

NIST

Standards Coordination Office

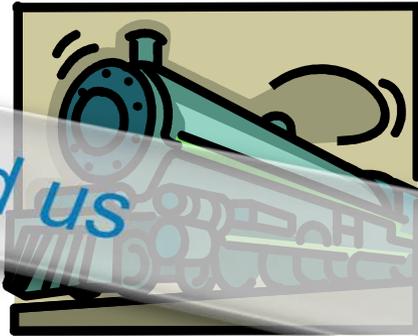
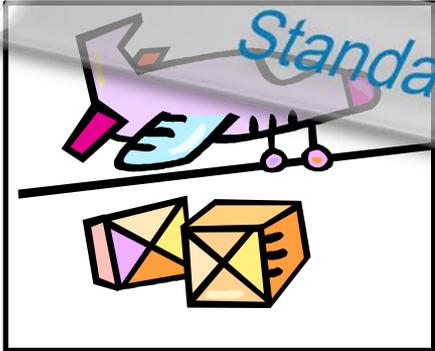
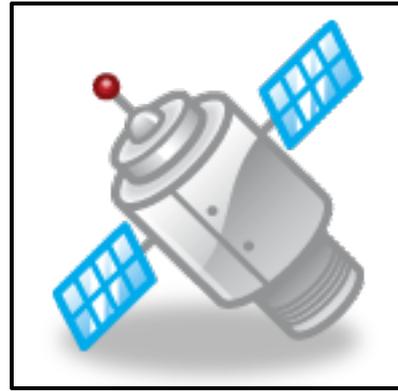


Fundamentals of Standards

June 14, 2012

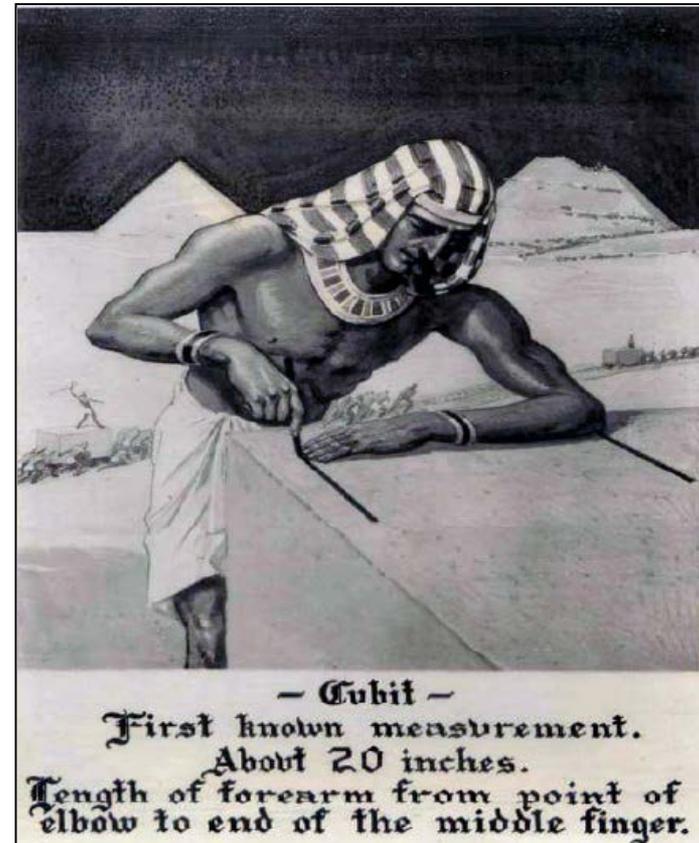
Today's Discussion

- Standards: A Historical Perspective
- Key Terms
- U.S. Standards System
- Key Players and Organizations

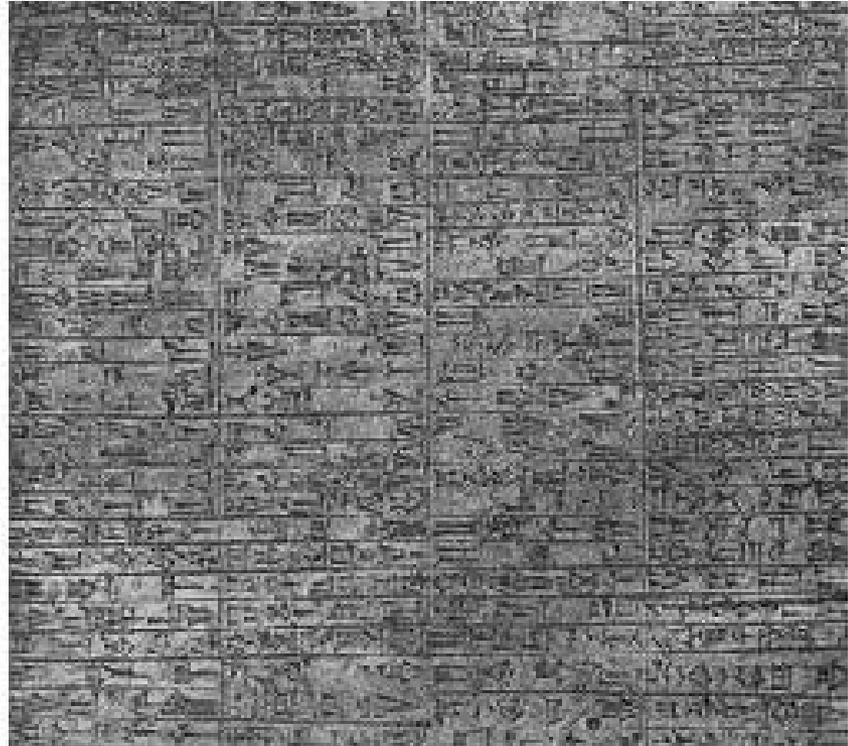


Standards are all around us

Standards in History



Standards in History



Early Drivers for Standards



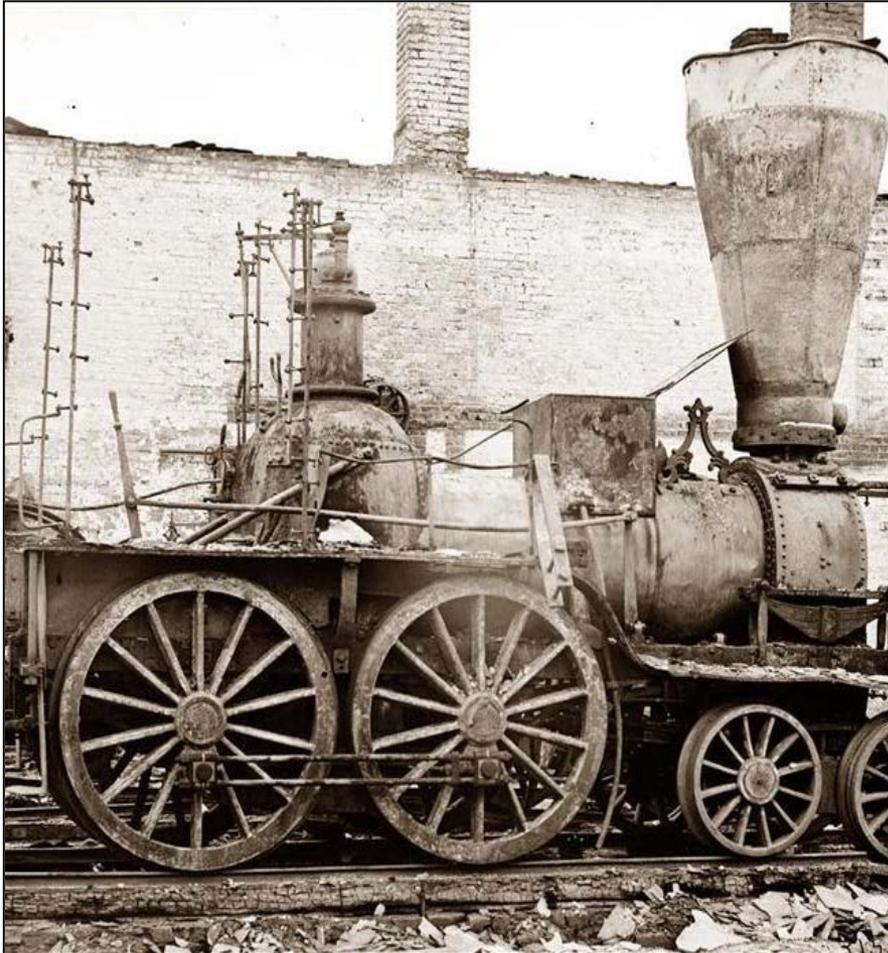
Baltimore
Fire of 1904

Early Drivers for Standards



New York City
Triangle Shirtwaist
Fire of 1911

Early Drivers for Standards



Uniform Practice
in Manufacture
of Train Rails
and Wheels

Key Terms

STANDARDS

Technical specifications for a product, service, person, process or system with which *compliance is voluntary*

TECHNICAL REGULATIONS

Technical specifications for a product, service, person, process or system with which *compliance is mandatory*

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, certification, inspection)

Definitions of a Standard (1)

Document, established by consensus and approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. Note. Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits. (ISO/IEC Guide 2:1994)

Document, approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. (WTO TBT Agreement of 1995)

Definitions of a Standard (2)

Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices. (NTTAA of 1995 and OMB Circular A-119 of 1998)

Market-driven technical specification for a product, service, person, process or system with which compliance is voluntary. (Anonymous)

How voluntary is a voluntary standard?

- The term voluntary creates confusion
- Voluntary because ...
 - developed by private sector, for market needs
 - not legally binding
 - created by participants who freely contribute and participate usually for business reasons
- When referenced or included in a regulation, the standard is (usually) no longer voluntary
- When the standard is well recognized in the market, not abiding by its requirements may not be a successful strategy for the manufacturer

Other terms

Recommendation

Best practice

Guide

Guideline

Guidance

Specification

De facto standard

Code

Performance and Design Standards

- Performance requirements – expressed in terms of required results without stating the method of achieving the functional or operational results
- Design (or descriptive) requirements – expressed in terms of specific design requirements such as materials, construction, dimensions
- Performance standards are usually preferred to design standards to accommodate innovation
- When requirements are expressed in terms of performance, it is harder to assess if the product meets the standards

What is an International Standard?

The WTO TBT Agreement states:

2.4 Where technical regulations are required and **relevant international standards** exist or their completion is imminent, **Members shall use them**, or the relevant parts of them, as a basis for their technical regulations **except** when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

WTO TBT Decision on International Standards (2002)

The Decision established the following principles for the development of international standards.

- Transparency
- Openness
- Impartiality and consensus
- Effectiveness and relevance
- Coherence
- Development Dimension

The WTO TBT Agreement (1)

- Multilateral governmental agreement; all WTO members are bound by the Agreement
- Recognizes the right of countries to regulate at the level they consider appropriate
- Defines the legitimate objectives of technical regulations
- Aims to facilitate trade
- Focuses on technical regulations and related conformity assessment procedures
- Applies to the central and subcentral government bodies

The WTO TBT Agreement (2)

- Requires transparency – notify proposed technical regulations early enough so that other members can learn about the proposals and have an opportunity to comment (more on this later)
- Requires that products from any source be treated no less favorably than domestic and products
- Requires that technical regulations and conformity assessment procedures be no more trade restrictive than necessary
- Includes a Code of Good Practice for the Preparation, Adoption and Application of Standards

The U.S. Standards System

The U.S. standards system is voluntary, decentralized, sector and market driven and is, sometimes, competitive and duplicative.

The system relies on cooperation and communication among:

- Industry
- Private sector standards organizations
- Stakeholders
- Government

The U.S. Standardization Model – “One Approach Among Many in the World”

The U.S. “standardization” model:

- resembles the nation’s economic structure: sector-based and driven by market needs
- reflects U.S. culture and traditions
- reflects government/private sector dynamics
- suits the size of the country and the complexity of the U.S. economy
- relies strongly on diversity and decentralization

POLLING QUESTION:

Are you interested in learning more now about other countries' approaches?

1. Yes

2. No



Key Concepts in Standards Development

Openness

All stakeholders may participate; no single interest may dominate

Transparency

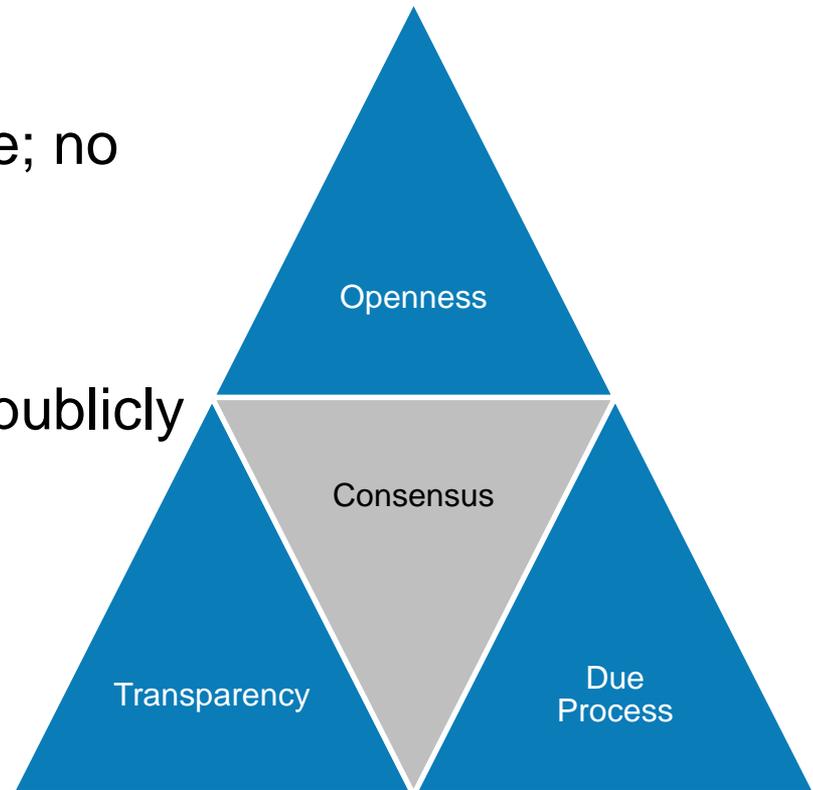
Records/ processes open and publicly available

Due Process

Appeals mechanism

Consensus

Decisions more than majority but not unanimity



What is Consensus?

General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments.

NOTE: Consensus need not imply unanimity. (ISO/IEC GUIDE 2:1994)

General agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments. (OMB Circular A-119 of 1998)

Consensus – you know when you see it!

The chairman of the standards committee is responsible to judge whether there is sufficient support and consensus to advance a standards draft, bearing in mind the definition of consensus. Participants should agree that consensus has been reached.

Consensus is not equivalent to balloting.

Consensus is a **process** and it needs to be achieved **in committee** at every stage of the process.

Consensus-Based Standards Development Process

- Standards are written in committee
- Stakeholders proposes subject matter
- Proposer usually present a first draft
- Discussed at length
- Incorporate changes
- Balloting process
- Consider comments
- Possible re-balloting
- Final approval and publication
- Review (typically, every 3-5 years)

Consensus-Based Standards Development

- Structured process
- Lengthy, laborious process
- Consideration of all views takes time
- Consensus takes time
- Procedural safeguards take time
- Volunteers workforce
- Very expensive

Key Players and Organizations

1. American National Standards Institute (ANSI)
2. National Institute of Standards and Technology (NIST)
3. Standards Developing Organizations (SDO)
4. Consortia Standards Setting Organizations
5. International Players
6. Committee members who provide technical input

Key Player - ANSI



- ANSI is a federation of about 1,000 members
- Was founded in 1918 by five professional/ technical societies and three federal government agencies
- Coordinates the U.S. standards system
- Does not write standards
- Accredits standards developers (about 228 SDO's are ANSI-accredited)
- Represents the United States in the ISO and IEC

Key Player – NIST



- Serves as the National Measurement Institute in the U.S.
- Staff participate in standards development
- Provides substantial technical contributions in thousands of committees
- Is a key contributor and leader in the development and implementation of U.S. standards policy
- NTTAA related responsibilities (more later)

NIST Participates in Documentary Standards Activities (1)

- Nearly 1/3 of the technical staff participate in over 100 standards organizations
- Staff serve as technical experts in the development of test methods; product, system, and process specifications; etc.
- Many also serve in leadership positions (chair, lead working groups)
- Focus is on analytical testing, building and construction, health care, information technology, manufacturing, and telecommunications, infrastructure, energy, interoperability

NIST Participates in Documentary Standards Activities (2)

- Organize and participate in round robins (interlaboratory comparisons) to collect data to support the development of test methods
- As an example, NIST conducted tests for elevator fire safety which ASME used in its elevator and escalator safety codes
- NIST provides standards reference materials (SRMs) needed to calibrate instruments used in test methods
- As an example, ASTM standards reference ~800 NIST Standard Reference Materials
- NIST provides knowledge and information on measurement traceability and uncertainty of measurements needed in testing

NIST Input to U.S. Standards Policy

Private Sector – NIST staff serve on ANSI and SDO policy committees

- Mechanism to provide input
- Informs NIST activities

Public Sector – NIST co-chairs the National Science and Technology Council's Sub-committee on Standards

- Intersection of technology, innovation, competition and trade related issues with standards
- U.S. government agencies' involvement in standards and standardization

Key Player - SDOs

- **Professional Societies** whose members seek to advance their professions, and also develop standards
- **Trade Associations** promote their industry's products, and also develop standards
- **Testing and certification organizations** produce their own standards and may also use those of other organizations
- **Organizations that only develop standards**



Key Player - Consortia

Consortia are groups of companies that come together to create a standard to address a (typically single) commercial need

Characteristics:

- Quick standards setting
- Arose in the late 1980s to meet changing technological needs
- Most often are joint ventures that “pay to play”
- Recently, many consortia in the food industry and in the environmental/sustainability sectors
- “Proprietary” standards
- Enormous variation among consortia in terms of openness, transparency and consensus

Key Player - International Players

- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- International Telecommunication Union (ITU-T)
- U.S. domiciled standards developing organizations
- Treaty organizations (government based)
- Regional bodies

ISO (and IEC)



- ISO is a member organization and is non governmental
- Members are the national standards institutes of 164 countries; one per country
- Central Secretariat is in Geneva but secretariats of technical committees held by members all over the world
- ISO has about 224 technical committees in all fields except electrotechnical; about 19,000 standards published
- U.S. participates thru ANSI
- U.S. has a single voice in ISO committees

How the US is Organized for ISO Work

- U.S. participation in any ISO committee is decided by a consultative process managed by ANSI International Policy Committee (NIST is represented)
- ANSI usually appoints a willing SDO to manage U.S. representation in an ISO committee
- The SDO organizes a Technical Advisory Group, TAG (or mirror committee)
- TAG rules are published by ANSI but SDOs have some flexibility in the administration of TAGs
- Membership fees in TAGs vary
- In TAGs, USG agencies may have different positions

Key Player - Committee Members

- Committee members create the standards by providing the technical input
- They are the heart and soul of standards
- You will hear more about what they do and how they do it later today



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Thank You

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