Overview of the U.S. Standards and Conformity Assessment System

Roles and Responsibilities of the American National Standards Institute

S. Joe Bhatia meeting with the NIST Visiting Committee on Advanced Technology

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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)
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 and Conformity Assessment System comparison with many other economies

Many other economies
Top Down
Standards bodies drive standardization activities

Approach in many economies

Approach in the United States
United States
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 a strong voice and greater authority to standards users and individual stakeholders
The American National Standards Institute leads standards, conformity assessment and related activities in the United States of America.
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
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

Overview of the U.S. Standardization and Conformity Assessment System
- 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
80% of world commodity trade is impacted by standards

30% of the total value of America’s exports is services

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

Standards

- ANSI Procedures
  - “Essential Requirements”
- SDO’s and U.S. TAGs

Conformity Assessment

- ISO/IEC 17024
- ISO/IEC 17065
- ISO/IEC 17021
- ISO/IEC 17025
- ISO/IEC 17020

- Personnel Certifiers
- Product Certifiers
- Management System Certifiers
- Laboratories
- Inspection Bodies
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
### Examples of ANSI-Accredited Standards Developers and U.S. TAGs

<table>
<thead>
<tr>
<th>ASTM International</th>
<th>UL Inc. Underwriters Laboratories</th>
<th>NFPA National Fire Protection Association</th>
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<tbody>
<tr>
<td>ADA American Dental Association</td>
<td>API American Petroleum Institute</td>
<td>ICC International Code Council</td>
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<tr>
<td>SAE Society of Automotive Engineers</td>
<td>IEEE Institute of Electrical and Electronics Engineers</td>
<td>TIA Toy Industry Association</td>
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<tr>
<td>U.S. Green Building Council</td>
<td>AHAM Association of Home Appliance Manufacturers</td>
<td>Others</td>
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Multiple Path Approach to Standard-Setting

- Traditional SDOs and consortia each have a role to play

  - Common concerns
    - Global recognition of work products
    - How best to serve a broad spectrum of industries
    - Intellectual property rights
    - Use of work products in regulations

  ANSI hosts an Annual “Open Forum for Standards Developers” to bring together SDOs and consortia
# U.S. Standards System

**different tools for different needs**

<table>
<thead>
<tr>
<th>National Participation</th>
<th>Direct Participation</th>
<th>Consortia</th>
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<tr>
<td>• Treaty Organizations</td>
<td>• Nationally Accepted</td>
<td>Examples</td>
</tr>
<tr>
<td>• Non-Treaty Organizations</td>
<td>• Internationally Accepted</td>
<td>ISO, IEC, ITU, CODEX, etc.</td>
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<td>Examples</td>
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<td>ASTM International, ASME, SAE, etc.</td>
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<td>Examples</td>
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<td>IGRS, W3C, etc.</td>
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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
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
Coordination and Harmonization Activities
ANSI Standards Panels (continued)

**Homeland Security Standards Panel**
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.

**Nanotechnology Standards Panel**
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.

**Healthcare Information Technology Standards Panel**
Contract with the U.S. Department of Health and Human Services to support widespread interoperability among healthcare software applications, accelerate decision making, and eliminate barriers to standards harmonization.
Coordination and Harmonization Activities
ANSI Standards Panels (continued)

ID Theft Prevention and ID Management Standards Panel
Partnering with the Better Business Bureau to facilitate within 18 months the timely development of voluntary consensus standards aimed at minimizing the scope and scale of identity theft and fraud.

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.
Coordination and Harmonization Activities
Next on the horizon . . .

<table>
<thead>
<tr>
<th>Chemical controls and regulations</th>
<th>Import safety / Supply Chain</th>
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<tbody>
<tr>
<td>Energy management</td>
<td>Biotechnology</td>
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U.S. Standards and Conformity Assessment System
The public-private partnership

- In the U.S., no single government agency has control over standards
  - Each government 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 needs
U.S. Standards and Conformity Assessment System
The public-private partnership (continued)

- NIST has the legal responsibility of implementing the NTTAA
- Coordinates the standards activities of Federal agencies
- Sets Legal Metrology Standards; Accredits Laboratories
MEMORANDUM OF UNDERSTANDING
between the
American National Standards Institute (ANSI) and the
National Institute of Standards and Technology (NIST)

1.0 Purpose

1.1 The underlying purpose of this Memorandum of Understanding (MOU) is to enhance and strengthen the national voluntary consensus standards system of the United States and to support continued U.S. competitiveness, economic growth, health, safety, and the protection of the environment.

1.2 The National Institute of Standards and Technology (NIST) of the Department of Commerce and the American National Standards Institute (ANSI) agree on the need for a unified national approach to develop the best possible national and international standards, as reflected in the U.S. National Standards Strategy adopted by ANSI on August 31, 2000. This approach requires the best technical efforts of the United States in standards to ensure that our needs and interests are considered as national and international standards are developed, so that our international competitiveness is strengthened.

1.3 ANSI and NIST agree on the need for better communication within and between the private sector and Federal Government on voluntary standards and conformity assessment. There is a need to ensure the timely flow of relevant information to the government and private sector about developments that affect these interests, and for improved liaison to facilitate decision-making and implementation actions on standards and conformity assessment at the national and international levels. It is also critical that effective U.S. Government agencies are encouraged to contribute to the development and implementation of national and international voluntary standards.

This MOU is intended to facilitate and strengthen the recognition of ANSI as the representative of U.S. interests at the international level by all participants, improve domestic communication and coordination among both private and public sector parties in the United States on voluntary standards issues, and increase the effectiveness of U.S. Government agency participation in the national and international voluntary standards-setting process. It is also intended to facilitate the implementation by both parties of the National Standards Strategy.

2.0 Agreement

2.1 ANSI is the recognized U.S. member body to the International Organization for Standardization (ISO), and, through the U.S. National Committee, to the International Electrotechnical Commission (IEC). It is also the U.S. member body to the Pacific Asia Standard Congress (PASC), the Pan American Standards Commission (CUPANT), and the International Accreditation Forum.
ANSI-NIST Memorandum of Understanding
Recent partnerships and accomplishments

Options for Action Summit
July 2006 event to identify standards-related actions to improve U.S. competitiveness

StandardsPortal.org
Online resource designed to facilitate U.S.-China trade
Looking ahead . . .

- Open discussion
American National Standards Institute

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