



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



Standards Alliance - Peru Workshop on Regulatory
Decision Making

October 29-30, 2014

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



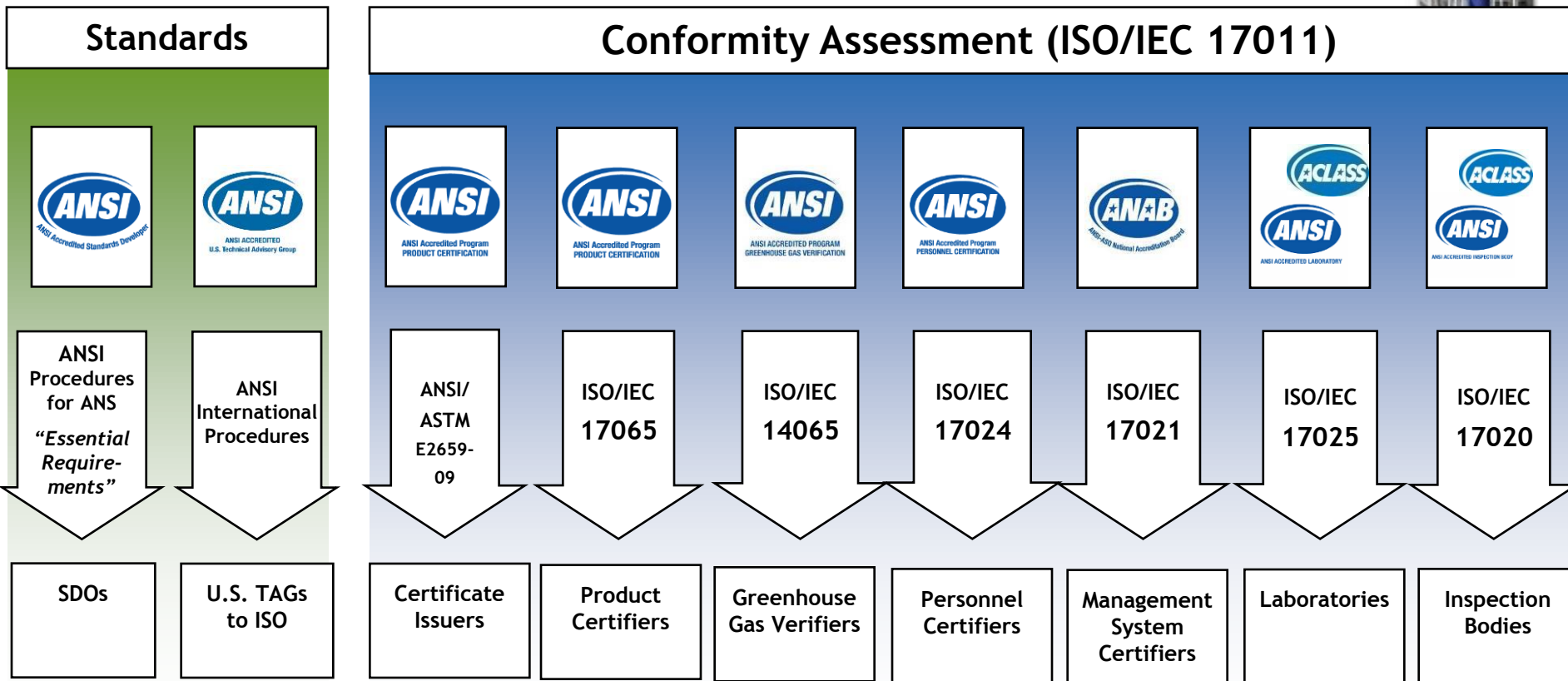
The ANSI Federation represents more than **125,000 companies and organizations** and **3.5 million professionals** worldwide

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



U.S. Standardization System

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



ASTM
International



ASTM
INTERNATIONAL
Standards Worldwide

American
Society of
Mechanical
Engineers




ASME
SETTING THE STANDARD

International
Code Council



ICC
INTERNATIONAL
CODE COUNCIL®

American
Dental
Association



ADA®

National
Electrical
Manufacturers
Association



NEMA®
Setting Standards for Excellence
www.nema.org

National Fire
Protection
Association




NFPA®

SAE International™

Society of Automotive Engineers


IEEE STANDARDS
ASSOCIATION

Institute of
Electrical and
Electronics Engineers



UL Underwriters
Laboratories Inc.®

Underwriters Laboratories Inc.



American
Society
of Civil
Engineers



ASCE®
American Society of Civil Engineers

American
Petroleum
Institute

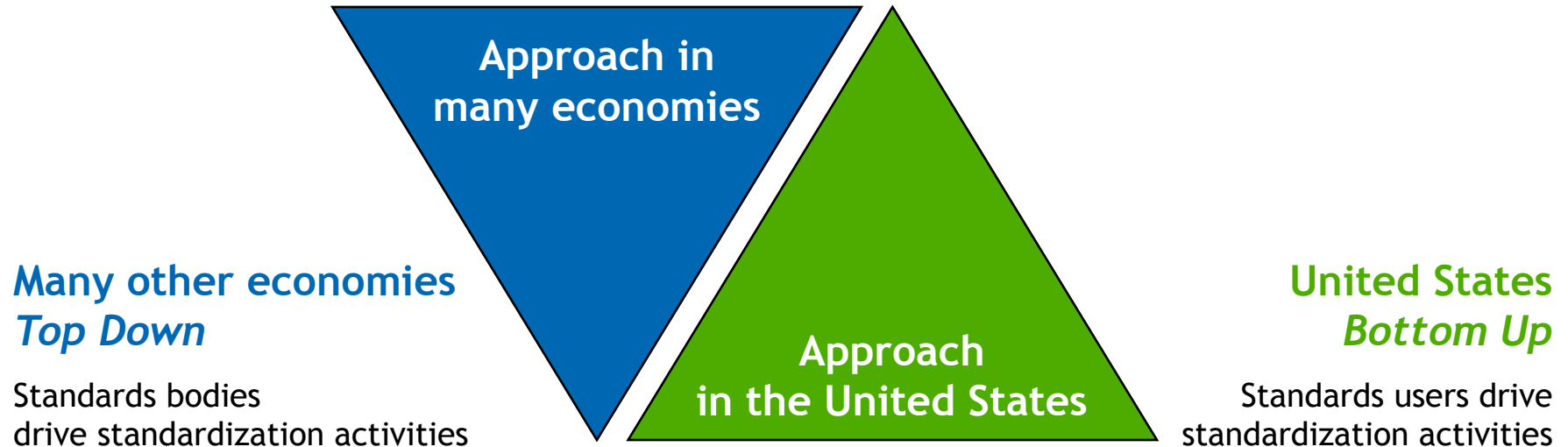


energy API

And more than 200
additional organizations



The U.S. System for Standards and Conformity Assessment System: a comparison with many other economies



- 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

Use of Standards in Regulations



- 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



Use of Conformity Assessment in Regulations



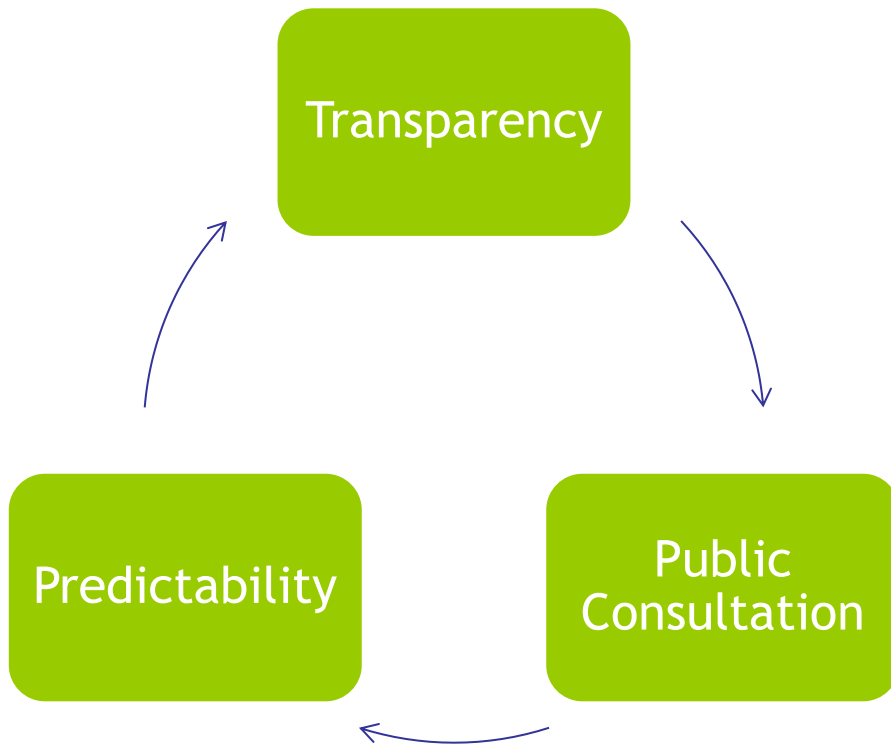
- Department of Health and Human Services established rules on the certification of Electronic Health Record Technologies pursuant to the Health IT for Economy and Clinical Health Act,
- Under the rule, HHS has designated ANSI as an approved accreditor for certifiers seeking to participate in the program
- HHS provides incentives to providers and hospitals that use products on a certified product list developed through this conformity assessment mechanism

Reliance on the private sector in post-market surveillance



- 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 a individual company/organization, or as part of a broader interest group

ANSI Provides Comments to Proposed Revision of OMB Circular A-119



A screenshot of the Federal Register website homepage. At the top, there is a navigation bar with links for Sections, Browse, Search, Policy, Learn, and Blog, along with a search box labeled 'Search Articles'. Below the navigation bar is the Federal Register logo and the text 'FEDERAL REGISTER The Daily Journal of the United States Government'. A blue banner indicates the date 'Monday, March 5th'. Below the banner is a green bar with 'Current Issue' and statistics: 108 Notices, 10 Proposed Rules, 11 Rules, 3 Presidential Documents, 3 Significant Documents, and 200 Pages. A 'Browse this & other dates' link is also present.

A screenshot of an article titled 'Regulation of Fuels and Fuel Additives' on the Federal Register website. The article is categorized under 'ENVIRONMENT' and 'Alternative Heat'. The text states: 'EPA published a direct final rule to amend the Renewable Fuel Standard program regulations. The amendments would identify additional renewable fuel production pathways and pathway components that could be used in producing qualifying renewable fuel under the Renewable Fuel Standard program.' At the bottom of the article, it says '44 NEW ARTICLES IN THIS ISSUE' and '50 COMMENT PERIODS ENDING SOON'.

RECENT BLOG POSTS

2011 Privacy Act Compilation

Posted by Michael White on February 9, 2012

A new edition of the Privacy Act Compilation is posted on our OFR.gov website. It covers all Privacy Act notices and regulations issued by agencies through 2011. The OFR's Privacy...
[Continue reading →](#)

ACUS Midnight Rules Project

Posted by Michael White on January 23, 2012

ACUS Recommendations

Posted by Michael White on January 14, 2012

- 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!



for more information

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