AAMI
Advancing Safety in Health Technology

2019 Resource Catalog

New and Noteworthy!

- AAMI Exchange
- eSubscription Standard Collections
- 2019 Industry Training Schedule

And much more...

www.aami.org

One source to maximize capital equipment performance

Medical Surgical • Patient Monitoring • Oncology Services • Ultrasound • Diagnostic Imaging

Avante Health Solutions provides a single source solution for all your capital equipment needs from one powerful partner. We are a one-stop, brand-agnostic supplier of high-quality, new and refurbished equipment at prices that stretch your dollar. And with best-in-class service, parts and repair, the perfect health solution is one click away.

Proud to Exhibit at AAMI eXchange

Booth #1113

Learn how easy one source can be at **AvanteHS.com**

GMI TRANSTATE Integrated DRE ONCOLOGY SERVICES INTERNATIONAL PACIFIC MEDICAL ems Ultra Solutions

2019 Resource Catalog

Whether dealing with the design, manufacturing, maintenance, or sterile processing of medical devices, AAMI provides you with standards, technical information reports, books, courses, and webinars to:

- Stay up to date on global regulatory requirements.
- Implement effective practices.
- Develop innovative and successful products.

We make it easy for you to get the information you need.

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3 WAYS TO ORDER

www.aami.org/store19

1-877-249-8226

**P.O. Box 0211,
Annapolis Junction, MD
20701-0211**

For details, visit www.aami.org/orderInfo.

AAMI Exchange

Cleveland, OH • June 7–10, 2019

The Health Technology Event of the Year

AAMI reimagined its premier health technology event from the AAMI Annual Conference & Expo to the AAMI Exchange. The Exchange will provide a forum for broad conversations among stakeholders on the ever-changing world of medical technology.

OUR PROMISE:

- **Deliver new opportunities** to exchange ideas, expand networks, and experience new technologies to empower professionals around the world.
- **Engage attendees with innovative learning.** The immersive and interactive program will deliver tracks on cybersecurity, sterilization, global perspectives, HTM, and more.
- **Share new and emerging products and technologies.** The Exhibit Hall showcases exciting products in the IoTXperience and the virtual reality theater.
- **Confirm AAMI's commitment to advancing health technology** through professional development.

Join us for the AAMI Exchange in Cleveland, OH at the Huntington Convention Center and Global Center for Health Innovation from June 7–10, 2019.

www.aami.org/aamiexchange

Certification

AAMI
Advancing Safety in Health Technology

ACI AAMI Credentials Institute

As healthcare technology becomes more complex, becoming and staying certified is a way to demonstrate knowledge, skills, and experience in core competencies. Additionally, certifications can demonstrate your ability to provide quality and trustworthy service.

Certifications for the HTM Professional

- Certified Biomedical Equipment Technician (CBET®)
- Certified Radiology Equipment Specialist (CRES®)
- Certified Healthcare Technology Manager (CHTM)

Certification for the Industry Professional

- Certified Industrial Sterilization Specialist (CISS)
  Ethylene Oxide, Moist Heat, and Radiation

Certification Calendar

EVENT	DATE
ACI Certification Exam Registration Deadline	April 17
ACI Certification Exams	May 1–15
ACI Certification Exam Registration Deadline	October 14
ACI Certification Exams	November 1–15

FIND OUT MORE
For complete details, visit **www.aami.org/certification**

Industry Training

Navigate the Regulatory World with Confidence

Let our experienced instructors and course material help you stay ahead of the fast-moving regulatory world. We have the insights and expertise you need to succeed in today's global market. All courses will be held in Arlington, VA at the new and innovative AAMI Center for Excellence (ACE).

2019 TRAINING SCHEDULE

QUALITY SYSTEMS

The Quality System Regulation 21 CFR 820 and ANSI/AAMI/ISO 13485: Navigating Regulatory Requirements (Aligned with the FDA's planned focus on the standard 13485:2016)

COST	DATE
AAMI MEMBERS: $2,985 / NONMEMBERS: $3,285 / GOVT. EMPLOYEES: $1,150	February 4–8, 2019 April 8–12, 2019 June 24–28, 2019 September 16–20, 2019 October 28–November 1, 2019 December 9–13, 2019

Design Control Requirements: Integrating the Quality System Regulation and ANSI/AAMI/ISO 13485 (Aligned with the FDA's planned focus on the standard 13485:2016)

COST	DATE
AAMI MEMBERS: $2,235 / NONMEMBERS: $2,535 / GOVT. EMPLOYEES: $950	January 30–February 1, 2019 March 26–28, 2019 September 24–26, 2019 December 10–12, 2019

Process Validation Requirements and Industry Practice

COST	DATE
AAMI MEMBERS: $2,235 / NONMEMBERS: $2,535 / GOVT. EMPLOYEES: $950	April 16–18, 2019 October 8–10, 2019

Corrective and Preventive Action Requirement and Industry Practice

COST	DATE
AAMI MEMBERS: $2,135 / NONMEMBERS: $2,435 / GOVT. EMPLOYEES: $950	June 18–19, 2019

Purchasing Controls & Supply Chain Management

COST	DATE
AAMI MEMBERS: $2,135 / NONMEMBERS: $2,435 / GOVT. EMPLOYEES: $950	June 19–21, 2019

Integrating Risk Management into the Product Lifecycle: Quality and 13485

COST	DATE
AAMI MEMBERS: $2,335 / NONMEMBERS: $2,635 / GOVT. EMPLOYEES: $950	March 12–14, 2019 August 27–29, 2019 November 13–15, 2019

FOR COMPLETE DETAILS AND TO REGISTER, VISIT www.aami.org/training.

STERILIZATION

Industrial Sterilization

COST	DATE
AAMI MEMBERS: $2,535 / NONMEMBERS: $2,835 / GOVT. EMPLOYEES: $1,050	May 14–17, 2019 October 1–4, 2019

Ethylene Oxide Sterilization

COST	DATE
AAMI MEMBERS: $2,335 / NONMEMBERS: $2,635 / GOVT. EMPLOYEES: $950	August 27–30, 2019

Radiation Sterilization for Medical Devices

COST	DATE
AAMI MEMBERS: $2,335 / NONMEMBERS: $2,635 / GOVT. EMPLOYEES: $950	November 5–8, 2019

HUMAN FACTORS

Human Factors for Medical Devices

COST	DATE
AAMI MEMBERS: $2,235 / NONMEMBERS: $2,535 / GOVT. EMPLOYEES: $950	January 23–25, 2019 April 30–May 2, 2019 September 10–12, 2019 November 19–21, 2019

SOFTWARE VALIDATION

Regulatory Requirements for Software Validation

COST	DATE
AAMI MEMBERS: $2,235 / NONMEMBERS: $2,535 / GOVT. EMPLOYEES: $950	May 7–9, 2019

Software Validation Workshop: Practical Tools and Techniques

COST	DATE
AAMI MEMBERS: $2,235 / NONMEMBERS: $2,535 / GOVT. EMPLOYEES: $950	May 7–9, 2019

Application of Agile to the Development of Medical Device Systems

COST	DATE
AAMI MEMBERS: $2,135 / NONMEMBERS: $2,435 / GOVT. EMPLOYEES: $950	September 25–27, 2019

Effective Application of Agile Practices in the Development of Medical Device Software

COST	DATE
AAMI MEMBERS: $2,135 / NONMEMBERS: $2,435 / GOVT. EMPLOYEES: $950	September 23–24, 2019

eSubscription

Digital Library of AAMI Standard & Guidance Documents

Whether you need a particular set of standards—such as sterilization—or a wide range of standards, eSubscription makes it easy to access them quickly from anywhere. It's more than a static document. It's an interactive platform where you can:

- Have easy access to the latest document version.
- Search within documents and across collections.
- Bookmark documents, annotate particular sections, and create your own personal library.
- Add and share comments for organizational collaboration (for enterprise users).
- Copy sections of standards and create your own personal document.

ANSI/AAMI ST79:2017

New! Now includes a self-assessment tool. This subscription is ideal for individuals, such as consultants. It is only for one user and cannot be transferred.

INDIVIDUAL PLAN	ENTERPRISE PLANS
MEMBER: $346 / LIST: $396	*Not applicable*

Sterilization in Healthcare Facilities

This collection includes sterilization standards and guidance documents, including ANSI/AAMI ST79:2017, ANSI/AAMI ST91:2015, and a new ST79 self-assessment tool.

INDIVIDUAL PLAN	ENTERPRISE PLANS	
MEMBER: $535 / LIST: $749	**2–5 Concurrent Users** (up to 100 named users)	**MEMBER: $2,500 / LIST: $3,725**
	6–10 Concurrent Users (up to 200 named users)	**MEMBER: $3,500 / LIST: $4,450**
	11–15 Concurrent Users (up to 300 named users)	**MEMBER: $4,500 / LIST: $6,300**
	16–20 Concurrent Users (up to 400 named users)	**MEMBER: $5,700 / LIST: $7,500**
	21–26 Concurrent Users (up to 500 named users)	**MEMBER: $6,800 / LIST: $8,800**
	27–30 Concurrent Users (up to 600 named users)	**MEMBER: $7,900 / LIST: $9,000**

*Access: Generic, Named, IP**

FIND OUT MORE

For a complete list of what's included, please visit **www.aami.org/esubscription**

Sterilization—Industrial Process Control

This 50-document collection is intended primarily for manufacturers who ship sterile products.

INDIVIDUAL PLAN	ENTERPRISE PLANS	
MEMBER: $490 / LIST: $660	**2–5 Concurrent Users** (up to 100 named users)	**MEMBER: $3,395 / LIST: $4,850**
	6–10 Concurrent Users (up to 200 named users)	**MEMBER: $3,880 / LIST: $5,545**
	11–15 Concurrent Users (up to 300 named users)	**MEMBER: $5,455 / LIST: $7,795**
	16–20 Concurrent Users (up to 400 named users)	**MEMBER: $6,790 / LIST: $9,700**
	21–26 Concurrent Users (up to 500 named users)	**MEMBER: $8,195 / LIST: $11,710**
	27–30 Concurrent Users (up to 600 named users)	**MEMBER: $8,735 / LIST: $12,475**

Sterilization Equipment Design and Use

This sterilization collection for manufacturers and users of sterilization equipment includes 40 AAMI standards and guidance documents.

INDIVIDUAL PLAN	ENTERPRISE PLANS	
MEMBER: $490 / LIST: $660	**2–5 Concurrent Users** (up to 100 named users)	**MEMBER: $2,770 / LIST: $3,960**
	6–10 Concurrent Users (up to 200 named users)	**MEMBER: $3,170 / LIST: $4,525**
	11–15 Concurrent Users (up to 300 named users)	**MEMBER: $4,450 / LIST: $6,360**
	16–20 Concurrent Users (up to 400 named users)	**MEMBER: $5,540 / LIST: $7,915**
	21–26 Concurrent Users (up to 500 named users)	**MEMBER: $6,690 / LIST: $9,555**
	27–30 Concurrent Users (up to 600 named users)	**MEMBER: $7,125 / LIST $10,180**

Sterilization Standards Collection

This comprehensive collection provides access to all sterilization standards and technical documents for hospitals and healthcare facilities, manufacturers and users of sterilization equipment, and manufacturers who ship sterile products. For a complete list of what's included, please visit www.aami.org/store.

INDIVIDUAL PLAN	ENTERPRISE PLANS	
MEMBER: $820 / LIST: $1,220	**2–5 Concurrent Users** (up to 100 named users)	**MEMBER: $4,400 / LIST: $5,750**
	6–10 Concurrent Users (up to 200 named users)	**MEMBER: $5,400 / LIST: $6,750**

*Access: Generic, Named, IP**

HTM Collection

This compilation includes valuable and practical resources, such as ANSI/AAMI EQ56, the *CHTM Study Guide*, and the *Electrical Safety Manual*.

INDIVIDUAL PLAN	ENTERPRISE PLANS	
MEMBER: $635 / LIST: $885	**2–5 Concurrent Users** (up to 100 named users)	**MEMBER: $1,950 / LIST: $2,900**

*Access: Generic, Named, IP**

eSubscription, Continued →

Dialysis Collection

This collection includes access to dialysis standards including ANSI/AAMI 13959, ANSI/AAMI 26722, ANSI/AAMI 23500, TIR58.

INDIVIDUAL PLAN	ENTERPRISE PLANS	
MEMBER: $360 / LIST: $535	**2–5 Concurrent Users** (up to 100 named users)	**MEMBER: $1,950 / LIST: $2,900**

Human Factors Collection

Includes ANSI/AAMI/IEC 62366, ANSI/AAMI HE75, HE75, TIR49, TIR50, and TIR51.

INDIVIDUAL PLAN	ENTERPRISE PLANS	
MEMBER: $360 / LIST: $535	**2–5 Concurrent Users** (up to 100 named users)	**MEMBER: $1,950 / LIST: $2,900**

*Access: Generic, Named, IP**

Complete Standards Collection

Access more than 200 comprehensive national and international standards and technical documents covering sterilization, dialysis, biological evaluation of medical devices, quality systems, and medical equipment. Updates and new documents are automatically added after their release.

INDIVIDUAL PLAN	ENTERPRISE PLANS	
MEMBER: $1,395 / LIST: $1,955	**2–5 Set Users**	**MEMBER: $4,000 / LIST: $5,900**
	2–5 Concurrent Users (up to 100 named users)	**MEMBER: $6,500 / LIST: $9,500**
	6–10 Concurrent Users (up to 200 named users)	**MEMBER: $10,500 / LIST: $15,500**
	11–15 Concurrent Users (up to 300 named users)	**MEMBER: $14,500 / LIST: $21,000**
	16–20 Concurrent Users (up to 500 named users)	**MEMBER: $19,000 / LIST: $28,000**
	21–25 Concurrent Users (up to 600 named users)	**MEMBER $23,500 / LIST $32,500**

*Access: Generic, Named, IP**

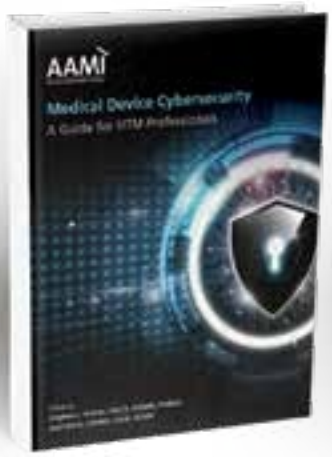
*Access Types:

Generic: The organization is provided provided with a link and generic username and password to place on its intranet. Users are required to create their own username and password the first time they access the site. A primary administrator of the site adds users and creates unique usernames and passwords for each user.

Named: Users are specific staff who can access the site. This option is best for a single facility or specialized unit. Set users are provided unique usernames and passwords.

IP: The organization provides AAMI with an IP address (or range of addresses) along with the company logo. A link is created and provided to the company to place on their internal site. Users are required to create their own username and password the first time they access the site. There is a one-time setup fee of $350.

Cybersecurity/IT



Medical Device Cybersecurity

A Guide for HTM Professionals

Edited by Stephen L. Grimes and Axel Wirth

A must-have resource for professionals in healthcare technology management, this comprehensive guide includes chapters on cybersecurity fundamentals, the regulatory and standards environment, and inventory and configuration management. It provides examples of purchase agreements and vendor contracts, risk assessment and management practices, and cybersecurity guidance from leading healthcare systems.

PRODUCT CODES: MDC AND MDC-PDF

MEMBER: $155 / LIST: $232

AAMI TIR57:2016

Principles for Medical Device Security—Risk Management

FDA RECOGNIZED

This technical information report provides medical device manufacturers with guidance on developing a cybersecurity risk management process for their products.

PRODUCT CODES: TIR57 AND TIR57-PDF

MEMBER: $163 / LIST: $274

80001 TIRs—Set of 4

This set aids users in applying 80001-1, application of risk management for IT networks incorporating medical devices. The set includes 80001-2-1:2012, 80001-2-2:2012, 80001-2-3:2012, and 80001-2-4:2012. Each TIR may be purchased individually at the online AAMI Store.

PRODUCT CODES: 80001TIRS AND 80001TIRS-PDF

MEMBER: $249 / LIST: $438

ANSI/AAMI SW91:2018

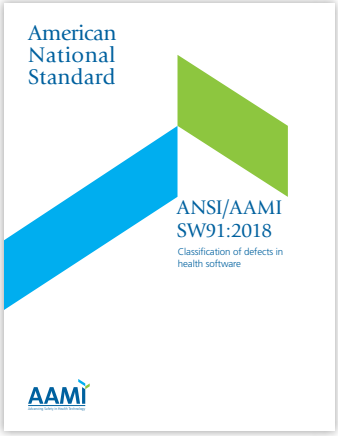
Classification of defects in health software

FDA RECOGNIZED

This standard provides a common language for the classification of defects occurring in health software.

PRODUCT CODE: SW912018 PDF

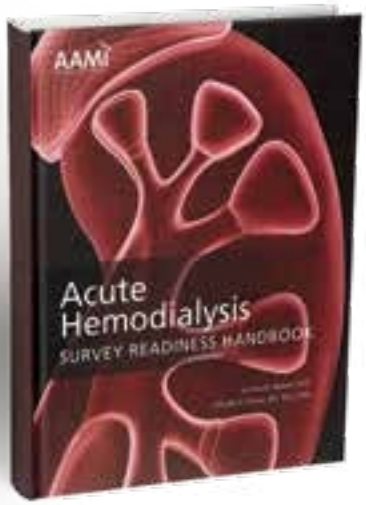
MEMBER: $133 / LIST: $236



FIND OUT MORE

To view the complete 8001 TIR series, visit **www.aami.org/store19**.

Dialysis



Acute Hemodialysis

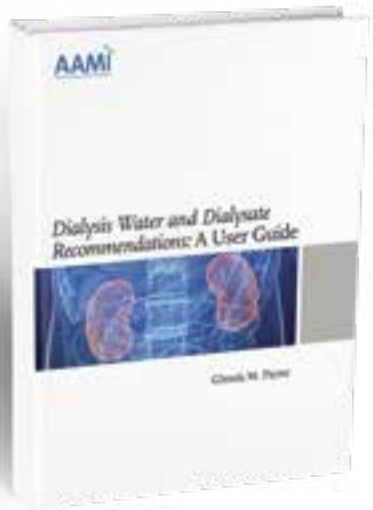
SurveyReadiness Handbook

Jo-Ann B. Maltais, PhD and Glenda M. Payne, MS, RN, CNN

This handbook provides a clear explanation of the federal requirements applicable to the acute hemodialysis service and an overview of the expectations for compliance with the standards of the four accreditation organizations that provide quality oversight of hospitals: The Joint Commission, American Osteopathic Association/Healthcare Facilities Accreditation Program, DNV GL Healthcare USA, Inc., and Center for Improvement in Healthcare Quality.

PRODUCT CODES: ACUTE AND ACUTE-PDF

MEMBER: $145 / LIST: $248



Dialysis Water and Dialysate Recommendations: A User Guide

Edited by Glenda M. Payne

This book provides a side-by-side comparison of key regulations and standards. Specifically, it looks at the Centers for Medicare & Medicaid Services (CMS) regulations and interpretive guidance for the Condition of Water and Dialysate Quality and the section related to water and dialysate from the Condition of Care at Home with the suite of ISO standards that have been adopted as replacement for ANSI/AAMI RD52:2004.

PRODUCT CODES: DUG AND DUG-PDF

MEMBER: $141 / LIST: $240

Healthcare Technology Management

ANSI/AAMI/ISO 13485:2016

Medical devices—Quality management systems—Requirements for regulatory purposes

Design a quality management system that establishes and maintains the effectiveness of your processes. This standard is meant to be used throughout a device's life cycle, from initial concept through post-production, including final decommission and disposal. It also covers topics such as storage, distribution, installation, and servicing, as well as the provision of associated services.

PRODUCT CODES: 13485 AND 13485-PDF

MEMBER: $133 / LIST: $236

Additional Quality Systems and Risk Management Resources

Courses

- The Quality System Regulation 21 CFR 820 and ANSI/AAMI/ISO 13485: Navigating Regulatory Requirements
- Design Control - Integrating The Quality System Regulation and ANSI/AAMI/ISO 13485 Requirements
- Integrating Risk Management into the Product Life Cycle: Quality and 13485

Free Download

- 80001: The Business Case for Health IT Risk Management

To download your copy, visit **www.aami.org/healthitrisk.**

ANSI/AAMI/ISO 16142-1:2016

Medical devices—Recognized essential principles of safety and performance of medical devices—Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards

PRODUCT CODES: 16142-1 AND 16142-1-PDF

MEMBER: $133 / LIST: $236

ANSI/AAMI/ISO 16142-2:2017

Medical devices—Recognized essential principles of safety and performance of medical devices—Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards

PRODUCT CODE: 16142-2-PDF

MEMBER: $133 / LIST: $236

Medical Device Cybersecurity

A Guide for HTM Professionals

Edited by Stephen L. Grimes and Axel Wirth

A must-have resource for professionals in healthcare technology management, this comprehensive guide includes chapters on cybersecurity fundamentals, the regulatory and standards environment, and inventory and configuration management.

PRODUCT CODES: MDC AND MDC-PDF

MEMBER: $155 / LIST: $232

Healthcare Technology Management, Continued →

Healthcare Technology Management, *Continued*

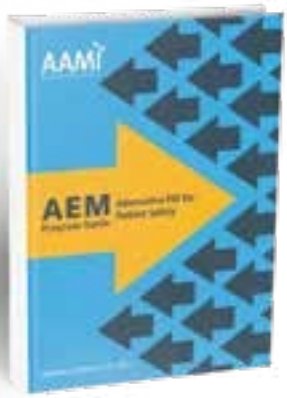
Computerized Maintenance Management Systems for Healthcare Technology Management

Ted Cohen, MS, FACCE and Matthew F. Baretich, PE, PhD

The third edition of this guide offers a foundation for working within a CMMS, which is essential to the success of every HTM department.

PRODUCT CODES: CMMS AND CMMS-PDF

MEMBER: $95 / LIST: $137



AEM Program Guide

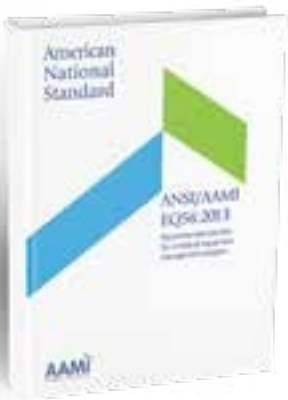
Alternative PM for Patient Safety

Matthew F. Baretich, PE, PhD

This guide offers practical implementation for alternate equipment management (AEM) and explains how to remain compliant with applicable standards and regulations.

PRODUCT CODES: AEM OR AEM-PDF

MEMBER: $62 / LIST: $96



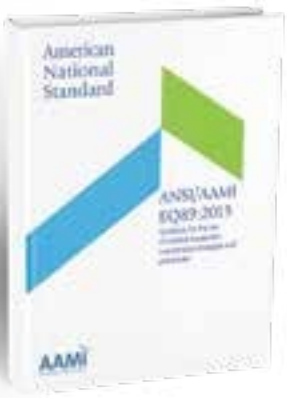
ANSI/AAMI EQ56:2013

Recommended practice for a medical equipment management program

This recommended practice specifies the minimum criteria for a management program designed to minimize certain risks associated with equipment used during routine patient care. It addresses the structure of the program, documentation, requirements, staffing, and resource allocation.

PRODUCT CODES: EQ56 AND EQ56-PDF

MEMBER: $111 / LIST: $194



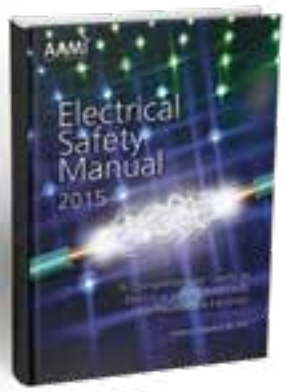
ANSI/AAMI EQ89:2015

Guidance for the use of medical maintenance strategies and procedures

This standard identifies and describes various strategies and methods for efficient, effective, and timely maintenance of medical equipment in healthcare facilities. It is intended to help HTM departments standardize and document their maintenance procedures, and provide guidance on selecting the most appropriate maintenance strategy for a given type of device.

PRODUCT CODES: EQ89 AND EQ89-PDF

MEMBER: $72 / LIST: $127



Electrical Safety Manual

Matthew F. Baretich, PE, PhD

This manual pulls together crucial information from the full range of applicable codes and standards, including ANSI/AAMI ES60601-1 and the 2012 editions of NFPA 70 and NFPA 99. It includes basic elements that should be contained in an electrical safety program and recommended steps for implementing a cost-effective program.

PRODUCT CODES: ESM4 AND ESM4-PDF

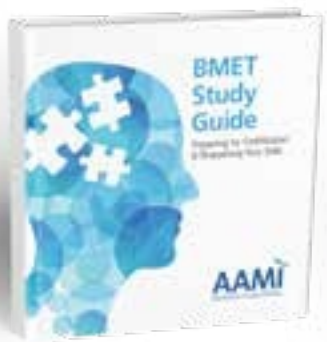
MEMBER: $135 / LIST: $233

Battery Management and Medical Devices

This 60-minute instructional video provides information essential to the understanding of medical device batteries and the development of a battery management plan, and includes practical guidance.

PRODUCT CODE: VID-BATT

MEMBER: $128 / LIST: $213



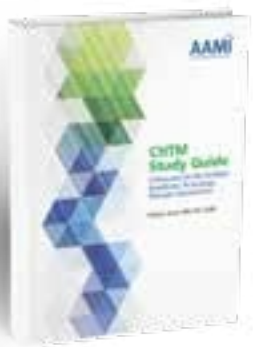
BMET Study Guide

Preparing for Certification

This study guide is a popular resource for those preparing for the CBET certification exam. It helps clinical engineers and biomedical equipment technicians test their knowledge and sharpen their skills with 850 interactive questions and answers—each with a detailed explanation. Topics range from anatomy and physiology, to electricity and electronics.

PRODUCT CODE: SGCD2

MEMBER: $112 / LIST: $186



CHTM Study Guide

Patrick K. Lynch, CBET, CCE, CHTM

Whether you're preparing for the CHTM certification exam or looking to sharpen your management skills, this guide covers financial, risk, and operations management, as well as training and human resources.

PRODUCT CODES: CHTMGD AND CHTMGD-PDF

MEMBER: $62 / LIST: $96

Additional HTM Resources

Books, Videos, & Resources

- Core Competencies for the Biomedical Equipment Technician (BMET)
- A Practicum for Healthcare Technology Management

Certifications

- Certified Biomedical Equipment Technician (CBET®)
- Certified Healthcare Technology Manager (CHTM)

Human Factors

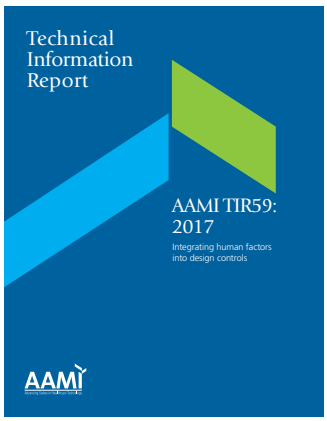
Writing Human Factors Plans & Reports

for Medical Technology Development

Michael Wiklund, Laura Birmingham, Stephanie Alpert Larsen

PRODUCT CODES: HFP AND HFP-PDF

MEMBER: $129 / LIST: $185

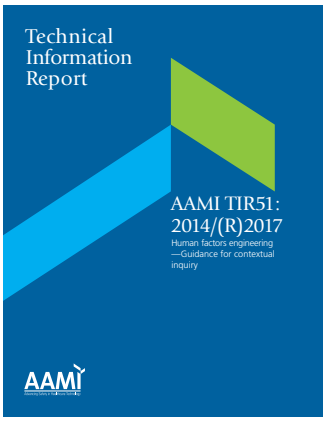


AAMI TIR59:2017

Integrating human factors into design controls

PRODUCT CODE: TIR59

MEMBER: $111 / LIST: $194

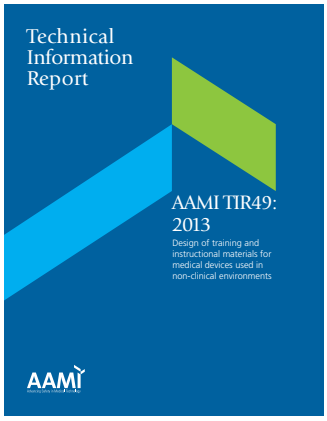


AAMI TIR51:2014/(R)2017

Human factors engineering—guidance for contextual inquiry

PRODUCT CODE: TIR51-PDF

MEMBER: $72 / LIST: $127

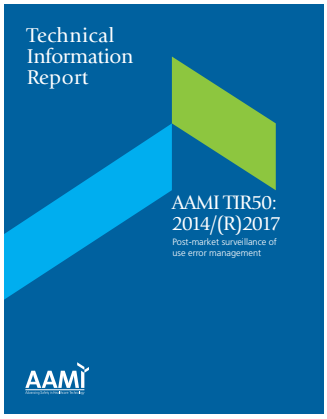


AAMI TIR49:2013

Design of training and instructional materials for medical devices used in non-clinical environments

PRODUCT CODE: TIR49

MEMBER: $111 / LIST: $194



AAMI TIR50:2014/(R)2017

Post-market surveillance of use error management

PRODUCT CODE: TIR50-PDF

MEMBER: $111 / LIST: $194

ANSI/AAMI HE75:2009/(R)2018

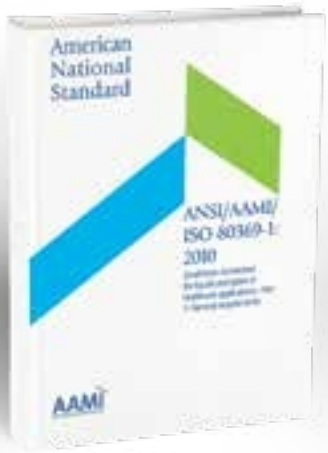
FDA RECOGNIZED

This recommended practice covers general human factors engineering (HFE) principles, specific HFE principles geared towards certain user-interface attributes, and special applications of HFE.

PRODUCT CODE: HE752018PDF

LIST: $415 / MEMBER: $235

Medical Equipment



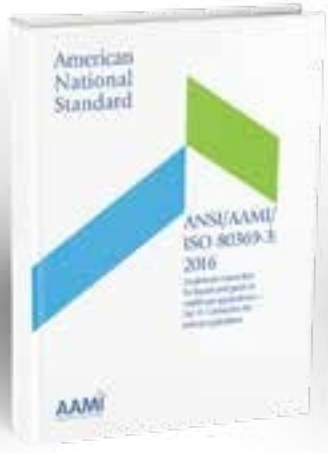
ANSI/AAMI/ISO 80369-1:2010

Small-bore connectors for liquids and gases in healthcare applications—Part 1

This covers general aspects of non-interchangeability and appropriate validation procedures for small bore connectors for liquids and gases in healthcare applications.

PRODUCT CODES: 8036901 AND 8036901-PDF

MEMBER: $72 / LIST: $127



ANSI/AAMI/ISO 80369-3:2016

Connectors for enteral applications

PRODUCT CODE: 80369-3-PDF

MEMBER: $133 / LIST: $236

ANSI/AAMI/ISO 80369-5:2016

Connectors for limb cuff inflation applications

PRODUCT CODES: 80369-5-2016 AND 80369-5-PDF

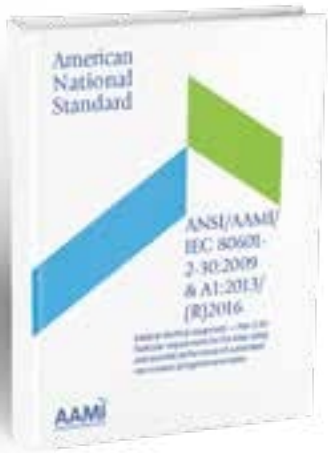
MEMBER: $111 / LIST: $194

ANSI/AAMI/ISO 80369-6:2016

Connectors for neuraxial applications

PRODUCT CODES: 80369-6-D AND 80369-6-D-PDF

MEMBER: $133 / LIST: $236



ANSI/AAMI/IEC 80601-2-30

Medical electrical equipment—Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers

PRODUCT CODES: 601230 AND 601230-PDF

MEMBER: $133 / LIST: $236

FIND OUT MORE

AAMI standards are also available as part of the Complete Standards Collection via the eSubscription. *See page 10 for details.*

Medical Equipment, Continued →

Medical Equipment

ANSI/AAMI ES60601-1

General requirement for basic safety and essential performance medical electrical equipment

FDA RECOGNIZED

This is the American adoption of the IEC 60601-1 standard, which includes U.S. deviations, such as the U.S. national electrical codes. This version contains the 2005 3rd edition of 60601-1 as well as Amendment 1, which was approved in 2012.

PRODUCT CODES: 606011 AND 606011-PDF

MEMBER: $604 / LIST: $1,029

Following are some of the other U.S. adopted IEC standards.

60601-1-12

Medical electrical equipment and systems intended for use in the emergency medical services environment

PRODUCT CODE: 601112-PDF

MEMBER: $133 / LIST: $236

60601-2-4

Cardiac defibrillators

PRODUCT CODES: 601204 AND 601204-PDF

MEMBER: $133 / LIST: $236

60601-2-25

Electrocardiographs

PRODUCT CODES: 601225 AND 601225-PDF

MEMBER: $186 / LIST: $329

60601-2-27

Electrocardiographic monitoring equipment

PRODUCT CODES: 601227

MEMBER: $133 / LIST: $236

60601-2-47

Ambulatory electrocardiographic systems

FDA RECOGNIZED

PRODUCT CODES: 601247 AND 601247-PDF

MEMBER: $133 / LIST: $236

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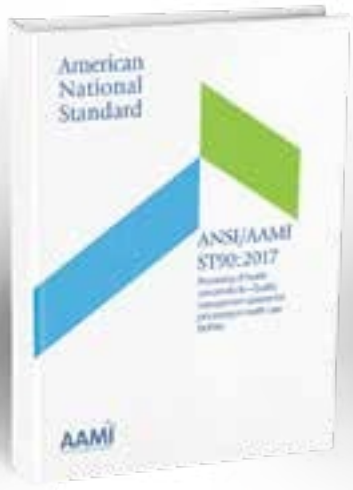
Sterilization



ANSI/AAMI ST79:2017

Comprehensive guide to steam sterilization and sterility assurance in health care facilities

BEST-SELLING STANDARD!
FDA RECOGNIZED

Included within the scope of this standard are functional and physical design criteria for sterilization processing areas (decontamination, preparation, sterilization, and sterile storage areas); staff qualifications, education, and other personnel considerations; processing procedures; installation, care, and maintenance of steam sterilizers; quality control; and quality process improvement.

PRODUCT CODES: ST79 AND ST79-PDF

MEMBER: $357 / LIST: $408

ANSI/AAMI ST90:2017

Processing of health care products—Quality management systems for processing in health care facilities

The first standard of its kind for sterile processing departments, ST90 offers a framework for a sustainable, process-driven quality management system. It provides guidance for repeatable results for all device processing areas within a healthcare facility.

PRODUCT CODES: ST90 AND ST90-PDF

MEMBER: $126 / LIST: $221

Sterilization in Healthcare Facilities eSubscription

Available as both an individual and enterprise subscription, this collection includes 14 sterilization standards and guidance documents, including ST8, ST40, ST41, ST58, ST65, ST79, ST90, ST91, TIR11, TIR12, TIR30, TIR34, TIR55, TIR63, and PB70.

See page 10.

ANSI/AAMI ST91:2015

Flexible and semi-rigid endoscope processing in health care facilities

FDA RECOGNIZED

This standard provides guidelines for precleaning, leak testing, cleaning, packaging, storage, high-level disinfecting, and/or sterilizing of flexible gastrointestinal (GI) endoscopes, flexible bronchoscopes, surgical flexible endoscopes, and semi-rigid operative endoscopes.

PRODUCT CODES: ST91 AND ST91-PDF

MEMBER: $140 / LIST: $236

Endoscope Reprocessing Video

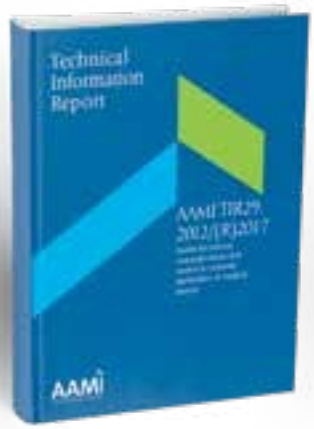
This instructional video covers how endoscopes work, correct handling, reprocessing guidance, and much more. It can be a key resource in promoting patient safety.

PRODUCT CODE: VID-ERCT

MEMBER: $132 / LIST: $220

Sterilization, Continued →

Sterilization



AAMI TIR29:2012/(R)2017

Guide for process characterization and control in radiation sterilization of medical devices

This document is intended to complement qualification and routine control activities as defined in ANSI/AAMI/ISO 11137 for gamma, X-ray, and electron beam sterilization.

PRODUCT CODE: TIR29-PDF

MEMBER: $126 / LIST: $221

ANSI/AAMI/ISO 17664:2017

Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices

The provisions of this standard are applicable to medical devices that are intended for invasive or other direct or indirect patient contact.

PRODUCT CODE: 17664-PDF

MEMBER: $111 / LIST: $194

Sterile Processing in Healthcare Facilities

Preparing for Accreditation Surveys, 3rd edition

Rose Seavey

This publication serves as a guide to healthcare facilities seeking to comply with accrediting body surveys (e.g. CMS, TJC, AAAASF) for the reprocessing of surgical instruments and other reusable medical devices in any healthcare setting.

PRODUCT CODES: SPHC3 AND SPHC3-PDF

MEMBER: $145 / LIST: $248

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AAMI TIR12:2010

Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

PRODUCT CODES: TIR12 AND TIR12-PDF

MEMBER: $133 / LIST: $236

ANSI/AAMI/ISO 11138-1:2017

Part 1: General requirements

Part 1 specifies general requirements for the production, labelling, test methods and performance characteristics of biological indicators, including inoculated carriers and suspensions, and their components, to be used in the validation and routine monitoring of sterilization processes.

PRODUCT CODE: 1113801-PDF

MEMBER: $133 / LIST: $236

ANSI/AAMI/ISO 11138-2:2017

Part 2: Biological indicators for ethylene oxide sterilization processes

Part 2 specifies requirements for test organisms, suspensions, inoculated carriers, biological indicators, and test methods in assessing the performance of sterilizers and sterilization processes employing ethylene oxide gas.

PRODUCT CODE: 1113802-PDF

MEMBER: $63 / LIST: $111

ANSI/AAMI/ISO 11138-3:2017

Part 3: Biological indicators for moist heat sterilization processes

Part 3 contains the requirements for test organisms, suspensions, inoculated carriers, and biological indicators, as well as test methods intended for use in assessing the performance of sterilization processes employing moist heat.

PRODUCT CODE: 1113803-PDF

MEMBER: $63 / LIST: $111

ANSI/AAMI/ISO 11138-4:2017

Part 4: Biological indicators for dry heat sterilization processes

Part 4 outlines the requirements for test organisms, suspensions, inoculated carriers, and biological indicators, as well as test methods intended for use in assessing the performance of sterilization processes employing dry heat.

PRODUCT CODE: 1113804-PDF

MEMBER: $63 / LIST: $111

ANSI/AAMI/ISO 11138-5:2017

Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes

Part 5 contains requirements for test organisms, suspensions, inoculated carriers, and biological indicators, as well as test methods intended for use in assessing the performance of sterilization processes employing low-temperature steam and formaldehyde.

PRODUCT CODE: 1113805-PDF

MEMBER: $63 / LIST: $111

Quality Systems & Risk Management

AAMI TIR57:2016

Principles for medical device security—risk management

FDA RECOGNIZED

This technical information report provides medical device manufacturers with guidance on developing a cybersecurity risk management process for their products. It blends security and safety risk management by showing how to apply the principles presented in *ANSI/AAMI/ISO 14971, Medical Devices—Application of risk management to medical devices*, to security threats that could impact the confidentiality, integrity, and/or availability of a medical device or information processed by the device.

PRODUCT CODES: TIR57 AND TIR57-PDF

MEMBER: $163 / LIST: $247

The Quality System Compendium

CGMP Requirements and Industry Practice

Jack Ward

Developed by a team of FDA and AAMI reviewers, this popular resource gives industry professionals clear guidance on 21 CFR Part 820, which deals with current good manufacturing practices for medical devices. The third edition includes new regulations, standards, and guidance documents in a reader-friendly layout.

PRODUCT CODE: QSC3

MEMBER: $390 / LIST: $650

AAMI/IEC TIR80001

Application of risk management for IT-networks incorporating medical devices

This set of technical documents provides guidance for managing healthcare IT networks.

ANSI/AAMI/IEC TIR80001-2-1:2012

Step-by-step risk management of medical IT-networks; Practical applications and examples

ANSI/AAMI/IEC TIR80001-2-2:2012

Guidance for the disclosure and communication of medical device security needs, risks and controls

ANSI/AAMI/IEC TIR80001-2-3:2012

Guidance for wireless networks

ANSI/AAMI/IEC TIR80001-2-4:2012

General implementation guidance for healthcare delivery organizations

PRODUCT CODES: 80001TIRS AND 80001TIRS-PDF

TIRS: MEMBER: $249 / LIST: $438 FOR ALL

TIRS-PDF: MEMBER: $249 / LIST: $438 FOR ALL

Quality Systems & Risk Management, Continued →

Writing Human Factors Plans & Reports

for Medical Technology Development

Michael Wiklund, Laura Birmingham, Stephanie Alpert Larsen

This book provides the foundation for developing specific human factors engineering (HFE) work products that are needed to meet the FDA's human factors engineering (HFE) guidance.

PRODUCT CODES: HFP AND HFP-PDF

MEMBER: $129 / LIST: $185

Premarket Risk Management

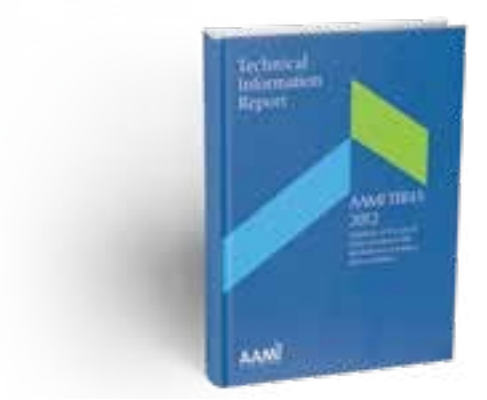
for New Medical Device Companies

Tom Shoup, PhD

As a complement to *ANSI/AAMI/ISO 14971*, this book explains risk management concepts in practical terms to walk you through the creation of a compliant risk management file for a medical device. The book contains templates for actionable tasks in creating a risk management plan that results in a successful product launch.

PRODUCT CODES: PRM AND PRM-PDF

MEMBER: $117 / LIST: $153



AAMI TIR45:2012

Guidance on the use of AGILE practices in the development of medical device software

FDA RECOGNIZED

AGILE methodologies have become increasingly accepted in developing software products. This TIR provides recommendations for complying with international standards and U.S. FDA guidance documents when using AGILE practices to develop medical device software.

PRODUCT CODE: TIR45-PDF

MEMBER: $133 / LIST: $236

ANSI/AAMI/ISO 14971:2007/(R)2016

Medical devices—Application of risk management to medical devices

This standard specifies a process for manufacturers to identify the hazards associated with medical devices, including in vitro diagnostics to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls throughout all stages of the product life cycle.

PRODUCT CODES: 14971 AND 14971-PDF

MEMBER: $155 / LIST: $274

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AAMI Khaki Baseball Cap

Khaki cap with the AAMI logo.

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AAMI Travel Tumbler

Stylish stainless steel 16 oz. tumbler will keep your beverage hot or cold while on the go.

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The AAMI Foundation is committed to reducing preventable patient harm and improving outcomes with the use of complex health technology.

Infusion Quick Guides

These guides include:

- What You Need to Know about Smart Pump Compliance and Drug Libraries
- Improving the Safety of Multiple IV Infusions
- Optimizing Patient Outcomes—Questions Senior Hospital Leaders Should Ask about Infusion Therapy Safety
- Managing Smart Pump Alarms

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www.surveymonkey.com/r/quickguide2
www.surveymonkey.com/r/infusionguide3
www.surveymonkey.com/r/quickguide4

Opioid Safety & Patient Monitoring Conference Compendium

Understand the importance of continuous monitoring of all patients on parenteral opioids.

www.aami.org/opioidcompendium

Clinical Alarm Management Compendium

Get recommendations to reduce nonactionable alarms in the ICU and medical/surgical units.

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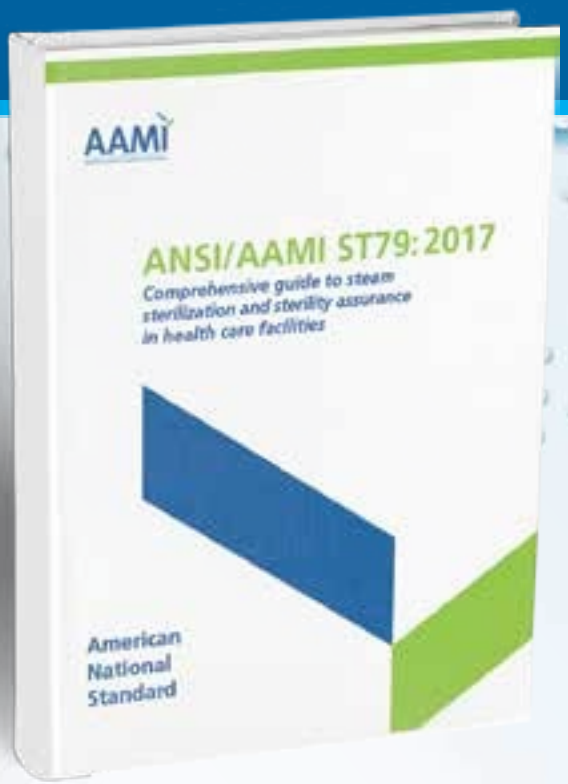
ST79

The Must-Have Standard for Steam Sterilization



Easier to use with reorganized content and color diagrams, ST79 covers every step in the process and can apply to a wide array of facilities where sterile products are reprocessed, stored, and used.

New features include guidance on the use of ultrasonic cleaners, new text on following manufacturers' instructions, and an annex on alternatives to cooling a sterile processing department (SPD).

This best-selling standard is an indispensable tool for any SPD. Use it to help you stay in compliance with accrediting bodies.

For complete details and to order, visit **www.aami.org/ST79.**

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A Guide for HTM Professionals

This book provides practical cybersecurity guidance from leading healthcare systems, along with examples of purchase agreements, vendor contracts, and risk assessment and management practices.

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Product Code: MDC

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