AAMI's Medical Device Standards Program

Presentation to AdvaMed – INVIMA Workshop on Medical Device Good Regulatory Practices

19 January 2018

Who Is AAMI?

Professional society

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

7,000+ members worldwide

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

Over 500 corporate and institutional members

Expertise and experience convening diverse stakeholder to drive consensus

AAMI's role

Leader in healthcare tech-oriented consensus-based problem solving

Sectoral preference for private consensus-based standards to support regulatory needs

Long track record of working with all stakeholders to develop national and international consensus standards

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The AAMI evolution

1960's
- Association for the Advancement of *Medical Instrumentation*

1970's
- Association for the Advancement of *Medical* ~~Instrumentation~~ *Devices*

2000's
- 2000's – Association for the Advancement of *Medical* ~~Devices~~ *Technology*

20i0's
- 2017 – Just call us "*AAMI*"

AAMI Standards Program

Accredited by American National Standards Institute (ANSI)

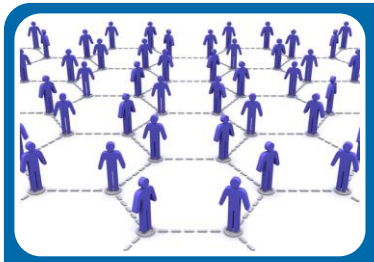
Administers technical committees of the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC)

Administers U.S. Technical Advisory Groups (TAGs) to ISO and IEC Committees

Develops American National Standards and technical reports

AAMI Standards – The Three Pillars of *Better Patient Outcomes*

AAMI Standards Philosophy



Standards only where there is a need

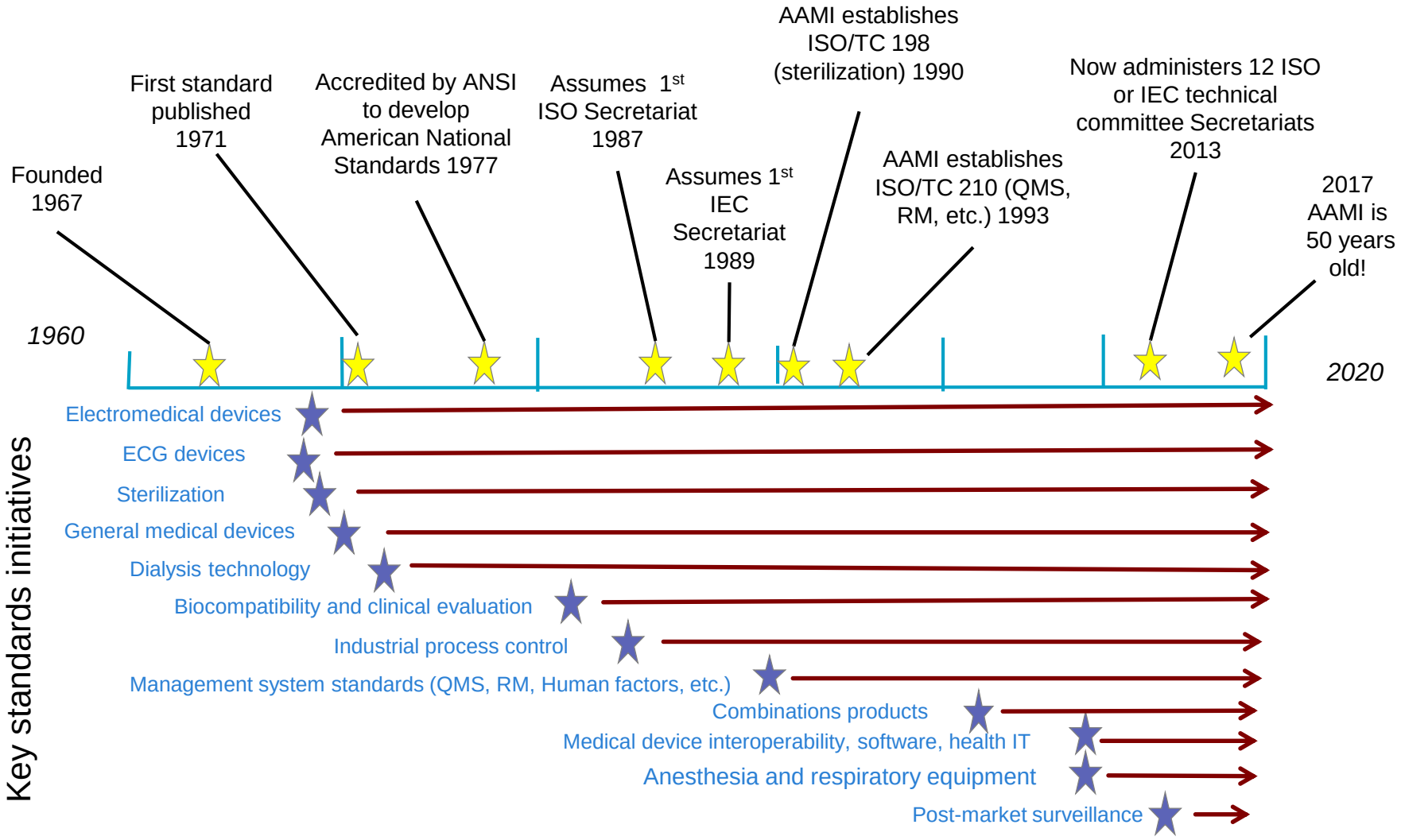
Preference for global solutions--"*One standard, one test, worldwide*"

Systems approach—Address safety and efficacy across full product lifecycle

Size of the standards program

- ~170 AAMI Committees
- Over 280 Standards and Technical Reports
- 12 (ISO or IEC) Secretariats & 19 U.S. mirror committees
- ~2300 Active domestic program participants

Evolution of AAMI Standards Program



Scope of the Standards Program (selected)

Quality systems	Risk management	Symbols	Nomenclature	General safety	Device Design
Usability	Human factors	Sterilization	Aseptic processing	Biological evaluation	Tissue product safety
Electrical safety/EMC	Software	Inter-operability	Wireless IT networks,	Mobile apps	Security
Devices for therapy	Devices for surgery	Patient monitoring	Protective barriers	Dialysis equipment & processes	Cardiovascular implants
Active implants	Sterilization equipment	Transfusion, infusion and injection	Neurosurgical devices	HIT networks	Animal tissue products

Key new areas of focus for medical device standards

Big Data	Cybersecurity of devices and networks	Medical device servicing and repair	Additive Manufacturing (3-D Printing)	Unique Device Identifiers (UDIs)	Artificial Intelligence/ Algorithms in clinical care

AAMI's International Footprint

Secretariat and TAG

- IEC/SC 62A, Common aspects of electrical equipment used in medical practice
- IEC/SC 62D, Electromedical equipment
- ISO/TC 121, Anesthetic and respiratory equipment and ISO/TC 121/ SC 2, SC 3, SC 4, SC 6
- ISO/TC 150/SC 2, Cardiovascular implants and extracorporeal systems
- ISO/TC 150/SC 6, Active implants
- ISO/TC 198, Sterilization of healthcare products ✓
- ISO/TC 210, Quality management and corresponding general aspects for medical devices ✓
- ISO/TC215-IEC/SC 62A JWG 7, Safe, effective and secure health software and health IT systems ✓

U.S. Mirror Committee only

- IEC/TC 62, Electrical equipment in medical practice
- 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 intravascular catheters ✓
- ISO/TC 121 SC 1, SC 4, SC 8
- ISO/TC 194, Biological evaluation of medical devices
- ISO/TC 194/SC 1, Tissue product safety

✓ = Participating member

✓ = Observer member

Benefits to regulators from International Standards

- Reduces the administrative burden of regulators
- Enables “smart”, nimble, and responsive regulation
- Ensures highest levels of **safety** and **effectiveness** of medical technology
- Lowers the cost of and improves **access** to technology
- Leverages the expertise and work of thousands of medical technology experts from around the world

For more information

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