of measuring equipment as accredited by legal metrology authority; calibration and validation measuring equipment and measuring systems;
- Product Certification in conformity with standards and technical regulations;
- Testing, evaluation, inspection on quality, safety and/or hygiene of products, commodities, services, materials, construction, inspection and evaluation of projects and site-works as requested by government authorities, companies and individuals;
- Examination, evaluation on technical conditions, technological status, technology transfer and industrial safety; consulting and supervision of construction site-works; examination, observation and assessment of environmental effects and status;
- Research, fabrication and supplying metrology standards, reference materials and measuring instruments; servicing laboratory equipment;
- Consulting on application of management systems, productivity, quality improvement tools and laboratory equipment;
- Carrying out research, development and application of science and technology in standardization, metrology and quality;
- Training on standardization, quality, metrology, laboratory practices, technology transfer and other related quality training activities;
- Receiving bar codes application as assigned by GS1 (EAN) Vietnam authority and providing services of bar code technical application;
- Participating in formulating Vietnamese National Standards (TCVN), Regional Standards and International Standards and providing standardization services;
- Providing information and publication of standards and other related documents on standards, metrology and quality.

Many testing laboratories of Quatest 3 are accredited by VILAS. Testing products and methods are similar as Quatest 1'.

Quatest 3 is also carrying out measurement calibration to meet needs of stakeholders in South provinces for such quantities and units as Weight, Volume, Length, Mechanical, Electrical Temperature and Chemical-physical.

For more information, please contact:

**QUATSET 3**

*Head Office*

*49 Pasteur, District 1,*

*Ho Chi Minh City, Vietnam*

*Phone: (84-8) 82 94 274*

*Fax: (84-8) 82 93 012*

*E-mail: [qt-xuctien@quatest3.com.vn](mailto:qt-xuctien@quatest3.com.vn) or [quatest3@hcm.vnn.vn](mailto:quatest3@hcm.vnn.vn)*

*<http://www.quatest3.com.vn/>*

*Testing House*

*7 Street 1, Bien Hoa Industrial Zone 1,*

*Dong Nai, Vietnam*

*Phone: (84-61) 83 62 12*

*Fax: (84-61) 83 62 98*

*E-mail: [testing@quatest3.com.vn](mailto:testing@quatest3.com.vn)*

*or [quatest3bh@hcm.vnn.vn](mailto:quatest3bh@hcm.vnn.vn)*

Metrology Instrumentation Service Dept.

*64 Le Hong Phong, District 5,*

*Ho Chi Minh City, Vietnam*

*Phone: (84-8) 92 32 431*

*Fax: (84-8) 92 34 302*

*Email: [dl-thietbi@quatest3.com.vn](mailto:dl-thietbi@quatest3.com.vn)*

STAMEQ's Productivity and SME Supporting Activity

Productivity Activity of STAMEQ is mainly performed by Vietnam Productivity Center.

### **Vietnam Productivity Center (VPC)**



VPC's programs cover a wide range of areas with special focus on productivity measurement and analysis, quality management, information technology, green productivity and environmental performance. VPC maintains a close and regular cooperative relationship with the Asian Productivity Organization (APO) as well as other international organizations. VPC's mission is to:

Enhance Productivity and Quality activities to increase the Vietnam's competitiveness through the promotion of advanced technology and solutions to enterprises and communities;

Promote strategic alliances with the national as well as international organizations and professional bodies for the socio-economic development;

VPC's programs cover the industry, service, and agriculture sectors, with special focus on socio-economic development, environmental performance, productivity measurement and analysis, quality management, information technology, green productivity and community development. Its main activities:

- To conduct research, organize conferences and workshops for quality and productivity enhancement in Vietnam;
- To create the member network at home and abroad, build and monitor the movement of productivity and business environment across the country.
- To coordinate and implement a great number of projects with international partners and sponsors such as the Asian Productivity Organization (APO), the Asian Society for Environmental Protection (ASEP), the Asia-Pacific Economic Cooperation (APEC)...
- To lead various important projects for the Vietnamese Government and other related ministry to improve the living standards of communities and organizations.
- To provide with high quality training and consulting programs to enhance the management systems and competitiveness of Vietnamese organizations and enterprises. Contents of those training and consulting programs cover a wide range of areas: ISO 9000, ISO 14000, SA8000, HACCP, TQM, SPC, Kaizen & 5S, CRM, CSM, HRM, KM ...

For more information, please contact:

*Vietnam Productivity Center (VPC)*

*8 Hoang Quoc Viet, Cau Giay, Hanoi-Vietnam*

## **SMEDEC 2**



SMEDEC HCMC was the unit of STAMEQ and established in 1995 under the decision of the MOSTE (2217/QĐ-TCCBKH issued on December 22<sup>nd</sup> 1995) and operates in accordance to Decree No. 35/HĐBT issued by the Government.

On July 13<sup>th</sup> 2006, relating to strengthening and reorganizing some units of STAMEQ, Small and Medium Enterprises Development Support Centre 2 (SMEDEC 2) was established by MOST (Decision No.1588/QĐ-BKHVN) based on SMEDEC HCMC activities.

### **Our main activities:**

- Examining and developing the programs which concerning to training and consultancy activities on Standard – Metrology – Quality, for instance, TQM (QCC, 7 tools, 5S, Kaizen, etc.), ISO 9000, ISO 14000, ISO 22000, ISO 27000, ISO 17025, product standard compliance, SA 8000, HACCP, etc.
- Cooperating and being a professional partner of international organization such as Mekong Private Development Facility – MPDF (IFC – World Bank), SIYB (ILO), DANIDA (Denmark), GTZ (Germany), InWent (Germany), to provide with the training courses and consultancy to organizations and enterprises on GHK (Good House Keeping), CSM (Chemical Safety Management), SEAL (Social Accountability),

- Better Work (Improving the working conditions in garment sector),
- Cleaner Production, SIYB (Start and Improve Your Business) etc.

For further information, please contact us: SMEDEC 2

Address: 64-66 Mac Dinh Chi – Dakao Ward – District 1 – Ho Chi Minh City

Tel: (84.8) 38248866

Fax: (84.8) 38225868

E-mail: [smedec2@vnn.vn](mailto:smedec2@vnn.vn)

Website : [www.smedec.com](http://www.smedec.com)

### Visit also SMEDEC 1

8 Hoang Quoc Viet, Cau Giay – Hanoi

Tel: 04 7564245

Fax: 04 7564244

E-Mail: [smedec1@fpt.vn](mailto:smedec1@fpt.vn)

### CODEX VIETNAM

Codex Vietnam is an Inter-branch Committee. The Committee's Office is a subsidiary of STAMEQ. This Office serves as a contact point of Codex Vietnam with Codex International (CAC) and its other members as well as with the relevant domestic organizations. The Office keeps a range of food standards and documents by CAC.

For more information, please contact:

*Codex Vietnam*

Address: Room 305, 70 Tran Hung Dao, Hanoi-Vietnam

Tel: 84-4-9428030

Fax: 84-4-8222520

Email: [codex@tcvn.gov.vn](mailto:codex@tcvn.gov.vn)

Website: [codexvn.org](http://codexvn.org)

### MRA related activity

#### STAMEQ International Cooperation Activity

The Membership of STAMEQ is in International and Regional Standards and Conformance is as follows:

	<b>Organization</b>	<b>Since</b>	<b>Membership Status</b>
1	<a href="#">ISO - International Organization for Standardization</a>	1997	Full member
2	<a href="#">IEC - International Electrotechnical Commission</a>	2002	Associate member
3	<a href="#">OIML - Organisation Internationale de Metrologie Legale</a>	2003	Full member
4	<a href="#">ILAC - International Laboratory Accreditation Cooperation</a>	1992	Full member
5	<a href="#">CAC - Codex Alimentarius Commission</a>	1989	Full member
6	<a href="#">EAN - European Article Numbering – International</a>	1995	Full member

	<b>Organization</b>	<b>Since</b>	<b>Membership Status</b>
1	PASC - Pacific Area Standards Congress	1992	Full member
2	APLAC - Asia Pacific Laboratory Accreditation Cooperation	1995	Full member
3	APMP -Asian Pacific Metrology Program	1995	Full member
4	APQO - Asian Pacific Quality Organization	1994	Full member
5	ACCSQ - ASEAN Consultative Committee for Standards and Quality	1995	Full member
6	APEC -SCSC Asian Pacific Economy Cooperation - Sub Committee for Standards Conformance	1998	Full member
7	TA - Technonet Asia	1998	Full member
8	APO - Asian Productivity Organization	1996	Full member
9	APLMF - Asian Pacific Legal Metrology Forum	1996	Full member
10	CGPM -The General Conference on Weights and Measures of Meter Convention		
11	ASEM/TFAP/SCA -Asia-Europe Meeting / Trade Facilitation Action Plan / Standards and Conformity Assessment	1997	Full member

**Vietnam has concluded and participated in, some cooperation and mutual recognition agreements/arrangements on standards and conformance.**

#### **Bilateral agreements:**

##### **Vietnam-Ukraine**

- Agreement on cooperation in the field of mutual recognition of the results of works on certification between the Ministry of science, Technology and environment of the socialist republic of Vietnam and the state committee of Ukraine for standardization, metrology and certification
- Agreement on cooperation in the field of standardization, metrology and certification between the Ministry of Science, technology and environment of the socialist republic of Vietnam and the State committee of Ukraine for standardization, metrology and certification

##### **Vietnam -China**

- Agreement on cooperation in the field of standardization, metrology and conformity assessment between the State bureau of quality and technical supervision of the people's republic of China and the Directorate for standards and Quality of the socialist republic of Vietnam
- Memorandum of understanding between Ministry of science technology and environment of the socialist republic of Vietnam and the State general

administration for quality supervision and inspection and quarantine of the people's republic of China

#### **Vietnam - Russia**

- Agreement on cooperation in the field of mutual recognition of the results of works on certification between the Ministry of Science Technology and Environment of the Socialist Republic of Vietnam Nam and the State Committee of Standardization Metrology and certification of the Russian Federation
- Agreement on cooperation in the field of standardization, metrology and certification between the Ministry of Science Technology and Environment of the Socialist Republic of Vietnam Nam and the State Committee of Standardization Metrology and certification of the Russian Federation

#### **Vietnam-Korea**

- VMI - KRISS Memorandum of Understanding on cooperation in the field of metrology.

#### **Vietnam-US**

- STAMEQ-ANSI Memorandum of Understanding

#### **Multilateral Agreements/Arrangements**

- GLOBAL MRA on Metrology of Conférence Générale des Poids et Mesures
- ILAC MRA on Laboratory Accreditation
- APLAC MRA on Laboratory Accreditation
- ASEAN EEMRA (electrical and electronic equipment)
- ASEAN TELMRA (telecommunication equipment)
- APEC EEMRA (electrical and electronic equipment)
- APEC TELMRA (telecommunication equipment)

### **5.3 Local Standards Metrology and Conformity Assessment Authorities**

As stipulated in legal documents, the local Departments of Science and Technology are appointed as local standards metrology and conformity assessment authorities. And as usually, local Departments of Standards and Quality thereof are bodies that carry out the activities and works covered by this function. Besides, these local Departments of Standards and Quality are also professionally directed by STAMEQ.

The responsibilities and rights of local departments of standards and quality are defined in the Circular No 08/2005/TT-BKHCN of 06 June 2005 as below:

- Study and propose draft legal documents to Directors of Department of Science and Technology for consideration and submission to Chairs of Local People Committees for approval, in order to realize guidelines, policies and legal documents by Central Government in the field of standards, metrology and quality of products, goods in conformity with local conditions.
- Set up master plans and work programs to develop activities in the field of standards, metrology and quality of products, goods in provinces and report them to Directors of Departments of Science and Technology for consideration and submission to Chairs of Local People Committees for approval.
- To guide and organize the implementation of legal documents, master plans, work programs in the field of standards, metrology and quality of products, goods in provinces.

- To guide the organizations and individuals to apply international, foreign and national standards if necessary; and assist to develop private standards as required by them.
- To develop and take control over verification network for measurement equipment in order to meet local measurement verification needs; organize verification works in compliance to authorized field and scope of measurements.
- To organize and take control over self-declaration of conformity of products, goods in compliance to standards and other management measures in appointment by the state competent bodies.
- To inspect quality and labeling of products, goods circulated in local markets; deal with violations and guide to settle disputes of quality and labeling of products, goods in compliance to appointment and authorization by the state competent bodies and laws.
- To carry out assessment and testing on quality of products, goods in local markets; supervise the performance of technical service providers in compliance to appointment and authorization by the state competent bodies.
- To carry out research and application works in the field concerned; to disseminate the knowledge and legal aspects in the field concerned.
- To provide consultative, training services related to standards, metrology and quality control in provinces.
- To coordinate with the relevant competent authorities in specialized inspection activities in the field concerned in compliance to appointment and authorization by the state competent bodies.
- To fulfill other activities under the appointment of Directors of Local Departments of Science and Technology.

Besides, under Decision No 114/2005/QĐ-TTg of 26/05/2005, Prime Minister has directed the heads of provinces to establish TBT points in Departments of Science and technology. Following this order as well as the guidance of Ministry of Science and Technology, Directors of Departments of Science and Technology have appointed local departments of standards and quality to operate local TBT points after the agreement given by the Chairmen of Local Committees.

For further information of organization, responsibilities and services of local departments of standards and quality, please access the following internet addresses:

A complete list is available in the attached folder on Vietnam and the TBT Agreement.

## SECTION 6. 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 (MAS-Q) in the development of economic policies. Understanding the link between global trade, MAS-Q and export competitiveness is at the forefront of trade policy. The removal of non-tariff barriers to trade and implementing a MAS-Q 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 MAS-Q infrastructure in place.**



The author and the sponsor of this handbook sincerely hope that the readers find the information presented useful and informative. For questions concerning permission to copy and or translate, contact Mr. Dan Rathbun, Project Director, STAR Vietnam at [Dan\\_Rathbun@dai.com](mailto:Dan_Rathbun@dai.com) or Mr. Edward Nemeroff, MAS-Q Advisor at [ednemeroff@live.com](mailto:ednemeroff@live.com), or Mr. Le Quoc Bao, Director of TBT Vietnam Office at [quocbao@tbtvn.org](mailto:quocbao@tbtvn.org)