



U.S. Legal Norms and Standards

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Definition of terms

Standard:

A Standard is a Document,
Not a Technical Regulation

Document [emphasis added] 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 achieving the optimum degree of order...

ISO/IEC Guide 2

Definition of terms

(continued)

- ◆ Standards become mandatory only when:
 - 4 They are incorporated into contracts; or
 - 4 They are adopted by government agencies as part of a regulation to protect public health, safety, or the environment.

Definition of terms

Conformity Assessment:

Any activity concerned with determining directly or indirectly that requirements are fulfilled

- ◆ Relevant to requirements for products, services, systems and organizations
- ◆ May be conducted by:
 - ⁴ a supplier (first party)
 - ⁴ a buyer (second party)
 - ⁴ an organization independent of both buyer and seller (third party)

Standardization and conformity assessment impact all industries

- ◆ In the U.S. alone, there are more than 95,000 recognized standards. These encompass:
 - 4 Product-Based Standards
(ISO film speed code; banking and telephone cards)
 - 4 Performance-Based Standards
(Safety of wire ropes; safety of toys)
 - 4 Management System Standards
(ISO 9000 Quality and ISO 14000 Environmental Management Systems)
 - 4 Personnel Certification Standards
(financial planners; food protection managers; others for services are expected)

The U.S. approach to market relevance

- ◆ These documents are being developed by
 - 4 more than 450 standards developing organizations (SDOs), with the ten largest of these organizations producing approximately 80% of the standards
 - 4 at least 150 consortia
 - 4 hundreds of committees addressing the technical requirements of standards

Cardinal Principles of the U.S. Consensus Standards Process

- ◆ **Openness**
All materially affected parties may participate in standards development
- ◆ **Transparency**
Records and processes open and publicly available (no secret meetings)
- ◆ **Consensus**
Decisions by more than a simple majority (not unanimity)
- ◆ **Due Process**
Written, documented appeals process

Most standards are developed and used on a voluntary basis

- ◆ Most standards are developed by technical committees formed within the private sector, very often with government participation.
- ◆ Government and industry representatives participate as “equal partners” in technical committees.
- ◆ Costs are borne by the participants, not the standards developing organization.

Acceptance and implementation of specific standards may be . . .

- ◆ Company-specific
- ◆ Industry-specific
- ◆ Cross-industry
(e.g. ISO 9000, ISO 14000)
- ◆ Geographic
 - 4 National, regional (e.g., Americas; Europe, Pacific Rim), or international
- ◆ Regulatory (if adopted by government)
 - 4 Mandatory for adoption at the local, state or province, or federal levels

Structure of the U.S. Standardization System

- ◆ ANSI
 - 4 Coordinator of the Private Sector
 - 4 Private sector, non-profit, membership organization
 - 4 Supported by membership fees, sale of publications
- ◆ NIST
 - 4 Coordinator of Federal Agencies
 - 4 Sets legal metrology standards; accredits laboratories
- ◆ Standards developing organizations (SDOs)
 - 4 Private trade and professional organizations, often non-profit
 - 4 Many, but not all, accredited by ANSI

The Role of Government

- ◆ In the U.S., no single government agency has control over standards.
 - 4 Each government agency determines which standards meet its needs.
 - 4 The agency is responsible for determining whether a private sector standard already exists that is appropriate for its needs.
 - If so, they will use the private sector standard.
 - If not, the agency is expected to work with the private sector to develop the needed standard.

As a matter of law . . .

- ◆ National Technology Transfer and Advancement Act (NTTAA) - 1995 (P.L. 104-113 – 1996)
 - 4 Encourages federal agencies to utilize voluntary consensus standards where feasible
 - 4 Encourages federal participation in voluntary consensus standards development activities
 - 4 Designates NIST as “coordinator” (no budgetary or policy authority) of government standards policy activities

Roles of ANSI and NIST

◆ ANSI

- 4 Non-profit private sector body with some government members
- 4 Accreditor of certifiers and standards-setting bodies
- 4 Approves American National Standards
- 4 U.S. member body of ISO and, via the USNC, the IEC and represents U.S. interests in non-treaty organizations
- 4 Coordinator of private-sector standards and conformity assessment policies
- 4 Coordinator of U.S. NSS implementation

◆ NIST

- 4 Government agency (part of Department of Commerce)
- 4 Chairs the Interagency Committee on Standards Policy
- 4 Responsible for official weights & measures (legal metrology)
- 4 National Center for Standards & Certification Information
- 4 Dues-paying member of ANSI
- 4 Holds some secretariats in ISO/IEC
- 4 WTO inquiry point
- 4 Coordinator of federal agency standards and conformity assessment policies

What does this mean in the “real world”?

- ◆ Federal regulatory and procurement agencies are directed to rely upon private sector standards whenever possible – and to participate in their development
- ◆ This is a substantive move away from the traditional “command and control” role of government and a move toward working with the private sector

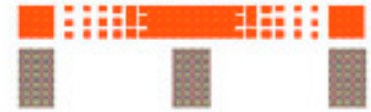


A Federation of members representing . . .

- Academia
- Individuals
- Government
- Manufacturing
- Trade Associations
- Professional Societies
- Service Organizations
- Standards Developers
- Consumer and Labor Interests
- and many more

Founded in 1918 by five technical societies and three government agencies



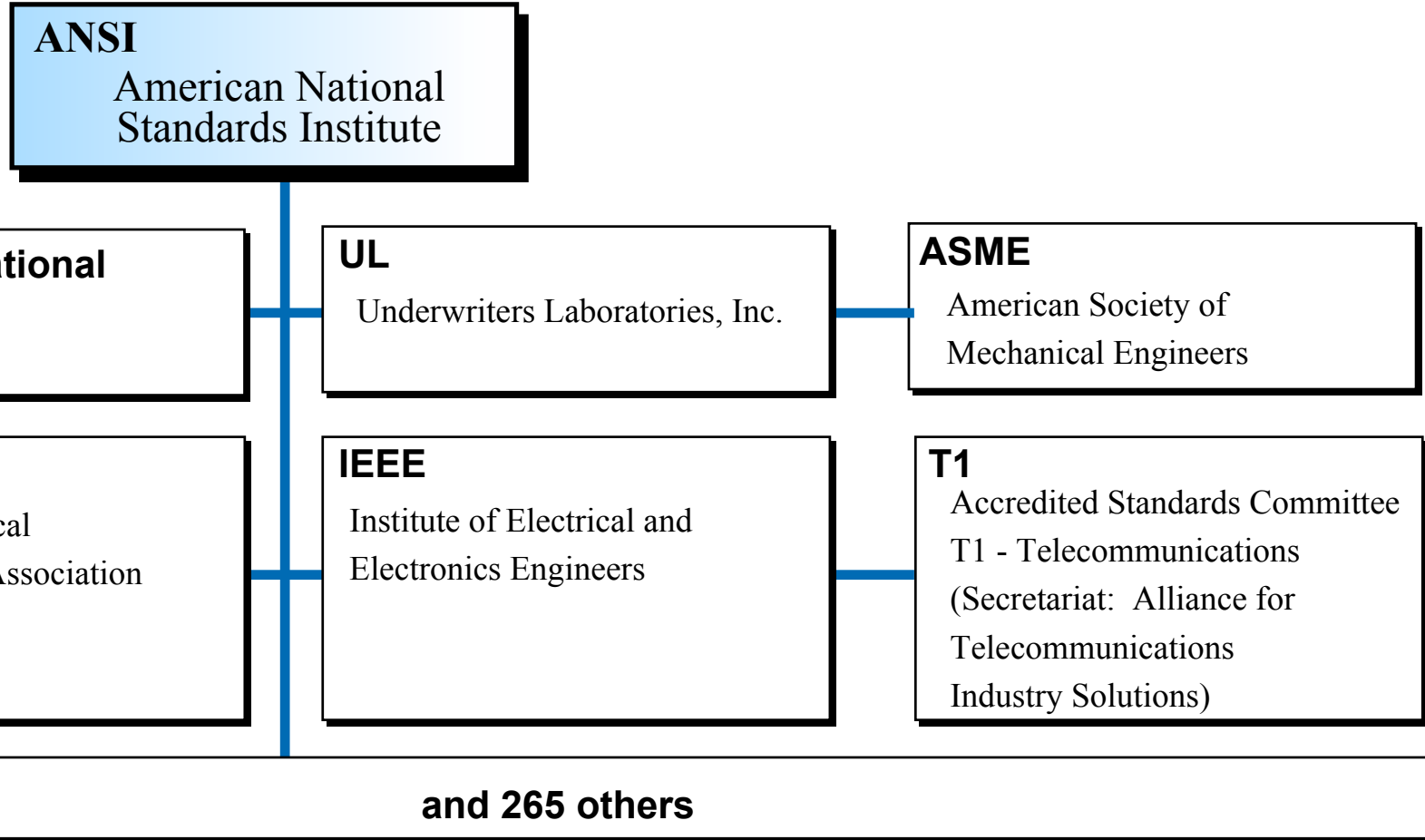


ANSI's Roles and Responsibilities

◆ Domestically

- 4 Accredits U.S. standards developers, U.S. Technical Advisory Groups and conformity assessment systems
- 4 Approves American National Standards
- 4 Protects the public's participation in standardization activities
- 4 Ensures integrity of the U.S. voluntary consensus standards system
- 4 Offers a neutral policy forum
- 4 Provides a central resource for information and education on standards, conformity assessment and related activities

Examples of ANSI-Accredited Standards-Setting Bodies



ANSI's Roles and Responsibilities

- ◆ Internationally
 - 4 Provides international & regional access and representation
 - U.S. member body to ISO (International Organization for Standardization) and, through the US National Committee, the IEC (International Electrotechnical Commission)
 - U.S. representative to other non-treaty international organizations, i.e., PASC and COPANT)
 - 4 Conducts international outreach on standards related issues for the U.S.

US International Participation via ANSI

- ◆ ANSI pays total dues for U.S. membership in both ISO and IEC
- ◆ ANSI sets policy for U.S. participation in ISO and IEC because the Institute is recognized as the official U.S. member of both organizations
- ◆ U.S. technical positions for ISO and IEC activities are developed by Technical Advisory Groups (TAGs)
 - 4 Allows all affected parties (including U.S. government) to participate in ISO or IEC standardization activities

U.S. Member Body of the ISO



- ◆ ISO – Geneva, Switzerland
 - 4 Comprised of 146 National Standards Bodies
- ◆ ANSI is one of
 - 4 5 permanent members to the Council of 18
 - 4 4 permanent members to the Technical Management Board of 12
- ◆ ANSI and its members
 - 4 participate in 79% of Technical Committees
 - 4 administer 18% of TC Secretariats

ANSI Representation of the U.S. in International and Regional Standardization Organizations

- ◆ International – official U.S. representative to:
 - 4 International Organization for Standardization (ISO)
 - 4 International Electrotechnical Commission (IEC) via the United States National Committee (USNC)
 - 4 International Accreditation Forum (IAF)
- ◆ Regional - official U.S. representative to:
 - 4 Pan American Standards Commission (COPANT)
 - 4 Pacific Area Standards Congress (PASC)
 - 4 Inter-American Accreditation Cooperation (IAAC)
 - 4 Pacific Accreditation Cooperation (PAC)
- ◆ Bilateral agreements and regional participation
 - 4 Formal agreements of cooperation with Argentina, Canada, China and Korea
 - 4 Annual dialogues with representatives of the European Union (CEN, CENELEC, ETSI and the EC)

Characteristics of the U.S. Conformity Assessment System

- ◆ Conformity assessment activities are not centrally organized
- ◆ Activities are a mix of government (regulatory programs) and private sector (market-based programs)
- ◆ Approaches vary among sectors

Issues in the marketplace

- ◆ Duplicative standards, regulations, requirements
- ◆ Transparency
- ◆ Due process requirements
- ◆ National treatment of WTO TBT obligations
- ◆ Suppliers' Declaration of Conformity
- ◆ 3rd Party value
- ◆ Manufacturers' Laboratories

Challenges (continued)

- ◆ Cost of developing an infrastructure of conformity assessment bodies
 - 4 ISO/DEVCO and ISO/CASCO are working together to leverage conformity assessment services in developed countries in support of developing countries
 - 4 U.S. is committed to its support of these efforts

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