Use of Standards and Conformity Assessment in U.S. Regulation: Perspective of the Private Sector

Standards Alliance - Peru Workshop on Regulatory Decision Making
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Presentation Objectives

- Brief introduction to ANSI and the U.S. system
- Reliance on private sector standards and conformity assessment in regulations
- Public consultation in the rulemaking process
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
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
ANSI’s accreditation roles and responsibilities

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## U.S. Standardization System

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

<table>
<thead>
<tr>
<th>Example SDOs and TAGs</th>
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<tbody>
<tr>
<td>ASTM International</td>
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<tr>
<td>American Society of Mechanical Engineers</td>
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<tr>
<td>International Code Council</td>
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<tr>
<td>American Dental Association</td>
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<tr>
<td>National Electrical Manufacturers Association</td>
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<tr>
<td>National Fire Protection Association</td>
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<tr>
<td>Society of Automotive Engineers</td>
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<tr>
<td>Institute of Electrical and Electronics Engineers</td>
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<td>Underwriters Laboratories Inc.</td>
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<tr>
<td>American Society of Civil Engineers</td>
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<tr>
<td>American Petroleum Institute</td>
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<tr>
<td>And more than 200 additional organizations</td>
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2013 ANSI Slide 7
The U.S. System for Standards and Conformity Assessment System: a comparison with many other economies

Many other economies: *Top Down*
Standards bodies drive standardization activities

Approach in the United States: *Bottom Up*
Standards users drive standardization activities

- Emphasizes private-sector **standards solutions**
- Relies on private-sector **compliance verification** for both regulatory and non-regulatory functions
The U.S. System: a 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)
  - Encourages government agencies to:
    - Use pre-existing private sector standards when regulating
    - Participate in the development of private sector standards
  - Directs NIST to coordinate federal standards and conformity assessment activities

- Office of Management and Budget (OMB) Circular A-119
  - Provides federal agencies with guidance on how to implement the requirements of the NTTAA
Department of Energy established rules on energy and water conservation for consumer products pursuant to The Energy Policy and Conservation Act.

CFR § 430.2 provides restrictions on the amount of water that can come out of a showerhead over a defined period of time and requires that these showerheads also meet the following standard:

- ASME/ANSI Standard A112.18.1M-1996, 7.4.4(a), which provides guidelines for the insertion of a flow control device into a shower head.
Department of Health and Human Services established rules on the certification of Electronic Health Record Technologies pursuant to the Health IT for Economy and Clinical Health Act,

Under the rule, HHS has designated ANSI as an approved accreditor for certifiers seeking to participate in the program.

HHS provides incentives to providers and hospitals that use products on a certified product list developed through this conformity assessment mechanism.
Regulators often rely on post-market surveillance because:

- Legal system can enforce penalties
- Speeds market access

Private sector plays an important role in post-market surveillance.

The Food and Drug Administration uses a number of post-market surveillance approaches, including:

- **Medical Product Safety Network**, which works with hospitals to understand and report on adverse outcomes from medical device uses
- **Post-market Surveillance Studies**, in which FDA may order a medical device manufacturer to conduct device testing, analysis of databases or trials to monitor for defects
Public Consultation : Good Regulatory Practice

- Transparency of regulations, standards and conformance
- Incorporation of industry views, expertise, and experience
- Greater predictability in market access requirements and smooth trade flow
Public consultation during the rulemaking process

- Executive Branch
  - Agency drafts and clears internally a proposed rule.
  - If “significant,” OMB reviews and clears draft proposed rule.
  - Agency publishes notice of proposed rulemaking (NPRM).
  - Public reviews NPRM and submits comments to agency.
  - Agency reviews public comments and develops/clears draft final rule.
  - If “significant,” OMB reviews and clears draft final rule.
  - Agency publishes final rule.
  - Rule takes effect.

- Public consultation during the “notice-and-comment” period
- Private sector provides comments as an individual company/organization, or as part of a broader interest group
ANSI Provides Comments to Proposed Revision of OMB Circular A-119

- February 11: Federal Register publishes notice from the OMB inviting input on proposed revisions to Circular A-119
- February 12: ANSI announces plan to develop consensus response on behalf of the standardization community, asks ANSI members to provide any input to ANSI and also to submit their own comments
- May 6: ANSI submits consensus response based on member feedback to Federal Register
- Final revised rule has yet to be published...
Why rely on the private sector?

**BENEFITS TO PRIVATE SECTOR**

- Decreased burden of compliance with regulations
- Decreased cost of goods and services
- Encourages innovation and economic competition
- Facilitates international trade and avoids unnecessary obstacles to trade

**BENEFITS TO REGULATORS**

- Eliminates cost of developing standards
- Easier to enforce
- Allows for timely and effective solutions to legitimate regulatory concerns
DISCUSSION AND Q&A

Thank you!