



Standards

Shaping the Future of
Health Technology

AAMI national and international standards address these critical issues:

- Anesthetic and Respiratory Equipment
- Artificial Intelligence
- Clinical Alarms
- Combination Products
- Cybersecurity
- Dialysis
- Electrical Safety
- Electromedical Devices
- Health Information Technology
- Home Care Devices
- Human Factors
- Infusion Devices
- IT/Device Security
- Medical Equipment Maintenance
- Networked Devices/ Wireless
- Quality Systems
- Risk Management
- Small-Bore Connectors
- Sterilization

Transform the Future of Healthcare

Standards participants have the unique opportunity to make a difference.

By participating on an AAMI standards committee or working group, you can have a direct role in shaping medical device standards, and work side by side with industry colleagues and participating government agencies (e.g., FDA). Standards, technical information reports, and recommended practices represent a national consensus, and many have been approved by the American National Standards Institute (ANSI).

AAMI standards committees and working groups make recommendations concerning the need for new standards and other technical publications within their areas of competency and expertise, determine when a document needs to be revised, draft new and revised technical documents, and develop committee and public consensus on those drafts.

Other duties, which occur less frequently, include developing consensus on official interpretations of standards and advising AAMI on responses to government initiatives and public policy matters within the committee's area of work. AAMI also plays a significant role in international standards development, helping to ensure harmonization and product safety worldwide.

U.S. Technical Advisory Groups (TAG) are committees accredited by ANSI for participation in ISO/IEC technical activities, which operate in compliance with the ANSI Criteria for the Development and Coordination of U.S. Positions in the International Standardization Activities of the ISO and IEC. AAMI administers several U.S. TAGs.

Strategic business benefits of participation in AAMI standards development

International Engagement Marketplace

Positioning

- Helps organizations maintain their voice, vote, and positioning in the rapidly changing global marketplace.

Systematic Access to Regulators

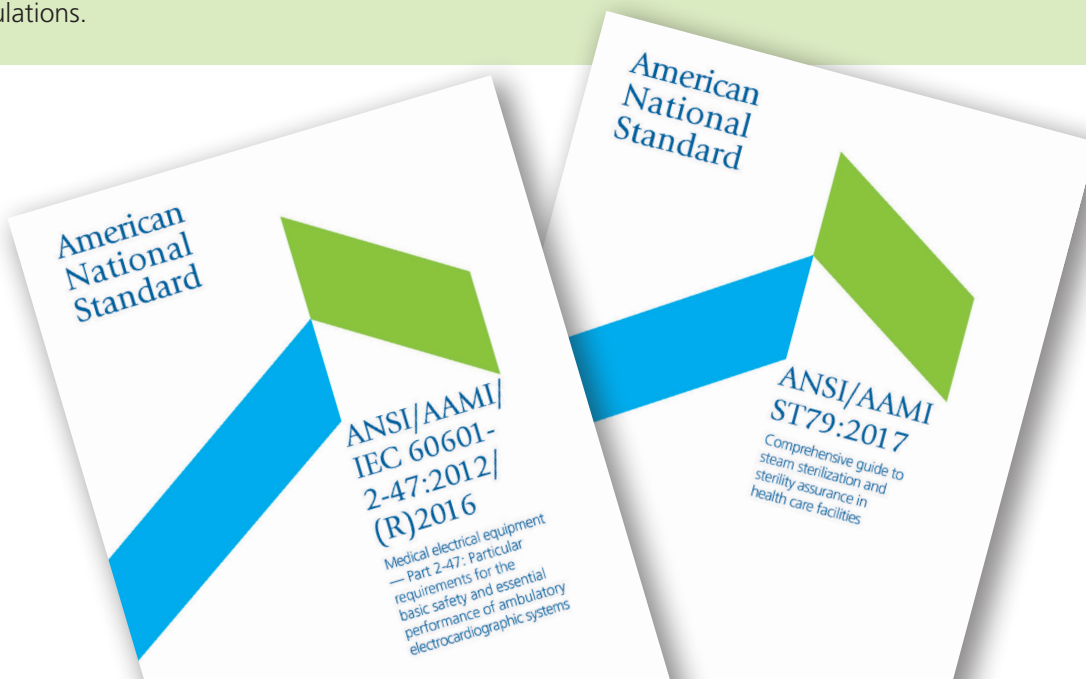
- Provides for the unique and valuable opportunity to engage with regulators (e.g., FDA) at consistently scheduled events. The ability to interact with regulatory bodies provides improved awareness and understanding of prospective actions or movements to incorporate standards into regulations.

Leveling the Competitive Industry Playing Field

- Provides an impartial basis for fair and equitable international markets as participants work side by side with their competitors to seek consensus on standards.

Visible Global Commitment to Patient Safety

- Provides a neutral forum where all stakeholders have the opportunity to share their expertise, learn from one another and work toward consensus, demonstrating clear and compelling evidence of a commitment to the safe and effective use of health technology worldwide.



Join a Standards Committee

Anesthetic and Respiratory Equipment Committee*[†]
Apnea Monitoring Committee
Biological Evaluation Committee*[†]
Blood Filter/Cell Salvaging Committee
Blood Pressure Monitoring Committee[†]
Blood/Gas Exchange Device Committee[†]
Cardiac Rhythm Management Device Committee*[†]
Cardiac Valve Prostheses Committee[†]
Cardiovascular Absorbable Implants Committee[†]
Cochlear Implants Committee[†]
Combination Products Committee
Common aspects of electrical equipment used in Medical Practice (U.S. TAG for IEC/SC 62A)[†]
Defibrillator Committee[†]
Devices for Injection Committee*
ECG Committee[†]
Electrical Equipment in Medical Practice (U.S. TAG for IEC/TC 62)[†]
Electrical Safety Committee[†]
Electromagnetic Compatibility Committee[†]
High Frequency Therapeutic Device Committee[†]
Human Factors Engineering Committee[†]
Implantable Infusion Pumps Committee[†]

Infant Incubator Committee[†]
Infusion Device Committee[†]
Mechanical Circulatory Support Systems Committee*[†]
Medical Device Alarms Committee[†]
Medical Device Particulates Committee
Medical Devices and Systems in Home Care Applications[†]
Medical electrical equipment (U.S. TAG for IEC/SC 62D)*[†]
Medical Equipment Management Committee
Multiparameter Patient Monitoring Equip Committee*[†]
Neurosurgery Committee*[†]
Protective Barriers Committee
Quality Management & Corresponding General Aspects for Medical Devices Committee*[†]
Renal Disease and Detoxification Committee[†]
Small-Bore Connectors Committee[†]
Software and Information Technology Committee*[†]
Sphygmomanometer Committee[†]
Sterilization Standards Committee*[†]
Sustainability Committee
Tissue Product Safety Committee*
Vascular Prostheses Committee*
Waveform Testing Committee

*Committees have additional working groups

[†]Committees with an international counterpart contributed to or managed by AAMI

Getting Involved Is Easy

There are several ways for to get involved—propose a new work item, join a committee or working group, submit comments on public review drafts, and attend open meetings of AAMI committees and working groups!

Medical device manufacturers, consultants, healthcare delivery professionals, clinicians, regulators, and others are invited to participate in the standards development process.

To join an AAMI standards committee or working group, visit www.aami.org/standards or e-mail standards@aami.org.



For AAMI membership information, visit www.aami.org/membership or call 703-253-8273.

Participate Today!

If you write the standards, you write the rules that regulate your business. Since regulators worldwide utilize standards as a means to demonstrate compliance with their regulations, participation in the standards development process provides a means for you and your business to directly influence the regulatory process.

— John G. Abbott, PhD
John Abbott Consulting

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Not an AAMI member? Visit www.aami.org/membership or call 703-253-8273 and join!



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