2019 Resource Catalog

New and Noteworthy!
- AAMI Exchange
- eSubscription Standard Collections
- 2019 Industry Training Schedule

And much more...

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

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one step at a time.

Writing

Human Factors Plans & Reports

for Medical Technology Development

For more information and to order this book, please visit www.aami.org/store.

Product Code: HFP and HFP-PDF

www.aami.org
Submitting a Device to the FDA?

HIGHPOWER Labs has been validating reusable medical devices for device manufacturers for 30 years. HIGHPOWER provides a wide range of validation and testing services, as well as consulting to medical device manufacturers. With every major FDA cleared sterilization process in-house, we are available to assist device manufacturers in all of their verification/validation or regulatory compliance needs.

Put our services to the test, contact us for a free consultation today.
Whether dealing with the design, manufacturing, maintenance, or sterile processing of medical devices, AAMI provides you with standards, technical information reports, books, courses, and webinars to:

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

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

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3 WAYS TO ORDER

www.aami.org/store19 1-877-249-8226 P.O. Box 0211, Annapolis Junction, MD 20701-0211

For details, visit www.aami.org/orderInfo.
The Health Technology Event of the Year

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

OUR PROMISE:

- **Deliver new opportunities** to exchange ideas, expand networks, and experience new technologies to empower professionals around the world.

- **Engage attendees with innovative learning.** The immersive and interactive program will deliver tracks on cybersecurity, sterilization, global perspectives, HTM, and more.

- **Share new and emerging products and technologies.** The Exhibit Hall showcases exciting products in the IoTXperience and the virtual reality theater.

- **Confirm AAMI's commitment to advancing health technology** through professional development.

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

www.aami.org/aamiexchange
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

<table>
<thead>
<tr>
<th>EVENT</th>
<th>DATE</th>
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<tbody>
<tr>
<td>ACI Certification Exam Registration Deadline</td>
<td>April 17</td>
</tr>
<tr>
<td>ACI Certification Exams</td>
<td>May 1–15</td>
</tr>
<tr>
<td>ACI Certification Exam Registration Deadline</td>
<td>October 14</td>
</tr>
<tr>
<td>ACI Certification Exams</td>
<td>November 1–15</td>
</tr>
</tbody>
</table>

FIND OUT MORE
For complete details, visit www.aami.org/certification
## Industry Training

### Navigate the Regulatory World with Confidence

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

### 2019 TRAINING SCHEDULE

#### QUALITY SYSTEMS


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

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

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

**Process Validation Requirements and Industry Practice**

<table>
<thead>
<tr>
<th>COST</th>
<th>DATE</th>
</tr>
</thead>
</table>
| AAMI MEMBERS: $2,235 / NONMEMBERS: $2,535 / GOVT. EMPLOYEES: $950 | April 16–18, 2019  
  October 8–10, 2019 |

**Corrective and Preventive Action Requirement and Industry Practice**

<table>
<thead>
<tr>
<th>COST</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAMI MEMBERS: $2,135 / NONMEMBERS: $2,435 / GOVT. EMPLOYEES: $950</td>
<td>June 18–19, 2019</td>
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**Purchasing Controls & Supply Chain Management**

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<th>DATE</th>
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</thead>
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<tr>
<td>AAMI MEMBERS: $2,135 / NONMEMBERS: $2,435 / GOVT. EMPLOYEES: $950</td>
<td>June 19–21, 2019</td>
</tr>
</tbody>
</table>

**Integrating Risk Management into the Product Lifecycle: Quality and 13485**

<table>
<thead>
<tr>
<th>COST</th>
<th>DATE</th>
</tr>
</thead>
</table>
| AAMI MEMBERS: $2,335 / NONMEMBERS: $2,635 / GOVT. EMPLOYEES: $950 | March 12–14, 2019  
  August 27–29, 2019  
  November 13–15, 2019 |

For complete details and to register, visit [www.aami.org/training](http://www.aami.org/training).
## STERILIZATION

<table>
<thead>
<tr>
<th>Sterilization Type</th>
<th>Cost</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industrial Sterilization</td>
<td>AAMI MEMBERS: $2,535 / NONMEMBERS: $2,835 / GOVT. EMPLOYEES: $1,050</td>
<td>May 14–17, 2019</td>
</tr>
<tr>
<td>Ethylene Oxide Sterilization</td>
<td>AAMI MEMBERS: $2,335 / NONMEMBERS: $2,635 / GOVT. EMPLOYEES: $950</td>
<td>August 27–30, 2019</td>
</tr>
<tr>
<td>Radiation Sterilization for Medical Devices</td>
<td>AAMI MEMBERS: $2,335 / NONMEMBERS: $2,635 / GOVT. EMPLOYEES: $950</td>
<td>November 5–8, 2019</td>
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</table>

## HUMAN FACTORS

<table>
<thead>
<tr>
<th>Human Factors for Medical Devices</th>
<th>Cost</th>
<th>Date</th>
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<tr>
<td></td>
<td>AAMI MEMBERS: $2,235 / NONMEMBERS: $2,535 / GOVT. EMPLOYEES: $950</td>
<td>January 23–25, 2019</td>
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<td></td>
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<td>April 30–May 2, 2019</td>
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<td></td>
<td></td>
<td>September 10–12, 2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td>November 19–21, 2019</td>
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## SOFTWARE VALIDATION

<table>
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<tr>
<th>Software Validation</th>
<th>Cost</th>
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<tr>
<td>Regulatory Requirements for Software Validation</td>
<td>AAMI MEMBERS: $2,235 / NONMEMBERS: $2,535 / GOVT. EMPLOYEES: $950</td>
<td>May 7–9, 2019</td>
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<tr>
<td>Software Validation Workshop: Practical Tools and Techniques</td>
<td>AAMI MEMBERS: $2,235 / NONMEMBERS: $2,535 / GOVT. EMPLOYEES: $950</td>
<td>May 7–9, 2019</td>
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<tr>
<td>Application of Agile to the Development of Medical Device Systems</td>
<td>AAMI MEMBERS: $2,135 / NONMEMBERS: $2,435 / GOVT. EMPLOYEES: $950</td>
<td>September 25–27, 2019</td>
</tr>
<tr>
<td>Effective Application of Agile Practices in the Development of Medical Device Software</td>
<td>AAMI MEMBERS: $2,135 / NONMEMBERS: $2,435 / GOVT. EMPLOYEES: $950</td>
<td>September 23–24, 2019</td>
</tr>
</tbody>
</table>
Digital Library of AAMI Standard & Guidance Documents

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

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

ANSI/AAMI ST79:2017
New! Now includes a self-assessment tool. This subscription is ideal for individuals, such as consultants. It is only for one user and cannot be transferred.

<table>
<thead>
<tr>
<th>INDIVIDUAL PLAN</th>
<th>ENTERPRISE PLANS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEMBER: $346 / LIST: $396</td>
<td>Not applicable</td>
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Sterilization in Healthcare Facilities

<table>
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<tbody>
<tr>
<td>MEMBER: $535 / LIST: $749</td>
<td>2–5 Concurrent Users (up to 100 named users)</td>
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<tr>
<td>6–10 Concurrent Users (up to 200 named users)</td>
<td>MEMBER: $3,500 / LIST: $4,450</td>
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<tr>
<td>11–15 Concurrent Users (up to 300 named users)</td>
<td>MEMBER: $4,500 / LIST: $6,300</td>
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<tr>
<td>16–20 Concurrent Users (up to 400 named users)</td>
<td>MEMBER: $5,700 / LIST: $7,500</td>
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<tr>
<td>21–26 Concurrent Users (up to 500 named users)</td>
<td>MEMBER: $6,800 / LIST: $8,800</td>
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<tr>
<td>27–30 Concurrent Users (up to 600 named users)</td>
<td>MEMBER: $7,900 / LIST: $9,000</td>
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</tbody>
</table>

Access: Generic, Named, IP*
Sterilization—Industrial Process Control
This 50-document collection is intended primarily for manufacturers who ship sterile products.

<table>
<thead>
<tr>
<th>INDIVIDUAL PLAN</th>
<th>ENTERPRISE PLANS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEMBER: $490 / LIST: $660</td>
<td>2–5 Concurrent Users (up to 100 named users) MEMBER: $3,395 / LIST: $4,850</td>
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<td></td>
<td>6–10 Concurrent Users (up to 200 named users) MEMBER: $3,880 / LIST: $5,545</td>
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<tr>
<td></td>
<td>11–15 Concurrent Users (up to 300 named users) MEMBER: $5,455 / LIST: $7,795</td>
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<td>16–20 Concurrent Users (up to 400 named users) MEMBER: $6,790 / LIST: $9,700</td>
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<td></td>
<td>21–26 Concurrent Users (up to 500 named users) MEMBER: $8,195 / LIST: $11,710</td>
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<td></td>
<td>27–30 Concurrent Users (up to 600 named users) MEMBER: $8,735 / LIST: $12,475</td>
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Sterilization Equipment Design and Use
This sterilization collection for manufacturers and users of sterilization equipment includes 40 AAMI standards and guidance documents.

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

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

<table>
<thead>
<tr>
<th>INDIVIDUAL PLAN</th>
<th>ENTERPRISE PLANS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEMBER: $820 / LIST: $1,220</td>
<td>2–5 Concurrent Users (up to 100 named users) MEMBER: $4,400 / LIST: $5,750</td>
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<tr>
<td></td>
<td>6–10 Concurrent Users (up to 200 named users) MEMBER: $5,400 / LIST: $6,750</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>INDIVIDUAL PLAN</th>
<th>ENTERPRISE PLANS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEMBER: $635 / LIST: $885</td>
<td>2–5 Concurrent Users (up to 100 named users) MEMBER: $1,950 / LIST: $2,900</td>
</tr>
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</table>

Access: Generic, Named, IP*
Dialysis Collection
This collection includes access to dialysis standards including ANSI/AAMI 13959, ANSI/AAMI 26722, ANSI/AAMI 23500, TIR58.

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<tr>
<th>INDIVIDUAL PLAN</th>
<th>ENTERPRISE PLANS</th>
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</thead>
<tbody>
<tr>
<td>MEMBER: $360 / LIST: $535</td>
<td>2–5 Concurrent Users (up to 100 named users)</td>
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</table>

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

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<tr>
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<tbody>
<tr>
<td>MEMBER: $360 / LIST: $535</td>
<td>2–5 Concurrent Users (up to 100 named users)</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>INDIVIDUAL PLAN</th>
<th>ENTERPRISE PLANS</th>
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<tbody>
<tr>
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<td>6–10 Concurrent Users (up to 200 named users)</td>
<td>MEMBER: $10,500 / LIST: $15,500</td>
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<tr>
<td>11–15 Concurrent Users (up to 300 named users)</td>
<td>MEMBER: $14,500 / LIST: $21,000</td>
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<tr>
<td>16–20 Concurrent Users (up to 500 named users)</td>
<td>MEMBER: $19,000 / LIST: $28,000</td>
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<tr>
<td>21–25 Concurrent Users (up to 600 named users)</td>
<td>MEMBER: $23,500 / LIST: $32,500</td>
</tr>
</tbody>
</table>

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.
Advancing Safety in Health Technology

ANSI/AAMI SW91:2018
Classification of defects in health software

ANSI/AAMI TIR57:2016
Principles for Medical Device Security—Risk Management

80001 TIRs—Set of 4

FIND OUT MORE
To view the complete 8001 TIR series, visit www.aami.org/store19.
Dialysis

**Acute Hemodialysis**
*Survey Readiness Handbook*
Jo-Ann B. Maltais, PhD and Glenda M. Payne, MS, RN, CNN

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

**PRODUCT CODES:** ACUTE AND ACUTE-PDF

**MEMBER:** $145 / **LIST:** $248

**Dialysis Water and Dialysate Recommendations: A User Guide**

*Edited by Glenda M. Payne*

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

**PRODUCT CODES:** DUG AND DUG-PDF

**MEMBER:** $141 / **LIST:** $240

---

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

[www.aami.org/aamiexchange](http://www.aami.org/aamiexchange)

ORDER ONLINE AT [www.aami.org/store19](http://www.aami.org/store19) OR CALL 1-877-249-8226
Medical devices—Quality management systems—Requirements for regulatory purposes
Design a quality management system that establishes and maintains the effectiveness of your processes. This standard is meant to be used throughout a device's life cycle, from initial concept through post-production, including final decommission and disposal. It also covers topics such as storage, distribution, installation, and servicing, as well as the provision of associated services.
PRODUCT CODES: 13485 AND 13485-PDF
MEMBER: $133 / LIST: $236

Medical devices—Recognized essential principles of safety and performance of medical devices—Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards
PRODUCT CODES: 16142-1 AND 16142-1-PDF
MEMBER: $133 / LIST: $236

ANSI/AAMI/ISO 16142-2:2017
Medical devices—Recognized essential principles of safety and performance of medical devices—Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards
PRODUCT CODE: 16142-2-PDF
MEMBER: $133 / LIST: $236

Additional Quality Systems and Risk Management Resources
Courses
- Design Control - Integrating The Quality System Regulation and ANSI/AAMI/ISO 13485 Requirements
- Integrating Risk Management into the Product Life Cycle: Quality and 13485

Free Download
- 80001: The Business Case for Health IT Risk Management
To download your copy, visit www.aami.org/healthitrisk.

Medical Device Cybersecurity
A Guide for HTM Professionals
Edited by Stephen L. Grimes and Axel Wirth
A must-have resource for professionals in healthcare technology management, this comprehensive guide includes chapters on cybersecurity fundamentals, the regulatory and standards environment, and inventory and configuration management.
PRODUCT CODES: MDC AND MDC-PDF
MEMBER: $155 / LIST: $232
Computerized Maintenance Management Systems for Healthcare Technology Management
Ted Cohen, MS, FACCE and Matthew F. Baretich, PE, PhD
The third edition of this guide offers a foundation for working within a CMMS, which is essential to the success of every HTM department.
PRODUCT CODES: CMMS AND CMMS-PDF
MEMBER: $95 / LIST: $137

AEM Program Guide
Alternative PM for Patient Safety
Matthew F. Baretich, PE, PhD
This guide offers practical implementation for alternate equipment management (AEM) and explains how to remain compliant with applicable standards and regulations.
PRODUCT CODES: AEM OR AEM-PDF
MEMBER: $62 / LIST: $96

ANSI/AAMI EQ56:2013
Recommended practice for a medical equipment management program
This recommended practice specifies the minimum criteria for a management program designed to minimize certain risks associated with equipment used during routine patient care. It addresses the structure of the program, documentation, requirements, staffing, and resource allocation.
PRODUCT CODES: EQ56 AND EQ56-PDF
MEMBER: $111 / LIST: $194

ANSI/AAMI EQ89:2015
Guidance for the use of medical maintenance strategies and procedures
This standard identifies and describes various strategies and methods for efficient, effective, and timely maintenance of medical equipment in healthcare facilities. It is intended to help HTM departments standardize and document their maintenance procedures, and provide guidance on selecting the most appropriate maintenance strategy for a given type of device.
PRODUCT CODES: EQ89 AND EQ89-PDF
MEMBER: $72 / LIST: $127
Electrical Safety Manual
Matthew F. Baretich, PE, PhD
This manual pulls together crucial information from the full range of applicable codes and standards, including ANSI/AAMI ES60601-1 and the 2012 editions of NFPA 70 and NFPA 99. It includes basic elements that should be contained in an electrical safety program and recommended steps for implementing a cost-effective program.

PRODUCT CODES: ESM4 AND ESM4-PDF
MEMBER: $135 / LIST: $233

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

PRODUCT CODE: VID-BATT
MEMBER: $128 / LIST: $213

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

PRODUCT CODE: SGCD2
MEMBER: $112 / LIST: $186

CHTM Study Guide
Patrick K. Lynch, CBET, CCE, CHTM
Whether you’re preparing for the CHTM certification exam or looking to sharpen your management skills, this guide covers financial, risk, and operations management, as well as training and human resources.

PRODUCT CODES: CHTMGD AND CHTMGD-PDF
MEMBER: $62 / LIST: $96

Additional HTM Resources
Books, Videos, & Resources
- Core Competencies for the Biomedical Equipment Technician (BMET)
- A Practicum for Healthcare Technology Management

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

Writing Human Factors Plans & Reports for Medical Technology Development
Michael Wiklund, Laura Birmingham, Stephanie Alpert Larsen
PRODUCT CODES: HFP AND HFP-PDF
MEMBER: $129 / LIST: $185

AAMI TIR59:2017
Integrating human factors into design controls
PRODUCT CODE: TIR59
MEMBER: $111 / LIST: $194

AAMI TIR51:2014/(R)2017
Human factors engineering—guidance for contextual inquiry
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AAMI TIR49:2013
Design of training and instructional materials for medical devices used in non-clinical environments
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AAMI TIR50:2014/(R)2017
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ANSI/AAMI HE75:2009/(R)2018
Human factors engineering—design of medical devices—FDA RECOGNIZED
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**ANSI/AAMI/ISO 80369-1:2010**

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**ANSI/AAMI/ISO 80369-3:2016**

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**ANSI/AAMI/ISO 80369-5:2016**

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**ANSI/AAMI/ISO 80369-6:2016**

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**ANSI/AAMI/IEC 80601-2-30**

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

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AAMI standards are also available as part of the Complete Standards Collection via the eSubscription. See page 10 for details.
ANSI/AAMI ES60601-1
General requirement for basic safety and essential performance medical electrical equipment

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

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

60601-1-12
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60601-2-4
Cardiac defibrillators
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60601-2-27
Electrocardiographic monitoring equipment
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60601-2-47
Ambulatory electrocardiographic systems
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Sterilization

ANSI/AAMI ST79:2017
Comprehensive guide to steam sterilization and sterility assurance in health care facilities

BEST-SELLING STANDARD! FDA RECOGNIZED

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

PRODUCT CODES: ST79 AND ST79-PDF
MEMBER: $357 / LIST: $408

ANSI/AAMI ST90:2017
Processing of health care products—Quality management systems for processing in health care facilities

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

PRODUCT CODES: ST90 AND ST90-PDF
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Sterilization in Healthcare Facilities eSubscription
Available as both an individual and enterprise subscription, this collection includes 14 sterilization standards and guidance documents, including ST8, ST40, ST41, ST58, ST65, ST79, ST90, ST91, TIR11, TIR12, TIR30, TIR34, TIR55, TIR63, and PB70.

See page 10.

ANSI/AAMI ST91:2015
Flexible and semi-rigid endoscope processing in health care facilities

FDA RECOGNIZED

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

PRODUCT CODES: ST91 AND ST91-PDF
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Sterilization

AAMI TIR29:2012/(R)2017
Guide for process characterization and control in radiation sterilization of medical devices
This document is intended to complement qualification and routine control activities as defined in ANSI/AAMI/ISO 11137 for gamma, X-ray, and electron beam sterilization.
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MEMBER: $126 / LIST: $221

ANSI/AAMI/ISO 17664:2017
Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices
The provisions of this standard are applicable to medical devices that are intended for invasive or other direct or indirect patient contact.
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MEMBER: $111 / LIST: $194

Sterile Processing in Healthcare Facilities
Preparing for Accreditation Surveys, 3rd edition
Rose Seavey
This publication serves as a guide to healthcare facilities seeking to comply with accrediting body surveys (e.g. CMS, TJC, AAAASF) for the reprocessing of surgical instruments and other reusable medical devices in any healthcare setting.
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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
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ANSI/AAMI/ISO 11138-1:2017
Part 1: General requirements
Part 1 specifies general requirements for the production, labelling, test methods and performance characteristics of biological indicators, including inoculated carriers and suspensions, and their components, to be used in the validation and routine monitoring of sterilization processes.
PRODUCT CODE: 1113801-PDF
MEMBER: $133 / LIST: $236

ANSI/AAMI/ISO 11138-2:2017
Part 2: Biological indicators for ethylene oxide sterilization processes
Part 2 specifies requirements for test organisms, suspensions, inoculated carriers, biological indicators, and test methods in assessing the performance of sterilizers and sterilization processes employing ethylene oxide gas.
PRODUCT CODE: 1113802-PDF
MEMBER: $63 / LIST: $111

ANSI/AAMI/ISO 11138-3:2017
Part 3: Biological indicators for moist heat sterilization processes
Part 3 contains the requirements for test organisms, suspensions, inoculated carriers, and biological indicators, as well as test methods intended for use in assessing the performance of sterilization processes employing moist heat.
PRODUCT CODE: 1113803-PDF
MEMBER: $63 / LIST: $111

ANSI/AAMI/ISO 11138-4:2017
Part 4: Biological indicators for dry heat sterilization processes
Part 4 outlines the requirements for test organisms, suspensions, inoculated carriers, and biological indicators, as well as test methods intended for use in assessing the performance of sterilization processes employing dry heat.
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ANSI/AAMI/ISO 11138-5:2017
Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes
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Quality Systems & Risk Management

AAMI TIR57:2016
Principles for medical device security—risk management
FDA RECOGNIZED
This technical information report provides medical device manufacturers with guidance on developing a cybersecurity risk management process for their products. It blends security and safety risk management by showing how to apply the principles presented in ANSI/AAMI/ISO 14971, Medical Devices—Application of risk management to medical devices, to security threats that could impact the confidentiality, integrity, and/or availability of a medical device or information processed by the device.

PRODUCT CODES: TIR57 AND TIR57-PDF
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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

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

Guidance for wireless networks

ANSI/AAMI/IEC TIR80001-2-4:2012
General implementation guidance for healthcare delivery organizations

PRODUCT CODES: 80001TIRS AND 80001TIRS-PDF
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Jack Ward
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Michael Wiklund, Laura Birmingham, Stephanie Alpert Larsen
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Tom Shoup, PhD
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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.
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Medical devices—Application of risk management to medical devices
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