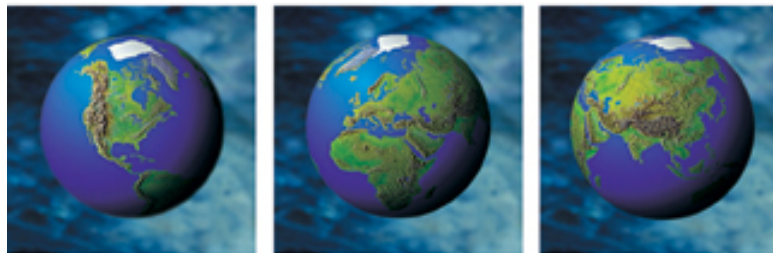




Overview of the U.S. Standards and Conformance Systems



Overview of the U.S. Standards and Conformance Systems

Premise

***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

May 18, 2004

What is a Standard?

In General . . . 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*

In Specific . . . 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.”

Most standards are developed and used on a voluntary basis

- Most standards are developed by technical committees formed within the private sector
- Government and industry representatives participate as “equal partners” in many of these technical committees
- Costs are borne by the participants

Voluntary vs. Mandatory

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

The U.S. Approach to Standards and Conformance

The U.S. Standardization Model

A Unique Approach Among Many in the World

- resembles the nation's governmental (federal) structure
- resembles the nation's economic structure
 - sector-based and driven by market needs
- relies strongly on diversity and decentralization

Structure of the U.S. Standardization System

- **American National Standards Institute (ANSI)**
- **Standards Developing Organizations (SDOs)**
- **Conformity Assessment Bodies (CABs)**
- **National Institute of Standards & Technology (NIST) – U.S. Department of Commerce**

Structure of the U.S. Standardization System

- **ANSI – Coordinator of the Private Sector led System**
 - Responsible for coordinating U.S. private sector participation in the U.S. private sector led Standards and Conformance systems
 - National Standards Body for the United States – Represent the U.S. in international and regional standards fora
 - Accreditation Body for private sector programs – Represent the U.S. in international and regional accreditation fora
 - Private sector, non-profit, membership organization
 - Supported by membership fees, sale of publications, funded programs, accreditation programs and periodic government grants

- **Standards Developing Organizations (SDOs)**
 - Responsible for the development of standards for the specific technical sectors
 - Some, but not all, accredited by ANSI
 - When accredited, can administer U.S. mirror committees to ISO and IEC
 - Private trade and professional organizations, often non-profit
 - Business models vary by sector

- **Conformity Assessment Bodies (CABs)**
 - Testing Laboratories, Certification Bodies, Inspection Bodies
 - Responsible for demonstrating compliance with standards (including those referenced by mandatory technical regulations)
 - Some, but not all, accredited by ANSI
 - Business models vary by sector (non-profit, for-profit, public sector, etc.)

- **NIST – National Institute of Standards & Technology – U.S. Department of Commerce**
 - Coordinates the activities of Federal agencies in the U.S. private sector led Standards & Conformance Systems
 - National Metrology Body for the United States – Represents the U.S. in international and regional metrology fora
 - Accreditation Body for public sector programs – Represent the U.S. in international and regional accreditation fora
 - U.S. government public sector body

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 WTO – TBT Inquiry Point
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. 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.”



Two primary approaches to standards-setting

Top Down

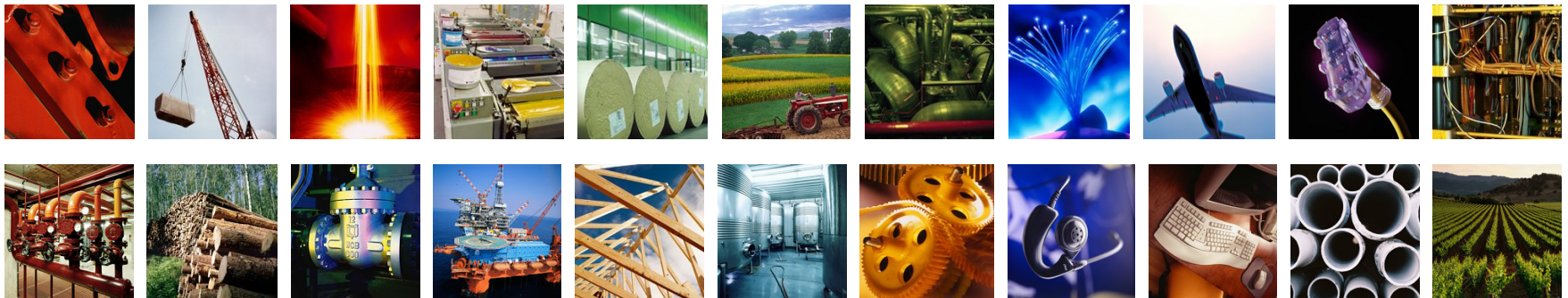
Standards bodies drive standardization activities

Approach in many economies

Approach in the United States

Bottom Up

Standards users drive standardization activities



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 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 and its Roles & Responsibilities

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

ANSI's Roles and Responsibilities Domestically

- Accreditation. ANSI Accredits:
 - U.S. Standards Developing Organizations (SDOs)
 - Certifiers of Products
 - Certifiers of Personnel
 - Certifiers of Quality and Environmental Management Systems (QMS/EMS) together with ASQ under the ANSI-ASQ National Accreditation Board (ANAB)
- Approves American National Standards (ANSs)
- Ensures integrity of the U.S. voluntary consensus standards system
- Protects the public's participation in standardization activities
- Offers a neutral policy forum
- Provides a central resource for information and education on standards, conformity assessment and related activities

American National Standards Institute (ANSI)



- Facilitates U.S. *standardization* policy development
- Develops and promotes global *standardization* policies

ANSI is the bridge for standardization

- between industry and government
- among and within industries

Examples of U.S. Standards Organizations Accredited by ANSI



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

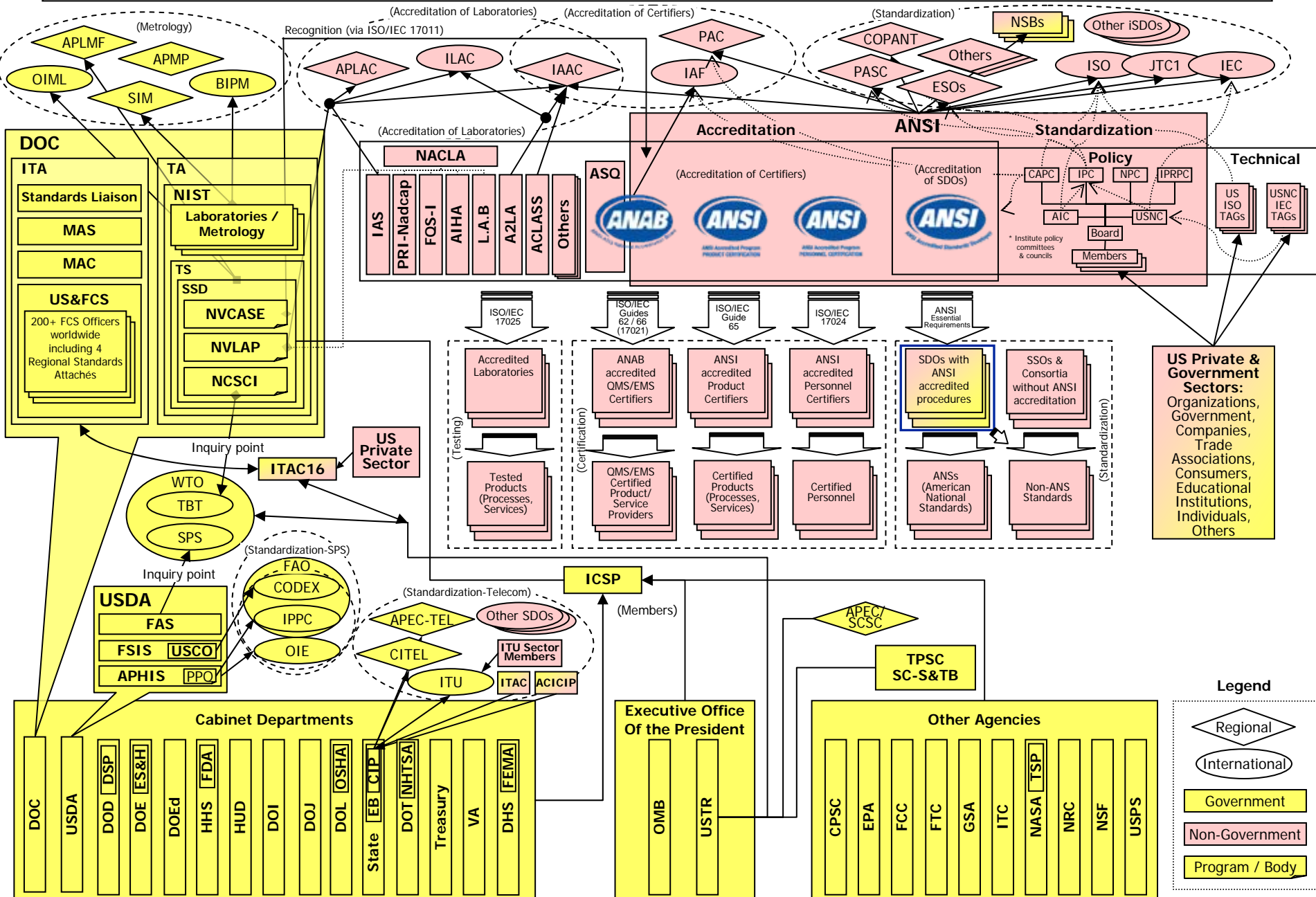


Approximately 200 Others

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	IEST	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

Standards and Conformity Assessment Bodies of the U.S.

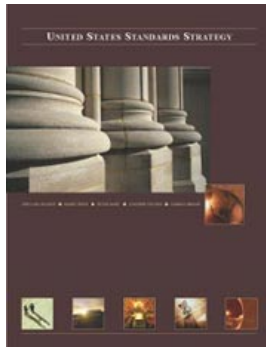


ANSI promotes alignment with Internationally Recognized Principles for Standards Development

*ANSI Essential Requirements
for the development of
American National Standards*

*WTO TBT Committee
Second Triennial Review –
Annex 4*

openness
transparency
due process
consensus



*Referenced in the United
States Standards Strategy*

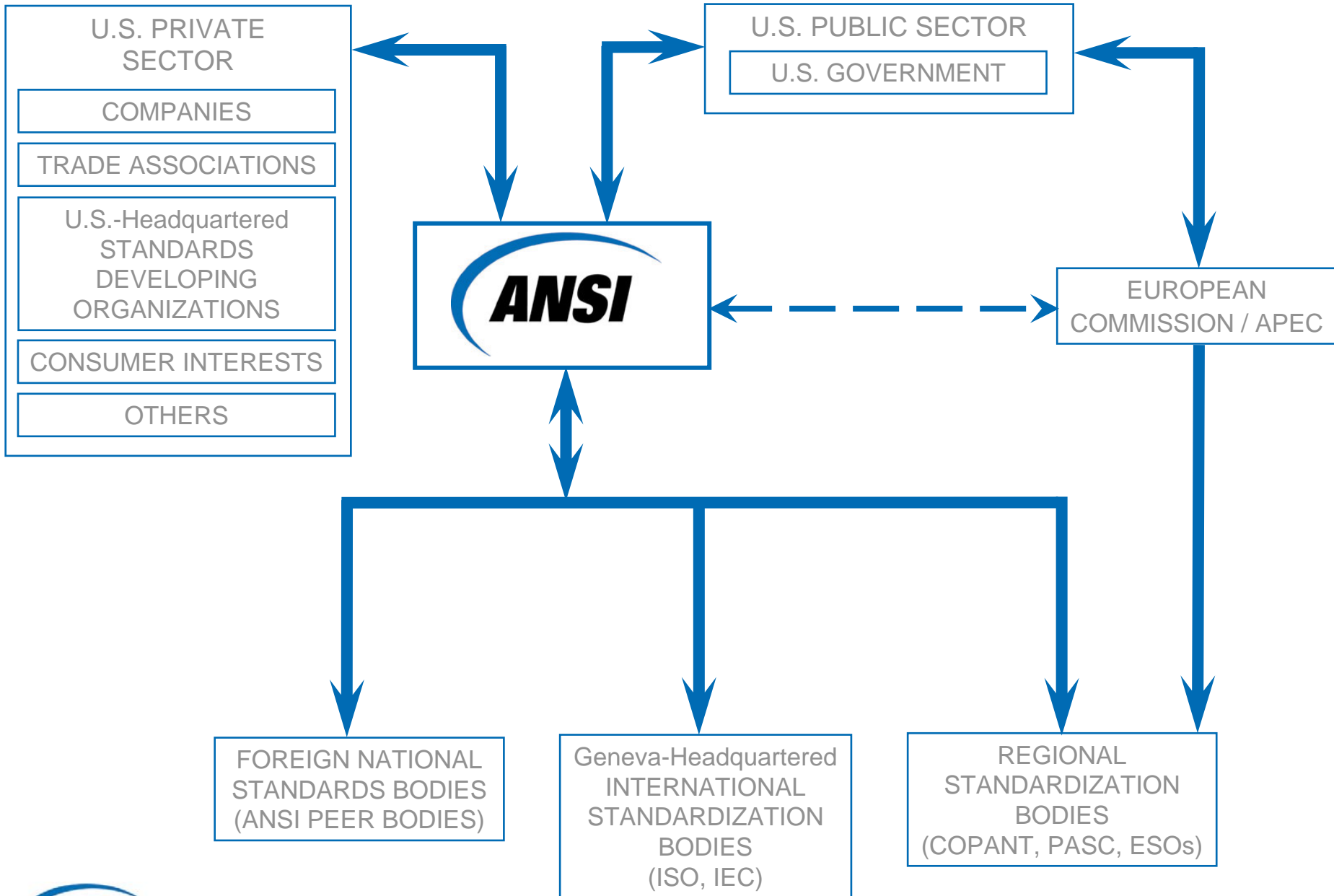
The Role of Government

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

The Role of Government Agencies

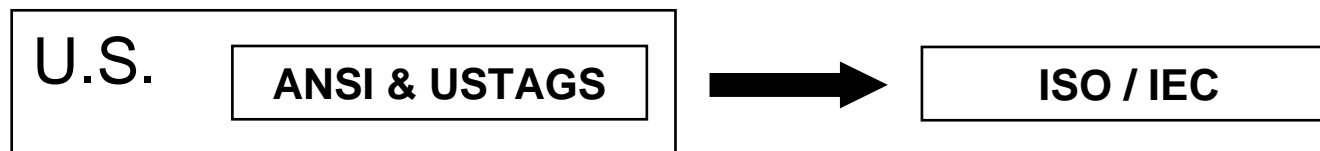
- OMB Circular A-119
- The National Technology Transfer and Advancement Act (NTTAA, Public Law 104-113)
 - Before regulating, each government agency is required to seek and consider using existing private sector standards that are appropriate for its needs
 - If so, the agency will use (i.e. reference) 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

ANSI's Roles and Responsibilities Internationally, Regionally, and Bilaterally



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's Role in ISO

ANSI Participation in ISO

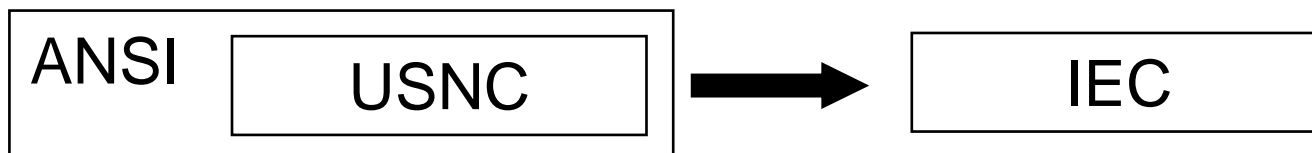
- ISO – Geneva, Switzerland
- ANSI one of
 - 5 permanent members to the Council of 18
 - 4 permanent members to the Technical Management Board of 12
- ANSI and its members
 - participate in 79% of Technical Committees
 - administer 18% of TC Secretariats



ANSI's Role in IEC

ANSI Participation in IEC

- IEC - Geneva, Switzerland
- U.S. National Committee to the IEC (USNC)
 - A board level committee of ANSI
 - one of 5 permanent members of the council board of 15
 - participates in 89% of Technical Committees
 - assigned Secretariats for 16% of TC Secretariats



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



ESOs



ANSI Regional Interaction (Asia Pacific)

The United States is highly engaged in Asia Pacific Standards and conformance activities:

- ANSI is the official U.S. member of the Pacific Area Standards Congress (PASC) and the Pacific Accreditation Cooperation (PAC)
- The U.S. is also represented in other Asia Pacific Specialist Regional Bodies (SRBs) . . .



Pacific Area Standards Congress (PASC) Members



- *Australia (SAI)*
- ***Brunei Darussalam (CPRU)***
- *Canada (SCC)*
- *Chile (INN – 2008)*
- *China (SAC)*
- *Colombia (ICONTEC)*
- *Fiji (FTSQCO)*
- *Hong Kong – China (ITCHSKAR)*
- ***Indonesia (BSN)***
- *Japan (JISC)*
- *Republic of Korea (KATS)*
- ***Malaysia (DSM)***
- *Mexico (DGN)*
- *Mongolia (MASM)*
- *New Zealand (SNZ)*
- *Papua New Guinea (NISIT)*
- *Peru (INDECOPI)*
- ***Philippines (BPS)***
- *Russia (GOST-R)*
- ***Singapore (SPRING SG)***
- *South Africa (SABS)*
- ***Thailand (TISI)***
- *USA (ANSI)*
- ***Vietnam (STAMEQ/TCVN)***

ASEAN / ACCSQ economies (in blue)

- *(Note: Cambodia (ISC), Laos (DISM), Myanmar (MSTRD) not in APEC / PASC)*

ANSI Regional Interaction (Americas)

The United States is engaged in standards and conformance activities in the Americas:

- ANSI is the official U.S. member of the Pan American Standards Commission (COPANT) and a full member of the InterAmerican Accreditation Cooperation (IAAC)
- The U.S. is also represented in the InterAmerican Metrology System (SIM) by NIST
- The three Specialist Regional Bodies (SRBs) of the Americas are:
 - [Pan American Standards Commission \(COPANT\)](#)
 - [InterAmerican Accreditation Cooperation \(IAAC\)](#)
 - [InterAmerican Metrology System \(SIM\)](#)
- The SRBs provide specialized support in the areas of standardization, accreditation and metrology in the Americas
- Many ANSI members and accredited SDOs currently engaged in specific technical cooperation activities with partners in the region



Pan American Standards Commission (COPANT) - Members



- *Argentina (IRAM)*
- *Barbados (BNSI)*
- *Bolivia (IBNORCA)*
- *Brazil (ABNT)*
- *Canada (SCC)*
- *Colombia (ICONTEC)*
- *Costa Rica (INTECO)*
- *Cuba (NC)*
- *Chile (INN)*
- *Dominican Republic (DIGENOR)*
- *Ecuador (INEN)*
- *El Salvador (CONACYT)*
- *Guatemala (COGUANOR)*
- *Grenada (GDBS)*
- *Guyana (GNBS)*
- *Honduras (COHCIT)*
- *Jamaica (JBS)*
- *Mexico (DGN)*
- *Nicaragua (MIFIC)*
- *Panama (COPANIT)*
- *Paraguay (INTN)*
- *Peru (INDECOPI)*
- *Saint Lucia (SLBS)*
- *Trinidad & Tobago (TTBS)*
- *USA (ANSI)*
- *Uruguay (UNIT)*
- *Venezuela (FONDONORMA)*

European Standards Organizations (ESOs)



- **CEN, CENELEC, and ETSI** are the European counterparts to the ISO, IEC, and ITU-T and are known collectively as the European Standards Organizations (ESOs)
- The ESO's are composed of the national standards bodies of Europe
- **CEN** the European Committee for Standardization, produces European standards in all areas except for electrotechnical and telecommunications
- **CENELEC** the European Committee for Electrotechnical Standardization, works to produce a single set of harmonized electrotechnical standards in Europe
- **ETSI** the European Telecommunications Standards Institute, determines and produces European telecommunications standards
- ANSI interacts with the ESOs in various ways, including holding 19 ANSI-ESO dialogues since 1989. In 2005, ANSI also began holding delegation meetings with the ESO's Joint Presidents Group (JPG).

European Standards Organizations (ESOs)



ANSI – ESO Interaction

- Ongoing interaction
- 20 dialogues since 1989
- February 2007, EC-CEN Biofuels Conference
- November 7, 2007, ANSI meeting with ESO Joint Presidents Group (JPG) and European Commission – Brussels
- February 6-7, 2008, CEN/CENELEC/ETSI/ANSI Interoperability Conference – Warsaw, Poland

Middle East and Africa

- Outside of ISO, IEC and the above mentioned regional groups, ANSI also interfaces with representatives of regional standards organizations from the Middle East and Africa
- In 2005, ANSI participated in an ASTM International Open House for standards leaders from the Middle East and Africa. The following countries and organizations were represented:
 - *Gulf Standardization Organization (GSO) for the GCC (Gulf Cooperation Council - an economic and political policy-coordinating forum for the six member states Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the UAE)*
 - *Arab Industrial Development and Mining Organization (AIDMO)*
 - *Bahrain (BSMD)*
 - *India (BIS)*
 - *Iraq (COSQC)*
 - *Israel (SII)*
 - *Lebanon (LIBNOR)*
 - *Jordan (JISM)*
 - *Kuwait (PAI)*
 - *Morocco (SNIMA)*
 - *Oman (DGSM)*
 - *Pakistan (PSQCA)*
 - *Palestine (PSI)*
 - *Qatar (QGOSM)*
 - *Saudi Arabia (SASO)*
 - *Tunisia (INORPI)*
 - *UAE (ESMA)*
 - *Yemen (YSMO)*

Middle East and Africa

- In 2007, ANSI participated in an ASTM International Open House for standards leaders from Sub-Saharan Africa. The following countries and organizations were represented:
 - *Botswana (BOBS)*
 - *Congo (OCC)*
 - *QUAE (Ethiopia)*
 - *Ghana (GSB)*
 - *Lesotho (LSQAS)*
 - *Malawi (MBS)*
 - *Mauritius (MSB)*
 - *Nigeria (SON)*
 - *Rwanda (RBS)*
 - *South Africa (SABS)*
 - *Swaziland (SQAS)*
 - *Zambia (ZABS)*
 - *Zimbabwe (SAZ)*

- **ANSI also works with:**
 - **ARSO – the African Organization for Standardization, and**
 - **SADCSTAN – The Southern African Development (SADC) Cooperation in Standardization**
 - **via SABS which is the designated coordinator for African standardization from the Pacific Area Standards Congress**

The United States Standards Strategy (USSS)

USSS - Highlights

- Strategy contains 12 initiatives focused on:
 - Participation of government
 - Importance of health, safety and the environment
 - Responsiveness to consumer interests, balance
 - Globally accepted principles for standards development
 - Government use of standards to meet regulatory needs
 - Preventing the use of standards as technical barriers to trade

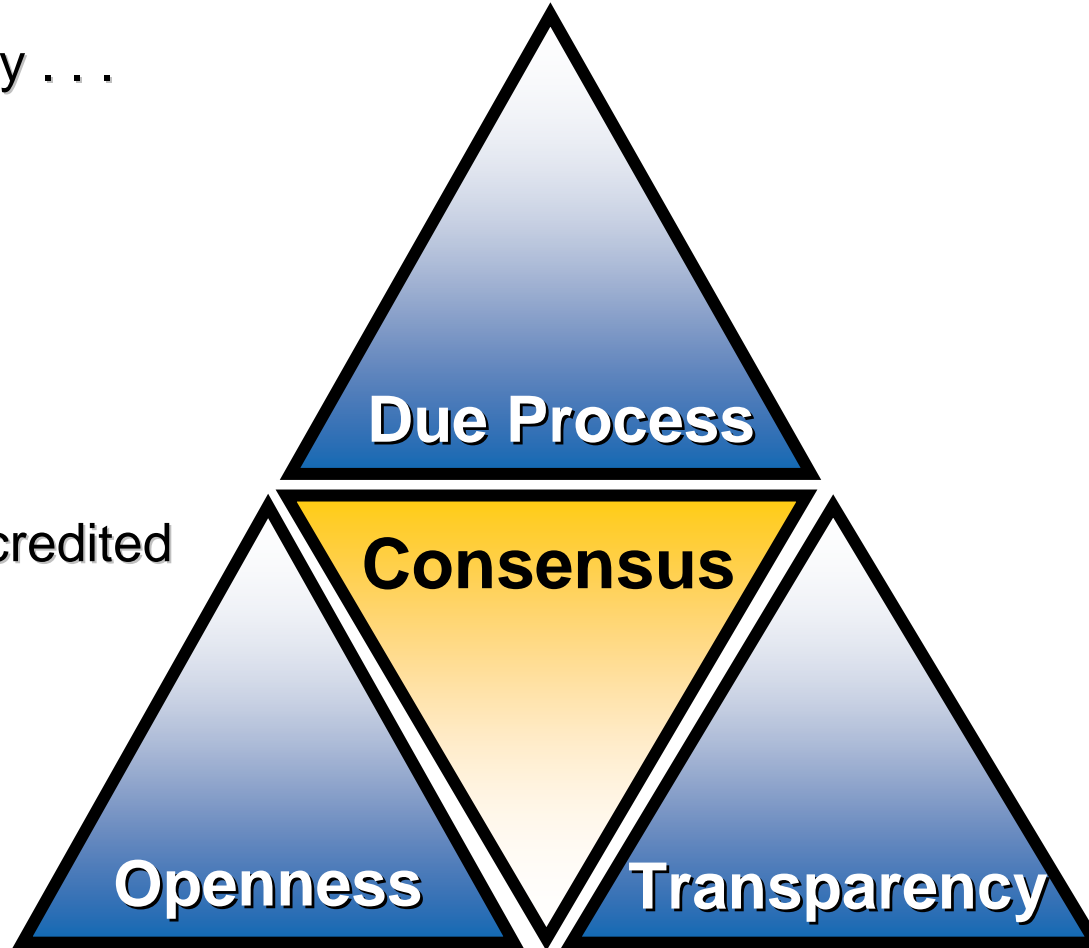
USSS - Highlights

- 12 initiatives (continued):
 - Outreach to promote consensus-based, market-driven processes – in the U.S. and internationally
 - Efficiency in development and distribution of standards
 - Cooperation and coherence within the U.S. system
 - Standards education as a high priority
 - Stable funding models for the U.S. system
 - Emerging national priorities and converging/cross-cutting technologies

Globalization & The Growing Impact of International Standards on Trade

Internationally Accepted Standards and Conformity Assessment Principles

- Agreed to by . . .
 - WTO
 - ISO
 - IEC
 - ANSI
 - ANSI Accredited SDOs



Roughly 80 percent of global merchandise trade is affected by standards and by regulations that embody standards.

Source:

National Institute of Standards and Technology

Testimony before the U.S. House of Representatives –

Committee on Science, Subcommittee on Technology

September 13, 2000

Objective

One Standard : One Test : One Acceptance (1:1:1)



In a global marketplace, the objective of the standardization process must be a single, technically valid and globally relevant standard with a single test of conformance to that standard.

This will allow products to be distributed for worldwide commerce without change or modification.

One Standard – One Test – One Acceptance

Global Impact to Trade – Trends



- Increasing use and adoption of international standards
- Increasing implementation of governmental regulations that reference voluntary consensus standards and conformity assessment programs
- Increasing participation in international and regional standards development and conformity assessment activities by all stakeholders (government, industry, local standards developers, and consumers)
- Increasing standards development in accordance with the WTO-TBT criteria: Transparency, Openness, Consensus, Due Process
- Standards and conformity assessment programs increasingly globally relevant, responsive to real world needs, and performance-based

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*

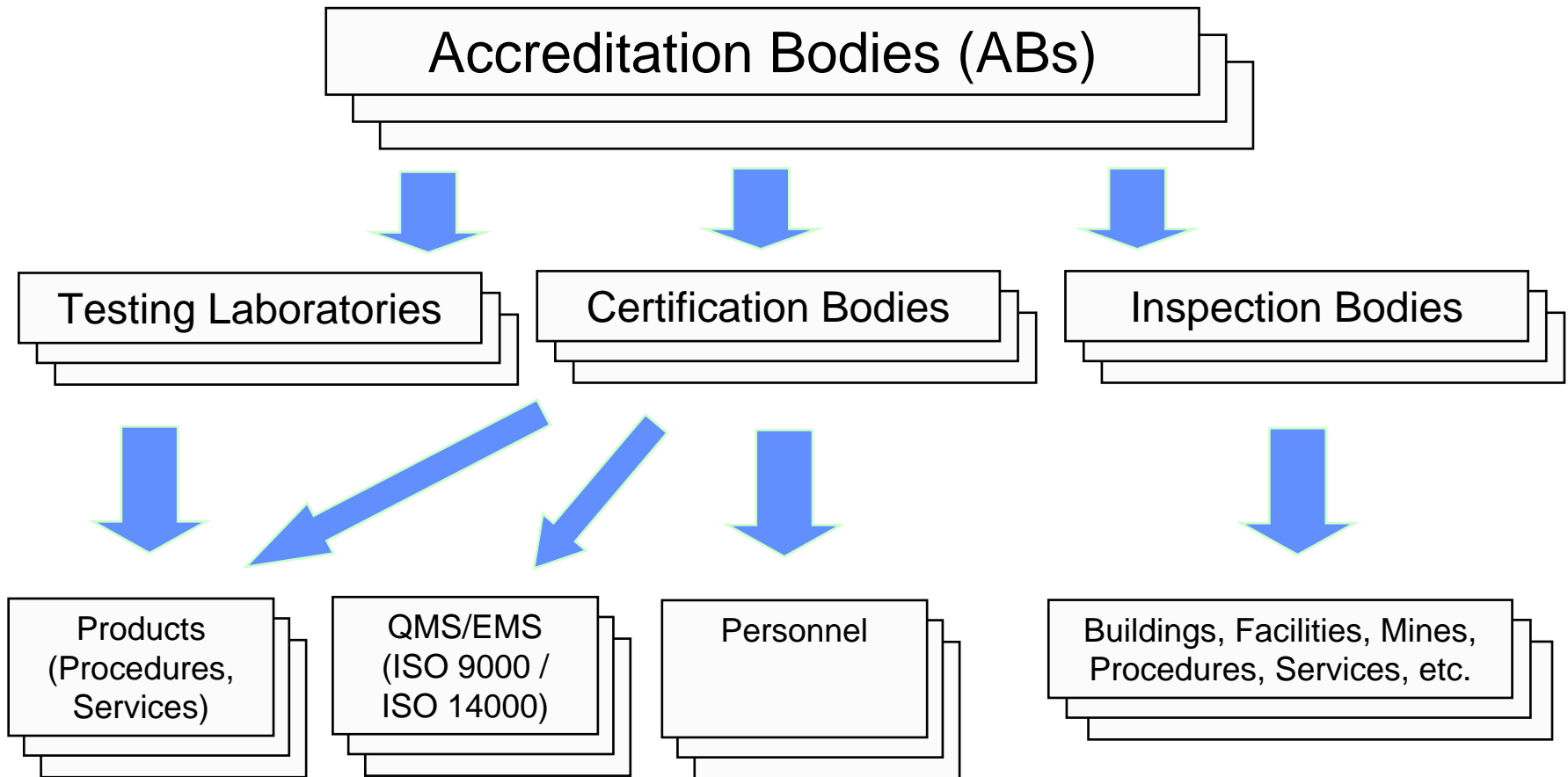
Conformity Assessment

- 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

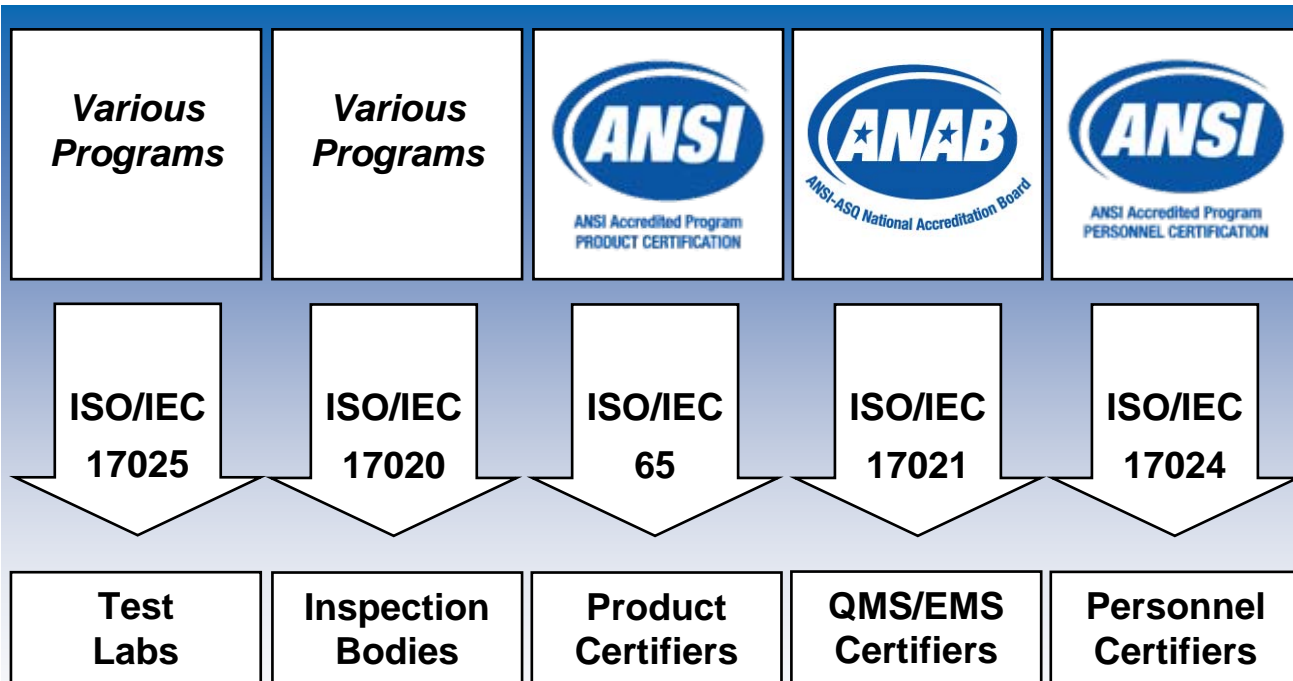
- **Metrology and measurement capabilities**
- **Sampling**
- **Testing**
- **Inspection**
- **Declaration of conformity**
- **Certification (products, services, personnel)**
- **Management system registration/certification**
- **Accreditation**
- **Enforcement**

Conformity Assessment System



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 complex and uses private-public sector partnership that insures industry sector input and supported by Federal legislation
- Conformity Assessment system, like Standards system, evolved in decentralized manner
- 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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