American National Standards Institute

United States Standards System

An Introduction



1918-2018

Key Terms



Standards

Market-driven product and service specifications
 (e.g., technical requirements, management systems, etc.)

Regulations

 Mandatory technical specifications, which may include particular standards or conformity assessment procedures

Conformity Assessment

Processes and systems used to verify the compliance of a product, person, process or system to either a standard or a regulation (e.g., testing, certification)







- The American National Standards Institute leads standards, conformity assessment, and related activities in the United States of America.
- ◆ Founded in 1918, ANSI is a private, non-profit organization.
- ANSI is not a government agency or a standards developer.







- Represents U.S. globally
- Ensures integrity of the standards and conformity assessment system
- Offers neutral forum

- Accredits standards
 developers and conformity
 assessment organizations
- Bridge between U.S. public and private sectors





ANSI represents and serves the diverse interests of more than 270,000 companies and organizations and 30 million professionals worldwide.

- Standards Developers
- Government
- Manufacturing
- Trade Associations
- Professional Societies

- Consumer Representatives
- Service Organizations
- Labor Interests
- Academia
- Individuals... and more



- U.S. member of ISO
- U.S. member of the IEC,
 via ANSI's U.S. National Committee
- a U.S. member of IAF and ILAC
- member of regional forums in the Pacific Rim and the Americas liaison with groups in Europe, Africa and the Middle East
- bilateral agreements with other national standards bodies











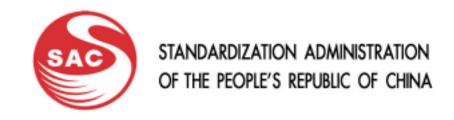














Snapshot: ANSI International, Regional, and Bilateral Activities

U.S. Private Sector U.S. Public Sector Companies, Trade Associations, Government Agencies SDOs, Consumers, Academia

International Bodies









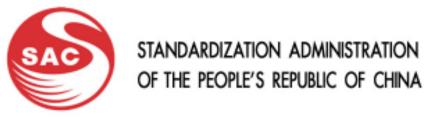
... among others

Foreign Bodies (ANSI Peers)











... among other bilateral relationships

Regional Bodies





COPANT

European Standardization Organizations (ESOs)









U.S. Standardization System comparison with many other economies

Approach in many economies Many other economies Top Down Approach Standards bodies in the United States drive standardization activities

United States Bottom Up

Standards users drive standardization activities



U.S. Standardization System comparison with many other economies

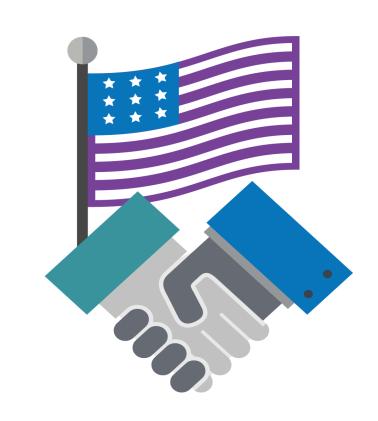
- Emphasizes private-sector standards solutions
- Relies on private-sector
 compliance verification
 (conformity assessment)
 for both regulatory and
 non-regulatory functions
- Provides a strong voice and greater authority to standards users and individual stakeholders





U.S. Standards & Conformity Assessment System the public-private partnership

- Activities are a mix of government (regulatory programs)
 and private sector (market-based programs)
- The system relies on private-sector mechanisms to achieve both non-regulatory and regulatory conformance
- Designed to provide more confidence in the quality of the product, service, or system by consumers, the public, and employers





U.S. Standards & Conformity Assessment System the public-private partnership

- No single government agency has control over standards
 - Each agency determines which standards meet its needs
- National Technology Transfer and Advancement Act (NTTAA) —
 Public Law 104-113
 - Encourages each government agency to seek existing private-sector standards that are appropriate for its purpose and mission





U.S. Standards & Conformity Assessment System the public-private partnership

National Institute of Standards and Technology U.S. Department of Commerce

- NIST has the legal responsibility of implementing the NTTAA
- Coordinates the standards activities of Federal agencies

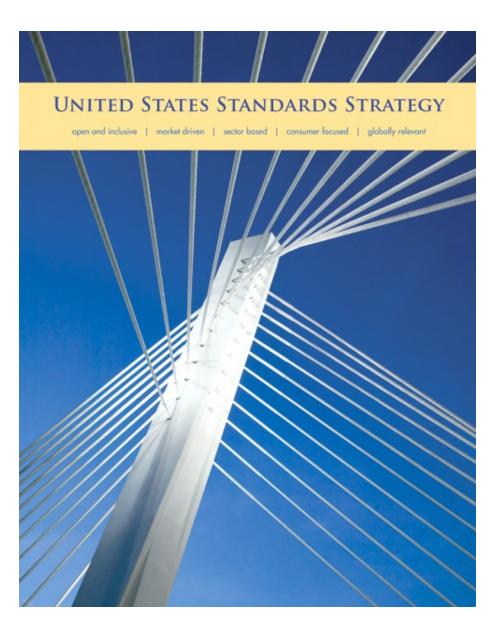
Sets legal metrology standards

Accredits Laboratories



U.S. Standards and Conformity Assessment System reliable – flexible – responsive

- Market driven
- Flexible and sector-based
- Industry-led and government-supported



This system is designed to . . .

- Support a broad range of stakeholder engagement
- Address emerging priorities and new technologies
- Allow stakeholders to find the solutions that best fit their respective needs

As defined in the *United States Standards Strategy*www.us-standards-strategy.org



U.S. Standards System guiding principles

- Standards should meet societal and market needs and should not be developed to act as barriers to trade
- The U.S. endorses the globally accepted standardization principles of the World Trade Organization Technical Barriers to Trade Agreement
 - Transparency
 - Openness
 - Impartiality
 - Effectiveness and relevance
 - Consensus
 - Performance-based

- Coherence
- Due process
- Technical Assistance
- Flexible
- Timely
- Balanced





U.S. Standards System different tools for globally relevant standards



National Participation (one country one vote)	Direct Participation	Consortia
Treaty OrganizationsNon-Treaty Organizations	Nationally AcceptedInternationally Accepted	
Examples ISO, IEC, ITU, CODEX, etc.	Examples ASTM International, ASME, SAE, etc.	Examples IGRS, W ₃ C, etc.

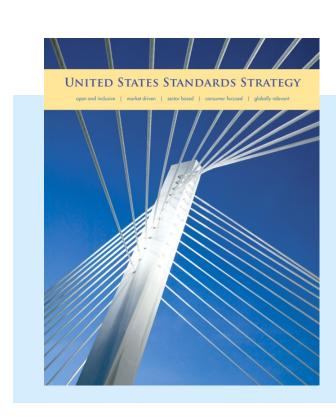


U.S. Standardization System ANSI-accredited SDOs and U.S. TAGs

 ANSI accreditation of SDOs and U.S. TAGs promotes alignment with the WTO's Internationally Recognized Principles for Standards Development

ANSI Essential Requirements for the development of American National Standards World Trade Organization Technical Barriers to Trade Agreement

Referenced in the United States Standards Strategy

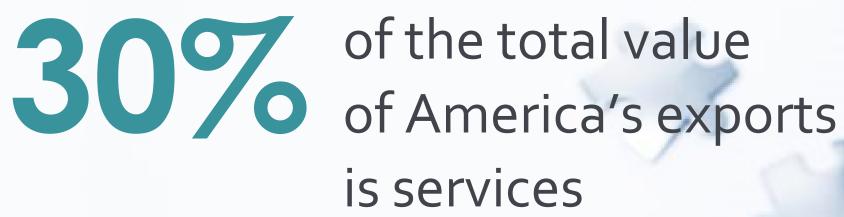


Openness
Transparency
Due Process
Consensus

Referenced in the WTO TBT Committee Second Triennial Review – Annex 4



93% of global exports are affected by standards and technical regulations



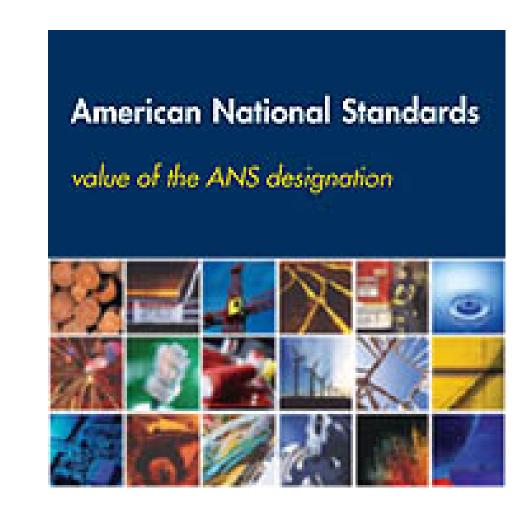


In line with the USSS, ANSI accreditation promotes the consistent, worldwide application of globally relevant standards and compliance programs.

American National Standards (ANS)

- Currently there are approximately 240 ANSI-accredited standards developers (ASD)
 - Only ASDs may submit standards for approval as ANS
 - Not all standards developed by these organizations are submitted for consideration as ANS
 - There are approximately 11,000 ANS
 - All ASDs are subject to ANSI's neutral third-party oversight including a routine audit of ANS and an annual compliance review of accredited procedures

Learn more: <u>www.ansi.org/ansvalue</u>





U.S. Standardization System examples of ANSI-accredited SDOs and U.S. TAGs

ASTM International



IEEE



National Fire Protection Association



IAPMO



AAMI



Health Level Seven



American
Society of
Mechanical
Engineers



NSF International



UL



American Society of Civil Engineers



Building
Institutional
Furniture
Manufacturers
Association



International Code Council





And more than 200 additional organizations

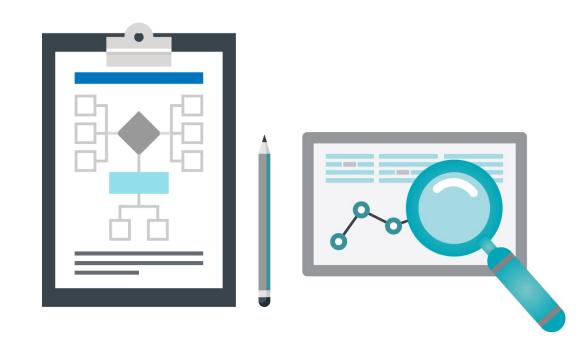
U.S. Standards System examples of roles and responsibilities

	ANSI	Standards Developers	Companies	Consumers	Government	NIST
Coordinates U.S. system and policy development	*					
Independently runs standards development activities		*				
Coordinates and monitors USG use of and participation in VCS activities						*
Legal metrology and WTO-TBT enquiry point						*
Provides technical input for standards development			*	*	*	*
Participates in U.S. policy development	*	*	*	✓	✓	*



U.S. Conformity Assessment System

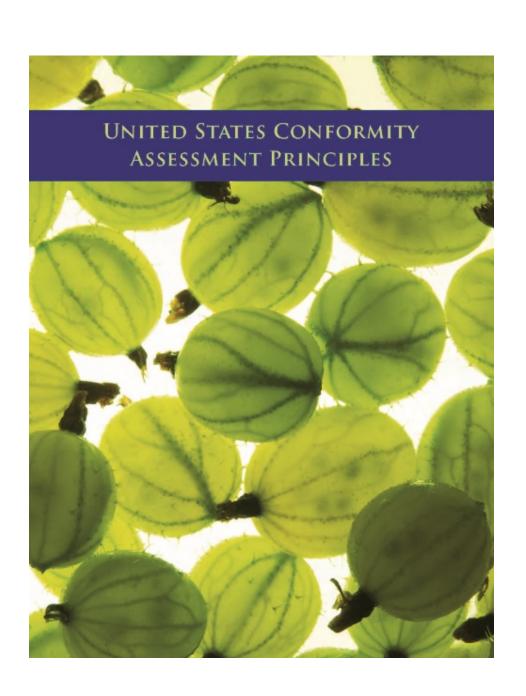
- Standards are just good ideas unless products, processes, systems, and personnel conform to them.
- ◆ The U.S. conformity assessment system much like the standards system – evolved in a decentralized manner.
 - Conformity assessment activities are not centrally organized
 - Approaches vary among sectors





U.S. Standards and Conformity Assessment System reliable – flexible – responsive

◆ The *United States Conformity Assessment Principles* (USCAP) explains key aspects of compliance verification.



The USCAP is a guidance document that can be considered in conjunction with the *United States Standards Strategy*.

United States Conformity Assessment Principles www.ansi.org/uscap



ANSI Accreditations

		client	standard	
ACCREDITED	Standards	SDO	ANSI Essential Requirements	
		USTAG (ISO)	ANSI International Procedures	
	t (150 17011)	Product Certification Body	ISO/IEC 17065	
		Personnel Certification Body	ISO/IEC 17024	
		Certificate Issuer	ANSI-ASTM E2659	
		GHG Validation/Verification Body	ISO/IEC 14065	
ANAB	Conformity Assessment	Management Systems Certification Body	ISO/IEC 17021	
		Laboratory	ISO/IEC 17025	
		Inspection Body	ISO/IEC 17020	
		Proficiency Test Provider	ISO/IEC 17043	
		Reference Material Producer	ISO Guide 34	
		Medical Lab	ISO 15189	

For More Information

Mary Saunders
Vice President,
Government Relations
+1.202.331.3610
msaunders@ansi.org

www.StandardsPortal.org

American National Standards Institute

Headquarters

1899 L Street, NW

11th Floor

Washington, DC 20036

T: 202.293.8020

F: 202.293.9287

New York Office

25 West 43rd Street

4th Floor

New York, NY 10036

T: 212.642.4900

F: 212.398.0023

www.ansi.org

webstore.ansi.org

