



Introduction to the International Framework and Obligations for Conformity Assessment

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Overview

- What is conformity assessment?
- How is the relationship between CA and international trade?
- What are the international rules on CA?
- What organizations are involved in CA?
- How is the U.S. conformity assessment system structured?
 - What is ANSI's role?

What Is Conformity Assessment?

ISO/IEC 17000:

“**demonstration that** specified **requirements** relating to a product, process, system, person or body **are fulfilled**”

NOTE: includes activities... such as testing, inspection, and certification, as well as accreditation of conformity assessment bodies

What is Conformity Assessment?

Example: An economy regulates toy safety by mandating that all toys meet the terms of an ASTM International standard, which requires that magnets be properly fastened to toys to ensure that children cannot swallow them

What is Conformity Assessment?

- The requirement to ensure that magnets are properly fastened is a **technical regulation** (it mandates that toys containing magnets have a particular performance characteristic)
- In this case, the technical requirement is contained in a **standard**, a *voluntary* document developed by the experts on an ASTM technical committee that becomes *mandatory* once compliance with its terms is incorporated in the technical regulation
- A **conformity assessment procedure** (e.g., testing) is a procedure to ensure that a technical requirement – the need to secure magnets properly -- is met.

What is the Relationship between CA and International Trade?



What are the International Rules on Conformity Assessment?

- Core concepts of the WTO Technical Barriers to Trade Agreement:
 - Transparency
 - Nondiscrimination
 - Avoidance of unnecessary obstacles to trade
 - Use of international standards

CA in the TBT Agreement

- Nondiscrimination
 - CAPs must be prepared, adopted and applied so as to grant access for suppliers of like products from other members on terms no less favorable
- Avoidance of unnecessary barriers to trade
 - CAPs cannot be stricter than necessary to provide adequate confidence of conformance with applicable requirements
- Reasonable CA application requirements
 - CA fees must be equitable
 - Procedures must be expeditious
 - Information disclosures must be limited to what is necessary
 - Confidential information is respected in a no less favorable manner
 - Citing of facilities must not be inconvenient

CA in the TBT Agreement, cont'd

- International standards
 - Use standards and guides issued by international standardizing bodies as the basis of conformity assessment
 - Members should participate in the development of such standards
 - If the CA is not based on an international standard and impacts trade, it should be notified to the WTO
- Mutual recognition
 - Conformity assessment procedures of other Members should be accepted, even if procedures are different, provided they give an assurance of conformity similar to domestic procedures

CA in U.S. Free Trade Agreements

- U.S. FTAs seek WTO-plus commitments
- The Trans-Pacific Partnership's TBT Chapter includes several new WTO-plus commitments
 - National treatment for CABs
 - Increased protection for business confidential information
 - Nondiscrimination for accreditation bodies

Conformity Assessment Infrastructure

- National measurement laboratories
- Standards bodies
- Laboratories
- Certification bodies
- Inspection bodies
- Accreditation bodies



Conformity assessment bodies **CAB's**

Accreditation bodies

Assess competence

Conformity assessment (CA) bodies

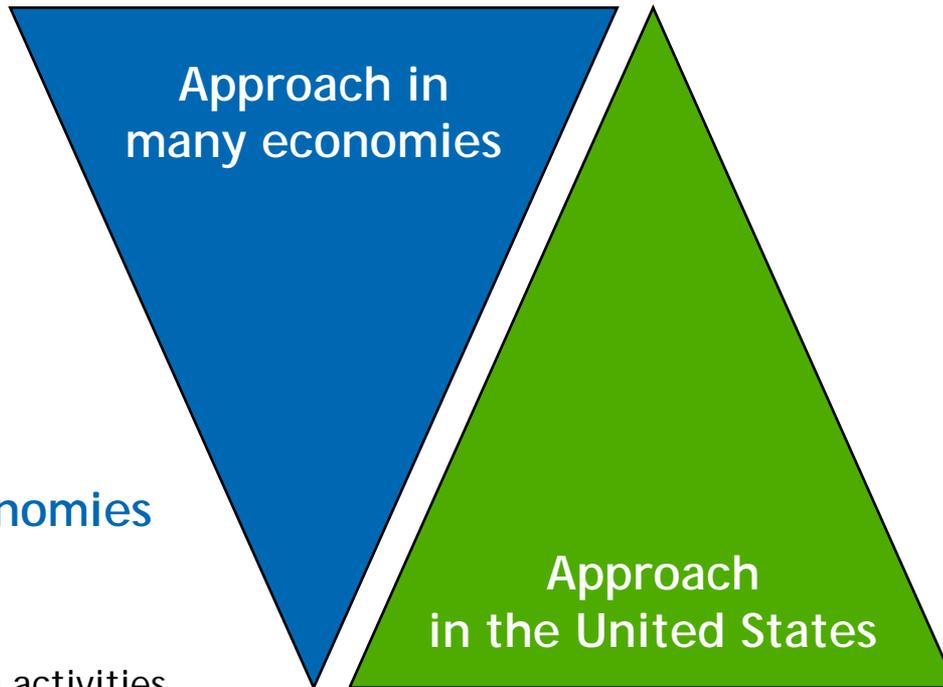
Audit/Test/Certify/Verify conformity

Object of CA (Product, Person, Organization, etc.)

Multilateral Recognitions are Essential



The U.S. Standards and Conformity Assessment System



Many other economies
Top Down

Standards bodies
drive standardization activities

United States
Bottom Up

Standards users drive
standardization activities

Overview of ANSI



- **ANSI** coordinates standards, conformity assessment, and related activities in the United States of America.
 - Founded **1918**, private, not-for-profit, (501(c)3)
 - Not a government agency, standards developer, or certifier
- **ANSI's mission:** enhance global competitiveness of U.S. business and American quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems and ensuring their integrity.

Overview of ANSI



The ANSI Federation represents more than **125,000 companies and organizations** and **3.5 million professionals** worldwide.

Members of the ANSI Federation include . . .

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

ANSI on the international stage

- U.S. national body member to ISO



- (International Organization for Standardization www.iso.ch)

- U.S. national body member to IEC



- (International Electrotechnical Commission www.iec.ch)

- Member of IAF & ILAC (International CA cooperatives)



- Member of regional forums in Pacific Rim/Americas



- Liaison with groups in Europe, Africa, Middle East



- Bilateral agreements with other national standards/CA bodies

ANSI's Role in Conformity Assessment

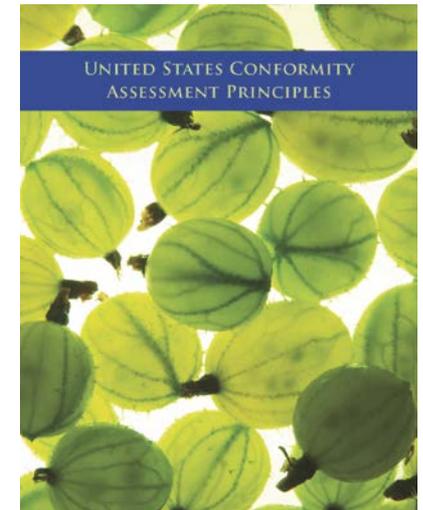
ANSI is committed to **2 related but distinct efforts**:

1. **ANSI Conformity Assessment Policy Committee (CAPC)** addresses conformity assessment policy issues.

- ANSI International Conformity Assessment Committee (ICAC) and ISO Conformity Assessment Committee (CASCO)
- Promotes education and understanding of conformity assessment

2. **ANSI Accreditation Programs** accredit conformity assessment bodies

- Serve market; open, flexible and efficient; technical rigor; highest integrity
- Strengthen, enhance government recognition for regulatory needs
- Support mutual recognition, interests and competitiveness of U.S. industry



ANSI's Accreditation Activities

	client	example	standard	scheme examples
Standards	SDO	INCITS, ASTM, UL	ANSI <i>Essential Req'ts</i>	n/a
	US TAG (ISO)	JTC-1, TC229, TC23	ANSI <i>Int'l Procedures</i>	n/a
Conformity Assessment (ISO 17011)	Product CB	BSI, IAPMO, NSF, UL	ISO/IEC 17065	FCC, EPA Energy Star, SQF, GFSI, ONCHIT
	Personnel CB	BPI, Cisco, GBCI, NFPA	ISO/IEC 17024	DoD, FDA, OSHA, <i>States</i>
	Cert Issuer	DRI, FBI, NRA, NSF	ANSI-ASTM E2659	CA Food Handlers, IREC
	GHG VVB	DNV, E&Y, KPMG, NSF, PWC, SAI, SII	ISO/IEC 14065	ACR, RGGI, TCR, Gold Std
	MS CB	BSI, IAPMO, ICONTEC, Intertek, NSF, PRI, SII	ISO/IEC 17021	AAQG, DHS, GFSI, QuEST
	Laboratory	Boston Scientific, NASA, Dole, Agilent	ISO/IEC 17025	DoD, EPA, FCC, US Customs
	Insp Body	UL, STR, Baltic Controls	ISO/IEC 17020	NYCDOB
	PT Provider	NAPT, Sigma Aldrich	ISO/IEC 17043	TNI
	RM Producer	US Pharmacopeia	ISO Guide 34	
	Medical Lab	LabPmm	ISO 15189	



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