American National Standard

ANSI/AAMI ST91:2015

Flexible and semi-rigid endoscope processing in health care facilities

AAMI
Advancing Safety in Healthcare Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

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All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

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Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

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American National Standard **ANSI/AAMI ST91:2015**

Flexible and semi-rigid endoscope processing in health care facilities

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Association for the Advancement of Medical Instrumentation

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Abstract: Provides guidelines for precleaning, leak-testing, cleaning, packaging (where indicated), storage, high-level disinfecting, and/or sterilizing of flexible gastrointestinal (GI) endoscopes, flexible bronchoscopes, surgical flexible endoscopes (e.g., flexible ureteroscopes), and semi-rigid operative endoscopes (e.g., choledochoscopes) in health care facilities. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these devices and accessories.

Keywords: flexible endoscopes, high-level disinfection, semi-rigid endoscopes, sterilization

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www.aami.org/standards/glossary.pdf

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Association for the Advancement of Medical Instrumentation

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This standard was developed by the AAMI Endoscope Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval. At the time this standard was published, the **AAMI Endoscope Reprocessing Working Group** had the following members:

Chairs:
Nancy Chobin, RN CSPDM, St Barnabas Healthcare System
Mary Ann Drosnock, MS, Olympus America Inc

Members:
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Barbara Ann Harmer, RN BSN MHA
Shanil Haugen, FDA/CDRH
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Susan G. Klacik, CCSMC FCS ACE, IAHCSMM
Stephen M. Kovach, Healthmark Industries Company Inc
Carole Kubiak, BSN RN CNOR, Brigham & Womens Hospital
Colleen Patricia Landers, RN, Timmins & District Hospital
Steve Maley, Crouse Hospital
Albert E. May, Andersen Products Inc
Gerald E. McDonnell, PhD, Steris Corporation
Terry Mistalski, Medivators Inc
Emily Mitzel, MS, Nelson Laboratories Inc
Frank Myers, USPHS Indian Health Service
Phillip Nosel, Microtest Laboratories Inc
Gerry A. O'Dell, MS, Gerry O'Dell Consulting
Janet M. Prust, 3M Healthcare
Wayne Jerome Rogers, Wayne J Rogers Consulting
Cheron Rojo, Childrens Hospital Central California
Janis Saunier, Medtronic Inc WHQ Campus
Rose E. Seavey, RN MBA CNOR CRCST, Seavey Healthcare Consulting, LLC
Frank Smith, RN CNOR CRCST, Department of Veteran Affairs
Donald Socha, Jr., Getinge USA
Cynthia Spry, RN, Spry Consulting
Christopher Strafaci, Vision Sciences Inc
Karen Swanson, Connecticut Childrens Medical Center
Lynne A. Thomas, Integrated Medical Systems
Sharon Van Wicklin, MSN RN CNOR/CRNFA, Association of Perioperative Registered Nurses
Don T. Williams, CRCST CIS CHL, Overlake Hospital Medical Center
Martha L. Young, Martha L Young, LLC

Alternates:
David E. Barlow, PhD, Olympus America Inc
Ralph J. Basile, MBA, Healthmark Industries Company Inc
Marcia Benedict, BS MI RAC MT ASCP, Steris Corporation
Denise Carey, Medtronic Inc WHQ Campus
Ramona Conner, RN MSN CNOR, Association of Perioperative Registered Nurses
Sylvie Dufresne, PhD, TSO3 Inc

Christian Escobar, Vision Sciences Inc
Tania Lupu, Case Medical Inc
Elaine S. Mayhall, PhD, FDA/CDRH
Kanwarjit Singh, Johnson & Johnson
Grace A. Thornhill, PhD, 3M Healthcare
Brian Wallace, Intuitive Surgical Inc
Ann Wheeler, Getinge USA

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Co-chairs:
Victoria M. Hitchins, PhD, FDA/CDRH
Michael H. Scholla, Dupont Protection Technologies

Members:
Christopher Anderson, Boston Scientific Corporation
Trabue D. Bryans, BryKor LLC
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Charles Cogdill, Covidien
Ramona Conner, RN MSN CNOR, Association of Perioperative Registered Nurses
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Mark N. Smith, Getinge USA
James Sidney Wiggs, BSN CRCST, Legacy Health System
Martell Kress Winters, BS SM, Nelson Laboratories Inc
William E. Young
William T. Young, Sterigenics International

Alternates:
Lloyd Brown, Covidien
Peter A. Burke, PhD, Steris Corporation
Dave Dion, Cardinal Health (MP&S)
Gordon M. Ely, WuXi AppTec Inc
Thomas J. Frazar, Johnson & Johnson
Martha M. Kadas, Sterigenics International
Jim Kaiser, Bausch & Lomb Inc
Natalie Lind, IAHCSMM
Ralph Makinen, Boston Scientific Corporation
Mary S. Mayo, CR Bard
David Ford McGoldrick, BS, Abbott Laboratories
Jerry R. Nelson, PhD, Nelson Laboratories Inc
Patrick Polito, Moog Medical Devices
Karen Polkinghorne, Dupont Protection Technologies
Shaundrea L. Rechsteiner, NAMSA
Mike Sadowski, Baxter Healthcare Corporation
Craig A. Wallace, 3M Healthcare

NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

Foreword

This standard was developed by the AAMI Endoscope Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this standard is to provide guidelines for precleaning, leak-testing, cleaning, packaging (where indicated), storage, high-level disinfecting, and/or sterilizing of flexible gastrointestinal (GI) endoscopes, flexible bronchoscopes, surgical flexible endoscopes (e.g., flexible ureteroscopes), and semi-rigid operative endoscopes (e.g., choledochoscopes) in health care facilities. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these devices and accessories.

Initially this document was proposed as a technical information report that would synthesize existing guidance in the area of endoscope processing. As the draft was developed, the working group identified a need in the field for more extensive guidance, and proposed revising the document to be an American National Standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed in order to conform to the standard; “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; “may” is used to indicate that a course of action is permissible within the limits of the standard; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

This standard should be considered flexible and dynamic. As technology advances and as new data are brought forward, the standard will be reviewed and, if necessary, revised.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Flexible and semi-rigid endoscope processing in health care facilities

Introduction

Flexible and semi-rigid endoscopes are used in various body cavities for diagnostic and therapeutic procedures. In United States, at least 11 million gastrointestinal endoscopies are performed each year and the number of procedures is increasing (Cullen et al, 2009; SGNA, 2012). A risk of all endoscopy procedures is the introduction of pathogens or cross-contamination between patients. Failure to clean, disinfect, or sterilize equipment carries not only risk associated with breach of host barriers but also risk for person-to-person transmission of pathogens and transmission of environmental pathogens (e.g., *Pseudomonas aeruginosa*). Further consequences of inadequate device processing can include device damage, inefficient use of the device, and toxic reactions in patients.

Endoscopic transmission of infection

Even though gastrointestinal endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine, more health care acquired infections (HAIs) have been linked with the use of contaminated endoscopes than to any other medical device and have been listed in the top ten technology hazards for patients for several years in a row (ECRI). The estimated patient risk, cited by the Centers for Disease Control (CDC) and other organizations, of infection associated with a flexible endoscopy has historically been considered to be rare at 1 in 1.8 million procedures. This estimate of patient risk of infection is not consistent with multiple, more recently published reports of lapses and tens of thousands of patient exposures both in the United States and other countries. In addition, there are other reports of patient exposures to contaminated endoscopes in the media and other public databases that have not been published in peer reviewed literature (Kimmery 1993, Rutala et al, 2007; ASGE, 2011, SGNA, 2012).

When the CDC Division of Healthcare Quality Promotion (formerly the Hospital Infection Program) reviewed its log of investigations between 1980 and 2002, no outbreaks of infection associated with GI endoscopy were found. Since 1990, health care facilities and manufacturers have been required to report to the FDA MAUDE (Manufacturer and User-Facility Device Experience) database any information that reasonably suggests that a device (such as an endoscope, accessory, or automated endoscope washer-disinfector) has caused or contributed to a death, injury, or serious illness of a patient. Review of this open access, non–peer-reviewed database from 1990 to 2002 revealed seven possible occurrences of pathogen transmission during GI endoscopy. Since 2002, the MAUDE database contains multiple references to infections suspected to have occurred after lapses in processing.

Currently, there are no well-designed, published, prospective studies on the incidence of pathogen transmission during GI endoscopy. Estimates of pathogen transmission based on retrospective case reports conclude the current risk estimate may underestimate the true incidence of infection. (Seonae-Vazquesz 2006, Holodny, 2012). Citing the 2008 CDC risk estimate may have led health care facilities not to inform, adequately screen for all potential disease transmitting organisms, or treat patients (Dirlam-Langley et al., 2013).

In some reports where patients have been exposed, they were not tested for all pathogenic organisms but only HIV or Hepatitis B viruses, despite documented outbreaks of non-viral pathogens. Recent reports support the conclusion that current risks are outdated and inaccurate (Ofstead et al., 2013; Dirlam-Langlay et al., 2013). Audits of facilities conducting GI procedures have found widespread lapses in infection control, including endoscope processing and in some cases endoscopes were virtually never processed in accordance with guidelines (Dirlam-Langlay et al., 2013). The true implications of inadequate processing are unknown because no epidemiologic studies have determined the risk of infections or other patient complications including residual chemical toxicity and device damage effect on patient outcomes (Leffler et al., 2010).

Multiple peer-reviewed publications in several countries including the United States have documented breaches in processing that have led to patient exposure to improperly reprocessed flexible and semi-rigid endoscopes and have caused serious infections (Sanderson, 2010; Gonzalez-Candelas et al., 2010; Carbonne et al., 2010; Aumeran et al., 2010; Holodny, 2012; CDC 2014). In nearly all of these cases, failure to comply with manufacturer's written instructions for use (IFU) or established guidelines or malfunctioning equipment that was undetected has led to numerous outbreaks of infection due to improperly processed flexible and semi-rigid endoscopes.

A northeastern Illinois outbreak in 2013 of infections with New Delhi metallo-β-lactamase (NDM) producing Carbapenem-resistant Enterobacteriaceae (CRE) was linked with contaminated endoscopes used to perform endoscopic retrograde cholangiopancreatography (ERCP). A total of 44 patients were identified as infected (Rutala 2014). Further outbreaks were similarly linked to ERCP scopes in Pittsburgh (McCool et al., 2012) and Seattle (Aleccia 2015).

Effects of endoscopy-related infection outbreaks and other adverse patient reactions may include:

- microorganisms may be spread from patient to patient by contaminated or improperly processed flexible and semi-rigid endoscopes or malfunctioning equipment (exogenous infections).
- microorganisms may spread from the GI tract through the bloodstream during an endoscopy procedure to susceptible organs, or may spread to adjacent tissues that are breached as a result of the endoscopic procedure (endogenous infections).
- microorganisms may be transmitted from patients to endoscopy personnel and/or from endoscopy personnel to patients.
- chemical substances can remain on devices from various chemicals used during the procedure or processing that can cause toxic reactions in subsequent patients.
- devices may be damaged or rendered difficult to use due to mishandling or inadequate processing.

Minimizing these risks begins with the correct handling procedures in preparation for processing, to include pre-cleaning steps at the point of use (e.g., bedside procedures), disassembly of parts, and safe transport. Cleaning according to the specific manufacturer's written IFU is then required to ensure that patient soil and other materials are removed prior to the antimicrobial processes of high-level disinfection or sterilization. Cleaning is a multi-step process and is critical not only to ensure that subsequent processing steps can be effective but also to remove any potential toxic chemicals or other materials that can lead to adverse patient reactions. Cleaning is followed by disinfection or sterilization to reduce or completely remove microbial contamination. At a minimum, it is recommended that devices are subjected to high-level disinfection after each use. When possible and practical, flexible and semi-rigid endoscopes should be sterilized due to the greater margin of safety built into sterilization. High-level disinfection is a multi-step process and is expected to be able to inactivate most pathogenic bacteria, viruses, and fungi but may not reliably inactivate certain types of microorganisms including bacterial spores. When these devices are used in sterile tissue procedures, sterilization is recommended (CDC 2008).

1 Scope

This standard provides guidelines for precleaning, leak-testing, cleaning, packaging (where indicated), storage, high-level disinfecting, and/or sterilizing of flexible gastrointestinal (GI) endoscopes; flexible bronchoscopes; flexible ear, nose, and throat endoscopes; surgical flexible endoscopes (e.g., flexible ureteroscopes); and semi-rigid operative endoscopes (e.g., choledochoscopes) in health care facilities. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these devices and accessories.

NOTE—For purposes of this standard, "health care facilities" means endoscopy centers, hospitals, nursing homes, extended-care facilities, free-standing surgical centers, ambulatory health centers (clinics), medical offices, and all other areas where flexible and semi-rigid endoscopes are processed.

1.1 Inclusions

This document specifically addresses

a) functional and physical design criteria for endoscope processing areas;

b) education, training, competency verification, and other personnel considerations;

c) processing recommendations;

d) installation, care, and maintenance of automated processing equipment;

e) quality control; and

f) quality process improvement.

Definitions of terms and a bibliography are also provided in this standard.

1.2 Exclusions

This standard does not cover

a) The processing of rigid endoscopes (e.g., arthroscopes, laparoscopes), transesophageal echocardiogram probes (TEE), or vaginal probes (See ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*; ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities*; and ANSI/AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*).

b) Specific construction and performance criteria for steam sterilizers (see ANSI/AAMI ST8, *Hospital steam sterilizers* and ANSI/AAMI ST55, *Table-top steam sterilizers*), ethylene oxide gas sterilizers (see ANSI/AAMI ST24, *Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities*), rigid sterilization container systems (see ANSI/AAMI ST77, *Containment devices for reusable medical device sterilization*), or rigid, protective organizing cases that require wrapping before sterilization (see ANSI/AAMI ST77).

c) The use of containment devices for packaging items other than instrument sets or procedural trays.

d) The processing of devices labeled for single use only (see Food and Drug Administration [FDA], 2000c).

NOTE—For more information on the subjects excluded from the scope of this recommended practice, and for additional background information on the inclusions, refer to the references listed in the bibliography.

2 Definitions and abbreviations

2.1 Automated endoscope reprocessor (AER): AERs or endoscope washer-disinfectors are machines designed for the purpose of cleaning and/or disinfecting endoscopes and components. The disinfection process uses a liquid chemical sterilant (LCS) or high-level disinfectant (HLD) solution to achieve at a minimum high-level disinfection.

2.2 bioburden: Population of viable microorganisms on a product and/or a sterile barrier system.

NOTE—When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units (CFUs) per single item.

2.3 biofilm: Accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily (Donlan, 2002).