

## STANDARDS, METROLOGY, & CONFORMITY ASSESSMENT:

TOOLS TO FACILITATE TRADE
AND MARKET ACCESS

An Interactive Reference Handbook

2022 Edition

INTRODUCTION

PREPARED BY THE STANDARDS ALLIANCE, A PARTNERSHIP BETWEEN THE U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID) & THE AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)





# THE STANDARDS ALLIANCE ORGANIZATIONAL BACKGROUND

The Standards Alliance is a public-private partnership between the American National Standards Institute (ANSI) and the U.S. Agency for International Development (USAID). The Alliance was announced in November 2012 as a funding facility designed to provide capacity-building assistance to developing countries, specifically related to implementation of the international best practices related to National Quality Infrastructure (NQI).



The Standards Alliance has generated lasting outcomes by uniting U.S. public and private sector partners with developing nations to enhance standards-related policy worldwide. Since its inception, the program has expanded to support a growing array of countries, sectors, and initiatives. Standards Alliance technical assistance focuses on building partner countries' NQI and supporting international best practices for standards and regulatory development. These efforts promote economic development and international market access.

The Standards Alliance seeks to increase the development and understanding of international best practices to improve NQI. This includes strengthening stakeholder engagement, enhancing intergovernmental coordination, encouraging transparency, and supporting international harmonization of best practices for regulatory development and standards preparation, adoption, and application.

A key goal of the Standards Alliance is to increase developing countries' capacity to implement accepted international best practices, thereby reducing the amount of unsafe or low-quality products, services, and infrastructure. Ultimately, better adoption and implementation of international standards will improve the quality and safety of goods on a global scale. The expansion of the program also seeks to forge new avenues for bilateral partnership and pursues inclusive approaches to support gender balance and responsiveness, especially in fields related to science, technology, and innovation.

This handbook is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of the American National Standards Institute (ANSI) and EN Industries LLC and do not necessarily reflect the views of USAID or the United States Government.

#### **ACKNOWLEDGEMENTS**



Since participating as an invited speaker at the first WTO Technical Barriers to Trade committee meeting in 1995, and then moving on to work on USAID, World Bank, and the Asian Development Bank projects in 34 countries, Hearned 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's the WTO? 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 this handbook. Over the years that followed, I created various versions that have been published in cooperation with USAID and the National Standards and Metrology Institutes of Afghanistan, Laos, Myanmar, and Mozambique. Versions have been published in English, Dari, Vietnamese, and Portuguese.

#### **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, 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 U.S. International Trade Commission (USITC), 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.

#### **TECHNICAL REVIEW**

Standards Alliance thanks the following individuals who provided direction, guidance, and technical support in the development of the original and current version of the handbook; their contribution is noted with thanks and appreciation: Dr. Seton Bennett, Deputy Director, National Physical Laboratory - UK; Dr. B. 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, External Relations, ASTM International - USA; John Owen, Secretary, IAF - Australia; Dr. R. Pettit, Editor, NCSLI Measure; Sandia National Laboratories (retired) – USA; Dianna Rodrigues, Director, Antigua & Barbuda Bureau of Standards; Past President SIM - Antigua; Peter Unger, President, A2LA; Past Chair, ILAC - USA; Dr. Svetlana Zhanaidarova, 1st Secretary, Central Asian Cooperation for NQI - Kazakhstan.

- Edward Nemeroff, EN Industries LLC, ednemeroff@cs.com

## 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 procedures, 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, and Conformity Assessment contain an introduction to the major regional and international technical organizations that support a National Quality Infrastructure. Hyperlinks are available to take the reader directly to the organization's website. 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

Introduction and 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 WTO 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: Conformity Assessment >

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

#### **ANNEX** ▶

Additional resource links.

## GLOSSARY OF ACRONYMS

AB	Accreditation Body
ANSI	American National Standards Institute
APEC	Asia-Pacific Economic Cooperation
APLAC	Asia Pacific Laboratory 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
ВІРМ	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
ССРМ	Conference Generale des et Poids (General Conference on Weights and Measures)
CODEX	Codex Alimentarius Commission
COOMET	Euro-Asian Cooperation of National Metrological Institutions
CRM	Certified Reference Material
DEVCO	ISO's Committee on Developing Country Matters
EA	European Co-operation for Accreditation
EASC	Euro-Asian Interstate Council for Standardization, Metrology and Certification
EC	European Commission
EMS	Environmental Management System
EOQ	European Organization for Quality
EOTC	European Organization for Conformity Assessment
ETSI	European Telecommunications Standards Institute
EU	European Union
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 IAAC Inter-American Accreditation Cooperation IAF International Electrotechnical Commission ILAC 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 MLA Multilateral Arrangement MRA Mutual Recognition Arrangement MRA Mutual Recognition Arrangement MSTQ Metrology, Standards, Testing and Quality NACLA National Cooperation for Laboratory Accreditation NAFTA North American Free Trade Agreement NATA 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 Valuntary Laboratory Accreditation Program OIML Organisation Internationale de Métrologie Légale (International Organization of Legal Metrology) PAC Pacific Accreditation Cooperation QMS Quality Management System RMO Regional Metrology Organization		
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RMO Regional Metrology Organization	PAC	Pacific Accreditation Cooperation
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	RMO	Regional Metrology Organization
SADCA Southern African Development Community Cooperation in Accreditation	SADCA	Southern African Development Community Cooperation in Accreditation
SADCMEL Southern African Development Community Cooperation in Legal Metrology	SADCMEL	Southern African Development Community Cooperation in Legal Metrology
SADCMET Southern African Development Community Cooperation in Measurement Traceability	SADCMET	

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 Indépendants (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
WEMC	Western European Metrology Club
WSSN	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 on 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. <sup>1</sup>
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." <sup>2</sup>
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 characteristics, production methods, and administrative provisions.

<sup>&</sup>lt;sup>1</sup> 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.

<sup>2</sup> World Trade Organization. Technical Barriers to Trade. Retrieved from <a href="https://www.wto.org/english/tratop\_e/tbt\_e/tbt\_e.htm">https://www.wto.org/english/tratop\_e/tbt\_e/tbt\_e.htm</a>