1st Invitational Workshop on
Body Area Network Technology and Applications
Future Directions, Technologies, Standards and Applications
June 19-20, 2011
Worcester Polytechnic Institute

www.aami.org

AAMI
Advancing Safety in Medical Technology

1st Inv. Workshop Body Area Network Technology and Applications

Future Directions, Technologies, Standards and Applications

June 20, 2011 @ WPI

Worcester, MA

Nat Sims, MD

Massachusetts General Hospital

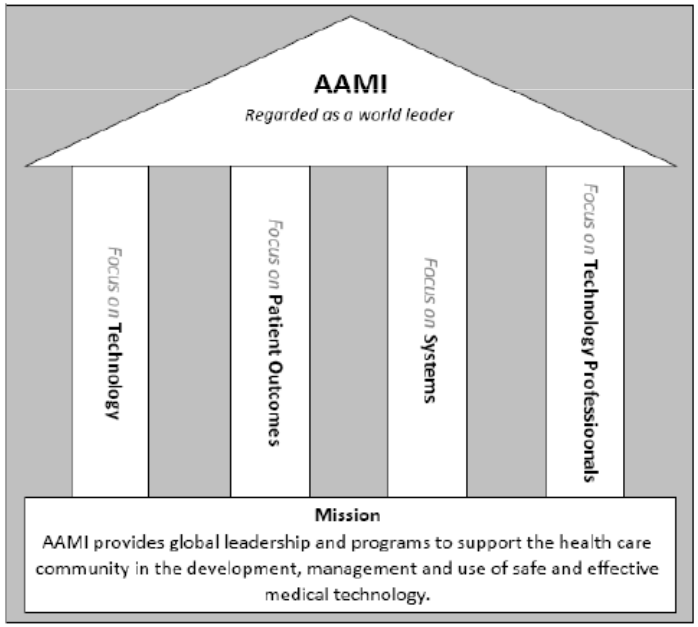
CONTACTS

- www.aami.org
- /catalog/2011Catalog.pdf
- /about/publications/AAMI.Brochure.pdf

- Arlington, VA
- Standards Development Organization

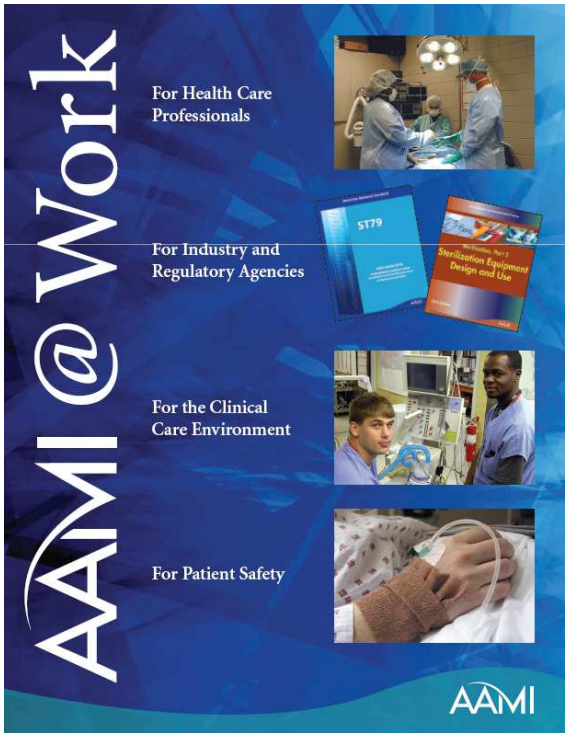
AAMI

- **Mission**: Support health care community (development, management and use of medical technology.
- **AAMI's best role**: convening diverse groups
- **Best Known for**: honest broker



AAMI Programs

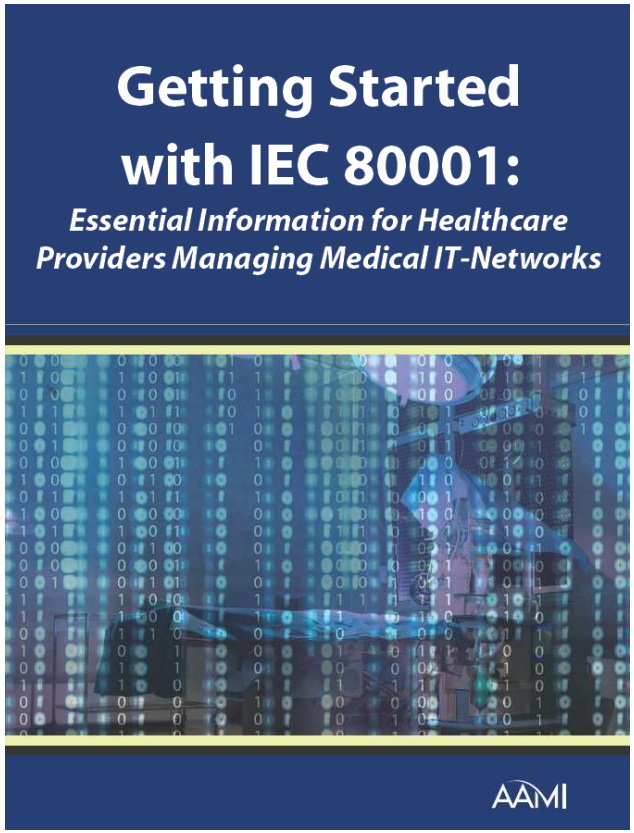
- Standards development
- Educational (QSR, risk management, software, sterilization)
- Conferences and exhibits
- Summits
- Publications
- Certification of technology specialists



Strategic Goal 1

By 2016. . .

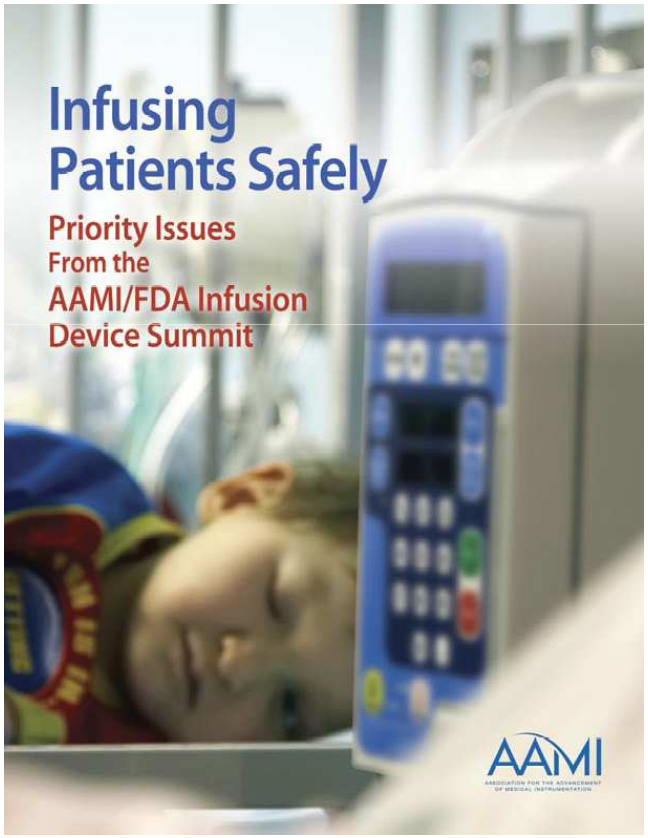
- Be **preferred resource**
- **High quality and objective information**
- On medical technology and related processes.



Strategic Goal 2

By 2016. . .

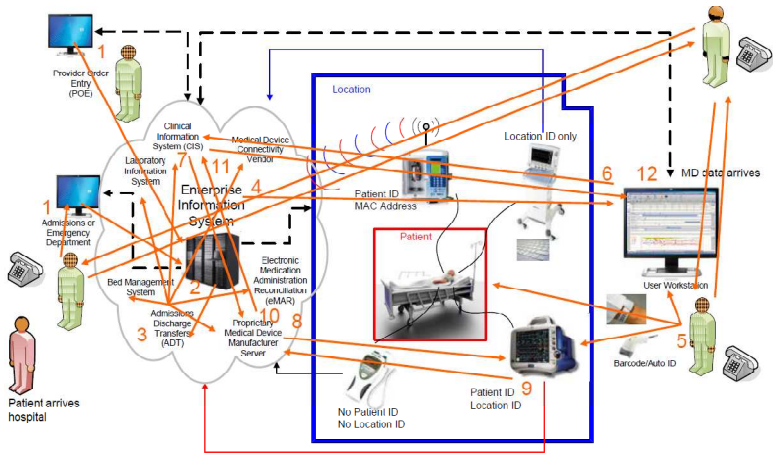
- Actions to improve patient outcomes
- From the consensus of broad-based discussions
- **[convener role: focus on patient outcomes]**



Strategic Goal 3

By 2016. . .

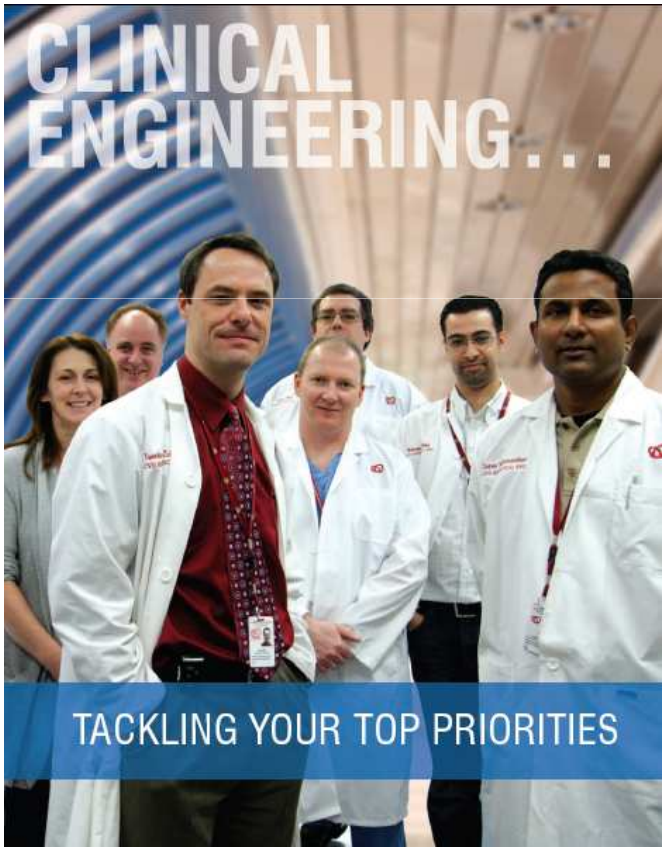
- Create awareness
- Interaction: technology, people, & patient care environment
- Crucial to positive patient outcomes.
- **[focus on systems]**



Strategic Goal 4

By 2016. . .

- Define profession & qualifications of biomed
- Profession's role and value in HC delivery. **[focus on HC technology professionals]**



The Strategic Imperative of Standards

- Important alternative to regulation
- Competitors are there
- Leg up on emerging issues; inside knowledge
- Restart later is more $$$ than standards participation as business tool

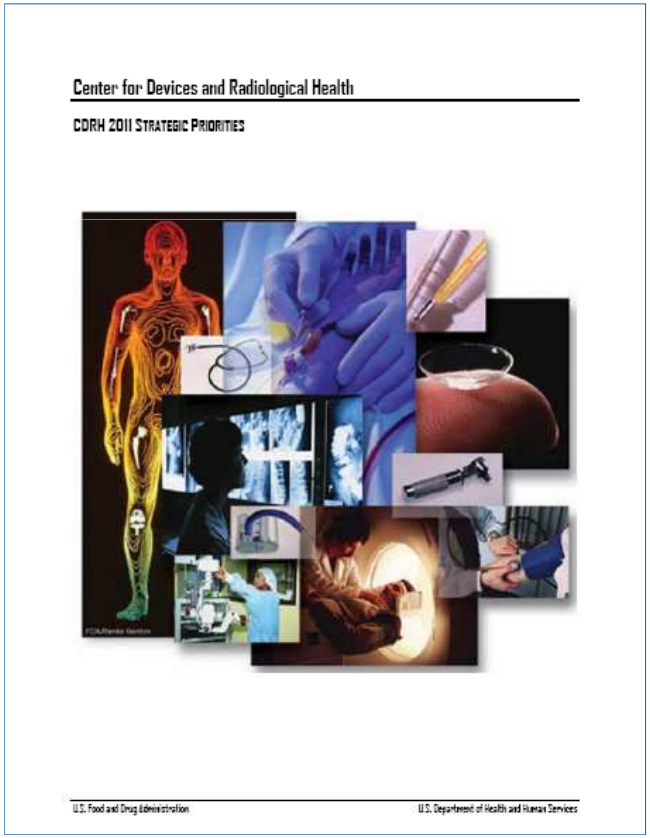
AAMI Standards Program

- Basic principles (national standards)
  - Open and transparent
    - open meetings
    - public review
    - participation not limited to US
    - published rationale for requirements

- Staff "referees" (national & international standards)

Business Imperative of Standards Participation for a *Regulated* Industry

- **Safe setting** to agree: minimum safety, performance and labeling requirements
- **Mutual education** (FDA/industry): risks/benefits
- Achieve acceptable level of safety **without** stifling innovation



In a Regulated Industry, Standards Also Provide…

- Forum to share information
- Practical way to address safety ("essential performance")
- Efficient use of resources for industry and regulators

U.S. Government Participation in Standards

- **Domestic:** Government agency appointments (FDA, CMS, CDC, DoD, NIST, OSHA, etc.).

- **International:** U.S. experts to ISO & IEC; FDA participates

AAMI Standards Program

- **Standards philosophy**: "*One product, one standard, one test worldwide.*"
- **How AAMI serves industry goals**:
  - Administering U.S. TAGs and International Secretariats
  - Focal point for U.S. *strategy and leadership*
  - Convening diverse stakeholders (industry, users, subject experts, government regulators) to solve problems together
  - Writing technical documents:
    - Guidance to users (use and maintenance issues)
    - Guidance to industry (applying international standards)

Scope of AAMI's Standards Program

Horizontal

- Quality systems for medical device mfg (13485, 14971, etc)
- General safety and design (60601-1, HE74, 62304, etc)
- Industrial sterilization processing
- Sterilization in health care facilities
- Biological evaluation; tissue product safety (10993 series)

Vertical

- Electromedical equipment (therapy, surgery, monitoring and diagnostic equipment, general hospital use – everything but imaging)
- Dialysis equipment and processes
- Cardiovascular implants; active implants
- Sterilization equipment
- Transfusion, infusion and injection; aids for ostomy and incontinence

AAMI Standards Program

- Accredited by American National Standards Institute (ANSI) to write American National Standards
- 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 – responsible for U.S. participation in committees and U.S. votes on documents
- Develops U.S. Standards, recommended practices and technical documents
  - Authored and adopted by AAMI committees

AAMI Participation in ISO and IEC

Secretariat and TAG

- IEC/SC 62D, Electromedical equipment
- 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

Secretariat Only

- IEC/SC 62A, Common aspects of electrical equipment used in medical practice

U.S. TAG only

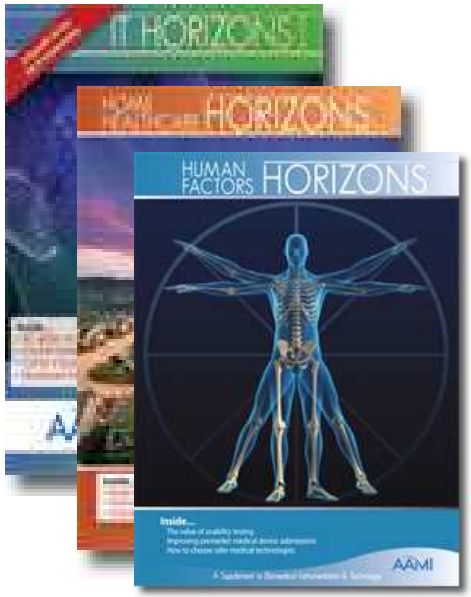
- ISO/TC 76, Transfusion, infusion and injection equipment for medical or pharmaceutical use
- ISO/TC/84, Devices for administration of medicinal products and intravascular catheters
- ISO/TC 173/SC 3, Aids for ostomy and incontinence
- ISO/TC 194, Biological evaluation of medical devices
- ISO/TC 194/SC 1, Tissue product safety

AAMI Participation in ISO and IEC

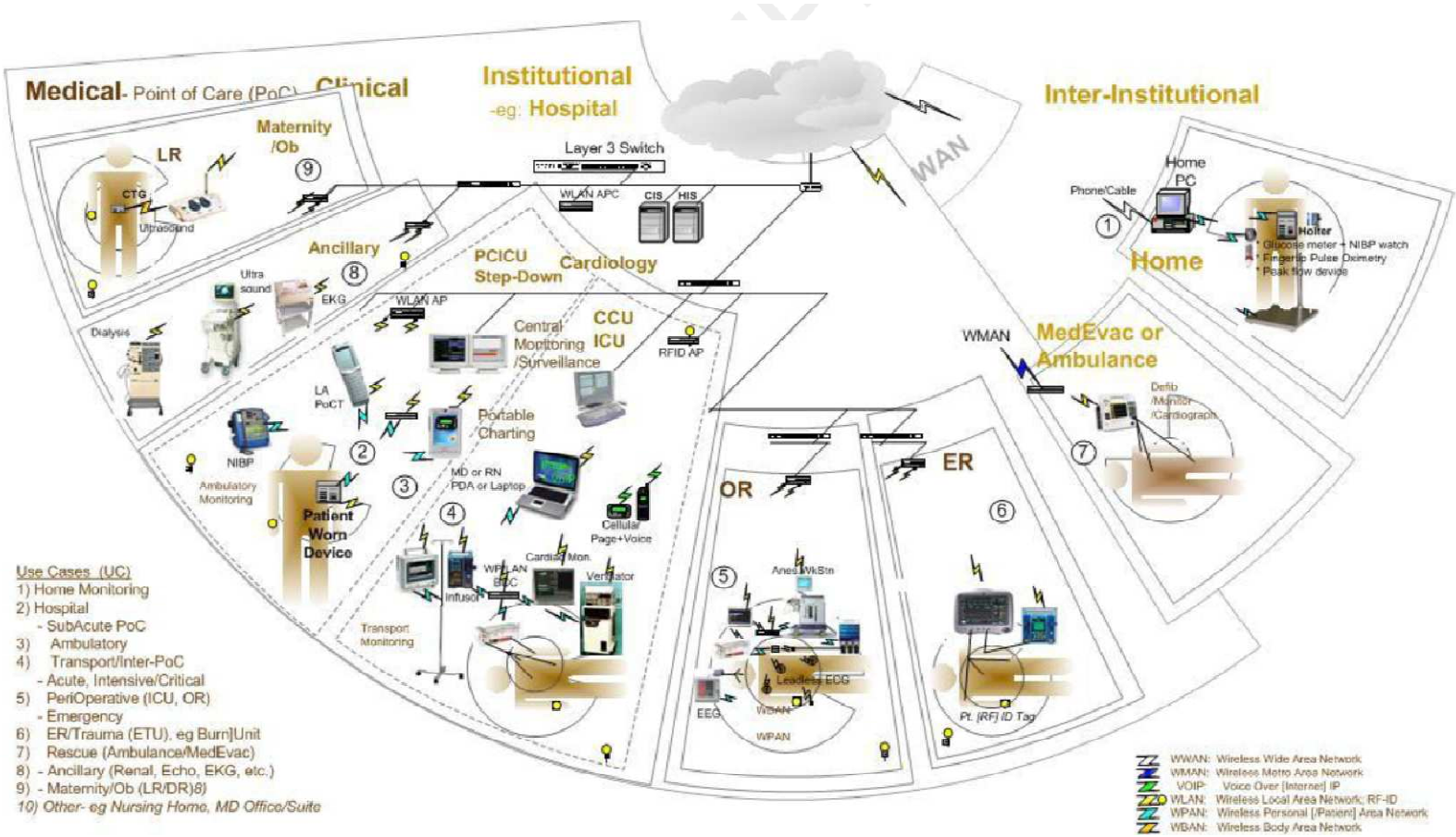
- AAMI also serves on the U.S. TAGs for:
  - ISO/TC 150, Implants for surgery
  - IEC/TC 113, Nanotechnology standardization for electrical and electronic products and systems, and ISO/TC 229, Nanotechnology
  - ISO/TC 176, Quality Management and Quality Assurance
  - ISO/TC 215, Health informatics
  - ISO/TC 249, Traditional Chinese medicine

"Hot" Areas

- Infusion Devices
- Combination Products
- Connectors
- Alarm Safety
- Human Factors ("device-user-patient care environment")
- Scope Reprocessing
- Home Health Care
- Hearing Devices
- Convergence of devices with IT
- Robotics



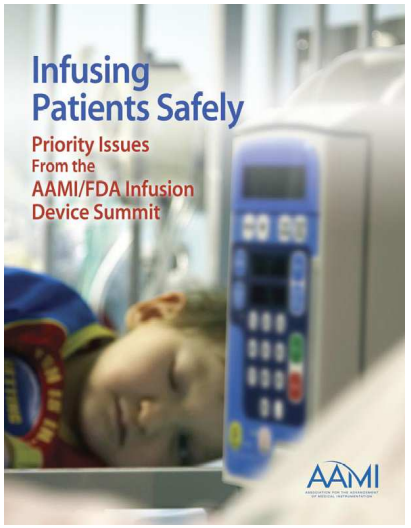
What's Different Now



This slide was developed by Todd Cooper and has been adapted with permission.

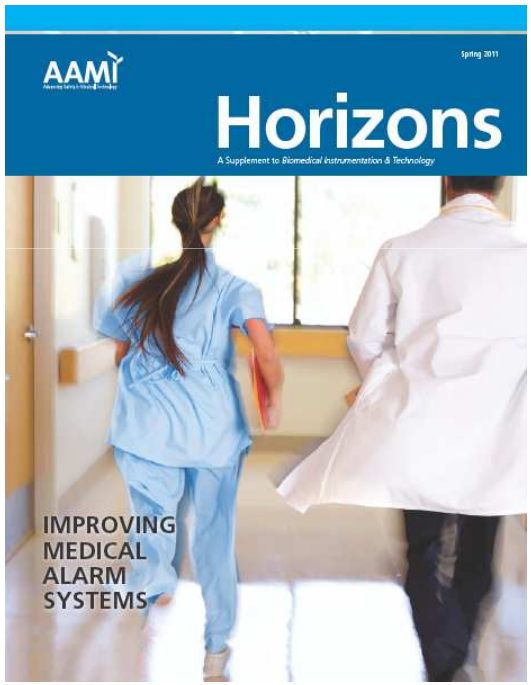
Hot Issue: Infusion System Safety

- 2010 AAMI/FDA Summit
- 13 Top Priorities
- Standards Committee: New Standard Needed
- AAMI Foundation Medical Device Safety Council
- Vision: "No patient will be harmed by a drug infusion"



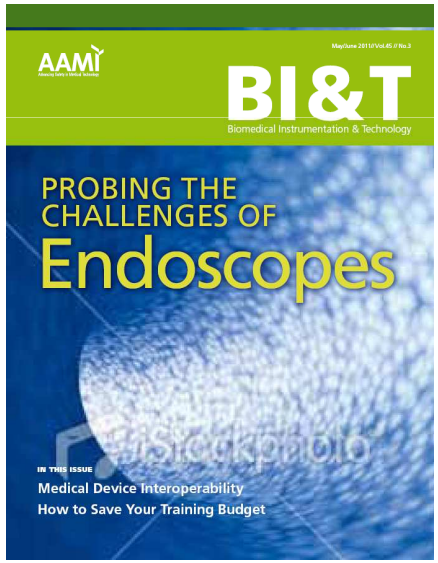
Hot Issue: Alarm Safety

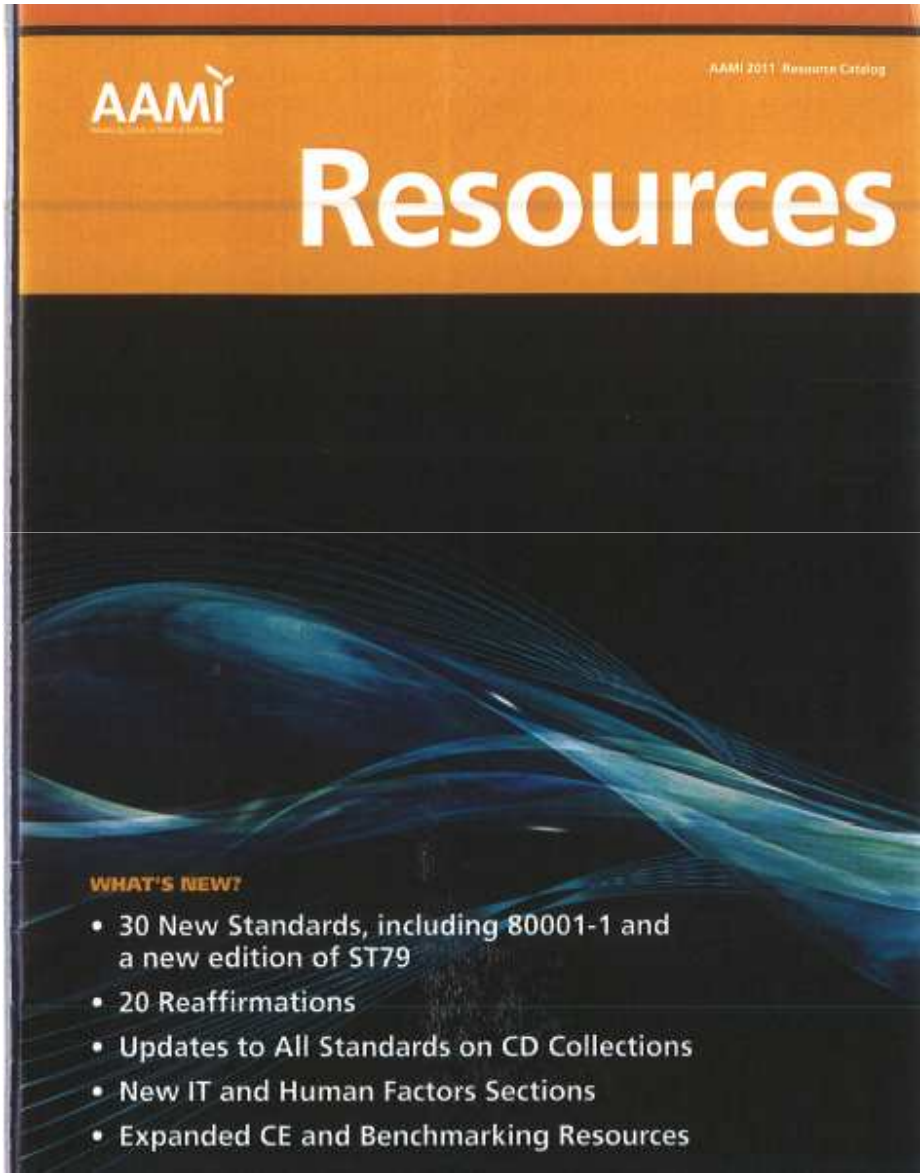
- 2011 AAMI/FDA/ECRI Institute/ACCE Summit (October 4-5, 2011)
- Top Priorities will be developed (no solutions yet)
- New AAMI Standards Committee will address the priorities
- AAMI Foundation Medical Device Safety Council will address non-standards priorities
- Vision: "No patient will be harmed by an alarm"

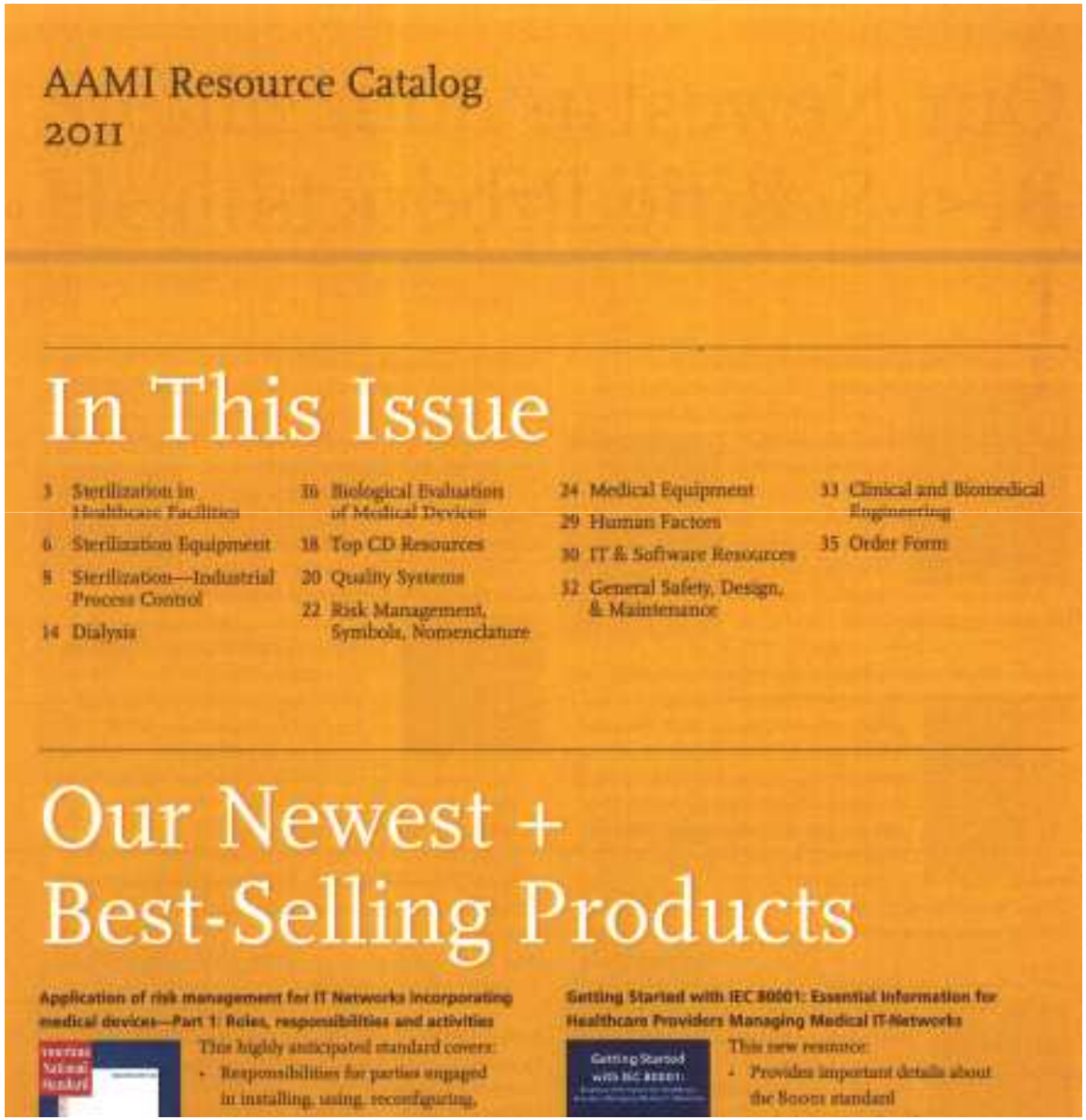


Hot Issue: Reprocessing of (Complex) Reusable Devices

- **2011 AAMI/FDA Summit: October 11-12 at FDA**
- **Priorities will be developed**
- **Standards: Additional guidance needed**
- **AAMI Foundation Medical Device Safety Council**
- **Vision: TBD!**







AAMI Resource Catalog
2011

In This Issue

Our Newest + Best-Selling Products

Application of risk management for IT Networks incorporating medical devices—Part 1: Roles, responsibilities and activities

This highly anticipated standard covers:

- Responsibilities for parties engaged in installing, using, reconfiguring,

Getting Started with IEC 80001: Essential Information for Healthcare Providers Managing Medical IT-Networks

This new resource:

- Provides important details about the 80001 standard

Medical Equipment

ELECTROCARDIOGRAPHY

COMING SOON! **Medical electrical equipment—Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment**
Revision of ANSI/AAMI EC13:2002/(R)2007.
Published Expected publication July 2011.
ANSI/AAMI/IEC 60601-2-27:2011
Order code 601227 or 601227-PDF
List $110 / AAMI member $55

ECG cables and leadwires and amendment
Covers safety and performance requirements for disposable and reusable leadwires and the cables used for surface electrocardiographic monitoring in cardiac monitors. Specifies a standard leadwire/trunk cable interface to allow interchangeability.
Published April 1996, Errata issued May 1998 and December 2001. Reaffirmed December 2008, 14 pages.
FDA RECOGNIZED, with amendment.
ANSI/AAMI EC53:1995/(R)2008 & A1:1998/(R)2008
Order code EC53 or EC53-PDF
List $80 / AAMI member $40

Medical electrical equipment—Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
Adoption of IEC 60601-2-47:2001 with national deviations.
Published June 2008, 36 pages.
FDA RECOGNIZED
ANSI/AAMI EC38:2007
Order code EC38 or EC38-PDF
List $110 / AAMI member $55

DIAGNOSTIC AND MONITORING EQUIPMENT

Sphygmomanometer Set
Includes ANSI/AAMI/ISO 81060-1:2007, ANSI/AAMI/ISO 81060-

IMPLANTABLE MEDICAL DEVICES

Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators, 2ed
Provides manufacturers of electromagnetic emitters with information about the level of immunity to be expected from active implantable cardiovascular devices.
Published November 2007, Errata issued July 2008, 81 pages.
FDA RECOGNIZED
ANSI/AAMI PC69:2007
Order code PC69 or PC69-PDF
List $120 / AAMI member $60

COMING SOON! **Active implantable medical devices—Four-pole connector system for implantable cardiac rhythm management devices—Dimensional and test requirements**

Published Expected publication July 2011.
ANSI/AAMI/ISO 27186:2010
Order code 27186 or 27186-PDF
List $100 / AAMI member $50

NEW! **Evaluation of particulates associated with vascular medical devices**

This TIR offers guidance to medical device manufacturers in application of analytical methods for particulate testing, identifying potential sources of particulates, and developing limits for particulates. Unintentional particulate matter on medical devices may be a quality control issue because of the manufacturing environment or a device design–related issue.
Published December 2010, 46 pages.

General Safety, Design, & Maintenance

General testing procedures for medical electrical equipment
Identical to IEC TR 62354/Ed.2.
Published March 2010, 206 pages.
ANSI/AAMI/IEC TIR62354:2009
Order code 62354 or 62354-PDF
List $240 / AAMI member $120

Guidance on electromagnetic compatibility of medical devices in healthcare facilities
Provides information and guidance on electromagnetic compatibility of medical devices. Includes case studies in radiated EMI problems and guidance on developing a hospital EMC/EMI policy together with a model policy. Focused on healthcare facilities, the home environment is briefly addressed.
Published May 2010, 66 pages.
AAMI TIR18:2010
Order code TIR18 or TIR18-PDF
List $100 / AAMI member $50

Medical electrical equipment, Part 1-2: General requirements for basic and essential performance—collateral standard: Electromagnetic compatibility—Requirements and tests, 2ed
Specifies requirements and tests for electromagnetic compatibility of equipment and/or systems and serves as the basis of electromagnetic compatibility requirements and tests in device-specific standards. Identical to IEC 60601-1-2/Ed.3.
Published July 2007, 108 pages.
FDA RECOGNIZED
ANSI/AAMI/IEC 60601-1-2:2007
Order code 601102 or 601102-PDF
List $120 / AAMI member $60

COMING SOON! Medical Electrical Equipment—Part 1-11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Published Expected publication June 2011.
ANSI/AAMI HA60601-1-11:2011
Order code 601111 or 601111-PDF
List $110 / AAMI member $55

60601-1, 3rd Edition, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance

Baseline of requirements for the basic safety and essential performance of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment. Also contains certain requirements for reliable operation to ensure safety. This standard can also be applied to equipment used for compensation or alleviation of disease, injury, or disability. Adoption, with national deviations, of IEC 60601-1/Ed.3.
What's New Includes amendments C1:2009 and A2:2010 which add further U.S. deviations to IEC 60601-1:2005.
Published March 2006, 299 pages.
FDA RECOGNIZED
ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD)
Order code 606011 (print), 606011-PDF, or 606011-CD
List $395 / AAMI member $195

Quality Systems

Medical devices—Quality management systems—Requirements for regulatory purposes, 2ed

Specifies requirements for a quality management system for medical devices where an organization needs to demonstrate its ability to provide products that consistently meet customer and applicable regulatory requirements. Identical to ISO 13485/Ed.2.

Published August 2003, Reaffirmed November 2009, 50 pages.
ANSI/AAMI/ISO 13485:2003/(R)2009
Order code 13485 or 13485-PDF
List $100 / AAMI member $50

Quality management systems—Medical devices—Guidance on the application of ISO 13485:2003, 2ed

Published January 2005, 75 pages.
ANSI/AAMI/ISO TIR14969:2004
Order code 14969 or 14969-PDF
List $110 / AAMI member $55

Quality System Collection

CD collection of AAMI standards for quality systems, design control, human factors, and software validation; important government guidance documents from FDA and GHTF; and quick links to government resources such as the Recall, PMA, Recognized Standards, and MDR databases. The perfect resource for medical device professionals looking for a single source for key standards, guidance documents, and expert analysis and advice

FDA's Guide to Inspections of Quality Systems (QSIT) (Handbook and CD-ROM Training Program)

The 100+ page handbook provides guidance to FDA field staff who manage the QSIT process. Includes flow charts and checklists of information that will be verified during the QSIT process. The CD contains the same training program used by FDA to train its inspectors in QSIT.

Produced 1999.
Order code QSIT or QSIT-CD
List $45 / AAMI member $35

The Quality System Compendium: GMP Requirements & Industry Practice (2nd edition)

The go-to resource for information on the requirements of FDA's Quality System regulation. Each requirement of the regulation is defined, with accompanying discussion of the requirements and industry practice. Also includes:

- Chapters on combination products and risk management for medical devices
- Chapter on FDA's organization and regulatory strategies
- A comprehensive index
- Bibliography that includes references and websites
- A full copy of the Final Rule for the Quality System regulation, including Preamble
- User-friendly tabs for easy navigation

The Compendium is also available for purchase on CD. Have the electronic version of the document available for easy access at work or on the road!

Published November 2007.

www.aami.org

Biological Evaluation of Medical Devices

Biological Evaluation of Medical Devices Series

This valuable resource brings together all of AAMI's standards for the biological evaluation of medical devices in a comprehensive, easy-to-use CD that makes switching from one standard to another as easy as clicking your mouse! Perfect for testing labs and manufacturers of products that need to be tested for biocompatibility. Includes every published document listed in this section!

What's New 10993-9, -10, -11, -16, and 14155.

Released April 2011 (CD is updated during the year. You get the current collection at the time of your order).

Order code BIOTCD

List $650

AAMI member $440

Part 1: Evaluation and testing within a risk management process, 4ed

Identical to ISO 10993-1/Ed.4.

Published November 2009, 24 pages.

FDA RECOGNIZED

ANSI/AAMI/ISO 10993-1:2009

Order code 1099301 or 1099301-PDF

List $90 / AAMI member $45

NEW! Part 9: Framework for identification and quantification of potential degradation products, 2ed

Identical to ISO 10993-9/Ed.2.

Published July 2010, 10 pages.

FDA RECOGNIZED

ANSI/AAMI/ISO 10993-9:2009

Order code 1099309 or 1099309-PDF

List $80 / AAMI member $40

NEW! Part 10: Tests for irritation and skin sensitization

Adoption of ISO 10993-10:2010

Published October 2010, 74 pages.

ANSI/AAMI/ISO 10993-10:2010

Order code 1099310 or 1099310-PDF

List $100 / AAMI member $50

NEW! Part 13: Identification and quantification of degradation products from polymeric devices

Identical to ISO 10993-13/Ed.2.

Published November 2010, 16 pages.

ANSI/AAMI/ISO 10993-13:2010

NEW! Part 16: Toxicokinetic study design for degradation products and leachables

Identical to ISO 10993-16/Ed.1.

Published July 2010, 14 pages.

ANSI/AAMI/ISO 10993-16:2010

Order code 1099316 or 1099316-PDF

List $80 / AAMI member $40

NEW! Clinical investigation of medical devices for human subjects

Addresses the technical aspects of clinical investigations carried out in human subjects to establish the performance and safety of medical devices for regulatory purposes by defining procedures for their design, conduct, recording and reporting. This revision of the standard merges Part 1 and 2 into an integrated document, provides more detail on key aspects of clinical study planning, execution and documentation, and addresses current topics such as quality systems for clinical research.

Published March 2011, 69 pages.

ANSI/AAMI/ISO 14155:2011

Order code 14155 or 14155-PDF

List $110 / AAMI member $55

IT & Software Resources

NEW! Application of risk management for IT Networks incorporating medical devices—Part 1: Roles, responsibilities and activities

Includes:

- Responsibilities for parties engaged in installing, using, reconfiguring, maintaining, and decommissioning IT-networks incorporating medical devices
- Essential properties such as safety, effectiveness, data & system security, and interoperability
- Risks related to patients, operators, and/or third parties

Published October 2010, 86 pages.
ANSI/AAMI/IEC 80001:2010
Order code 8000101 or 8000101-PDF
List $100 / AAMI member $50

NEW! Getting Started with IEC 80001: Essential Information for Healthcare Providers Managing Medical IT-Networks

Includes:

- Important details about the standard, its purpose, roles and responsibilities, life cycle risk management process, and integrating other IT and CE standards and guidelines
- Practical guidance to help get started with 80001, CE-IT collaboration, assessing and managing risk, and reviewing overall risk
- Advice on maintaining what has been achieved—monitoring medical IT-network operation, safety incidents and problem reports, and much more

Published March 2011, 76 pages.
Order code 80001-GS or 80001-GS-PDF
List $140 / AAMI member $85

BUY THE SET AND SAVE!
(80001-1 and Getting Started with IEC 80001)
Order code 80001-GS-S or 80001-GS-S-PDF
List $205
AAMI member $115

Medical device software—Software life cycle processes

Specifies requirements for medical device software life cycle processes including primary life cycle development and maintenance processes, and supporting processes such as software hazard management, documentation, configuration management, verification, and problem resolution. Includes a compliance section based on whether or not the software can cause a hazard or controls risk. Revision of ANSI/AAMI SW68:2001. Identical adoption of IEC 62304:2006.

Published June 2006, 67 pages.
FDA RECOGNIZED
ANSI/AAMI/IEC 62304:2006
Order code 62304 or 62304-PDF

Medical device software risk management

Provides information useful to performing effective software risk management. It does this in the context of ANSI/AAMI/ISO 14971:2000, Medical devices—Application of risk management to medical devices, and in the context of ANSI/AAMI SW68:2001, which was the base document for IEC 62304:2006.

Published February 2005, 65 pages.
AAMI TIR32:2004
Order code TIR32 or TIR32-PDF
List $110 / AAMI member $55

Medical device software—Part 1: Guidance on the application of ISO 14971 to medical device software

Provides information useful for the performance of effective software risk management, as part of the overall risk management process for medical devices containing software.

Validation of software for regulated processes

Applies to any software used to automate device design, testing, component acceptance, manufacturing, labeling, packaging, distribution, and complaint handling, or to automate any other aspect of the quality system as defined by the Quality System Regulation (21 CFR 820). It also applies to software used to create, modify, and maintain electronic records and to manage electronic signatures subject to the validation requirements (21 CFR 11). This TIR can be broadly applied wherever software automates processes regulated by FDA. This TIR applies to software used in the production of a device and software used in implementation of the device manufacturer's quality system. It does not apply to software used as a component, part, or accessory of a medical device or software that is itself a medical device.

Published March 2008, 99 pages.
AAMI TIR36:2007
Order code TIR36 or TIR36-PDF
List $120 / AAMI member $60

IT World Reference CD: A Biomed's Guide

Just updated, this comprehensive CD includes more than 130 articles from AAMI publications, specifically focused on major IT issues in the medical technology profession, plus a detailed glossary of terms, and a search function that enables you to easily find what you need. Topics covered include:

- Device connectivity
- Wireless security
- PACs
- Networked devices
- RFID, DICOM
- Network firewall basics
- Routing fundamentals
- UNIX
- Telemedicine
- Security standards
- Training, and more.

Order code ITCD
List $150 / AAMI member $80

NEW! Medical Device Software: Verification, Validation, and Compliance

This comprehensive book is designed specifically to help medical device and software engineers, quality assurance and compliance professionals, and managers better understand and implement critical verification and validation processes for device software. The book:

- Helps readers to think critically about software validation
- Presents validation activities for each phase of the development lifecycle
- Demonstrates why these activities are important and add value, how to undertake them, and what outputs are needed to document the validation process

From software embedded in medical devices to software that performs as a medical device itself, this book explains how properly handled validation throughout the development lifecycle can bring devices to completion sooner, at higher quality, in compliance with regulations. Written by David Vogel.

Published October 2010 by Artech House; 428 pages.
Order code DSV
List $145 / AAMI member $115

Medical Technology for the IT Professional

This practical guide provides detailed information about medical technologies that are heavily IT-based or highly integrated into IT infrastructures. Each chapter examines a specific medical technology—what it is and how it works—and then dives deeper into the issues affecting IT.

Topics covered include:

- Physiologic monitors
- Infusion technology
- Asset tracking systems
- Clinical laboratory
- OR integration and surgical video systems
- Anesthesia information management systems
- Telemedicine; imaging systems and
- New regulatory, safety, and environmental concerns

Plus, each chapter ends with a concise "what you need to know" summary.

Published 2009 by ECRI Institute, 94 pages.
Order code MT-IT
List $139 / AAMI member $99

IT Horizons

This 5-volume set of AAMI's popular magazine, *IT Horizons*, is filled with practical articles and cutting-edge research about the convergence of medical technology and IT. For example, articles highlight IEC 80001, device integration efforts, distributed antenna systems, applications of RFID, wireless LANs, indoor positioning systems, and much more.

Order code ITCOMBO
List $100 / AAMI member $75

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AAMI

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Welcome to the **Association for the Advancement of Medical Instrumentation**, dedicated to increasing the understanding, safety, and efficacy of medical instrumentation.

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In the News

- Reception Seeks to Bring Together Military Biomeds 6.15.11
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- FDA Workshop Highlights Device Reprocessing Issues 6.15.11
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What's New

Marketplace News

Getting Started with IEC 80001, Essential information for healthcare providers managing medical IT networks with practical guidance and advice.

80001 Application of risk management for IT Networks incorporating medical devices-Part 1: Roles, responsibilities and activities.

AAMI's Benchmarking

Thank you ….

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