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

- PAC: Pacific Accreditation Cooperation
- ILAC: International Laboratory Accreditation Cooperation
- APLAC: Asia-Pacific Laboratory Accreditation Cooperation
- IAF: International Accreditation Forum
- EA: European Accreditation Cooperation
- AFRAC: African Accreditation Cooperation
- IAAC: Inter American Accreditation Cooperation
The U.S. Standards and Conformity Assessment System

Many other economies
*Top Down*
Standards bodies drive standardization activities

Approach in the United States

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.
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](http://www.iso.ch))
- U.S. national body member to IEC
  - (International Electrotechnical Commission [www.iec.ch](http://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

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For More Information

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