International Standards: Their Role in the Regulation of Medical Devices

Presentation to the Medical Device Regulatory Convergence Project

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Amanda Benedict, AAMI, Vice President, Sterilization

The Value of International Standards

What are standards?

- In its "*A Guide to Standards*" publication, SES - the Society for Standards Professionals describes a standard as "A document that applies collectively to codes, specifications, recommended practices, classifications, test methods, and guides, which have been prepared by a standards developing organization or group, and published in accordance with established procedures."

The Value of International Standards

How are standards used?

- **To establish technical specifications** and **provide a common language.**
- To provide a **minimum essential** threshold.
- As a **foundation** for technology development and innovation**.**
- As a basis for **conformity assessment.**
- As a means to **facilitate** market entry and trade.

The Value of International Standards

The Big Picture: medical device standards…

- Promote health safety, access, security, and privacy that best serves the patient.
- Help to facilitate trade, a competitive marketplace, quality, and efficiency for production and support the complete value chain to the patient.
- Are preferential to additional regulation.
- Provide a presumption of conformance with regulatory requirements.
- Internationally are “a building block for harmonized regulatory processes to assure the safety, quality and performance of medical devices.” (IMDRF)

Global harmonization of standards can facilitate regulatory convergence.

The Value of International Standards

- Legal and professional value of standards and standards participation
- What should we want in standards?

How Standards are Developed

The standards landscape

- Types of standards and related documents
  - Standard
  - Technical specification
  - Technical report
  - Other, including “fast track” deliverables
- Stakeholder groups and committee leadership
- Medical device standards development organizations (types, specific organizations, and areas applicable)
  - National (e.g., KEBS, AAMI, PDA, BSI)
  - Regional (e.g., CEN, CENELEC, ARSO)
  - International (e.g., ISO, IEC, ASTM, IEEE)

How Standards are Developed

ISO and IEC technical committees relevant to medical devices:

- IEC/TC 62, Electrical equipment in medical practice
- IEC/TC 66, Safety of measuring, control and laboratory equipment
- IEC/TC 87, Ultrasonics
- ISO/IEC JTC 1/SC 42, Artificial intelligence
- ISO/TC 76, Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use
- ISO/TC 84, Devices for administration of medicinal products and catheters
- ISO/TC 106/SC 4, Dental instruments
- ISO/TC 121, Anaesthetic and respiratory equipment
- ISO/TC 150, Implants for surgery
- ISO/TC 157, Non-systemic contraceptives and STI barrier prophylactics
- ISO/TC 168, Prosthetics and orthotics
- ISO/TC 170, Surgical instruments
- ISO/TC 172/SC 5, Microscopes and endoscopes
- ISO/TC 172/SC 7, Ophthalmic optics and instruments
- ISO/TC 173/SC 3, Aids for ostomy and incontinence
- ISO/TC 194, Biological evaluation of medical devices
- ISO/TC 198, Sterilization of health care products
- ISO/TC 209, Cleanrooms and associated controlled environments
- ISO/TC 210, Quality management and corresponding general aspects for medical devices
- ISO/TC 212, Clinical laboratory testing and in vitro diagnostic test systems
- ISO/TC 215, Health informatics
- ISO/TC 338, Menstrual products

AAMI administered secretariat and/or US mirror group

How Standards are Developed

- Principles of standards development
- Legal aspects of standard development process
- Standards development procedures
- Relationship of national and international standards and adoption criteria

Development Process for Medical Device Standards

Common acronyms:

- ISO = International Organization for Standardization
- IEC = International Electrotechnical Commission
- CEN = European Committee for Standardization
- CENELEC = European Committee for Electrotechnical Standardization
- TC = ISO or IEC technical committee
- SC = ISO or IEC subcommittee
- WG = Working group
- TS = Technical specification
- TR = Technical report
- WD = Working draft
- CD = Committee draft
- CDV = Committee draft for vote
- DIS = Draft International Standard
- FDIS = Final Draft International Standard
- NWIP (or NP) = new work item proposal

Development Process for Medical Device Standards

- Standards development stages/status
  - Preliminary stage (PWI)
  - New work item proposal (NWIP/NP)
  - Iterative drafting for comment/comment and vote (WD, CD, CDV, DIS, etc.)
  - Publication
    - Recognized or referenced by authorities
  - Systematic Review

Development Process for Medical Device Standards

- Defining the scope
- Differentiating between requirements and requirements
  - Normative vs. Informative clauses and references
  - “shall”, “should”, “may”, “can”, “must”
- Terminology and definitions

Development Process for Medical Device Standards

- Proper reference format to a standard
  - Normative, general
  - Normative, specific
  - Informative, general
  - Informative, specific

Effective Engagement in Standards Development

- National and international standards development programs vary by:
  - Participation
  - Requirements
  - Process
- Pathways to participate in international standardization

Effective Engagement in Standards Development

- Kenya's national standards body is the Kenya Bureau of Standards (KEBS)
- KEBS engages as either a P- or O-member in many ISO and IEC technical committees and subcommittees, but…

Effective Engagement in Standards Development

KEBS participation in ISO and IEC technical committees relevant to medical devices:

- ~~IEC/TC 62, Electrical equipment in medical practice~~
- ~~IEC/TC 66, Safety of measuring, control and laboratory equipment~~
- ~~IEC/TC 87, Ultrasonics~~
- ISO/IEC JTC 1/SC 42, Artificial intelligence
- ~~ISO/TC 76, Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use~~
- ISO/TC 84, Devices for administration of medicinal products and catheters
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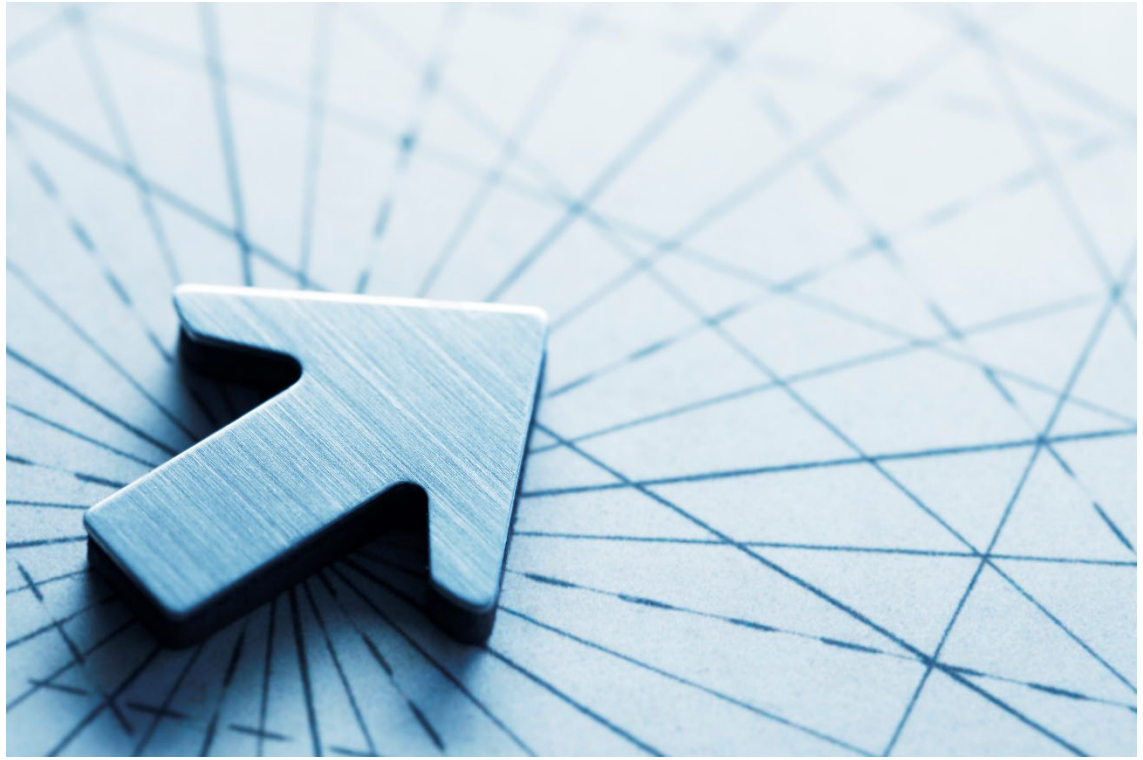
Participating member

Observing member

Effective Engagement in Standards Development



- Skill sets required and time commitment for effective standards participation
- Leadership opportunities
- Development routes

In Summary

- Standards advance patient safety and improve outcomes.
- Global harmonization of standards aligns with regulatory convergence efforts.
- Standards development needs the regulatory voice!

Questions?

AMANDA BENEDICT
AAMI
VICE PRESIDENT, STERILIZATION
ABENEDICT@AAMI.ORG