AAMI
Advancing Safety in Health Technology

2020 Resource Catalog

New and Noteworthy!

- AAMI Exchange
- eSubscription Standard Collections
- 2020 Industry Training Schedule

And much more...

www.aami.org

2020 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.

Table of Contents

3 WAYS TO ORDER

www.aami.org/store

1-877-249-8226

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

AAMI Exchange

Engaging Minds, Empowering Success

The AAMI Exchange is the premier global health technology event that connects healthcare technology management (HTM) professionals, biomedical and clinical engineers, technicians, cybersecurity and sterilization experts, hospital administrators and managers, and the industry's leading service and solution providers. The AAMI Exchange provides a forum for broad conversations among these stakeholders on the ever-changing industry 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.

AAMI Exchange 2021 — **June 4–7** — Charlotte, NC

AAMI Exchange 2022 — **June 3–6** — San Antonio, TX

AAMI Exchange 2023 — **June 16–19** — Long Beach, CA

AAMI Exchange 2024 — **June 14–17** — Phoenix, AZ

www.AAMIExchange.org

Certification

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	June 1
ACI Certification Exams	August 1–August 31
ACI Certification Exam Registration Deadline	October 16
ACI Certification Exams	November 1–15

* Dates may change

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

Training

Navigate the Regulatory World with Confidence

All training for the remainder of 2020 will have a virtual attendance option. AAMI uses Zoom for virtual accessibility. You can test your connectivity and ability to use Zoom at **www.zoom.us/test**.

2020 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: **$3,060** / NONMEMBERS: **$3,400** / GOVT. EMPLOYEES: **$1,225**	June 22–26 September 7–11 | *Dublin, Ireland* September 21–25 November 2–6

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: **$2,340** / NONMEMBERS: **$2,600** / GOVT. EMPLOYEES: **$935**	July 21–23 | *Las Vegas, Nevada* September 21–23 | *Dublin, Ireland* September 30–October 2 December 15–17

Integrating Risk Management into the Product Lifecycle: Quality and 13485

COST	DATE
AAMI MEMBERS: **$2,340** / NONMEMBERS: **$2,600** / GOVT. EMPLOYEES: **$935**	August 18–20 October12–14 | *Dublin, Ireland* November 17–19

Process Validation Requirements and Industry Practice

COST	DATE
AAMI MEMBERS: **$2,340** / NONMEMBERS: **$2,600** / GOVT. EMPLOYEES: **$935**	September 28–30 | *Dublin, Ireland*

Corrective and Preventive Action Requirement and Industry Practice

COST	DATE
AAMI MEMBERS: **$1,980** / NONMEMBERS: **$2,200** / GOVT. EMPLOYEES: **$935**	June 1–2

Purchasing Controls & Supply Chain Management

COST	DATE
AAMI MEMBERS: **$1,980** / NONMEMBERS: **$2,200** / GOVT. EMPLOYEES: **$935**	June 3–5

Navigating 510(k) and De Novo Requirements

COST	DATE
AAMI MEMBERS: **$2,700** / NONMEMBERS: **$3,000** / GOVT. EMPLOYEES: **$1,080** DeNovo Course Virtual Attendence Registration is an additional $360.	May 18–20 - 510(k) May 18–21 - 510(k) + De Novo

STERILIZATION

Industrial Sterilization for Medical Devices

COST	DATE
AAMI MEMBERS: **$2,700** / NONMEMBERS: **$3,000** / GOVT. EMPLOYEES: **$1,080**	May 12–15 October 6–9

Ethylene Oxide Sterilization for Medical Devices

COST	DATE
AAMI MEMBERS: **$2,520** / NONMEMBERS: **$2,800** / GOVT. EMPLOYEES: **$1,000**	August 25–28

Radiation Sterilization for Medical Devices

COST	DATE
AAMI MEMBERS: **$2,520** / NONMEMBERS: **$2,800** / GOVT. EMPLOYEES: **$1,000**	October 27–30

HUMAN FACTORS

Human Factors for Medical Devices

COST	DATE
AAMI MEMBERS: **$2,340** / NONMEMBERS: **$2,600** / GOVT. EMPLOYEES: **$935**	September 1–3 September 21–23 | *Dublin, Ireland* December 1–3

SOFTWARE VALIDATION

Production & Quality System Software

COST	DATE
AAMI MEMBERS: **$1,980** / NONMEMBERS: **$2,200** / GOVT. EMPLOYEES: **$800**	June 23–25

Application of Agile Practices in Medical Device Software

COST	DATE
AAMI MEMBERS: **$1,980** / NONMEMBERS: **$2,200** / GOVT. EMPLOYEES: **$800**	July 14–15

Medical Device Software Validation

COST	DATE
AAMI MEMBERS: **$2,340** / NONMEMBERS: **$2,600** / GOVT. EMPLOYEES: **$935**	September 9–11 October 12–14 | *Dublin, Ireland*

Interested in attending these courses virtually? Experience these courses from anywhere in the world by registering for virtual training! All classes for the remainder of the year are now open for virtual attendance. For more information or to register today, visit **www.aami.org/training** or email **solutions@aami.org**.

eSubscription

Digital Library of AAMI Standards & 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 very 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.
- **Coming soon!** eSubscription mobile app

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	2–5 Concurrent Users (up to 100 named users)—$1,700 member | $2,400 non-member 6–10 Concurrent Users (up to 200 named users)—$2,700 member | $3,800 non-member

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.

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 →

eSubscription, *Continued*

Dialysis Collection

This collection includes access to dialysis standards including the new 23500 series and RD47.

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, TIR49, TIR50, and TIR51.

INDIVIDUAL PLAN	ENTERPRISE PLANS	
MEMBER: $360 / LIST: $535	**2–5 Concurrent 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 Named 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**

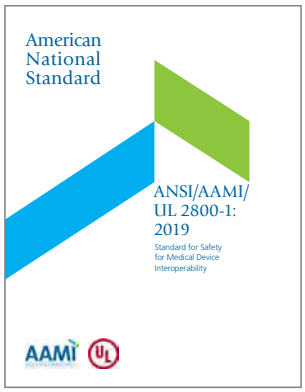
***Access Types:**

Generic: The organization is provided 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



NEW! ANSI/AAMI/UL 2800-1:2019

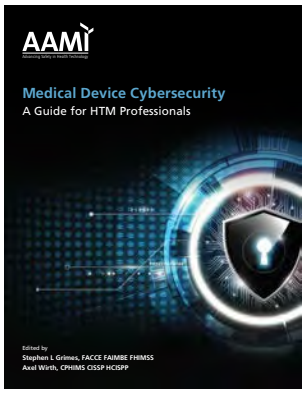
Standard for Safety for Medical Device Interoperability

FDA RECOGNIZED

The standard employs a life cycle process approach to organizing requirements, providing a set of interoperability planning, realization, deployment, and monitoring activities that incorporate cross-cutting requirements for security and risk management. AAMI/UL 2800-1 also provides supplementary guidance on key clinical and engineering properties essential for ensuring effective interoperability.

PRODUCT CODE: UL280001

MEMBER: $247 / LIST: $414



Medical Device Cybersecurity

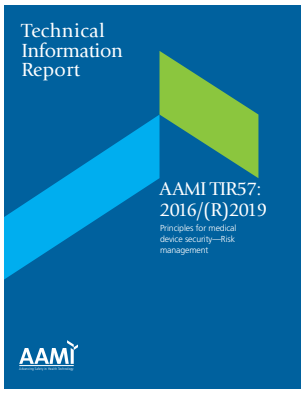
A Guide for HTM Professionals

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: $160 / LIST: $239



AAMI TIR57:2016/(R) 2019

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 CODE: TIR57-PDF

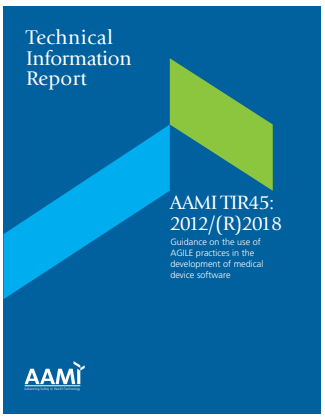
MEMBER: $168 / LIST: $282

Be a part of AAMI

Membership is the best way to take advantage of all that AAMI has to offer!

- Member benefits include deep discounts on AAMI products, education and training, and conferences and events.
- Engage with other members on a wide range of trending topics via AAMI Connect online discussion groups.
- Be a leader in developing medical device standards used around the world.
- Stay up-to-date with industry news and hot topics through *AAMI News* and *AAMI NewsWeekly*, as well as AAMI's award-winning journal, *BI&T*.

Cybersecurity/IT, *Continued*



AAMI TIR45:2012/(R)2018

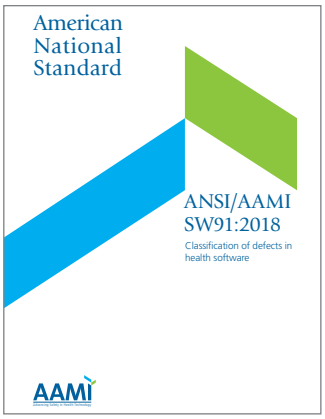
Guidance on the use of AGILE practices in the development of medical device software

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: $137 / LIST: $243



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: $137 / LIST: $243

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 CODE: 80001TIRS-PDF

MEMBER: $256 / LIST: $451 FOR ALL

Dialysis

NEW! ANSI/AAMI/ISO 23500-1:2019

Preparation and quality management of fluids for haemodialysis and related therapies—Part 1: General requirements

PRODUCT CODE: 2350012019

MEMBER: $160 / LIST: $282

NEW! ANSI/AAMI/ISO 23500-2:2019

Preparation and quality management of fluids for haemodialysis and related therapies—Part 2: Water treatment equipment for haemodialysis applications and related therapies

PRODUCT CODE: 2350022019

MEMBER: $130 / LIST: $228

NEW! ANSI/AAMI/ISO 23500-3:2019

Preparation and quality management of fluids for haemodialysis and related therapies—Part 3: Water for haemodialysis and related therapies

PRODUCT CODE: 2350032019

MEMBER: $93 / LIST: $162

NEW! ANSI/AAMI/ISO 23500-4:2019

Preparation and quality management of fluids for haemodialysis and related therapies—Part 4: Concentrates for haemodialysis and related therapies

PRODUCT CODE: 2350042019

MEMBER: $114 / LIST: $200

NEW! ANSI/AAMI/ISO 23500-5:2019

Preparation and quality management of fluids for haemodialysis and related therapies—Part 5: Quality of dialysis fluid for haemodialysis and related therapies

PRODUCT CODE: 2350052019

MEMBER: $93 / LIST: $162

NEW! ANSI/AAMI RD47:2020

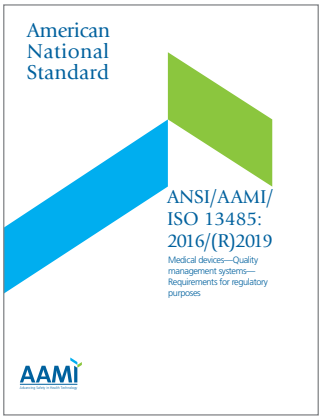
Reprocessing of hemodialyzers

This recommended practice is addressed to the physician responsible for reprocessing hemodialyzers. It covers personnel and patient considerations, records, equipment, physical plant and environmental safety, reprocessing material, patient identification and hemodialyzer labeling, reprocessing and storage procedures, disposition of rejected dialyzers, preparation for subsequent use, patient monitoring, and quality assurance and quality control. This document does not endorse either single use or reuse of dialyzers.

PRODUCT CODE: RD47-2020

MEMBER: $137 / LIST: $243

Quality Systems/ Regulatory Affairs



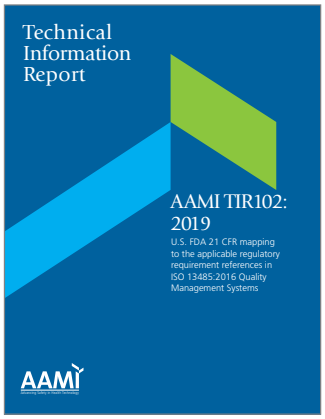
ANSI/AAMI/ISO 13485:2016/(R)2019

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: $137 / LIST: $243

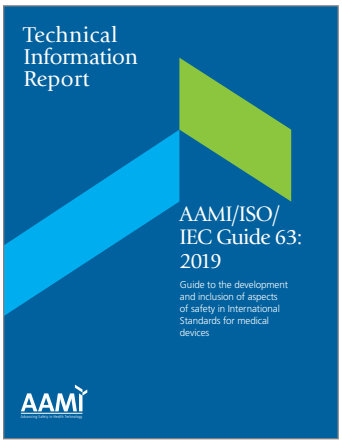


NEW! AAMI TIR102:2019

U.S. FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016 Quality Management Systems

This document provides a mapping of the US FDA 21 CFR requirements to the "regulatory requirements" references in ISO 13485:2016. This mapping is intended to be a tool for US industry to help identify the regulatory requirements from the US medical device regulations to be addressed through an ISO 13485 quality management system.

PRODUCT CODE: TIR102-PDF
MEMBER: $160 / LIST: $282



NEW! AAMI/ISO/IEC Guide 63:2019

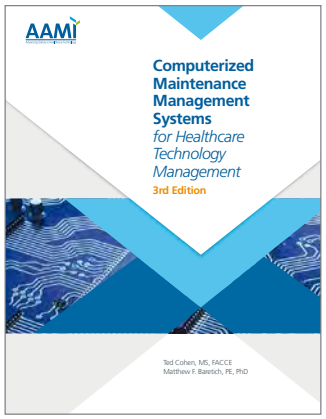
Guide to the development and inclusion of aspects of safety in International Standards for medical devices

This document provides requirements and recommendations to writers of medical device standards on the inclusion of aspects related to safety in International Standards, based on well-established risk management concepts and methodology. This document is applicable to any aspect related to the safety of people, property, the environment, or a combination of these.

PRODUCT CODE: GUIDE632019

MEMBER: $111 / LIST: $194

Healthcare Technology Management



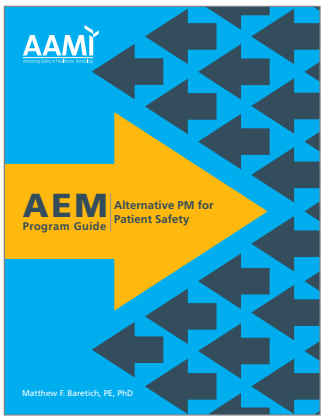
Computerized Maintenance Management Systems for Healthcare Technology Management

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: $98 / LIST: $141



AEM Program Guide

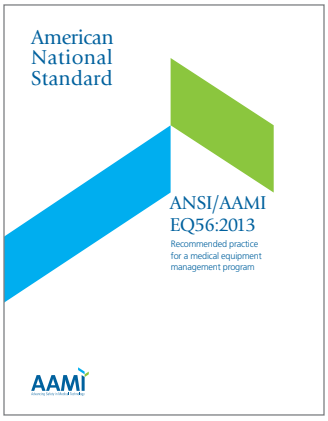
Alternative PM for Patient Safety

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: $64 / LIST: $99



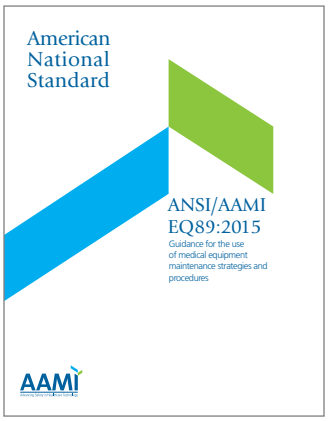
ANSI/AAMI EQ56:2013

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: $114 / LIST: $200



ANSI/AAMI EQ89:2015

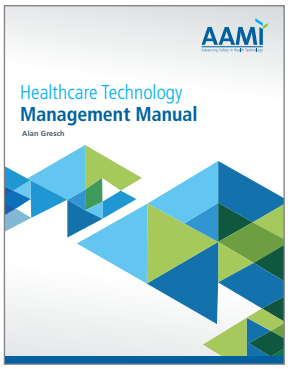
Guidance for the use of medical maintenance strategies and procedures

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: $74 / LIST: $131

Healthcare Technology Management, *Continued*



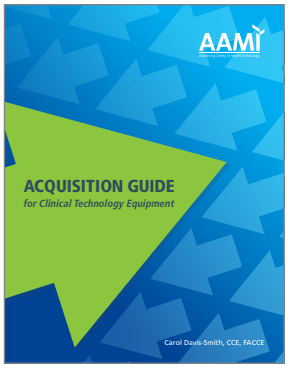
Healthcare Technology Management Manual

Alan Gresch

Take your HTM department to the next level. The *Healthcare Technology Management Manual*, the successor to the popular Medical Equipment Management Manual, can help you get there. This edition covers "all aspects of running a successful HTM department," from accreditation and standards to HTM operations, personnel, and services, according to author Al Gresch, vice president of client success at Accruent.

PRODUCT CODES: HTMM AND HTMM-PDF

MEMBER: $160 / LIST: $239

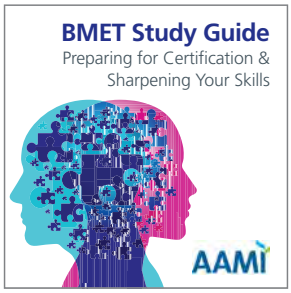


Acquisition Guide for Clinical Technology Equipment

The Acquisition Guide outlines a clear, practical, and scalable process for healthcare organizations to procure and install devices and technology.

PRODUCT CODES: ACQ AND ACQ-PDF

MEMBER: $64 / LIST: $99



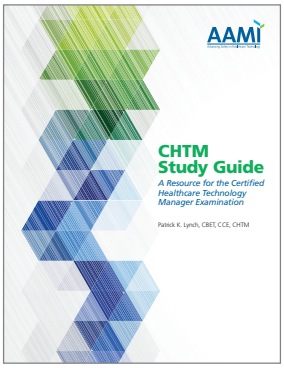
BMET Study Guide 2020

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 950 interactive questions and answers—each with a detailed explanation. Topics range from anatomy and physiology, to electricity and electronics.

PRODUCT CODE: SGBMET3

MEMBER: $124 / LIST: $206



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: $64 / LIST: $99

Additional HTM Resources

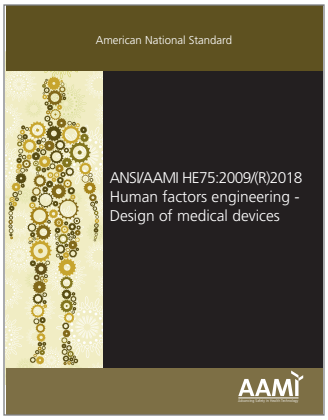
Books

- 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



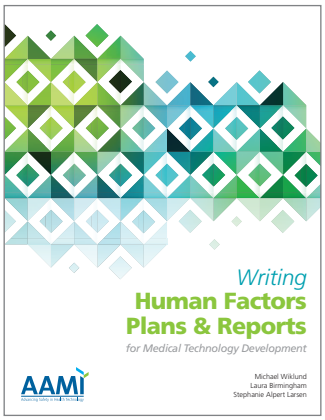
ANSI/AAMI HE75:2009/(R)2018

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

MEMBER: $242 / LIST: $427



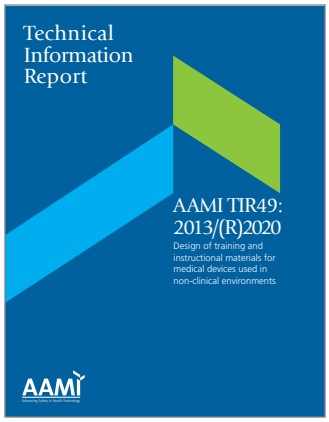
Writing Human Factors Plans & Reports

for Medical Technology Development

Michael Wiklund, Laura Birmingham, Stephanie Alpert Larsen

PRODUCT CODE: HFP-PDF MEMBER:

$131 / LIST: $191

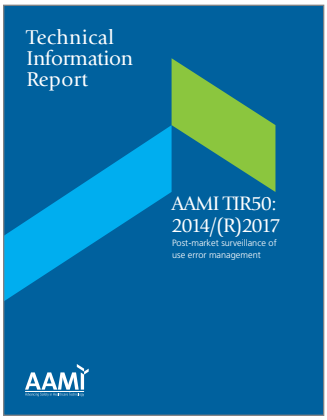


AAMI TIR49:2013/(R)2020

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

PRODUCT CODE: TIR492020

MEMBER: $130 / LIST: $228

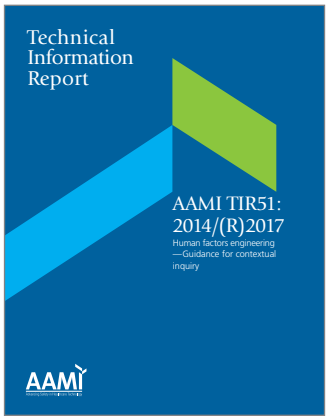


AAMI TIR50:2014/(R)2017

Post-market surveillance of use error management

PRODUCT CODE: TIR50-PDF

MEMBER: $114 / LIST: $200

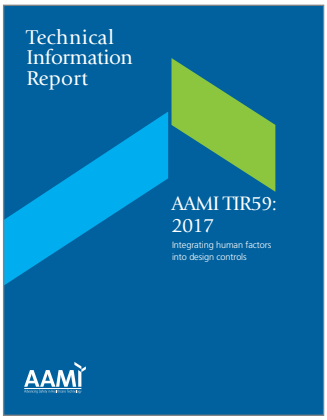


AAMI TIR51:2014/(R)2017

Human factors engineering—guidance for contextual inquiry

PRODUCT CODE: TIR51-PDF

MEMBER: $74 / LIST: $131



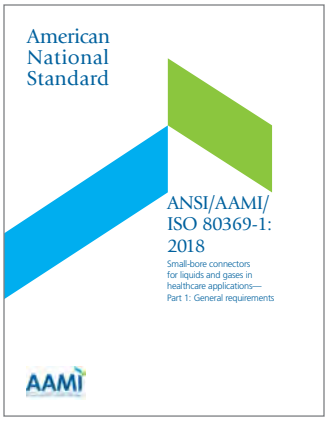
AAMI TIR59:2017

Integrating human factors into design controls

PRODUCT CODE: TIR59

MEMBER: $114 / LIST: $200

Medical Equipment



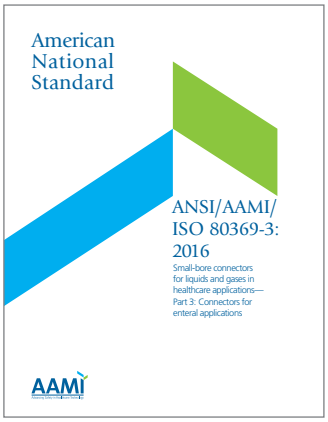
ANSI/AAMI/ISO 80369-1:2018

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

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

PRODUCT CODE: 8036901-PDF

MEMBER: $72 / LIST: $127



ANSI/AAMI/ISO 80369-3:2016

Connectors for enteral applications

PRODUCT CODE: 80369-3-PDF

MEMBER: $137 / LIST: $243

ANSI/AAMI/ISO 80369-5:2016

Connectors for limb cuff inflation applications

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

MEMBER: $114 / LIST: $200

ANSI/AAMI/ISO 80369-6:2016

Connectors for neuraxial applications

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

MEMBER: $137 / LIST: $243

ANSI/AAMI/IEC 80601-2-30:2018

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

PRODUCT CODE: 601230-PDF

MEMBER: $137 / LIST: $243

FIND OUT MORE

AAMI standards are also available as part of the Complete Standards Collection via the eSubscription.

See page 10 for details.

ANSI/AAMI ES60601-1

Part 1: General requirements for basic safety and essential performance

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: $622 / LIST: $1,060

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

ANSI/AAMI/IEC 60601-1-12:2016

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

PRODUCT CODE: 601112-PDF

MEMBER: $137 / LIST: $243

NSI/AAMI/IEC 60601-2-4:2010/A1:2018

Cardiac defibrillators

PRODUCT CODE: 601204-PDF

MEMBER: $160 / LIST: $282

ANSI/AAMI/IEC 60601-2-25:2011/(R)2016

Electrocardiographs

PRODUCT CODES: 601225 AND 601225-PDF

MEMBER: $192 / LIST: $339

ANSI/AAMI/IEC 60601-2-27:2011/(R)2016

Electrocardiographic monitoring equipment

PRODUCT CODE: 601227

MEMBER: $137 / LIST: $243

ANSI/AAMI/IEC 60601-2-47:2012/(R)2016

Ambulatory electrocardiographic systems

FDA RECOGNIZED

PRODUCT CODES: 601247 AND 601247-PDF

MEMBER: $137 / LIST: $243

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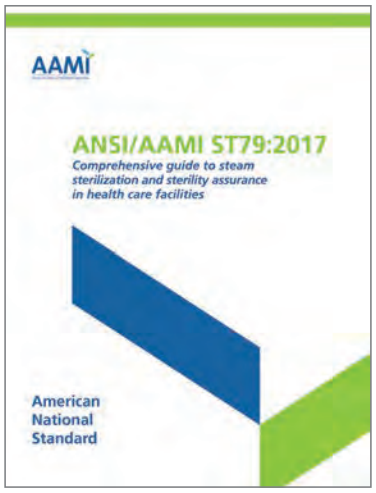
Sterilization



ANSI/AAMI ST79:2017

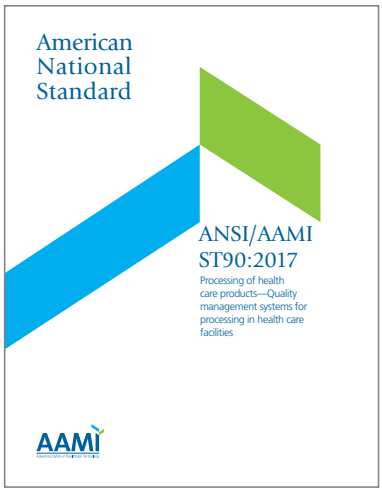
Comprehensive guide to steam sterilization and sterility assurance in health care facilities

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

This document specifies minimum requirements for quality management systems (QMSs) to effectively, efficiently, and consistently process (transport, clean, decontaminate, disinfect, inspect, package, sterilize, and store) medical devices to prevent adverse patient events and nonmanufacturer-related device failures.

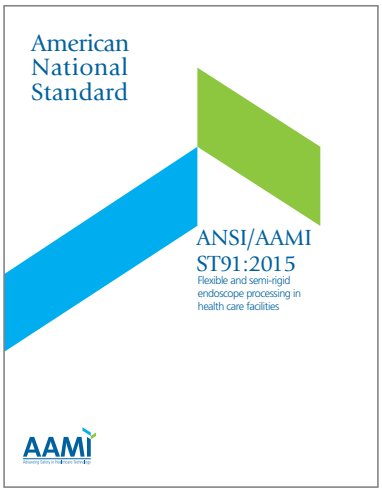
PRODUCT CODES: ST90 AND ST90-PDF

MEMBER: $130 / LIST: $228

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 8.



ANSI/AAMI ST91:2015

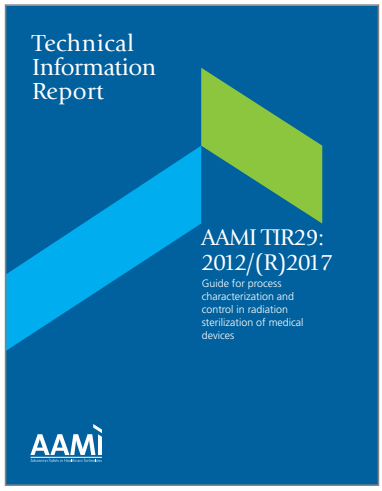
Flexible and semi-rigid endoscope processing in health care facilities

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 CODE: ST91-PDF

MEMBER: $144 / LIST: $243



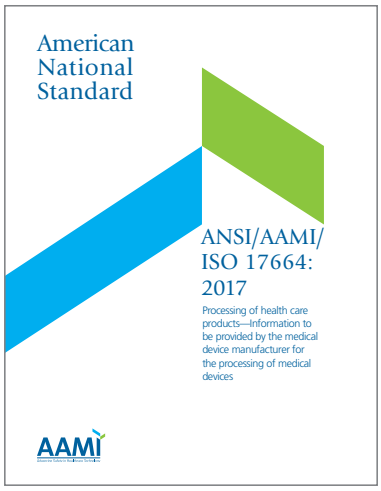
AAMI TIR29:2012/(R)2017

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: $130 / LIST: $228



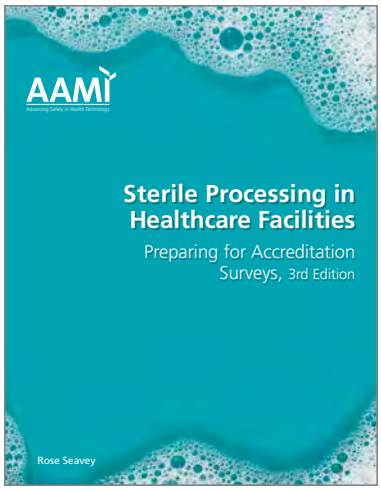
ANSI/AAMI/ISO 17664:2017

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: $114 / LIST: $200



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: $149 / LIST: $255

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Sterilization, *Continued*

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: $137 / LIST: $243

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: $137 / LIST: $243

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: $65 / LIST: $114

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: $65 / LIST: $114

ANSI/AAMI/ISO 11138-4:2017

Part 4: Biological indicators for dry heat sterilization processes

Part 4 specifies 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: $65 / LIST: $114

ANSI/AAMI/ISO 11138-5:2017

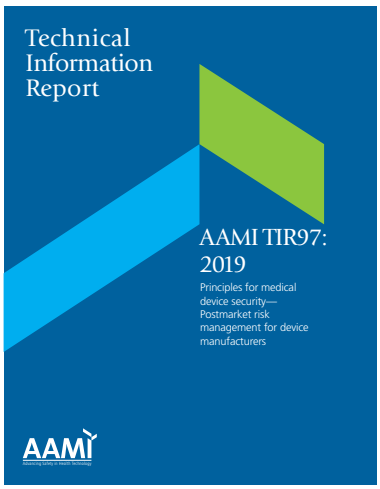
Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes

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: $65 / LIST: $114

Risk Management



NEW! AAMI TIR97:2019

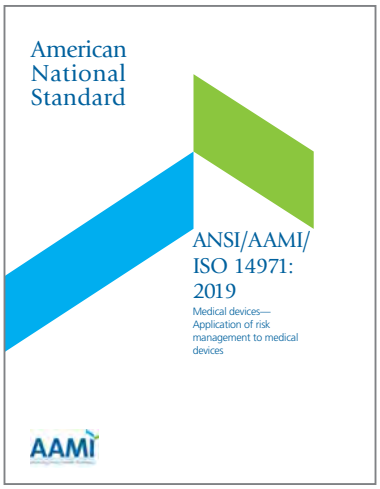
Principles for medical device security—Postmarket risk management for device manufacturers

FDA RECOGNIZED

This technical information report provides guidance on methods to perform postmarket security risk management for a medical device in the context of the Safety Risk Management process required by ISO 14971. This TIR is intended to be used in conjunction with AAMI TIR57:2016.

PRODUCT CODE: TIR972019PDF

MEMBER: $137 / LIST: $243



NEW! ANSI/AAMI/ISO 14971:2019

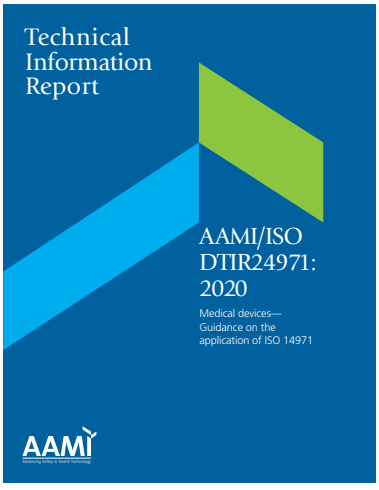
Medical devices—Application of risk management to medical devices

FDA RECOGNIZED

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 CODE: 14971-PDF

MEMBER: $137 / LIST: $243



NEW! AAMI/ISO DTIR24971:2020

Medical devices—Guidance on the application of ISO 14971

This Technical Report will provide guidance that addresses specific areas that experience has shown are problematic for those implementing a risk management system. This guidance would not require any change to existing implementations of ISO 14971. The proposed document would not be a general guidance on implementation of risk management. Such documents already exist from various sources. Rather the document envisioned would focus on expectations in certain critical areas such as guidance on formulation of a risk management policy; the role of product and process standards in the risk management process; guidance on how the feedback loop can work; guidance on the differentiation of information for safety as a risk control measure and disclosure of residual risk; and an expansion of the discussion of overall residual risk.

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PRODUCT CODES: TS19MGRAY, TS19LGRAY, TS19XLGRAY, TS19XXLGRAY

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PRODUCT CODE: BBCAP19NAVY

MEMBER: $15 / LIST: $20

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Khaki cap with the AAMI logo.

PRODUCT CODE: BBCAP19KHAKI

MEMBER: $15 / LIST: $20

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PRODUCT CODE: AAMITUMBLR19

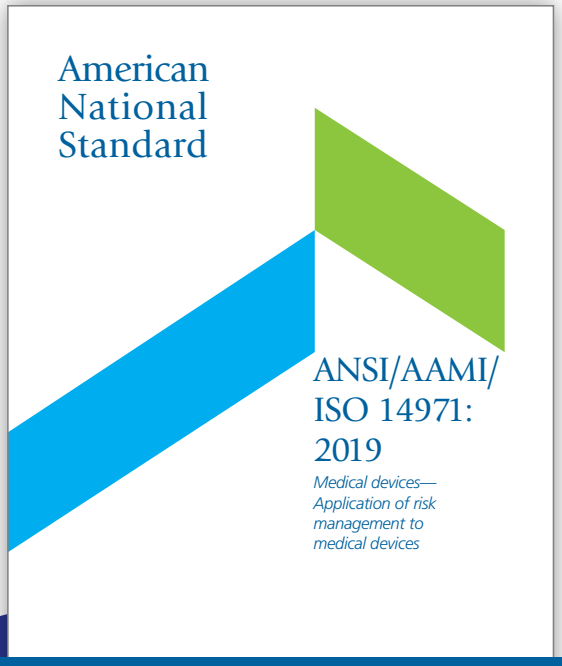
MEMBER: $18 / LIST: $24

Introducing a New Risk Management Resource

ANSI/AAMI/ISO 14971, *Medical devices—Application of risk management to medical devices*

This American National Standard specifies a process by which a manufacturer can identify the hazards associated with medical devices. This standard is now available in the AAMI Store.

Product Code: 149712019PDF



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See page 8 for details.

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