



**Supporting  
Transatlantic Trade**

Standards and Conformance  
for Business and Regulators



## Overview of the U.S. Standards System

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a conference organized by the American National Standards Institute  
in cooperation with the European Standards Organizations

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# ***Importance of Standards***

# Key Terms / Concepts

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## Standards

**Market-driven** specifications for a product, service, person, process or system, with which compliance is voluntary

## Technical Regulations

**Mandatory** specifications, which may include (or reference) particular standards or conformity assessment procedures

## Conformity Assessment

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

# Importance of Standards

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Standards impact companies' bottom lines.

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

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# ***The U.S. Approach to Standards***

# U.S. Standards System

## comparison with many other economies (continued)

Top Down

Standards bodies  
drive standardization activities

Bottom Up

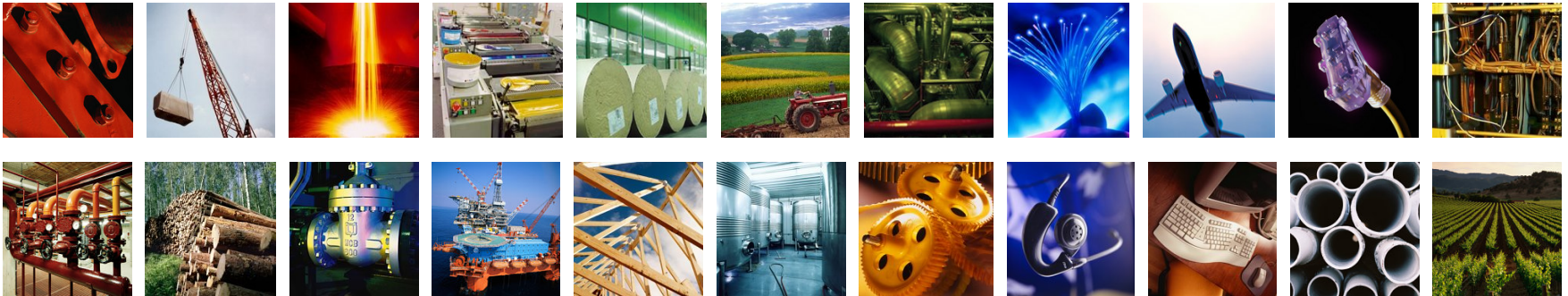
Standards users drive  
standardization activities



# U.S. Standards and Conformity Assessment System

comparison with many other economies

- Emphasizes private-sector **standards solutions**
- Relies on private-sector **compliance verification** for both regulatory and non-regulatory functions
- Provides greater authority to standards users and stakeholders





## **Guiding Principles**

of the United States  
Standardization System

**Standards and their related compliance criteria 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 (WTO-TBT)**

**The U.S. is supportive of international standards that are technically suitable, used throughout a given market sector worldwide, and developed in accordance with the WTO-TBT principles**

## The WTO Principles

Transparency

Openness

Impartiality

Effectiveness and relevance

Consensus

Performance-based

Coherence

Due process

Technical Assistance

## Also in the U.S. Standards Strategy

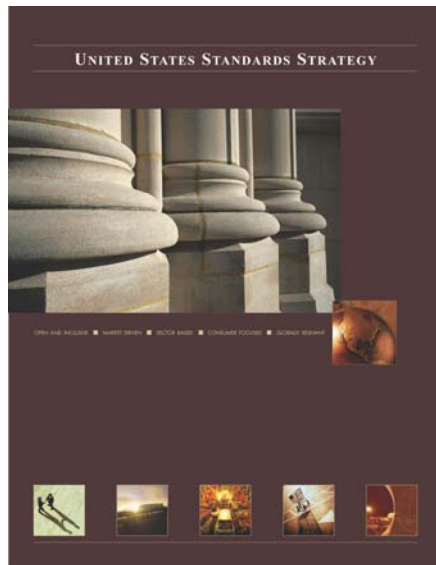
*Flexible | Timely | Balanced*



# U.S. Standards and Conformity Assessment System

## Flexible - Responsive

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



As defined in the ***United States Standards Strategy***, this system is designed to . . .

- **Support** stakeholder engagement
- **Address** emerging priorities
- **Allow** stakeholders to find custom-fit solutions

[www.ansi.org/usss](http://www.ansi.org/usss)

# U.S. Standards System

## Different tools for developing globally-relevant standards



<b>National Participation</b>	<b>Direct Participation</b>	<b>Consortia</b>
<ul style="list-style-type: none"><li>▪ Treaty Organizations</li><li>▪ Non-Treaty Organizations</li></ul>	<ul style="list-style-type: none"><li>▪ Nationally Accepted</li><li>▪ Internationally Accepted</li></ul>	
<u>Examples</u> ISO, IEC, ITU, CODEX, etc.	<u>Examples</u> ASTM International, ASME, SAE, IEEE, etc.	<u>Examples</u> IGRS, W3C, etc.

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# *Overview of the ANSI Federation*

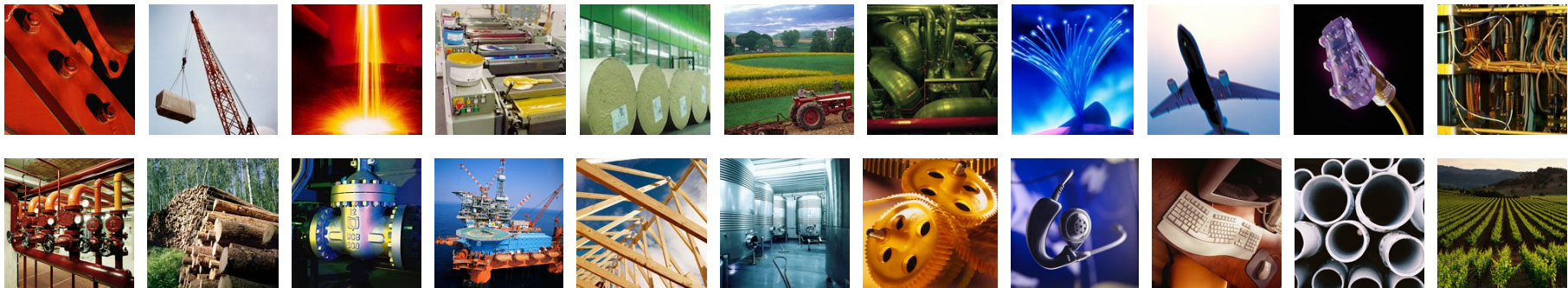


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September 24, 2008 | Washington, DC



*ANSI is the “Umbrella Organization” for the U.S. Standards System.*

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



# Examples of ANSI-Accredited Standards Developers

ASTM  
International



American  
Society of  
Mechanical  
Engineers



International  
Code Council



American  
Dental  
Association



National  
Electrical  
Manufacturers  
Association



National Fire  
Protection  
Association



**SAE** *International*

Society of Automotive Engineers



Institute of  
Electrical and  
Electronics Engineers



Underwriters Laboratories Inc.

American  
Society  
of Civil  
Engineers



American  
Petroleum  
Institute



**And more than 200  
additional organizations**



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# ***The Role of Government in the U.S. Standards and Conformance Systems***



# U.S. Standards and Conformity Assessment System

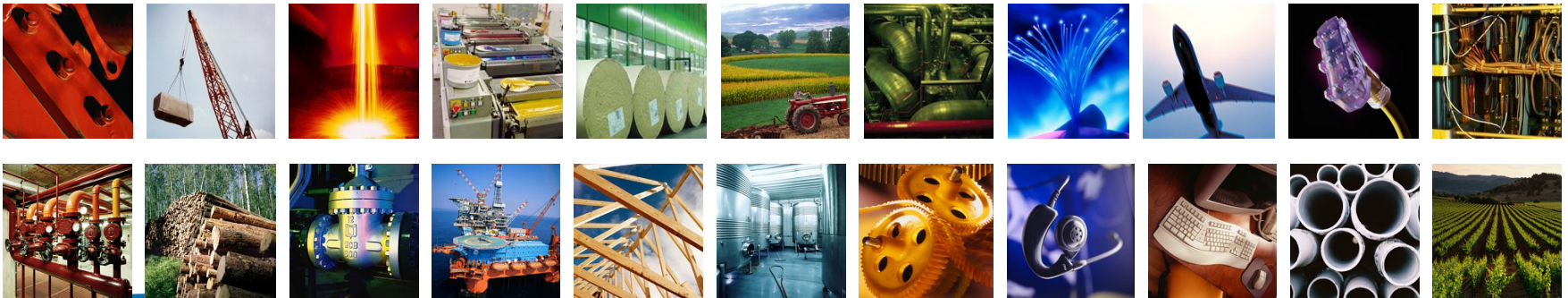
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Top Down

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drive standardization activities

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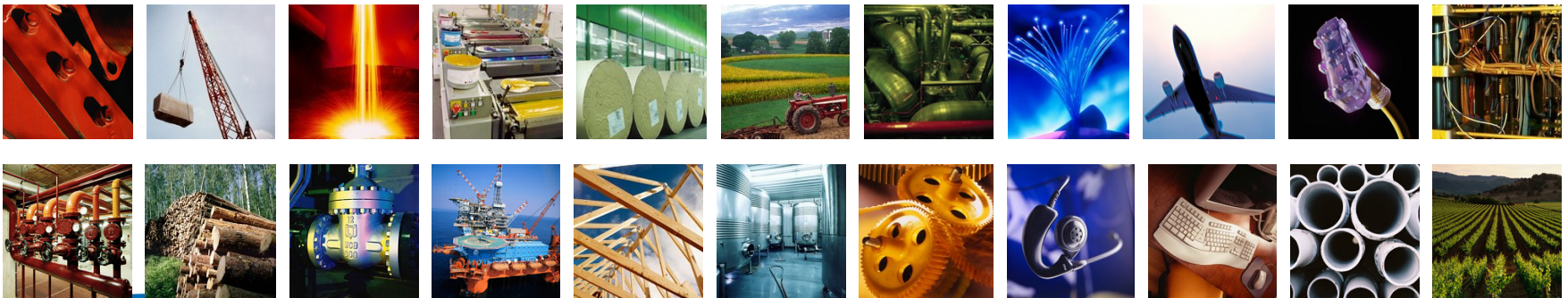
Standards users drive  
standardization activities



# U.S. Standards and 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



# The Role of Government Agencies

- **OMB Circular A-119**
- **The National Technology Transfer and Advancement Act (NTTAA, Public Law 104-113)**
  - Before regulating, each government agency is required to seek and consider using 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

# The Role of Government Agencies

- Significant elements of OMB Circular A-119 and The NTTAA:
  - U.S. regulators and procurement officials can use any standard from any source in the world which help them meet their Congressional mandates
  - These standards do not need to first be transposed into American National Standards by ANSI
  - These directly referenced standards include ISO, IEC, SDOs
  - These standards may also be consortia standards
  - Regulators and procurement officials may make reference to applicable parts of standards – i.e. are not limited to referencing only whole standards

# Structure of the U.S. Standardization System

- **ANSI – Coordinator of the Private Sector led System**
  - Responsible for coordinating U.S. private sector participation in the U.S. private sector led Standards and Conformance systems
  - The National Standards Body for the United States – Represent the U.S. in intl. and regional standards fora
  - An Accreditation Body for private sector programs – Represent the U.S. in intl. and regional accreditation fora
  - Private sector, non-profit, membership organization
  - Supported by membership fees, sale of publications, funded programs, accreditation programs and periodic government grants
- **Standards Developing Organizations (SDOs)**
  - Responsible for the development of standards for the specific technical sectors
  - Some, but not all, accredited by ANSI
  - When accredited, can administer U.S. mirror committees to ISO and IEC
  - Private trade and professional organizations, often non-profit
  - Business models vary by sector
- **Conformity Assessment Bodies (CABs)**
  - Testing Laboratories, Certification Bodies, Inspection Bodies
  - Responsible for demonstrating compliance with standards (including those referenced by mandatory technical regulations)
  - Some, but not all, accredited by ANSI
  - Business models vary by sector (non-profit, for-profit, public sector, etc.)
- **NIST – National Institute of Standards & Technology – U.S. Department of Commerce**
  - Coordinates the activities of Federal agencies in the U.S. private sector led Standards & Conformance Systems
  - National Metrology Institute for the U.S. – Represents the U.S. in international and regional metrology fora
  - Accreditation Body for public sector programs – Represent the U.S. in international and regional accreditation fora
  - U.S. government public sector body

# U.S. Standards System

## Examples of roles and responsibilities

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

\*Documentary Standards, excluding “national participation models”

# U.S. Standards System

## Examples of roles and responsibilities

	ANSI	Standards Developers	Companies	Consumers	Government	NIST
Coordinates U.S. private-sector led system and policy development	<b>X</b>					
Coordinates and monitors USG use of and participation in Voluntary Consensus Standards (VCS) activities						<b>X</b>
Participates in U.S. private-sector led standardization policy development	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Provides technical input for standards development			<b>X</b>	<b>X</b>	<b>X</b>	<b>X</b>
Independently runs standards development activities*		<b>X</b>				
Legal metrology and WTO-TBT enquiry point						<b>X</b>

\*Documentary Standards, excluding “national participation models”



# Coordination and Harmonization Activities

- ANSI **Standards Panels** are cross-sector coordinating bodies established to promote the development and compatibility of voluntary consensus standards and conformity assessment programs necessary to support national and global priorities
  - **Coordinate** the efforts of the private and public sectors
  - **Identify** existing standards and compliance programs
  - **Define** where gaps exist
  - **Recommend** where additional work is needed
  - **Identify** organizations that can perform the needed work
- Open to ANSI and non-ANSI Members alike



# Coordination and Harmonization Activities

## ANSI Standards Panels



2003

**Homeland  
Security  
Standards  
Panel**



2004

**Nanotechnology  
Standards Panel**



2005

**Healthcare  
Information  
Technology  
Standards  
Panel**



2006

**ID Theft  
Prevention  
and ID  
Management  
Standards  
Panel**



2007

**Biofuels  
Standards  
Coordination  
Panel**

# For more information:



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***Thank you!***