AAMI’s Medical Device Standards Program

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

19 January 2018
Who Is AAMI?

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

Professional society

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

Safety
Access
Effectiveness
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

- Founded 1967
- First standard published 1971
- Accredited by ANSI to develop American National Standards 1977
- Assumes 1st ISO Secretariat 1987
- Assumes 1st IEC Secretariat 1989
- AAMI establishes ISO/TC 198 (sterilization) 1990
- AAMI establishes ISO/TC 210 (QMS, RM, etc.) 1993
- Now administers 12 ISO or IEC technical committee Secretariats 2013
- 2017 AAMI is 50 years old!

Key standards initiatives:
- Electromedical devices
- ECG devices
- Sterilization
- General medical devices
- Dialysis technology
- Biocompatibility and clinical evaluation
- Industrial process control
- Management system standards (QMS, RM, Human factors, etc.)
- Combinations products
- Medical device interoperability, software, health IT
- Anesthesia and respiratory equipment
- Post-market surveillance
- 2020
## Scope of the Standards Program (selected)

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<th>Quality systems</th>
<th>Risk management</th>
<th>Symbols</th>
<th>Nomenclature</th>
<th>General safety</th>
<th>Device Design</th>
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<td>Aseptic processing</td>
<td>Biological evaluation</td>
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<td>Electrical safety/EMC</td>
<td>Software</td>
<td>Inter-operability</td>
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<tr>
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<td>Devices for surgery</td>
<td>Patient monitoring</td>
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<td>Dialysis equipment &amp; processes</td>
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<td>Active implants</td>
<td>Sterilization equipment</td>
<td>Transfusion, infusion and injection</td>
<td>Neurosurgical devices</td>
<td>HIT networks</td>
<td>Animal tissue products</td>
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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
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