



Inter-American
**Coalition for
Regulatory Convergence**

MEDICAL TECHNOLOGY SECTOR

International Standards and Conformity Assessment to Support GRP

June 2020



Key Terms

- **Standards**
 - **Market-driven** product and service specifications, established by **consensus** and approved by a recognized body that provides for common and repeated use (e.g., technical requirements, management systems, etc.)
- **Technical Regulations**
 - **Mandatory** technical specifications, which may include particular standards or conformity assessment procedures
- **Conformity Assessment**
 - **Processes and systems** used to verify the compliance of a product, person, process or system to either a standard or a regulation (e.g., testing, certification)
 - **Accreditation** is the assessment of the competence of conformity assessment bodies, and may be included in “conformity assessment”



What is consensus?

Substantial agreement has been reached by directly and materially affected interest categories. This signifies the concurrence of more than a simple majority, but not necessarily unanimity.

Consensus requires that all views and objections be considered, and that an effort be made toward their resolution and to reconcile any conflicting arguments.



International obligations: WTO TBT Agreement

- The World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement ensures that regulations, standards, and testing and certification procedures do not create unnecessary obstacles to trade.
 - Notification
 - International standards and recognition
 - Non-discrimination
 - Reasonable time to implement



Guiding Principles: WTO TBT Agreement

- Transparency
- Openness
- Impartiality
- Effectiveness and relevance
- Flexible
- Consensus
- Performance-based
- Coherence
- Due Process
- Technical Assistance
- Timely
- Balanced





International Standards

- Standards should meet societal and market needs and should not be developed to act as barriers to trade
- Standards that meet the WTO TBT principles are “international standards”, regardless of the organization that developed
- Code of Good Practice – TBT Agreement, Annex 3



What are ANSI-accredited SDO's?

- ANSI accreditation of SDOs and U.S. TAGs promotes alignment with the WTO's Internationally Recognized Principles for Standards Development

ANSI Essential Requirements
for the development of
American National Standards

World Trade Organization
Technical Barriers to Trade
Agreement

Openness
Transparency
Due Process
Consensus



What is ISO?



- The **International Organization for Standardization (ISO)** is a non-governmental organization established in 1947 and based in Geneva, Switzerland.
- ISO is a federation of national standards bodies from more than 160 countries, with one body representing each country.
- Its mission is to promote the development of standardization and related activities in the world; to facilitate the international exchange of goods and services; and to develop cooperation in intellectual, scientific, technological and economic activity.



ISO members from the Americas

- Argentina (IRAM)
- Bolivia (IBNORCA)
- Brazil (ABNT)
- Chile (INN)
- Colombia (ICONTEC)
- Costa Rica (INTECO)
- Cuba (NC)
- Dominican Republic (INDOCAL)
- Ecuador (INEN)
- El Salvador (OSN)
- Guatemala (COGUANOR)
- Honduras (OHN)
- Mexico (DGN)
- Nicaragua (DNM)
- Panama (COPANIT)
- Peru (INACAL)
- Uruguay (UNIT)



What is IEC?



- The **International Electrotechnical Commission (IEC)** is a not-for profit, quasi-governmental organization located in Geneva, Switzerland.
- Founded in 1906 specializing in the electrical and the electronic products field.
- The IEC's members (per country member structure) are National Committees and they appoint experts and delegates coming from industry, government bodies, associations and academia to participate in the technical and conformity assessment work of the IEC.



IEC members from the Americas

- Argentina (IRAM)
- Brazil (ABNT)
- Chile (INN)
- Colombia (ICONTEC)
- Cuba (NC)
- Mexico (DGN)
- Peru (INACAL)



Regional Standards Bodies



- **COPANT (Pan-American Standards Commission)**
 - Standards setting body for Latin and South American countries
 - Founded as the Pan American Technical Standards Committee in 1949 to develop regional standards
 - Currently 28 Active and 7 Adherent member countries
- **PASC (Pacific Area Standards Congress)**
 - Founded in 1972 in Honolulu, Hawaii
 - Currently 22 members
 - Does not set standards; rather, coordinates on standards issues
- **CEN (European Committee for Standardization)**
- **CENELEC (European Committee for Electrotechnical Standardization)**
- **ETSI (European Telecommunications Standards Institute)**



What is accreditation?

- Accreditation is the **independent evaluation** of conformity assessment bodies (CABs) against recognized standards to carry out specific activities **to ensure** their impartiality and **competence**.



ABs vs. CABs?

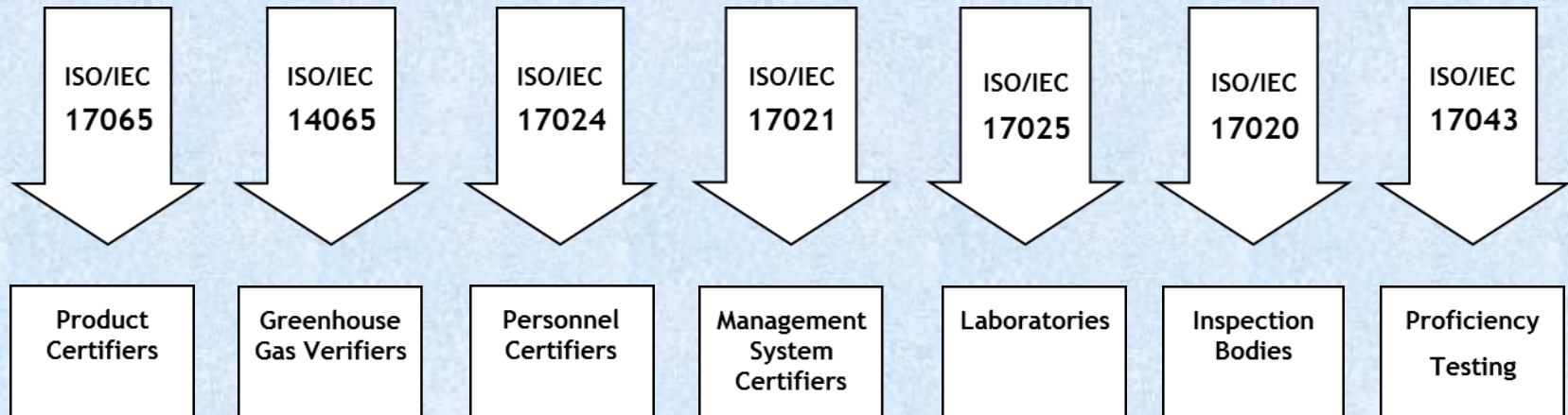
- An accreditation body (AB) is an organization that provides accreditation services, which is a formal, third party recognition of competence to perform specific tasks.

VS

- A conformity assessment body (CAB) is an organization that evaluates compliance with voluntary consensus standards or technical regulations.



Conformity Assessment (ISO/IEC 17011: Accreditation of CABs)





What is the IAF?



- **International Accreditation Forum (IAF)** is the world association of conformity assessment accreditation bodies in the fields of management systems, products, services, personnel and other similar programs of conformity assessment.
- Objective: “Certified Once – Accepted Everywhere”



What is ILAC?



- **The International Laboratory Accreditation Cooperation (ILAC)** is an international cooperation of laboratory and inspection accreditation bodies.
- Operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies.



IAAC members from the Americas

- **Argentina** - Organismo Argentino de Acreditación (OAA)
- **Brazil** - Coordenação Geral de Acreditação (Cgcre)
- **Chile** - Instituto Nacional de Normalización (INN)
- **Colombia** - Organismo Nacional de Acreditación de Colombia (ONAC)
- **Costa Rica** - Ente Costarricense de Acreditación (ECA)
- **Cuba** - Organo Nacional de Acreditación de la República de Cuba (ONARC)
- **Ecuador** - Servicio de Acreditación Ecuatoriano (SAE)
- **El Salvador** - Organismo Salvadoreño de Acreditación, (OSA)
- **Guatemala** - Oficina Guatemalteca de Acreditación (OGA)
- **Mexico** - entidad mexicana de acreditación a.c. (ema)
- **Nicaragua** - Oficina Nacional de Acreditación, (ONA)
- **Panama** - Consejo Nacional de Acreditación (CNA)
- **Paraguay** - Organismo Nacional de Acreditación (ONA)
- **Peru** - Instituto Nacional de Calidad – Dirección de Acreditación (INACAL-DA)
- **Uruguay** - Organismo Uruguayo de Acreditación (OUA)



Why are standards important?

- Standards are tools that help to reduce costs, minimize waste, limit errors and increase productivity.
- Standards help companies to access new markets in developing countries and facilitate global trade.
- Standards contribute to safety, provide protection for the environment, provide for product protection against climatic or other adverse conditions.





Why is conformity assessment important?

- Non acceptance of test reports and certificates is a non-tariff obstacle to trade.
- A harmonized approach to conformity assessment standards facilitates international trade.



Resources for future reference:

- WTO TBT: www.wto.org
- ANSI: www.ansi.org
- ISO: www.iso.org
- IEC: www.iec.ch
- IAF: www.iaf.nu
- ILAC: www.ilac.org



Questions?





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The logo for ANSI features a large, blue, curved swoosh that arches over the word "ANSI" in a bold, black, sans-serif font.

ANSI

American National Standards Institute