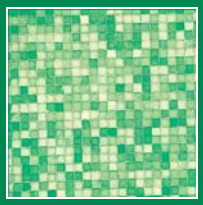
OVERVIEW OF THE U.S. STANDARDIZATION SYSTEM

Voluntary Consensus Standards and Conformity Assessment Activities

Third Edition | 2010 Published by the American National Standards Institute



Published and printed in the
United States of America

Third Edition — 2010
American National Standards Institute

OVERVIEW OF THE U.S. STANDARDIZATION SYSTEM

Voluntary Consensus Standards and Conformity Assessment Activities

BACKGROUND

Standardization encompasses a broad range of considerations — from the actual development of a standard to its promulgation, acceptance, implementation, and demonstration of compliance. As a primary facilitator of commerce, standards and conformity assessment programs have become the basis of a sound national economy and the key to global market access.

Voluntary consensus standards serve as the cornerstone of the U.S. standardization system. These documents arise from an open process that depends upon data gathering, a vigorous discussion of all viewpoints, and agreement among a diverse range of stakeholders. Thousands of individual experts representing the viewpoints of industry, consumer and labor organizations, and government agencies[1] come together to contribute their knowledge, talents, and efforts to standard-setting activities.

Voluntary refers only to the manner in which the document was developed; it does not necessarily refer to whether compliance to the standard is optional or whether a government entity or market sector has endorsed the document for mandatory use.

1. Unless a more specific indication is included in future references, "government" should be read as "government at all levels and all jurisdictions, whether federal, state, or local."

A REFLECTION OF AMERICAN VALUES

Firmly rooted in American history and experience, the U.S. standardization infrastructure is reliable, flexible, and responsive. It reflects a basic national belief that society will benefit and innovation and creativity will flourish in a system that is free from government control but strengthened through essential governmental participation via effective public-private partnerships.

It is a *decentralized* system that is naturally partitioned into industrial sectors and supported by independent, private sector standards developing organizations (SDOs) and conformity assessment bodies. It is a *demand-driven* system in which standards are created in response to specific concerns and needs expressed by industry, government, and consumers. And it is a *voluntary* system in which both standards development and compliance are driven by stakeholder needs. One of its hallmarks is a direct linkage to the ever-evolving marketplace.

Standards stimulate the innovation of products, services, and systems — just as innovation stimulates standardization. In some cases, a standard fosters innovation by establishing a baseline for design and performance that will satisfy user requirements. Standards should provide enough flexibility that suppliers or manufacturers can vary features, function, or price to establish their own niche in the marketplace. These variances can help to elevate user expectations of a product or service, thus raising the bar for future editions of the applicable standard. In other cases, innovation comes first. A single set of performance or design criteria are agreed upon and serve as the baseline for ongoing improvements. A standard becomes the physical documentation of an agreed-upon solution that has already been time-tested and proven.

STRENGTH THROUGH DIVERSITY

By the 20th century, the need for coordination among U.S. standards-setting groups became evident. In October 1918, three government agencies and five private sector organizations[2] joined together to form a coordination body known as the American Engineering Standards Committee, the predecessor of what is now known as the American National Standards Institute (ANSI).

Since its formation, ANSI has held the unique responsibility of bringing together and coordinating the standardization efforts of diverse interests and standards development organizations. The Institute has helped to forge the robust working partnership that now exists among all private and public sector stakeholders. This relationship has led to the development of thousands of voluntary consensus standards for the United States, the effective representation of U.S. needs and viewpoints in regional and international standards-setting activities, and the minimization or elimination of overlap and duplication in standards-setting activities.

Today, the U.S. standardization community is comprised largely of non-governmental SDOs and consortia, groups that are primarily supported by industry participation. In the global marketplace, buyers, suppliers, and regulators are turning increasingly to voluntary consensus standards and conformity assessment programs as a means of building confidence in their products and services. The U.S. recognizes that many international standards bodies coexist to develop standards for global use and that no single method of standards development can satisfy the needs of all sectors.

U.S. government and private-sector stakeholders currently participate in a wide range of standards activities, both domestically and abroad: through treaty organizations where governments are members; through non-treaty organizations where private-sector entities are members; through professional and technical organizations whose membership is on an individual or organizational basis; and through consortia and other fora.

Scientific and professional societies like ASME, the Acoustical Society of America (ASA), and the American Society of Safety Engineers (ASSE) are involved in standards development activities that further the work of their organizations and the professions that they support. Trade associations, on the other hand, deal with a particular industry and promote its products or services. Some associations, such as the Aerospace Industries Association (AIA) and the Telecommunications Industry Association (TIA), develop standards for the products manufactured by their members, while others might focus on developing standards for products used by their industries.

2. The American Institute of Electrical Engineers (now IEEE), the American Society of Mechanical Engineers (ASME), the American Society of Civil Engineers (ASCE), the American Institute of Mining and Metallurgical Engineers (AIMME), the American Society for Testing Materials (now ASTM International), the U.S. Departments of War and the Navy (now Defense), and the U.S. Department of Commerce.

Organizations such as IEEE and the American Society for Quality (ASQ) develop standards that cut across many industries. Large umbrella groups such as ASTM International recognize standardization as their primary focus; yet other organizations, such as Underwriters Laboratories (UL), develop standards as a logical complement to their testing and certification activities.

Consortia, usually a group of companies working together to solve a specific market need, also develop standards. Often seen in areas of rapidly developing technologies, consortia standards offer many solutions and may be developed under an accelerated timeframe, but participation in the development process may be limited to members of the consortia and tied to a substantial financial contribution.

De facto standards are developed outside the traditional framework and appeal to a more narrow market than standards written by voluntary consensus standards-focused organizations. These standards do not feature the broad and open participation, due process or consensus-based approval often sought by users such as regulators and procurement agents.

The costs of developing and implementing most types of voluntary standards are typically borne by those who will derive benefit from the document. Certain expenses are assumed by the entity responsible for facilitating the standard's development; others by the subject matter experts and organizations that participate in its creation. The end user bears the cost of purchase, if applicable, and may assume responsibility for implementation expenditures. The equitable distribution of expenses incurred during the standardization life cycle helps to mitigate the risk that any single group will attempt to exercise undue influence because it has taken on an inordinate share of the expenses.

HARMONIZING U.S. GOVERNMENT AND PRIVATE-SECTOR STANDARDIZATION ACTIVITIES

Many other countries adhere to a "top-down" approach to standardization where the government serves as the standards setter or mandates what standards will be developed. The U.S. favors a decentralized approach, meaning no central government

agency is responsible for oversight of the entire system. Decisions about which standards are most appropriate for U.S. government use are left to the discretion of individual agencies. Since the mid-1990s, voluntary consensus standards have been increasingly referenced by U.S. agencies and regulatory bodies.

In 1995, Congress stepped forward with the enactment of the *National Technology Transfer and Advancement Act* (NTTAA – Public Law 104-113), which assigned the responsibility for coordinating standards policy among federal agencies to the National Institute of Standards and Technology (NIST), a non-regulatory federal agency within the U.S. Department of Commerce. As NIST is also the federal agency responsible for measurement standards (weights and measures) in the United States, it works in close collaboration with ANSI.

There is also strong coordination of standards policy. Government bodies such as the U.S. Department of Commerce and its agencies, including NIST and the International Trade Administration (ITA); the U.S. Department of State; the U.S. Department of Defense; the U.S. Department of Energy; the Environmental Protection Agency; the Office of the U.S. Trade Representative (USTR), and regulatory agencies throughout the federal system work closely with each other, with ANSI, and with others in the private sector on issues affecting U.S. competitiveness in the global marketplace.

The U.S. public and private sectors joined together under ANSI auspices to publish the first-ever *National Standards Strategy* for the United States in 2000, which reaffirmed reliance upon the basic structure of the U.S. system and made recommendations for its improvement. A second edition, now known as the *United States Standards Strategy*, was published in 2005. These documents reaffirmed the basic structure and market-driven approach of the U.S. standardization community.

The *Strategy* also confirms the U.S. commitment to internationally accepted principles of standardization endorsed by the World Trade Organization (WTO) — transparency, openness, impartiality, effectiveness and relevance, consensus, performance-based, coherence, due process, and technical assistance. As a signatory of the WTO Agreement on Technical Barriers to Trade (WTO/TBT), the U.S. pursues standardization activities that are in full compliance with these principles, as well as processes that are flexible, timely, and balanced.

ANSI fosters the U.S. standardization system by accrediting the procedures of standard-setting organizations and subsequently approving individual documents as American National Standards (ANS). More than 220 ANSI-Accredited Standards Developers are now engaged in the creation and maintenance of voluntary consensus standards that are being used in virtually every industry sector. These standards developers — and the experts that populate them — work cooperatively to enhance the U.S. quality of life and improve the competitiveness of businesses operating in the global marketplace.

THE GLOBAL STAGE

In addition to the Institute's role within the domestic standardization infrastructure, ANSI promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international and regional standards organizations, and encourages the adoption of international standards as national standards where they meet the needs of the user community.

As the U.S. member body to the International Organization for Standardization (ISO), and, via the U.S. National Committee (USNC), the International Electrotechnical Commission (IEC), ANSI offers U.S. technical experts immediate access to standards development activities on the global stage. As a founding member of ISO, ANSI plays a strong leadership role in its governing body, while U.S. participation, via the USNC, is equally strong in the IEC. The United States participates in almost the entire technical program of both the ISO and the IEC, and administers many key committees and subgroups.

In order to complete technical work at the ISO and IEC table, U.S. Technical Advisory Groups (TAGs) are responsible for developing U.S. positions on activities and ballots of international technical committees. As is the case with organizations accredited by ANSI to develop American National Standards, ANSI-accredited TAGs to ISO and USNC-appointed TAGs to IEC must demonstrate adherence to a set of essential requirements that align with the tenets of the WTO/TBT and the NTTAA.

EXAMINING CONFORMITY ASSESSMENT

On the other side of the standardization coin is conformity assessment, a term used to describe the demonstration that products, processes, systems, services, or personnel fulfill the requirements identified in a specified standard. Conformity assessment forms a vital link between standards that define product characteristics or requirements and the products themselves. It can verify that a particular product meets a given level of quality or safety. And it can provide explicit or implicit information about the product's characteristics, the consistency of those characteristics, and the performance of the product.

As described in the *National Conformity Assessment Principles for the United States*, conformity assessment includes sampling and testing, inspection, supplier's declaration of conformity, certification, and management system assessment and registration. It can also include accreditation of the competence of those activities by a third party and recognition (usually by a government agency) of an accreditation program's capability. While each of these activities is a distinct operation, they are closely interrelated. The choice of the most appropriate assessment processes, as well as the quality with which they are performed, can have a significant effect on the confidence in and reliance on the results of the entire conformity assessment.

U.S. conformity assessment activities enhance the confidence of consumers, buyers, sellers, regulators and other interested parties in the products that are being purchased, while avoiding the creation of unnecessary barriers to trade. For this reason, conformity assessment has become a critically important aspect of conducting business in the global marketplace and is often made visible through product marking or other marketing and promotional efforts. Conformity assessment increases buyers' confidence in products and services and helps to substantiate advertising and labeling claims. Information on conformance (or nonconformance) to a particular standard can provide an efficient method of conveying information needed by regulators or buyers on the product's safety and suitability.

Depending on the risks of nonconformance and the confidence level necessary, there are several ways to assess whether products and services meet global requirements — from supplier's self-declaration to accredited third-party certification.

ANSI's role in the conformity assessment arena includes accreditation of third-party organizations including those that certify that products or personnel meet recognized standards; validation/verification bodies engaged in the reduction and removal of greenhouse gases; and certificate programs for organizations that issue education and training certificates to the workforce.

The ANSI-ASQ (American Society for Quality) National Accreditation Board provides accreditation services under the ACLASS and ANAB brands. Through ACLASS they accredit testing and calibration laboratories, inspection bodies, and reference material producers. Through ANAB the organization serves as the U.S. accreditation body for management systems registrars, in areas such as quality, safety, and environmental management.

ANSI also is involved in several international and regional organizations (such as the International Accreditation Forum) to promote multilateral recognition of conformity assessments across borders to preclude redundant and costly barriers to trade.

CONCLUSION

The U.S. commitment to voluntary consensus standards and related conformity assessment programs is strong and unequivocal.

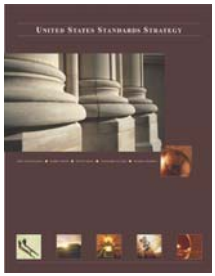
Within the U.S. standardization system, stakeholders — companies, government agencies, public interest organizations, and individuals — follow the method of standards development and the conformity assessment scheme most appropriate for their particular needs. Rapidly evolving fields have requirements that are far different from those of traditional manufacturers or highly regulated technologies.

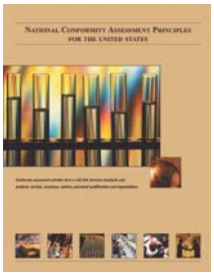
The decentralized, flexible, sector-based, and market-driven standards system is extremely responsive to changing market demands. It guides the energy of U.S. innovation and enhances the global competitiveness of business while at the same time improving the U.S. quality of life. It is an outstanding example of how a strong, dynamic partnership between the private sector and government can help the nation achieve its economic and societal goals.

SUGGESTED READING

United States Standards Strategy
www.us-standards-strategy.org

National Conformity Assessment Principles for the United States
www.ansi.org/ncap





Headquarters
1819 L Street, NW
Washington, DC 20036

Tel: 202.293.8020
Fax: 202.293.9287

Operations
25 West 43rd Street
Fourth Floor
New York, NY 10036

Tel: 212.642.4900
Fax: 212.398.0023

www.ansi.org