



International Standards and Conformity Assessment Support GRP

February 1, 2023

Medical Device Regulatory Convergence Project (MDRC) Workshop on Good Regulatory Practices and its implementation in the Medical Device Sector Africa - MDRC Project Countries



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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



WORLD TRADE
ORGANIZATION

WTO TBT Annex 3: Code of Good Practice for the Preparation, Adoption, and Application of Standards

- Key provisions:
 - Standards should not act as technical barriers to trade
 - Preference for international standards
 - Avoid duplication and overlap, strive for consensus
 - Publish a work program
 - Allow for a 60-day comment period
 - Take comments into account
- ANSI has accepted the CGP on behalf of its accredited SDOs.

Code of Good Practice: Substantive Provisions

Clause	Summary
F	Use international standards as a basis, except where inappropriate or ineffective
G	Play a full part in standards development of relevant international standardizing bodies
H	Make every effort to avoid duplication of work of other standardizing bodies (national or international)
I	Preference of performance-based product requirements over design-based or descriptive characteristics
J/K (P)	Publication of a work programme every 6 months
L/M/N	Allow public comment period of at least 60 days for draft standards; provide copy of draft standard upon request; take comments into account and reply promptly to other signatories to the Code
O	Promptly publish standards once adopted
Q	Afford opportunity for consultation on the operation of the Code

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

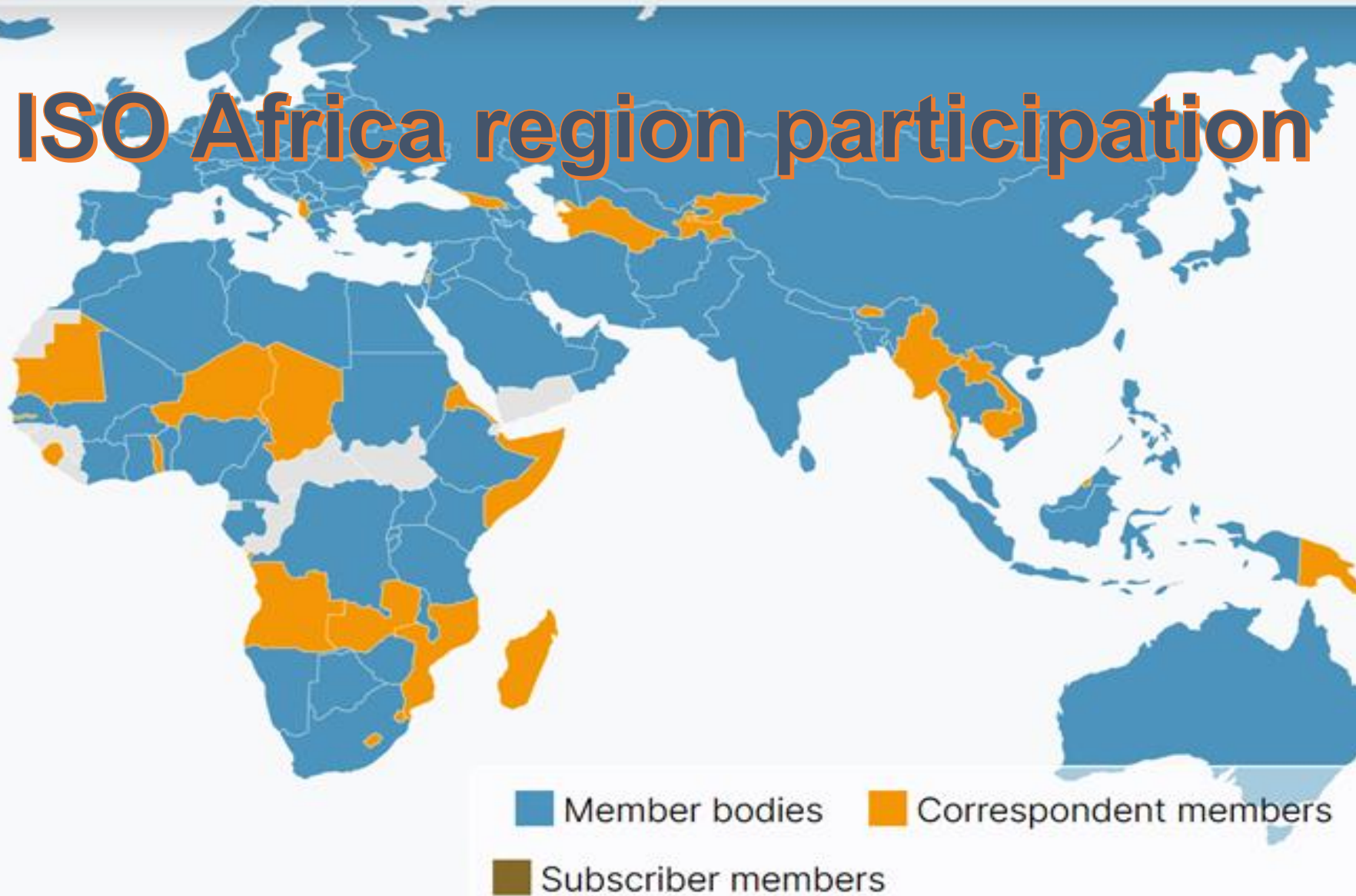
Openness
Transparency
Due Process
Consensus

What is ISO?



- **The International Organization for Standardization (ISO):**
 - non-governmental organization
 - established in 1947
 - Based in Geneva, Switzerland
 - Federation of national standards bodies from more than 165 countries, of which include many NSBs in the Africa region.
 - One body representing each country

ISO Africa region participation



What is IEC?



- The **International Electrotechnical Commission (IEC)**
 - 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.

Ghana IEC Associate Member

General **TC/SC Membership** TC/SC Secretariat Votes

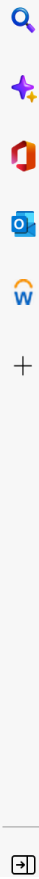
Participating Member 4 Observer Member 1 Total 5

en fr

TC/SC Membership



Committee	Description	P/O Status	Publications	Work Programme
TC 8	System aspects of electrical energy supply	P-Member	8	7
TC 57	Power systems management and associated information exchange	P-Member	151	66
TC 61	Safety of household and similar electrical appliances	P-Member	80	28
TC 64	Electrical installations and protection against electric shock	P-Member	45	24
ISO/IEC JTC 1/SC 25	Interconnection of information technology equipment	O-Member	22	20



Kenya IEC Associate Member

General **TC/SC Membership** TC/SC Secretariat Votes

Participating Member 5 Observer Member 1 Total 6

en fr

TC/SC Membership



Committee	Description	P/O Status	Publications	Work Programme
TC 21	Secondary cells and batteries	P-Member	33	9
TC 82	Solar photovoltaic energy systems	P-Member	74	65
SC 121B	Low-voltage switchgear and controlgear assemblies	P-Member	11	4
SyC LVDC	Low Voltage Direct Current and Low Voltage Direct Current for Electricity Access	P-Member		
ISO/IEC JTC 1/SC 25	Interconnection of information technology equipment	P-Member	22	20
ISO/IEC JTC 1/SC 41	Internet of Things and Digital Twin	O-Member		



South Africa IEC Full Member

General **TC/SC Membership** TC/SC Secretariat Votes

Participating Member **74** Observer Member **61** Total **135**

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TC/SC Membership

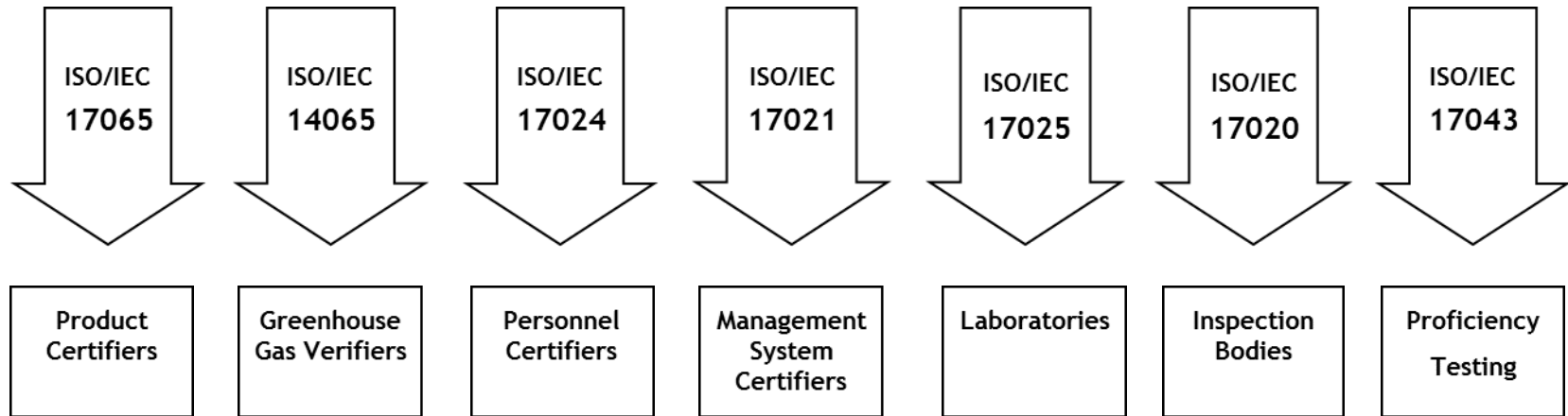


Committee	Description	P/O Status	Publications	Work Programme
TC 1	Terminology	O-Member	86	7
TC 2	Rotating machinery	P-Member	53	13
TC 7	Overhead electrical conductors	P-Member	18	4
TC 8	System aspects of electrical energy supply	P-Member	8	7

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**.

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




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.
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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



Q & A



Thank you!

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