

Welcome

Using Standards in Regulation

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ASTM International

Objectives for this Presentation

- Introduction to ASTM International
- Explain why and how standards are used in regulation in the United States
- How to obtain information
- Domestic and international examples
- Final thoughts

About ASTM International

- Established 1898
- Provides an open forum for developing voluntary consensus standards used globally
- Non-profit, non-government organization funded primarily through the sale of its publications

About ASTM International

- Currently 135 technical committees serve 90 industry sectors
- Publishes over 12,000 standards and various technical publications
- Approximately 170 staff provide support
- Over 32,000 members participating from over 115 nations

About ASTM International

- Approximately 350 ASTM International standards are cited in the model codes, referenced cumulatively over 1300 times
- Over 2000 ASTM International standards are used as the basis of or cited in the legislation of over 50 nations

Using Standards in Regulation

How are Standards Used in Legislation?

- There is no single U.S. government agency that has control over standards
- Standards may be cited in the legislation or may be cited by the agency charged with implementing the legislation.

How Are Standards Used in Legislation?

- Used for regulation
- Typically set health, safety or environmental criteria, for example
 - U.S. Food and Drug Administration
 - U.S. Environmental Protection Agency
- Used for procurement
- Sets the requirements that must be met by those supplying to the government, for example
 - U.S. Department of Housing and Urban Development
 - U.S. Department of Defense

Who Makes the Decision to Use a Private Sector Standard?

- Decentralized system of selecting standards by federal agencies. Each agency asks:
 - Does a standard that might meet the agency's needs currently exist in the private sector?
 - If such standards exist, which private sector standard meets the agency's needs best?
 - How will the agency ensure compliance with and/or enforcement of the standard?

Why Use Private Sector Standards?

- National Technology Transfer and Advancement Act (Public Law 104-113)
 - Minimizes cost to the government
 - In standards development
 - Procurement of goods and services
 - Eliminates duplication of effort and of standards
 - Increases private sector acceptance of regulation
 - Furthers the policy of the Government's reliance on the private sector to supply goods and services

About the NTTAA

- Encourages federal agencies to use public sector standards, where appropriate.
- Encourages federal agencies to participate in the development of the private sector standards
- Federal agencies must explain why they write their own standards rather than use a private sector standard

Additional Supporting Legislation

- **Defense Authorization Bill of 2003 – ANSI Amendment (Public Law 107-107)**
 - Permits the use of public funds to pay for membership and participation on private sector activities such as standards development

Agency Specific Directives

- Some federal agencies have additional legislation or directives urging the use of private sector standards. For example
 - Food and Drug Modernization Act
 - Department of Defense

Regulatory Agency

■ U.S. Food and Drug Administration

- Food and Drug Administration Modernization Act indicates that the product manufacturer “may declare conformity” to “recognized” standards to meet some or all regulatory requirements
- FDA publishes an annual list of “Recognized Medical Device Standards”
- Includes deviations from the standard contained in a Supplementary Data Sheet

Procurement Agency

■ U.S. Department of Defense

- MILSPEC and MILSTD reform policy
 - **Use of Non-Government Standards:** I encourage the Under Secretary of Defense (Acquisition and Technology) to form partnerships with industry associations to develop non-government standards for replacement of military standards where practicable.

--Defense Secretary William J. Perry (6/94)

Are Private Sector Standards Being Used?

- According to the National Institute of Standards and Technology
 - 7985 citations of standards incorporated by reference for regulation; 6600(~83%) are private sector standards
 - 10,559 citations of standards incorporated by reference for procurement

Federal Government's Role...

- ...in private sector standardization
 - Government is a standards user
 - In product purchases and by incorporating standards by reference
 - Government representatives contribute knowledge to standards development as an equal partner
 - Govern laboratories participate in testing and contribute data to the content of private sector standards

Benefits of Private Sector Standardization

- Economical forum for all stakeholders
- Open, neutral and balanced forum
- Private sector provides all administration
- Reflects the needs of the marketplace
- Ensures regular review and revision
- Facilitates discussion of new technologies
- Encourages round-robin testing
- Manages editing, marketing and distribution of codes and standards

This Practice Is Not Unique

- Other nations report using private sector standards in regulation and legislation. An example (specific to ASTM International)
 - 50 nations use ASTM standards as the basis of a national standard or by reference in that nation's regulations
 - Over 2000 ASTM standards from 85 technical committees are used for this purpose.

China's Use of Private Sector Standards

- Determined from the WTO enquiry point for the United States
- China uses 490 standards from 69 ASTM International technical committees as the basis of its national standards

Where to Find Information

■ About U.S. regulations

- Code of Federal Regulations
- Lists the codification of the general and permanent rules published in the Federal Register by executive departments and agencies of the U.S. federal government
- <http://www.gpo.gov/nara/cfr.index.html>

Where to Find Information

- About U.S. legislation and ongoing modifications, new rulemaking, etc.
- Federal Register
- The official daily federal publication for rules, proposed rules, and notices of federal agencies and organizations
 - http://www.gpo.gov/su_doc/aces/aces140.html

Where to Find Information

■ National enquiry point

- Each member must establish an enquiry point which is able to answer all reasonable enquiries from other members and interested parties as well as to provide, relevant documents.
- Peoples Republic of China Enquiry Point Research Center, State General Administration of the People's Republic of China for Quality, Supervision and Quarantine (AQSIQ)

Where to Obtain Information

- About standards
- Standards.gov (<http://www.standards.gov>)
 - One stop location for information related to use of voluntary consensus standards
 - Each federal agency has information on standards (Standards.gov provides links to agency sites)
- NSSN (<http://www.nssn.org>)
 - A central point to search standards information from multiple sources

Where to Obtain Information

- About standards...
- Websites of individual standards developers
 - For example, www.astm.org
 - Use the “Tracker Service” to receive free weekly email alerts about new standards or new work items
 - You choose the information you wish to view and identify the relevant sectors

Applying the practice in a local jurisdiction

Construction Codes and Standards

Description of Codes

- Codes state when and where something must be done in construction
 - For example, ICC Building Code states...
 - **1507.15 Liquid-applied coatings.** The installation of liquid-applied coatings shall comply with the provision of this section
 - **1507.15.1 Slope.** Liquid-applied roofs shall have a design slope of a minimum of one-fourth unit vertical in 12 units horizontal (2-percent slope)

Description of Standards

- Standards are referenced by the codes and provide the specifications for materials, products and systems, or provide instruction on application or installation.
 - For example, ICC Building Code states
 - **1507.15.2 Material standards.** Liquid-applied roof coatings shall comply with ASTM C836, ASTM C957, ASTM D6083, ASTM D1227 or ASTM D3468.

Why do Codes Cite Standards?

- Clarify specific requirements
- Reflect the latest technology in materials and procedures
- Provide a common reference to facilitate the flow of goods and services
- Gain the benefit of the technical research contained with the standard without having specific expertise on the topic of the standard

Why do Codes Cite Standards?

- For convenience
- To incorporate technological advances
- For efficiency and economic advantages
- To incorporate safety aspects contained in the standards

A Few Final Thoughts

■ In the past...

- ASTM joined the China Association for Standards in publishing a Chinese language version of *Standardization News* and the 9th edition of *ASTM Dictionary of Science and Engineering*

Moving Forward

- ASTM and SAC recently signed a Memorandum of Understanding
- ASTM has also signed agreements of cooperation with the China National Institute for Standardization and the Shanghai Institute of Standardization.

- The agreements will serve as bridges between global and Chinese enterprises. The agreements provide
 - Membership
 - Access to ASTM Standards
 - Cooperation in training
 - Hosting of interns at ASTM International

Thank you for your participation!

We look forward to increased
Cooperation with China

Questions?

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