Overview of the U.S. Standards and Conformance Systems

Gary W. Kushnier
Vice President – International Policy
American National Standards Institute
Importance of Standards

“The international language of commerce is standards.”

Source:
U.S. Secretary of Commerce – Donald Evans
Report on Standards and Competitiveness –
Removing Standards-Related Trade Barriers Through Effective Collaboration
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Importance of Standards and Conformance
WTO/TBT Definitions

- **Standard** - Document that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, *with which compliance is not mandatory*. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

- **Technical Regulations** – Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, *with which compliance is mandatory*.

- **Conformity Assessment (Conformance)** – Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. (e.g., testing, certification)

*Informally any or all of these areas may be referred to as “Standards,” “Standardization,” “Standards and Conformance,” or “SCATR.”*
Statistics: Standards and Trade

- According to the WTO, global export trade surpassed $12.5 trillion in 2005.

- Those who understand how to effectively influence standardization and compliance programs will have the greatest success in the global marketplace.
Importance of Standards

Standards impact companies’ bottom line.

When developed and used responsibly, standards facilitate a company’s ability to open and access markets.

For Example…
Importance of Standards

- Compatibility and interoperability between components
- Quality of components and raw material inputs and
- Containerization for storage and shipping
- Verification of workforce qualification
- Measure for business profitability and economic performance
Importance of Standards

When overlooked, standards can negatively impact a company’s ability to do business in the U.S. and abroad.

For example: Coke and Pepsi in India
Importance of Standards

- Full or partial bans of Coke and Pepsi in seven Indian States
- Allegations that Coke and Pepsi contain excessive pesticide residue – unsafe
- Loss of market share and brand integrity for U.S. soft drink giants
- Avoidable with globally acceptable food safety and hygiene standards and certification
Importance of Standards

International standards harmonize cross-border requirements – opening markets for large, medium and small enterprises.

The global market follows standards.
Attributes of Standards

**Facilitate trade in many ways**
- Provide agreed-upon specifications for products, services, and systems, reducing costs and enabling commerce and trade
- Driven by the marketplace
- Enable innovation, competitiveness, and economic growth
- Protect health, safety, the environment, and national security
- Can provide a common way for implementing regulations
- Enable interoperability of complex technologies
- Promote supply-chain flexibility

**BUT inhibit trade when misapplied**
- Constrain technology and entrench inferior technologies
- Pose technical barriers to trade
The U.S. Approach to Standards and Conformance
The U.S. System: A Toolbox

- Rather than mandating a “one-size fits all” solution, the U.S. system allows players to find the tools and solutions that best fit their needs.

- Approaches, philosophies and positions often vary across industry sectors. Such variations are seen as beneficial and are promoted in the “U.S. Standards Strategy.”
“Bottom-up” vs. “Top-down”

Approach in the U.S.

- National Standards Bodies (e.g. ANSI)
- Standards Developers
- Standards Users (e.g. regulators, companies, etc.)

Strength and trade relevance come through effective representation of member interests – including private and public sectors.

Approach in many other economies

Some National Standards Bodies are top down: Market the most significant driving force in support of trade.
The U.S. System: Comparisons

Compared with many other economies, the U.S. standards system:

- Emphasizes private-sector solutions to ensure quality and protect Environment, Health and Safety (EHS)
- Places a high degree of confidence in private-sector conformity assessment activities for regulatory and non-regulatory functions
- Provides a strong voice and greater authority to standards users and individual stakeholders
- Relies on judicial system, brand-name recognition, open media and corporate social responsibility
- Is highly decentralized... and highly robust
The U.S. System: Benefits

- **Speed and flexibility** – solutions are delivered to market and implemented quickly
- **Participation** – able to accommodate input from a wide spectrum of stakeholders
- **Efficiency** – prevents unnecessary or costly regulation and allows multiple approaches to ensure health, safety, and quality

*The U.S. approach facilitates economic development and innovation*
The U.S. System: Choice by Sector

Focus in the U.S. System is on

Use and Choice for standards users

- determined by each sector -
Standards Used in the U.S.:
Different tools for different market needs

**National Participation**
- Treaty Organizations
- Non-Treaty Organizations

**Direct Participation**
- Nationally Accepted
- Internationally Accepted

**Consortia**
- IGRS, W3C, etc.

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**Examples**
- ISO, IEC, ITU, CODEX, etc.
- ASTM International, ASME, SAE, etc.
- IGRS, W3C, etc.

**Features**
- Formality in process
- One country, one vote
- Direct link between technical experts and SDOs
- Many are accredited by ANSI
- Wide range of processes and procedures allows flexibility

Overview of the U.S. Standards and Conformance Systems
The ANSI Federation
What is ANSI?

ANSI is the “Umbrella Organization” for and coordinator of the U.S. voluntary standards and conformity assessment system

Duties and responsibilities include:

- Develop and promote U.S. policies and positions
- Accredit SDOs and approve American National Standards (ANS)
- Accredit certifiers of products, personnel and management systems
- Provide standards and compliance solutions domestically and internationally
American National Standards Institute (ANSI)

A Federation of members representing 125,000 companies and organizations and 3.5 million professionals worldwide:

- Academia
- Individuals
- Government
- Manufacturing
- Trade Associations
- Professional Societies
- Service Organizations
- Standards Developers
- Consumer and Labor Interests
- and many more

ANSI is not a government agency or a standards developer
ANSI: A Private-Sector Organization

ANSI is an independent not-for-profit (501(c)3) organization. ANSI does not receive government oversight or subsidization.

Advantages:
- Public and private sectors are coequal partners
- Impartiality
- Market relevance
ANSI in Numbers

- **Revenue**
  - $25 million annual budget
  - Development of Standards: 0% ($0.0m)
  - Sale of Publications: 50% ($12.5m)
  - Membership Dues and Fees: 20% ($5.0m)
  - Accreditation Services: 19% ($4.8m)
  - Other: 11% ($2.7m)
  - *Est. total public sector portion of all of the above*: 10% ($2.5m)

- ISO/IEC Annual Dues: $2.1 million
- Technical Committees of ANSI: 0
- Number of Standard Developing Organizations (SDOs) accredited by ANSI: 208
- Technical Committees of ANSI’s SDO members: 565
- Number ANSI Standards Panels: 5
- Total number of American National Standards published as of 12/31/05: 9,915
- Estimated number of voluntary standards published in the U.S.: 100,000
- Number of voluntary standards referenced in U.S. laws & regulations: over 6,000
- Number of company interests represented by ANSI: 125,000
- Number of professionals represented by ANSI: 3.5 million
- Year ANSI was established: 1918
Examples of U.S. Standards Organizations Accredited by ANSI

- ANSI: American National Standards Institute
- U.S. Government (Federal, State and Local)
- ASTM International
- UL: Underwriters Laboratories, Inc.
- ASME: American Society of Mechanical Engineers
- IEEE: Institute of Electrical and Electronics Engineers
- ARI: Air-Conditioning and Refrigeration Institute
- NEMA: National Electrical Manufacturers Association
- Approximately 200 Others
## ANSI Accredited Standards Developing Organizations (SDOs)

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Link to full list of ANSI accredited and non-ANSI accredited SDOs: [www.nssn.org/acrodesc.html](http://www.nssn.org/acrodesc.html)
American National Standards (ANS): Based on Internationally Recognized Principles

Principles for international Standards development outlined
By the WTO/TBT Committee*:
- Openness
- Transparency
- Due Process
- Consensus

ANSI Essential Requirements for Accredited Standards Development:
- Openness
- Transparency
- Due Process
- Consensus

*WTO TBT Committee Third Triennial Review – Annex 4
ANSI International Interaction (Standardization)

- ANSI serves as the official U.S. member and sets policy for U.S. participation in the
  - International Organization for Standardization (ISO)
  - International Electrotechnical Commission (IEC)

- U.S. technical positions for ISO and IEC activities are developed by Technical Advisory Groups (US TAGs)
  - Allows all affected parties (including U.S. government) to participate in standardization activities
ANSI Regional Interaction (Standardization)

- ANSI serves as the official U.S. member of two regional bodies
  - Pan American Standards Commission (COPANT)
  - Pacific Area Standards Congress (PASC)

- The Institute has a dialogue with representatives of the European Standards Organizations (ESOs) (CEN, CENELEC and ETSI) and the European Commission
Overview of the U.S. Standards and Conformance Systems

The U.S. System: The Role of Government

- In the U.S., **no** single government agency has control over standards

- National Institute of Standards & Technology (NIST) – Technology Administration (TA) - U.S. Department of Commerce
  - Coordinates the standards activities of Federal agencies
  - Sets Legal Metrology Standards; Accredits Laboratories

- Each government agency determines which standards meet its needs
The U.S. System: The Role of Government Agencies

- The National Technology Transfer and Advancement Act (NTTAA, Public Law 104-113)
  - Each government agency is encouraged to seek existing private sector standards that are appropriate for its needs
  - If so, the agency will use (i.e. reference) the private sector standard
  - If not, the agency is expected to work with the private sector to develop the needed standards, and to reference them in its regulations
  - Agencies creating their own standards must report to the Administration and Congress on an annual basis the justifications for doing so
  - NIST has the legal responsibility of implementing the NTTAA
Overview of Conformity Assessment
What is Conformity Assessment?

Conformity Assessment

*Demonstration that specified requirements* relating to a product, process, system, person or body *are fulfilled*

*ISO/IEC 17000:2004*
Conformity Assessment – Vocabulary and general principles
Conformity Assessment

- Facilitates trade globally and eliminate barriers
- Builds **confidence** and reduces risk for customers
- Offers a range of tools to assist in procurement
  - Suppliers Declaration of Conformity (SDoC) to
  - Third-party testing and certification
Components of Conformity Assessment

- Metrology and measurement capabilities
- Sampling
- Testing
- Inspection
- Declaration of conformity
- Certification (products, services, personnel)
- Management system registration/certification
- Accreditation (ANSI role)
- Enforcement
Conformity Assessment System Structure

Accreditation Bodies (ABs)

Testing Laboratories

Certification Bodies

Inspection Bodies

Products (Procedures, Services)

QMS/EMS (ISO 9000 / ISO 14000)

Personnel

Buildings, Facilities, Mines, Procedures, Services, etc.
Accreditation Programs

Conformity Assessment (ISO/IEC 17011)

- Various Programs
- ISO/IEC Guide 17025
- Test Labs

- Various Programs
- ISO/IEC Guide 17020
- Inspection Bodies

- ANSI
- ISO/IEC Guide 65
- Product Certifiers

- ANAB
- ISO/IEC Guide 17021
- QMS/EMS Certifiers

- ANSI
- ISO/IEC Guide 17024
- Personnel Certifiers

Standards

- ANSI
- Procedures “Essential Requirements”

- Standards Developing Organizations and U.S. TAGs

Overview of the U.S. Standards and Conformance Systems

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Key Characteristics of U.S. CA System

- In the United States, conformity assessment activities are not centrally organized

- Activities are a mix of government (regulations) and private sector (market activities)

- Approaches vary among sectors
Overview of the U.S. Standards and Conformance Systems

Conformity Assessment - Summary

- U.S. System is uses private-public sector partnership that insures industry sector input and is supported by Federal legislation
- Conformity Assessment system, like Standards system, evolved in decentralized manner with a sector-based approach
- Conformity Assessment ranges from Self Declaration of Conformity (SDoC) to 3rd-party review (accreditation)
- Is generally effective, open, and transparent
- Designed to provide more confidence in the quality of the product, service, or system by consumers, the public, and employers
For more information:

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Additional Slides
A Standard is a Document

Standard

Document established by consensus and approved by recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities …

Standardization and related activities –
General vocabulary

Voluntary Consensus Standard • Conformity Assessment Procedure
Technical Regulation • Metrology Standard
The U.S. Standards System

**Government**

- Regulators
  - CPSC, EPA, FCC, USDA, etc.
- Procurement Agencies
  - DOD, NASA, USDA, etc.

NIST coordinates Federal activities in voluntary standards

NIST

**Private-Sector**

- Standards Developers
- Companies
- NGOs
- Academics
- Consumers
- Trade Associations
- Others

Government Agencies are members of ANSI and of SDOs. Agencies participate directly in voluntary standards development and policy setting and use voluntary standards when it supports their missions.

U.S. Policies and Positions

Activities Carried out independent of the ANSI Structure
# The U.S. Standards System: Who's Who

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*Documentary Standards, excluding "national participation models"
The U.S. Conformity Assessment System

**International Activities**
- IEC (IECEE, IECx, IECQ)
- ISO (CASCO)

**Domestic Activities**
- Designating Authorities
- Accreditors
- Testers, Inspectors & Certifiers

**Designating Authorities**
- FCC (Telecom)
- USDA (Food)
- NIST (NVLAP)
- EPA (ENLAP)

**Accreditors**
- ANSI (ANAB)
- A2LA
- UL
- Intertek
- TUV

**Testers, Inspectors & Certifiers**
- John Deere
- HP

**Other**
- Includes accredited and non-accredited bodies
- Generally manufacturers of high-tech and low-volume products

**Other International Fora**
- IAF
- ILAC
- ANSI
- ABs
- Other

No “official” U.S. representative

Overview of the U.S. Standards and Conformance Systems

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