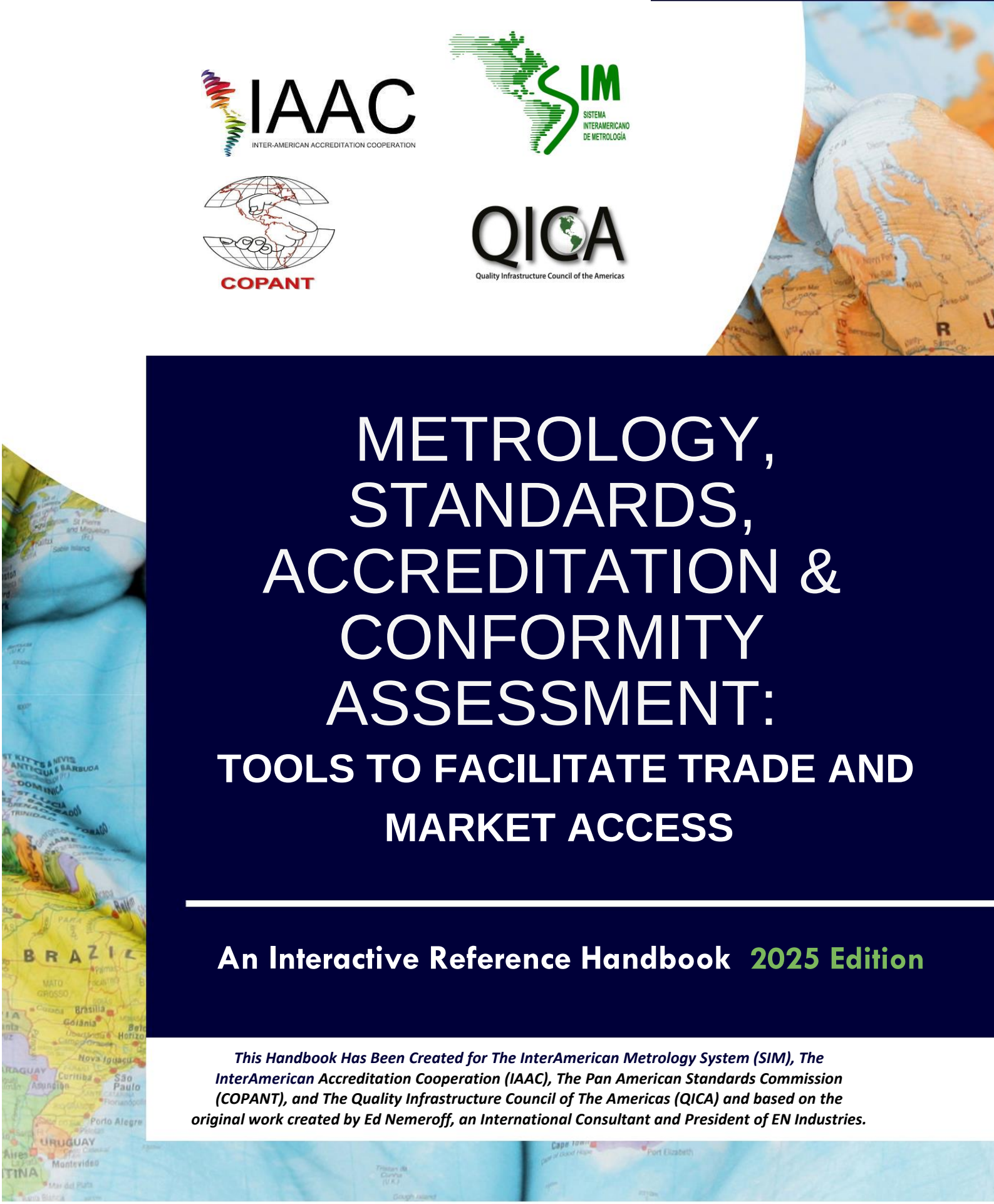

METROLOGY, STANDARDS, ACCREDITATION & CONFORMITY ASSESSMENT:

TOOLS TO FACILITATE TRADE AND MARKET ACCESS

An Interactive Reference Handbook 2025 Edition

This Handbook Has Been Created for The InterAmerican Metrology System (SIM), The InterAmerican Accreditation Cooperation (IAAC), The Pan American Standards Commission (COPANT), and The Quality Infrastructure Council of The Americas (QICA) and based on the original work created by Ed Nemeroff, an International Consultant and President of EN Industries.

The Quality Infrastructure Council of the Americas

The Quality Infrastructure Council of the Americas (QICA) comprises the three independent regional organizations involved in quality infrastructure in the Americas:

Pan American Standards Commission (COPANT): Is the reference for technical standardization and conformity assessment for the countries of the Americas for its members and international peers and promotes the development of its members.

Inter-American Accreditation Cooperation (IAAC): Manages the Multilateral Recognition Arrangements among Accreditation Bodies and supports the qualitative and quantitative growth of the activity of accreditation in the countries focused on the development of structures of conformity assessment, to demonstrate the quality of products, processes and services.

InterAmerican Metrology System (SIM): Is the result of a broad agreement among national metrology institutes in the Americas countries. Its mission is to promote and support in the Americas an infrastructure of integrated measurements, which enable each National Metrology Institute to stimulate innovation, competitiveness, trade, consumer protection and sustainable development through effective participation in the regional metrology community.

QICA is a platform for developing joint projects, information sha ring, and cross-functional training and development that, by acting collaboratively, exceeds the abilities of any single organization acting alone.
The Council is the contact point for actions of cooperation which help to strengthen the national quality infrastructure in all countries of the Americas. In this framework, its basic objective is to promote a shared vision for mutual support in standards development, the development of accreditation and scientific, industrial and legal metrology.

On August 29, 2014, in Guatemala, QI leaders of the three regional organizations signed a Memorandum of Understanding creating QICA. The creation of QICA is the result of a joint effort between the three regional organizations of the QI in technical cooperation projects. It considers the initiative of Ministers and High Authorities of Science and Technology of the Organization of American States (OAS), for access to quality infrastructure services.

QICA´S MISSION:

QICA is made up of the regional accreditation, metrology and standardization organizations in the Americas, focused on fostering regional cooperation and national collaboration to promote the benefits and use of the Quality Infrastructure in support of the sustainable development of the countries in the region**.**

QICA´S VISSION:

To be the facilitator recognized for its contribution to the widespread use of quality infrastructure in the countries of the Americas, and an international benchmark for regional collaboration.

QICA´S STRATEGIC LINES:

Establish	Generate	Achieve	Make
Establish QICA presence and leadership in the region.	Generate links of integration and communication between all the actors of the quality infrastructure of America and its interested parties.	Achieve the use of integrated quality infrastructure in America and focused on the Industrial Revolution 4.0 and the achievement of the Sustainable Development Goals.	Make QICA activities financially sustainable

QICA is pleased to support the edition of this handbook, reinforcing the value of robust quality infrastructure across the Americas. Our commitment is to advance the role of metrology, standards, accreditation and conformity assessment as essential tools for economic resilience, sustainability, and regional integration.

We thank the author for his valuable contribution and invite stakeholders to join in our vision for a unified approach to quality infrastructure that opens doors to global markets and promotes the sustainable development of our region.

Mauricio Céspedes

COPANT
President

Javier Arias

SIM
President

Andrea Melo

IAAC
President

ACKNOWLEDGEMENTS & BACKGROUND

Since participating as an invited speaker at the first World Trade Organizations (WTO) Technical Barriers to Trade committee meeting in 1995, and then moving on to work for NIST's Office of International and Academic Affairs, the United States Agency for International Development (USAID), the World Bank, the Asian Development Bank projects in 34 countries, I learned many things working in developing countries. It became apparent that there was a fundamental lack of awareness of who the international and regional metrology, standards, and conformity assessment organizations are, and what is their contribution and assistance in supporting developing countries trade activities. In addition, there were questions like, *what's the difference between certification and accreditation? How are international standards developed? What is the World Trade Organization? Where can we get basic information?* In 2008, working on a USAID project in Vietnam with their National Standards and Metrology Institute, we conducted a series of workshops and seminars, and the same questions were asked. This led to the creation of the first version of the handbook. The purpose of the handbook was to provide the reader with an overview of the importance of a National Quality Infrastructure (NQI) as it relates to enhancing trade facilitation and market access. The pdf version of the handbook contained over 300 hyperlinks that enabled readers to access referenced documents and the web sites of international and regional standards, metrology, and conformity assessment organizations and the WTO.

Over the years that followed, I created various versions of the handbook that has been published in cooperation with USAID and the National Metrology and Standards Institutes of Afghanistan, Laos, Myanmar, and Mozambique. Versions have been published in English, Dari, Vietnamese, and Portuguese. In 2021 at the request of the USAID Standards Alliance program and working with the American National Standards Institute (ANSI) a special version of the handbook was created. This version is available on the Standards Alliance web site and can be viewed at their Web Site: Resources (ansi.org).

In late 2024, in cooperation with the InterAmerican Metrology System (SIM), the InterAmerican Accreditation Cooperation (IAAC), the Pan American Standards Commission (COPANT) the Quality Infrastructure Council of the Americas (QICA) we created this current special version. The first of its kind, a joint publication. I want to personally thank SIM President Javier Arias and SIM Secretary Claudia Santo for their work in getting this special version of the handbook completed.

TECHNICAL DEVELOPMENT

This handbook reflects the basic concepts developed by regional and international organizations including the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), ASTM International, the World Trade Organization (WTO), the World Bank, Codex Alimentarius, the International Bureau of Weights and Measures (Bureau international des poids et mesures; BIPM), the International Laboratory Accreditation Cooperation (ILAC), the International Accreditation Forum (IAF), the National Institute of Standards and Technology (NIST), the American National Standards Institute (ANSI), the Inter-American Metrology System (El Sistema Interamericano de Metrología; SIM), and many others. Much of the material presented in the handbook concerning regional and international organizations was obtained from their web sites or other published information.

TECHNICAL REVIEW

I want to thank the following individuals who provided direction, guidance, and technical support in the development of the original and other following versions of the handbook; their contribution is noted with much thanks and appreciation:

- ✓ Dr. Seton Bennett, Deputy Director, National Physical Laboratory – UK.
- ✓ Dr. Stephen Carpenter, Director Office of International and Academic Affairs, NIST – USA.
- ✓ Dr. Charles Ehrlich, Weights, and Measures Division, NIST – USA.
- ✓ Dr. Mauricio Frota, Past President, Brazilian Metrology Society – Brazil.
- ✓ Paul Hanssen, Senior Trainer, A2LA WorkPlace Training (AWPT) – USA.
- ✓ Carol Hockert, President, NCSL International – USA.
- ✓ Dr. Charles Motzko, President, C. A. Motzko & Associates – USA.
- ✓ James Olshefsky, Director, American Society for Testing Materials – USA.
- ✓ John Owen, Secretary, IAF – International Accreditation Forum - Australia.
- ✓ Dr. R. Pettit, Editor, NCSLI Measure; Sandia National Laboratories USA.
- ✓ Dianna Rodrigues, Director, Antigua & Barbuda Bureau of Standards; Past President SIM – Antigua.
- ✓ Peter Unger, Past President, A2LA; Past Chair, ILAC – USA.
- ✓ Dr. Svetlana Zhanaidarova**,** 1st Secretary, Central Asian Cooperation for NQI – Kazakhstan.
- ✓ Mr. David Jankowski, Manager, International Development – American National Standards Institute – USA.

Thank you all

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INTRODUCTION

The objective of this handbook is to provide the reader with a basic overview of the elements that comprise a National Quality Infrastructure (NQI) system, including standardization, metrology, conformity assessment and accreditation, as tools to enhance trade facilitation, market access, and export competitiveness.

The handbook is divided into an introduction, five major sections, and an annex. The sections on Standards, Metrology, Accreditation and Conformity Assessment contain an introduction to the major regional and international technical organizations that support a National Quality Infrastructure. Hyperlinks, more than 250 are available to take the reader directly to the organization's website or a specific document . Each section is followed by a list of reference documents and web pages for additional reading.

We hope this handbook becomes the reader's go-to reference for NQI concepts.

INTRODUCTION

This section contains some background information and an overview of SIM, IAAC, COPANT, QICA and a list of acronyms and abbreviations, followed by a brief glossary of technical terms and definitions in plain language.

SECTION 1: **An Overview of NQI**

NQI and its relationship to trade facilitation.

SECTION 2: **Technical Barriers to Trade**

The background and structure of the World Trade Organization TBT and SPS Agreements, including member obligations.

SECTION 3: **Standards and Technical Regulations**

The role of standards and technical regulations in international trade, international and regional standards organizations, and the standards development process.

SECTION 4: **Metrology**

An overview of the science of measurement and the international system of metrological units, the different categories of metrology, the vocabulary of metrology, and regional and international metrology organizations.

SECTION 5: **Accreditation & Conformity Assessment**

An introduction to the principles of conformity assessment activities that determine compliance with standards and technical regulations.

ANNEX

Additional resource links.

GLOSSARY OF ACRONYMS

AB	Accreditation Body
ANSI	American National Standards Institute
APAC	Asia-Pacific Economic Cooperation
APAC	Asia Pacific Accreditation Cooperation
APLMF	Asia Pacific Legal Metrology Forum
APMP	Asia Pacific Metrology Programme
ARSO	African Regional Organisation for Standardisation
ASTM	ASTM International (formerly American Society for Testing Materials)
ASEAN	Association of Southeast Asian Nations
BIPM	Bureau International des Poids et Mesures (International Bureau of Weights and Measures)
CA	Conformity Assessment
CAB	Conformity Assessment Body
CAC-MASQ	Central Asian Cooperation on Metrology, Accreditation, Standardization, and Quality
CASCO	ISO's Committee on Conformity Assessment
CE Marking	European mark of conformity
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CEOC	International Confederation of Inspection and Certification Organisations
CGPM	Conference Generale des et Poids (General Conference on Weights and Measures)
CODEX	Codex Alimentarius Commission
COOMET	Euro-Asian Cooperation of National Metrological Institutions
COPANT	Pan American Standards Commission
CRM	Certified Reference Material
DEVCO	ISO's Committee on Developing Country Matters
EASC	European Co-operation for Accreditation
EC	European Commission
EMS	Environmental Management System
EOQ	European Organization for Quality
EOTC	European Organization for Conformity Assessment
ETSI	European Telecommunications Standards Institute
EURAMET	European Association of National Metrology Institutes
EUROLAB	European Federation of National Associations of Measurement, Testing and Analytical Laboratories

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 Inter-American
IAAC	Inter American Accreditation Cooperation
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
IMEKO	International Measurement Confederation
IRCA	International Register of Certificated Auditors
ISO	International Organization for Standardization
ITC	International Trade Centre
ITU	International Telecommunication Union
JCDCMAS	Joint Committee on Coordination of Assistance to Developing Countries in Metrology, Accreditation and Standardization
JCRB	Joint Committee of the Regional Metrology Organizations and the BIPM
MAS-Q	Metrology, Accreditation, Standards and Quality
MRA	Mutual Recognition Arrangement Metrology, Standards,
NACLA	Laboratory Accreditation North American Free Trade
NAFTA	Agreement National Association of Testing Authorities
NCSLI	NCSL International (formerly National Conference of Standards Laboratories International)
NIST	National Institute of Standards and Technology
NMI	National Metrology Institute
NORAMET	North American Metrology Cooperation
NSB	National Standards Body
NQI	National Quality Infrastructure
NVLAP	National Voluntary Laboratory Accreditation Program
OIML	Organisation Internationale de Métrologie Légale (International Organization of Legal Metrology)
QIAC	Quality Infrastructure Council of the Americas
QMS	Quality Management System
QICA	Quality Infrastructure of the Americans
RMO	Regional Metrology Organization
SADCA	Southern African Development Community Cooperation in Accreditation
SADCMEL	African Development Community Cooperation in Legal Metrology
SADCMET	Southern African Development Community Cooperation in Measurement Traceability

SANAS	South African National Accreditation System
SI	Système International (d'unités) – the International System of Units
SIM	El Sistema Interamericano de Metrología (Inter-American Metrology System)
SoA	Scope of Accreditation
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
SQAM	Standards, Quality Assurance, Accreditation and Metrology
TBT	Technical Barriers to Trade Agreement
UILI	Union Internationale des Laboratories Independents (International Union of Independent Laboratories)
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
USMCA	United States, Mexico, and Canada Free Trade Agreement
VIM	International Vocabulary of Metrology
VIML	International Vocabulary of Terms in Legal Metrology
WECC	Western European Calibration Cooperation
WELAC	Western European Laboratory Accreditation Cooperation
WELMEC	Western European Cooperation in Legal Metrology Western
WEMC	European Metrology Club World Standards Services Network
WTO	World Trade Organization

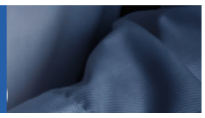
GLOSSARY OF TECHNICAL TERMS IN SIMPLE LANGUAGE

Accreditation	Refers to both a status of conformity to a specific standard and a process denoting commitment to continual improvement. Accreditation recognizes the competence of testing and calibration laboratories, product certification bodies, system certification bodies, inspection bodies, and other activities.
Calibration	A written process of verification that an instrument is within its designated accuracy. This is most often achieved by formal comparison with a measurement standard that is traceable to national or international measurement standards.
Certification	Assures the conformity of products, services, and processes by means of technical evaluation with the proper combinations of defined operations.
Conformity Assessment	Demonstrates that specific product or service requirements are met. This includes technical procedures such as testing, verification, inspection, certification, and accreditation to confirm products or processes fulfill the requirements as defined in standards or technical regulations.
Inspection	A verification of the quantity and/or weight of traded goods. If it occurs at a border, verification can consist of examining import/export documents with a visual check of cargo on the basis of professional judgment.

Legal Metrology	The practice and process of applying regulatory structure and enforcement to metrology to support a credible measurement system. All measurements related to trade and consumer protection come under legal metrology.
Metrology	The science of measurement.
Mutual Recognition Arrangement & **Multilateral Arrangements**	Formal non-government agreements to recognize the results of one another's testing, inspection, certification, or accreditation.
National Metrology Institute	The national body designated to develop and maintain national measurement standards for one or more quantities.
Product Certification	May consist of initial testing of a product combined with assessment of a quality management system. This may be followed by surveillance that takes into account the supplier's quality management system and testing of samples from the factory or the market. Other product certification schemes comprise of initial testing and surveillance, while still others rely on the testing of a sample product (type testing).
Quality Management System Certification	Assures that a quality management system, or a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives, fulfills a defined set of requirements (such as the requirements of ISO 9001, Quality Management Systems).
Standard (document)	A technical document detailing the performance or important features of a product, service, or system. Compliance is voluntary.[1]
Standard (measuring)	An instrument, reference material, or measuring system intended to define or reproduce one or more values of a quantity to serve as a reference.
TBT Agreement	The World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) is an international treaty administered by the WTO that "aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade."[2]
Technical Barrier to Trade (TBT)	A type of non-tariff barrier to trade resulting from divergent standards, conformity assessment practices, or technical regulations.
Technical Regulation	A mandatory document issued by a government authority detailing product characteristic, production methods, and administrative provisions.

[1] 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] World Trade Organization. Technical Barriers to Trade. Retrieved from https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

SECTION 1



AN OVERVIEW

NATIONAL QUALITY INFRASTRUCTURE (NQI)

The term Quality Infrastructure is relatively new and has so far been familiar to experts only. In this section, we explain the term in more detail.

Quality infrastructure describes a system of institutions that guarantee the definition and control of quality criteria. These institutions can also be seen as the underlying foundation of international trade. Like the physical infrastructure, the provision of Quality Infrastructure is considered a public task. In many countries, however, various Quality Infrastructure services are also provided by private and non-profit organizations.

For countries, understanding the link between national quality infrastructure (NQI) and global trade, consumer safety, and export competitiveness is at the forefront of trade policy. An effective NQI is an integral part of the way we protect consumers globally. NQI makes our world easier, safer, and more accessible for consumers, businesses, and governments. And non-binding NQI often goes on to form widely used legislation and act as a compliance system throughout the world.

National quality infrastructure refers to a country's legal and institutional framework that supports the quality of goods and services. A properly functioning NQI incorporates public- and private-sector cooperation across four pillars of quality: standards, conformity assessment, accreditation, and metrology. These pillars unlock a wide array of domestic and international benefits. Domestically,

NQI supports market predictability, promotes product reliability, enhances consumer protections, and spurs innovation. Internationally, an effective

NQI facilitates global trade, increases market access, expands export competitiveness, encourages knowledge transfer, and underpins product interoperability.

NQI is particularly important for developing and emerging nations seeking to encourage economic growth and foreign investment. These benefits hinge on the implementation of international best practices for each of the four pillars of quality. Best practices include the use of international standards, open and transparent development of standards and regulations, and accreditation.

Deviations from best practice have the potential to undermine international trade flows by erecting unnecessary obstacles to trade, diminishing the quality of goods and services, damaging market predictability, and misguiding or even endangering consumers. Further, domestically, a lack of clear quality frameworks can lead to poor-quality products entering markets and low consumer access to reliable product information.

Approximately two-thirds of the World Trade Organization's (WTO) membership is comprised of developing countries or countries in transition from centralized to market economies.[1] For these countries, international standards and conformity assessment provide an existing source of technological expertise to support economic development and global competitiveness.

This handbook aims to describe the basic components of NQI and to provide the user with information to guide the improvement or development of an effective NQI.

1 https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm

DEVELOPING A NATIONAL QUALITY INFRASTRUCTURE

All countries should have and implement a National Quality Infrastructure to realize the benefits that will be gained from embracing quality as a driver for economic development. A well-designed NQI supports consumer protection, international trade, technological innovation, and compliance with international agreements like the WTO Technical Barriers to Trade (TBT) and Sanitary and Phyto-Sanitary (SPS) Agreements.

It should be noted: Not all countries have a formal National Quality Policy (NQP) but may have implemented well-organized elements of NQI. For countries in the process of establishing a quality infrastructure, an NQP may be a useful tool to inform the development of a fully functioning NQI.

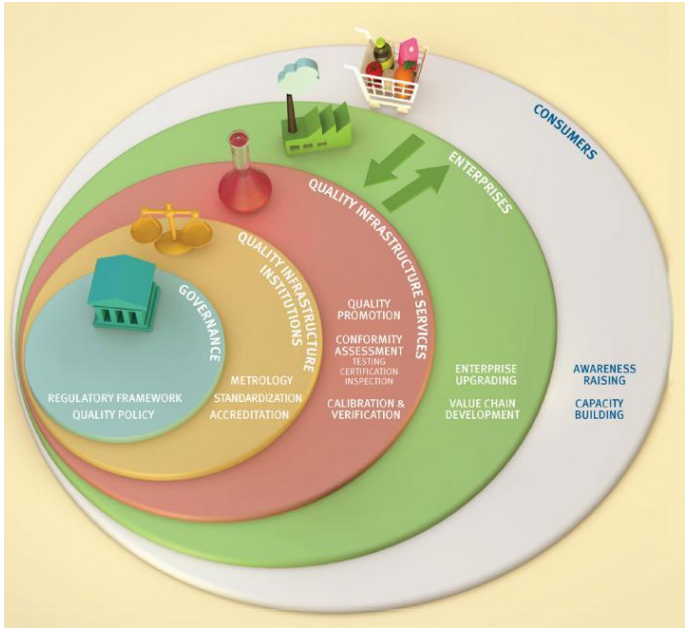
As countries develop or refine their NQI, transparency helps to ensure predictability in domestic and international trade. As with any changes to national law, maintaining open and transparent access to early draft NQI measures and allowing for public comment periods are considered international best practices. In fact, some countries elect to notify draft NQI measures with open comment periods to the WTO. This practice can provide valuable feedback for policymakers and provide trading partners with increased awareness of pending changes to national policy.

Establishing a National Quality Infrastructure

There several approaches to establishing an NQI, but there had been no universally accepted international definition. On June 30, 2017, the United Nations Industrial Development Organization (UNIDO) hosted the annual meeting of the Network on metrology, accreditation and standardization for developing countries in which one definition of quality infrastructure (QI) was developed. The meeting focused on quality infrastructure as a pillar supporting competitiveness, trade, and sustainable development, and the key outcome of the meeting was the adoption of the following definition of quality infrastructure:

"The system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes. The quality infrastructure is required for the effective operation of domestic markets, and its international recognition is important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing.

It relies on metrology, standardization, accreditation, conformity assessment, and market surveillance.



Quality Infrastructure System. Source: UNIDO

2ISO (2013). National Standards Bodies in Developing Countries. Retrieved from https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/fast_forward.pdf

The Four Pillars of a Quality Infrastructure

Metrology, standards, accreditation, and conformity assessment form the foundation of quality infrastructure. These QI components act as separate but interdependent pillars. While often underappreciated by consumers and government officials, these four pillars are vital to safeguard the integrity of products and processes. When well-coordinated under an NQI, they enable sustainable development and create a path for global trade, market access, technological innovation, and export competitiveness by supporting consumer confidence, product quality and safety, health and environmental protection.[2]

Effective NQI supports local exporters by helping producers understand, meet, and demonstrate adherence to requirements in target markets. This is especially true for agricultural products. If clear frameworks for quality are not in place, or are underdeveloped, exporters will struggle to enter and compete in foreign markets. Examples of such failures include product certification reports issued without citing the international standard or conformity assessment method used, which can lead to unsafe or poor-quality products.

Why Develop a National Quality Strategy?

Building a clear NQI enables domestic enterprises to meet the demands of the multilateral trading system and to provide proof that their products conform to international standards. Unfortunately, in many developing and transitional economies NQI is underdeveloped or non-existent. Often the national metrology and standards institutes provide all NQI services, which creates a centralization of quality control and supervision that can lead to competing interests, undermining quality and providing openings for corruption. These risks are mitigated by separating quality institutes which delegate relevant roles and responsibilities to domestic NQI components.

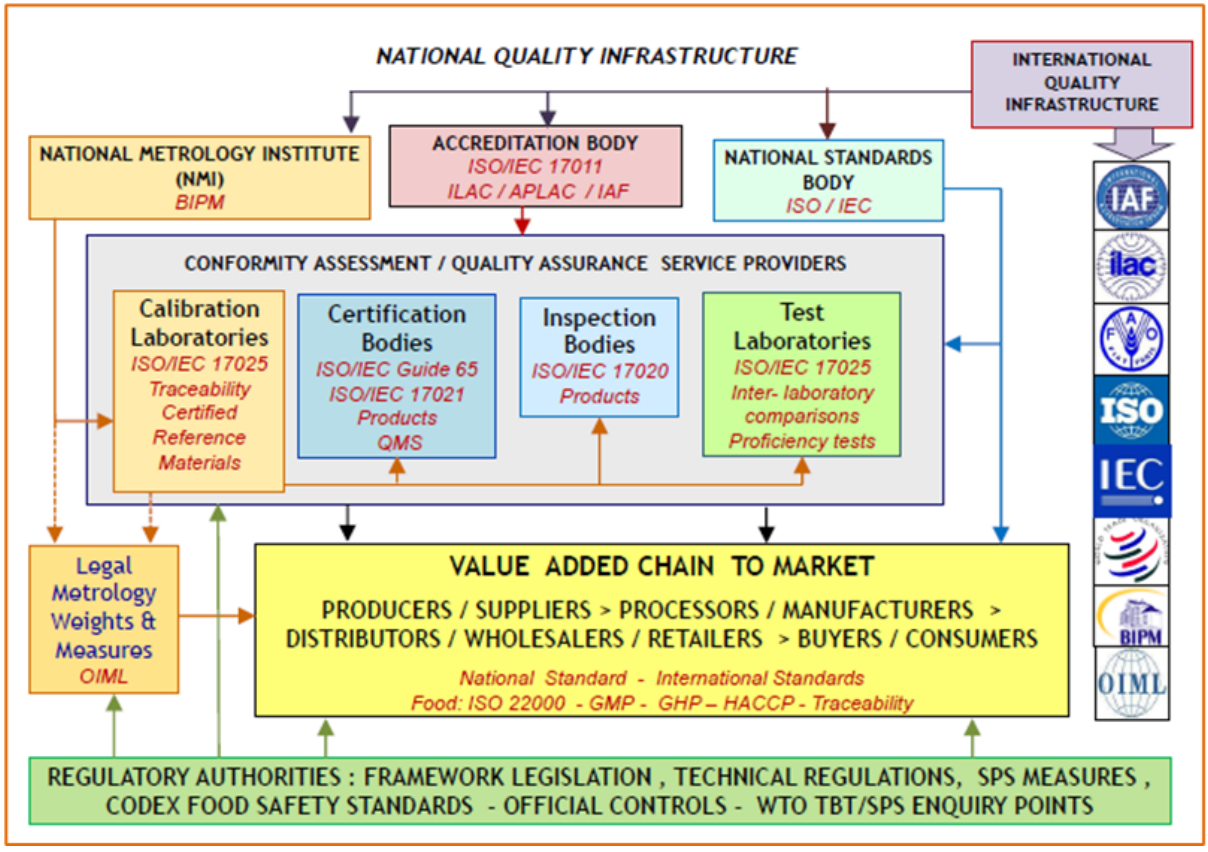
To achieve this, many developing nations created an NQP.

The NQP should detail the relationship of the quality infrastructure with the country's technical regulations and create space for private sector participation. Some countries create an NQI committee that includes private sector members. Developing an effective NQI is a complex challenge that requires the participation of various interest groups. These include the public and private sectors, academia, trade associations, consumer interest groups, and other stakeholders. Within this list, the importance of the private sector is crucial to the overall success of NQI. Private sector participation provides valuable information on market and technological trends to minimize harm and increase buy-in for government measures. An inclusive and open NQI ensures that the private sector and consumers are the ultimate beneficiaries of quality systems.

For example, the International Organization for Standardization (ISO) states that: "The views of consumers also need to be considered when developing standards. Standards often shape product characteristics. If consumers play an active role in developing standards, the characteristics of a product.
or service are more likely to meet their needs. This creates a win-win situation for the consumer and manufacturer or service provider. Consumers have a voice in the development of ISO International Standards through the participation of the NGO Consumers International and the consumer representatives of national members in the technical committees."[3]

A useful starting point in the development of an NQP is to ensure adherence to the WTO TBT and Sanitary and Phytosanitary (SPS)
Agreements: these agreements contain many of the foundational elements of NQI and are discussed further in Section 2 of this handbook.

3 UNI ISO (2021). Who Develops Standards? Retrieved from www.iso.org/who-develops-standards.html



BUILDING BLOCKS OF A SUCCESSFUL NQI

An NQI should consist of structures that support the four pillars mentioned above: standards, metrology, accreditation, and conformity assessment. This should include a set of parallel paths describing the technical and legal/regulatory aspects of quality.

National Standards Body: An institution that oversees national standards activities and serves as the member body for that country to regional, international, and/or multilateral organizations. An NQI should support the development and growth of a market-driven system based on voluntary consensus standards for products, processes, and services that are harmonized with relevant international standards. Strong private-sector involvement throughout the standardization process is essential.

National Metrology Institute: An institution that realizes, maintains, and disseminates national measurement units that are traceable to the International System (SI) (scientific metrology); and develops and implements a weights and measures program in order to ensure the appropriate quality and credibility of measurements related to official controls, trade, health, safety, and the environment (legal metrology).

Accreditation Body: An institution that validates the competence of testing and calibration laboratories, product certification bodies, quality system certification bodies, and inspection bodies. An NQI should provide technical and financial support for the development of an accreditation system. Many countries approach this element of QI differently; some maintain a National or Regional Accreditation Body, while many others rely on private-sector organizations to fill this role. For example, France maintains a National Accreditation Body, the Comite Français d 'Accreditation (COFRAC), whereas the United States recognizes various private-sector accreditation bodies including the American National Standards Institute (ANSI).

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

Conformity Assessment Bodies: These organizations perform conformity assessment processes to determine if specified requirements relating to a product, process, system, person, or body are fulfilled. This can include testing, certification, and inspection. An NQI should ensure conformity assessment bodies are competent, impartial, and work with integrity, and that they are accredited in accordance with international standards and best practices.

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

CONTINUE READING HANDBOOK ▸
METROLOGY, STANDARDS, ACCREDOTATION& CONFORMITY ASSESSMENT: TOOLS TO FACILITATE TRADE AND MARKET ACCESS

Technical Path: A unified NQI should both strengthen and align the predictability and consistency of the national metrology, standards, and conformity assessment organizations within the public and private sectors.

Legal and Regulatory Path: An effective NQI should avoid the use of overly restrictive legal and regulatory requirements, conflicts of interest, and political interference. Additionally, quality systems should align with international best practice. The legal framework should establish and foster transparent, independent public- and private-sector institutions.

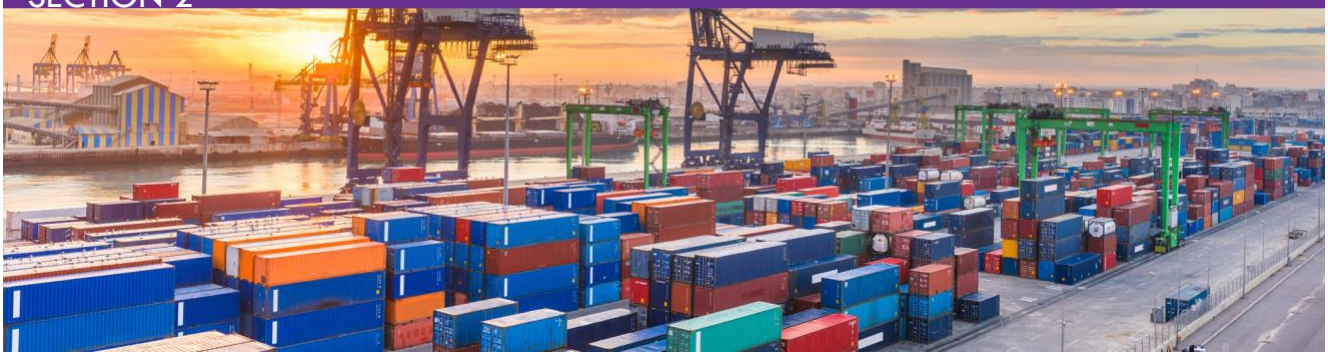
SUMMARY

Standards, metrology, conformity assessment, and accreditation form the foundation for a country's NQI. With a firm and well-coordinated foundation in these elements, countries can support product quality, spur innovation, ensure consumer safety, promote trade and development, and protect human health and the environment. As a country considers legal or regulatory changes to existing quality systems, it is helpful to understand each component and its role within the quality infrastructure.

The next sections of this handbook address these building blocks in more detail:

SECTION 2: TECHNICAL BARRIERS TO TRADE ▸
SECTION 3: STANDARDS & REGULATIONS ▸
SECTION 4: METROLOGY ▸
SECTION 5: Accreditation & Conformity Assessment
ANNEX ▸
INTRO & GLOSSARY ▸

SECTION 2



TECHNICAL BARRIERS TO TRADE

As tariff barriers to trade decline globally, non- tariff barriers continue to emerge as obstacles to trade. Among these are standards-related trade barriers, often called Technical Barriers to Trade (TBT), which can arise from divergent measures countries use to assess and regulate goods. This can include differences intended to create barriers to market access from foreign countries or products.

TBTs can include voluntary standards, technical regulations, and conformity assessment procedures that disrupt trade flows or protect local markets from competition. Internationally, governments recognize the importance of minimizing these barriers to enhance trade flows and support global prosperity. This sentiment is reflected by the agreements establishing the World Trade Organization (WTO), primarily the WTO Technical Barriers to Trade (TBT) Agreement.

The World Trade Organization is the global international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments.

The goal is to ensure that trade flows as smoothly, predictably, and freely as possible,

Examples of potential barriers to trade:

- Tariffs and nontariff measures (NTMs)
- Price controls
- Quotas
- Sanitary and phytosanitary (SPS) measures
- Standards
- Technical regulations
- Certification requirements

WHY FOCUS ON TECHNICAL BARRIERS TO TRADE?

Due to increasing living standards worldwide, the number of technical regulations and standards adopted by countries continues to expand to meet consumer demand for safe and high-quality products. Further, concerns surrounding environmental pollution and protection have encouraged modern societies to explore standards that promote environmentally friendly products and production methods. Other ethical production standards that include metrics such as labor and equity are also on the rise. With the increasing adoption of these regulations and standards comes the potential to create TBTs that restrict international trade flow.

KEY DEFINITIONS

Standards, technical regulations, and conformity assessment procedures are three distinct categories of TBTs, but the terms "standard" and "technical regulation" are often confused. In the TBT Agreement, standards refer to voluntary specifications or procedures, while technical regulations are mandatory.[1] For further reference, definitions from Annex 1 of the WTO TBT Agreement are included below.[2]

Standards

"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 labelling requirements as they apply to a product, process, or production method."

Technical Regulations

"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 labelling requirements as they apply to a product, process, or production method."

Conformity Assessment Procedures

"Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. Conformity assessment procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification, and assurance of conformity; registration, accreditation and approval as well as their combinations." When considering these three components, it is important to dive more deeply into the WTO definitions to help clarify these measures. Standards are defined as voluntary documents developed by a wide array of public and private sector, or non-governmental, organizations. They outline guidelines or characteristics for products or processes. These guidelines can be descriptive (size, weight, dimensions) or performance based.

When referring to conformity assessment, the TBT Agreement includes accreditation of third-party competence and the recognition (usually by a government agency) of an accreditation program's capability. Generally, manufactures and exporters bear the cost of these procedures. Non-transparent and discriminatory conformity assessment procedures can create harmful barriers to trade.

AVOIDING TECHNICAL BARRIERS TO TRADE

In practice, TBTs result from legal and regulatory acts and the inadequate preparation, adoption, and application of different standards, technical regulations, and conformity assessment procedures. When these barriers are established, absent of a legitimate policy objective, they divert trade flows and create inefficiency in markets.

It is important to emphasize that differing standards, conformity assessment practices, and technical regulations between countries can have legitimate origins, such as differences in local tastes or levels of income, health risks, as well as geographical or other factors. For example, countries with areas prone to earthquakes might have stricter requirements for building construction materials; others, facing serious air-pollution problems, might want to impose lower tolerable levels of automobile emissions. Dietary differences between countries also have an impact.

[1] 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] World Trade Organization (1995). Agreement on Technical Barriers to Trade. https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

A preferred method to avoid TBTs is to ensure transparent approval and review processes for draft standards, conformity assessment, and technical regulations. Signatories to the WTO TBT Agreement have agreed to notify draft technical regulations and provide an open comment period for member feedback. This process helps countries avoid TBTs, while enhancing market trust and predictability for trading partners.

Potential Costs of Technical Barriers to Trade

Increases in technical regulations and standards worldwide, increase the potential for regulatory divergence, TBTs, and ultimately financial costs.[3] For example, divergent regulatory requirements can lead to a decrease in economies of scale. This occurs when producers are forced to adjust production facilities or practices to comply with diverse technical requirements in individual markets, adding costs to each unit of production. This imposes handicaps on producers, particularly small and medium enterprises (SMEs) that tend to have lower profit margins and can lead producers to pass increased costs on to their consumers.

At times, countries attempt to protect domestic industries from competition while requiring open trade for their exports. These practices can include additional testing or product certification at borders that extend beyond national requirements placed on local companies. Additional layers of review for foreign products add costs that curtail competition and are ultimately passed on to the consumer.

Unnecessary regulatory differences impose further costs that prevent businesses, especially SMEs, from engaging in trade.[4] Incompatible product requirements, while sometimes legitimate due to specific WTO exclusions, can create unintended regulatory silos, or national systems operating outside the international system. These issues can often be avoided by including a wide array of public and private sector stakeholders in standards and regulatory development for example, many countries invite consumer interest groups, international companies, and trade associations to participate in standards development.

When adequately involved, SME participation can reduce trade costs while respecting differences in regulatory objectives. This cooperation may take several forms, many of which are directly relevant to trade outcomes.

Further costs arise from a lack of transparency in the standardization or regulatory process. Without clear and publicly available information on standards and technical regulations, many companies face high costs associated with evaluating the technical impact of foreign regulations and preparing to make organizational changes to meet new requirements. Additionally, in terms of adjustments costs, exporters are often at a disadvantage relative to domestic firms when confronted with new Regulations.

International Standards & Trade Agreements

What are trade agreements? Trade agreements set down rules to cover trade in goods and services between countries or among several parties. Some of these rules relate to tariffs or quotas in place between the negotiating players, and others might be related to the quality, safety or other characteristics of the products or services being traded. The World Trade Organization (WTO) deals with the rules governing trade among its 166-members (as of August 2024) states. WTO agreements cover goods, services, and intellectual property. Trade agreements can also be negotiated between specific countries or several parties, although these are subject to certain conditions to ensure they remain consistent with the WTO agreement.

What are the benefits of using International Standards in trade agreements?

A key WTO agreement is the Technical Barriers to Trade (TBT) agreement which aims to ensure that technical regulations, standards, and conformity assessment procedures, which governments might use to describe the characteristics of products being traded, do not create unnecessary technical barriers to trade. IEC, ISO and ITU have national member bodies from all over the world and fulfil the WTO TBT definition of International Standards development organizations as their membership is open to the relevant bodies of at least all Members* of the WTO.

Standards developed by IEC, ISO and ITU are consistent with the decision of the WTO's TBT committee on principles for the development of International Standards. IEC, ISO and ITU International Standards are an ideal tool to support trade agreements, to ensure that parties that are involved in trade agreements respect their TBT obligations, and to provide confidence that requirements for products and testing have global relevance and are accepted worldwide. Within the TBT agreement, WTO members are strongly encouraged to base their non-tariff measures on International Standards as a means of facilitating trade. The consistent use of International Standards also means that policy and regulatory compatibility can extend to other countries that are not party to a bilateral or multilateral agreement. Any other approach can artificially create new technical barriers to trade through the use of additional, unique, or partially accepted Standards and provisions. In addition, this use of International Standards supports regulatory harmonization and helps avoid the waste of resources that can result from additional testing or other duplicative procedures that can occur when regulators develop their own solutions

IEC, ISO and ITU Standards

IEC (International Electrotechnical Commission), ISO (International Organization for Standardization) and ITU (International Telecommunications Union), are leading international organizations that develop international standards and work together under the banner of the World Standards Cooperation to strengthen and advance a voluntary consensus-based International Standards system and related conformity assessment activities. Standards developed by these three organizations respect the principles of openness, transparency, impartiality and consensus, effectiveness and relevance, coherence, and the development dimension, agreed by the WTO's TBT committee. Policy makers can have confidence when using IEC, ISO or ITU International Standards that they are fulfilling their WTO obligations, and not creating any unnecessary obstacles to international trade.

THE WORLD TRADE ORGANIZATION AGREEMENTS AS A FOUNDATION[5]

Global Trade Rules

Global rules of trade provide assurance and stability. Consumers and producers know they can enjoy secure supplies and a greater choice of finished products, components, raw materials, and services they use. Producers and exporters know foreign markets will remain open to them. The WTO and the WTO Agreement on Technical Barriers to Trade form the foundation of international best practice related to standards, conformity assessment, and technical regulations.

The main function of the WTO is to ensure that trade flows as smoothly, predictably, and freely as possible; therefore, a basic understanding of the WTO and its agreements is a useful starting point in the development of a nation's quality infrastructure and to avoid TBTs.

The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments.

The WTO has many roles: it operates a global system of trade rules, it acts as a forum for negotiating trade agreements, it settles trade disputes between its members, and it supports the needs of developing countries. All major decisions are made by the WTO's member governments: either by ministers (who usually meet at least every two years) or by their ambassadors or delegates (who meet regularly in Geneva).

3OECD (2017). International Regulatory Cooperation and Trade. Retrieved from https://read.oecd-ilibrary.org/governance/international-regulatory-co-operation-and-trade_9789264275942-en#page8

4 OECD (2019). Improving the business environment for SMEs through effective regulation. Retrieved from https://www.oecd.org/cfe/smes/ministerial/documents/2018-SME-Ministerial-Conference-Parallel-Session-1.pdf

5 World Trade Organization (2021). Retrieved from https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

The WTO currently has 166 members with 22 countries having formally stated their intention to accede or join. By acceding to the WTO, countries commit to the agreements that underpin the organization and support the free flow of goods and services. These Agreements have been negotiated and signed by all 16 members. The Agreements provide the legal framework for international trade in goods (General Agreement on Tariffs and Trade – GATT), services (General Agreement on Trade in Services – GATS), and intellectual property (Trade-Related Aspects of Intellectual Property Rights – TRIPS) and are based on three overarching principles: non-discrimination, market predictability, and technical assistance. They are contracts, binding governments keeping their trade policies within agreed limits.

WTO agreements emphasize the importance of ensuring countries' technical regulations, standards, testing, and certification procedures are non-discriminatory and do not create unnecessary barriers to international trade. In addition, WTO agreements further recognize the rights of member countries to enact measures to achieve legitimate policy objectives, including the protection of human health and safety, and protection of the environment.

Origin of the Technical Barriers to Trade Agreement[6]

The TBT Agreement was developed out of multiple rounds of multilateral trade negotiations, beginning with the GATT in 1947. Its general principles were refined during the 1979 Tokyo Round of negotiations, which resulted in the signing of the Agreement on Technical Barriers to Trade (Tokyo Round Standards Code) by the 32 GATT Contracting Parties. The Agreement established the rules for preparation, adoption, and application of technical regulations, standards, and conformity assessment procedures.

These rules were further strengthened during the Uruguay Round of GATT negotiations in 1994, the result of which was the establishment of the WTO. The current TBT Agreement enter into force on January 1, 1995, as one of the Agreements Establishing the WTO. The Agreement covers all trade in goods and reflects the foundational principles of the WTO, including non-discrimination and the promotion of market predictability.

The TBT Agreement obliges members to ensure 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 burden of complying with different foreign technical regulations and standards on international trade, it certainly involves significant costs for producers and exporters. A 2016 study by the U.S. Department of Commerce estimated that 92% of global exports may face foreign technical regulations that make it difficult to compete in international markets.[7]

While it emphasizes the avoidance of unnecessary barriers to trade, the TBT Agreement also recognizes the rights of member countries to enact measures to achieve legitimate policy objectives, including the protection of human, animal, and plant life; public health and safety; and the environment. Transparency is the centerpiece of the TBT Agreement. This component of the Agreement requires members to establish a national

6World Trade Organization (1995). Agreement on Technical Barriers to Trade. https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm
7 https://legacy.trade.gov/td/osip/documents/osip_standards_trade_full_paper.pdf

enquiry point and notification authority for the purpose of notifying and clarifying draft technical regulations and conformity assessment procedures to the WTO Secretariat.

Purpose of the WTO TBT Agreement

Avoiding unnecessary/ discriminatory obstacles to international trade

Preserving members' right to regulate to protect legitimate interests

A key distinction in the TBT Agreement is the difference between a standard and a technical regulation. In the Agreement, standards are voluntary while technical regulations are mandatory. Producers voluntarily meet standards to demonstrate that their products achieve a stated level of quality and/or performance. Often, standards – or their components – are referenced in regulations. When this occurs, the standard becomes a mandatory requirement, or technical regulation, that must be met by all goods or services within the jurisdiction of the regulation.[9]

This process supports market predictability by allowing member nations to understand and gain clarification on new technical regulations that may have disrupted trade.

The TBT Agreement: Main Structure and Content[8]

The TBT Agreement is comprised of a preamble, 15 articles, and three annexes that codify the international process for the preparation, adoption, and application of technical regulations, standards, and conformity assessment procedures that affect the trade of goods. The annexes of the Agreement provide definitions for terms used in the agreement; procedures for technical expert groups; and the Code of Good Practice for the Preparation, Adoption and Application of Standards.

Example: The United States–Mexico– Canada Agreement (USMCA) is a free trade agreement concluded between Canada, Mexico, and the United States that emphasizes the importance standards as the foundation for trade and investment. The USMCA enshrines the principles of the TBT Agreement, requiring the three parties to use international standards as the basis for technical regulation. This requirement supports greater regulatory harmonization and aids the avoidance of unnecessary obstacles to trade.

The TBT Agreement requires members to ensure 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 burden of complying with divergent technical regulations and standards, it certainly involves costs for producers and exporters. A 2016 study by the U.S. Department of Commerce estimated that 92% of global exports may face foreign technical regulations that make it difficult to compete in international markets.[10]

While it emphasizes the avoidance of unnecessary barriers to trade, the TBT Agreement also provides very specific exemptions for member countries to enact measures to achieve legitimate policy objectives related to the protection of human, animal, and plant life; public health and safety; and the environment.

Transparency is a centerpiece of the TBT Agreement and requires members to establish a national enquiry point and notification authority for the purpose of notifying and

8 World Trade Organization (1995). Agreement on Technical Barriers to Trade. https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

9 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.

10 https://legacy.trade.gov/td/osip/documents/osip_standards_trade_full_paper.pdf

clarifying draft technical regulations and conformity assessment procedures to the WTO Secretariat. This process supports market predictability by allowing member nations to understand and comment on technical regulations that may disrupt trade.

TBT Agreement Principles:

- Requires equal treatment for domestic and foreign products.
- Obligates that regulations may not limit trade unnecessarily.
- Prohibits import bans 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.
- Prohibits import bans imposed on goods by a given process. Members shall specify technical regulations based on product requirements based on performance, rather than design or descriptive characteristics.
- Prohibits import bans based on a technically meaningless standard. Where technical regulations are required and relevant international standards exist, members shall use them.
- Prohibits import bans 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.

KEY PRINCIPLES OF THE TBT AGREEMENT: AN OVERVIEW

The TBT Agreement recognizes a number of foundational principles that are essential to the proper functioning of barrier-free international trade in goods. By encouraging equal treatment among member states, these principles have helped guide progress toward lowering trade barriers and encouraging international trade. These principles are briefly outlined below.

National Treatment: National treatment allots imported and domestically produced goods equal treatment (Article 2.1).

Most Favored Nation (MFN): The MFN principle grants all WTO members equal trade advantages c for example, equal tariff or quota rates. With permission from the WTO, Members are allowed to grant preferential trade terms to developing Members (see Special and Differential Treatment).

Special and Differential Treatment: Developing country Members are permitted preferential treatment in their implementation of WTO agreements and provisions and Members are invited to provide favorable treatment to developing Members.

Harmonization: Members are encouraged to use existing international standards for the basis of their national regulations whenever appropriate.

Equivalence: Members are asked to consider the recognition of technical regulations and conformity assessment practices of other Members when these requirements meet the goals of national requirements.

Standards Alliance

As part of the development component of the WTO, many organizations support the implementation of the WTO Agreements. The Standards Alliance, a public-private partnership between the American National Standards Institute (ANSI) and the U.S. Agency for International Development (USAID), is one such program that supports partners on issues related to the TBT Agreement and NQI.

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."

Mutual Recognition: Members are strongly encouraged to negotiate agreements of mutual acceptance of conformity assessment results.

Notification: Members are required to establish a national enquiry point and notification authority to support regulatory transparency. These bodies are required to notify draft technical regulations and conformity assessment procedures and respond to member enquires regarding pending legislation.

Transparency: Members are required to notify Members of any draft technical regulations that may influence international trade. Members are also required to publish TBT measures regularly. More information on transparency requirements is included in the following section.

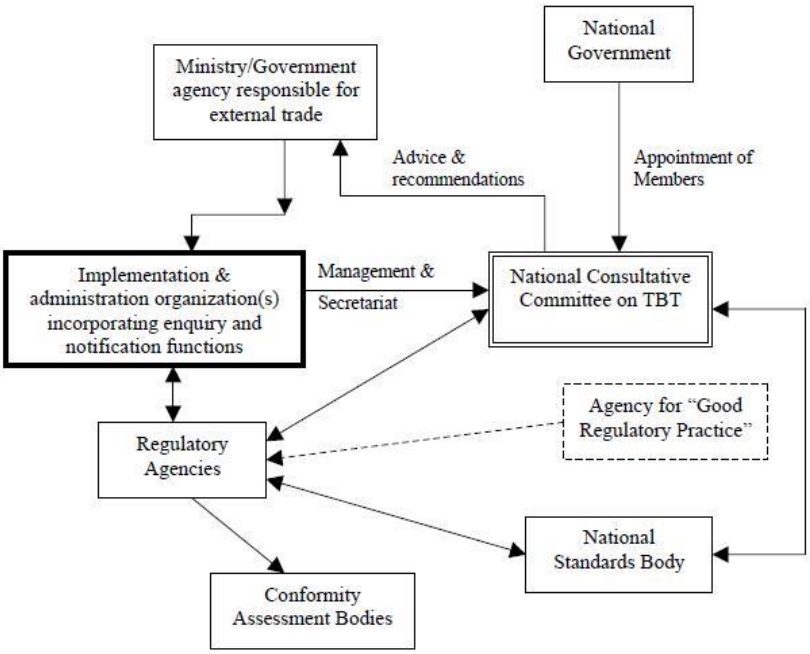
Technical Assistance

Any Member can request technical assistance from the WTO Secretariat or other Members to support the implementation of the TBT Agreement (Article 11). Requests for technical assistance received from least-developed Members have priority.

AN IN-DEPTH LOOK AT THE TBT AGREEMENT PROVISIONS

Participation in International Standards Bodies

Widespread and open participation in international standards bodies ensure that international standards reflect diverse production and trade interests while creating space for innovation and knowledge sharing. The TBT Agreement encourages Members to participate, within the limits of their resources, in the work of international bodies for the preparation of standards (TBT Article 2.6) and guides or recommendations for conformity assessment procedures (TBT Article 5.5).[11]



The example at left shows that a national government has established a TBT committee that guides the development of technical regulations to ensure WTO compliance.

Source: World Bank

11 World Trade Organization (1995). Agreement on Technical Barriers to Trade. Retrieved from https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

Avoiding Unnecessary Obstacles to Trade

Unnecessary obstacles to trade can result when a regulation is more restrictive than necessary to achieve a given policy objective,[12] or when it does not fulfill a legitimate objective or when a conformity assessment procedure is unnecessarily strict. 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 example above).

Governments can minimize the risk of developing unnecessarily restrictive regulations by considering alternative measures that have less trade-restricting effects. Members can assess these risks using technical and scientific information, technology, or end-uses of the products.

Labelling is one of the subjects assigned to the WTO Committee on Trade and Environment (CTE). It is part of an item (3b) on the committee's work program, in which the committee is assigned to consider the relationship between the provisions of the WTO's agreements and the requirements governments make for products in order to protect the environment. In addition to labelling, this includes standards and technical regulations, as well as packaging and recycling requirements.

Some countries have formed a National Commission or Committee for the Preparation, Adoption, and Application of Technical Regulations to minimize the development of restrictive trade measures.

When Is Conformity Assessment an Unnecessary Obstacle to Trade?

WTO members' obligation to avoid unnecessary obstacles to trade also applies to conformity assessment procedures.

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

Legitimate Objectives for Technical Regulations

The TBT Agreement recognizes the existence of legitimate divergences of preference, income, geographical and other factors between countries. For these reasons, the Agreement accords to Members a degree of flexibility in the preparation, adoption, and application of their national technical regulations.

Article 2.2 of the TBT 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. An Example: "Environmental labelling schemes are complex, causing concerns about developing countries and small businesses' ability to export. How do you use labelling to inform consumers about environmental protection without jeopardizing these weaker players? Opinions are divided. Two WTO committees are grappling with the question."[13]

Transparency and Notifications: The WTO Notification System

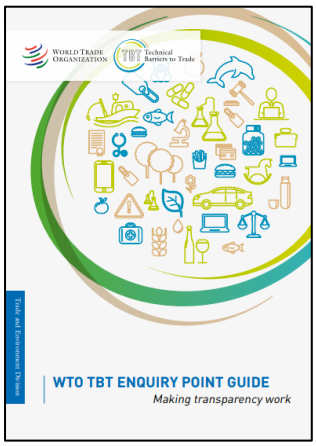
According to the TBT Agreement, transparency is the process whereby the creation, terms, and application of technical regulations, standards, and conformity assessment procedures are made public, and opportunities are provided for the public (including other WTO Members) to comment on proposed technical regulations, standards, and conformity assessment procedures.

12 World Trade Organization (2018). Labelling. Retrieved from https://www.wto.org/english/tratop_e/envir_e/labelling_e.htm

13 World Trade Organization (1995). Agreement on Technical Barriers to Trade. https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

The WTO notification system is handled through the TBT-Information Management System (TBT IMS). This system is a comprehensive online database that allows users to search all TBT notifications as well as Specific Trade Concerns (STCs). STCs are official concerns raised in the TBT committees. This database also includes information on Enquiry Points, Statements on Implementation, Agreements between Members, and other TBT-related documents.[14]

Enquiry Point and Notification Authority



As an integral part to the obligation of transparency, each WTO Member must set up a national enquiry point (NEP) and national notification authority (NNA). The NEP acts as a focal point where other WTO Members can obtain information and documentation on technical regulations, standards, and test procedures. The NNA sends notifications of draft technical regulations to the WTO Secretariat, typically through the online notification portal called ePing. This includes pending or adopted measures, as well as on participation in bilateral or multilateral standard-related agreements, regional standardizing bodies, and conformity assessment systems (Article 10).[15]

The Code of Good Practice

Contained in Annex 3 of the TBT agreement, the Code of Good Practice for the Preparation, Adoption, and Application of Standards establishes disciplines in respect of central government, local government, and non-governmental and regional standardizing bodies developing voluntary standards.

The Code aims to harmonize standards, promoting participation of all Members in the development of international standards when possible. The Code of Good Practice provides overarching principles that guide the acceptable development of international standards, so that voluntary standards follow the appropriate criteria to be received internationally. These six principles are transparency, openness, impartiality/ consensus, effectiveness/relevance, coherence, and development dimension. The Code of Good Practice also encourages signatories to use existing international standards, or the relevant parts of them, as a basis for any standardization activities. Members are encouraged to consider whether existing international standards meet the need of the standard developing body before developing new standards.

WTO Members with national standardizing bodies must accept and comply with the provisions of the Code. A standardizing body wishing to adhere to or withdraw from the Code must notify using the appropriate notification format (paragraph C of the Code). The Code has been accepted by 192 standardization bodies. Those that have accepted the Code must notify other Members of their work program and where it can be obtained.

RELATED QUALITY PRACTICES ASSOCIATED WITH THE TBT AGREEMENT

Good Regulatory Practice

Over the past two decades, delegates to the TBT have increasingly stressed the importance of Good Regulatory Practice (GRP) in avoiding unnecessary barriers and facilitating trade.[16]

While the TBT Agreement itself does not address Good Regulatory Practice (GRP), the WTO plays an ongoing and important role in supporting international regulatory cooperation and implementation of GRP at the domestic level, while reducing unnecessary barriers to trade.[17]

14 World Trade Organization (2021). Technical Barriers to Trade Information Management System. http://tbtims.wto.org/
15 WTO (2018). WTO TBT Enquiry Point Guide. https://www.wto.org/english/tratop_e/tbt_e/tbt_enquiry_point_guide_e.pdf
16 World Trade Organization (2021). Technical barriers to trade. https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

The TBT and SPS Agreements, in particular, offer a framework for cooperation and use of relevant international standards in regulation. GRPs – or the systemic application of procedures, tools, and institutions that ensure regulatory outcomes are transparent, stable, effective, and inclusive – are increasingly recognized internationally.

Many bilateral and multilateral trade agreements have incorporated language on the application of GRPs. Examples include Chapter 28 on GRPs under the USMCA, the ASEAN Guidelines on GRP, and several EU proposals for Free Trade Agreement (FTA) chapters on GRP (i.e., Japan, Indonesia, Mexico). Generally, GRP can be separated into three pillars: government coordination, stakeholder engagement or transparency, and regulatory impact assessment (RIA).

Regulatory Impact Assessment

When designing a policy, law, regulation, or any type of "rule," governments should always consider its likely effects. Regulatory impact Assessment (RIA) provides crucial information to decision-makers to analyze the costs and benefits of regulatory and non-regulatory policy options, including inaction, to achieve public policy goals. RIA examines the anticipated consequences of a range of policy options.

This thorough analysis provides policy makers with data to support a regulatory decision or a decision not to intervene in markets where the costs of doing so outweigh the benefits. RIA provides policymakers, civil servants, and other public sector practitioners with a practical instrument for better designing and implementing regulatory systems and strategies. RIA principles cover a wide range of institutional organizations, tools, and practices, and present a list of critical steps as well as "do's and don'ts" for developing frameworks. Extensive research and analysis have been undertaken by the Organization for Economic Cooperation and Extensive research and analysis have been undertaken by the Organization for Economic Cooperation and Development (OECD) on conducting RIA, including methodological issues, country experiences, and challenges in implementation. The materials also offer guidance on improving performance of RIA, encouraging early integration with policymaking while promoting regulatory coherence across institutions. RIA will continue to remain a key component of evidence-based approaches to policymaking.[18] Please visit OECD's website on RIA for more information.

The Committee on Technical Barriers to Trade

The TBT Agreement is further strengthened by regular meetings of the TBT Committee. The TBT Committee typically meets three times per year to discuss specific trade concerns regarding technical regulations and standards and conformity assessment procedures, and to consult with other Members on issues related to the TBT Agreement. The Committee also meets on a triannual basis to deliberate on matters relating to the operation or interpretation of the TBT Agreement. Summary reports of the meetings as well as annual reviews and officially record discussions can be found on the WTO TBT Official Documents website.

Why is the TBT Agreement Necessary? Benefits of Harmonization

Producers' Benefits

The arguments for harmonization of technical regulations and standards are well known.

17 World Trade Organization (2019). Facilitating trade through regulatory cooperation: The case of the WTO's TBT/SPS Agreements and Committees. https://www.wto.org/english/res_e/booksp_e/tbtsps19_e.pdf

18 OECD (2021). Regulatory impact assessment. https://www.oecd.org/regreform/regulatory-policy/ria.htms

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 U.S. market could not be sold in Europe due to divergences in color broadcasting formats (NTSC vs. PAL or SECAM). The costs of designing and manufacturing the same product in various configurations may be high. Harmonization can greatly reduce these costs and supports more consistent product quality and performance.

Consumers' Benefits

Additionally, technical harmonization increases 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).

Importance of Mutual Recognition

One of the main difficulties exporters faces is the costly redundant testing or certification as part of differing conformity assessment procedures. 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 and regional accreditation bodies.

In practice, countries agree to accept the results of one another's conformity assessment procedures, although these procedures might differ. This is achieved by mutual recognition of the verification (also called accreditation) of conformity assessment bodies. In this arrangement, participants agree to accept results that have been accredited
by a recognized signatory to an agreement. This minimizes duplication of testing and certification, reduces costs, and decreases delays to market access. Article 6.3 of the TBT Agreement strongly encourages WTO Members to enter negotiations with other Members for the mutual acceptance of conformity assessment results.[19]

The SPS Agreement

The Sanitary and Phytosanitary (SPS) Agreement complements the TBT Agreement, specifically focusing on food safety and potential barriers to trade from overly burdensome food-based regulation. The SPS Agreement was formalized in 1995 as an Establishing Agreement of the WTO.[20] It describes international best practices for animal and plant health to support food safety. As in the TBT Agreement, the SPS Agreement provides space for WTO Members to adopt relevant national standards for food safety. However, as the SPS Agreement deals with many human safety concerns, it requires that standards and regulations are based on scientific evidence and applied to the extent necessary to protect human, animal, or plant life or health.

As with the TBT Agreement, Member countries are encouraged to use existing international standards, recommendations, and guidelines. However, the SPS Agreement allows for the use of higher standards given scientific justification or based on an appropriate assessment of risks, as long as the approach is consistent and not arbitrary. Different standards and inspection methods are still allowed.

Sanitary (human and animal health) and phytosanitary (plant health) measures can vary in their approach, particularly due to differences in climate, local pests or diseases, and food safety conditions, among others.[21] Such measures are designed to protect humans, animals, and plants from pathogens, diseases, and other risks such as pests or toxins. Examples include prohibiting

19 World Trade Organization (1995). Agreement on Technical Barriers to Trade. https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

20 World Trade Organization (1998). Understanding the WTO Agreement on Sanitary and Phytosanitary Measures. https://www.wto.org/ english/tratop_e/sps_e/spsund_e.htm

21 World Trade Organization (2010). WTO Agreement Series: Sanitary and Phytosanitary Measures. https://www.wto.org/english/res_e/ booksp_e/agrmntseries4_sps_e.pdf

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

THE TBT AGREEMENT TYPICALLY DEALS WITH:

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

products from disease areas, inspections, treatment or processing requirements, allowable maximum levels of chemicals such as pesticides, or limiting certain additives in food. These can be applied to domestically produced food or local animal/ plant disease, as well as imported products.

From TBT to SPS

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

Much like many of the WTO Establishing Agreements, the SPS and TBT Agreements are complementary, and build on previous GATT rules (i.e., Article XX, section b). Further, the SPS Agreement closely complements the Agreement on Agriculture, which covers domestic support, market access, and export subsidies, and entered into force in 1995.[22]

The SPS Agreement includes the following main rules:

- 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.

How Do the SPS and TBT Agreements Differ?

Both the TBT and SPS Agreements aim to prevent unnecessary barriers to trade. While measures that limit trade can generally be viewed under the TBT Agreement, a measure with the specific goal of protecting health is taken under the SPS Agreement. The splitting of the two categories allows for high-level international consensus of non-health measures, while allowing exceptions for health-protection measures for the purpose of adaptability based on domestic circumstances, so long as they are justified by science.

The SPS Agreement: Applies only to measures directly affecting the life or health of humans (mostly food safety), animals, and plants.

The TBT Agreement: Applies to every kind of measure for whatever purpose. As noted earlier in this section, this can include measures related to national security, prevention of deceptive practices, protection of the environment, and protection of human health or safety, or animal or plant life or health.

22 World Trade Organization (2021). Agreement on Agriculture. https://www.wto.org/english/docs_e/legal_e/14-ag_01_e.htm

TBT REFERENCE INFORMATION

Official TBT documents from the WTO (www.wto.org)
http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

- The TBT Agreement
- Technical explanation of WTO Agreement on Technical Barriers to Trade
- National enquiry points by country in alphabetical order
- Notifications submitted by Members on technical regulations and conformity assessment procedures
- Notifications related to Code of Good Practice for the Preparation, Adoption and Application of Standards
- Working documents of the TBT Committee
- What are Technical Barriers to Trade?
- Sign up to receive TBT notifications by e-mail
- Technical Assistance related to Technical Barriers to Trade

General documents of the TBT Agreement in relation to Technical Assistance

- Transparency provisions of the TBT Agreement
- Databases on TBT-related technical assistance
- The TBT Committee
- Harmonization
- Transparency

SPS REFERENCE INFORMATION

- TBT Workshop on Statements on the Implementation and Administration of the Agreement under Article 15.2
- TBT Learning Event on Labeling
- Introduction to SPS measures: "Understanding the SPS Agreement"
- How to apply the transparency provisions of the SPS Agreement
- The Full SPS Agreement
- Interactive course on the SPS Handbook
- Members' Transparency Toolkit on Work in SPS
- New mentoring system available for national notification authorities and enquiry points
- SPS notification formats
- A practical guide on how to notify SPS measures to the WTO, establish an enquiry point, and respond to enquiries

CONTINUE READING HANDBOOK ▸
METROLOGY, STANDARDS, ACCREDOTATION& CONFORMITY ASSESSMENT: TOOLS TO FACILITATE TRADE AND MARKET ACCESS

SECTION 3: STANDARDS & TECHNICAL REGULATIONS ▸
SECTION 4: METROLOGY ▸
SECTION 5: ACCREDITATION & CONFORMITY ASSESSMENT ▸
ANNEX ▸
INTRO & GLOSSARY ▸
SECTION 1: AN OVERVIEW OF NQI ▸

SECTION 3

STANDARDS & TECHNICAL REGULATIONS

Standards provide consistency and predictability to our lives while providing a foundation for global trade, market access and export competitiveness. In expanding trade, 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, implementation of the TBT Agreement would not be possible.

Standards support a wide array of societal benefits including environmental protection, health and safety, national security, consumer protection, market predictability, and overall economic efficiency and consistency. When developed and implemented correctly, standards make our lives easier and safer; however, improperly implemented standards have the potential to create issues.

For example, standards that do not consider the end-user jeopardize product and consumer safety. This oversight has been well documented in Upton Sinclair's 1906 novel *The Jungle,* which outlines poor working conditions and injuries resulting from a lack of safety standards. This example demonstrates the importance of considering all aspects of a product throughout its lifespan when developing the relevant standard, from production to use by the consumer to environmental impact, with the inclusion of a wide variety of stakeholders that can speak to each element.

Additionally, the variation in standards across countries and regions can make production and export difficult. Poorly developed or intentionally deviant standards create technical barriers to trade across borders and have been used as a way to block competition. This practice undermines consumer choice and global markets. It is therefore preferable to use international standards to harmonize product specifications across borders whenever possible.

"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."

– ISO/IEC Guide 2:2004, *Standardization and Related Activities*[1]

1 Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of the World Trade Organization (WTO). Agreement on Technical Barriers to Trade (TBT), standards are defined as voluntary and technical regulations are defined as mandatory.

Standards become technical regulations when made mandatory by a governing body. This happens by either referencing the standard or having the standard directly developed for regulatory purposes. Technical regulations are used when voluntary standards are considered insufficient to protect consumers, plant and animal health, public safety, the environment, or other government purposes. Generally, it is considered best practice to avoid regulation unless necessary. Please see Section 2: Technical Barriers to Trade for more information.

The Evolution and Recognition of the Need for Standards

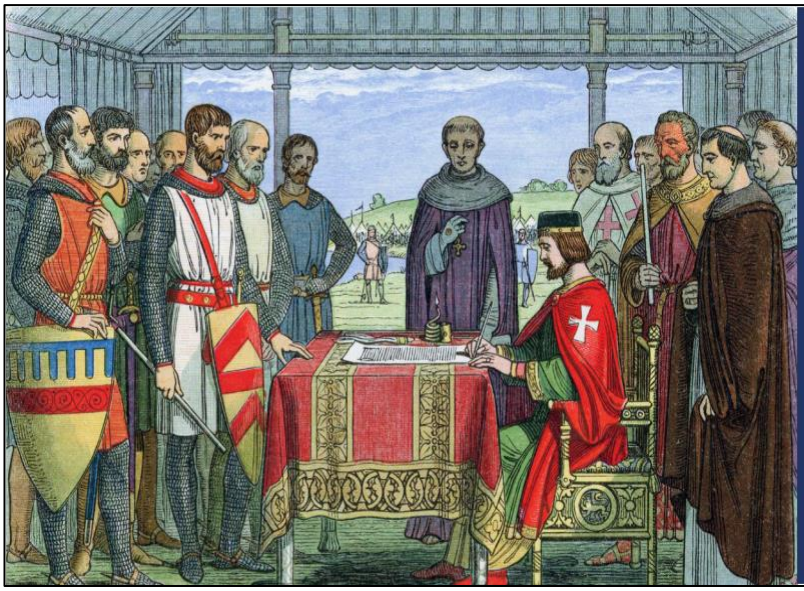
Standards have been used for millennia throughout the world and across ancient civilizations. Some of the first known standards include the Aztec Calendar, the Royal Egyptian cubit and methods used to build the Egyptian Pyramids, and standardized symbols that facilitated the development of written language. Standards for accounting date back to 3300 BC, with archaeologists having discovered standardized accounting on clay tablets from Egypt and Mesopotamia.[2] The Mesopotamian shekel – the first known form of currency – emerged nearly 5,000 years ago, making it the first standard for an exchange currency. The earliest known mints date to 650 and 600 B.C. in Asia Minor.[3]

Over time, standardization has become increasingly advanced. In 1215, the Magna Carta noted the use of standards, and the industrial revolution led to standards and measures that supported the creation of interchangeable production and interoperability (i.e., a railway gauge). These changes catalyzed a drastic leap forward in production capacity and mechanization that facilitated decreased costs of production. As a wider array of products became available to the public, standards that protect workers and consumers also rose in prominence.

INTERNATIONAL APPROACHE TO STANDARDS AND TECHNICAL REGULATIONS

How Are International Standards Developed?

International standards are developed according to the basic principles of consensus, voluntary involvement, and creating industry-wide global solutions. All three are interdependent, and critical to successful international standards. International standardization is often market-driven and dependent on the involvement of all interested parties and stakeholders,



"There is to be one measure of wine throughout our kingdom, and one measure of ale, and one measure of corn, namely the quarter of London, and one breadth of dyed, russet and haberget cloths, that is, two ells within the borders; and let weights be dealt with as with measures."

– Clause 35, *Magna Carta Libertatum,* 1215

BBC (2017). How the world's first accountants counted on cuneiform. Retrieved from https://www.bbc.com/news/business-39870485

[3] Curtis, C (1907). Coins from Asia Minor. American Journal of Archaeology

which would require consensus built out of voluntary involvement, and it is consensus that then leads to industry-wide acceptance of a standard.

While the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) does not designate any standards body as "international," it offers a set of principles for developing international standards. They are openness; transparency; impartiality and consensus; relevance and effectiveness; coherence; and the development dimension. As an example, U.S. policy defines the term "international standard" as standards developed in line with these principles. The U.S. further supports open participation by diverse interest groups and individual experts in the development of international standards, which does not limit participation based on national delegations.

Example: ISO's Standards Development Process

The need for a standard is usually expressed by an industry sector, which communicates its need to the national member body. Once the need for an appropriate standards development organization. It is now also possible to publish interim documents at different stages in the standardization process. Most standards require periodic revision. Several factors combine to render a standard out of date: technological evolution, new methods and materials, new quality, and safety requirements. To take account of these factors, SDOs generally recommend a defined period for review. On occasion, it is necessary to revise a standard earlier. Find out more: https://www.iso.org/developing-standards.html.

Who Develops Standards?

Standards developing organizations (SDOs) develop voluntary standards for materials, products, systems, and services. These SDOs are independent organizations that identify market needs and react accordingly, working directly with technical experts from around the globe to develop appropriate standards. Most SDOs welcome – or even actively encourage – participation from companies, government officials, organizations, and other stakeholders from around the globe. SDOs in the U.S. include ASHRAE, ASTM International, the International Association of Plumbing & Mechanical Officials (IAPMO), the National Fire Protection Association (NFPA), NSF International, and UL, among many hundreds of others.

Benefits of Participating in International Standards Development for SMEs[4]

- ✓ Help improve the quality of goods and services.
- ✓ Help drive growth, cut costs, and increase profits.
- ✓ Give business a competitive edge.
- ✓ Open up export markets for goods and services.
- ✓ Open doors to new customers and strengthen existing business.
- ✓ Help SMEs compete with larger enterprises.
- ✓ Enhance credibility and secure customer confidence.
- ✓ Sharpen business processes and increase efficiency.
- ✓ Strengthen marketing pitch.
- ✓ Help complies with regulations.

Consortia also play a large role in standards development. Consortia standards are developed by companies who agree to work together to solve a specific market need. Consortia documents may offer a solution to a problem, but participation in standards setting is limited to members of the consortia. Examples of consortia include 3rd Generation Partnership Project (3GPP), Ecma International, IEEE Industry Connections Industry Consortium on Learning Engineering (ICICLE), and World Wide Web Consortium (W3C). As a more granular example, W3C is an international membership organization that develops Web standards,

4 ISO (2014). Ten good things for SMEs. https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100283.pdf

primarily protocols, and guidelines that ensure long-term growth for the Web. Participants include member organizations, full-time staff, and interested participants from the public. Funding is provided by member dues, research grants and other sources of private and public funding, and individual donations of money and equipment.

Benefits of International Standards

There are many benefits of using international standards, which can be applied by a variety of businesses from small to large and across sectors. International standards can help improve productivity, increase efficiency by reducing costs, and above all help businesses access new markets and gain global market access. And this can be particularly true for small to medium-sized enterprises (SMEs).

ISO, IEC & ITU Standards Are Internationally Agreed By Experts

Think of them as a formula that describes the best way of doing something.

It could be about making a product, managing a process, delivering a service, or supplying materials – standards cover a huge range of activities. Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators.

For instance,

- Quality management standards to help work more efficiently and reduce product failures.
- Environmental management standards to help reduce environmental impacts, reduce waste and be more sustainable.
- Health and safety standards to help reduce accidents in the workplace.
- IT security standards to help keep sensitive information secure.
- .Food safety standards to help prevent food from being contaminated

..Discover some of the best-known and most widely-used standards, as well as those that address recently emerged challenges affecting us all.

Standards Support SMEs

Standards can make market access easier for SMEs by offering a guarantee to customers that a product is safe and reliable if the product lacks established brand recognition. Below are some of the other benefits SMEs can reap from not just the option of standards, but from participation in international standards development.

SMEs can get assistance from their countries' national standards body or relevant standards developing organizations (SDOs). The International Organization for Standards (ISO) also has a series of publications and brochures for SMEs.5

There are a wide variety of international development programs that focus on supporting both developing nations and SMEs to adopt and implement international standards. These include programs sponsored by organizations like the United States Agency for International Development (USAID), the American National Standards Institute (ANSI), ISO, IEC, the United Nations Industrial Development Organization (UNIDO), the Physikalisch-Technische Bundesanstalt (PTB, the national metrology institute of Germany), and many more.

In particular, the Standards Alliance responds to requests from government bodies, national standards bodies, and private sector entities to increase local understanding and capacity to implement relevant international standards. This technical assistance program informs participating SMEs about ways they can meet international market requirements through the implementation of product, service, and management standards.

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NATIONAL STANDARDS POLICY FOR THE UNITED STATES
Jointly created by NIST and ANSI

Key Provisions

- Lack of participation in international standards will cause the USA to lose market share.
- Historic US principles should apply in the international arena (Consensus, openness, balance, transparency, due process etc.)
- IEC/ISO, Engineering Societies and industry groups all are legitimate global SDOs
- Cooperation/coordination is required for focus and to avoid overlap
- Recent use of standards in the US regulatory process should be promoted
- Vienna/Dresden agreements &"1 nation/1vote" rule revisited

New partnership for ISO and ICC

A new *Memorandum of Understanding* is set to accelerate opportunities for standards, business, and trade. In an agreement signed in Paris, ISO and the International Chamber of Commerce (ICC), the world business organization, have agreed to explore and develop new ways of working together.

The partnership brings significant benefits to both parties. For ICC it is a reflection of the important role that international standards play in international trade, as well as the numerous solutions that ISO standards bring to businesses of all sizes. Representing more than 45 million businesses in over 130 countries, the ICC membership comprises a wide diversity of cultures, sectors, and sizes.

One of ISO's ambitions for the partnership is to enable and empower businesses through standards. Through this collaboration ISO intends to better understand the ways in which it can respond to the changing needs of business, and SMEs in particular.

Through this collaboration ISO intends to better understand the ways in which it can respond to the changing needs of business, and SMEs in particular.

Key Concepts of the International System WTO TBT Agreement[7]

As noted above, international standards support a variety of economic and development benefits when developed using internationally accepted best practices. These principles for standards development in the WTO TBT Agreement. The TBT Agreement is the international framework that governs outlined in the WTO TBT Agreement. The TBT Agreement is the international framework that governs the international approach to standards, technical regulations, and their development. For a more in-depth overview of this agreement, please see Section 2: Technical Barriers to Trade.

Standards and technical regulations outline specific characteristics of products. These can include product functions, performance, shape, size, or design. They can also describe packaging or labelling characteristics. Often, the manufacturing process can affect these characteristics, in which case it may be appropriate to draft standards or technical regulations in terms of process and production methods instead of – or in addition to – product characteristics.

Compliance is the key difference between standards and technical regulations. Because standards are voluntary, and technical of process and production methods instead of – or in addition to – product characteristics. Compliance is the key difference between standards and technical regulations. Because standards are voluntary, and technical regulations are mandatory (enforced by law), each can have different implications for international trade. For example, imported products that do not comply with relevant technical regulations will not be allowed to enter the market.

On the contrary, products that do not comply with relevant standards will be allowed; however, their marketability can be negatively impacted by consumer preference.[8] In a free market economy, most standards are voluntary (>90%).

The WTO TBT Definitions

Standard: "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."

Technical Regulation: "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.

STANDARDS

- Are **voluntary** in nature
- Can be developed by a **variety of bodies** in the public or private sector.
- Contains **only product characteristics** or **technical requirements**.
- Are developed in a stakeholder inclusive **consensus process**.

TECHNICAL REGULATIONS

- Are **mandatory** and form part of legislation.
- Are the responsibilities of the **government**.
- They address:
  - **product characteristics** and
  - **administrative procedures**

Technical Regulations and Standards in the TBT Agreement

The TBT Agreement encourages the of use performance where possible in lieu of design or descriptive standards (Article 2.8, Annex 1, and Annex 3).[9] Furthermore, it is important to emphasize that under the TBT Agreement, Members commit to considering existing relevant international standards. While a definition for international standards is not included in the text of the TBT Agreement, Second Triennial Review of the Agreement established that international standards are developed in accordance with key principles including transparency, openness, due process, balance, and consensus.[10] Therefore, a standard is considered international based on its adherence to best practices for development, rather than which organization developed the standard. For example, many non-governmental bodies and organizations produce international standards.

7World Trade Organization (1995). Agreement on Technical Barriers to Trade. https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

8 World Trade Organization (2021). Technical Information on Technical barriers to trade. https://www.wto.org/english/tratop_e/tbt_e/tbt_info_e.htm

The TBT Agreement establishes the procedures for the preparation, adoption, publication, and application of technical regulations by central government bodies(Article 2) or local government or non-governmental bodies (Article 3), and of standards (Article 4). These include enforcement in the form of conformity assessment (Articles 5-9).

Regulation is an important tool used by governments to keep people safe and healthy, preserve the environment and promote sustainability. However, when regulation becomes too complex, or when it differs unnecessarily across countries, costs can rise, and trade can suffer. When this happens, differing standards and regulations can be counterproductive because they may undermine cooperative efforts to solve problems of the global commons, including those related to climate change, health, and digitalization.

A key tenet for WTO rules is that regulation and standards should facilitate trade, not hinder it. But non-tariff measures (of which standards and regulations are an important part) are notoriously thorny. WTO Members frequently attempt to resolve their concerns – often pre-emptively – at the WTO by engaging with trading partners, including at the Committee on Technical Barriers to Trade (TBT Committee).

TBT Notification System for New or Revised Technical Regulations

According to the TBT Agreement, countries must publish notifications of proposals of new technical regulations or amendments to existing regulations before the final versions are published.[11] The purpose of a notification is to allow interested parties (usually trading partners whose trade will be affected by the regulation) to comment on the draft regulation and for the requisite changes to be made before the regulation enters into force. Members have 60 days from the date of publication of the notification to respond.

Notifications are sent to the WTO Secretariat in Geneva or through the WTO online notification portal, ePing (epingalert. org/). These notifications are circulated to all Members and posted on the WTO website (where they can be downloaded). Individual enterprises or industry associations should contact their NEP and request it to forward notifications of interest to them. They should send their comments back to the enquiry point within the required time, to allow their governments to defend their interests by responding to the notifications at the WTO. The WTO has introduced a guide for Enquiry Points and Notification Authority that describes the notification process.

Additionally, the WTO's online platform, ePing, allows users from across the globe to track and review all TBT and SPS notifications to the WTO online. This platform allows users to search key terms, follow target markets, and provides access to contact information for each TBT and SPS NEP.

SPS & TBT Platform

9 World Trade Organization (1995). Agreement on Technical Barriers to Trade. https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm
10 World Trade Organization (2021). Second Triennial Review, G/TBT/9. Retrieved from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/G/TBT/9.pdf&Open=True
11 World Trade Organization (1995). Agreement on Technical Barriers to Trade. https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

Legitimate Objectivities

Compared to voluntary standards, technical regulations can result in more difficult trade barriers to overcome. Because of this, a basic principle for the creation of technical regulations is that they must be based on "legitimate objectives," defined in the TBT Agreement[12] as:

Protection of Human Safety or Health: The largest number of standards and technical regulations fall under this category. Examples include vehicle safety requirements, electrical socket design, and labeling of harmful substances.

Protection of Animal and Plant Life or Health: Also, a very common category, these technical regulations aim to safeguard animal and plant species from extinction. Examples include prohibited products from foreign pest or disease areas, and invasive species.

Protection of the Environment: Due to rising levels of environmental pollution, increased environmental concerns among consumers and governments have led to the adoption of regulations that aim to protect the environment. Examples include recycling, vehicle emissions, and eco-labeling.

Prevention of Deceptive Practices: With a key goal of consumer protection through information, regulations such as classification definitions, packaging, or other measurement requirements aim to avoid deceptive or fraudulent practices. An example is labeling requirements.

National Security Requirements: This refers to regulations with the aim of protecting public safety. Examples include chemical detection levels and cybersecurity.

NOTE: Quality is not considered a Legitimate Objectivities

Standards: Sub-Categories

While technical regulations are differentiated by objectives, standards can be differentiated based on type as defined by purpose, classified by user group, or by the manner in which they specify requirements. A basic standard has a broad ranging effect in a particular field.

Standards can be classified by purpose:

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, establish 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.

12 World Trade Organization (1995). Agreement on Technical Barriers to Trade. https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

Standards may also be classified by the intended user group:

Company/private standards are meant for use by a single industrial organization and are usually developed internally.

Developing, promoting and

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. Adherence to government standards is voluntary unless they are included in technical regulations.

Standards can additionally be distinguished by the manner in which they specify requirements:[13]

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.

ACCESSING INTERNATIONAL STANDARDS

International and Regional Standards Bodies

Standards organizations around the world include private, voluntary organizations whose membership is on a national body basis, treaty organizations (where governments are members), professional and technical organizations whose membership is on an individual or organizational basis, and consortia, whose membership is typically company and industry based. Additional information about four international organizations as well as regional standard organizations are addressed later in this section.

National Standards Body/Organization

A national standards body (NSB) is defined as a country's nationally recognized body responsible for developing, promoting and maintaining documentary standards. In many countries this organization will also engage in international standards development activities. The NSB generally hosts a standards information center and maintains a collection of national standards as well as collections of national, regional, and international standards. At the information centers, there is typically the option to consult catalogs of standards from various standards bodies. An NSB will be able to sell its own standards and will be licensed to sell the standards of other bodies. If it does not have a particular standard, the standard can be requested to be ordered.

Online

Because standards are constantly being updated and created, online resources are valuable tools in searching for and acquiring the latest standards from NSBs, regional standards bodies, or directly from standard developers. Standards are generally not distributed for free, though some are made publicly available.

Codex standards, for example, can be downloaded at no cost from their online portal.[14] ISO also has a portal of publicly available standards.[15] Standards that are not publicly available are often priced in relation to their length (i.e., number of pages) for purchase online.

Standards Information from Other Countries – Enquiry Points

The TBT Agreement requires each WTO Member to establish a National Enquiry Point (NEP) on standards, technical regulations, and conformity assessment, and to notify its contact details to the WTO Secretariat in Geneva. Each enquiry point is responsible for ensuring that any enquiry on national and even subnational technical regulations is adequately answered. Each WTO Member must inform the WTO Secretariat of any draft technical regulation within its territory. The WTO Secretariat then makes this information available to all WTO Members. By making these requirements, the WTO TBT Committee tries to ensure that the TBT Agreement system of technical regulations is open and transparent.[16]

A standards user can request their NEP to forward a request for information to a counterpart in the country of interest. Alternatively, a standards user can address a query directly to a WTO Member's NEP. For non-WTO members, assistance from NEPs is still available in some markets. While most NEPs will respond to all enquiries, these organizations are only required to respond to questions from WTO members.

THE UNITED STATES APPROACH TO STANDARDS

Standards- and test methods developed under the U.S. system have long provided safety and promoted innovation. Standards developed by U.S.-based organizations also underpin many international economic structures, and the absence or the lack of continual revision to these standards would destabilize large areas of international trade, disrupt communication, and significantly reduce quality of life around the world.

Standardization activities in the U.S. are diverse and decentralized. Private and public sector volunteers participate in the work on such activities with funding provided by themselves or their employers, not by U.S. government subsidy. The U.S. standards system places a high value on consensus, where no single organization is permitted to control the process, which is industry-led, even when government representatives participate.

For the most part, standards in the U.S. are developed by the private sector and are based on a consensus process in which the developmental committees consider different perspectives. Some standards in technological areas that are subject to rapid change (such as electronics and information technology) may be developed by industry consortia.

Key Concepts of the U.S. Standards System

The United States Standards Strategy (USSS)[17] affirms that the U.S. is committed to a sector-based approach to voluntary standardization activities, both domestically and globally. It establishes a standardization framework that is built upon the traditional strengths of the U.S. system, such as consensus, openness, due process, and transparency. These vital concepts ensure a system that is open to all interested parties, transparent, and based on broad participation by a diverse group of affected parties.

14 Codex Alimentarius (2021). Standards. http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/
15 ISO. https://standards.iso.org/ittf/PubliclyAvailableStandards/index.html
16 United Nations (2004). Exporting Automotive Components: An Answer Book for Small and Medium-sized Enterprises. https://shop. un.org/books/exporting-automotive-components-25845
17 American National Standards Institute (2020). https://www.ansi.org/resource-center/publications-subscriptions/usss

How Are Standards Developed in the United States?

Any entity or individual, domestic or foreign, can participate in U.S. standards development activities. It is heavily dependent on the interested party to initiate participation, by narrowing the focus of interest and then finding the appropriate SDO. The benefits of the U.S. market-driven, sector-based approach to standards development are that it allows for greater flexibility, drives innovation, and offers greater responsiveness than approaches in most other nations.

The U.S. system capitalizes on standards that are already being developed by companies, organizations, consumer groups, government agencies, and trade associations. At the same time, these groups are an active part of the process, and benefit from early access to information, influence over the technical development, and ability to respond quickly to new markets for technology, products, and services. This keeps market access open and fluid, and constantly improves the competitiveness of U.S. industry globally.

Who Develops Standards in the U.S.?

Hundreds of private organizations in the U.S. develop standards. SDOs differ greatly in size, membership, number of standards produced, and scope of work.

General categories of SDO include:

- **Professional societies** that support members who seek to advance their professions and develop standards.
- **Trade associations** that promote their industry's products, and also develop standards.
- **Testing and certifying organizations** that produce their own standards and may also use those of other organizations.
- **Organizations that only develop standards**
- **Industry consortia,** sometimes referred to as standards setting organizations (SSOs).

Although no single government organization oversees the voluntary standards development process in the U.S., the National Institute of Standards and Technology (NIST) housed within the U.S. Department federal agencies, as well as state and local governments, to achieve greater reliance on voluntary standards and decreased dependence on government-produced standards, as directed by the U.S. National Technology Transfer and Advancement Act.

In particular, NIST works closely with the American National Standards Institute (ANSI), the private sector coordinator of the U.S. standards system. ANSI is a federation of standards developers, industry representatives, government agencies, consumers, academia, and other stakeholders that coordinates U.S. private sector standards development activities; is the U.S. Member Body to ISO; and is the U.S. Member Body to the IEC through its U.S. National Committee. NIST and ANSI have signed a Memorandum of Understanding recognizing their respective roles in strengthening the national voluntary consensus standards system.

The NIST and ANSI collaboration performs a vital coordinating role for the entire standards community. Because the U.S. standards system is diverse and decentralized, a comprehensive list of all bodies that develop standards in the U.S. does not exist.

As a member of the WTO and signatory to the TBT Agreement, the U.S. is required to base technical regulations and conformity assessment procedures on relevant international standards, guides, and recommendations, except where they would be inappropriate or ineffective in meeting a legitimate objective.

THE EUROPEAN APPROACH TO STANDARDS AND TECHNICAL REGULATIONS

The formation of the single market in Europe 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. 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 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 15 Member States, which were required to adopt the new harmonized laws.

THE AFRICAN APPROACH TO STANDARDS AND TECHNICAL REGULATIONS

In Africa, the increased reference to standardization in trade and economic policies and as a regulatory instrument and development tool by development partners and institutions, political actors, policy makers, economists, and industrialists is a clear pointer on the future prospects of Africa's sustainable development, and the eminent role of ARSO and the Pan African Quality Institutes (PAQI) in general.

PAQI are the overarching quality institutes for the African continent. These institutes were developed as part of the African Union Commission to increase continental coordination in the area of standards, conformity assessment, metrology, and accreditation. PAQI is comprised of four organizations. These include ARSO, the African Electrotechnical Standardization Commission (AFSEC), the African Accreditation Cooperation (AFRAC), and the Intra-African Metrology System (AFRIMETS).

INTERNATIONAL AND REGIONAL STANDARDS ORGANIZATIONS

The International Organization for Standardization (ISO)

www.iso.org

ISO is an independent, non-governmental international organization with a membership of 167 national standards bodies.

THE ISO STORY

1946 In London 65 delegates from 25 countries meet to discuss the future of International Standardization. In 1947, ISO officially comes into existence with 67 technical committees (groups of experts focusing on a specific subject).

Through its international membership, ISO coordinates standards development. To develop a standard, each ISO member elects or nominates technical experts to participate in a given technical committee, who will work to develop a draft standard(s) to meet a specified market need. Following initial development, draft standards are shared for a period of comment and discussion and a voting process which seeks to gain consensus. If consensus cannot be reached, the draft will be further amended before returning to the voting process. This process generally lasts three years from proposal to finalization of a new ISO standard.

Through the activities of DEVCO (ISO Committee on Developing Country Matters), ISO has been providing assistance to developing countries for nearly 50 years. The DEVCO website 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, reference publications, and training materials, including e-learning.

The International Electrotechnical Commission (IEC) www.iec.ch

IEC is a global organization that prepares and publishes international standards for all electrical, electronic, and related technologies (over 10,000 standards). Similar to ISO, the IEC promotes international cooperation on all questions of electrotechnical standardization and related matters. IEC standards cover a vast range of technologies and include participation from 173 countries. IEC members are represented by technical experts who are nominated by and represent their respective national committees.

Together, nearly 20,000 experts from industry, government, testing and research laboratories, academia, and consumer interest groups support the development of IEC standards.

IEC standards are developed over seven stages, beginning with the preliminary stage, in which future projects are considered for development, and working toward final approval (stage 6) and publication (stage 7). Between these stages, members assemble relevant technical committees (TC) to develop a working draft of newly proposed standards before sharing an approved draft with the full technical committee of observing (O-) and participating (P-) national committee members for comment and approval.

In the IEC, it is important to note the respective roles of P-members and O-members. These distinctions refer to IEC member country status in a TC. P-members can send national experts to participate in technical work in the development and approval of a standard, while O-members only retain observer status. IEC also has a program to include developing countries: The Affiliate Country Program. www.iec.ch/acp.

The International Telecommunications Union (ITU) www.itu.int

ITU is the leading United Nations (UN) agency for information and communication technologies (ICT). As a UN agency, it serves as the global focal point for governments and the private sector in helping the world communicate across its three core sectors: radio communications, standardization, and development. Since its establishment in 1865, ITU has led contribution and consensus-based standards development or ITU-T Recommendations.

The ITU standards development process begins with membership, as member organizations can submit ICT issues that they have identified as in need of standardization. Following submission of an inquiry, a Study Group is assembled to assess and approve further development of a draft Recommendation (draft Rec) by a Working Party (WP). A mature draft Rec is forwarded to the Alternative Approval Process for review and consideration by members. At this stage, draft Recs enter a comment process before a final ITU-T Recommendation is approved.

Codex Alimentarius Commission www.fao.org/fao-who-codexalimentarius/

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.

Regional Standards Organizations

African Organization for Standardization (ARSO) www.arso-oran.org

ARSO facilitates inter-African and global trade through harmonized standards and conformity assessment procedures. In Africa, the increased reference to standardization in trade and economic policies and as a regulatory instrument and development tool is a clear indication of the future prospects of Africa's sustainable development, and the eminent role of ARSO and the Pan African Quality Infrastructure (PAQI) in general. PAQI are the overarching quality institutes for the African continent. These institutes were developed as part of the African Union Commission to increase continental coordination in the area of standards, conformity assessment, metrology, and accreditation. PAQI is comprised of four organizations: ARSO, the African Electrotechnical Standardization Commission (AFSEC), the African Accreditation Cooperation (AFRAC), and the Intra-African Metrology System (AFRIMETS).

European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI)

The European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI) – known collectively as the European Standards Organizations (ESOs) – have a special role in Europe. This includes supporting European regulations and legislation through the creation of harmonized European Standards. Only standards developed by the three ESOs are recognized as European Standards (ENs). A variety of stakeholders are involved in CEN, CENELEC, and ETSI work, including business, industry, commerce, service providers, public authorities, regulators, academia and research centers, European trade associations, and interest groups representing environmentalists, consumers, trade unions, small and medium enterprises, and other public and private institutions.

Association of Southeast Asian Nations (ASEAN) Consultative Committee on Standards and Quality (ACCSQ) https://asean.org/meetingreportparent/asean-consultative-committee-for-standards-and-quality-accsq/

The ASEAN consultative Committee on Standards and Quality is a sectoral body under the purview of the ASEAN economic Ministers. ACCSQ is tasked to address the removal of technical barriers to trade in order to realize the goals of the ASEAN Free Trade Area (AFTA). The ASEAN realized that conformity assessment procedures such as testing and certification, which determines a product's marketability, may pose barriers to trade. This can be caused by a duplicative testing procedure arising from different systems of conformity assessment in various countries. ACCSQ was established to harmonize national standards with international standards and implement mutual recognition arrangements on conformity assessment to achieve the end-goal of "One Standard, One Test, Accepted Everywhere."

Euro-Asian Interstate Council for Standardization, Metrology and Certification (EASC) of the Commonwealth of Independence States (CIS) https://www.rst.gov.ru/portal/eng/home/cooperation/eacs

EASC is an intergovernmental body for formulation and implementation of coordinated policy for standardization, metrology, and certification. Members of the EASC are the national metrology and standards bodies of the former USSR. The Interstate Council was created in accordance with the "Agreement on realization of coherent policy in the field of standardization, metrology, and certification of the 13 of March 1992." The Agreement supports coordination in the field of national quality infrastructure (NQI) and provides a framework for standardization, metrology, certification, and accreditation in specified fields.

Pacific Area Standards Congress (PASC) www.pascnet.org

PASC was formed in 1972, when standards body representatives from Pacific Rim countries met in Honolulu, Hawaii, to create a program leading to the development of a voluntary, independent organization for the region's national standards organizations. In 1973 the first official meeting took place, again in Honolulu, and the group then assumed the name PASC. 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) www.apec.org/Groups/Committee

APEC SCSC assists the APEC 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.

CARICOM Regional Organization for Standards & Quality (CROSQ) www.crosq.org

CROSQ was established in 2003 by a Caribbean Common Market (CARICOM) Community treaty as an intergovernmental organization and the regional center for promoting efficiency and competitive production in trade and services, through the process of standardization and the verification of quality. Located in Barbados, CROSQ is the successor to the Caribbean Common Market Standards Council and supports the CARICOM mandate for 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.

The Pan-American Standards Commission (COPANT) www.copant.org

The Pan American Standards Commission is a non-profit civil association that brings together the National Standards Bodies of the America's, it is the reference for technical standards and conformity assessment of the countries of the America's and its international peers and promotes the development of its members. COPANT aims to improve the quality of life in member countries. And achieve recognition for its contributions to regional development.

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STANDARDS & TECHNICAL REGULATIONS REFERENCE INFORMATION

ASTM Standardization News sn.astm.org
Bimonthly covering ASTM's international standardization work, ASTM standards development, industry professional perspectives, and how ASTM standards benefit governments, industries, consumers, and global trade.

Standards & Competitiveness – Coordinating for Results

https://share.ansi.org/shared%20documents/News%20and%20Publications/Links%20Within%20Stories/trade_barriers_report.pdf
Produced by the U.S. Department of Commerce (DOC), this document addresses "Removing Standards – Related Trade Barriers through Effective Collaboration."

Codex Alimentarius Publications
http://www.fao.org/fao-who-codexalimentarius/publications/en/
Codex Alimentarius is the preeminent international organization dealing with food safety and fair practices in the food trade. Its food standards, guidelines, and codes of practice contribute to international food trade safety, quality, and fairness.

ISO Focus https://www.iso.org/isofocus/x/
Released six times per year in English, Spanish, and French, covers standards and global trends.
ISO publications and brochures for SMEs https://www.iso.org/iso-and-smes.html

Standards Strategy for the United States www.ansi.org/usss
The U.S. Standards Strategy (USSS) reaffirms the U.S. commitment to a sector-based approach to voluntary standardization activities domestically and globally. It established a standardization framework built upon consensus, openness, and transparency while emphasizing speed, relevance, and public need.

The Economic Value of Standardization https://www.scc.ca/en/about-scc/publications/general/economic-value-standardization-report-presented-scc-conference-board-canada
Produced by the Standards Council of Canada (SCC), the study examines the impact of standardization on the Canadian economy and includes a review of standards-oriented economics literature, an empirical analysis of the impact of standards on Canadian labor productivity, interviews, and case studies.

The WTO Agreements Series - Technical Barriers to Trade
https://www.wto.org/english/res_e/publications_e/tbttotrade_e.pdf
This report offers brief overview of the background, purpose and scope of the TBT Agreement. It sets out the key principles of the Agreement and discusses recent disputes brought under the TBT Agreement.
WTO Members Transparency Toolkit https://www.wto.org/english/tratop_e/tbt_e/tbt_transparency_toolkit_e.htm

WTO eLearning Series https://wtolearning.csod.com/client/wtolearning/default.aspx
Online courses on the founding of the WTO, its structure, and agreements.

CONTINUE READING HANDBOOK ▸
METROLOGY, STANDARDS, ACCREDITATION & CONFORMITY ASSESSMENT:
TOOLS TO FACILITATE TRADE AND MARKET ACCESS

SECTION 4: METROLOGY ▸
SECTION 5: ACCREDATION & CONFORMITY ASSESSMENT
ASSESSMENT ANNEX ▸
INTRO & GLOSSARY ▸
SECTION 1: AN OVERVIEW OF NQI ▸
SECTION 2: TECHNICAL BARRIERS TO TRADE ▸

SECTION 4

METROLOGY THE SCIENCE OF MEASUREMENT

WHAT IS METROLOGY?

Metrology is the science of measurement; it has been stated that the necessity of a trading system is metrology. Without the ability to determine length, weight (mass), volume, time, and temperature, even the simplest of transactions would be open to abuse, fair trade would be impossible, and legislation aimed at protecting the health and welfare of citizens would be of no effect. No technical standards could exist for products because there would be no reliable means of measurement of their performance against requirements. A national measurement or metrology system is therefore the first step in economic development and facilitating trade.

The Bureau International des Poids et Measures (BIPM – the International Bureau of Weights and Measures) defines metrology as "the science of measurement, embracing both experimental and theoretical determinations at any level of uncertainty in any field of science and technology." [1]

Trade: A sound measurement system

A sound measurement system is an essential element in achieving globally accepted calibration and testing results. Essential factors for such a system are:Traceability to the International System of Units, or SI (scientific metrology).

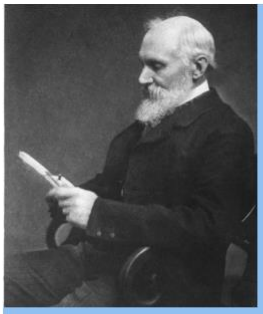
- Regulated measurements and measuring instruments (legal metrology), and confidence in testing and measurement results via certification, standardization, accreditation and calibration (industrial metrology).

REMINDERS FROM A METROLOGIST

- What cannot be measured cannot be manufactured.
- What cannot be measured cannot be tested.
- What cannot be measured cannot be certified.

In every institute, company, or organization, concepts such as safety, security, efficiency, reliability, and precision are of paramount importance in designing systems, which provide guarantees of product quality. Accurate and widely accepted measurements are important in ensuring that market transactions can take place and that consumers can feel confident that the goods they buy are of the quantity and quality they except. Importantly for developing countries, accurate and internationally accepted measurements allow market access for food and commodity exports. Accurate and precise measurements curb the buyer's tendency to want more and the seller's tendency to give less.

1 Bureau International des Poids et Mesures (2021). BIPM. Retrieved from https://www.bipm.org/en/home



"I often say that when you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind; it may be the beginning of knowledge, but you have scarcely in your thoughts advanced to the state of science, whatever the matter may be."

–William Thomson, Lord Kelvin, 1824 – 1907

Metrology in Our Daily Life

A study of history shows that the economic progress and growth of a nation is directly related to their progress in implementing and maintaining a unified national measurement system. Many decisions in life are based on measurements. Measurements influence and are an integral part of our daily lives, a fact that we often forget.

Almost everything we buy is purchased by weight, length, volume, or measure: a kilogram of meat, a liter of gas, a meter of clothing.

In a conversation, one might ask:

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

All of these assume an accurate unit of measurement.

A BRIEF HISTORY OF METROLOGY

The concept of measurement long pre-dates the establishment of formal bodies such as national metrology institutes (NMIs) or other designated institutes. The creation of internationally agreed upon measurement units, standards, and methodology have contributed to the recognition of measurement standards across these bodies.

The Royal Egyptian Cubit

One of the earliest records of precise measurement comes from Ancient Egypt.[2] The Egyptians studied the science of geometry to assist them in the construction of the great pyramids and temples

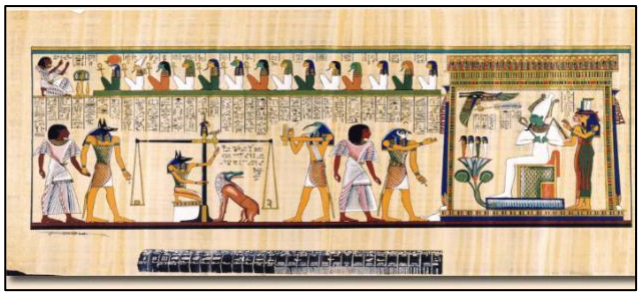
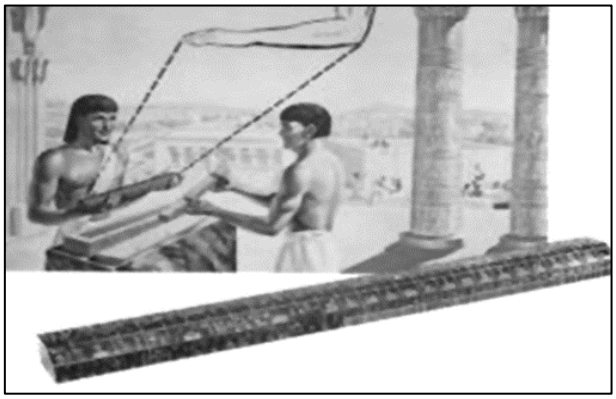


Photo: provided by Ed Nemeroff

The Egyptian unit of length came into being about 3000 years BC. The "Royal Egyptian Cubit" was defined as 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 ruling at that time.[3]

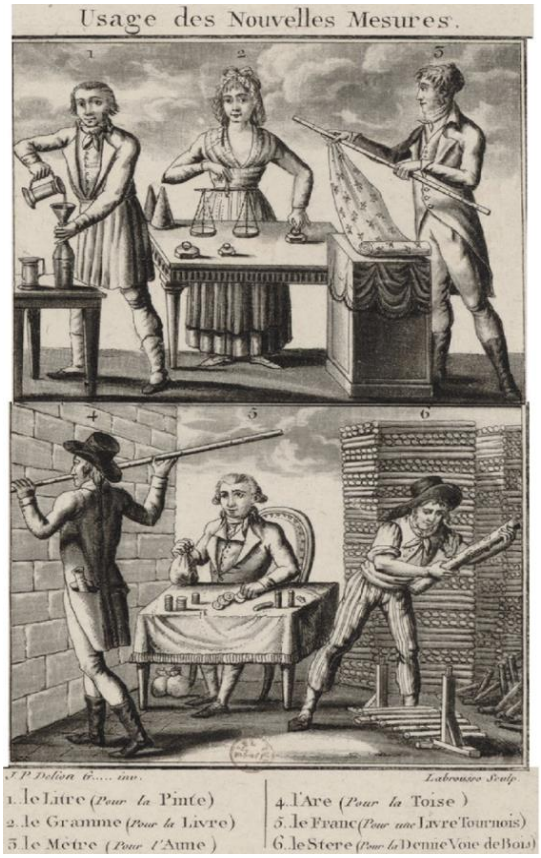
The "Royal Cubit Master"[4] was a rod carved out of a block of black granite.[5] Workers engaged in building tombs, temples, pyramids, and other buildings used cubits made of wood or granite.



The Royal Architect or Foreman of the construction site was responsible for maintaining and 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, and failure to comply was punishable by death.[6] Thanks to this standardization and uniformity of length, the Egyptians achieved tremendous accuracy. The Egyptian commitment to accuracy was essential in building the Great Pyramid of Giza. With the use of cubit sticks, the thousands of workers enlisted to build the Pyramid achieved an accuracy of 0.05%. Sides of the pyramid measured roughly 756 feet or 9,069.4 inches and were within 4.5 inches of the desired result.[7]

2Bruel & Kjaer (2021). The Birth of Calibration. Retrieved from https://www.bksv.com/en/knowledge/blog/perspectives/egyptian-cubit
3Bruel & Kjaer (2021). The Birth of Calibration. Retrieved from https://www.bksv.com/en/knowledge/blog/perspectives/egyptian-cubit
4 The Story of the Egyptian cubit and the Papyrus was presented to Ed Nemeroff 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, Alexandria Egypt. June 9-13, 1996.
5Bruel & Kjaer (2021). The Birth of Calibration. Retrieved from https://www.bksv.com/en/knowledge/blog/perspectives/egyptian-cubit

Beyond the cubit, Egyptians set precedents for modern measurements of weight, time, and the monetary system. They used scales to weigh precious metals and gems and later initiated the modern monetary system by stamping gold and silver coins with their weight. This practice spread throughout the Mediterranean region. Additionally, our conception of time is based on the sexagesimal system (based on the number 60) developed near Egypt, in Mesopotamia, and our calendar is derived from the original 365-day Egyptian calendar. The contributions of the Egyptians to the current system of metrology are clear to this day.



The Importance of Mutual Recognition of Measurements

Mutual recognition of measurements plays an important role in reducing technical barriers to trade, and thus facilitating global trade.

International measurement systems are built on consensus, established by the world's National Metrology Institutes (NMI). These bodies base measurement and measurement uncertainties on the International Systems of Units (SI). Adopted in 1960, the SI consists of seven independent base units: meter (length), kilogram (weight), second (time), ampere (electric current), kelvin (thermodynamic temperature), mole (amount of substance), and candela (luminous intensity

These base units are combined to create derived units defining new quantities, such as the volt, watt, newton, pascal, and joule.[8]

Comparing national measurement, through an NMI, is essential in establishing mutual equivalence among measurements and enhances measurement capabilities while strengthening international trade through the reduction of technical barriers to trade (TBT). Thus, the capacity of NMIs to concretize this mutual equivalence of national measurement standards and calibration capacity becomes a key factor in a nation's ability to engage in global trade. Such equivalence is determined through bilateral agreements, as well as regional multilateral agreements organizations. In 1999, the Comité International des Poids et Mesures (CIPM – International Committee for Weights and Measures) and the BIPM jointly established the Mutual Recognition Arrangement (MRA) program to serve as a tool within wider trade and commercial agreements among nations.[9]

The Earliest Unit of Mass (Weight)

The earliest unit of mass (weight) recorded is the grain. While the magnitude of each measurement differed from civilization to civilization, these systems all served the greater purpose of facilitating trade. Commercial

Seed, grains, and stones were used as weights – the earliest units of mass.

6 Bruel & Kjaer (2021). The Birth of Calibration. Retrieved from https://www.bksv.com/en/knowledge/blog/perspectives/egyptian-cubit
7 NSCL International (2021). What is Metrology. Retrieved from https://ncsli.org/page/WIM
8 BIPM (2021). The International System of Units (SI). Retrieved from https://www.bipm.org/en/measurement-units
9 Bureau International des Poids et Mesures (2021). CIPM Mutual Recognition Arrangement (CIPM MRA). Retrieved from https://www.bipm.org/en/measurement-units

goods were originally traded by number or volume, but this was slowly replaced by the weighing of goods. In these early systems of measurement, mass was based on a volume of grain or water. It is likely that the overlap among units with same or similar name across different regions and languages arises from these early trade relationships.

1875 – Meter Convention – The Creation of BIPM

In May 1875, the "Convention of the Meter" treaty (Convention du Mètre) spurred the establishment of the International Bureau of Weights and Measures (BIPM). The BIPM is an intergovernmental organization that falls under the authority of the General Conference on Weights and Measures (CGPM), and under the supervision of the CIPM. Today, there are 64 Member States of the Meter Convention, and 36 Associate States and Economies of the General Conference.[10] The convention served to lay a foundation for the creation, financing, and management of the BIPM, and further as a convening body and organizational structure for member governments to coordinate action on matters relating to units of measurement.

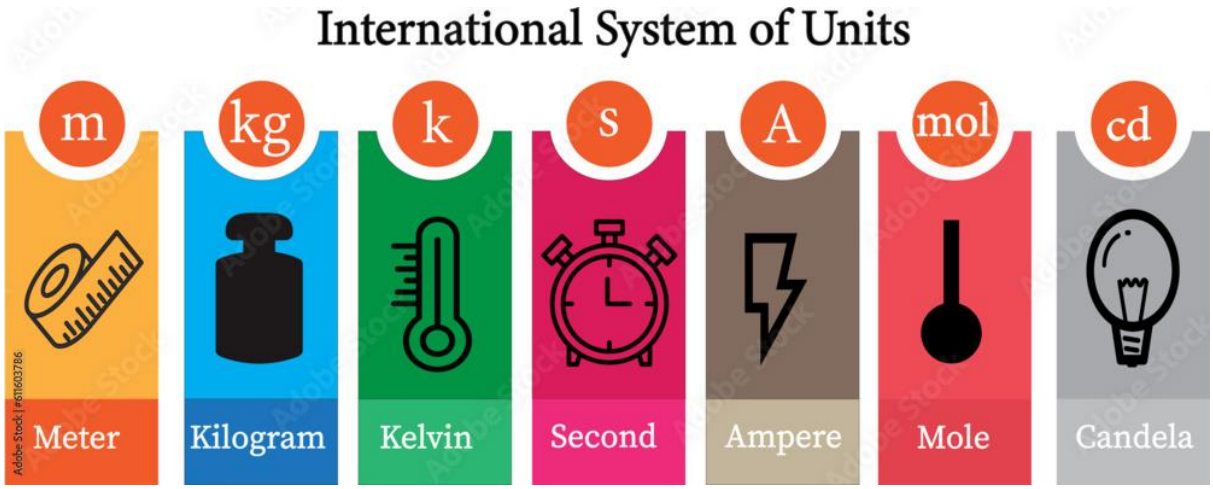
The BIPM is a pivotal actor in world metrology and provides important guidance in providing measurement standards that are increasingly accurate, wide-ranging, and diverse. This is of specific interest in the domain of national measurement standards, where demonstrating equivalence is all the more important for actors.[11]

1960 – International System of Units (SI)

The Système International d'Unités (SI) was adopted in 1960 as the recommended practical system of units of measurement. The SI is a system of units founded on older metric systems and adopted by the CGPM, the highest international authority on units.

As stated above, the SI consists of seven independent base units, and these base units can be combined to create derived units defining new quantities. In sum, the base and derived units form the coherent SI units. Ultimately, the SI is not static. Rather, it evolves to accommodate the world's increasingly demanding requirements for specific measurement.

The Seven Base Units of the SI[12]



10 NIST (2021). The NIST Reference on Constants, Units, and Uncertainty. Retrieved from https://physics.nist.gov/cuu/Units/international.html

11 Bureau International des Poids et Mesures (2021). The Metre Convention. Retrieved from https://www.bipm.org/en/metre-convention

12 BIPM. The International System of Units (SI): Base units. Retrieved from https://www.bipm.org/en/measurement-units/si-base-units

BIPM Revision of the International System of Units (SI)

In the 2018 revision of the SI, the definitions of four of the SI base units - the kilogram, the ampere, the kelvin, and the mole – were changed. Their new definitions are based on fixed numerical values of the Planck constant (h), the elementary charge (e), the Boltzmann constant (k), and the Avogadro constant (N_A), respectively. Further, the definitions of all seven base units of the SI are now uniformly expressed using the explicit-constant formulation. Specific mises en pratique (practices) have been drawn up to explain the realization of the definitions of each of the base units in a practical way. This revision ensures flexible usage and stability of the SI as new technologies, such as quantum technologies, continue to impact our understanding of measurement and the natural world.[13]

CATEGORIES OF METROLOGY

Depending on the field of application, metrology can be sub-divided into three categories:

- Scientific Metrology
- Legal Metrology
- Industrial Metrology

Scientific Metrology

Scientific Metrology is the foundation of all the subfields of metrology. It involves "the establishment of and maintenance of measurement units, unit systems, development of new measurement methods, realization and the transfer of traceability from these standards to users in society."[14] In general, scientific metrology is developed by NMIs and internationally[15] coordinated by BIPM.

Scientific metrology covers three main tasks:

- Definitions for internationally accepted units of measurement.
- Establishment and dissemination of units of measurement by scientific methods.
- Establishment of traceability chains in documenting the accuracy of a measurement.

Legal Metrology

Legal metrology is 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 insure in a regulatory of contractual man, the appropriate quality and credibility of measurements related to official controls, trade, health, safety, and the environment.[17]

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.

13 Bureau International des Poids et Mesures (2018). 26th meeting of the CGPM. https://www.bipm.org/en/committees/cg/cgpm/26-2018

14 Standards and Metrology Institute for Islamic Countries/Metrology Council (2021). Scientific Metrology. https://mc.smiic.org/en/scientific-fundamental-metrology

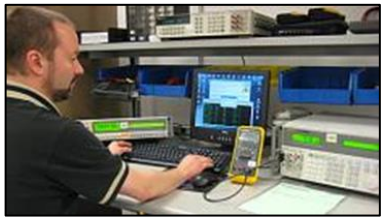
15 Standards and Metrology Institute for Islamic Countries/Metrology Council (2021). Scientific Metrology. https://mc.smiic.org/en/scientific-fundamental-metrology

16 Euramet (2008). Metrology https://www.euramet.org/

17 International Organization of Legal Metrology (OIML) (2021). What is legal metrology? https://www.oiml.org/en/about/legal-metrology

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

Industrial Metrology



The function of industrial metrology is the application of measurements and proper calibration and control of measuring equipment in a manufacturing process. It is carried out against certified equipment, with a known valid relation to standards such as, a national reference standard. The purpose is to ensure that the products produced comply with required standards

THE ROLE OF A NATIONAL METROLOGY INSTITUTE (NMI)

An NMI is an organization designated by governmental decision to develop, maintain, and disseminate the national measurement system based on the SI. It represents the country internationally in relation to the NMIs of other countries, as well as in relation to the Regional Metrology Organizations (RMO) and to the BIPM. NMIs are the backbone of the international metrology system.

Some countries operate a centralized metrology organization with one NMI. In others, the NMI may outsource the maintenance of specific standards to other government agencies or a competent in-country laboratory without these having the status of a NMI. A third structure that some countries use is a decentralized organization

National Metrology Institutes

NIST - USA

INNOQ -Mozambique

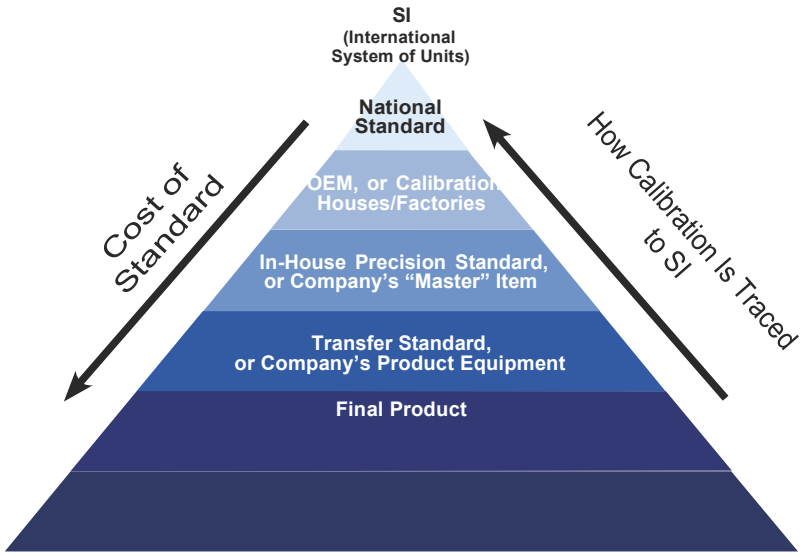
ANSA - Afghanistan

NPL –United Kingdom

NIMM –Myanmar

BSJ – Jamaica

Measurement Traceability



with a multiplicity of institutes, all having the status of an NMI. NMIs oversee the traceability of measurement, calibration, and measurement standards activities of a county.

Traceability of Measurement

Traceability ensures that a measurement result or the value of the standard is related to references through an unbroken chain of comparisons. A calibration laboratory "establishes traceability of its own measurement standards and instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement."[19]

Linking calibration to SI units is done through national measurement standards, which may be primary standards. SI units are primary standards when tethered too fundamental physical constants. All test equipment requiring calibration should undergo an initial calibration before being put into service.

Calibration

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

Measurement Standards

A measurement standard (etalon/artifact) is a material measure, measuring instrument, reference material, or measuring system intended to define, realize, conserve, or reproduce a unit or one or more values of a quantity to serve as a reference. NMI's are responsible for overseeing legislation relating to measurement and its application in everyday commerce.

Types of Measurement Standards

Within the field of metrology, experts rely on three main types of measurement standards. These include primary measurement standards, secondary measurement standards, and working measurement standards.

A primary measurement standard

Is based on physical constants. These are widely acknowledged as having the highest metrological quantities, and their value is accepted without reference to other standards of the same quantity.

A secondary measurement standard

is valued in comparison with a primary standard of the same quantity. That is, they are calibrated upon the primary standard.

A working measurement standard

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

[19] ISO Budgets blog (2016). Measurement Traceability: Complying with ISO 17025 Requirements. Retrieved from https://www.isobudgets.com/measurement-traceability-complying-iso-17025-requirements/

INTERNATIONAL METROLOGY ORGANIZATIONS

Bureau International des Poids et Mesures (BIPM)

www.bipm.org

The BIPM is an intergovernmental organization through Which Member States act together on matters related to measurement science and measurement standards. The goal of the BIPM is to ensure worldwide uniformity of measurements and their traceability to the International System of Units (SI). It does this with the authority of the Convention of the Metre, a diplomatic treaty between 51nations, and it operates through a series of committees whose members are the National Metrology Institutes of the Member States of the Convention.

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

- To coordinate the realization and improvement of the worldwide measurement system to ensure it delivers accurate and comparable measurement results.
- To undertake selected scientific and technical activities that are more efficiently carried out in its own laboratories on behalf of Member States.
- To promote the importance of metrology to science, industry, and society, in particular through collaboration with other intergovernmental organizations and international bodies and in international forums.[20]

International Organization of Legal Metrology (OIML)

www.oiml.org

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

REGIONAL METROLOGY ORGANIZATIONS

Intra-Africa Metrology System (AFRIMETS)

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

To harmonize metrology activities in Africa, AFRIMETS was established, based on the Regional Metrology Organization (RMO) of the Americas, SIM (Inter-American Metrology System). An assembly meeting was held in July 2007 at the premises of the New Partnership for Africa's Development (NEPAD), and an MOU was finalized and signed by five sub-regional metrology organizations (SRMOs)

- SADCMET, EAMET, CAMET (later changed to CEMACMET), SOAMET, and MAGMET - representing 42 countries in Southern, Eastern, Central, Western, and Northwestern Africa.

In addition, three countries have signed on as individual (Ordinary) members, and multiple other metrology organizations participate as[22] Associate or Observer members.

Inter-American Metrology System (SIM)

https://sim-metrologia.org/

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 sub-regions that corresponds to the five main economic and commercial groups in the region. These metrology groups are NORAMET (North America), CAMET (Central America),

[20] Retrieved from https://www.bipm.org/en/home
[21] Retrieved from https://www.oiml.org/en/
[22] Retrieved from http://www.afrimets.org/SitePages/Home.aspx

CARIMET (the Caribbean), ANDIMET (Andean Group), and SURAMET (South America).[23]

Euro-Asian Cooperation of National Metrological Institutions (COOMET) www.coomet.org

COOMET is the regional organization originally establishing cooperation of state metrology institutes of countries of Central and Eastern Europe. It was founded in June 1991, and renamed in "Euro-Asian Cooperation of State Metrology Institutions" in May 2000.
. The current 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.[24]

European Cooperation in Legal Metrology (WELMEC) www.welmec.org/

When WELMEC was founded in June 1990, the acronym 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.[25]

European Association of National Metrology Institutes (EURAMET) www.euramet.org

EURAMET is the Regional Metrology Organization for Europe. European metrology was coordinated successfully over almost 20 years by EURAMET as a collaboration based on a Memorandum of Understanding (MOU). 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 that could enter into contractual obligations on behalf of its Members, the European National Metrology Institutes (NMIs).

Gulf Metrology Association www.gulfmet.org

A regional metrological body (RMO) established under the umbrella of the Standardization Organization for the Cooperation Council for the Arabic States of the Gulf (GSO), brings together national metrology institutes (NMIs) in the State of U.A.E., Kingdom of Bahrain, Saudi Arabia, Sultanate of Oman, Qatar State and State of Kuwait.

Asia Pacific Metrology Program (APMP) http://www.apmpweb.org

APMP is primarily responsible for developing international recognition of the measurement capabilities of the region's 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.[27]

Asia-Pacific Legal Metrology Forum (APLMF) www.aplmf.org

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. APLMF was established in November 1994 with 14 member economies but now includes 21 Full members

[23] Retrieved from https://sim-metrologia.org/ [24] Retrieved from http://coomet.org/
[25] Retrieved from https://www.welmec.org/ [26] Retrieved from https://www.euramet.org/
[27] Retrieved from http://www.apmpweb.org/ [28] Retrieved from https://www.aplmf.org/

METROLOGY REFERENCES

RESOURCES

NCSL International (NCSLI) 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 hundreds of member organizations from academic, scientific, industrial, and commercial and government facilities around the world. The mission of NCSL International is to advance technical and managerial excellence in metrology, measurement standards, conformity assessment, instrument calibration, and test and measurement through voluntary activities aimed at improving product and service quality, productivity, and the competitiveness of its members in the international marketplace.

SIM Metrologia: Measurement Uncertainty
https://sim-metrologia.org/wp-content/uploads/2020/10/PossoloMeija2020-MeasurementUncertainty.pdf
A brief summary of the method of evaluating and for expressing uncertainty in measurement.

The International System of Units (BIPM) https://www.bipm.org/en/publications/si-brochure
A reference guide for the proper use of the SI system.

Metrologia www.bipm.org
An international journal published by BIPM dealing with scientific aspects of metrology.

A2LA/WorkPlace Training (computer-based, interactive metrology training)
http://www.A2LAWPT.org
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.

CALAB – The International Journal of Metrology
www.callabmag.com
This quarterly published magazine is a resource of current metrology information that contains technical articles, calendar of metrology events, industry and research news, and new products and services.

International Vocabulary of Metrology – Basic and General Concepts and Associated Terms
https://www.bipm.org/en/committees/jc/jcgm/publications
This document is a terminological dictionary containing designations and definitions from the field of metrology. It covers the basic principles governing quantities and units.

The International Vocabulary of Terms in Legal Metrology (VIML) viml.oiml.info
A set of terms and definitions published by OIML, intended for use by metrologists and other specialists involved in various activities related to legal metrology, from measurement and legal metrological control to legislation.

CONTINUE READING HANDBOOK ▸
NETROLOGY, STANDARDS, ACCREDITATION, & CONFORMITY ASSESSMENT:
TOOLS TO FACILITATE TRADE AND MARKET ACCESS

SECTION 5: ACCREDITATION & CONFORMITY ASSESSMENT ▸
ANNEX ▸
INTRO & GLOSSARY ▸
SECTION 1: AN OVERVIEW OF NQI ▸
SECTION 2: TECHNICAL BARRIERS TO TRADE ▸
SECTION 3: STANDARDS & TECHNICAL REGULATIONS ▸

SECTION 5

ACCREDTATION & CONFORMITY ASSESSMENT

What is Accreditation?

Accreditation is the independent evaluation of conformity assessment bodies against recognized standards to ensure their impartiality and competence to carry out specific activities, such as tests, calibrations, inspections and certifications. Through the application of national and international standards, the government, procurers and consumers can therefore have confidence in the calibration and test results, inspection reports, certifications and validation and verification statements provided.

What is conformity assessment?

Conformity assessment is the term given to techniques and activities that ensure a product, process, service, management system, person or organization fulfils specified requirements. The International Standard ISO/IEC 17000, *Conformity assessment—Vocabulary and general principles,* defines conformity assessment as the: "Demonstration that specified requirements relating- to a product, process, system, person, or body are fulfilled."

Standards and conformity assessment (CA) are intertwined. Each supports the other, influencing nearly every aspect of society. Whereas **standards** set important specifications for products, systems, and personnel, **conformity assessment** activities ensure those requirements are followed. Said another way, CA process, system, person, or organization are met.CA activities provide numerous benefits across society, which help to safeguard human health and safety as well as our environment. Additionally, CA supports consumer and business confidence while also creating more predictable international trade. Conformity assessment activities include sampling and testing, inspection, supplier's declaration of conformity, certification, and management system assessment. It also includes accreditation of the competence of those activities by a third party and recognition (usually by a government agency) of an accreditation program's capability.[1]

Conformity assessment can be voluntary or mandatory depending on the level of risk. When voluntary, it can provide useful information to a buyer and help substantiate advertising and labeling claims. When mandatory, it supports policy objectives, verifies compliance, and/or identifies needed corrective actions.

Conformity assessment has become increasingly relevant as nations seek to participate in the international trading system. When a country accepts products from a foreign market, for instance, the need to verify product claims, quality, and safety is paramount. To support effective product verification and testing, the World Trade Organization (WTO) outlines the foundational principles of CA to balance regulated public protection and support healthy competition.

1 American National Standards Institute (2011). United States Conformity Assessment Principles. Retrieved from https://share.ansi.org/shared%20documents/news%20and%20publications/brochures/uscap%202011.pdf

The benefits of conformity assessment activities are unlocked through cooperation among international conformity assessment bodies (CABs) and/or accreditation bodies (ABs). Referred to as mutual recognition, this process involves international trading partners agreeing to adhere to similar or equivalent CA procedures or to recognize each other's CA results. Mutual recognition helps avoid added time and monetary costs of duplicative testing. Together, CA and mutual recognition promote market access, support consumer confidence, and decrease barriers to trade.

THE PRINCIPAL COMPONENTS OF CONFORMITY ASSESSMENT

CA centers on the verification process, which is performed using various procedures. The most common components of CA include:

Certification

Certification is a third party, written assurance that a product, service, process, person, organization, or system conforms to specific requirements. Many certification variants exist. For example, product certification may consist of initial testing of a product combined with assessment of the supplier's quality management system. This may be followed by surveillance to further assess the supplier's quality management system, plus testing of samples from the factory and/or the open market.

Who can perform certification? There are a variety of certification bodies that perform quality services across the globe; however, the best method to ensure that certification is accurate and consistent is to work with accredited certification bodies. This process includes the verification, or accreditation,

of a certification body by a recognized accreditation body confirming that the certification body is qualified to perform internationally accepted certification. Another option for recognizing certification bodies is through bilateral trade agreements.

Testing

Testing is likely the most common form of CA.

Testing may be undertaken by a

While metrology is not generally considered a conformity assessment (CA) activity, CA relies on metrology to perform laboratory accreditation, testing, and product certification.

manufacturer, user, or CAB. It is often accompanied by certification, which allows the product or service to advertise its certified compliance with a specific technical standard. Testing itself can include a variety of verification practices including quantitative methods (measurement and calibration) as well as qualitative methods.

Inspection

Inspection bodies examine a wide range of products, materials, processes, work procedures, and services, in the public and private sectors. The goal of inspection is to reduce risks for the buyer, owner, user, or end consumer of the product or service being inspected.

General requirements for the operation of various types of inspection bodies is described in the International Standard ISO/ IEC 17020, *Requirements for the operation of various types of bodies performing inspection,* developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

Verifying Conformity

There are three internationally recognized and accepted methods for verifying conformity. These are referred to as first, second-, and third-party assessment or

verification. Typically, these are chosen based on the risk associated with the product or service (with the highest risk items requiring third party assessment).

- **First party/self-assessment (usually by the supplier) –** A supplier's declaration of conformity (sDoc) is widely used in commercial transactions. This document states a supplier's assurance that products or services meet relevant technical specifications. These can be used to increase brand reputation in competitive markets and can decrease testing burdens on local governments. A doc can put additional liabilities on the supplier if products are found not to meet declared specifications. Overall, sDoc is time and cost efficient, and does not require a producer to disclose proprietary or commercially sensitive information.
- **Second party assessment (usually by the buyer) –** Includes inspectors commissioned by customers to assess manufacturers' premises. This provides a detailed indication of a product being manufactured in accordance with specified requirements.
- **Third party assessment (usually by independent persons or bodies) –** Generally considered the strictest and most thorough approach to CA. Third parties may be involved at all stages of ensuring compliance, individually or combined, of the verification process.

WHO CHECKS THE CHECKERS?

Accreditation

The terms accreditation and certification are often confused, but these should not be used interchangeably. Accreditation is the formal recognition by a specialized body verifying the competence of a certification body to provide specified services. Certificates issued by accredited certification bodies may be perceived as having increased validity.

Accreditation is third party attestation related to a conformity assessment body (CAB), conveying formal demonstration of the CAB's competence to carry out specific conformity assessment activities.[2]

CABs may want to demonstrate reliability and distinguish themselves from competitors by having an impartial evaluation of their competence based upon internationally recognized criteria. This process of evaluation is called accreditation.

Accreditation confirms the quality and reliability of test data and provides assurance of the competence and independence of a CAB to carry out specific CA tasks. This process provides a framework to establish mutual recognition of CABs through internationally accepted principles. Mutually recognized CABs help minimize testing and certification duplication, reduce costs, decrease barriers to trade, and shorten delays to market access.

DEFINITIONS OF KEY CONFORMITY ASSESSMENT CONCEPTS

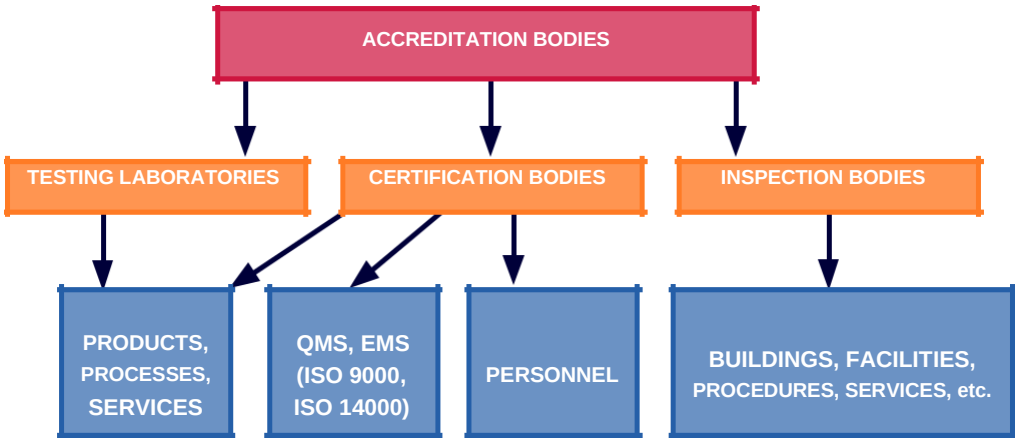
Accreditation: Formal evaluation and notice of a conformity assessment body's competence to carry out conformity assessment tasks, such as certification or testing

Certification: Third party, written assurance that a product, service, process, person, organization, or system meets specific requirements

First, Second-, and Third-Party Assessment: The three accepted methods for verifying conformity. First party assessment (also called self-assessment) is a supplier's own declaration of conformity. Second party assessment is evaluation by inspectors who have been commissioned by buyers. Third party assessment, considered the strictest, is evaluation conducted by independent bodies.

2 International Organization for Standardization (2021). Certification & Conformity. https://www.iso.org/conformity-assessment.html

Conformity Assessment Activities and Processes



Inspection: Examination of products, materials, processes, work procedures, and services to determine conformity to specific requirements.

Recognition: Formal evaluation and notice of an accreditation body's competence to carry out specific tasks, such as accreditation of testing laboratories and inspection, certification, and registration bodies.

Sampling: Evaluation and testing of a sample of a product to determine conformity to specific requirements.

Supplier's Declaration of Conformity (SDOC): Written assurance by a supplier that confirms conformity to specific requirements.

Testing: The use of a specified technical procedure (test method) to determine one or more characteristics of a product, material, procedure, or service.

CONFORMITY ASSESSMENT TOOLS TO SUPPORT PUBLIC POLICY

Conformity Assessment in Regulation

When using CA in regulation, a variety of interrelated considerations should be respected, and many can be applied more than once during regulatory development process. For example, risk management helps identify which products should be subject to CA or decide which techniques (audit, test, or inspection) should apply based on product risk. In regulation, government authorities ensure products and services meet national safety, health, and environmental requirements and provide assurances to prevent fraud or market manipulation. In the private sector, many production sectors have established CA systems and approval processes to enable comparability and ensure open competition.

A prerequisite for fair trade is that a product or service accepted in one market must be accepted (or treated equally) in other markets without additional restrictions or duplicative testing, inspection, and certification.[3] This principle is foundational to both ISO/IEC 17011, *Requirements for accreditation bodies accrediting conformity assessment bodies,* as well as the WTO GATT Article 3 provisions regarding national treatment.[4]

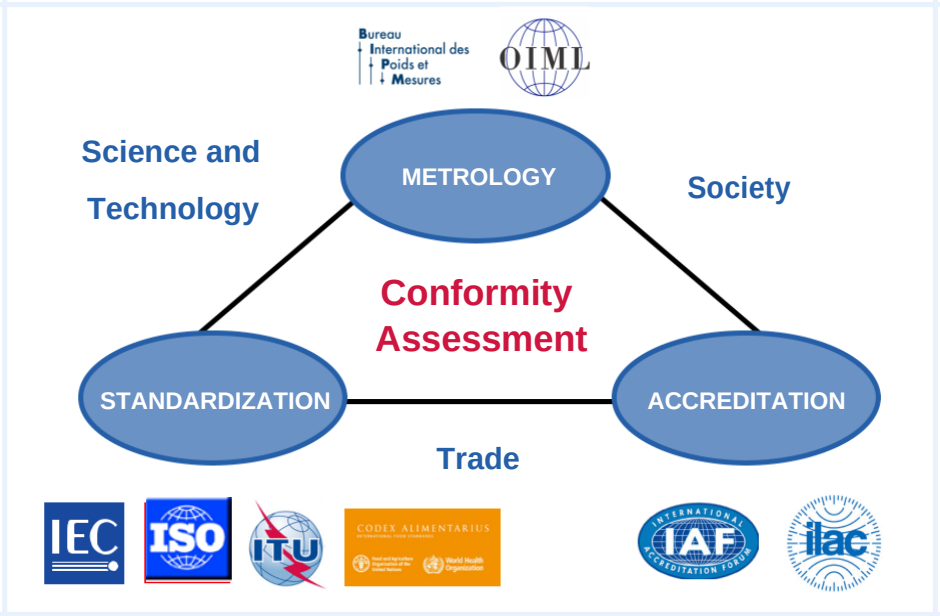
MARKS OF CONFORMITY

A mark of conformity is a symbol found on a product or information documents about a product, process, or service that indicates it has been verified by a certification body to comply with relevant standards or regulations. There are many different marks of

International Organization for Standardization (2004). ISO/IEC 17011:2004, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies. Retrieved from https://www.iso.org/standard/29332.html

3World Trade Organization (1994). The General Agreement on Tariffs and Trade (GATT 1947). Retrieved from https://www.wto.org/english/docs_e/legal_e/gatt47_01_e.htm

A Conformity Assessment Model



Conformity that corresponds to a product standard or technical regulation and demonstrates the marked product adheres to the relevant standard or technical regulation.

Marks of conformity play a major role in consumer safety and international trade. Before 1990, certification was fundamentally concerned with consumer safety of products; today, certification also addresses environmental practices and can evaluate processes and services in addition to products. Products and documents that display an authorized mark of conformity (also called a certification mark) indicate that they have met certain safety, health, or environmental standards. Officials and consumers consider marks of conformity a sign that a product is 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:

- Marks that identify or describe products, processes or services and their characteristics. These are not marks of conformity.
- Marks that indicate compliance with a specification, code of practice, management system or product or service standard. These marks of conformity are normally based on CA by an independent certification, accreditation, or inspection body, or placed on the product by the supplier through self-declaration of compliance. Some marks not based on CA 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 CA, such labeling is usually done without a formal, structured CA process and therefore are not considered marks of conformity.

Marks can convey important messages about a product or service, but are the messages understood by consumers? Common questions include:

- 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 the mark belong to the supplier or an independent CAB?

- 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?

While consumers may not fully understand the significance of every mark of conformity, the marks provide some information and/or a pathway to gain more information about the products they purchase.

Marks of Conformity: General Requirements

In order to obtain a conformity mark for a product, the manufacturer may be required to undergo a comprehensive product-testing program. Samples of the product are tested to nationally or internationally recognized standards and must be reasonably free from foreseeable risk of fire, electric shock, and related hazards. The certifying body may periodically, and without notice, visit each manufacturer's production facility to counter check that products continue to adhere to safety requirements. Even after the initial product evaluation, the certification body will continue to check samples of the product.

The Declaration of Conformity

A product conformity mark is not intended to include detailed technical information, but information must appear on a document called a declaration (certificate) of conformity that enables the inspector to trace the product back to the manufacturer or the authorized representative established in the exporting country. This is sometimes known as the manufacturer's declaration, and the manufacturer, authorized representative, or importer must be able to provide it at any time, along with the product's technical file.

Minimum Requirements for the Declaration of Conformity

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

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

QUALITY MANAGEMENT SYSTEM STANDARDS[5]

What Is a Management System?

A management system describes the set of procedures an organization needs to follow to meet its objectives. Some small organizations may use informal rather than official management systems; however, the larger the organization, the more likely that procedures need to be recorded to ensure roles are clearly defined. This process of systemizing how things are done is known as a management system.

Quality Management Principles -The Foundation for success

As the business world continues to navigate uncharted waters, companies, and organizations of every size face unprecedented pressure. To thrive, they must consistently deliver exceptional quality and customer experience. That means striking a delicate balance: delivering excellence alongside the pursuit of operational efficiency. To do this, they must be able to lean on a rock-solid foundation, with core principles for quality management built into their processes and culture at every level. These principles enable continual improvement for the benefit of the organization, its people, its stakeholders, and its customers.

International Organization for Standardization (2021). Certification & Conformity. https://www.iso.org/conformity-assessment.html

International Organization for Standardization (2021). Certification & Conformity. https://www.iso.org/conformity-assessment.html

Management System Certification Standards

An organization's management system can follow relevant standards. Assurance the organization adheres to management standards provide national and international stakeholders confidence that the organization's operations follow accepted practices.

SECTOR	STANDARD
General	ISO 9001:2015
Environmental	ISO 14000:2018
Food Safety	HACCP, ISO 22000:2018
Information Security	ISO/IEC 27001:2022
IT Service Management	ISO/IEC 2000-1:2018
Medical	ISO 13485:2016
Supply Chain Security	ISO 28000:2022
Petroleum & Gas	ISO 29001:2020
Energy	ISO 50001:2018

Certification to ISO 9001, *Quality management systems,* is likely the most well-known example of conformity assessment of management systems, as more than one million organizations in 170 counties have been certified to ISO 9001. This standard is a benchmark for quality systems and supports a framework to enhance and assure an organization's ability to satisfy quality requirements. Using quality management systems like ISO 9001 helps ensure customers get consistent, high-quality products and services. This process provides consumers with confidence and attracts business.[7]

It is important to note that ISO itself does not perform QMS certification, nor does it issue certificates of conformity to ISO 9001 or any other standard. Rather, independent, international certification bodies perform QMS certification.

In addition to quality management, many other branches of management are guided by standards. Additional examples include:

- API Specification Q2, *Quality Management for Service Supply Organizations for the Petroleum and Natural Gas Industry*
- AS9100, for the aerospace industry
- ASTM E1578 – 06, *Standard Guide for Laboratory Information Management Systems*
- IEEE 2030.11-2021, IEEE Guide for Distributed Energy Resources Management Systems
- ISO 50001, *Energy Management*
- ISO 22000, *Food Safety Management*
- ISO/IEC 27001, *Information Security Management*

INTERNATIONAL BEST PRACTICES – CONFORMITY ASSESSMENT

There are significant similarities in many national CA systems; however, no national approach to CA is considered agreement. Rather, best practices for CA are based on a common set of principles aimed at facilitating trade and supporting the health and safety of a nation's citizens, environmental protection, and good regulatory practice.

The following are basic international principles for CA:

- CA should safeguard public health, safety, and the environment.
- CA should be based on relevant international standards, agreements, and protocols, and should avoid undue national bias.
- CA should avoid creating unnecessary obstacles to trade by upholding the WTO TBT Agreement. See more on the TBT Agreement below.
- Information regarding CA requirements, accreditation procedures, and results should be made publicly available.
- CA procedures should be conducted with regard to confidentiality while ensuring full disclosure of CA results to regulatory authorities.

International Organization for Standardization (2021). ISO 9000 Family. https://www.iso.org/iso-9001-quality-management.html

- CA is generally voluntary, but certain local or market demands may necessitate CA requirements in regulation.
- CA should operate in an explicit, credible, and transparent manner and should be accessible, equitable, and provide fair treatment to all users.

The following are some of the most common conformity assessment elements used globally:

Using qualified inspectors, auditors, and assessors: Technical competence, qualifications, and integrity of inspectors, auditors, and assessors are major requirements of implementing a successful conformity assessment system. Most inspectors and auditors have special training, experience, and internationally recognized credentials. One example of an international certification body is the United Kingdom-based International Register of Certificated Auditors (IRCA). IRCA is the first and largest international certification body for auditors and inspectors and has certified more than 11,500 auditors/inspectors in over 105 countries.

WTO Compliance: Economies that have officially stated their intention to accede to the WTO, and those that have already completed the accession process, have had to develop, or revise laws governing mandatory inspection and certification to bring them into compliance with the WTO Technical Barriers to Trade (TBT) Agreement and the Sanitary and Phytosanitary Measures (SPS) Agreement. The relevant WTO agreements for CA include:

- WTO Agreement on Technical Barriers to Trade (TBT Agreement)
- WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement)
- WTO General Agreement on Trade in Services (Services Agreement)
- WTO Agreement on Preshipment Inspection (Pre-shipment Inspection Agreement)
- WTO Agreement on Trade Facilitation (Trade Facilitation Agreement)

Inspection and certification bodies use harmonized international standards, procedures, and guides: One commonly used standard for inspection bodies is ISO/ IEC 17020, Requirements 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 (ISO/IEC 17025, *General Requirements for the competence of Testing, and calibration laboratories)* is implemented. Many countries have formally adopted this standard as a national standard, including the U.S., Canada, Mexico, Laos, Myanmar, Vietnam, Egypt, the EU, and others.

Authoritative Agencies: The government agency responsible 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.

CONFORMITY ASSESSMENT AND THE WTO TBT PROVISIONS

The WTO TBT Agreement obligates members to avoid unnecessary obstacles to trade. This obligation also applies to CA procedures. For CA, barriers to trade may include overly strict or time-consuming procedures that do not serve a necessary function in the assessment of product compliance with the domestic

Adopting International Standards and Procedures: Whenever possible, international best practice is to consider adoption of existing international standards rather than developing new and potentially duplicative standards or procedures.

regulations (Articles 5.2.3 and 5.2.6).[8]

As for standards and technical regulations, the WTO TBT Agreement also provides clear guidance on internationally accepted, best practices for conformity assessment. The key provisions of these sections of the TBT Agreement are listed below.[9]

- CA 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 CA 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.
- CA procedures shall not be stricter or be applied more strictly than is necessary.
- CA procedures shall 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 apply to CA procedures. CA shall be applied to products from 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). Members are required to maintain confidentiality regarding CA results for imported products to ensure commercial interests are not infringed.
- Members shall ensure government bodies use relevant international guides or recommendations, or the relevant parts of them, as a basis for CA procedures. Exceptions can be made for issues of national security; 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; and fundamental technological or infrastructural problems.
- Members are required to actively participate, within the limits of their resources, in the preparation of guides and recommendations for CA procedures.
- When possible, Members must ensure results of CA procedures are accepted, even when those procedures differ from their own. The validity of CA results should be assessed based on whether results are satisfactory to confirm conformity to equivalent standards or technical regulations.

INTERNATIONAL RECOGNITION AND ACCEPTANCE OF CONFORMITY ASSESSMENT

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

8World Trade Organization (2021). Technical Information on Technical barriers to trade. Retrieved from https://www.wto.org/english/tratop_e/tbt_e/tbt_info_e.htm

9World Trade Organization (2021). Technical Information on Technical barriers to trade. Retrieved from https://www.wto.org/english/tratop_e/tbt_e/tbt_info_e.htm

why internationally traded goods and services are subject to repeated CA controls is a lack of confidence by users of CA in one country regarding the competence of bodies carrying out CA activities in other countries. Mutual recognition of accreditation and certification systems helps to mitigate excessively repeated CA procedures.

Mutual recognition of accreditation and certification systems facilitates access to international markets, providing the technical underpinning to international trade by promoting cross-border stakeholder confidence and acceptance of accredited test data and certified results.

"Certified Once, Accepted Everywhere"

The present international concept for accreditation 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). The International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) have begun the process of incorporating the Global Accreditation Cooperation (GLOBAC), a single international organization for accreditation. The target date for GLOBAC to become operational, taking over the roles of IAF and ILAC, is provisionally January 2026.

International Laboratory Accreditation Cooperation (ILAC)

ILAC is the international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration

A Roadmap to Mutual Recognition

Source: EN Industries LLC

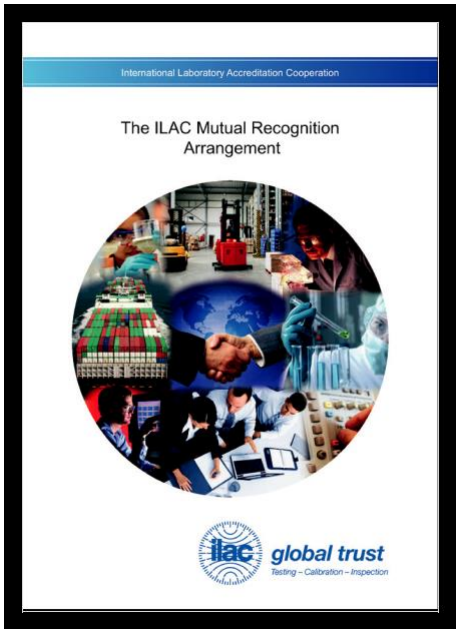
laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189), inspection bodies (using ISO/IEC 17020), proficiency testing providers (using ISO/IEC 17043) and reference material producers (using ISO 17034).

ILAC also manages international arrangements for calibration, testing, inspection, proficiency testing providers' accreditation, and in coordination with IAF in the fields of management systems, products, services, personnel, and other similar programs of CA.

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 and the Mutual Recognition Arrangement In 2000, the 36 full members of ILAC representing 28 economies signed the ILAC Mutual Recognition Arrangement (ILAC MRA) in Washington, DC, to promote mutual acceptance of technical test and calibration data. The ILAC MRA came into effect on January 31, 2001.



The ILAC MRA has been expanded three times since its establishment. These expansions added accreditation of inspection bodies (2012), accreditation of proficiency testing providers (2019), and accreditation of reference material producers (2020) to the ILAC MRA.

How does the ILAC Mutual Recognition Arrangement Work?[10]

According to the ILAC website, "[t]he ILAC MRA links the existing regional MRAs/MLAs of the Recognized Regional Cooperation Bodies. For the purposes of the ILAC MRA and based on ILAC's evaluation and recognition of the regional MRAs/MLAs, ILAC delegates authority to its Recognized Regional Cooperation Bodies for the evaluation, surveillance, re-evaluation, and associated decision making relating to the signatory status of the accreditation bodies that are ILAC Full Members (ILAC MRA signatories).

The accreditation bodies that are signatories to the ILAC MRA have been peer evaluated in accordance with the requirements of ISO/IEC 17011 to demonstrate their competence. A full list of accreditation bodies that have signed the ILAC MRA can be found on ILAC MRA Signatory Search.

Using the signatory search and the accredited facilities directories, regulators and consumers can locate laboratories, inspection bodies, proficiency testing providers or reference material producers that are accredited for the specific calibrations, tests, inspections, provision of proficiency testing programs or production of reference material required, as well as the contact details of these facilities, thereby ensuring the service and results will be accepted under the ILAC MRA.

10 ILAC (2021). ILAC MRA and Signatories. Retrieved from https://ilac.org/ilac-mra-and-signatories/

International Accreditation Forum (IAF)[11]

The IAF is an international association of CABs and bodies interested in CA. The forum supports the development of a single, international program for CA, thereby assuring accredited certificates to minimize business and consumer risk. The organization focuses on CA in the fields of management systems, products, services, personnel, and other similar programs.[12]

Practically, IAF functions in two main ways. First, it ensures its AB members only accredit competent bodies and are not subject to conflicts of interest. Second, it establishes MRAs, known as the IAF Multilateral Recognition Arrangements (MLA), between its members.

IAF Multilateral Recognition Arrangement The IAF Multilateral Recognition Arrangement (MLA) aims to ensure mutual recognition of accredited certification between signatories to the MLA and, subsequently, international acceptance of accredited certification based on one accreditation. Accreditations granted by IAF MLA signatories are recognized worldwide based on their equivalent accreditation programs, therefore reducing costs and adding value to business and consumers. IAF's goal and motto is, "Certified once, accepted everywhere."

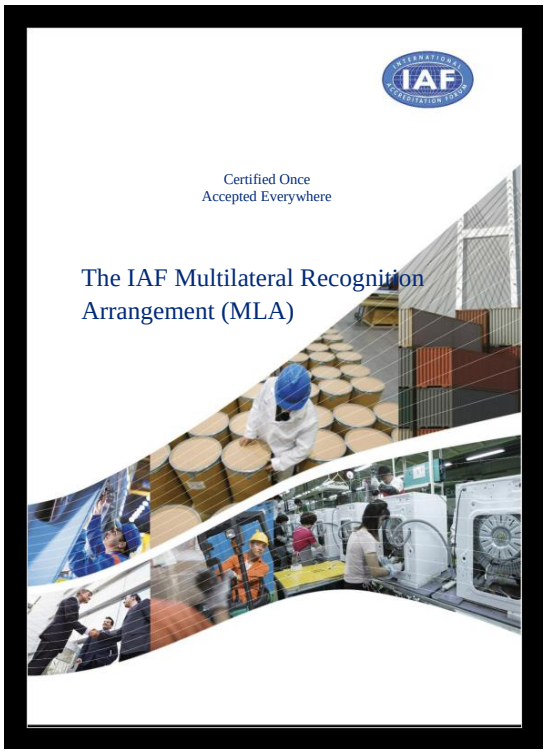
MLA Signatories

Following a stringent evaluation of AB operations by a peer evaluation team, IAF members are admitted to the MLA. The peer evaluation team is responsible for assessment of applicant member compliance with international standards and IAF guidelines.

Each IAF MLA signatory commits to:

- Maintain conformity with the current version of ISO/IEC 17011, Requirements for accreditation bodies accrediting conformity assessment bodies, and supplementary requirements documents.
- Recognize the competence and impartiality of accreditations of CABs by all other members of the MLA.

Six Regional Accreditation Groups (RAGs) have been granted special recognition to the MLA by the IAF: the European Co-operation for Accreditation (EA), the Inter-American Accreditation Cooperation (IAAC), and the Pacific Accreditation Cooperation (PAC). Membership to the IAF MLA is recognized as being satisfied by membership to any of the three RAG MLAs: EA MLA, IAAC MLA, and PAC MLA. IAF members who are signatories of RAG MLAs are automatically accepted into the IAF MLA.[13]



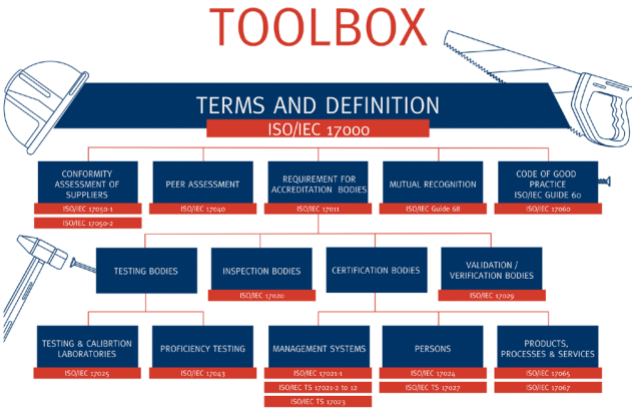
11 IAF (2021). International Accreditation Forum. Retrieved from https://www.iaf.nu/
12 IAF (2021). International Accreditation Forum. Retrieved from https://www.iaf.nu/
13 IAF (2021). The Evaluation Process. Retrieved from https://iaf.nu/en/evaluation-process/

ADDITIONAL RESOURCES

The ISO–CASCO Toolbox[14]

In the realm of conformity assessment, ISO plays an important international role through its Committee on Conformity Assessment, CASCO. This committee works to develop guides and international standards for CA as joint ISO/IEC publications.

CASCO is among the largest committees in ISO, with 107 participating members, 35 observing members, and 18 international organizations that serve as liaison members. Liaison members include Bureau International des Poids et Mesures (BIPM), IAF, International Federation of Standards Users (IFAN), International Federation of Inspection Agencies (IFIA), International Certification Network (IQNet), ILAC, International Personnel Certification Association (IPC), and the



Organisation Internationale de Métrologie Légale (OIML), among others. Perhaps the most well-known output of the ISO CASCO is the CASCO Toolbox. The Toolbox provides a series of tools (standards) for managing compliance and creating clear public policy to support market access and protect consumers.

Using the CASCO Toolbox Benefits Many Stakeholders

From ISO: "For regulators, it provides a tool for managing compliance and providing an objective and defensible means to implement public policy and enforce national health, safety and environmental legislation. The CASCO toolbox provides a means for organizations to take responsibility for their own *compliance and can reduce costs for governments when regulatory schemes utilize recognized private sector conformity assessment providers.

For manufacturers, wholesalers, retailers, and service providers, they can make sure that their products and services meet specified requirements and deliver on customer expectations. Assessing their products and services in accordance with the CASCO toolbox helps them to meet the current best practice and avoid the financial costs and reputational damage of product failure in the market, including subsequent activities such as product recalls, product returns and destruction of unsuitable product.

Consumers also derive benefit from the CASCO toolbox because it provides them with a basis for selecting products or services in the market, including matters such as quality, price, safety, reliability, compatibility, interoperability, efficiency, and effectiveness, and even the color of a product. Consumers may have more confidence in products or services that are supported by a formal mark or certificate of conformity that attests to quality, safety, or other desirable characteristics.

And finally, for traders, importers, and exporters the CASCO toolbox is the recognized International Standards and Guides for conformity assessment procedures under the World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT Agreement). Application of the CASCO toolbox can be a basis for mutually accepting trading partners' products and services and avoiding unnecessary barriers to trade."[15]

14 ISO (2021). CASCO – Conformity Assessment Tools to Support Public Policy. Retrieved from https://casco.iso.org/toolbox.html
15 ISO (2021). CASCO – Conformity Assessment Tools to Support Public Policy. Retrieved from https://casco.iso.org/toolbox.html

CONFORMITY ASSESSMENT REFERENCES

International Laboratory Accreditation Cooperation (ILAC)

www.ilac.org

The International Laboratory Accreditation Cooperation (ILAC) is an international cooperation of laboratory and inspection accreditation bodies. ILAC produces a series of publications, all of which can be viewed and downloaded via their website.

ILAC has created a series of promotional materials to support awareness and understanding of accreditation. They can be downloaded at ilac.org/publications-and-resources/ilac-promotional-brochures/. The series includes brochures on:

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

ILAC offers additional documents available for download at ilac.org/publications-and-resources.

International Accreditation Forum (IAF)

www.iaf.nu

The International Accreditation Forum, Inc. (IAF) is the world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of quality management systems, products, services, and personnel. IAF produces reference documents and guides that can be viewed and downloaded via their website.

The South African National Accreditation System (SANAS)

www.sanas.co.za

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

Southern African Development Community Accreditation (SADCA)

www.sadca.org

The Southern African Development Community Accreditation (SADCA), as a 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 called SADCAS.

African Accreditation Cooperation (AFRAC)

www.intra-afrac.com

The African Accreditation Cooperation (AFRAC) is a cooperation of accreditation bodies, sub-regional accreditation cooperations, and stakeholders whose objective is to facilitate trade and contribute to the protection of health, safety, and the environment in Africa and thereby improve Africa's competitiveness.

Asia Pacific Accreditation Cooperation (APAC)

www.apac-accreditation.org

The Asia Pacific Accreditation Cooperation (APAC) was created in 2019 by the amalgamation of two former regional accreditation cooperations -- the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the Pacific Accreditation Cooperation (PAC). APAC manages and expands MRAs among accreditation bodies in the Asia Pacific Region. Members include accreditation bodies, accreditation focal points, and other stakeholders interested in accredited conformity assessment results.

The Inter-American Accreditation Cooperation (IAAC)

www.iaac.org.mx

The Inter-American Accreditation Cooperation (IAAC) 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.

The European Co-operation for Accreditation (EA)

www.european-accreditation.org

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

The Arab Accreditation Cooperation (ARAC)

www.arabaccreditation.org

The Arab Accreditation Cooperation (ARAC) is one of the main pillars of the Pan Arab quality infrastructure established by the Ministerial Council Resolution of the Arab Industrial Development, Standardization and Mining Organization (AIDSMO) in June 2008. ARAC has been recognized at international level as an independent Regional Accreditation Group by IAF (International Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation.

United States Conformity Assessment Principles (USCAP)

www.ansi.org/uscap

The USCAP 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.

ISO Guide to Good Practice

www.iso.org/iso/casco_guide.pdf

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

ANNEX

STANDARDS, METROLOGY, & CONFORMITY ASSESSMENT:
TOOLS TO FACILITATE TRADE AND MARKET ACCESS

This annex contains additional information for added reference for Sections 2-5. Below is a summary of the additional information for each section.

- **Section 2: Technical Barriers to Trade** Additional information includes reference links for the WTO TBT and SPS Agreements.
- **Section 3: Standards and Technical Regulations** Additional information includes overview of key international and regional standards organizations, as well as links to news, publications, and other reference information.
- **Section 4: Metrology** Includes overview of international and regional metrology organizations and some supplementary information.
- **Section 5: Accreditation & Conformity Assessment** Includes overview of international and regional conformity assessment organizations and some supplementary information.

SECTION 2: TECHNICAL BARRIERS TO TRADE

Reference Links: Official TBT documents from the WTO (www.wto.org)

The Technical Barriers to Trade (TBT)

- **The TBT Agreement:** Main reference page.
- **Technical Barriers to Trade - Third Edition (PDF):** This document provides an overview of the purpose and scope of the WTO Agreement on Technical Barriers to Trade (TBT), the types of measures it covers, and the key principles of the Agreement. Prepared by the WTO Secretariat, this new edition in the "WTO Agreements" series aims at enhancing understanding of the TBT Agreement.
- **Facilitating trade through regulatory cooperation: The case of the WTO's TBT/SPS Agreements and Committees (PDF):** The WTO plays an important role in supporting efforts to facilitate trade through regulatory cooperation. This publication highlights how the WTO's Agreements on Technical Barriers to Trade (TBT) and on Sanitary and Phytosanitary Measures (SPS) and the work of their committees promote opportunities for regulatory cooperation among governments and ease trade frictions.
- **National enquiry points by country**
- **Submission of notifications:** The TBT Committee has adopted **Guidelines for Notification Procedures for Draft Technical Regulations and Conformity Assessment Procedures** as well as a **recommendation** (PDF) on when to use which notification format. Governments can submit notifications to the WTO Central Registry of Notifications through the online notification submission system or by email.

- **TBT Notification Submission System (TBT NSS):** For access, contact the TBT NSS team at **tbtnss@wto.org**.
- Notifications can be submitted by email as an alternative to the Central Registry of Notifications, at **crn@wto.org**. **Please visit the WTO website** for the format for submissions.
- **WTO ISO Standards Information Gateway:** Includes information on TBT, on notifications from standardizing bodies under the TBT Code of Good Practice **including all the standardizing bodies** that have accepted the TBT Code of Good Practice, and other reference documents and links.
- **TBT Official Documents:** Working documents of the TBT Committee
- **Electronic circulation of TBT Notifications:** Sign up to receive TBT notifications by e-mail.
- **Technical Assistance related to Technical Barriers to Trade:** Technical Assistance related to Technical Barriers to Trade is essential to the participation of developing and least developed countries in the multilateral trading system. It allows them to effectively implement as well as benefit from the TBT Agreement.
- **Principles for the Development of International Standards, Guides and Recommendations**

General documents of the TBT Agreement in relation to Technical Assistance

- **Transparency provisions of the TBT Agreement** (MS Word)
- **Databases on TBT-related technical assistance**
- **Technical cooperation programme of the TBT Committee**
- **WTO Events, Workshops, and Training on TBT**

Sanitary and Phytosanitary Measures (SPS)

- **Understanding the WTO Agreement on Sanitary and Phytosanitary Measures:** Introduction to SPS measures
- **How to apply the transparency provisions of the SPS Agreement** (PDF)
- **The full text of the SPS Agreement**
- **SPS Handbook Training Module**
- **Members' Transparency Toolkit on Work in SPS**
- **Operating the SPS notification authority**
- **A practical manual for SPS National Notification Authorities and SPS National Enquiry Points** (PDF)

SECTION 3: STANDARDS AND TECHNICAL REGULATIONS

International, Regional, and National Standards Organizations

A wide array of organizations participates in the coordination, harmonization, and development of international standards. This section provides a brief introduction to a few of the main players in this field.

International Standards Organizations – National Bodies Membership

The following are international standards organizations whose main members are official national standards bodies or organizations.

The International Organization for Standardization www.iso.org

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

Through its international membership, ISO coordinates standards development. To develop a standard, each ISO member elects to nominate technical experts to participate in a given technical committee, who will work to develop a draft standard(s) to meet a specified market need. Following initial development, draft standards are shared for a period of comment and discussion, which is preceded by a voting process which seeks to gain consensus. If consensus cannot be reached, the draft will be further amended before returning to the voting process. This process generally lasts three years from proposal to finalization of a new ISO standard.

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

The IEC is a global organization that prepares and publishes international standards for all electrical, electronic, and related technologies (over 10,000 standards). Similar to ISO, the IEC promotes international cooperation on all questions of electrotechnical standardization and related matters. IEC standards cover a vast range of technologies and include participation from 173 countries.

Members of the IEC are represented by technical experts who are nominated by and represent their respective national committee. Together, nearly 20,000 experts from industry, government, testing and research laboratories, academia, and consumer interest groups support the development of IEC standards.

IEC standards are developed over seven stages beginning with the preliminary stage, in which future projects are considered for development and working toward final approval (stage 6) and publication (stage 7). Between these stages, members assemble relevant technical committees (TC) to develop a working draft of newly proposed standards before sharing an approved draft with the full TC of observing (O) and participating (P) national committee members for comment and approval.

In the IEC, it is important to note the respective roles of P-members and O-members. These distinctions refer to member country status in a TC. P-Members can send national experts to participate in technical work in the development and approval of a standard, while O-members only retain observer status.

The International Telecommunications Union (ITU) www.itu.int

ITU is the leading United Nations (UN) agency for information and communication technologies. As a UN agency, it serves as the global focal point for governments and the private sector in helping the world communicate across its three, core sectors: radio communications, standardization, and development. Since its establishment in 1865, ITU has led contribution and consensus-based standards development or ITU-T Recommendations.

The ITU standards development process begins with membership as member organizations can submit information and communication technologies (ICT) issues that they have identified as in need of standardization. Following submission of an inquiry, a Study Group is assembled to assess and approve further development of a draft Recommendation (draft Rec) by a Working Party (WP). A mature draft Rec is forwarded to the Alternative Approval Process for review and consideration by members. At this stage, draft Recs enter a comment process before a final ITU-T Recommendation is approved.

Codex Alimentarius Commission www.fao.org/fao-who-codexalimentarius

Codex 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.

Regional Standards Bodies

African Organization for Standardization (ARSO) facilitates inter-African and global trade through harmonized standards and conformity assessment procedures.

In Africa, the increased reference to standardization in trade and economic policies and as a regulatory instrument and development tool is a clear indication of the future prospects of Africa's sustainable development, and the eminent role of ARSO and the Pan African Quality Infrastructure (PAQI) in general.

PAQI are the overarching quality institutes for the African continent. These institutes were developed as part of the African Union Commission to increase continental coordination in the

area of standards, conformity assessment, metrology, and accreditation. PAQI is comprised of four organizations: ARSO, the African Electrotechnical Standardisation Commission (AFSEC), the African Accreditation Cooperation (AFRAC), and the Intra-African Metrology System (AFRIMETS).

The **European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI)** are all officially recognized European Standards Organizations.

The formation of the single market in Europe 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 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, for example on safety, written in general terms that must be met before products may enter the market in the European Community. European harmonized standards provide 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 that 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. However, some Directives do not require CE Marking. These directives cover a very wide range of product areas (except food, which is covered in the old approach). Third party testing can be mandatory, but not always. Nonetheless, false claims of compliance face prosecution.

It is important to note that non-EU members that have significant trade with the region 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 technical regulations and standards and simplifies trade between the developing country and EU member states. CEN-CENELEC members are able to access the European standards.

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

Euro-Asian Interstate Council for Standardization, Metrology and Certification (EASC) of the Commonwealth of Independence States (CIS) is an intergovernmental body for formulation and implementation of coordinated policy for standardization, metrology, and certification. Members of the EASC are the national metrology and standards bodies of the former USSR. The Interstate Council was created in accordance with the "Agreement on realization of coherent policy in the field of standardization, metrology, and certification of the 13 of March 1992." The Agreement supports coordination in the field of national quality infrastructure (NQI) and provides a framework for standardization, metrology, certification, and accreditation in specified fields.

Pacific Area Standards Congress (PASC) was formed in 1972, when standards body representatives from Pacific Rim countries met in Honolulu, USA to create a program leading to the development of a voluntary, independent organization for the area national standards organizations. In 1973, the first meeting, which then assumed the name PASC, met again 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) 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.

CARICOM Regional Organization for Standards & Quality (CROSQ) was established in 2003 by a Caribbean Common Market (CARICOM) Community treaty as an Intergovernmental Organization and the regional center for promoting efficiency and competitive production in trade and services, through the process of standardization and the verification of quality. Located in Barbados, CROSQ is the successor to the Caribbean Common Market Standards Council and supports the CARICOM mandate for 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.

The **Pan-American Standards Commission (COPANT)** is a private, non-profit association that promotes standardization and related activities for member bodies of the Americas. The objective of COPANT is to promote the development of technical standardization and related activities in member countries with the aim of stimulating commercial, industrial, scientific and technological development. These objectives benefit the economic and commercial integration of the region, while facilitating cooperation in the intellectual, scientific, economic and social spheres.

News and Publications

- **ASTM Standardization News (sn.astm.org):** The official bimonthly covering ASTM's international standardization work, development of ASTM standards, professional perspectives, and the benefit of ASTM standards for governments, industries, consumers, and global trade.
- **Standards and Competitiveness—Coordinating for Results:** Removing Standards-Related Trade Barriers Through Effective Collaboration, produced by the U.S. Department of Commerce (DOC).
- **Codex Alimentarius Publications:** Codex Alimentarius is the preeminent international organization dealing with food safety and fair practices in the food trade. Its food standards, guidelines, and codes of practice contribute to international food trade safety, quality and fairness.
- **ISO Focus** and **ISO News:** ISO regularly publishes articles and special features on a wide array of international standardization topics.
- **National Standards Strategy for the United States:** The United States Standards Strategy (USSS) reaffirms the U.S. commitment to a sector-based approach to voluntary standardization activities, both domestically and globally. It established a standardization framework, built upon the traditional strengths of the U.S. system — consensus, openness, and transparency — while emphasizing speed, relevance, and meeting public interests and needs.
- **The Economic Value of Standardization**: This report examines the impact of standardization on the Canadian economy and was produced by the Standards Council of Canada (SCC). The study involved a review of the standards-oriented economics literature, an empirical analysis of their impact on Canadian labor productivity, a series of interviews, and two case studies.
- **The WTO eLearning Series:** Online courses on the founding of the WTO, its structure, and agreements.
- **ISO and Small & Medium Enterprises:** Information hub on how ISO International Standards can help businesses of any size and sector reduce costs, increase productivity and access new markets.

SECTION 4: METROLOGY

International Metrology Organizations

Bureau International des Poids et Mesures (BIPM) www.bipm.org

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

- Scientific discovery and innovation,
- Industrial manufacturing and international trade,
- Sustaining the quality of life and the global environment.
- The unique role of the BIPM is based on its international and impartial character enabling it:
- To coordinate the realization and improvement of the worldwide measurement system to ensure it delivers accurate and comparable measurement results.
- To undertake selected scientific and technical activities that are more efficiently carried out in its own laboratories on behalf of Member States.
- To promote the importance of metrology to science, industry and society, in particular through collaboration with other intergovernmental organizations and international bodies and in international forums.

International Organization of Legal Metrology (OIML) www.oiml.org

An intergovernmental treaty organization whose membership includes Member States and Corresponding Members (observer countries). The OIML was established in 1955 to promote global harmonization of legal metrology procedures.

NCSL International (NCSLI) ncsli.org

The world's premier technical organization dedicated to the fields of metrology and conformity assessment. NCSLI currently boasts over 700 member organizations. Its mission is to advance technical and managerial excellence in the fields of metrology, measurement standards, conformity assessment, and instrument calibration, as well as test and measurement.

Regional Metrology Organizations

Intra-Africa Metrology System (AFRIMETS) www.afrimets.org

Harmonizes metrology activities in Africa. AFRIMETS represents 37 countries in Southern, Eastern, Central, Western and Northwestern Africa. In addition, Nigeria and Cote d'Ivoire participate as individual (Ordinary) members.

Inter-American Metrology System (SIM) www.sim-metrologia.org

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 sub-regions that corresponds to the five main economic and commercial groups in the region: NORAMET (North America), CAMET (Central America), CARIMET (the Caribbean), ANDIMET (Andean Group), and SURAMET (South America).

Euro-Asian Cooperation of National Metrological Institutions (COOMET) www.coomet.org

Founded in 1991 as the regional organization for countries of Central and Eastern Europe and renamed "Euro-Asian cooperation of state metrology institutions" in May 2000. COOMET members include 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.[1]

European Cooperation in Legal Metrology (WELMEC) www.welmec.org

WELMEC was founded in June 1990 for the countries of Western Europe. Today, WELMEC extends beyond Western Europe and includes representatives from Central and Eastern Europe. Its aim is to establish a harmonized and consistent approach to European legal metrology.

European Association of National Metrology Institutes www.euramet.org

The Regional Metrology Organization (RMO) for Europe. Its members are the European NMIs.

Euro-Asian Cooperation of National Metrological Institutions www.coomet.net

COOMET is a joint forum of metrologists of Euro-Asian region, steadily and effectively working regional metrology organization which successfully fulfils its tasks. Cooperation within COOMET and its results allow its Member Countries to successfully solve metrological issues, which national economies face under the conditions of market globalization.

Gulf Metrology Society www.gulfmet.org

GULFMET is a Regional Metrology Organization (RMO) established under the auspices of GCC Standardization Organization (GSO), bringing together National Metrology Institutes (NMIs) of the United Arab Emirates, Kingdom of Bahrain, Kingdom of Saudi Arabia, Sultanate of Oman, State of Qatar, State of Kuwait and the Republic of Yemen

The Asia Pacific Metrology Programme (APMP) www.apmpweb.org

Primarily responsible for developing international recognition of the measurement capabilities of the region's national and territorial measurement laboratories in the Asia-Pacific. It is the oldest continually operating metrological grouping in the world.

The Asia-Pacific Legal Metrology Forum (APLMF) www.aplmf.org

A grouping of legal metrology authorities representing 20 economies from the Asia-Pacific Economic Cooperation (APEC) and across the Pacific Rim. The group aims to coordinate on the development of legal metrology and to promote free trade in the Asian Pacific region by removing technical or administrative barriers in the field of metrology.[2]

1 Euro-Asian Cooperation of National Metrological Institutions (2021). COOMET. Retrieved from http://www.coomet.org/
2 Asia-Pacific Legal Metrology Forum (2021). APLMF. Retrieved from https://www.aplmf.org/

Supplemental Resources

NCSL International: Metrologist quarterly magazine www.ncsli.org

The NCSL International's publication focusing on people, networking, and members. It includes sections on Learning and Development, an Educator's Corner, Education Outreach, Scholarship Promotion, Lab Tours, Accreditation, and Publication Reviews and Summaries.

A2LA/WorkPlace Training (computer-based, interactive metrology training)

www.A2LAWPT.org

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.

CALAB – The International Journal of Metrology www.callabmag.com

This quarterly published magazine is a resource of current metrology information that contains technical articles, calendar of metrology events, industry and research news, and new products and services.

International Vocabulary of Metrology – Basic and General Concepts and Associated Terms

www.bipm.org/en/committees/jc/jcgm/publications

This document is a terminological dictionary containing designations and definitions from the field of metrology. It covers the basic principles governing quantities and units.

The International Vocabulary of Terms in Legal Metrology (VIML)

viml.oiml.info/en/index.html

Jointly prepared by seven international organizations (BIPM, the International Electrotechnical Commission [IEC], the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), ISO, the International Union of Pure and Applied Chemistry (IUPAC), the International Union of Pure and Applied Physics (IUPAP) and OIML). This document identifies general concepts in metrology that form the basic terminology common to various technical disciplines.

SECTION 5: ACCREDITATION & CONFORMITY ASSESSMENT

International Accreditation & Conformity Assessment Organizations

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

The International Laboratory Accreditation Cooperation (ILAC) is an international cooperation of laboratory and inspection accreditation bodies. ILAC produces a series of publications, all of which can be viewed and downloaded via their website.

International Accreditation Forum (IAF) www.iaf.nu

The International Accreditation Forum, Inc. (IAF) is the world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of quality management systems, products, services, and personnel. IAF produces reference documents and guides that can be viewed and downloaded via their website. Listed below is a sample of the publications that are available.

Regional Accreditation & Conformity Assessment Organizations

The South African National Accreditation System (SANAS) www.sanas.co.za

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

Southern African Development Community Accreditation (SADCA) www.sadca.org

The Southern African Development Community Accreditation (SADCA), as a 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 called SADCAS.

African Accreditation Cooperation (AFRAC) www.intra-afrac.com

The African Accreditation Cooperation (AFRAC) is a cooperation of accreditation bodies, sub-regional accreditation cooperations, and stakeholders whose objective is to facilitate trade and contribute to the protection of health, safety, and the environment in Africa and thereby improve Africa's competitiveness.

Asia Pacific Accreditation Cooperation (APAC) www.apac-accreditation.org

The Asia Pacific Accreditation Cooperation (APAC) was created in 2019 by the amalgamation of two former regional accreditation cooperations – the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the Pacific Accreditation Cooperation (PAC). APAC manages and expands MRAs among accreditation bodies in the Asia Pacific Region. Members include accreditation bodies, accreditation focal points, and other stakeholders interested in accredited conformity assessment results.

The Inter-American Accreditation Cooperation (IAAC) www.iaac.org.mx

The Inter-American Accreditation Cooperation (IAAC) 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.

The European Co-operation for Accreditation (EA) www.european-accreditation.org

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

Supplemental Resources

U.S. Conformity Assessment System: Introduction The USCAP 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.

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

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

ILAC Reference Documents and Guides ILAC has created a series of promotional materials to support awareness and understanding of accreditation. This link includes additional publications and resources for download.

CONTINUE READING HANDBOOK ▸
METROLOGY, STANDRDS, ACCREDITATION & CONFORMITY ASSESSMENT: TOOLS TO FACILITATE TRADE AND MARKET ACCESS

INTRO & GLOSSARY ▸
SECTION 1: AN OVERVIEW OF NQI ▸
SECTION 2: TECHNICAL BARRIERS TO TRADE ▸
SECTION 3: STANDARDS & TECHNICAL REGULATIONS ▸
SECTION 4: METROLOGY ▸
SECTION 5: ACCREDITATION & CONFORMITY ASSESSMENT ▸

SUMMARY

Developing countries and economies in transition; today it is virtually impossible to underestimate the importance of metrology, accreditation, standards, certification, and quality (NQI) in the development of economic policies. Understanding the link between global trade, NQI and export competitiveness is at the forefront of trade policy. The removal of non-tariff barriers to trade and implementing a NQI system that is World Trade Organization (WTO) compliant and recognized internationally has become a central political task for many developing and transitional economies. Countries must have an adequate National Quality Infrastructure in place.