



Private Sector Perspective:

Key "Best Practices" that Strengthen Protection of Environment, Health and Safety while Facilitating Trade and Economic Development







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American National Standards Institute

Amman, Jordan April 26-28, 2010

Presentation Topics

- U.S. Approach to Standards and Conformance and Overview of ANSI
- U.S. Conformity Assessment
- ANSI's International Development Activities
- Overview of U.S. Best Practices



Overview of U.S. Approach to Standards and Conformance



Key Concepts

Standards

Voluntary specifications for a product, service, person, process or system. Not mandated by a government, but may be necessary for market acceptance.

Technical Regulations

Mandatory specifications, which may include (or reference) particular standards or conformity assessment procedures. Mandated and enforced by a government.

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, inspection, certification, etc.). May mandatory or voluntary.

**Collectively, these concepts may be referred to as "Standards and Conformance"



Introduction to ANSI

ANSI is an a 501(c)3 private sector organization that serves as an "Umbrella Organization" for the U.S. standards and conformance systems.



Duties and responsibilities include:

- Develop and promote policies and positions in U.S. private-sector led system
- Accredit Standards Developing Organizations and approve American National Standards (ANS)
- U.S. Representative to ISO, IEC and other international and regional bodies
- Accredit laboratories, inspection bodies, certifiers of products, personnel, management systems, and greenhouse gas emissions
- Provide standards and compliance solutions domestically and internationally





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

Members of the ANSI Federation include . . .

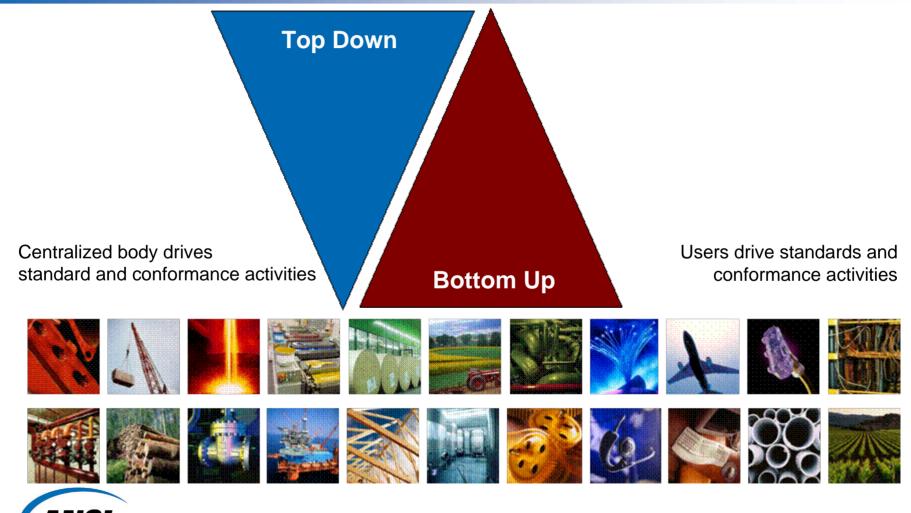
- Academia
- Individuals
- Government
- Manufacturing
- Trade Associations

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



The Bottom-up U.S. Approach

American National Standards Institute



Unique Characteristics of the U.S. Approach

- Emphasizes private-sector activities and solutions
- Relies on private-sector compliance verification for both regulatory and non-regulatory functions
- Empowers standards users (companies, consumers, etc.) to influence what standards will be developed and used in the market

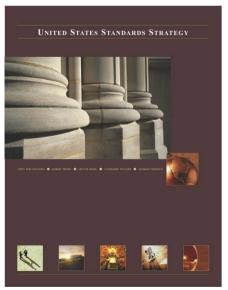




U.S. Standards System: guiding principles

Reliable - 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.us-standards-strategy.org



Guiding Principles

The U.S. endorses the globally accepted standardization principles of the World Trade Organization Technical Barriers to Trade Agreement and Related Decisions:

Transparency
Openness
Impartiality and Consensus
Effectiveness and Relevance
Coherence
Development Dimension





U.S. Standards SystemDifferent tools for developing globally-relevant standards



National Participation	Direct Participation	Consortia		
Treaty OrganizationsNon-Treaty Organizations	Nationally AcceptedInternationally Accepted			
Examples Non-Treaty: ISO, IEC Treaty: ITU, CODEX	Examples ASTM International, ASME, SAE, etc.	Examples IGRS, W3C, etc.		



U.S. Standards SystemDifferent tools for developing globally-relevant standards



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Summary of U.S. Participation in ISO and IEC

<u>ISO</u>

 Participation in 620 TCs and SCs (roughly 79% of total)

> P Memberships: 570

O Memberships: 50

 U.S. – held International Secretariats: 18% of total

<u>IEC</u>

 Participation in 153 TCs and SCs (roughly 89% of total)

> P Memberships: 153

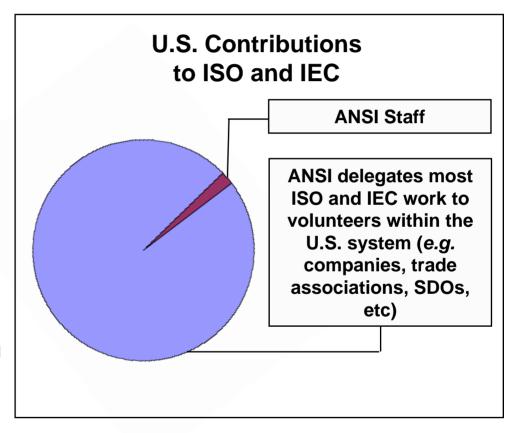
O Memberships: 0

 U.S. – held International Secretariats: 14% of total



ANSI: Coordinator for U.S. Participation

- U.S. Reps. to ISO Council / IEC CB
 - ANSI staff on ISO Council -- 1
 - USNC President on IEC Council Board -- 1
- U.S. Reps. to TMB/SMB
 - ANSI Staff 1 on TMB and 1 on SMB
 - Volunteers 1 (on SMB)
- ISO and IEC International Secretariats
 - Most U.S. held Secretariats are administered by volunteers
 - ANSI staff administer U.S. held Secretariats only at the request of ANSI constituents.
 - 13 U.S. held Secretariats are administered by ANSI staff.
- Leadership of U.S. mirror committees (TAGs)
 - Leadership positions on U.S. TAGs are held by ANSI member volunteers.
- U.S. Technical Expert Participation
 - U.S. technical contributions to ISO and IEC are provided by ANSI member volunteers.





U.S. Standards SystemDifferent tools for developing globally-relevant standards



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Standards Used in the U.S.: Accredited/Approved Standards

- ANSI is responsible for accrediting SDOs and approving standards as "American National Standards."
- National and international SDOs voluntarily choose to receive ANSI accreditation/approval (the U.S. has no legal requirement)
- Accreditation and approval do not guarantee U.S. market acceptance; individual users have complete freedom to choose which standards best suit their needs.
- ANSI accreditation and approval processes do not evaluate a standard's technical merit, but only evaluate the process by which a standard was developed.



Many American National Standards (ANS) are International Standards

<u>Criteria</u>	WTO/TBT Principles	Criteria Reflected in the ANS Process		
Transparency	☑	\square		
Openness	☑	\square		
Impartiality & Consensus				
Effectiveness & Relevance		✓*		
Coherence	☑	✓		
Development Dimension		✓**		

^{*} Although the ANS process does not directly evaluate Effectiveness & Relevance, adherence to the other ANS criteria helps to assure the effectiveness and global relevance of ANS.



^{**} Although the ANS process does not evaluate for this criteria, it is strongly encouraged in the U.S. Standards Strategy, and many SDOs engage in extensive international outreach and development activities

Examples of ANSI-Accredited SDOs

ASTM International



American Society of Mechanical **Engineers**



International Code Council



American Dental Association



National Electrical Association



National Fire Protection Association





Society of Automotive Engineers

American Society of Civil **Engineers**





American Petroleum Institute



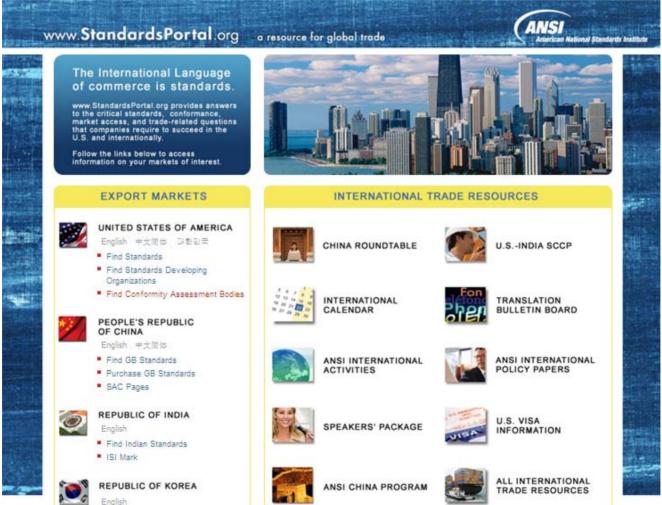


Underwriters Laboratories Inc.

And more than 200 additional organizations



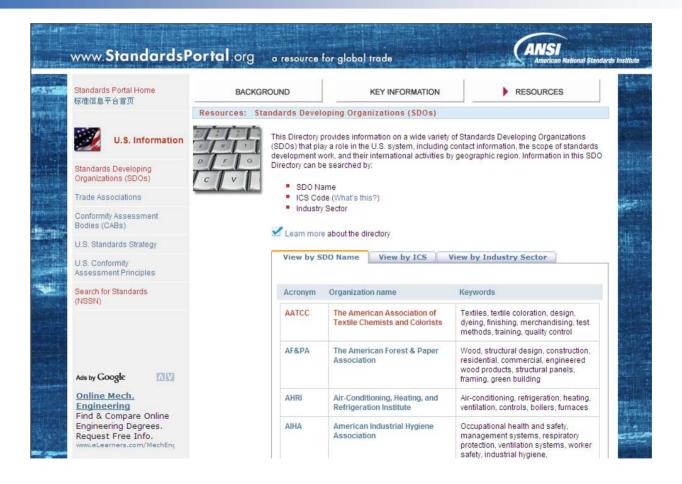
Getting Involved in U.S.-Based SDOs





. Conformity Marks Used in Korea

Getting Involved in U.S.-Based SDOs (2)





Getting Involved in U.S.-Based SDOs (3)





Getting Involved in U.S.-Based SDOs (4)



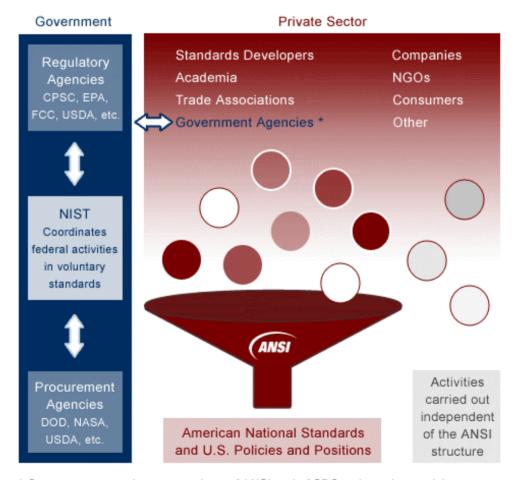


U.S. Standards System: organizational roles

	ANSI	SDOs	Companies	Consumers	Regulators/ Government Procurement	NIST
Coordinates U.S. system and policy development	4					
Independently runs standards development activities		4				
Coordinates and monitors USG use of and participation in VCS activities						4
Legal metrology and WTO-TBT enquiry point.						4
Provides technical input for standards development			4	4	4	1
Participates in U.S. policy development		4	4	4	4	4



U.S. Standards System: policy development

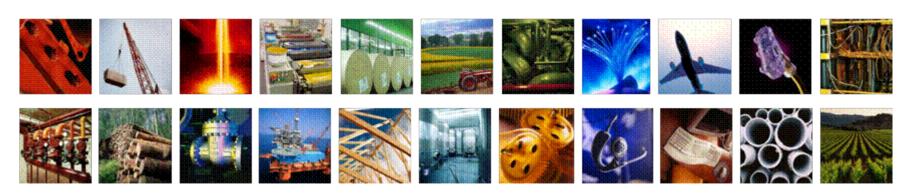




 Government agencies are members of ANSI and of SDOs. Agencies participate directly in voluntary standards development and policy setting and use voluntary standards when it supports their missions.

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

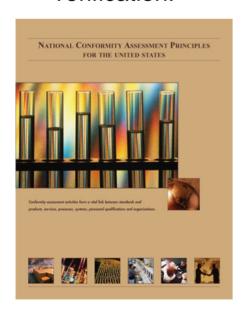




U.S. CA System: guiding principles

Reliable - Flexible - Responsive

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

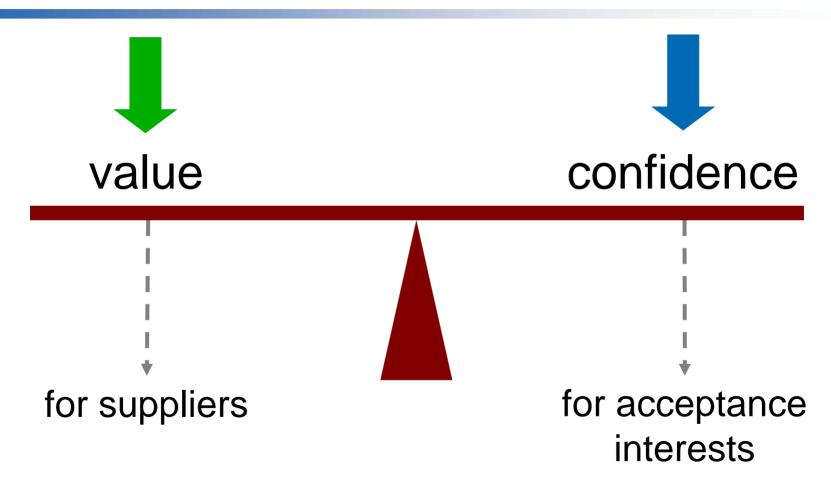


The NCAP recognize various CA approaches, including 3rd party, 2nd party and Suppliers' Declaration of Conformance (SDoC)

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

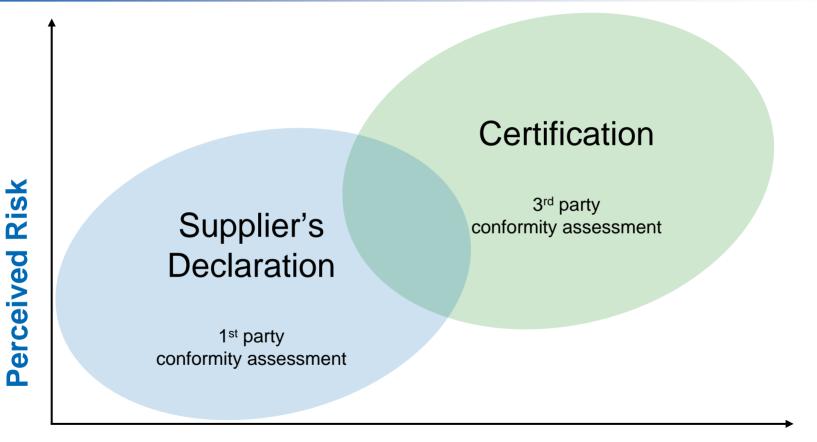


The Conformity Assessment Balance





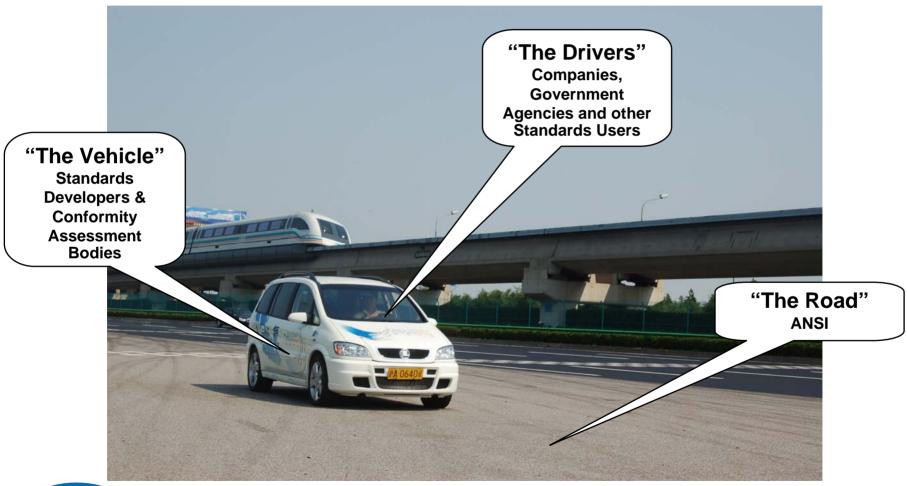
Conformity Assessment and Risk



Independence and Rigor of Conformity Assessment



Summary of the U.S. System





ANSI International Development Activities



Why StandardsPortal?

Problem:

No central resource to help companies find the standards, conformity assessment and technical regulations needed to enter and compete in target markets.

Solution:

StandardsPortal answers key questions exporters face when attempting to enter their target markets



www.StandardsPortal.org

a resource for global trade



The International Language of commerce is standards.

www.StandardsPortal.org provides answers to the critical standards, conformance, market access, and trade-related questions that companies require to succeed in the U.S. and internationally.

Follow the links below to access information on your markets of interest.



EXPORT MARKETS



UNITED STATES OF AMERICA

English 中文简体 대한민국

- Find Standards
- Find Standards Developing Organizations
- · Find Conformity Assessment Bodies



PEOPLE'S REPUBLIC OF CHINA

English 中文简体

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REPUBLIC OF INDIA

English

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REPUBLIC OF KOREA

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INTERNATIONAL TRADE RESOURCES



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U.S.-INDIA SCCP



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ANSI CHINA PROGRAM



ALL INTERNATIONAL TRADE RESOURCES



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Manufacturer Member Roundtable in China

- Forum for manufacturing companies to exchange information on key issues in China across industry sectors
- Areas of Focus: CCC Mark, China RoHS, Energy Efficiency, China's Standards Strategy, Special Equipment Regulations, etc.
- Monthly meetings held in Mandarin Chinese; alternate between Beijing and Shanghai
- Provides front-line perspectives and "Early Warning" to all ANSI full members



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SPEAKERS' PACKAGE



U.S. VISA



ANSI CHINA PROGRAM



ALL INTERNATIONAL TRADE RESOURCES











The ANSI Manufacturer Member Roundtable in China provides a forum for manufacturing companies to discuss challenges and strategies, exchange information across industry sectors, and provide perspectives on issues that affect their ability to do business in China, including:

- China Compulsory Certification (CCC) regulations
- Dealing with China's Restriction of Hazardous Substances (RoHS)
- China's new energy efficiency requirements
- Chinese special equipment regulations
- China's proposed Information Security certification
- Participation in Chinese standards development
- And other priority issues for companies doing business

Monthly meetings of the Roundtable are conducted primarily in Mandarin Chinese, alternate between Beijing and Shanghai, and frequently feature briefings from PRC government officials and other top experts. Participation in these meetings is a benefit for ANSI full company members that manufacture or sell physical products in China.

The Roundtable also serves the broader ANSI membership by providing front-line insights and early warning on developments in China related to standards and conformance. While not a policy committee itself, the Roundtable informs ANSI's policy committees with front-line perspectives on top issues in China.

Monthly reports from the ANSI Manufacturer Member Roundtable in China are made available as a benefit to all ANSI full members.

Learn more at www.standardsportal.org.

FOR MORE INFORMATION

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International Guest Researcher Program (IGRP)

- Through IGRP, ANSI hosts international government officials and leaders with the aim of fostering mutual understanding and cooperation
- Recent Participants:
 - Ms. Xu Dongmei, China Electronics Standardization Institute (CESI)
 - Dr. Li Aixian (Ashley), China National Institute for Standardization (CNIS)
 - Dr. Wiro Lee and Dr. Sangme Han, Korea Agency for Technology and Standards (KATS)



U.S.-India Standards and Conformance Cooperation Program (SCCP)

Key Organizations

- Funding Agency –U.S. Trade and Development Agency (<u>www.ustda.gov</u>)
- Grantee –Confederation of Indian Industry (<u>www.ciionline.org</u>)
- Contractor American National Standards Institute (<u>www.ansi.org</u>)
- An SCCP Advisory Panel will provide recommendations as to the direction of the program and will be comprised of individuals from U.S. government and private sector organizations



U.S.-India Standards and Conformance Cooperation Program (SCCP)

Program Components

- Expand StandardsPortal to include information on India
- Create additional U.S. information on StandardsPortal
- Create Directories on the standards, conformity assessment, and technical regulations used by U.S. industry for at least five (5) industry sectors
- Provide matching funding and support for at least five (5) sectoral workshops on China
 - Proposed Sectors: Fire Protection, Aerospace, Biometrics, Agricultural Equipment, Safe Storage of LNG, PV Technologies



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CHINA ROUNDTABLE



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ALL INTERNATIONAL TRADE RESOURCES



U.S.-INDIA STANDARDS AND CONFORMANCE **COOPERATION PROGRAM**



















Sponsored by the U.S. Trade Development Agency (USTDA) and coordinated by the American National Standards Institute (ANSI) and the Confederation of Indian Industry (CII), the program will help continue the recent increase in Indo-U.S. trade and facilitate technical dialogue between targeted industry sectors. The program will be carried out in close cooperation with the Bureau of Indian Standards (BIS).

The U.S.-India SCCP will include three main components:

- Development of a U.S. Standards Directory which will include information on standards, conformance procedures, technical regulations, and trade capacity building initiatives for five key sectors
- Standards and Conformance Workshops sponsored and co-organized by U.S. private-sector organizations and designed to provide targeted technical exchange between small groups of industry stakeholders to address specific issues related to standards and conformance
- Expansion of StandardsPortal (www.standardsportal.org) to include new features such as expanded information on the standards and conformance systems in India, a guide to U.S. best practices, a directory of conformance bodies in the U.S., and a directory of U.S. regulatory agencies

To learn more about the U.S.-India SCCP or to express interest in sponsoring or participating in a workshop, please visit www.standardsportal.org/us-indiascep.







www.standardsportal.org/us-indiasccp



Overview of U.S. Best Practices for Standards and Conformance



Overview of Key "Best Practices"

In the U.S., these key "best practices" help strengthen protection of environment, health and safety (EHS) while facilitating trade and economic development:

- Transparency
- Use of Voluntary Consensus Standards in Regulations
- Use of Private Sector Conformity Assessment to Verify Compliance with Regulations
- Non-Regulatory Approaches for the Protection of Environment, Health and Safety (EHS)



Transparency

Benefits

- Leverages input from all stakeholders (government, companies, consumers, etc.) so that the best and most effective solutions are leveraged
- Allows "early warning" to companies, allowing them to better integrate new requirements into their business cycles



Transparency (2)

Mechanisms used in the U.S.

- WTO Notifications for Technical Regulations
- Public consultation and feedback for national standards and regulations
- National Gazette for regulatory updates (i.e. "Federal Register")
- Publication of Regulatory Agenda (i.e. "Unified Agenda")
- Centralized listings of regulations, national standards and other information (i.e. "Code of Federal Regulations"; "NSSN"; etc.)



Use of Voluntary Consensus Standards in Regulations

Benefits

- Can reduce costs for regulators
- Encourages market-relevant regulations
- Facilitates regulatory harmonization when international standards are referenced



Use of Voluntary Consensus Standards in Regulations (2)

Mechanisms used in the U.S.

- U.S. law and policies call federal regulatory agencies to:
 - Use technical standards developed or adopted by voluntary consensus standards bodies for regulation or procurement if they are available
 - consult with, and participate in private sector standards developing activities of voluntary, private sector, consensus standards bodies
 - Annually report any use of government-unique standards and provide an explanation to Congress with the reasons for doing so.



Use of Private Sector Conformity Assessment to Verify Compliance with Regulations

Benefits

- Can reduce costs for regulators
- Can reduce testing, certification and inspection costs for industry
- Can reduce unnecessary delays to market and add predictability to the business cycle



Use of Private Sector Conformity Assessment to Verify Compliance with Regulations (2)

Mechanisms used in the U.S.

- U.S. law encourages government agencies to coordinate their conformity assessment activities with the private sector to eliminate unnecessary duplication and complexity
- Individual federal agencies have autonomy to chose how to work with the private sector



Non-Regulatory Approaches for the Protection of Environment, Health and Safety (EHS)

Benefits

- Where appropriate, non-regulatory approaches can create flexibility for government agencies and companies to find new and creative solutions for addressing EHS
- Can create "EHS Protection Culture" rather than focus on meeting minimum requirements



Non-Regulatory Approaches for the Protection of Environment, Health and Safety (2)

Mechanisms

- Requirements that risk assessment and impact analysis be conducted prior to regulation
- Incentive programs organized by regulators
- Reliance on private sector standards and other programs where they adequately address risk



Questions or Comments?



For more information:



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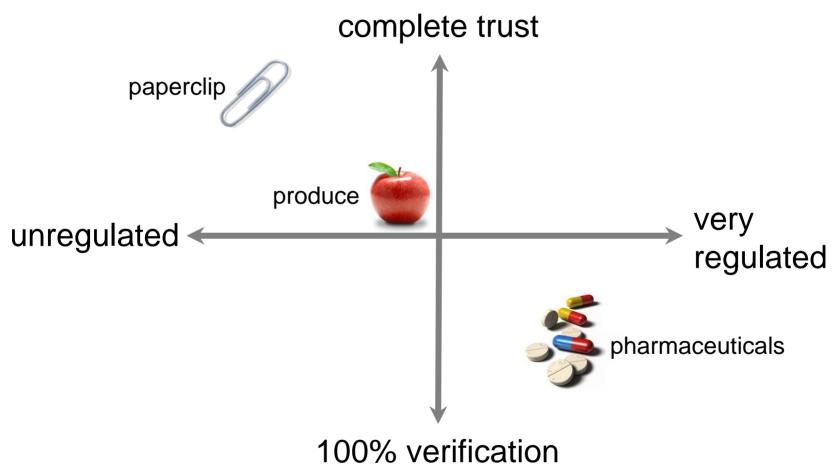
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Additional Slides on Conformity Assessment

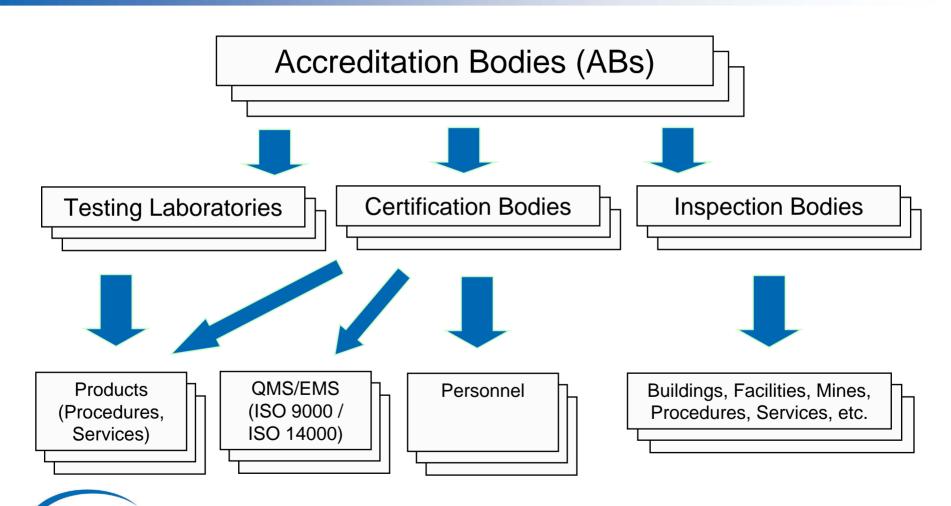


Confidence/Regulation Spectrum





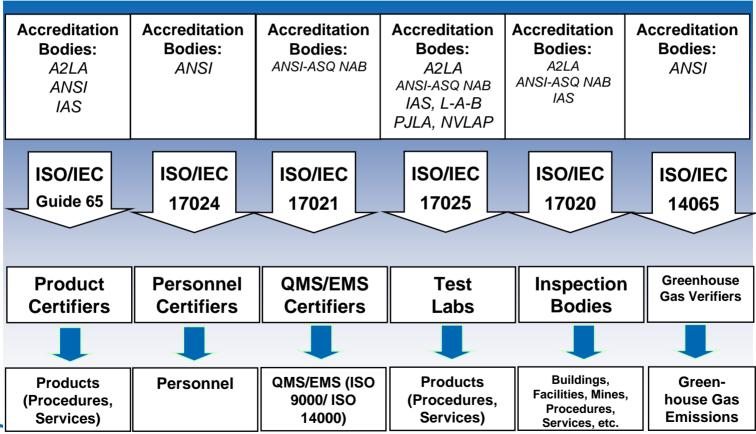
3rd Party Conformity Assessment System Structure



American National Standards Institute

Examples of Accreditation Programs in the United States

Conformity Assessment (ISO/IEC 17011)









Additional Slides on U.S. Resources



Where can I find American National Standards?

- To search by **key word**:
 - ➤ Go to <u>www.nssn.org</u>
 - Click on Find Title, Abstract or Keyword
 - > Type the keyword (i.e. "construction materials and building") in the search box
 - > Select Go Find It



A NATIONAL RES

SEARCH FOR STANDARDS

construction materials and building

GO FIND IT



Where can I find American National Standards?

- To search by **Document Number**:
 - ➤ Go to <u>www.nssn.org</u>
 - Click on Find Document Number
 - > Type the document number (e.g. "ASTM 963" or just "963") in the search box



A NATIONAL RE

SEARCH FOR STANDARDS

91

GO FIND IT



FIND DOCUMENT NUMBER



Where can I find ANSI accredited SDOs and scopes?

- Search ANSI Accredited Programs:
 - Go to http://www.ansi.org/about_ansi/accredited_programs/overview.aspx ?menuid=1
 - Click ANSI-Accredited Standard Developers



HOME CONTACT US HELP

Search >> 90

	o	
Access	Standards	

Overview
Introduction to ANSI
History
Offices

Street Address and Directions Local Accommodations

Staff Directory

Structure and Management

Organization Chart
Board of Directors
Code of Ethics
Constitution and By-Laws
Annual Report
ANSI Accredited Programs
Product Certification

ANSI Accredited Programs

Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks (As defined in ISO/IEC Guide 2:1996)

One of ANSI's important functions is accreditation. ANSI accredits standards developers, certification bodies and technical advisory groups (TAGs) to both the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

ACCREDITED STANDARDIZATION ACTIVITIES

- ANSI-Accredited Standard Developers
 A list of standardization bodies accredited by ANSI to develop, maintain and withdraw American National Standards.
- U.S. Technical Advisory Groups (TAGs) to ISO Technical Committees



Where can I find ANSI accredited SDOs and scopes?



Accredited Standards Developers

Developer Name: 3-A Sanitary Standards, Inc.

Acronym: 3-A

Committee Title: N/A Secretariat: N/A

Contact: Timothy Rugh

Title: CAE, Executive Director

Address: 1451 Dolley Madison Boulevard Suite 210

McLean, VA 22101

Phone: (703) 790-0295 Fax: (703) 761-4334 E-Mail: trugh@3-a.org WWW URL: http://www.3-a.org/

Scope: 3-A Sanitary Standards, Inc. seeks to formulate voluntary consensus sanitary standards and accepted practices for equipment and systems used to produce, process, and package food, beverages and pharmaceutical products.

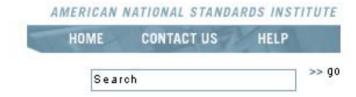
Over a history of more than 80 years, the list of 3-A Standards has grown to nearly 70 individual standards for products, components and systems and nine Accepted Practices



Where can I find information for commenting on proposed U.S. voluntary standards?

- Search ANSI Standards Action:
 - Go to http://www.ansi.org/publicreview
 - Click on Standards Action





Access Standards About ANSI Membership Standards Activities Overview International Policy Papers and Charts U.S. Standards Strategy Public Review and Comment Standards Action ANSI Procedural Revisions Accreditation Actions Domestic Programs (American National

American National Standards Institute

Public Review and Comment

Openness is a very important feature of the U.S. voluntary standardization system. To help ensure such openness, ANSI procedures require a public review and comment period for American National Standards activities, changes to ANSI's own procedural documents, and for any procedures submitted for accreditation or reaccreditation by a standards developer or U.S. Technical Advisory Group (TAG) to ISO.

Standards Action is the Institute's key public review vehicle. Published weekly, it provides members and the public with timely, accurate information and enables effective participation in the standards development process - both in this country and internationally.



Where can I find information for commenting on proposed U.S. voluntary standards?

- > To view the current publication schedule, click on View Current Standards Action publication schedule.
- > To view current calls for comment, click on **Current Standards Action** issues



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Congressional Standards

Update Archive

MY ANSI

Where can I find notification of proposed U.S. regulations?

- Search the Federal Register by keyword:
 - > Go to http://www.gpoaccess.gov/fr/index.html
 - > Type the keyword (i.e. "construction materials and building") in the search box
 - Select Submit



DATABASE FEATURES

- FR Main Page
- Browse
- Simple Search
- Advanced Search
- Retrieve an FR Page

The Federal Register (FR): Main Page

Published by the Office of the Federal Register, National Archives and Records Administration (NARA), the Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents. More.

2008 (Volume 73) Only

Quick Search: (ex: "page 12345", "40 CFR part 55", "environmental protection agency" AND superfund)

construction materials and building

Submit [Search Tips]

Where can I find notification of proposed U.S. regulations?

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 - > Type the agency name (i.e. "Environmental Protection Agency") in the search box

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Slide 67

Select Submit



Where can I find notification of proposed U.S. regulations?

- Search the Federal Register by CFR Part Number:
 - Go to http://www.gpoaccess.gov/fr/index.html
 - > Type the CFR Part Number (i.e. "21 CFR Part 33") in the search box
 - > Select Submit



Where can I find responses to comments on proposed U.S. regulations?

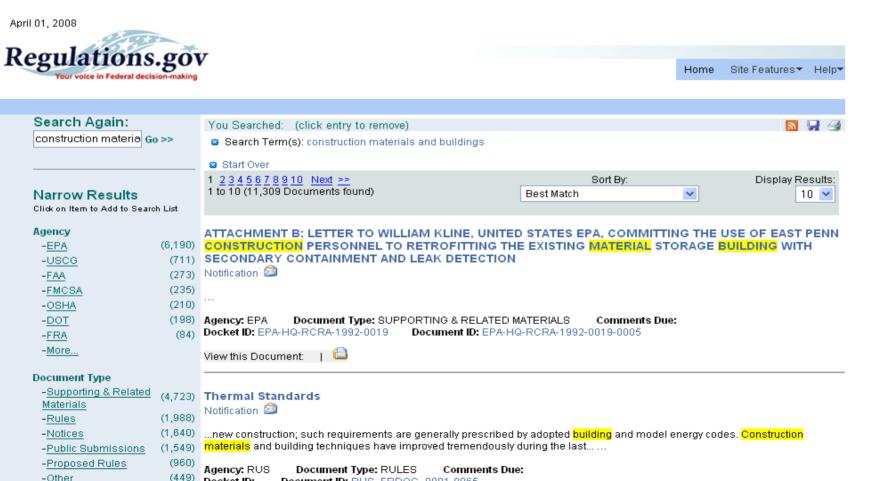
- Search <u>www.regulations.gov</u> by **keyword:**
 - Enter a keyword (i.e. "construction materials and buildings" in the text box under **Search** or **Comment or Submission.**
 - > Click Go.





Where can I find responses to comments on proposed U.S. regulations?

Results for the keyword search "Construction materials and buildings":



Where can I find responses to comments on proposed U.S. regulations?

- Search <u>www.regulations.gov</u> with other criteria:
 - Under the More Search Options tab, click Go.
 OR
 - Under the More Search Options, select an Advanced Docket or Document Search and select click here.

Regulations.gov

What Is on This Site MORE SEARCH OPTIONS SEARCH COMMENT OR SUBMISSION Search all documents by entering a Enter a keyword, phrase, or other term to Need more help finding what you're looking How to Use This Site keyword, phrase, identification number, or find documents accepting comments or to for? Click 'Go' for more search options. Go other term. file a submission. Site Features Looking for our old searches? Go >> G0 >> Advanced Docket Search click here. Advanced Document Search click here.



Links of Interest

Where can I find regulations in force in the U.S?

- Search the Code of Federal Regulations by keyword:
 - Go to http://www.gpoaccess.gov/cfr/index.html
 - > Type the keyword (i.e. "construction materials and building") in the search box
 - Select Submit



DATABASE FEATURES

- CFR Main Page
- Browse and/or Search
- Retrieve by CFR Citation
- Search Tips

Code of Federal Regulations (CFR): Main Page

The Code of Federal Regulations (CFR) is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation. Each volume of the CFR is updated once each calendar year and is issued on a quarterly basis. More.

©ole of Federal Regulations

Most Current 50 Titles (2006-2007)

Quick Search: (ex: title 20 part 404, prescriptions AND "drug enforcement administration")
 construction materials and building

Submit [Search Tips]

- Regulator risk assessments can be found on the websites of individual regulatory agencies.
 - Search a search engine (e.g. Google) for the U.S. regulatory agency from which a risk assessment is required.



Environmental Protection Agency

Google Search I'm Feeling Lucky

Advanced Search
Preferences
Language Tools

A Cool World: Enjoy a rosier future as a Virgle Pioneer.

Click on the relevant link. In this case, it is **U.S. Environmental Protection Agency**



Environmental Protection Agency

Search

Advanced Search Preferences

Web News Personalized Results 1 - 10 of about 14.

U.S. Environmental Protection Agency

Current issues information (Sept. 11, anthrax), reports on 17 key environmental topics from air to water, kids page, laws/regulations and further official ...

www.epa.gov/ - 45k - Cached - Similar pages - Note this

Quick Finder Careers

Air Laws, Regulations

Information Sources Water

Contact Us About EPA

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Enter risk assessment in the search text box and click Go:



This search leads to the **EPS's Risk Assessment Portal.**Click on the link.

EPA Newsroom

Browse EPA Topics

Laws, Regulations, & Dockets

Where You Live

Frequent Questions

Information Sources

Educational Resources

About EPA

Programs

Partnerships

Business Opportnities

Start here for risk assessment

- Air -> Air Pollution Effects -> Risk Assessment
- Cleanup -> Superfund -> Risk Assessment
- Environmental Management -> Risk Assessment -> (Ecological Risk Assessment, Hun
- Pesticides -> Pesticide Effects -> Risk Assessment
- Radiation And Radioactivity -> Radiation Effects -> Risk Assessment
- Radiation And Radioactivity -> Radiation Protection -> Risk Assessment
- Research -> Risk Assessment
- Treatment/Control -> Waste Treatment -> Risk Assessment
- Wastes -> Risk Assessment
- Wastes -> Waste Treatment -> Risk Assessment

Results 1 - 10 of 143,312 for risk assessment. This query was conducted agai

[1] EPA's Risk Assessment Portal

This site provides basic information about environmental **risk assessments** for the public.

http://www.epa.gov/risk (HTML)

- This portal provides information on risk assessments and draft and final EPA risk assessments.
- Remember: when in doubt, your national TBT Enquiry Point can request risk assessments from U.S. regulators through the U.S. enquiry point.

What's new in risk assessment



Draft Guidance & Tools Available for Public Comment and/or Peer Review

- 03/08: <u>Toxicological Review of Propionaldehyde (IRIS External Review Draft)</u>
- 03/08: <u>Toxicological Review of 2-Hexanone (IRIS External Review Draft)</u>
- 02/08: Framework for Determining a Mutagenic Mode of Action for Carcinogenicity
- 01/08: <u>Draft FY2009 Brownfields Assessment Grant Guidelines (PDF)</u>
 (82 pp, 337K, <u>about PDF</u>)

Final Guidance & Tools

- 01/08: Methods/Indicators for Determining when Metals are the Cause of Biological Impairments of Rivers and Streams
- 02/08: Older adult physiological parameters database
- 10/07: Benchmark Dose Software (BMDS)
- 03/07: Framework for Metals Risk Assessment

More tools & quidance

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Where can I find information about standards referenced in technical regulations?

- Search <u>www.standards.gov</u> for information on:
 - The National Technology Transfer and Advancement Act (NTTAA)
 - ➤ The OMB Circular A-119
 - How voluntary standards are used in regulations
 - Standards Incorporated in Laws, Policies, and Regulations (SIBR Database)
 - Proposed and Adopted State Legislation



Where can I find Standards referenced in regulations and in procurement?

- Search the SIBR Database on <u>www.standards.gov</u>:
 - In the left hand column, under SIBR Search, select a Quick Link or search by keyword.



Standards Incorporated by Reference (SIBR) Database Home Page

The **Standards Incorporated by Reference (SIBR) Database** includes the voluntary consensus standards, government unique standards, private industry standards, and international standards referenced in the Code of Federal Regulations (CFR) and those used by U.S. Federal Government Agencies in their procurement activities.

The Code of Federal Regulations (CFR) is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation. Each volume of the <u>CFR</u> is updated once each calendar year and is issued on a guarterly basis. More data on the CFR can be found at the GPO Access Home Page.

In this database, Regulatory Standards Incorporated by Reference are sometimes referred to as as R-SIBR and Procurement Standards Incorporated by Reference as P-SIBR.

This database is continually being updated as the <u>CFR</u> changes, procurement policy, requirements, and standards change, and new standards are incorporated. If you find any errors, ommissions, or want a new standard to be considered, then please notify the SIBR Administrator at sibr@nist.gov using the <u>Contact</u> Us link.

To begin using the SIBR Database select a Quick Link, either one of the Procurement, Regulatory, or Help tabs, or Click this Procurement Link, Regulatory Link, or Help Link.

Where can I find Standards referenced in regulations and in procurement?

- > To search by keyword:
 - select Regulatory or Procurement from the dropdown list
 - Enter a keyword (i.e. "Construction materials and building" in the search box.
 - Click Go.



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Additional Slides on ANSI Essential Requirements



What are the ANSI Essential Requirements?

- **Balance:** The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance.
- Consensus: Substantial agreement (more than a simple majority, but not necessarily unanimity) has been reached by directly and materially affected interest categories. Consensus requires that all views and objections be considered, and that an effort be made toward their resolution.
- **Due Process:** Any person (organization, company, government agency, individual, etc.) with a direct and material interest has a right to participate by: a) expressing a position and its basis, b) having that position considered, and c) having the right to appeal.



What are the ANSI Essential Requirements?

- Openness/Transparency: Participation shall be open to all persons who are directly and materially affected by the activity in question. Records and processes shall be open and publicly available.
- Lack of dominance: The standards development process shall not be dominated by any single interest category, individual or organization.
- Coordination and harmonization: Good faith efforts shall be made to resolve potential conflicts between and among existing American National Standards and candidate American National Standards.
- Notification of standards development: Notification of standards activity shall be announced in suitable media as appropriate to demonstrate an opportunity for participation by all directly and materially affected persons.



What are the ANSI Essential Requirements Used For?

ANSI Essential Requirements are used to:

- Distinguish American National Standards (ANS)
- Accredit the standards development processes of SDOs



How is Compliance Evaluated?

- The ANSI Board of Standards Review (BSR) approves standards as American National Standards (ANS).
- The ANSI BSR approval of a standard as an ANS is based on evidence of *procedural* compliance as provided by the standards developer. ANSI approval does not indicate that the ANSI BSR (or any other committee within ANSI) has reviewed the *technical* content of the document.
- Approval as an ANS is based on a review of evidence of compliance with accredited procedures, i.e., the process by which the technical content was developed.



How is Compliance Evaluated?

- Criteria of the American National Standards process include:
 - > Consensus on a proposed standard by a group or "consensus body" that includes representatives from materially affected and interested parties
 - Broad-based public review and comment on draft standards
 - Consideration of and response to comments submitted by voting members of the relevant consensus body and by public review commenters
 - Incorporation of approved changes into a draft standard
 - The right to appeal by any participant that believes that due process principles were not sufficiently respected during the standards development in accordance with the ANSI-accredited procedures of the standards developer.



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 - Incorporation of approved changes into a draft standard
 - > The right to appeal by any participant that believes that due process principles were not sufficiently respected during the standards development in accordance with the ANSI-accredited procedures of the standards developer.



How is Continued Compliance Verified?

- Reaccreditation Requirement: whenever procedures change, they must be submitted to ANSI
- Review by ANSI Board of Standards Review: any standard for which unresolved negative votes or public comments exist are given a procedural review.
- Audit: procedural audit every 5 years; special audits for cause as needed.
- Annual Compliance Statement; all ANSI-Accredited Standards Developers are required to submit a certification of continued compliance with the ANSI Essential Requirements.



Why do U.S. companies seek ANS distinction for their standards?

- To boost consumer confidence: The ANS distinction reassures consumers and other users that the product they are using has been subject to <u>neutral third-party oversight</u>.
- To create brand name recognition: The ANS distinction may provide U.S. companies with a competitive edge.
- To respond to de facto industry requirements: Some industry sectors may be required to pursue the ANS distinction simply because their major competitors have chosen to do so. This is typically the case for high-risk sectors.
- To minimize legal risk.
- To obtain government recognition as ANS approval indicates preferred government due process considerations have been satisfied.

