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MEDICAL TECHNOLOGY SECTOR

Good Regulatory Practices & TBT Training Webinar 3/3

June 9, 2020

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Questions?

Please use the Questions/Chat pane of the GoToWebinar Control Panel

Agenda

TIME (MIN)	AGENDA
5	**Welcome Message & Training Objectives** *Sandra Ligia González, Executive Secretary*
15 + 5 Q&A	**Tiers 1&2 – World Trade Organization & TBT Agreement as GRP (15 Mins)** *Presented by: Renata Amaral – Technical Secretariat* ▪ Non-Tariff Trade Barriers (NTBs) ▪ Coverage of the TBT Agreement ▪ Main Principles of the Agreement ▪ Relevant Provisions ▪ ePing System **Q&A (5 Mins)** *Moderator: Sandra Ligia González, Executive Secretary*
15 + 5 Q&A	**Tiers 1&2 – International Standards and Conformity Assessment as GRP (15 Mins)** *Presented by: Jessica Roop – ANSI* ▪ Relationship of WTO/TBT to Standards and Conformity Assessment ▪ International Standards System ▪ International Accreditation System **Q&A (5 Mins)** *Moderator: Sandra Ligia González, Executive Secretary*
30 + 10 Q&A	**Tier 2 – International Standards and SDOs for Medical Technology (30 Mins)** *Presented by: Joe Lewelling – AAMI* ▪ ISO, IEC, AAMI, ASTM, CLSI, IEEE, CLSI, et al ▪ Overview of ISO/IEC member bodies from LatAm active in medical technology standardization ▪ International Standards and Trade Agreements in the Americas **Q&A (10 Mins)** *Moderator: Sandra Ligia González, Executive Secretary*
5	**Conclusions & Closing Remarks** *Sandra Ligia González, Executive Secretary*

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Technical Barriers to Trade and the Impact for the Medical Technology Sector

TBT Webinar

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Tiers 1&2 – World Trade Organization & TBT Agreement as GRP

Renata Amaral,
Technical Secretariat

Outline

- WTO General Rules
- Non-Tariff Trade Barriers
- Coverage of the TBT Agreement
- Main Principles of the Agreement
- Relevant Provisions
- ePing System

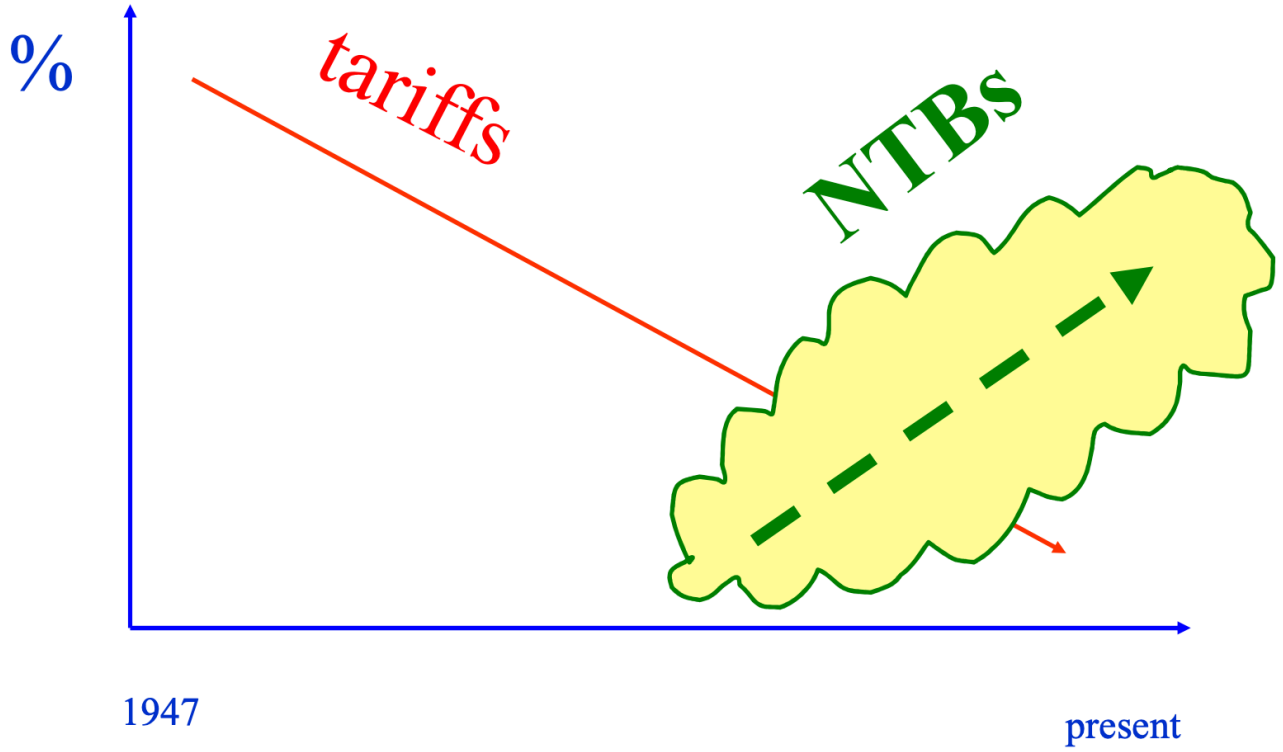
WTO General Rules

- The only international body dealing with rules of trade between nations (164 Members).
- WTO agreements provide the legal ground- rules for international commerce.
- They bind governments to keep their trade policies within agreed limits.
- Help trade flow as freely as possible (e.g. by removing obstacles, providing confidence, transparency and predictability).

Non-Tariff Barriers to Trade

- Technical measures (e.g. in standards)
- Internal taxes or charges
- Customs rules and procedures
- Quantitative import restrictions
- Public procurement practices
- Subsidies and related government supports
- Investment restrictions or requirements
- Transport regulations or costs …

Non-Tariff Barriers to Trade



Coverage of the TBT Agreement

- Technical measures (e.g. in standards)
- Internal taxes or charges
- Customs rules and procedures
- Quantitative import restrictions
- Public procurement practices
- Subsidies and related government supports
- Investment restrictions or requirements
- Transport regulations or costs …

The TBT Agreement

- **The acts as an instrument to:**
  - Encourage Members to use less-trade restrictive approaches to meet regulatory objectives
  - Harmonize through the use of relevant international standards
  - Provide transparency
  - Avoid and resolve trade disputes related to standards matters

The TBT Agreement

- **The Agreement safeguards against:**
  - The use of technical requirements as disguised restrictions on trade
  - The development of inefficient technical requirements and procedures

The relevance of the WTO for GRP

- Unnecessary regulatory differences can impose costs that prevent businesses from engaging in trade.

- The WTO plays an important role in supporting efforts to facilitate trade through regulatory cooperation among its 164 members, offering a **multilateral platform for dialogue among governments on trade rules, and throughout the full rule-making cycle.**

- The disciplines of the TBT Agreement can help contribute with effectiveness and efficiency of regulations through GRP. It laws down specific legal disciplines, which directly address the preparation, adoption and application of domestic regulations on goods.

- The TBT Agreement provides a unique multilateral transparency framework for regulations affecting the trade in goods.

TBT Agreement: main principles

- Non-discrimination
- Avoidance of unnecessary barriers to trade
- Harmonization through the use of international standards, guides and recommendations
- Transparency (notifications and enquiry points)
- Concepts of equivalence of technical regulations and mutual recognition of results of conformity assessment procedures

TBT Agreement

- Article 2.2: Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of **creating unnecessary obstacles to international trade**.

- Article 2.3: Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a **less trade-restrictive manner.**

- Article 2.4: Where technical regulations are required and relevant **international standards exist** or their completion is imminent, **Members shall use them**, or the relevant parts of them, **as a basis** for their technical regulations.

Principles to Develop International Standards

- The WTO Committee on Technical Barriers to Trade adopted a set of principles to which an organization engaged in the development of international standards must comply.

- These principles have been captured in document "G/TBT/ 1/REV. 8. Section IX," titled ***Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement.***

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TBT Agreement - Definitions

Annex 1 of the TBT Agreement

Technical Regulation:
A document that lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory.

Standard:
A document approved by a recognized body, 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

Conformity Assessment:
Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. Includes, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval.

Major Medical Technology Regulatory / Trade Challenges

1. **TBT agreement not implemented with most medical device regulators**

   - Most medical device regulators (staff drafting regulations) either not aware of the TBT agreement or not required to implement it by trade ministries
   - Most medical device regulators are not aware of the IMDRF guidance documents and the hundreds of relevant medical device standards upon which they should be basing their regulations (ISO, IEC, et al.)
   - Most medical device regulators still opting to dedicate their limited public health resources towards developing their own country/agency-unique requirements
   - If there is awareness of the TBT agreement, implementation is ex post and not ex ante

2. **Medical devices improperly regulated as drugs**

ePing system - WTO

ePing is an SPS & TBT notification alert system is a publicly available and self-subscribing service, whereby subscribers are able to receive email alerts regarding SPS and TBT notifications covering particular products and/or markets of interest to them.

In addition, users can search notifications, share notifications, upload additional information and participate in discussions.

ePing also offers an Enquiry Point Management Tool to facilitate domestic as well as international information sharing and discussion.

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ePing system - WTO

ePing track product requirements in export markets

World Trade Organization | International Trade Centre | United Nations

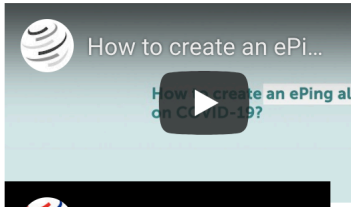
About | Search notifications | Enquiry points | News & events | Reference materials | Register | Log in | EN

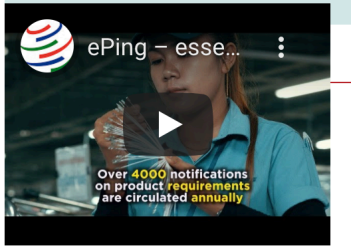
ePing enables timely access to evolving product requirements and facilitates dialogue amongst the public and private sector in addressing potential trade problems at an early stage.

64108
notifications included

#epingalert, #wtotbt, #wtosps

Step-by-step video on how to set up an email alert on COVID-19 related notifications





Search

Search notifications on product requirements, filtering by specific products or export markets

Receive alerts

Register for free to receive email alerts on new SPS & TBT notifications

Collaborate

Once registered, benefit from additional features such as the national forum

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ePing system - WTO

ePing track product requirements in export markets

WORLD TRADE ORGANIZATION | International Trade Centre | UNITED NATIONS

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TBT Enquiry Points | SPS Enquiry Points | SPS Notification Authorities

Export to Excel

Country/territory	City	Address	Contact	Email	Phone	Website
Search by country/territor						
Afghanistan		Jalalabad Highway Industrial Parks, Kabul P.O Box No: 5172 Central Post Office, Kabul	WTO/TBT Enquiry Point	noorhabib31@gmail.com	(+93) 75 20 86 743; (+93) 77 1 76 79 95	
Afghanistan		Kabul - Jalalabad Highway Industrial Parks Kabul P.O Box No: 5172 Central Post Office, Kabul	Afghan National Standards Authority (ANSA)	tbt@ansa.gov.af	(+ 93)75 20 86 74 3; (+93)77 17 67 99 5	http://ansa.gov.af
Albania		Rr: "Mine Peza", Nr.143/3	General Directorate of Standardization Tirana - Albania Contact person: Mr. Riza Hasanaj, General Director of General Directorate of Standardization Head of Sector of WTO/TBT	info@dps.gov.al; hasanaj.r@dps.gov.al; dea.nini@dps.gov.al	+(355 42) 22 62 55; +(355 42) 22 71 76	http://www.dps.gov.al/

Q & A

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Thank you!

Renata Amaral

Technical Secretariat

Inter-American Coalition for Regulatory Convergence
for the Medical Technology Sector

Renata@interamericancoalition-medtech.org

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International Standards and Conformity Assessment Support GRP

June 2020

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Tiers 1&2 – International Standards and Conformity Assessment as GRP

Jessica Roop, Senior Manager, International Policy for the America National Standards Institute (ANSI)

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

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

ANSI
American National Standards Institute

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.

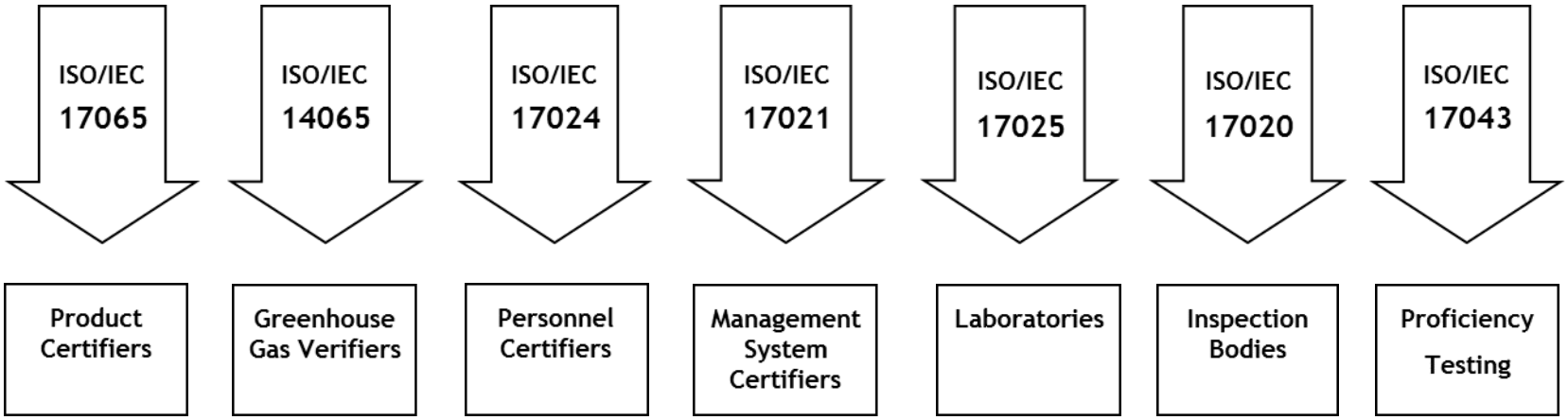
What is IEC?

- 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.

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)



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.
- Its primary function is to develop a single worldwide program of conformity assessment which reduces risk for business and its customers by assuring them that accredited certificates are reliable.
- 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 including calibration laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189), inspection bodies (using ISO/IEC 17020) and proficiency testing providers using ISO/IEC 17043.

IAF MLA Mark

- Multilateral Recognition Arrangement (MLA)
  - Based on ISO/IEC 17011 “Peer Assessment”
- Value:
  - assurance of equality, reduced time and cost
- MLA Scope
  - “Main” Scope: “equally reliable”
    - (e.g., management system, product)
  - “Sub” Scope: “equivalent”
    - (e.g., quality or environmental management system)

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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

Q & A

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Thank you!

Jessica Roop

Senior Manager, International Policy for the America National Standards Institute (ANSI)

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Using International Standards to Support the Regulation of Medical Technology

Joe Lewelling, VP of Standards Strategy and Emerging Technologies, AAMI

9 June 2020

Tier 2 – International Standards and SDOs for Medical Technology

Joe Lewelling, Vice President of Standards Strategy and Emerging Technologies at the Association for the Advancement of Medical Instrumentation (AAMI)

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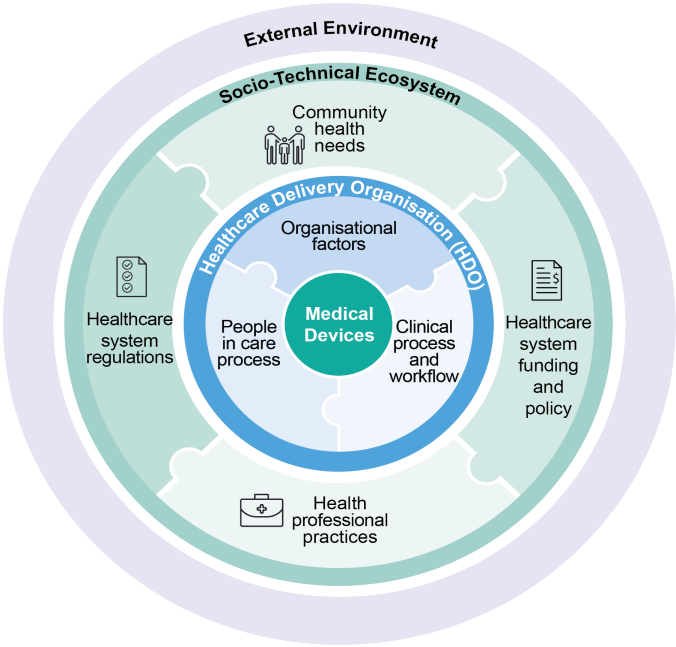
Principles and purpose of medical device standardization

Principles

- Standards only where there is a need
- Openness, transparency, due process (WTO TBT Principles)
- Focus on safety, efficacy, security and access (avoid design specifications)
- One standard—Preference for global solutions
- Aligned with technical regulations!
- Goal is *better* patient outcomes

The Healthcare Technology Ecosystem



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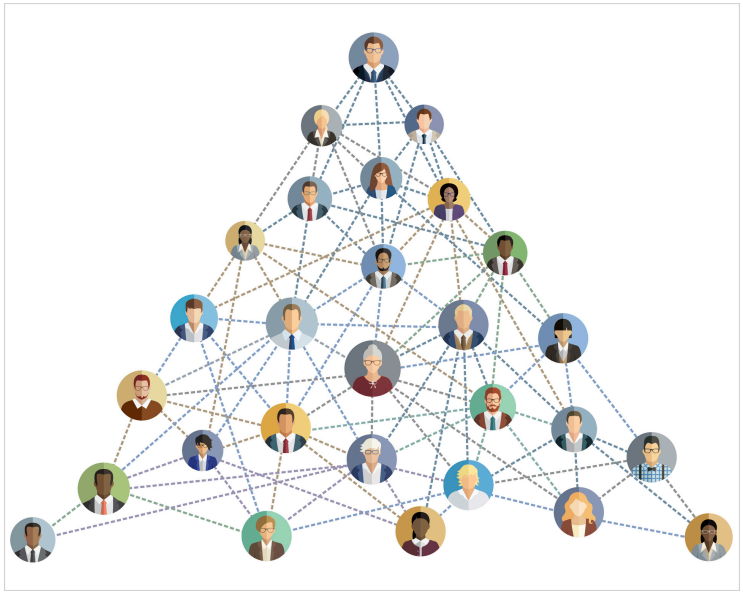
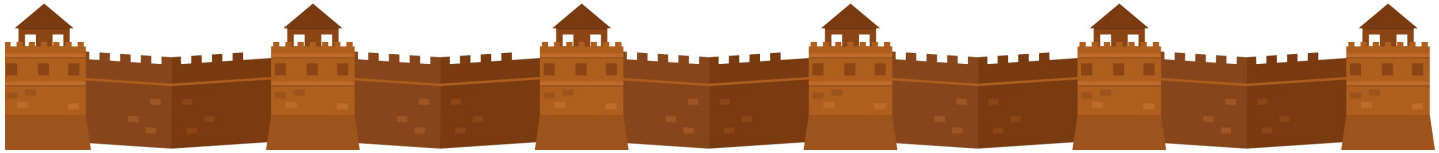
Goal of Standards→ "*Better Patient Outcomes*"…..



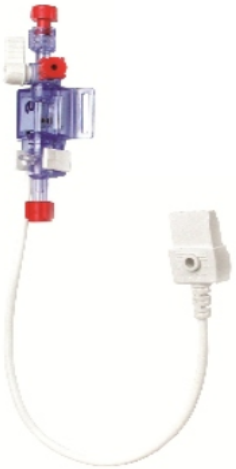
Tens of thousands of clinical, regulatory and government experts involved, worldwide

Gate-keeper (pre-market) approach to safety and effectiveness



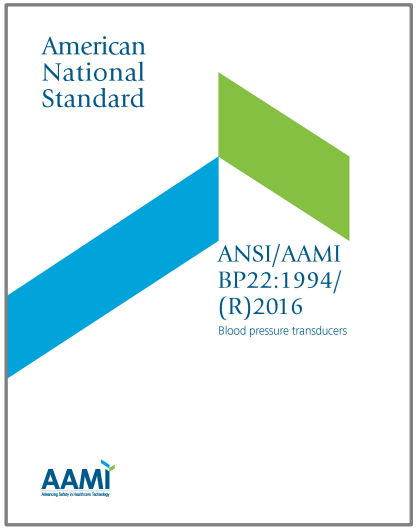
- ✓ Ensures effectiveness
- ✓ Ensures devices meet state of the art requirements for safety
- ✓ Comparatively simple
- ✗ Hinders access to new products
- ✗ Does not ensure ongoing product quality
- ✗ Does not promote (may hinder) improvement and innovation
- ✗ Does not ensure on-going quality of devices/emergent defects
- ✗ Does not address emergent hazards or defects

Gate-keeper (pre-market) approach



U.S. Code of Federal Regulations 21

- §870.2870 (Transducer, Pressure, Catheter Tip)
- §870.2850 (Transducer, Blood-Pressure, Extravascular)
- §870.2060 (Amplifier And Signal Conditioner, Transducer Signal)



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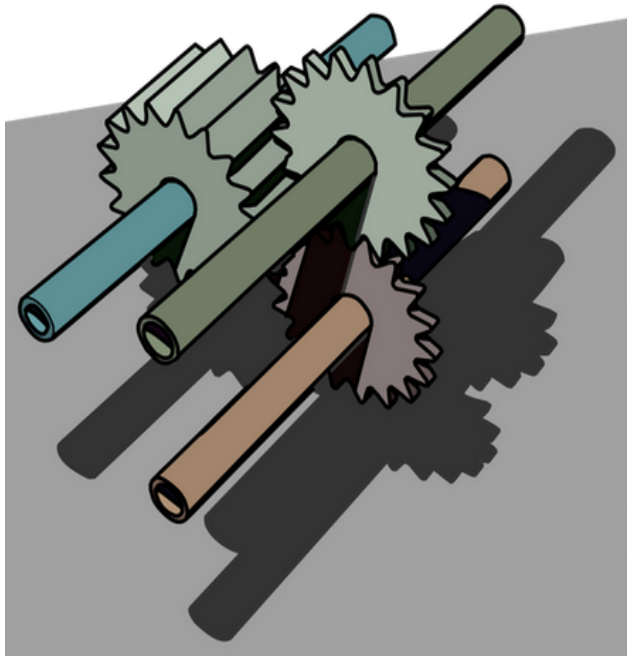
Systems (life cycle) approach to managing safety and effectiveness



- ✓ Promotes safety and effectiveness, throughout product lifecycle
- ✓ Facilitates entry of new products
- ✓ Encourages product improvement and innovation
- ✓ Ensures on-going quality of products
- ✓ Ensures emergent hazards or defects are identified and addressed

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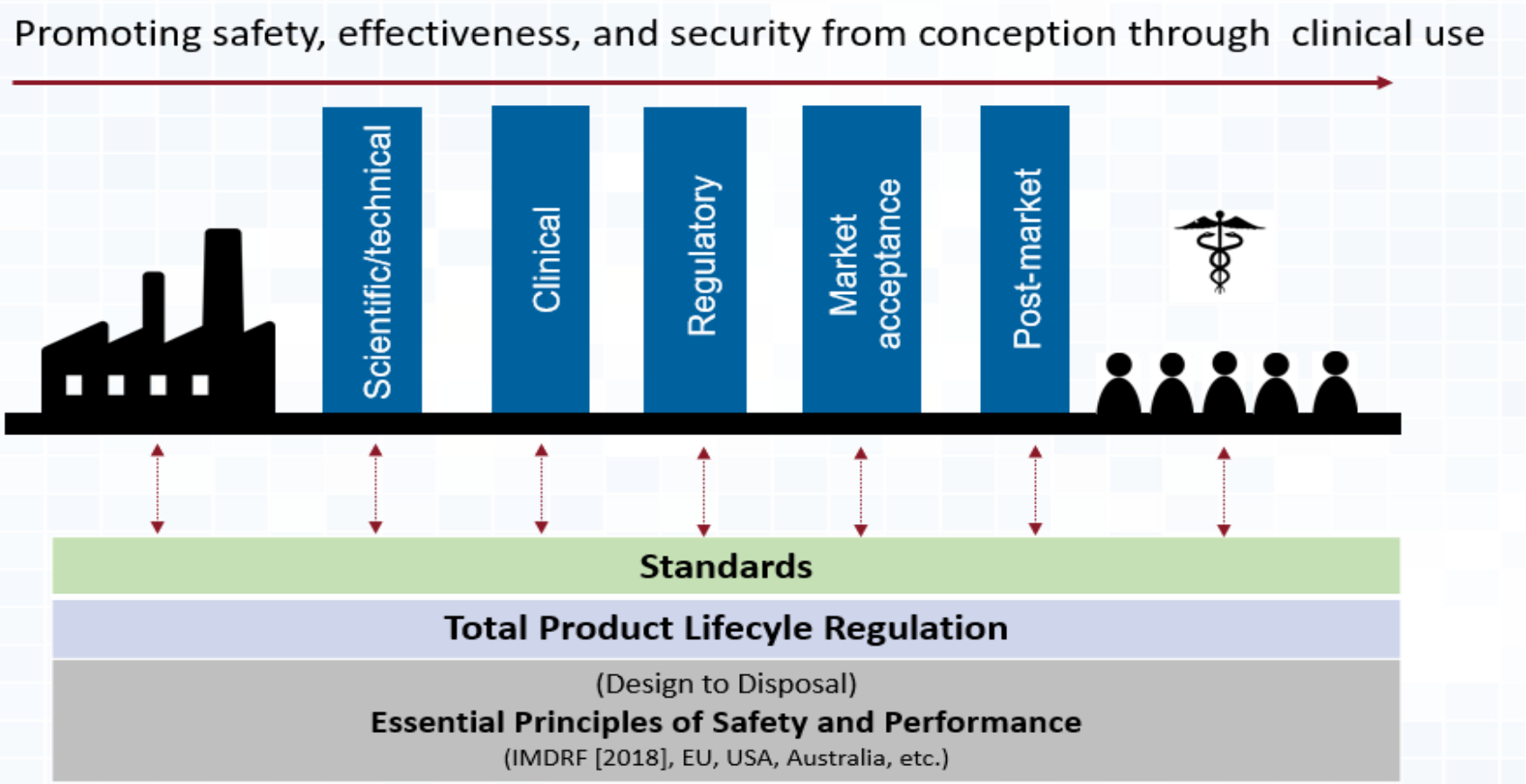
Systems (life cycle) approach



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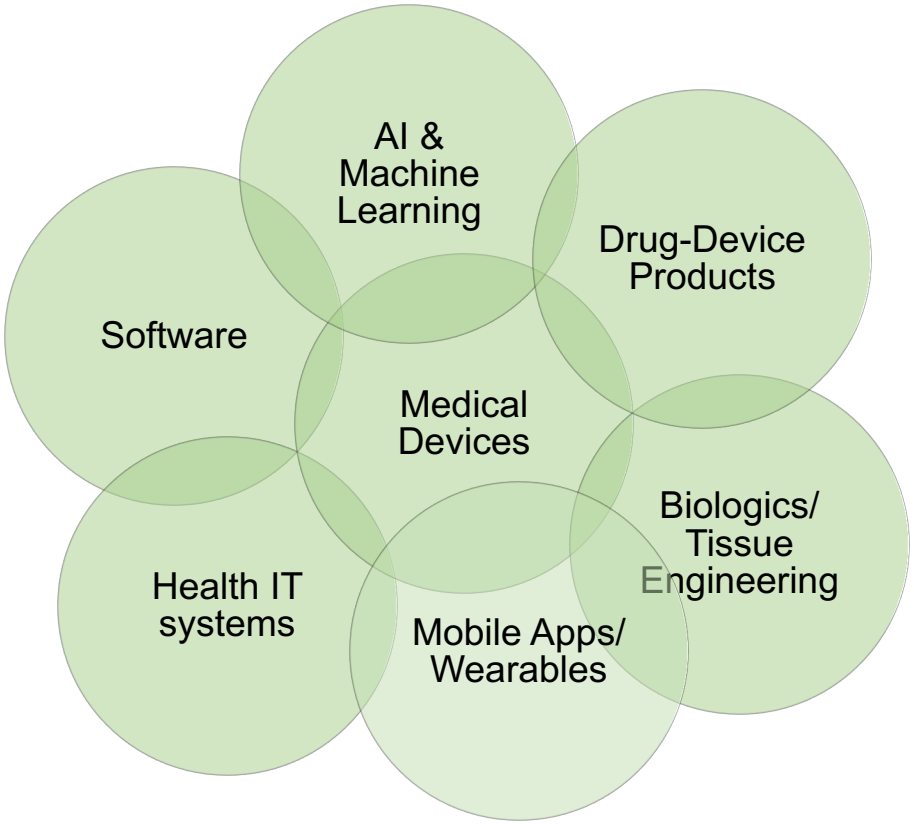
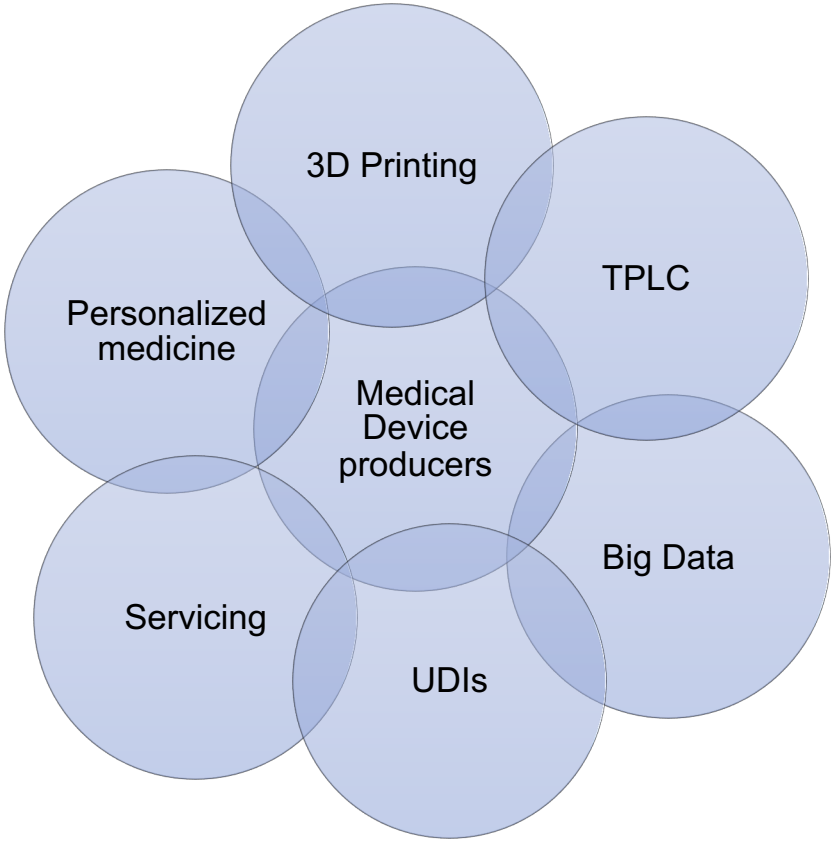


Future view: Unprecedented convergence of technologies

Medical devices are becoming more sophisticated, more complex and more effective

Future view: Change drivers

Advances in manufacturing and information technology are changing medical device companies from producers of products to providers of health care services



Focus for Medical Device Standards Developers

- Shared safety management across the TPLC
- Combination products
- Emergent Technologies
- Distributed (remote) healthcare
- Faster processes
- Consumerization/Commoditization
- Personalized health

Regulatory participation in standards development..

- Ensures regulators, concerns are addressed
- Promotes achievement of regulatory goals
- Facilitates common understanding of the standards
- Provides credibility for the standards

Regulator involvement in standards development

- Reduces administrative burden
- Enables “smart”, nimble, and responsive regulation
- Ensures state-of-the-art levels of **safety** and **effectiveness** and **security**
- Lowers costs and improves **access**
- Leverages the expertise of thousands of medical technology experts from around the world

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Current Coalition participation in International Organization for Standardization (ISO) Medical Device Committees	Argentina	Brazil	Canada	Chile	Colombia	Costa Rica	Ecuador	Dominican R.	Mexico	Panama	Peru	USA
ISO/TC 76, Transfusion, infusion, injection and blood processing equipment	O											P
ISO/TC 84, Devices for admin of medicines & catheters	O		P		O							P
ISO/TC 106, Dentistry	O	P	P									P
ISO/TC 121, Anesthesia and respiratory equipment*	P	P	P									P
ISO/TC 150, Implants for surgery	P	P				O						P
ISO/TC 157, (non-systemic) Contraceptives and STI prophylactics	O	P							P			P
ISO/TC 194, Biological and clinical evaluation of medical devices	P	P	P									P
ISO/TC 198, Sterilization of health care products	P	P	P		P	O					O	P
ISO/TC 209, Cleanrooms and associated environs.	O	P	P									P
ISO/TC 210, Quality Mgt and associated aspects for medical devices	P	P	P	O	P		O		P	P		P
ISO/TC 212, Clinical lab testing and IVD test systems	P	O	P	P	P					P	O	P
ISO/TC 215, Health informatics	O	P	P		O		O		P		O	P

P = Participating member | O = Observer member

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Current Coalition participation in International Electrotechnical Commission (IEC) Medical Device Committees (abbrev. titles)IECIEC	Argentina	Brazil	Canada	Chile	Colombia	Costa Rica	Ecuador	Dominican R.	Mexico	Panama	Peru	USA
IEC/TC 62, Electrical equipment in medical practice		P	P						O			P
IEC/SC 62A, Common aspects of electrical equipment used in medical practice		P	P						O			P
IEC/SC 62B, Diagnostic imaging equipment		P	P									P
EC/SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry		P	P									P
IEC/SC 62D, Electromedical equipment		P	P									
IEC/TC 66, Safety of measuring, control and laboratory equipment		P	P									
IEC/TC 76, Optical radiation safety and laser equipment		P	P									P
TC 87, Ultrasonics		P										P

P = Participating member | O = Observer member

AAMI
Advancing Safety in Health Technology

Professional Society (est. 1967) dedicated to the development, management, and use of safe and effective health technology. It pursues this mission through events, publications, education and the development of standards.

www.aami.org

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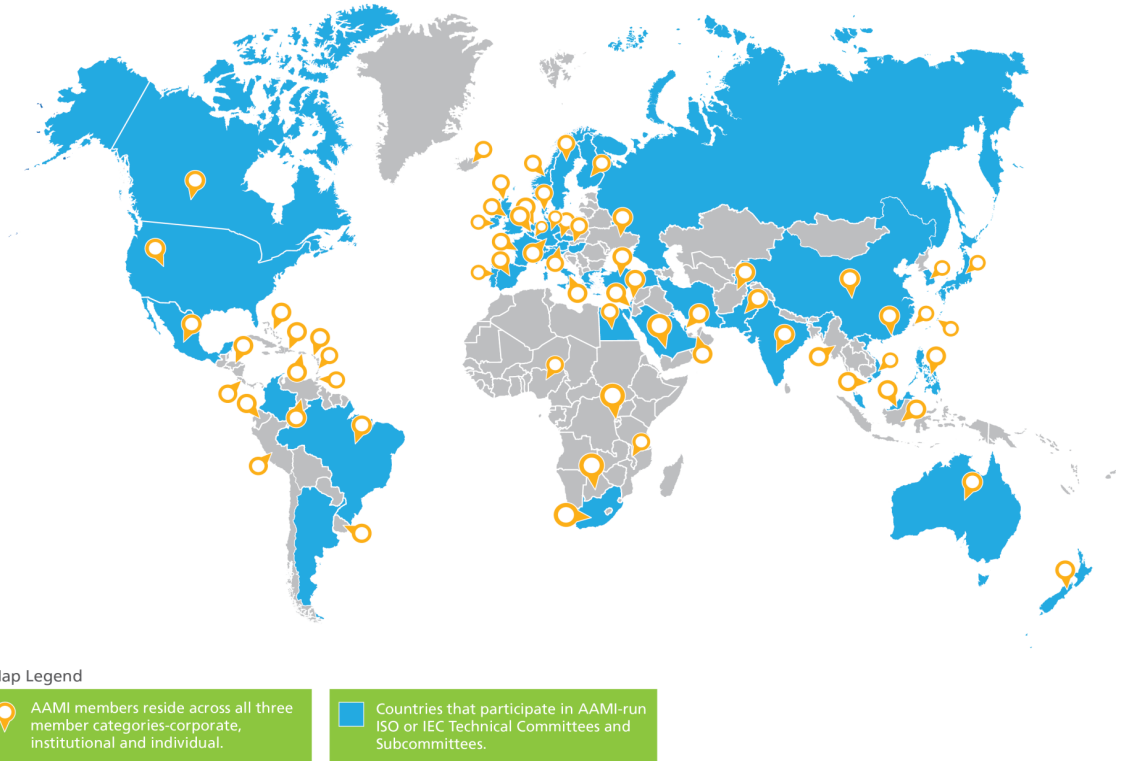
AAMI

Advancing Safety in Health Technology

- **7,500+ members**, including clinicians, academics, regulators, industry
- **Convenes** a global community of health technology professionals with more than 4,000 active participants.
- **Administers** ~230 standards committees or working groups (AAMI, ISO, IEC).
- **Develops and updates** a portfolio of more than 250 AAMI-branded standards and technical reports on health technology and more than 350 ISO or IEC technical documents.



ASTM INTERNATIONAL
Helping our world work better

- www.astm.org - one of the world's oldest and largest standards development organizations
- Open and direct membership has resulted in members from over 100 countries
- Meets WTO Technical Barriers to Trade principles for international standards
- Regulating authorities in at least 100 countries reference ASTM standards in regs or guidance
- Cooperation agreements with most National Standards Bodies in Inter-American region facilities cooperation and adoption

ASTM INTERNATIONAL
Helping our world work better

Committee F04 on Medical and Surgical Materials and Devices

- Formed in 1962
- Membership of 900 including US FDA and Health Canada
- 34 technical subcommittees
- 305 standards play preeminent role in FDA guidance for
  - ✓ materials
  - ✓ orthopedic devices
  - ✓ testing
  - ✓ tissue engineering
  - ✓ medical/surgical instruments

Committee F23 on Personal Protective Clothing and Equipment

- Membership approx. 260
- US & WHO recommend ASTM PPE masks and gowns standards
- 44 F23 standards address issues relating to hazards
  - ✓ physical
  - ✓ chemical
  - ✓ biological
  - ✓ human factors
  - ✓ flame and thermal
  - ✓ radiological

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Clinical and Laboratory Standards Institute

The Highest Standards for Global Health Care

- CLSI is a standards development organization that creates global best practices for medical laboratories.
- 250+ Standards and Companion Products.
- Secretariat for ISO Technical Committee (TC) 212.
- WHO collaborating center for clinical laboratory standards development.

International Organization for Standardization

World Health Organization

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MEDICAL TECHNOLOGY SECTOR

Clinical and Laboratory Standards Institute

The Highest Standards for Global Health Care

- CLSI standards are recognized by laboratories, accreditors, and regulators around the world as the way to improve medical laboratory testing.
- 1700+ organizational members from 80+ countries
- 22,000+ individuals with membership access
- 2600+ volunteers

CDC Centers for Disease Control and Prevention
CMS Centers for Medicare & Medicaid Services
Mayo Clinic
Department of Defense, United States of America
Department of Veterans Affairs, United States of America
The Joint Commission, National Quality Approval
Cleveland Clinic
NIST
FDA The Food and Drug Administration
Johns Hopkins School of Medicine
College of American Pathologists

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MEDICAL TECHNOLOGY SECTOR

MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

The Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA), is the leading organization and collective voice of medical imaging equipment, radiopharmaceutical manufacturers, innovators and product developers.

Mission: Reduce regulatory barriers, establish standards, and advocate for the medical imaging industry

www.medicalimaging.org

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MEDICAL TECHNOLOGY SECTOR

MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

- MITA represents companies whose sales make up **more than 90 percent** of the global market for advanced imaging technologies
- Collaborates with associations across **North America, Asia, and Western Europe** on industry standards and policy advocacy
- **Promotes the industry voice** through publication of MITA-branded reports, whitepapers, and research studies

Q & A

Inter-American
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MEDICAL TECHNOLOGY SECTOR

Thank you!

Joe Lewelling

Vice President of Standards Strategy and Emerging Technologies at the Association for the Advancement of Medical Instrumentation (AAMI)

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National Standards Bodies

National Standards Bodies (NSBs)
ISO Member Bodies from the Americas
(Members of the Pan-American Standards Commission)

Antigua and Barbuda	ABBS	Cuba	NC	Nicaragua	DNM
Argentina	IRAM	Dominica	DBOS	Panama	COPANIT
Bahamas	BBSQ	Dominican Republic	INDOCAL	Paraguay	INTN
Barbados	BNSI	Ecuador	INEN	Peru	INACAL
Belize	BZBS	El Salvador	OSN	Saint Kitts and Nevis	SKNBS
Bolivia	IBNORCA	Guatemala	COGUANOR	Saint Lucia	SLBS
Brazil	ABNT	Guyana	GNBS	Saint Vincent and the Grenadines	SVGBS
Canada	SCC	Haiti	BHN	Sao Tome and Principe	SENAPIQ STP
Chile	INN	Honduras	OHN	Suriname	SSB
Colombia	ICONTEC	Jamaica	BSJ	Trinidad and Tobago	TTBS
Costa Rica	INTECO	Mexico	DGN	United States	ANSI
				Uruguay	UNIT

IEC National Committees from the Americas (* Members of the Forum of the IEC National Committees of the Americas – FINCA)

Argentina *	aea.org.ar
Brazil *	cobei.org.br
Canada *	scc.ca
Chile *	cornelec.cl
Colombia *	icontec.org
Cuba	nc.cubaindustria.cu
Mexico *	economia.gob.mx
Peru	inacal.gob.pe
United States of America *	ansi.org

Standards Bodies with Memoranda of Understanding with ASTM International

Antigua and Barbuda	ABBS	El Salvador	OSN	Panama	COPANIT
Bahamas	BBSQ	Greneda	GDBS	Paraguay	INTN
Barbados	BNSI	Guatemala	COGUANOR	Peru	INACAL
Belize	BZBS	Guyana	GNBS	Saint Kitts and Nevis	SKNBS
Bolivia	IBNORCA	Haiti	BHN	Saint Lucia	SLBS
Chile	INN	Honduras	OHN	Saint Vincent and the Grenadines	SVGBS
Colombia	ICONTEC	Jamaica	BSJ	Sao Tome and Principe	SENAPIQ STP
Costa Rica	INTECO	Mexico	DGN	Suriname	SSB
Dominica	DBOS	Monserrat	MALHE	Trinidad and Tobago	TTBS
Ecuador	INEN	Nicaragua	DNM	Uruguay	UNIT

Every Coalition association, member company and MD RA should have:

- An Organization-wide Standards Strategy / Policy
- A Designated Standards Lead (Standards Executive)
- A Designated liaison to the local National Standards Body
  - and medical device technical / policy committees
- A Mapping of organization participation in international standardization (technical and policy) – worldwide
- Identification of who tracks WTO/TBT notifications and submits comments on them
- Identification and coordination between QARA and GR/Trade teams

Closing Remarks