# Standards and Innovation

## Overview of the U.S. Standards and Conformity Assessment System and Problem-Solving through Public-Private Partnerships

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American National Standards Institute

May 27, 2009

# An Overview of the
# United States Standards and
# Conformity Assessment System

*The international language of commerce is* *standards*.

**Source:**

Former U.S. Secretary of Commerce – Donald Evans

*Report on Standards and Competitiveness – Removing*
  *Standards-Related Trade Barriers Through Effective Collaboration*

May 18, 2004

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# 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)

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# Standardization: A Global Community

Standards Developers
and Conformity
Assessment Bodies

Commercial
and Consumer
Acceptance

Government
Acceptance

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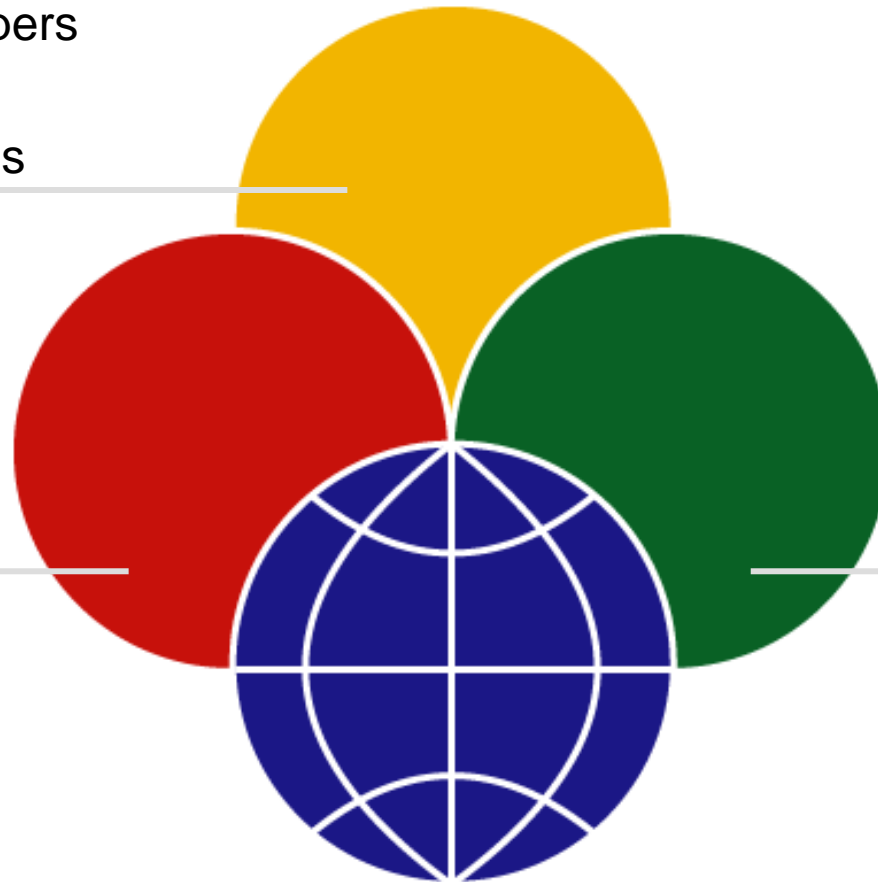
# Standards and Innovation

*Innovation is the fuel of economic engines.*
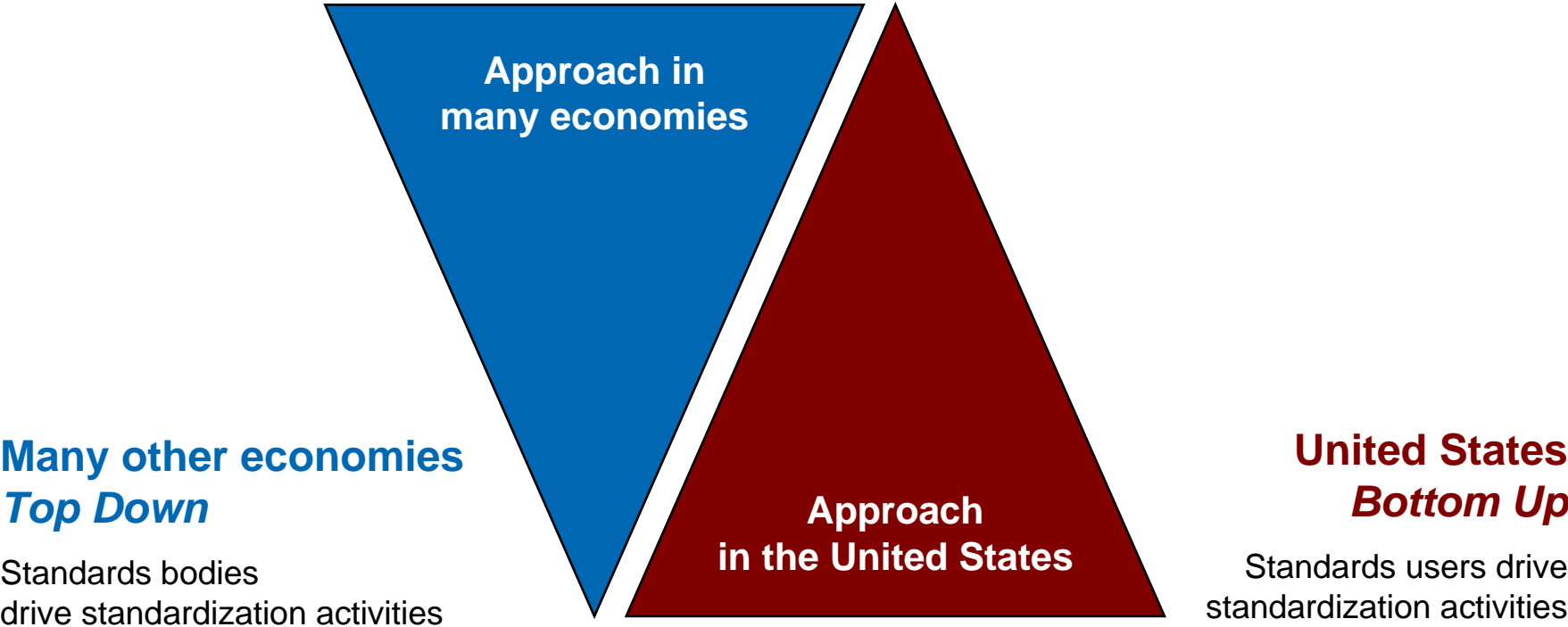
*Standards are a critical element of the formula.*

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# Standards and Innovation (continued)

- In some cases, a standard will precede innovation by establishing a baseline for design and performance that will satisfy user requirements. That standard must provide enough flexibility that suppliers or manufacturers can vary features, function or price to establish a niche that positions them with a marketplace advantage.

- Other times, an innovative idea that finds its place in the market becomes the foundation of a new standard, which then becomes the physical documentation of an agreed-upon solution that has already been time-tested and proven.

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# U.S. Standards and Conformity Assessment System
comparison with many other economies

**Approach in many economies**

**Approach in the United States**

**Many other economies**
*Top Down*

Standards bodies
drive standardization activities

**United States**
*Bottom Up*

Standards users drive
standardization activities

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# 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 a strong voice and greater authority to standards users and individual stakeholders

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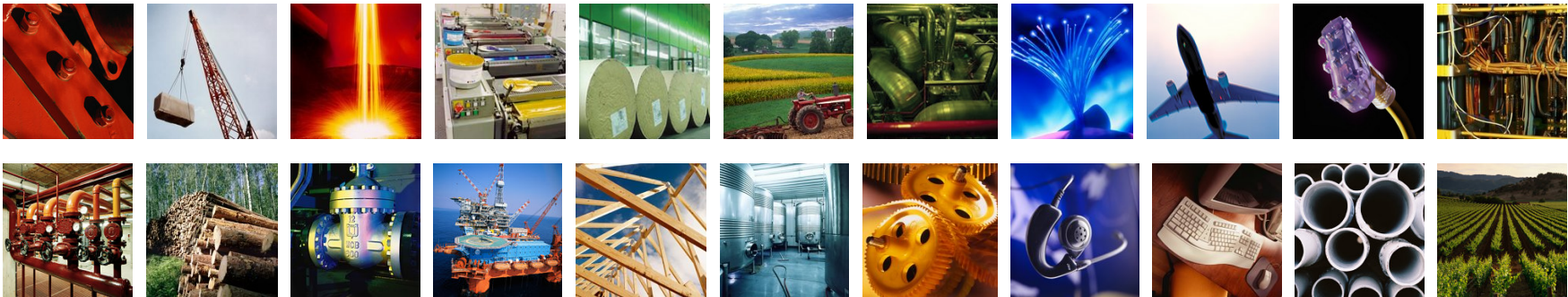
# U.S. Standards System
## a market driven approach

■ In the U.S. alone, there are more than 95,000 recognized standards.

■ These documents are being developed by:

◆ standards developing organizations (SDOs), with the twenty largest
   of these organizations producing approximately 80% of the standards

◆ nearly 500 consortia

◆ hundreds of committees addressing the technical requirements of standards

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# 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 | ◆ Coherence |
| ◆ Openness | ◆ Due process |
| ◆ Impartiality | ◆ Technical Assistance |
| ◆ Effectiveness and relevance | ◆ Flexible |
| ◆ Consensus | ◆ Timely |
| ◆ Performance-based | ◆ Balanced |

WORLD TRADE ORGANIZATION

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# U.S. Standards System
## Different tools for developing globally-relevant standards

| National Participation | Direct Participation | Consortia |
|---|---|---|
| ▪ Treaty Organizations<br>▪ Non-Treaty Organizations | ▪ Nationally Accepted<br>▪ Internationally Accepted | |
| Examples<br>ISO, IEC, ITU, CODEX, etc. | Examples<br>ASTM International, ASME, SAE, IEEE etc. | Examples<br>IGRS, W3C, etc. |

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

- Market driven

- Flexible and sector-based

- Industry-led and government-supported



UNITED STATES STANDARDS STRATEGY
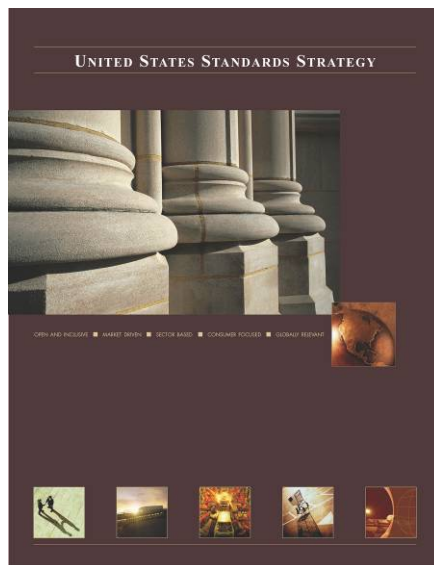
**This system is designed to . . .**
- **Support** a broad range of stakeholder engagement
- **Address** emerging priorities and new innovations
- **Allow** stakeholders to find the solutions that best fit their respective needs

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

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

- The National Conformity Assessment Principles (NCAP) for the United States document explains key aspects of compliance verification.
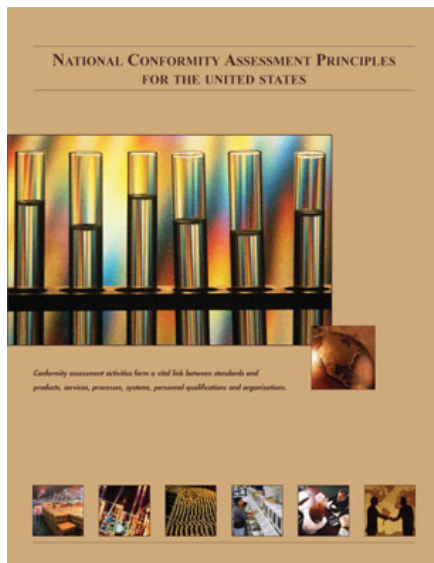


The NCAP is a guidance document that can be considered in conjunction with the *United States Standards Strategy* (USSS).

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

# 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 decentralized manner.

  - ◆ Conformity assessment activities are not centrally organized
  - ◆ Approaches vary among sectors

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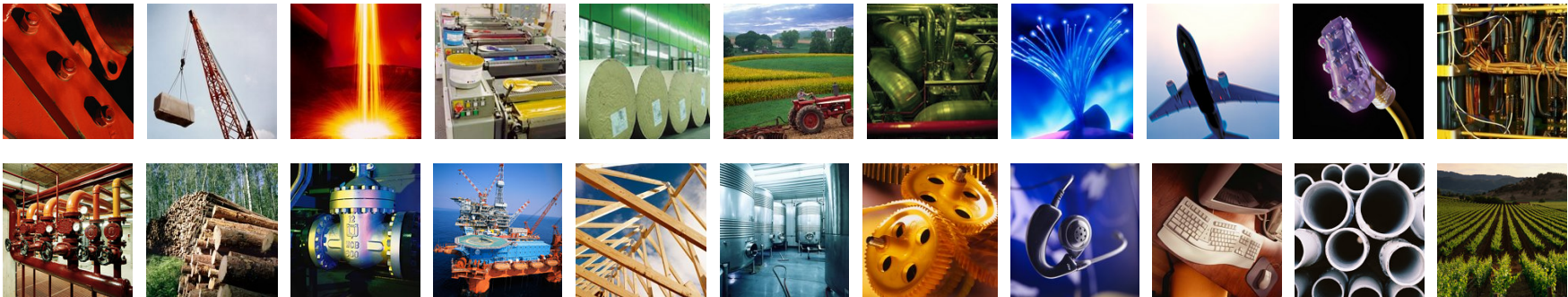
# U.S. Conformity Assessment System

- 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
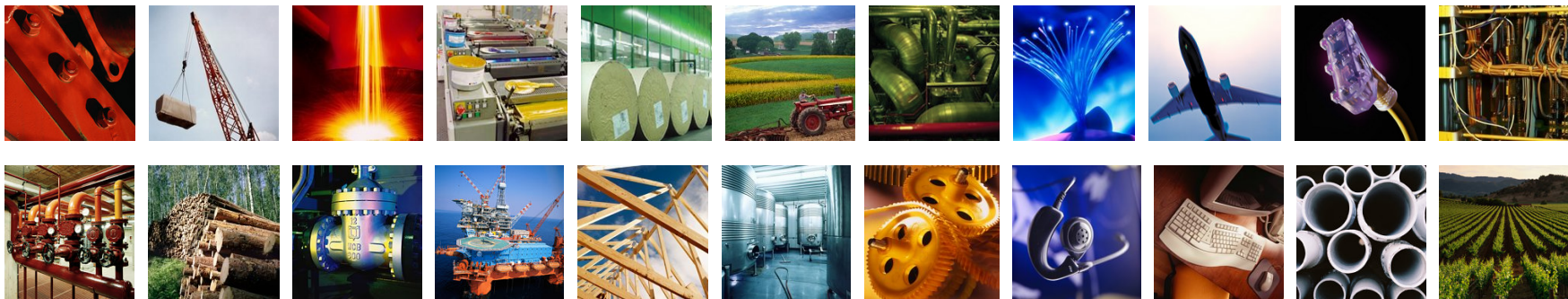
# Achieving Results Through Public-Private Partnerships

# 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

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# U.S. Standards and Conformity Assessment System
the public-private partnership (continued)

- **OMB Circular A-119**

  - ◆ Confirms critical need for cooperation between public and private sectors

  - ◆ Supports innovation, competitiveness, and participation by all interested parties

    - ☞ Supports multiple-path approach – including not just ANSI-accredited SDOs but also consortia

- **The National Technology Transfer and Advancement Act**

  - ◆ 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

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# U.S. Standards and Conformity Assessment System
the public-private partnership (continued)

**NIST**
**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

# Consensus is Key to the Public-Private Partnership

- No matter the challenge, solutions cannot be developed in a vacuum

- By collaborating through consensus-driven efforts, the public and private sectors can find real-world solutions that are efficient, effective, and scalable.
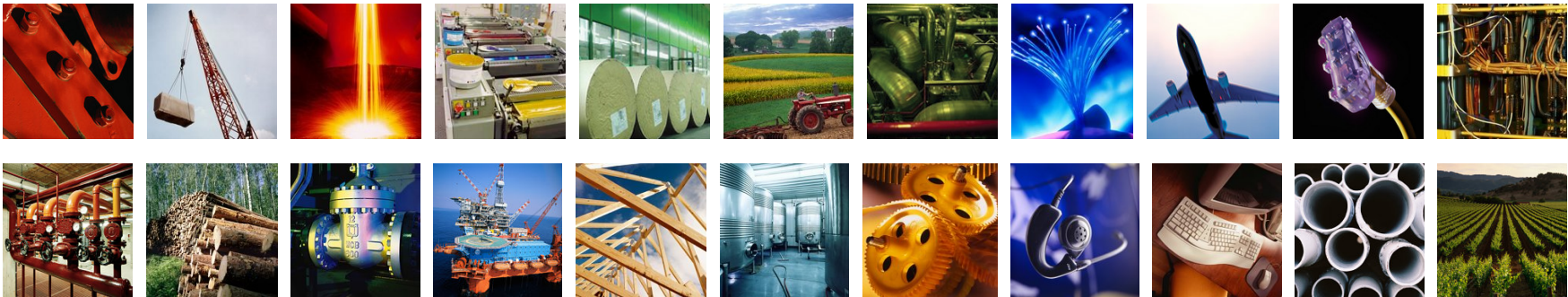
# Building onto the ANSI Foundation:
## Why We Need Public-Private Partnerships

*ANSI's reputation of developing practicable (and consensus-driven) solutions to difficult issues resonates well in our tough economic times and with the new faces in Washington*

- ANSI has a record of problem solving; whether import safety, the environment, security issues or Health IT

- We are recognized by policymakers as a respected (and neutral), resource for information, expertise and solutions

- Our role as facilitator and convener allows us to reach into the ANSI Federation for the resources needed to populate the public-private partnerships that will drive solutions
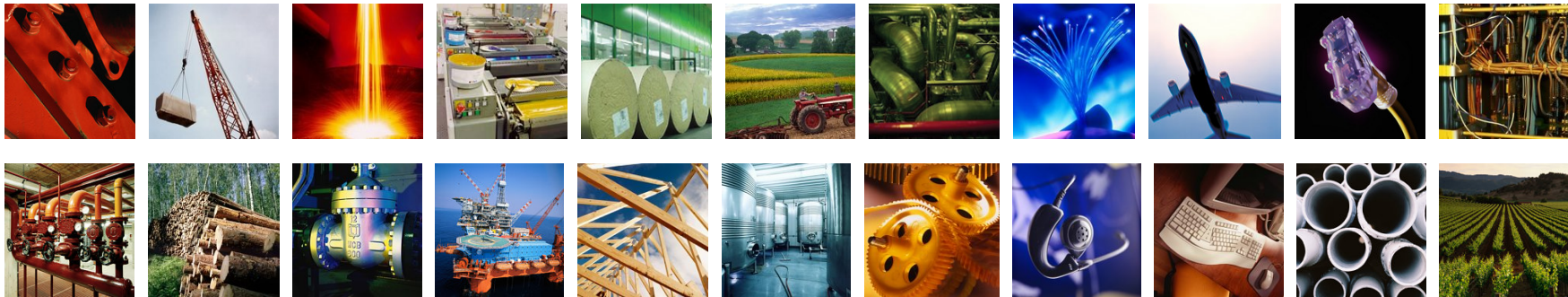
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# About ANSI

**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.

ANSI's mission is to enhance the global competitiveness of U.S. business and the American quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems and ensuring their integrity.
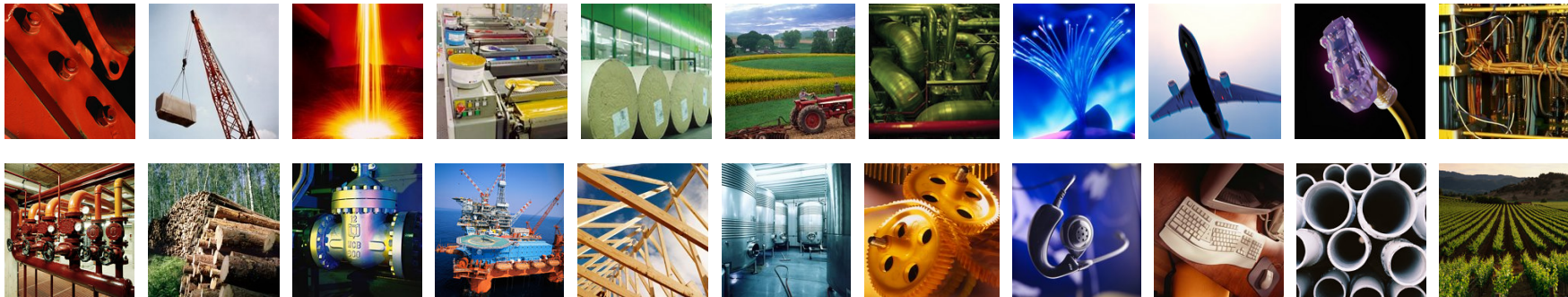
- Represents U.S. globally

- Ensures integrity of the standards and conformity assessment system

- Offers neutral forum

- Accredits standards developers and conformity assessment organizations
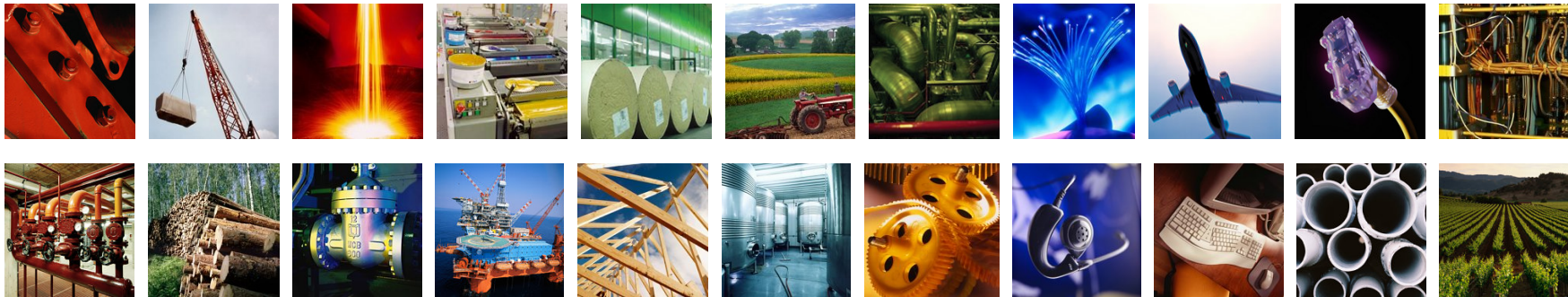
- U.S. member of ISO

- U.S. member of the IEC,
  via ANSI's U.S. National Committee

- 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

The ANSI Federation represents more than **125,000 companies and organizations** and **3.5 million professionals** worldwide

**Members of the ANSI Federation include . . .**

- Academia
- Individuals
- Government
- Manufacturing
- Trade Associations

- Professional Societies
- Service Organizations
- Standards Developers
- Consumer and Labor Interests
- and many more

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

| | | |
|---|---|---|
| ASTM International | American Society of Mechanical Engineers | International Code Council |
| American Dental Association | National Electrical Manufacturers Association | National Fire Protection Association |
| 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** |

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

- ANSI accreditation of SDOs and U.S. Technical Advisory Groups 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* |

openness

transparency

due process

consensus

Referenced in the *United States Standards Strategy*

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

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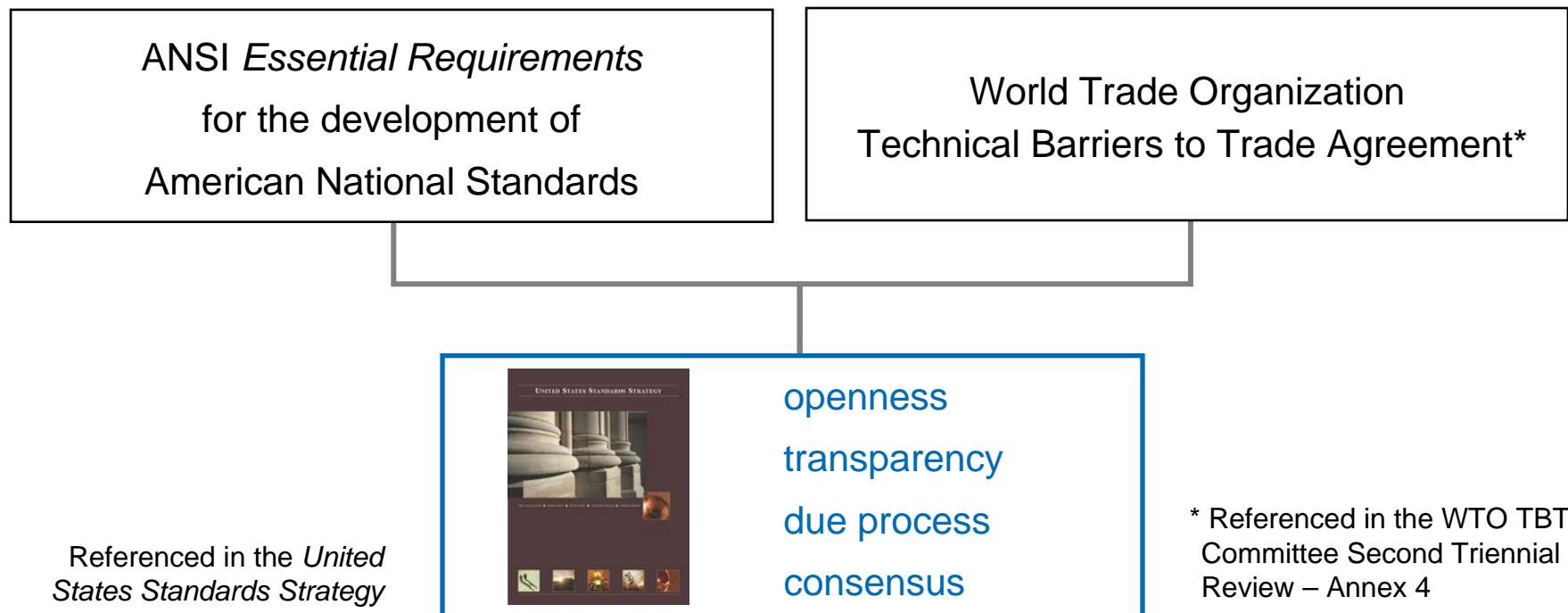
# Coordination and Harmonization Activities

■ 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

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# ANSI Panels, Forums, and Workshops



| 2003 | 2004 | 2005 | 2006 | 2007 | 2007 | 2009 | 2009 |
|------|------|------|------|------|------|------|------|
| **Homeland Security** Standards Panel | **Nanotechnology** Standards Panel | **Healthcare Information Technology** Standards Panel | **ID Theft Prevention** and **ID Management** Standards Panel | **Biofuels** Standards Coordination Panel | ANSI/NAM Network on **Chemical Regulation** | Workshop Toward **Product Standards for Sustainability** | ANSI-NIST **Nuclear Energy** Standards Coordination Collaborative |

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# ANSI Panels, Forums, and Workshops (continued)

### Homeland Security Standards Panel
www.ansi.org/hssp

Partnership with the U.S. Department of Homeland Security to accelerate development and adoption of consensus standards critical to homeland security. Support also provided to the 9-11 Commission for private sector preparedness. Key areas of focus are addressed in a workshop format, including: transit security, financial risk for cyber security, credentialing/access control for disaster management, and emergency preparedness for persons with disabilities and special needs.
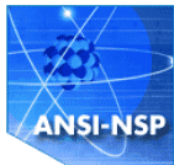
### Nanotechnology Standards Panel
www.ansi.org/nsp

Established at the request of the Office of Science and Technology Policy, Executive Office of the President of the United States to facilitate the development of standards supporting nomenclature/terminology; materials properties; testing, measurement and characterization procedures; and health, safety and environmental issues. The Panel's efforts are primarily focused on the coordination of U.S. interests in the international standardization arena, particularly within IEC Technical Committee (TC) 113 and ISO TC 229.

# ANSI Panels, Forums, and Workshops (continued)

**Healthcare Information Technology Standards Panel**     www.hitsp.org

A cooperative partnership between the public and private sectors, HITSP is a national, volunteer-driven, consensus-based organization that is working to ensure the interoperability of electronic health records in the United States. Operating under contract to U.S. Department of Health and Human Services (HHS), HITSP has already completed Interoperability Specifications in a number of priority areas, including electronic health record laboratory results reporting, biosurveillance, consumer empowerment, and quality.

**ID Theft Prevention & ID Management Standards Panel**     www.ansi.org/idsp

Administered by ANSI, the IDSP is a cross-sector coordinating body whose objective is to facilitate the development and use of voluntary consensus standards and guidelines that will equip and assist the private sector, government and consumers in minimizing the scope and scale of identity theft and fraud.

In 2009, the Panel will convene two workshops:  the first will explore the identity verification process across government agencies that issue identity credentials; the second will examine how research companies measure and report on identity theft.

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# ANSI Panels, Forums, and Workshops (continued)



**Biofuels Standards Coordination Panel**

Launched in conjunction with the U.S. Department of Energy and several other federal agencies to promote the development and compatibility of voluntary consensus standards and related conformity assessment programs necessary to support the large-scale commoditization of biofuels.



**ANSI/NAM Network on Chemical Regulation**

Established to empower U.S. manufacturers and other stakeholders with one voice when addressing domestic, regional, foreign and global chemical regulations, including REACH (Registration, Evaluation, Authorization and Restriction of Chemicals).

# ANSI Panels, Forums, and Workshops (continued)



### ANSI Workshop

### *Toward Product Standards for Sustainability*

Launched with the support of the U.S. Environmental Protection Agency, this workshop brought together a broad range of experts and advocates to share insights and develop recommendations on product standards for sustainability. The workshop, which took place April 8-9, 2009, in Arlington, VA, was attended by over 240 in-person participants and over 100 more via a live webinar, representing government, industry, standards developing organizations (SDOs), consortia, and consumers



### Nuclear Energy Standards Coordination Collaborative

In Spring 2009, ANSI and NIST announced the formation of the Nuclear Energy Standards Coordination Collaborative (NESCC), a joint initiative to identify and respond to the current standards-related needs of the nuclear industry. The first NESCC meeting will be held on June 1, 2009.

# Coordination and Harmonization Activities
next on the horizon . . .



**Food safety**



**Import safety / supply chain**



**Energy management**



**Biotechnology**

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# For more information

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