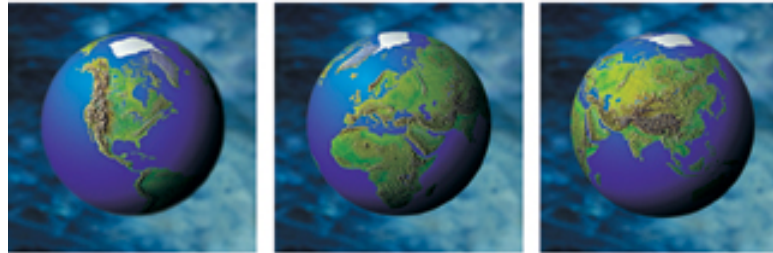




Overview of the U.S. Standards and Conformance Systems



Gary W. Kushnier

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American National Standards Institute

Importance of Standards

“The international language of commerce is standards.”

Source:

U.S. Secretary of Commerce – Donald Evans

Report on Standards and Competitiveness –

Removing Standards-Related Trade Barriers Through Effective Collaboration

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Importance of Standards and Conformance

WTO/TBT Definitions

- **Standard** - Document 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.
- **Technical Regulations** – Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, **with which compliance is mandatory**.
- **Conformity Assessment (Conformance)** – Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. (e.g., testing, certification)

Informally any or all of these areas may be referred to as “Standards,” “Standardization,” “Standards and Conformance,” or “SCATR.”

Statistics: Standards and Trade

- According to the WTO, global export trade surpassed \$12.5 trillion in 2005.
- Those who understand how to effectively influence standardization and compliance programs will have the greatest success in the global marketplace.

Importance of Standards

Standards impact companies' bottom line.

When developed and used responsibly, standards facilitate a company's ability to open and access markets.

For Example...

Importance of Standards

- Compatibility and interoperability between components
- Quality of components and raw material inputs and
- Containerization for storage and shipping
- Verification of workforce qualification
- Measure for business profitability and economic performance



Importance of Standards

When overlooked, standards can negatively impact a company's ability to do business in the U.S. and abroad.

For example: Coke and Pepsi in India

Importance of Standards

- Full or partial bans of Coke and Pepsi in seven Indian States
- Allegations that Coke and Pepsi contain excessive pesticide residue – unsafe
- Loss of market share and brand integrity for U.S. soft drink giants
- Avoidable with globally acceptable food safety and hygiene standards and certification



Importance of Standards

International standards harmonize cross-border requirements – opening markets for large, medium and small enterprises.

The global market follows standards.

Attributes of Standards

Facilitate trade in many ways

- Provide agreed-upon specifications for products, services, and systems, reducing costs and enabling commerce and trade
- Driven by the marketplace
- Enable innovation, competitiveness, and economic growth
- Protect health, safety, the environment, and national security
- Can provide a common way for implementing regulations
- Enable interoperability of complex technologies
- Promote supply-chain flexibility

BUT inhibit trade when misapplied

- Constrain technology and entrench inferior technologies
- Pose technical barriers to trade

The U.S. Approach to Standards and Conformance

The U.S. System: A Toolbox

- Rather than mandating a “one-size fits all” solution, the U.S. system allows players to find the tools and solutions that best fit their needs.
- Approaches, philosophies and positions often vary across industry sectors. Such variations are seen as beneficial and are promoted in the “U.S. Standards Strategy.”

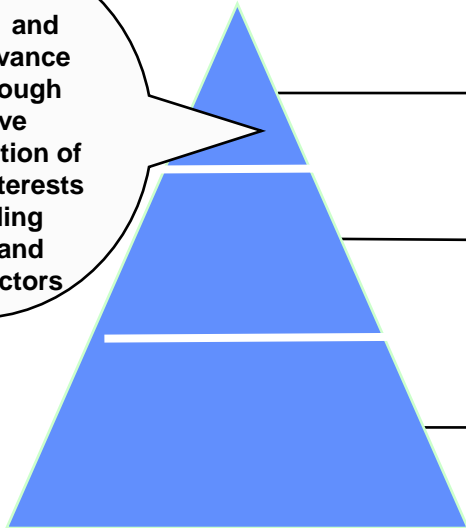


Overview of the U.S. Standards and Conformance Systems

“Bottom-up” vs. “Top-down”

Approach in the U.S.

Strength and trade relevance come through effective representation of member interests – including private and public sectors



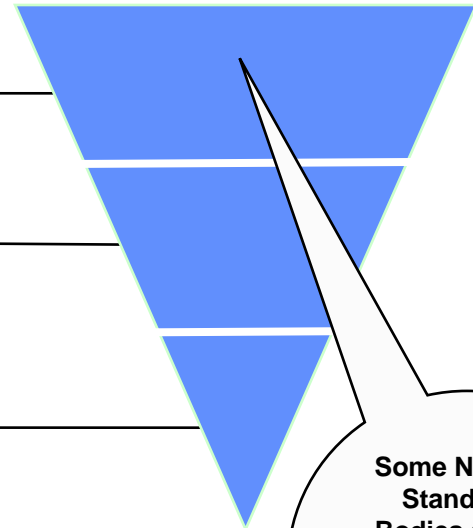
National Standards Bodies (e.g. ANSI)

Standards Developers

Standards Users (e.g. regulators, companies, etc.)

Approach in many other economies

Some National Standards Bodies are top down: Market the most significant driving force in support of trade



The U.S. System: Comparisons

Compared with many other economies, the U.S. standards system...

- Emphasizes private-sector solutions to ensure quality and protect Environment, Health and Safety (EHS)
- Places a high degree of confidence in private-sector conformity assessment activities for regulatory and non-regulatory functions
- Provides a strong voice and greater authority to standards users and individual stakeholders
- Relies on judicial system, brand-name recognition, open media and corporate social responsibility
- Is highly decentralized . . . and highly robust

The U.S. System: Benefits

- Speed and flexibility – solutions are delivered to market and implemented quickly
- Participation – able to accommodate input from a wide spectrum of stakeholders
- Efficiency – prevents unnecessary or costly regulation and allows multiple approaches to ensure health, safety, and quality

The U.S. approach facilitates economic development and innovation

The U.S. System: Choice by Sector

Focus in the U.S. System is on
Use and Choice for standards users
- determined by each sector -

Standards Used in the U.S.:

Different tools for different market needs

National Participation

- Treaty Organizations
- Non-Treaty Organizations



Examples

ISO, IEC, ITU, CODEX, etc.

Features

Formality in process
One country, one vote

Direct Participation

- Nationally Accepted
- Internationally Accepted



Examples

ASTM International, ASME, SAE, etc.

Features

Direct link between technical experts and SDOs
Many are accredited by ANSI

Consortia



Examples

IGRS, W3C, etc.

Features

Wide range of processes and procedures allows flexibility

The ANSI Federation

What is ANSI?

ANSI is the “Umbrella Organization” for and coordinator of the U.S. voluntary standards and conformity assessment system



Duties and responsibilities include:

- Develop and promote U.S. policies and positions
- Accredit SDOs and approve American National Standards (ANS)
- Accredit certifiers of products, personnel and management systems
- Provide standards and compliance solutions domestically and internationally

American National Standards Institute (ANSI)

A Federation of members representing 125,000 companies and organizations and 3.5 million professionals worldwide:

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

ANSI is not a government agency or a standards developer

ANSI: A Private-Sector Organization

ANSI is an independent not-for-profit (501(c)3) organization. ANSI does not receive government oversight or subsidization.

Advantages:

- Public and private sectors are coequal partners
- Impartiality
- Market relevance

support and revenue

Accreditation services (19%)

International standards programs (4%)

Fee-based programs (5%)

Net investment gains (2%)

Membership dues and assessment fees (20%)

Publications (50%)



ANSI in Numbers

- Revenue

- \$25 million annual budget

• Development of Standards	0%	(\$0.0m)
• Sale of Publications	50%	(\$12.5m)
• Membership Dues and Fees	20%	(\$5.0m)
• Accreditation Services	19%	(\$4.8m)
• Other	11%	(\$2.7m)
• <i>Est. total public sector portion of all of the above</i>	10%	(\$2.5m)

■ ISO/IEC Annual Dues	\$2.1 million
■ Technical Committees of ANSI	0
■ Number of Standard Developing Organizations (SDOs) accredited by ANSI	208
■ Technical Committees of ANSI's SDO members	565
■ Number ANSI Standards Panels	5
■ Total number of American National Standards published as of 12/31/05	9,915
■ Estimated number of voluntary standards published in the U.S.	100,000
■ Number of voluntary standards referenced in U.S. laws & regulations	over 6,000
■ Number of company interests represented by ANSI	125,000
■ Number of professionals represented by ANSI	3.5 million
■ Year ANSI was established	1918

Examples of U.S. Standards Organizations Accredited by ANSI

ANSI
American National Standards Institute

U.S. Government
(Federal, State and Local)

ASTM International

UL
Underwriters Laboratories, Inc.

ASME
American Society of Mechanical Engineers

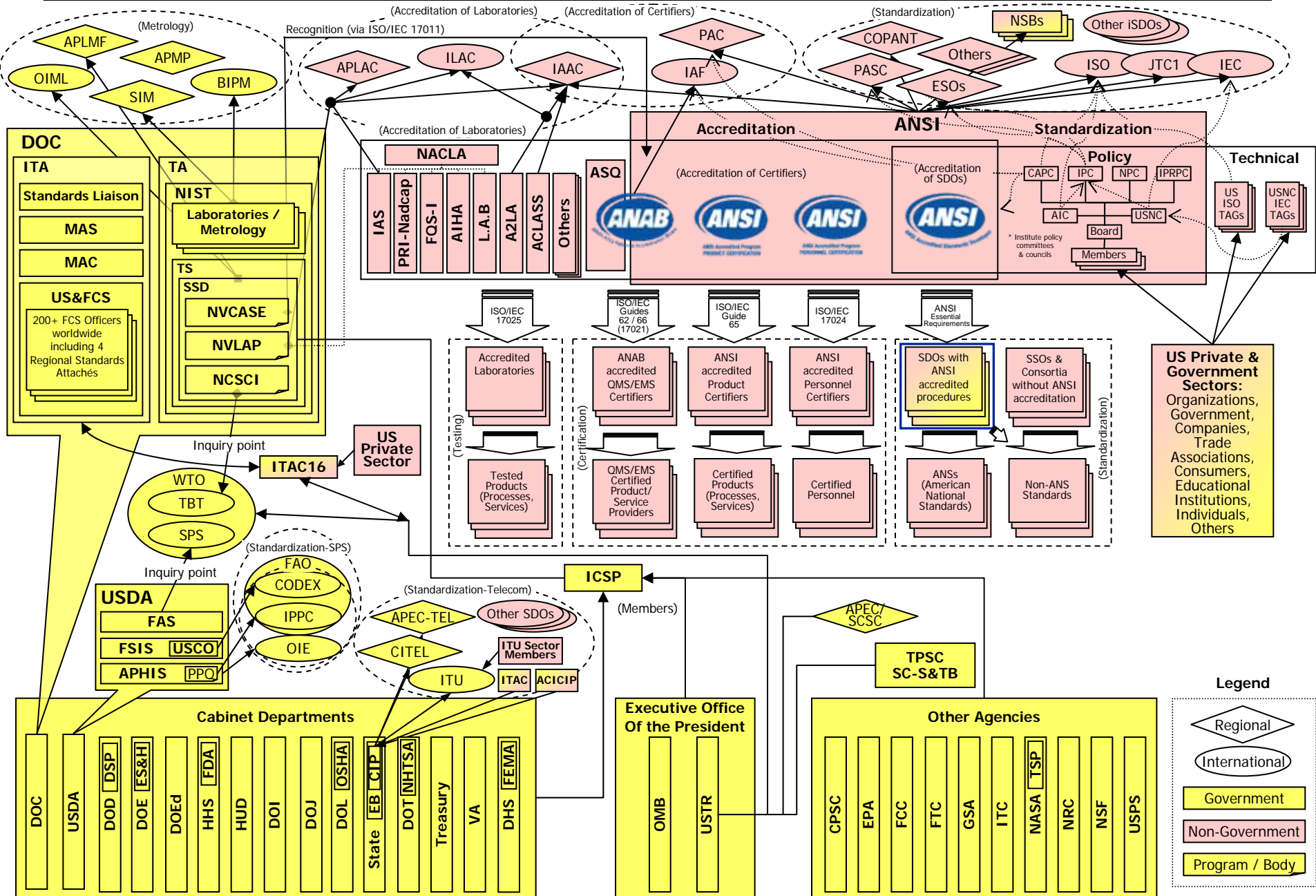
IEEE
Institute of Electrical and Electronics Engineers

ARI
Air-Conditioning and Refrigeration Institute

NEMA
National Electrical Manufacturers Association

Approximately 200 Others

Standards and Conformity Assessment Bodies of the U.S.



ANSI Accredited Standards Developing Organizations (SDOs)

3-A	ASC X9	ASA	ACCA	AMCA	ARI	ATIS	AA	AAMA	AAMVA	ABMA	ABYC	ABMA	ACC	ACI	ADA	AFPA	AGA
AGMA	AH&LA	AIHA	AIAA	AISC	AITC	AISI	ALI	ANS	ANLA	API	ASNT	ASQ	ASAE	ASB	ASCE	ASHRAE	ASME
ASSE	AWWA	AWS	AWEA	ATA	ACMI	ASIS	AIIM	AMT	NPES	AAMI	ACDE	AHAM	ARMA	ASTM	AIM	AGRSS	ALI
BHMA	BICSI	BOMA	BIFMA	CCPA	CSAA	CAPA	CLSI	CFPMI	CAP	CPA	CAGI	CGA	CAM-I	CEA	CSPA	CEMA	CTI
CSA	DISA	DASMA	EIMA	EASA	EIA	ESTA	EIA	EOS/ ESD	FCI	FM	GTEEMC	GICC	GEIA	GEI	HPVA	HIBCC	HL7
HPS	HFES	HI	IESNA	ITSDF	IEEE	TEST	IIE	INMM	12AMA	IAF	IAAMC	IAPMO	ICPA	ICC	ITI	NETA	I3A
IIAR	ISEA	ISA	ISANTA	IWCA	IPC	ISA	JCSEE	KCMA	LIA	MSS	MHI	MBC	NACE	NAHBRC	NAAMM	NBBPVI	NBFAA
NCMA	NCSL	NCPDP	NECA	NEMA	NFPA	NGA	NGCMA	NISO	NIMS	NIST/ ITL	NPPC	NSC	NSAA	NADCA	NERC	NAESB	NALFA
NASPO	NSF	NIRMA	OLA	OPCC	OEOSC	OPEI	PMMI	PSA	PCA	PWMA	PMI	RPTIA	RSTC	RVIA	RESNA	RIA	RMA
SIA	SSFI	SIA	SMA	SPRI	SBS	SAE	SCTE	SMPTE	SVIA	SAAMI	SES	SDI	SJI	SSCI	TIA	TCATA	CI
TMS	SPI	TCA	TOY-TIA	TAPS	TCIA	TPI	USDA	USPRO	UL	UAMA	UAMA	UCC	VITA	WQA	WDMA	WCMA	WMMA

Link to full list of ANSI accredited and non-ANSI accredited SDOs: www.nssn.org/acrodesc.html

American National Standards (ANS): Based on Internationally Recognized Principles

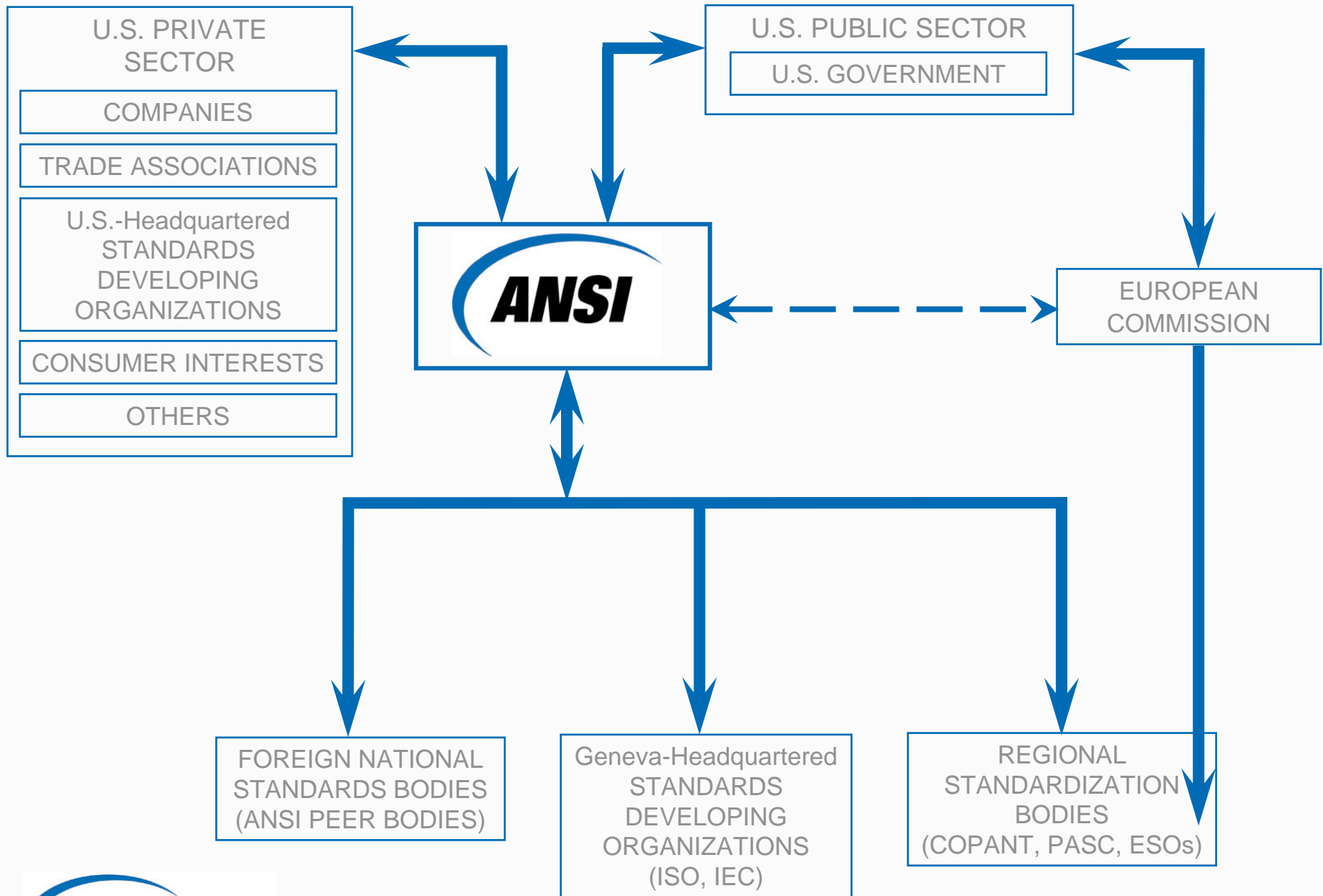
*Principles for international
Standards development outlined
By the WTO/TBT Committee*:*

- Openness
- Transparency
- Due Process
- Consensus

*ANSI Essential Requirements for
Accredited Standards
Development:*

- Openness
- Transparency
- Due Process
- Consensus

*WTO TBT Committee Third Triennial Review – Annex 4



ANSI International Interaction (Standardization)

- ANSI serves as the official U.S. member and sets policy for U.S. participation in the
 - International Organization for Standardization (ISO)
 - International Electrotechnical Commission (IEC)
- U.S. technical positions for ISO and IEC activities are developed by Technical Advisory Groups (US TAGs)
 - Allows all affected parties (including U.S. government) to participate in standardization activities



ANSI Regional Interaction (Standardization)

- ANSI serves as the official U.S. member of two regional bodies
 - Pan American Standards Commission (COPANT)
 - Pacific Area Standards Congress (PASC)
- The Institute has a dialogue with representatives of the European Standards Organizations (ESOs) (CEN, CENELEC and ETSI) and the European Commission



The U.S. System: The Role of Government

- In the U.S., **no** single government agency has control over standards
- National Institute of Standards & Technology (NIST) –
Technology Administration (TA) - U.S. Department of Commerce
 - Coordinates the standards activities of Federal agencies
 - Sets Legal Metrology Standards; Accredits Laboratories
- Each government agency determines which standards meet its needs

The U.S. System: The Role of Government Agencies

- **The National Technology Transfer and Advancement Act (NTTAA, Public Law 104-113)**
 - Each government agency is encouraged to seek existing private sector standards that are appropriate for its needs
 - If so, the agency will use (i.e. reference) the private sector standard
 - If not, the agency is expected to work with the private sector to develop the needed standards, and to reference them in its regulations
 - Agencies creating their own standards must report to the Administration and Congress on an annual basis the justifications for doing so
 - NIST has the legal responsibility of implementing the NTTAA

Overview of Conformity Assessment

What is Conformity Assessment?

Conformity Assessment

Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled

ISO/IEC 17000:2004

*Conformity Assessment –
Vocabulary and general principles*

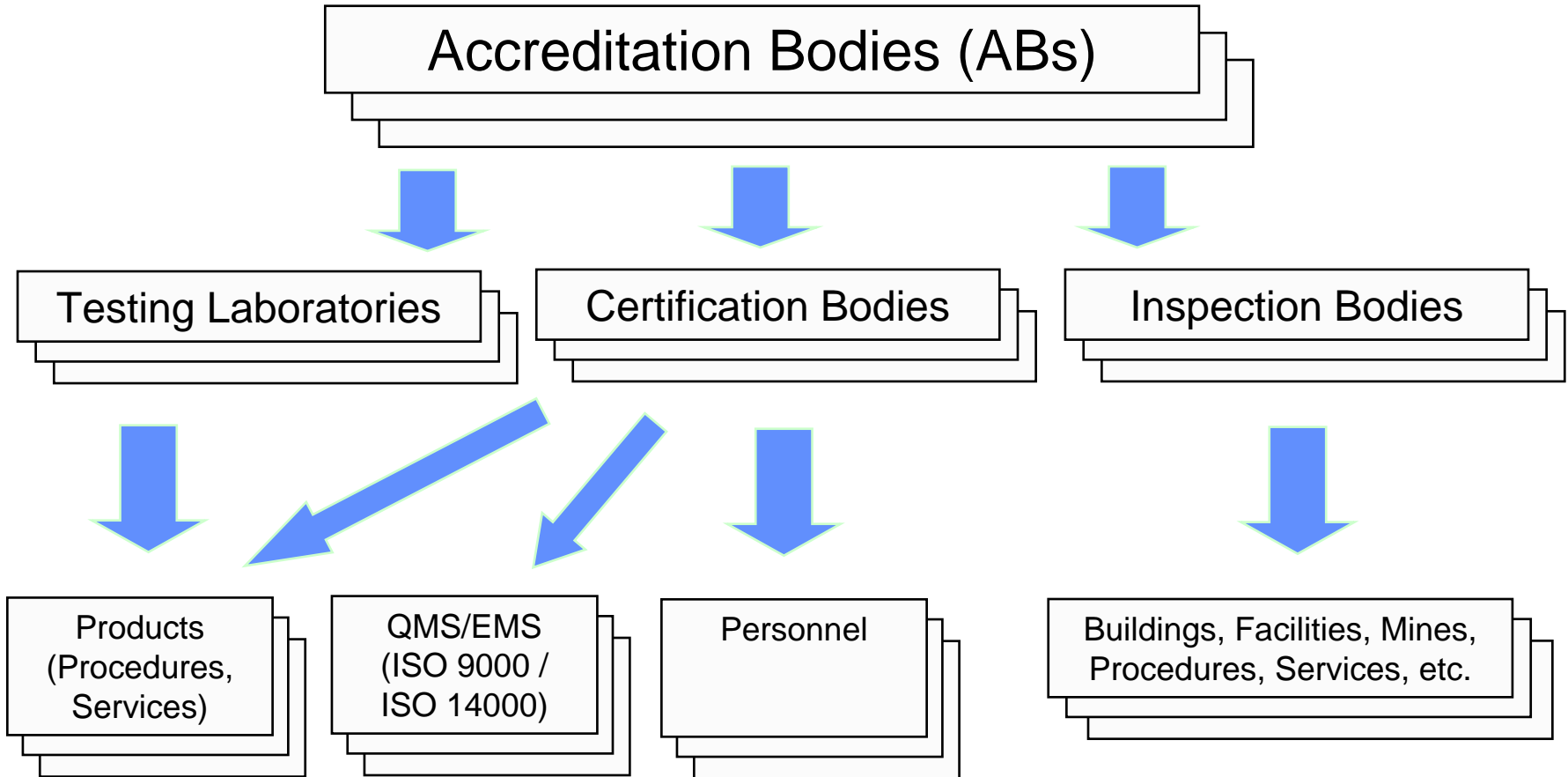
Conformity Assessment

- Facilitates trade globally and eliminate barriers
- Builds **confidence** and reduces risk for customers
- Offers a range of tools to assist in procurement
 - Suppliers Declaration of Conformity (SDoC) to
 - Third-party testing and certification

Components of Conformity Assessment

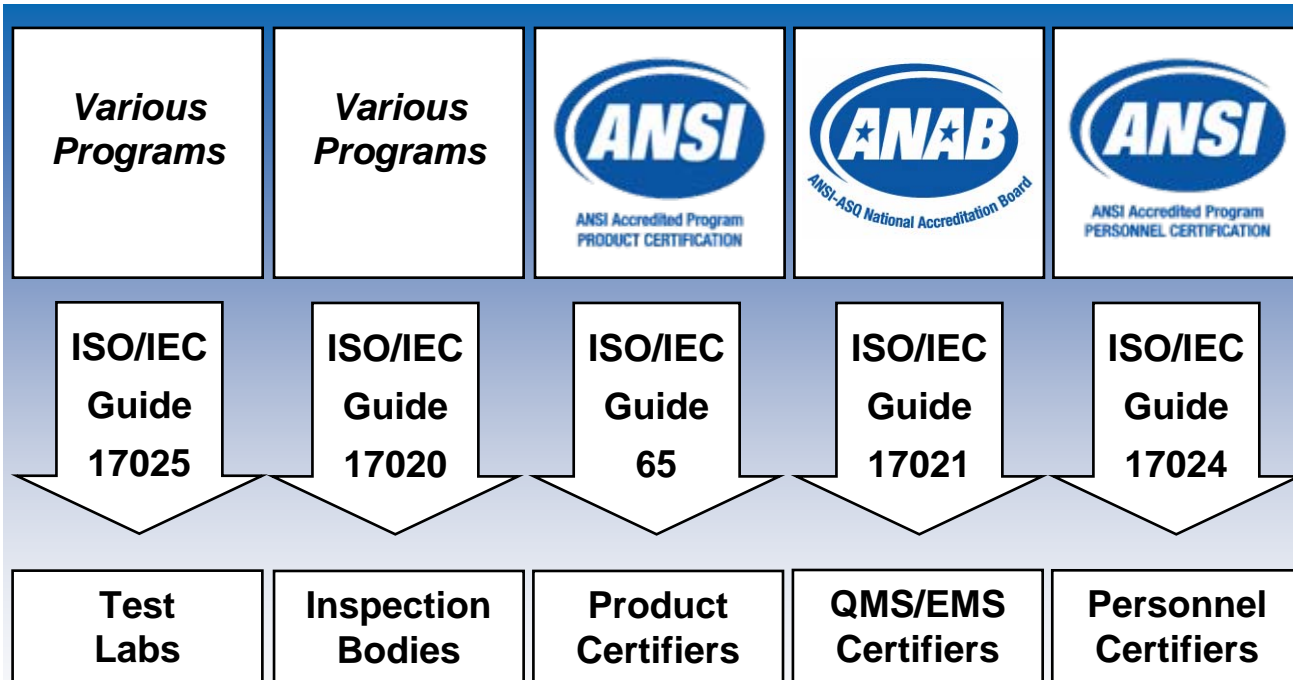
- **Metrology and measurement capabilities**
- **Sampling**
- **Testing**
- **Inspection**
- **Declaration of conformity**
- **Certification (products, services, personnel)**
- **Management system registration/certification**
- **Accreditation (ANSI role)**
- **Enforcement**

Conformity Assessment System Structure



Accreditation Programs

Conformity Assessment (ISO/IEC 17011)



Standards



Key Characteristics of U.S. CA System

- In the United States, conformity assessment activities are not centrally organized
- Activities are a mix of government (regulations) and private sector (market activities)
- Approaches vary among sectors

Conformity Assessment - Summary

- U.S. System is uses private-public sector partnership that insures industry sector input and is supported by Federal legislation
- Conformity Assessment system, like Standards system, evolved in decentralized manner with a sector-based approach
- Conformity Assessment ranges from Self Declaration of Conformity (SDoC) to 3rd-party review (accreditation)
- Is generally effective, open, and transparent
- Designed to provide more confidence in the quality of the product, service, or system by consumers, the public, and employers

For more information:

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Additional Slides

A Standard is a Document

Standard

***Document** established by consensus and approved by recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities ...*

ISO/IEC Guide 2:2004

*Standardization and related activities –
General vocabulary*

Voluntary Consensus Standard • Conformity Assessment Procedure
Technical Regulation • Metrology Standard

The U.S. Standards System

Government

Regulators

*CPSC, EPA,
FCC, USDA,
etc.*

NIST coordinates Federal activities in voluntary standards

NIST

Procurement Agencies

*DOD, NASA,
USDA, etc.*

Private-Sector

Standards Developers

Companies

NGOs

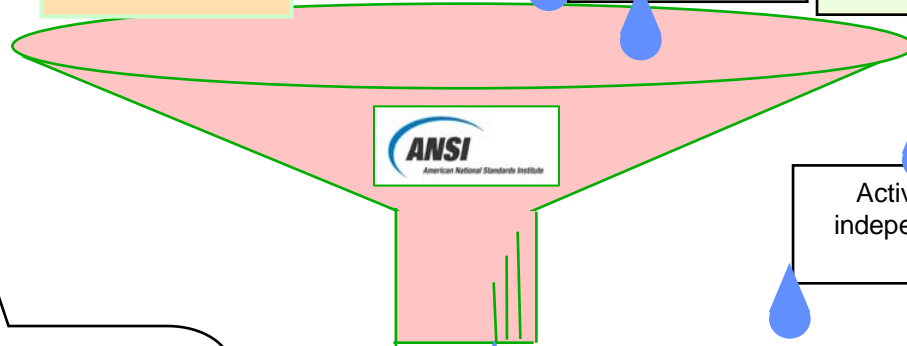
Academics

Consumers

Trade Associations

Others

Government



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. Policies and Positions

Activities Carried out independent of the ANSI Structure

The U.S. Standards System: Who's Who

	Coordinates U.S. System and policy development	Coordinates USG use & participation	Participates in U.S. policy development	Provides technical input for standards development	Independently runs standards development activities*	Legal metrology
ANSI	X		X			
Standards Developers			X		X	
Companies			X	X		
Government Agencies (regulators and procurement)			X	X		
NIST		X	X	X		X

*Documentary Standards, excluding "national participation models"

The U.S. Conformity Assessment System

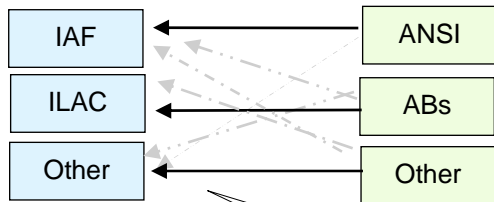
International Activities

IEC (IECEE, IECx, IECQ)

ISO (CASCO)



Other International Fora



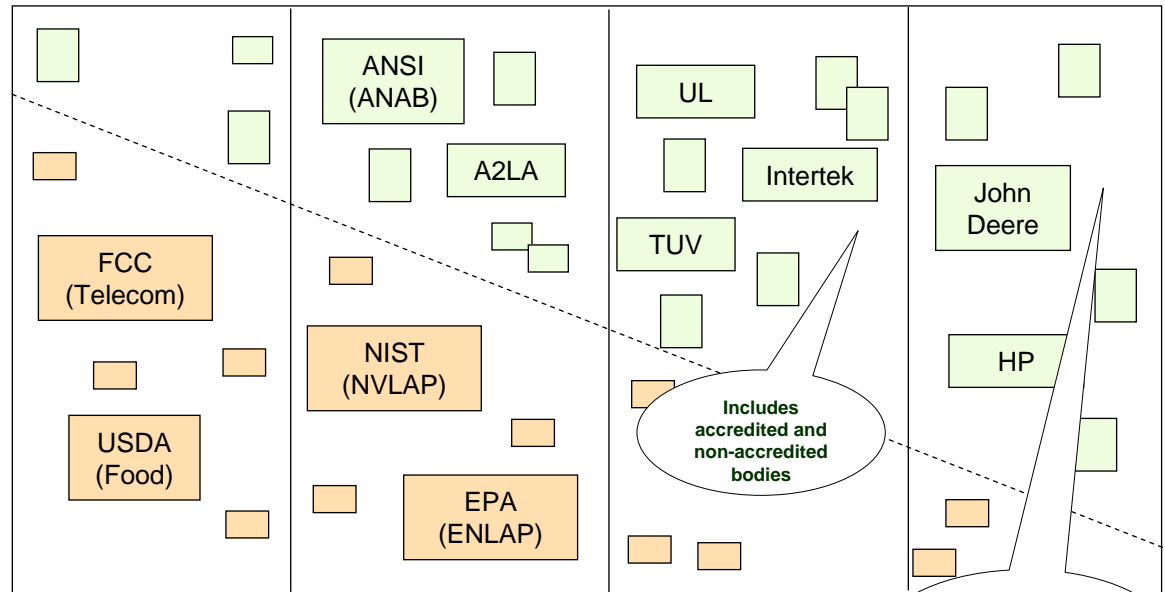
Domestic Activities

Designating Authorities

Accreditors

Testers, Inspectors & Certifiers

SDOC



Overview of the U.S. Standards and Conformance Systems