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- Dialysis Collection
- HTM Resources including CBET Smart Practice

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

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AAMI eSUBSCRIPTION—COLLECTIONS

ANSI/AAMI ST79:2017


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.
**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.
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**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.  
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**ANSI/AAMI/ISO 23500-1:2019**
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**ANSI/AAMI/ISO 23500-2:2019**
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Preparation and quality management of fluids for haemodialysis and related therapies—Part 3: Water for haemodialysis and related therapies
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**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
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**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
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**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

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ELECTROMEDICAL EQUIPMENT

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

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

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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 Planning
• HTM Training Guide
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.

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ST79

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

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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
Basic Concepts in Validation and Qualification of Cleaning and Sterilization Processes for Reusable Medical Devices

Donna Swenson

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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
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

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

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

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**

**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**

**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**
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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