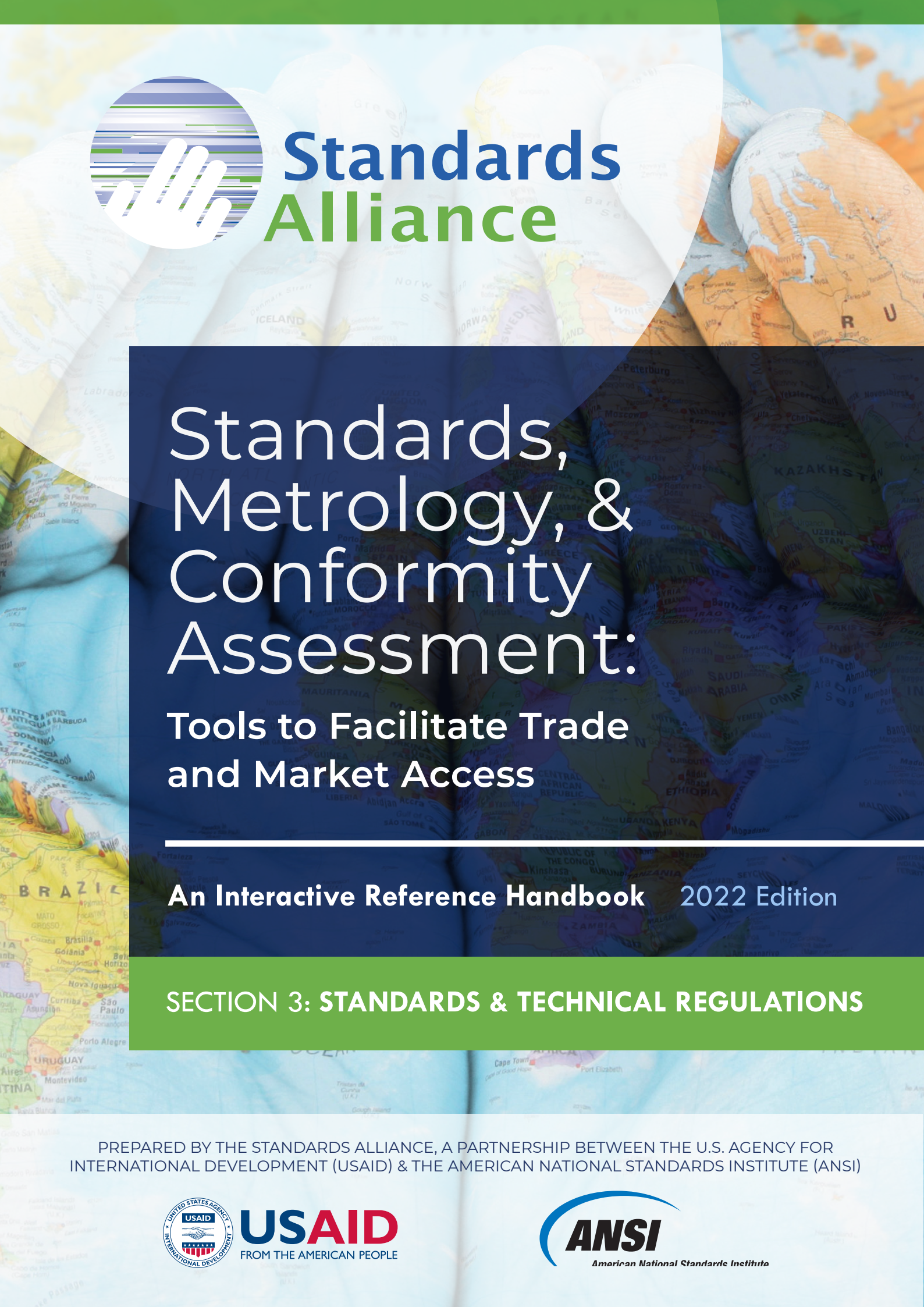

Standards Alliance

# Standards, Metrology, & Conformity Assessment:

## Tools to Facilitate Trade and Market Access

**An Interactive Reference Handbook** 2022 Edition

SECTION 3: **STANDARDS & TECHNICAL REGULATIONS**

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

USAID FROM THE AMERICAN PEOPLE

ANSI American National Standards Institute


# 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.

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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 APPROACHES 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**

[2] 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. 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.

**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

### 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 comply with regulations

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

develops Web standards, primarily protocols, and guidelines that ensure long-term growth for the Web. Participants include member organizations, full-time staff, and interested participants from the general 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 TO 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).

### 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

### The Increasing Importance of Gender-Responsive Standards

A key component of balanced participation in the development of international standards is ensuring involvement of a wide array of stakeholders. This includes stakeholders from various backgrounds, perspectives, and genders. The importance of gender in standardization is increasingly recognized globally, particularly as it impacts economic development. The increased emphasize on gender has resulted in various initiatives, such as the Gender Responsive Standards Initiative, that aims to strengthen the use of technical regulations and standards as tools to attain gender equality. A key development in gender responsive standards was the drafting of the Declaration for Gender Responsive Standards and Standards Development, which offers a framework for standards bodies seeking to ensure their standards development processes are responsive to gender components.[6]

This international focus is reflected in the current work of the Standards Alliance, where equal gender representation and responsiveness are seen as key indicators of programmatic success.

[5] ISO (2021). ISO and Small & Medium Enterprises. https://www.iso.org/iso-and-smes.html
[6] Gender Responsive Standards Initiative (2021). Retrieved from https://unece.org/gender-responsive-standards-initiative

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, a partnership between USAID and ANSI, 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.

## INTERNATIONAL BEST PRACTICE: WTO TBT AGREEMENT[7]

### Key Concepts of the International System

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 are 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

### 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 | VS. | TECHNICAL REGULATIONS |
|---|---|---|
| ■ Are **voluntary** in nature | | ■ Are **mandatory** and form part of legislation. |
| ■ Can be developed by a **variety of bodies** in the public or private sector. | | ■ Are the responsibilities of the **government**. |
| ■ Contain **only product characteristics** or **technical requirements**. | | ■ They address:<br>• **product characteristics** and<br>• **administrative procedures** |
| ■ Are developed in a stakeholder inclusive **consensus process**. | | |

[7] World 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

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, the majority of standards are voluntary (>90%).

Open and inclusive development of voluntary standards that emphasize private sector involvement and transparency of development spurs innovation, ensures rapid response to market and consumer demands, and is less disruptive to local and global markets.

## 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.

The TBT Agreement establishes the procedures for the preparation, adoption, publication, and application of technical regulations by central government bodies


WTO's ePing online tracking system

(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).

## 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

[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

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.

## 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 to protect public safety. Examples include chemical detection levels and cybersecurity.

## 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.

**International standards** are developed and promulgated by organizations that comply with the WTO/TBT principles for the development of international standards.

**Harmonized standards** can be either an attempt by a country to make its standard compatible with an international, regional, or other standard or it can be an agreement by two or more nations on the content and application of a standard, the latter of which tends to be mandatory.

**Industry standards** are developed and promulgated by an industry for materials and products related to that industry.

**Government standards** are developed and promulgated by federal, state, and local agencies to address needs or applications peculiar to their missions and functions. 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) typically functions as a national clearinghouse for standards and oversees standards development. In many countries this organization will also engage in 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

[13] The TBT agreement encourages to write technical regulations and standards in terms of performance, rather than design characteristics.

publicly available. Codex standards, for example, can be downloaded at no cost from their 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 enquires, 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 sssociations** 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 of Commerce brings together 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

### 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 (ISO)

www.iso.org

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

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 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 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.

### 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 Standardisation 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)

http://www.cencenelec.eu/

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 Ordanizations (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 centres, 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

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.

## 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.

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

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