Intro to AAMI and getting involved in standards development

Presentation for MedTech Standards and Conformity Assessment Webinar

3 March 2022

Who Is AAMI?

Professional society

- Of those interested in health technology
- Not a trade association (no advocacy!)

10,000+ members

- HDOs, industry, vendors , government, technology professionals, engineers, doctors, nurses, students, academics, researchers, consultants, regulators

Over 500 corporate and institutional members

Expertise and experience convening diverse stakeholder to drive consensus

AAMI Standards Program

Accredited by American National Standards Institute (ANSI)

Administers technical committees of the International Organization for Standardization (ISO) and U.S. Technical Advisory Groups (TAGs) to ISO
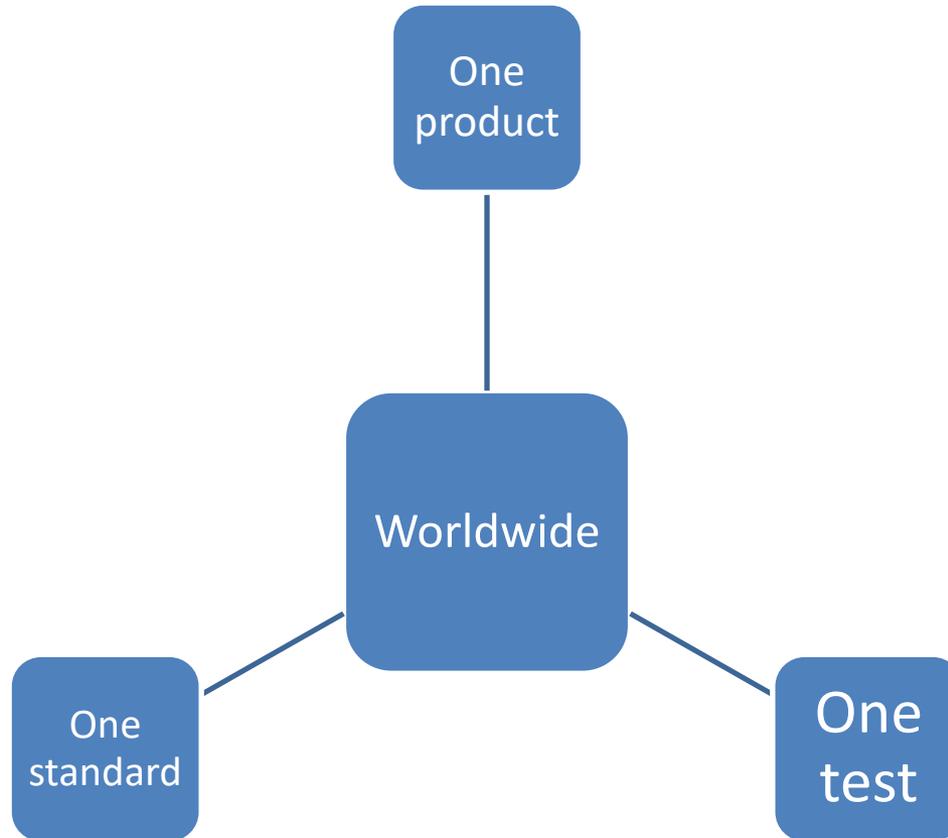
Administers technical committees of the International Electrotechnical Commission (IEC) and U.S. Technical Advisory Groups (TAGs) to IEC

Develops American National Standards and technical reports
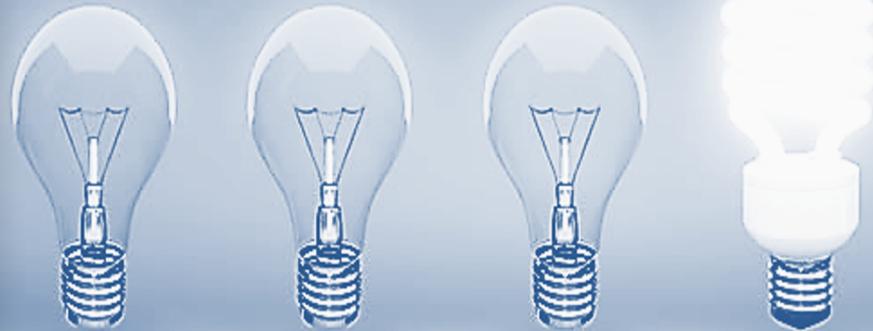
AAMI Standards philosophy

Size of the standards program

~170 Domestic Committees

Over 290 Standards and Reports

11 (ISO or IEC) Secretariats & 18 U.S.TAGs

~2300 Active domestic program participants

Think Bigger. Set Standards. Make a Difference.

AAMI's role with IEC

- Secretariat for IEC/SC 62A (Common aspects of electrical equipment used in medical practice)

- Secretariat for IEC/SC 62D (Electromedical equipment)

- U.S. TAG for IEC/TC 62 (Electrical equipment in medical practice)

- U.S. TAG for IEC/SC 62A

- U.S. TAG for IEC/SC 62D

AAMI's role with ISO

- Secretariat for ISO/TC 121 (Anesthetic and respiratory equipment) and subcommittees 2, 3, 4, 6

- Secretariat for ISO/TC 150/SC 2 (Cardiovascular implants and extracorporeal systems) and ISO/TC 150/SC 6 (Active implants)

- U.S. TAG for ISO/TC 121 and SCs 1, 2, 3, 4, 6, 8

- U.S. TAG for ISO/TC 150/SC 2

- U.S. TAG for ISO/TC 150/SC 6

AAMI's role with ISO

- Secretariat for ISO/TC 198 (Sterilization of healthcare)

- Secretariat for ISO/TC 210 (Quality management and corresponding general aspects for medical devices)

- U.S. TAG for ISO/TC 198

- U.S. TAG for ISO/TC 210

- U.S. TAG for ISO/TC 76 (Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use)

- U.S. TAG for ISO/TC 84 (Devices for administration of medical products and intravascular catheters)

- U.S. TAG for ISO/TC 194 (Biological evaluation of medical devices) and SC 1(Tissue Product Safety)
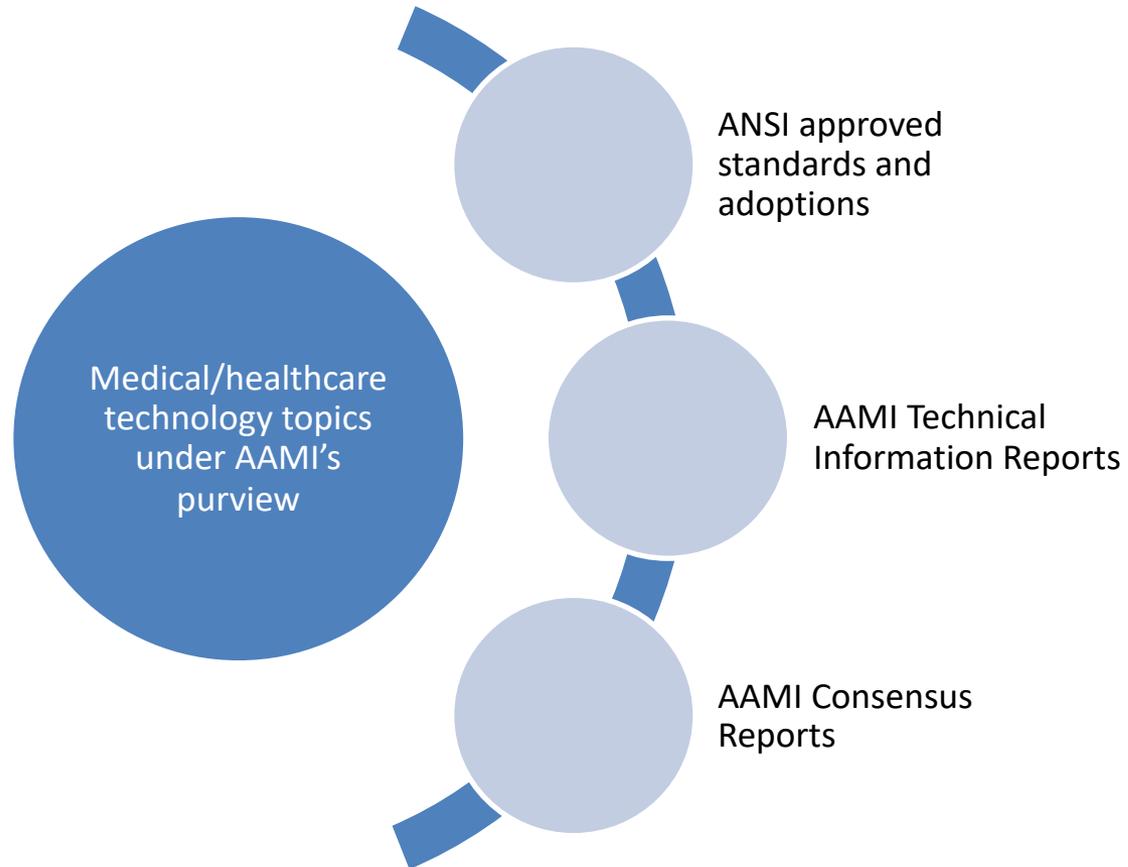
Other international role

- Secretary, ISO/TC 215 – IEC/SC 62A/Joint Working Group 7 (Safe, effective and secure health software and health IT systems, including those incorporating medical devices)
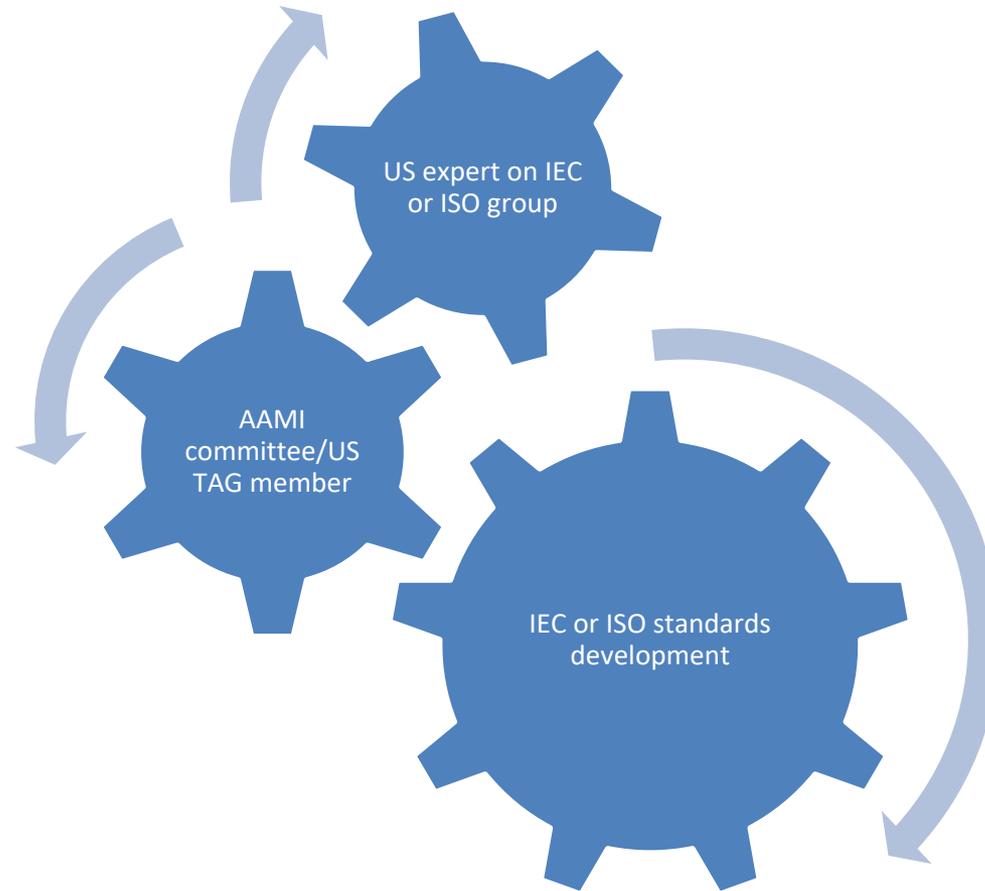
U.S. adoption of ISO or IEC standards

- The decision to propose adoption of an IEC or ISO standard is taken by an AAMI technical committee/working group.

- The committee may decide to adopt an International Standard, harmonize with an International Standard, or maintain a divergent standard.

- Adoptions require the same due process procedures as the development of other ANSI standard.

American National Standard

ANSI/AAMI/ISO 14971:2008

Medical devices—
Application of risk management to medical devices

AAMI

Types of Documents developed by AAMI

Medical/healthcare technology topics under AAMI's purview

ANSI approved standards and adoptions

AAMI Technical Information Reports

AAMI Consensus Reports

Standards involvement at AAMI to IEC/ISO

US expert on IEC or ISO group

AAMI committee/US TAG member

IEC or ISO standards development

Few Key areas in AAMI Standards Program

Sterilization – ANSI/AAMI ST79

Electrical safety – ANSI/AAMI ES60601-1

Human factors/usability – ANSI/AAMI HE75, ANSI/AAMI/IEC 62366

Quality systems/Risk management – ANSI/AAMI/ISO 13485, 14971, 24971

Biological evaluation – AAMI adoption of the ISO 10993 series

* Artificial intelligence – Consensus Report/Technical Information Report to be issued

Get involved!

https://www.aami.org/

Thank You!

For questions, please contact:

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