AAMI

Advancing Safety in Health Technology

2021 RESOURCE CATALOG

New and Noteworthy!

- ST79 with 4 New Amendments
- Dialysis Collection
- HTM Resources including CBET Smart Practice

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Thanks to the healthcare technology management community

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All of us at Dräger are honored to support you – the technical experts who make it possible for front-line healthcare and emergency teams to help those affected by COVID-19. Together, we are part of one amazing community united in the fight against #Covid19.

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2021 RESOURCE CATALOG

TABLE OF CONTENTS

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

- Stay up to date on global regulatory requirements.
- Implement effective practices.
- Develop innovative and successful products.
- Learn more about the field.

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

Included in this catalog are popular documents. For our complete selection of publications, visit **www.aami.org/store**.

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When you subscribe to AAMI's eSubscription, you gain immediate access to AAMI's entire library of national and international standards, recommended practices, technical information reports, and other resources including sterilization, dialysis, biological evaluation of medical devices, quality systems, and medical equipment.

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Access Types

Generic: The organization is provided with a link and generic username and password to place on its Intranet. 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 password.

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.

AAMI eSUBSCRIPTION—COLLECTIONS

ANSI/AAMI ST79:2017

FDA RECOGNIZED

ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* is the sterilization asset that every hospital needs. *Updated in 2020.*

STERILIZATION IN HEALTHCARE FACILITIES

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

STERILIZATION—INDUSTRIAL PROCESS CONTROL

This sterilization collection for manufacturers and users of sterilization equipment includes **58** AAMI standards and guidance documents.

STERILIZATION EQUIPMENT DESIGN AND USE

This sterilization collection, which is pertinent to manufacturers and users of sterilization equipment, includes 30 AAMI standards and guidance documents.

ALL 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.

AAMI eSUBSCRIPTION—COLLECTIONS, *CONTINUED*

DIALYSIS COLLECTION

Access all the latest dialysis standards including the 23500 series and RD47.

HEALTHCARE TECHNOLOGY MANAGEMENT (HTM) COLLECTION

Important and valuable resources for the HTM professional are available here, including: ANS/AAMI EQ56, the *CHTM Study Guide*, and the *Electrical Safety Manual*.

HUMAN FACTORS COLLECTION

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

COMPLETE STANDARDS COLLECTION

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

AAMI eSUBSCRIPTION—DETAILS

ANSI/AAMI ST79:2017

FDA RECOGNIZED

MEMBER: $346–$2,700
NON-MEMBER: $396–$3,800

STERILIZATION IN HEALTHCARE FACILITIES

MEMBER: $535–$7,900
NON-MEMBER: $749–$9,000

STERILIZATION—INDUSTRIAL PROCESS CONTROL

MEMBER: $490–$8,735
NON-MEMBER: $660–$12,475

STERILIZATION EQUIPMENT DESIGN AND USE

MEMBER: $490–$7,125
NON-MEMBER: $660–$10,180

ALL STERILIZATION STANDARDS COLLECTION

MEMBER: $820–$5,400
NON-MEMBER: $1,220–$6,750

AAMI eSUBSCRIPTION—DETAILS, *CONTINUED*

DIALYSIS COLLECTION

MEMBER: $360–$1,950
NON-MEMBER: $535–$2,900

HEALTHCARE TECHNOLOGY MANAGEMENT (HTM) COLLECTION

MEMBER: $635–$1,950
NON-MEMBER: $885–$2,900

HUMAN FACTORS COLLECTION

MEMBER: $360–$1,950
NON-MEMBER: $535–$2,900

COMPLETE STANDARDS COLLECTION

MEMBER: $1,395–$23,500
NON-MEMBER: $1,955–$32,500

AAMI Connect

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- HTM
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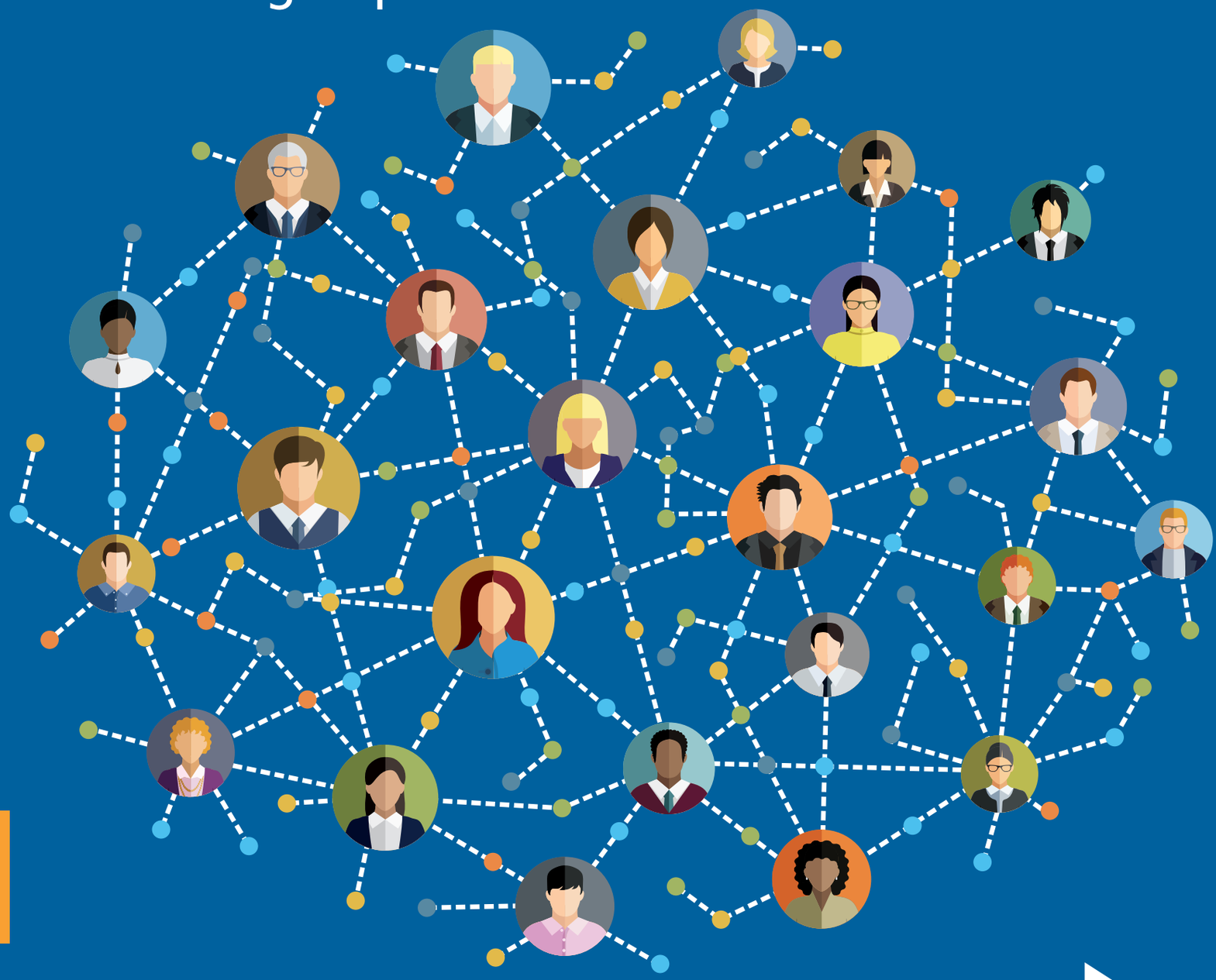


www.aami.org

AAMI
Advancing Safety in Health Technology

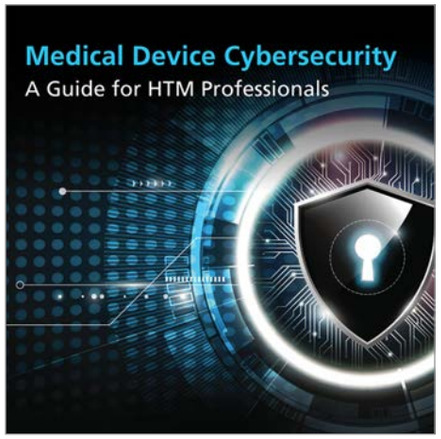
CYBERSECURITY/IT

ANSI/AAMI/UL 2800-1:2019

Standard for Safety for Medical Device Interoperability

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. UL 2800-1 also provides supplementary guidance on key clinical and engineering properties essential for ensuring effective interoperability.

MEMBER: $254 | NON-MEMBER: $426



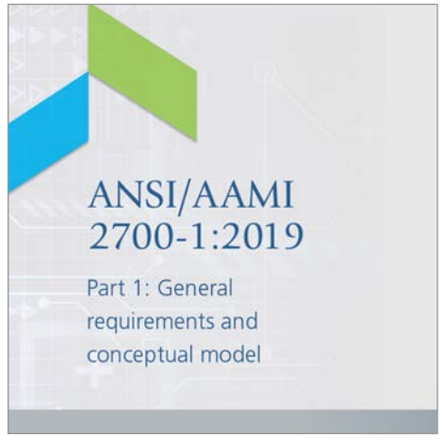
Medical Device Cybersecurity

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.

MEMBER: $165 | NON-MEMBER: $246



ANSI/AAMI 2700-1:2019

Medical Devices and Medical Systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE)—Part 1: General requirements and conceptual model

This standard specifies general requirements, a model, and framework for integrating equipment to create an integrated clinical environment (ICE). Learn the specific characteristics necessary for the safe integration of medical devices and other equipment, via an electronic interface, from different manufacturers into a single medical system for the care of a single high acuity patient.

MEMBER: $117 | NON-MEMBER: $206

AAMI TIR57:2016/(R)2019

Principles for medical device security—Risk management

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

MEMBER: $165 | NON-MEMBER: $290

DIALYSIS

The New 23500 series:

ANSI/AAMI/ISO 23500-1:2019

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

MEMBER: $165 | **NON-MEMBER:** $290

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

MEMBER: $134 | **NON-MEMBER:** $235

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

MEMBER: $96 | **NON-MEMBER:** $167

ANSI/AAMI/ISO 23500-4:2019

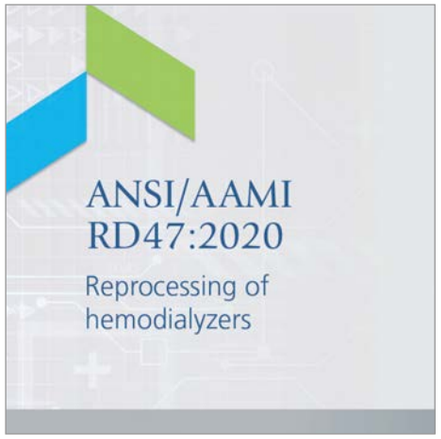
Preparation and quality management of fluids for haemodialysis and related therapies—Part 4: Concentrates for haemodialysis and related therapies

MEMBER: $117 | **NON-MEMBER:** $206

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

MEMBER: $96 | **NON-MEMBER:** $167

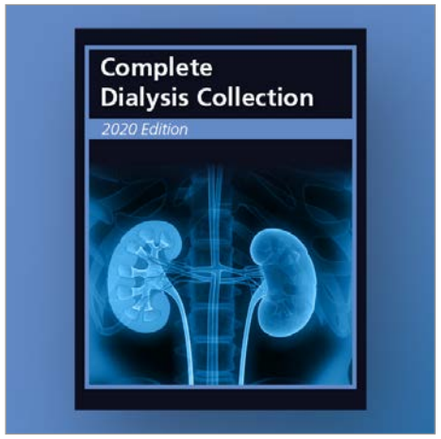


ANSI/AAMI RD47:2020

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.

MEMBER: $141 | **NON-MEMBER:** $250



COMPLETE DIALYSIS COLLECTION

This collection of 15 AAMI dialysis standards and technical information reports includes the latest versions of all dialysis documents. AAMI adopted the 2019 ISO 23500 series of dialysis fluid standards as replacements for the ANSI/AAMI 2014 versions, which have been technically revised. AAMI also adopted the ISO 8637 series standards, which supersede the previous versions that had been published under separate designations.

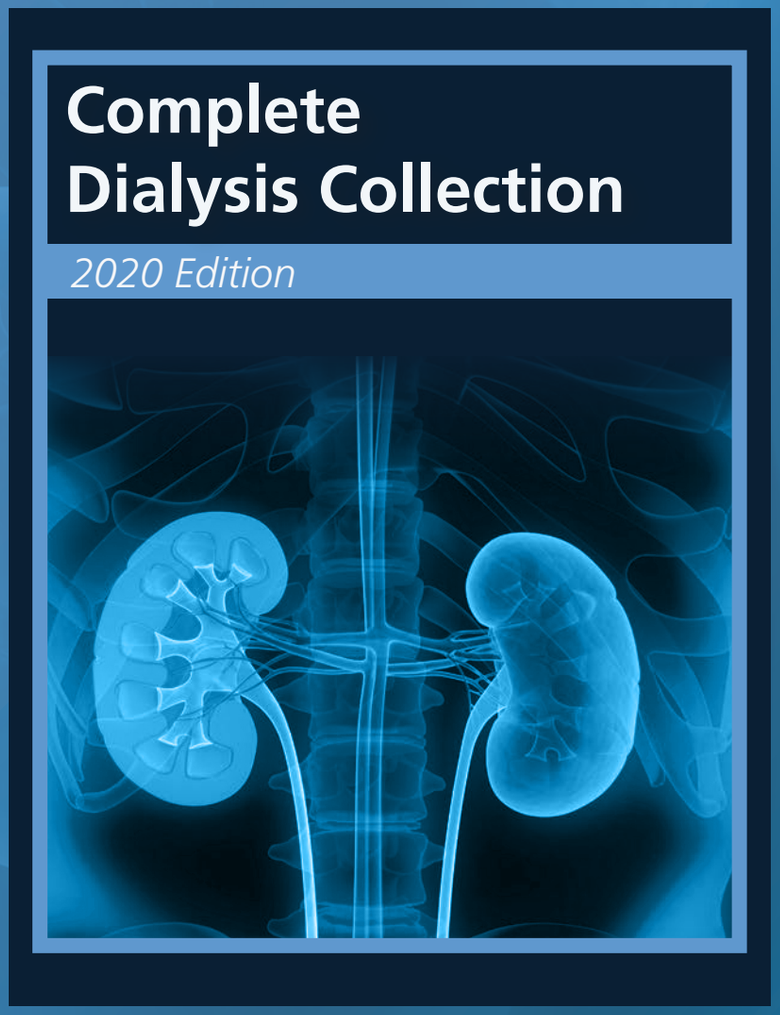
MEMBER: $499 | **NON-MEMBER:** $699

Complete Dialysis Collection

Get the latest standards and technical reports in one resource designed to promote safe, current, and effective dialysis practice.

New standards included for the first time:

- Plasmafilters
- Peritoneal dialysis equipment
- Dialysis fluid chemical composition
- Sorbent-based regenerative hemodialysis



Download from the AAMI Store:

bit.ly/AAMI-Dialysis

ELECTROMEDICAL EQUIPMENT

FDA RECOGNIZED

ANSI/AAMI ES60601-1

Medical electrical equipment— Part 1: General requirements for basic safety and essential performance

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.

MEMBER: $622 | **NON-MEMBER:** $1,060

ANSI/AAMI/IEC 60601-1-12

Medical electrical equipment—Part 1-12: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment & medical electrical systems intended for use in emergency medical services environment

MEMBER: $141 | **NON-MEMBER:** $250

ANSI/AAMI/IEC 60601-2-4 FDA RECOGNIZED

Medical electrical equipment—Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators, including Amendment 1

MEMBER: $165 | **NON-MEMBER:** $290

ANSI/AAMI/IEC 60601-2-25

Medical electrical equipment—Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

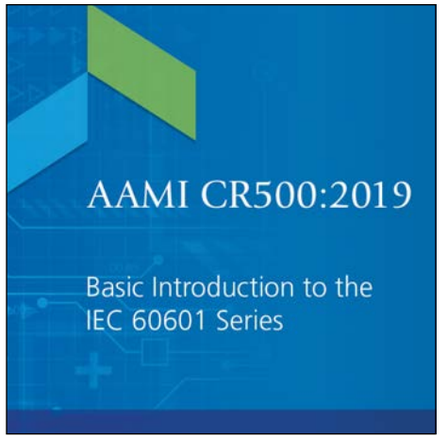
MEMBER: $198 | **NON-MEMBER:** $349

ANSI/AAMI/IEC 60601-2-27 FDA RECOGNIZED

Medical electrical equipment—Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment

MEMBER: $141 | **NON-MEMBER:** $250

ELECTROMEDICAL EQUIPMENT, *CONTINUED*



AAMI CR500:2019

Basic Introduction to the IEC 60601 Series

A key objective of this document is to provide stakeholders with sufficient information about the 60601 series to grasp its significance and value.

MEMBER: $96 | NON-MEMBER: $167

ANSI/AAMI/IEC 80601-2-77:2020

Medical electrical equipment—Part 2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment

This standard applies to the basic safety and essential performance of robotically assisted surgical equipment (RASE) and robotically assisted surgical systems (RASS), referred to as ME equipment and ME systems together with their interface conditions.

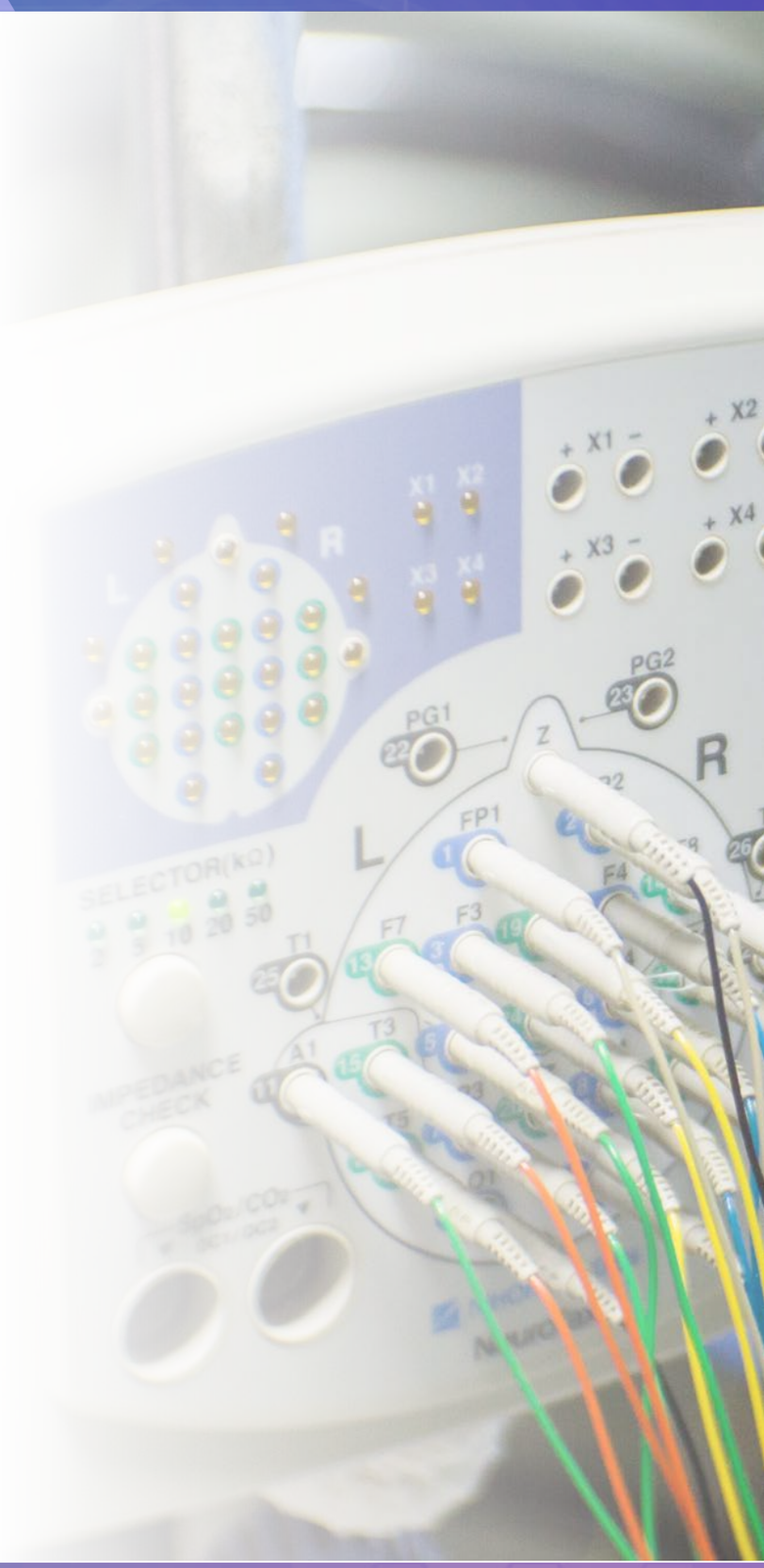
MEMBER: $141 | NON-MEMBER: $250

ANSI/AAMI/IEC 80601-2-78:2020

—Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation

This standard applies to the general requirements for basic safety and essential performance of medical robots that physically interact with a patient with an impairment to support or perform rehabilitation, assessment, compensation or alleviation related to the patient's movement functions, as intended by the manufacturer.

MEMBER: $141 | NON-MEMBER: $250



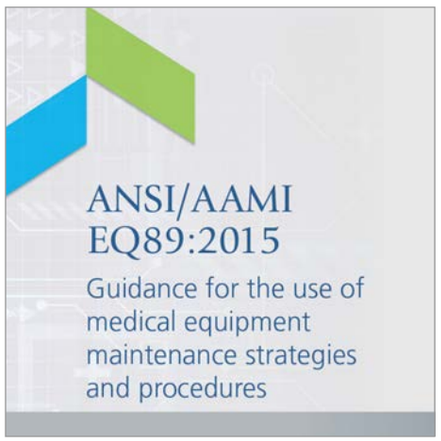
HEALTHCARE TECHNOLOGY MANAGEMENT

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.

MEMBER: $117 | **NON-MEMBER:** $206



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.

MEMBER: $76 | **NON-MEMBER:** $135

AEM PROGRAM GUIDE: ALTERNATIVE PM FOR PATIENT SAFETY

Author: 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.

MEMBER: $66 | **NON-MEMBER:** $102

HEALTHCARE TECHNOLOGY MANAGEMENT, *CONTINUED*

ACQUISITION GUIDE FOR CLINICAL TECHNOLOGY EQUIPMENT

This guide outlines a clear, practical, and scalable process for healthcare organizations to procure and install devices and technology. It lays out seven stages and a set of concentrated activities in the acquisition process. Intended to help organizations make optimum decisions that will serve them well, it guides the process throughout the equipment's life cycle by taking a wide variety of stakeholders into consideration.

MEMBER: $66 | NON-MEMBER: $102

HEALTHCARE TECHNOLOGY MANAGEMENT MANUAL

Author: 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.

MEMBER: $165 | NON-MEMBER: $246

CBET SMART PRACTICE

AAMI's interactive *CBET Smart Practice*, presented online now for the first time, features more than 900 interactive multiple-choice questions and answers, each with a detailed explanation. Covering topics ranging from anatomy and physiology, to electricity and electronics, this is an essential resource for those preparing for the certification exam. While it does not mimic the exam, it provides insights regarding topic areas, such as anatomy and physiology or the fundamentals of electricity and electronics, that may require more attention and further study. Discover your strengths and weaknesses before you take the ACI certification exam.

MEMBER: $117 | NON-MEMBER: $195

OTHER HTM RESOURCES

- AAMI's Career Planning Handbook
- AAMI's Leadership Development Guide
- Core Competencies for the HTM Entry-Level Technician
- HTM Levels Guide and new online version
- HTM Succession Plaining
- HTM Training Guide

HOSPITAL STERILIZATION

ANSI/AAMI ST79:2017 WITH AMENDMENTS 1-4, 2020

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

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.

MEMBER: $367 | NON-MEMBER: $420

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.

MEMBER: $134 | NON-MEMBER: $235

ANSI/AAMI ST91:2015

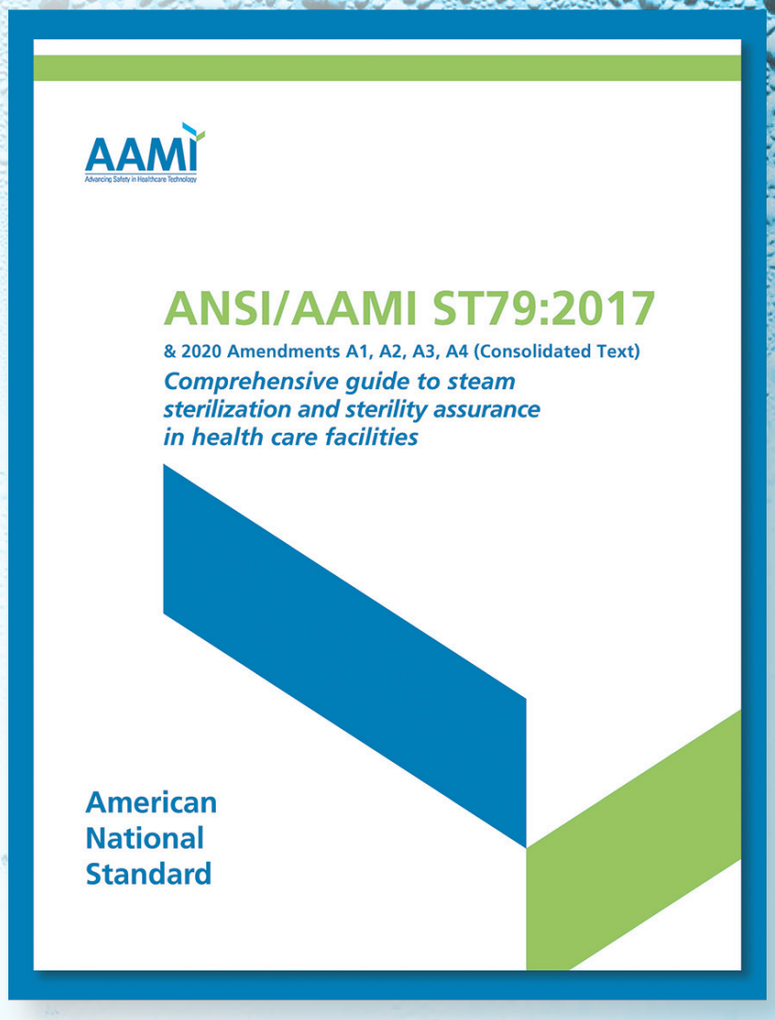
Flexible and semi-rigid endoscope processing in health care facilities

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.

MEMBER: $141 | NON-MEMBER: $250

ST79

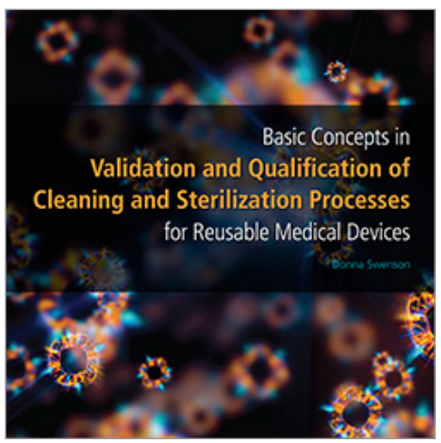
The Must-have Steam Sterilization Standard, Now With 4 New Amendments



PURCHASE YOUR COPY:

bit.ly/AAMI-ST79

ANSI/AAMI ST79:2017
with Amendments A1:2020, A2:2020, A3:2020, A4:2020



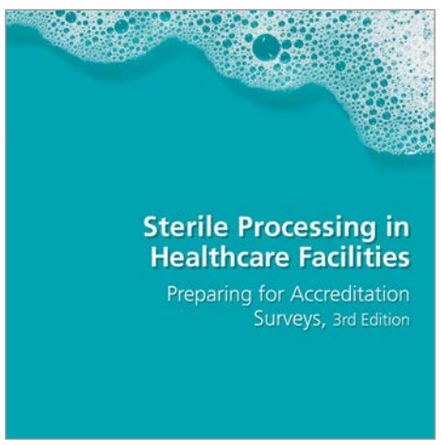
BASIC CONCEPTS IN VALIDATION AND QUALIFICATION OF CLEANING AND STERILIZATION PROCESSES FOR REUSABLE MEDICAL DEVICES

Author: Donna Swenson

2020 edition of Donna Swenson's best-selling resource for sterile processing personnel and medical device manufacturers. This edition has been expanded to include all sterilization modalities that are commonly used by healthcare facilities to process reusable medical devices.

Learn about the basic information on the science behind sterilization, quality management, and the principles of validation. The text then applies those principles to cleaning processes, the validation of various sterilization processes, and product quality assurance testing of cleaning and sterilization processes. The intent of the book is to help sterile processing and medical device manufacturing personnel be on the "same page" and able to use the same language and concepts in discussing and understanding cleaning and sterilization processes.

MEMBER: $153 | NON-MEMBER: $263



STERILE PROCESSING IN HEALTHCARE FACILITIES: PREPARING FOR ACCREDITATION SURVEYS, 3RD EDITION

Author: 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.

MEMBER: $153 | NON-MEMBER: $263

STERILIZATION IN HEALTHCARE FACILITIES ESUBSCRIPTION

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

See page **5**.

Basic Concepts in

Validation and Qualification of Cleaning and Sterilization Processes

for Reusable Medical Devices

Donna Swenson

Download your copy of the newly-updated bestselling book from the AAMI Store today

www.aami.org

AAMI

Advancing Safety in Health Technology

HUMAN FACTORS

ANSI/AAMI HE75:2009/(R)2018

Human factors engineering—Design of medical devices

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

MEMBER: $249 | NON-MEMBER: $440

WRITING HUMAN FACTORS PLANS & REPORTS FOR MEDICAL TECHNOLOGY DEVELOPMENT

Authors: 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.

MEMBER: $91 | NON-MEMBER: $197

AAMI TIR49:2013/(R)2020

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

It is widely recognized that medical devices are increasingly being used outside of a traditional healthcare setting and by individuals with little, or no, prior training on the use of these devices. The purpose of this TIR is to support safe, accurate, and efficient user performance by providing guidance on the design of user instructions and training.

MEMBER: $134 | NON-MEMBER: $235

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.

MEMBER: $141 | NON-MEMBER: $250

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.

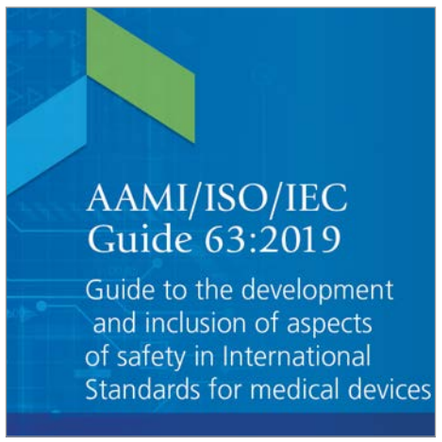
MEMBER: $165 | NON-MEMBER: $290

AAMI/ISO TIR20416:2020

Medical devices–Post-market surveillance for manufacturers

This technical information report (TIR) provides a common understanding of post-market surveillance, or PMS facilitating international cooperation in this area. The Technical Report is intended for use by manufacturers of medical devices.

MEMBER: $134 | NON-MEMBER: $235



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.

MEMBER: $114 | NON-MEMBER: $200

RISK MANAGEMENT

AAMI TIR97:2019

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

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.

MEMBER: $141 | NON-MEMBER: $250

ANSI/AAMI/ISO 14971:2019

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.

MEMBER: $141 | NON-MEMBER: $250

AAMI/ISO TIR24971:2020

Medical devices—Guidance on the application of ISO 14971

This Technical Report provides guidance that addresses specific areas that experience has shown are problematic for those implementing a risk management system. This guidance does not require any change to existing implementations of ISO 14971. The document is not a general guidance on implementation of risk management. Such documents already exist from various sources. Rather the document focuses 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.

MEMBER: $76 | NON-MEMBER: $135

STERILIZATION—EQUIPMENT

ANSI/AAMI ST8:2013/(R)2018

Hospital steam sterilizers

This standard is intended primarily for use by equipment manufacturers in the performance and design qualification of steam sterilizers intended for use in health care facilities.

MEMBER: $117 | NON-MEMBER: $206

ANSI/AAMI/ISO 11607-1:2019

Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems

This standard specifies requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

MEMBER: $96 | NON-MEMBER: $167

ANSI/AAMI/ISO 11607-2:2019

Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes

This standard specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized and maintain sterility to the point of use. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems, and packaging systems.

MEMBER: $76 | NON-MEMBER: $135

STERILIZATION—INDUSTRIAL

ANSI/AAMI ST67:2019

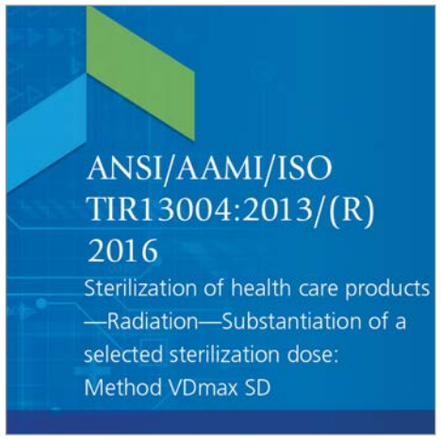
Sterilization of health care products—Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile"

MEMBER: $76 | NON-MEMBER: $135

ANSI/AAMI ST72:2019

Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing

MEMBER: $141 | NON-MEMBER: $250



AAMI TIR76:2021

Sterilization of health care products—Radiation—Substantiation of a selected sterilization dose at a specified sterility assurance level: Method VDmax SD-S

This report describes a method for substantiating a selected sterilization dose that achieves maximally a selected sterility assurance level (SAL) for radiation sterilization of healthcare products.

MEMBER: $124 | NON-MEMBER: $235

INDUSTRIAL STERILIZATION: PROCESS OPTIMIZATION AND MODALITY CHANGES

This special supplement to AAMI's flagship journal *Biomedical Instrumentation & Technology*, was inspired by discussions at the 2019 Kilmer Conference. It provides a compilation of articles focusing on simplifying the move from one sterilization modality to another, optimization of current sterilization processes, and other important research from the field.

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