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.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

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.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

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.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

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

Flexible and semi-rigid endoscope processing in health care facilities

Approved 30 March 2015 by
Association for the Advancement of Medical Instrumentation

Approved 8 April 2015 by
American National Standards Institute Inc.

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

AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Dr., Ste. 301
Arlington, VA 22203-1633

Printed in the United States of America

ISBN 1-57020-585-X

Contents

Page

Tables

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Endoscope Reprocessing Working Group

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:
Jahan Azizi, CBET, University of Michigan Health System
James Weldon Baker, AmeriWater
Damien Berg, Medical Center of the Rockies
Holger Biering, PhD, Holger Biering
Harriet Chan-Myers, Johnson & Johnson
James W. Collins, RN, Cleveland Clinic Foundation
Linda Condon, Johns Hopkins Hospital
Jacqueline Daley, Sinai Hospital of Baltimore
Robert Dumont, Case Medical Inc
Jon Fish, Prezio Health
Sarah Friedberg, Stryker Instruments Division
Shelley Green, WuXi AppTec Inc
Garland Grisby, Kaiser Permanente (US)
Barbara Ann Harmer, RN BSN MHA
Shanil Haugen, FDA/CDRH
Emily A. Hildebrand, Phoenix VA Health Care System
Rachel Hill, CareFusion
Nupur Jain, Intuitive Surgical Inc
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

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.

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

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
Nancy Chobin, RN CSPDM, St Barnabas Healthcare System
Charles Cogdill, Covidien
Ramona Conner, RN MSN CNOR, Association of Perioperative Registered Nurses
Jacqueline Daley, Sinai Hospital of Baltimore
Kimbrell Darnell, CR Bard
Lisa Foster, Medpoint LLC
Joel R. Gorski, PhD, NAMSA
Joyce M. Hansen, Johnson & Johnson
Douglas F. Harbrecht, Sterility Assurance LLC
Deborah A. Havlik, Hospira Worldwide Inc
Susan G. Klacik, CCSMC FCS ACE, IAHCSMM
Byron J. Lambert, PhD, Abbott Laboratories
Colleen Patricia Landers, RN, Timmins & District Hospital
Reynaldo Lopez, Cardinal Health (MP&S)
Jeff Martin, Alcon Laboratories Inc
Patrick J. McCormick, PhD, Bausch & Lomb Inc
Gerald E. McDonnell, PhD, Steris Corporation
Janet M. Prust, 3M Healthcare
Nancy Rakiewicz, Moog Medical Devices
Mark Seybold, Baxter Healthcare Corporation
Andrew Sharavara, PhD, Propper Manufacturing Co Inc
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).

NOTE—Some microscopic organisms have the ability, when growing in water or water solutions or in vivo (e.g., the bloodstream), to adhere to a surface and then exude over themselves a polysaccharide matrix. The matrix contains cells, living and dead, as well as polysaccharide (sometimes referred to as glycocalyx), and prevents antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells.

2.4 biological indicators (BIs): Test systems containing viable microorganisms providing a defined resistance to a specified sterilization process.

NOTE 1—According to FDA, "a biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization." [21 CFR 880.2800(a)(1)]

NOTE 2—Biological indicators are intended to demonstrate whether or not the conditions were adequate to achieve sterilization. A negative BI does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

NOTE 3—See ANSI/AAMI/ISO 14161 for information on the selection, use, and interpretation of biological indicators.

2.5 Bowie-Dick test: Diagnostic test of a dynamic-air-removal steam sterilizer's ability to remove air from the chamber and prevent air re-entrainment.

2.6 case/cassette: Sterilization containment device that consists of a lid and base tray that has perforations to allow the sterilant to penetrate and that is enclosed in a sterilization wrap (or sterilization pouch) suitable for specified sterilization method[s]) to maintain sterility.

2.7 challenge test pack: Pack used in qualification, installation, and routine quality assurance testing of health care sterilizers. See also process challenge device.

2.8 chemical indicators (CIs): Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or are used in specific tests of sterilization equipment.

ANSI/AAMI/ISO 11140-1, *Sterilization of health care products—Chemical indicators—Part 1: General requirements,* defines six classes of CIs and specifies performance requirements for them:

Class 1 (process indicators): chemical indicators intended for use with individual units (e.g., packs, containers) to indicate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.

Class 2 (indicators for use in specific tests): chemical indicators intended for use in a specific test procedure (e.g., the Bowie-Dick test used to determine if air removal has been adequate in a steam sterilization process).

Class 3 (single-variable indicators): chemical indicators designed to react to one of the critical variables and intended to indicate exposure to a sterilization process at a stated value of the chosen variable.

Class 4 (multi-variable indicators): chemical indicators designed to react to two or more of the critical variables and intended to indicate exposure to a sterilization process at stated values of the chosen variables.

Class 5 (integrating indicators): chemical indicators designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs.

Class 6 (emulating indicators): chemical indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specified sterilization process.

NOTE 1—FDA recognition of chemical indicators is limited to Class 1 Process Indicators; Class 2 Indicators for use with special tests; and Chemical Integrators, which have resistance characteristics consistent with the "Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators," issued 12/19/2003.

NOTE 2—See ANSI/AAMI/ISO 15882 for information on the selection, use, and interpretation of chemical indicators.

2.9 cleaning: Removal of contamination from an item to the extent necessary for further processing or for the intended use.

NOTE—In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent organic and inorganic soil (e.g., blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

2.10 competency verification: An activity designed to substantiate or confirm the ability of an individual to successfully complete a particular skill, task, complex series of tasks, or behavior necessary to perform effectively.

2.11 containment device: Reusable rigid sterilization container, instrument case, cassette, or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization.

2.12 decontamination: The process of removing pathogenic microorganisms from objects so they are safe to handle, use, or discard (CDC, 2008).

2.13 decontamination area: Area of a health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.

2.14 education: The knowledge, comprehension, and insight acquired by an individual after studying a specific subject.

2.15 endoscope sheath: A sterile, single-use protective barrier for various type of endoscopes, intended to cover the entire insertion tube of the endoscope. The sheath may contain air, water, or suction channels but most often is single channel. (FDA, 2000b)

2.16 engineering controls: The concept that, to the extent feasible, the work environment and the job itself are designed to eliminate or reduce exposure to hazards.

2.17 expiration date: Date that is calculated by adding a specific period of time to the date of manufacture or sterilization of a medical device or component and that defines its estimated useful life.

2.18 expiration statement: Statement, also known as a day-to-day expiration date, indicating that the contents of a package are sterile indefinitely unless the integrity of the package is compromised.

2.19 exposure control plan: According to OSHA, “a written [plan] designed to eliminate or minimize employee exposure.” (29 CFR 1910.1030)

2.20 exposure time: Period for which sterilization or high-level disinfection process parameters maintain their specific tolerances.

NOTE—In a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature and pressure.

2.21 foot-candle: Standard unit of illumination equivalent to the light produced by one standard candle at a distance of 1 foot.

2.22 gaseous chemical sterilization (GCS): Validated process employing gaseous chemical sterilants (e.g., ethylene oxide [EO], hydrogen peroxide, ozone).

2.23 high-level disinfectant (HLD): "A germicide that inactivates all microbial pathogens, except large numbers of bacterial endospores, when used according to labeling" (Rutala, 1990).

NOTE—According to the FDA, HLD is a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass the AOAC International sporocidal activity test as a sterilant.

2.24 high-level disinfection: Process that kills all microbial pathogens but not necessarily high numbers of bacterial spores.

NOTE—For a process that can be used for both liquid chemical sterilization and high-level disinfection, the contact time for high-level disinfection is shorter than that necessary for sterilization, under otherwise identical conditions.

2.25 installation qualification (IQ): Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications.

2.26 labeling: Any literature, including instructions for use, provided with a device as well as all advertising claims published by the manufacturer. (21 CFR 801)

2.27 liquid chemical sterilant (LCS): Solution of a chemical that has been validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim.

2.28 liquid-resistant material: Material that inhibits the penetration of liquids. According to ANSI/AAMI PB70, a liquid-resistant material would be defined as a Level 1, 2, or 3 barrier material.

2.29 lot control number (load control number): Numbers, letters, or a combination of both, by which a particular group of products can be traced to a particular manufacturing or sterilization operation.

2.30 lux: Approximately one tenth of a foot-candle.

2.31 manufacturer's written instructions for use (IFU): Written recommendations provided by the manufacturer of a device that provide instructions for operation and safe and effective processing.

2.32 medical device: Instrument, apparatus, material, or other article, whether used alone or in combination, including the software necessary for its application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;
- investigation, replacement, or modification of the anatomy or of a physiological process; or
- control of conception

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

2.33 minimum effective concentration (MEC): "Minimum concentration of a liquid chemical sterilant/high-level disinfectant that achieves the claimed microbicidal activity; the MEC is determined by dose response testing." [FDA, 2000a].

2.34 minimum recommended concentration (MRC): Minimum concentration at which the manufacturer of a liquid chemical sterilant or high-level disinfectant tested the product and validated its performance.

NOTE—The term "minimum effective concentration" (MEC) is sometimes used interchangeably with "minimum recommended concentration." The MRC is not necessarily an MEC as determined by dose response testing. Some older IFU may state MEC, not MRC.

2.35 occupational exposure: Contact, through inhalation, ingestion, skin contact, or absorption, with a potentially hazardous material during the course of employment. Occupational exposure to hazardous materials, including chemical and biological agents and potentially infectious materials, is regulated by OSHA (29 CFR Part 1910).

NOTE—The OSHA blood-borne pathogens standard (29 CFR 1910.1030) specifically defines occupational exposure as "reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties."

2.36 performance qualification (PQ): Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

2.37 personal protective equipment (PPE): According to OSHA, "specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment." [29 CFR 1910.1030].

2.38 preventive maintenance: The routine servicing of equipment for the purpose of maintaining it in good working condition.

2.39 process challenge device (PCD): Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.

NOTE—For purposes of this standard, a PCD is a challenge test pack containing a BI or a BI and a CI. See AAMI TIR31.

2.40 processing: Process carried out on a device to allow its subsequent safe use, which can include cleaning, disinfection, sterilization, and related procedures.

2.41 processing area: Area of a health care facility where devices are decontaminated, cleaned, inspected, assembled into trays, and prepared for high-level disinfection and/or sterilization.

2.42 reprocessing: The process (see processing) of rendering a clinically used device safe and ready for its intended use.

2.43 reusable medical device: Device intended for repeated use on different patients, with decontamination and other processing between uses.

NOTE—Examples include surgical instruments, endoscopes, basins, and electromedical equipment.

2.44 rigid sterilization container system: Sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents.

NOTE—The system generally consists of a bottom or base with carrying handles and a lid that is secured to the base by means of a latching mechanism. A basket or tray to hold instruments or other items to be sterilized is placed inside. A filter or valve system is incorporated into the lid and/or base to provide for air evacuation and sterilant penetration during the sterilization cycle and to act as a barrier to microorganisms during storage, handling, and transport.

2.45 shelf life: When the term is used with respect to a sterilized medical device, the period of time during which the item is considered safe to use.

2.46 solution test strip: Device used to monitor the concentration of the active ingredient(s) in a liquid chemical sterilant/high-level disinfectant solution and determine if the MRC or MEC is acceptable for effective use.

2.47 spore test strip: Test system containing a known number of bacterial spores (at least 10^5 per strip) of known resistance to a LCS/HLD and used in a defined liquid chemical sterilant processing system.

2.48 standard precautions: "The minimum infection prevention measures that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is delivered. These evidence-based practices are designed to both protect healthcare personnel and prevent the spread of infections among patients. Standard Precautions replaces earlier guidance relating to Universal Precautions and Body Substance Isolation. Standard Precautions include: 1) hand hygiene, 2) use of personal protective equipment (e.g., gloves, gowns, facemasks), depending on the anticipated exposure, 3) respiratory hygiene and cough etiquette, 4) safe injection practices, and 5) safe handling of potentially contaminated equipment or surfaces in the patient environment." (CDC, 2011)

2.49 steam sterilization: Sterilization process that uses saturated steam under pressure, for a specified exposure time and at a specified temperature, as the sterilizing agent.

2.50 sterile: Free from viable microorganisms.

2.51 sterile processing area: Area within a health care facility that processes and controls medical supplies, devices, and equipment, sterile and not sterile, for some or all patient care areas of the facility.

2.52 sterilization: Validated process used to render a product free from viable microorganisms.

2.53 sterilization cycle: Defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber.

2.54 sterilizer: Apparatus used to sterilize medical devices, equipment, and supplies by direct exposure to the sterilizing agent.

2.55 terminal sterilization: Process whereby product is sterilized within its sterile barrier system.

2.56 training: A process or organized activity designed to help an individual attain the necessary skill or behavior required to perform, or improve an individual's performance of a particular task. The specific goals of training are to improve capability, capacity, productivity, and performance.

2.57 treated water: Water that has been processed to reduce impurities such as by using filtration, deionization, distillation, or reverse osmosis (RO), either singly or in combination.

2.58 user verification: Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met.

2.59 validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

NOTE 1—Validation covers three activities: installation qualification, operational qualification, and performance qualification.

NOTE 2—Validation is performed by the device manufacturer.

3 Design of endoscope processing area

3.1 General considerations

The design of the endoscope processing area should facilitate both infection prevention and patient and employee safety. When designing an endoscope processing area, considerations include, but are not limited to:

a) Work flow

b) Patient volume (current and anticipated)

c) Number and types of endoscopes/equipment

d) Quantity and type(s) of processing equipment

e) Scopes/equipment storage requirements

f) Supply/chemical storage requirements

g) Traffic flow

h) Required utilities (e.g., medical-grade air, water quality, ventilation)

3.2 Work flow

3.2.1 General considerations

Work flow should be unidirectional from the decontaminated area to the clean area and then to the storage area. Work flow patterns should be designed to contain contaminants, prevent damage to endoscopes, and minimize employee exposure to blood-borne and other disease-producing organisms.

Ergonomic factors affecting worker safety and comfort should be considered when designing work areas. For example, counters and work surfaces should be height adjustable or positioned at heights that take into account the average height of employees and the tasks to be performed at each location. The counter space should be sufficient to accommodate the endoscope length. Anti-fatigue mats should be used in areas where prolonged standing is required. Anti-fatigue mats should be constructed of materials capable of withstanding frequent cleaning.

Work area design also should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas. A pass-through window at counter height between the decontamination area and clean processing area is also recommended.

Rationale: Adherence to these functional design recommendations can help contain potential contaminants within the processing area and prevent cross-contamination or recontamination. Designing the area to facilitate efficient work flow and to provide adequate space for necessary equipment can reduce the potential for cross-contamination and enhance efficiency. Considering ergonomic factors during the design phase can help prevent worker injury. A pass-through window is convenient for delicate instrumentation and water-sensitive equipment that has been manually decontaminated.

3.2.2 Physical separation

The processing area should be physically separated from the patient procedure rooms. The manufacturer's written IFU should be reviewed to determine any necessary point-of-use precleaning, disassembly, or safety precautions in preparation for transport of the endoscope, accessories (e.g., biopsy forceps) and components (e.g., valves) from the patient procedure area to the processing area. An area designed with environmental needs such as lineal surfaces, lighting, and utility support of electricity should be provided in areas used for endoscope processing. The processing area should be defined for processing only and designed to allow for the unidirectional flow of devices from the receipt of new and/or used endoscopes to storage prior to next patient use. This will include receipt of devices, cleaning (decontamination), disinfection or packaging and sterilization, and storage. Physical separation of these steps is preferred but not always possible. In all cases facilities should ensure a unidirectional flow; conduct an analysis to identify risks; and minimize these risk by policies, procedures, and education and training of processing personnel.

An area should be defined at the incoming end of the unidirectional flow process for the receipt and temporary holding of devices before cleaning. If a lift is used for transport, it should be dedicated to the transport of either clean or contaminated items only.

Adequate space shall be provided to allow for the manual cleaning and rinsing of devices during decontamination. Although a number of automated endoscope reprocessors (AERs) or washer-disinfector designs claim to be able to clean and disinfect in one processing cycle, many endoscope designs may still require a point-of-use precleaning step and cleaning (to include lumen brushing) according to the endoscope manufacturer's or AER manufacturer's written IFU. If the AER is cleared for cleaning and high-level disinfection, consult with the AER manufacturer and the health care facility's infection preventionist for guidance on the location of the AER. It is optimal that the manual cleaning area is physically separated by walls or partitions to control contaminants generated during manual cleaning. Doors and pass-through windows separating the decontamination area from the adjoining disinfection/sterilization area should remain closed.

An area should be defined for disinfection/sterilization that is separate from the manual cleaning/processing area. For manual processing, this could include a designated area for the immersion of the device for disinfection followed by rinsing in accordance with the disinfectant manufacturer's written IFU. For automated processing, the AER, washer-disinfector, or sterilizer forms an essential barrier between the dirty and clean areas of the processing area. Strict unidirectional processing procedures should be in place to reduce risks of cross-contamination following an antimicrobial process. This should include a designated drying area, when applicable, to dry the device prior to patient use, storage, or in preparation for packaging and gaseous sterilization.

A separate area should also be defined and controlled for the storage of devices, either temporarily or more long-term, before patient use. Physical separation of this area from the main processing area is preferred to minimize any risk of cross-contamination during storage.

An area designed with environmental needs such unidirectional workflow, lighting, and utility support of electricity should be provided in areas used for endoscope processing.

Rationale: Physical enclosure of the decontamination area is necessary because contaminated aerosols, droplet nuclei, and dust particles can be carried from "dirty" to "clean" areas by air currents. Separating "clean" and "dirty" areas helps prevent environmental contamination. Segregation of contaminated items from items being removed from mechanical processing equipment can help protect processed items (e.g., flexible and semi-rigid endoscopes) from recontamination.

3.2.3 Traffic control

Traffic in the processing area should be restricted to authorized personnel. Criteria for authorized entry, movement, and attire within the decontamination and clean areas should be specified in the policies and procedures of the facility.

It may be necessary for visitors (e.g., repair personnel) to enter restricted areas. Visitors should comply with facility policies and procedures. The responsibility and authority for enforcing traffic-control policies and procedures should be specified in the facility policies and procedures, as should methods of compliance.

Rationale: Personnel and visitors can carry microorganisms into the processing areas, thus increasing the potential for environmental contamination in these areas. It is also important to protect personnel and visitors from the microorganisms present on contaminated items being processed in the decontamination area.

3.3 Physical facilities

3.3.1 Space requirements

The needs of the facility should determine the size of the processing areas. Sufficient space should be provided for each function and include dedicated storage space.

Considerations for space requirements include the operational systems, equipment, and anticipated workload in each functional work area. Space requirements should be based on the volume of work anticipated, the amount of product that will be routinely stored, and disposal needs. The degree of mechanization, the product mix (e.g., reusables vs. disposables), and the storage methods used also affect space requirements and may change over time. There should be adequate space to maneuver, queue, and unload carts or other transportation systems at times of average daily peak workload. Space is also required for record keeping, either manual or computerized.

In the decontamination area, sufficient space should be allocated for manual clean-up sinks, trash bins, laundry bins, separate handwash sinks, an emergency eyewash station, storage of cleaning chemicals and cleaning implements, PPE, automated flushing systems, suction machines, compressed air, adapters, connectors, and gauges. Sink and/or counterspace for leak testing should be considered.

If an AER is being considered, sufficient space and utilities for the unit(s) should be allocated. Adequate space for storage of chemicals near the AER should also be considered.

In the clean area, sufficient space should be allocated for manual high-level disinfectant (HLD) containers and separate sinks for rinsing the HLD. In addition, space should be allocated for the storage of HLD chemicals, sterilant chemicals, packaging for terminal sterilization, spill kits, PPE, compressed air, alcohol, adapters, connectors, filters, and storage of reprocessed endoscopes.

Rationale: Space requirements can vary significantly depending upon the specific processing needs of the facility and are often underestimated during the planning process.

3.3.2 Sinks and accessories

Processing areas should have dedicated plumbing and drains.

Sinks should be deep enough to allow complete immersion of the endoscope to minimize aerosolization. The size of the sink should be adequate (i.e., 16 inches x 30 inches) to ensure the endoscope can be positioned without tight coiling. Sinks should not be so deep that personnel have to bend over to clean instruments. An ideal decontamination sink is approximately 36 inches (91 centimeters [cm]) from the floor and 8 to 10 inches (20 to 25 cm) deep, enabling a person of average size to work comfortably without undue strain on the back; foot stools should be readily available to accommodate shorter personnel.

At a minimum, two sinks or one sink with two separate basins should be used, One sink or sink basin should be designated for leak testing and manual cleaning, and the other only for rinsing. Optimally, three sinks or one sink with three separate basins should be used, with each function in a separate sink or basin.

The sink or sinks should have faucets or manifold systems, adapters that attach to the faucet, or other accessories that facilitate the flushing of instruments with lumens. Sinks should have attached solid counters or adjacent work surfaces on which to place and separate soiled and clean items.

Lighting should be placed above the sink and counter area so that personnel can adequately perform inspection activities as the endoscope is processed.

The processing area may need pressurized systems such as compressed air (high-pressure, low-pressure, or both) and vacuum systems. Forced air with an upper limit of pressure as described in the endoscope manufacturer's written IFU should be provided at the sink for flushing lumened devices.

NOTE—Best practices include that the nozzle of the pressurized air source should be wiped, disinfected, and allowed to dry before placing in the opening of the channel for drying.

A source of treated water for final rinsing should be provided in necessary locations (see AAMI TIR34).

Rationale: The design and location of sinks can facilitate cleaning as well as employee safety. Tight coiling of the endoscope could damage components, including image or light bundles, internal channels, tubes, and/or angulation wires. Sinks located too high or too low increase the risk of back injury or strain. Current medical technology may require complex equipment and systems to inspect, maintain, or verify device performance.

3.3.3 Electrical systems

Electrical systems should be designed to allow for the safe and effective operation of the equipment (e.g., cleaning equipment, sterilization equipment, computers, telephones, lighting) used in the processing area. The emergency power service of the facility should be extended to include sterilization and processing equipment. The electrical engineers involved in the design processes should be aware of the work performed in the processing area and should collaborate with managerial or other designated personnel when determining electrical system requirements. For some equipment, uninterruptible power sources are recommended.

Rationale: The complexity of processing and sterilization technologies, as well as patient and personnel safety, requires adequate, safe, and reliable electrical service.

3.3.4 Floors and walls

Floors in the processing areas should be level (i.e., should have no ridges or bumps), monolithic or joint-free, and should be constructed of materials that will withstand daily or more frequent wet cleaning and the application of chemical cleaning agents. Carpet should not be used in the processing areas.

Walls should be constructed of materials capable of withstanding frequent cleaning. Wall protectors should be installed at the level of possible cart impacts.

Materials used in floors and walls should be of a non-particulate- or non-fiber-shedding composition.

Rationale: Uneven floors may make it difficult for personnel to push carts; also, uneven floors can cause items on carts to shake and even fall off the cart. Joints and crevices in floors may harbor microorganisms. The materials used in construction of floors and walls should be able to withstand frequent cleaning and should not be adversely affected by the chemical agents typically used for environmental cleaning. Some sterilizer carts have blunt ends that can nick walls, eventually removing the cover material and exposing porous fibers that can shed into the environment.

3.3.5 Ceilings

Processing area ceilings should be constructed to create a flush surface with recessed, enclosed fixtures. Pipes and other fixtures above work areas should also be enclosed. Ceilings should be constructed of non-particulate, non-fiber-shedding materials.

Rationale: A finished ceiling with enclosed fixtures limits condensation, dust accumulation, and other possible sources of contamination.

3.3.6 Doors

A door should provide access to the decontamination area from the corridor, and from the decontamination area to the clean area.

Doors in the processing area should be made of a durable, nonporous material that can withstand frequent bumping from back tables and carts and that can be cleaned frequently. Doors should not have thresholds and should open easily following the one-way directional work flow. The door swing should be hands-free, as personnel might be holding endoscopes with both hands.

Rationale: Carts are frequently pushed from one area to the next. Doors require frequent cleaning. It can be difficult for personnel to pull open a door and push a cart through it. The frequent bumping of doors by carts may damage the door surface and expose porous materials that may harbor bacteria and other contaminants and are difficult to clean. Bumping against a threshold can cause carts to spill and may necessitate picking up the cart to traverse the threshold.

3.3.7 Temperature, relative humidity, and ventilation

3.3.7.1 Temperature and relative humidity

The processing area should be temperature controlled for the comfort of personnel (typically between 16°C and 23°C [60°F and 73°F]). The temperature in any storage and personnel support areas (e.g., locker rooms) may be as high as 24°C (75°F). (FGI, 2014)

The temperature should be monitored. Processing or other designated personnel should be responsible for monitoring and recording the temperature to verify that the correct temperature is being maintained in each area.

Rationale: Processing areas should be comfortable for personnel. Comfort is a particular consideration in the decontamination area, where PPE is worn for long periods of time and where temperatures suitable for other areas might be uncomfortably hot. Controlling the temperature in sterilization equipment access rooms may promote higher efficiency of the equipment contained within the enclosures.

Relative humidity should not exceed 60% in all work areas; in the sterile storage area, the recommended minimum humidity level is 20%. (FGI, 2014)

Relative humidity should be monitored. Processing or other designated personnel should be responsible for monitoring and recording the relative humidity to verify that the relative humidity is being maintained within the recommended range in each area.

Rationale: A relative humidity higher than recommended can promote microbial growth. Relative humidity lower than 30% may permit absorbent materials to become excessively dry, which can adversely affect certain sterilization parameters (such as steam penetration) and the performance of some products (such as BIs and CIs).

3.3.7.2 Ventilation

It is recommended that a decontamination area be under negative pressure in relation to the adjoining rooms, whereas the clean area should be under positive pressure. This is not always possible, but in the case of a single room for device processing, the room should be under negative pressure.

If separate rooms are available, the decontamination area should be designed so that air flows into the area (negative pressure), with a minimum of 10 air exchanges per hour, and so that all air is exhausted to the outside atmosphere

via a nonrecirculating system. Whenever possible, dedicated local exhaust systems should be used in place of dilution ventilation to reduce exposure to hazardous gases, vapors, fumes, or mists.

A designated clean area should be provided with positive air pressure with at least 10 air exchanges per hour.

The ventilation system should be designed to provide at least 10 air exchanges per hour to minimize air contaminants. For separated room areas, air should flow from areas of positive pressure to areas of negative pressure.

The exhaust system should be designed to permit a high volume of air to be exhausted from the processing area. Combining exhaust systems can enhance the efficiency of recovery devices required for energy conservation. Air inlets should be located in the ceiling. The exhaust ducts should be located at floor level in the wall and should be designed so that effective filtering systems can be installed and maintained. The exhaust filtering system will vary, depending on whether the system exhausts directly to the outside atmosphere or whether some of the exhausted air is recirculated.

Duct covers or grids should be cleaned regularly and filters should be changed on a scheduled basis according to the manufacturer's written IFU.

Fresh air intakes should be located at least 25 feet (7.62 meters) from exhaust outlets of ventilation systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vents, or areas that might collect vehicular exhaust or other noxious fumes. Prevailing winds and/or proximity to other building structures might necessitate a longer distance.

Neither fixed nor portable fans should be permitted in the processing area, with the exceptions of exhaust fans on ventilation systems and installed and operated fume control hoods. Other aspects of ventilation should comply with the guidelines set forth by the Facility Guidelines Institute (FGI, 2014). See also American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) (2007a) and ASHRAE (2007b).

FGI (2014) recommends 6 air exchanges per hour in the decontamination area and 4 air exchanges per hour in the preparation and packaging area.

Rationale: Ventilation patterns affect the proliferation and spread of potentially dangerous microorganisms. Down-draft-type air circulation systems limit contamination by carrying contaminants toward the floor and away from work surfaces. The recommended number of air exchanges per hour reflects the committee’s consensus on the minimum air exchange rate necessary to effectively reduce environmental contamination by air dilution. Fans create highly turbulent air flow, which recirculates dust and microorganisms from the floor and work surfaces and thus interferes with designed airflow characteristics. Ventilation should be provided to remove toxic vapors of disinfection chemicals and to handle any aerosolized particles or microbes. Airborne microbial and particulate contamination is likely to be high in the decontamination area because of the type of work done there (e.g., staging of grossly soiled items before cleaning and manual cleaning that produces aerosols). Exhausting air directly to the outside prevents the reintroduction of contaminants onto clean items and into clean work spaces where they could pose a risk to personnel and patients.

3.3.8 Lighting

Adequate lighting of work surfaces should be provided in accordance with the engineering practices and recommendations of the Illuminating Engineering Society of North America (IES) for minimum levels of illuminance for various categories of work environments (see Table 1).

The three levels of lighting for each category were calculated on the basis of the following factors:

1) the age of the workers (persons under 40 years of age require the least amount of illuminance, persons 40 to 55 years of age require an average amount of illuminance, and persons more than 55 years of age require the highest amount of illuminance);

2) the importance of speed or accuracy of the work done in the area (the greater the importance of speed or accuracy, the more illuminance needed); and

3) the amount of light reflection in the work area (lighter colors reflect light; darker colors absorb light; the greater the reflectance, the less illuminance required).

Table 1—IES-recommended illuminance levels for work environments

Work area/function	Least illuminance	Average illuminance	Highest illuminance
General inspection	500 lux (50 foot-candles)	750 lux (75 foot-candles)	1,000 lux (100 foot-candles)
Detailed inspection	1,000 lux (100 foot-candles)	1,500 lux (150 foot-candles)	2,000 lux (200 foot-candles)
Sink areas	500 lux (50 foot-candles)	750 lux (75 foot-candles)	1,000 lux (100 foot-candles)
General work areas	200 lux (20 foot-candles)	300 lux (30 foot-candles)	500 lux (50 foot-candles)
Processed storage	200 lux (20 foot-candles)	300 lux (30 foot-candles)	500 lux (50 foot-candles)

A qualified illumination engineer, in consultation with the processing managerial or other designated personnel, should determine the correct illuminance for each work space within the processing area. Generally, all functions performed within a processing area require detailed and accurate inspection. Ancillary lighting should be considered for areas where instruments are manually cleaned and inspected. Lighting fixtures should be selected and mounted in positions that focus the light in front of the employee so that they are not working in their own shadows.

Lights and other fixtures should be recessed and sealed to prevent the accumulation of dust or soil and to facilitate cleaning.

Rationale: Adequate lighting is essential to the performance of decontamination, preparation, inspection, and other processing tasks. Dust on lighting fixtures can act as a carrier of microorganisms.

3.3.9 Hand hygiene facilities

Hand hygiene facilities (i.e., sink, soap dispenser, towel dispenser, or alcohol-based hand rub dispensers) should be conveniently located and designed to allow good hand hygiene practices. The hand hygiene sink should be separate from the sink used to clean endoscopes. Hand hygiene facilities should be located in or near all areas where endoscopes and other devices are decontaminated and in the clean area where endoscopes are high-level disinfected or sterilized. The installation of hands-free equipment (e.g., foot controls, electronic sensors) for use with sinks, towel dispensers, and soap dispensers should be considered during the design of new facilities. If electronic sensors are used, there should be a backup system for operation during power outages.

State regulations might dictate when and where alcohol-based hand rubs may be used and placed within the facility. The health department of the particular state should be consulted for specific regulations.

Rationale: Conveniently located hand hygiene facilities and alcohol-based hand rub dispensers help to promote hand hygiene and increase compliance with hand hygiene policies and procedures. Handwashing in the sinks used for endoscope cleaning could leave handwash soap and bacteria on the endoscopes or contaminate personnel's hands. The use of alcohol-based, waterless hand hygiene agents is an effective means of hand decontamination when hands are not visibly soiled. Hands-free equipment helps personnel avoid touching faucet handles, soap dispensers, or towel dispensers, and may help to decrease microorganism transfer between patients, personnel, and inanimate objects. Some electronic sinks and towel dispensers operate only by the use of electricity and cannot function if the electrical power is off; a backup power system for hands-free equipment will ensure its continued operation.

3.3.10 Emergency eyewash/shower equipment

Suitable eyewash units must be available for immediate emergency use in all places where chemicals are used. The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units (ANSI Z358.1). ANSI Z358.1 requires that eyewash units provide a minimum of 0.4 gallons per minute continuously for at least 15 minutes, that they be designed to flush both eyes simultaneously, and that they have a "hands-free, stay open" feature once activated. Under the ANSI standard, drench hoses or eyewash bottles are not acceptable emergency eyewash units.

Eyewash stations should be located:

a) so that travel time is no greater than 10 seconds from the location of chemical use or storage, or immediately next to or adjoining the area of chemical use or storage, if the chemical is caustic or a strong acid; and

b) on the same level as the hazard with the path of travel free of obstructions (e.g., doors) that may inhibit immediate use of the eyewash station (ANSI Z358).

When walking at a normal pace, the average person covers a distance of 55 feet in 10 seconds; however, a person who has experienced a chemical splash to the eyes or face may be visually impaired, in discomfort or pain, and in a state of panic. For this reason, it is prudent to consider the physical and emotional state of the person as well as the availability of assistive personnel in the immediate area when determining the location of eyewash stations (ANSI Z358).

For a strong acid or strong caustic, the eyewash unit should be immediately adjacent to the hazard. The eyewash facilities should be identified with a highly visible sign and should be maintained in accordance with the manufacturer's written IFU. Before attempting to implement the ANSI standard, health care personnel should consult the standard to familiarize themselves with all its provisions.

Plumbed eyewashes/facewashes and showers should be activated weekly for a period long enough to verify operation and ensure that the flushing solution is available. When activating plumbed eyewashes, eye/facewashes, and showers, personnel should also verify that they are providing lukewarm, tepid water (between 15°C and 43°C [60°F and 100°F]). (ANSI Z358.1). Routine testing should be documented.

Rationale: Many chemicals are classified as eye irritants. Eye contact with such chemicals can cause moderate to severe irritation, experienced as discomfort or pain, excessive blinking, and tear production, with marked redness and swelling of the conjunctiva.

The availability of eyewash units for immediate emergency use is required by OSHA. Maintenance of eyewash units is necessary to ensure adequate performance and to prevent contamination.

See also OSHA's Eye and Face Protection Standard (29 CFR 1910.133), OSHA's Medical and First Aid Standard (29 CFR 1910.151), and ANSI Z358.1.

3.3.11 Environmental cleaning

Environmental cleaning and disinfection procedures in areas used for any aspect of decontamination, preparation, or sterilization should ensure a high level of cleanliness at all times. Floors and horizontal work surfaces should be cleaned at least daily. Other surfaces, such as walls, storage shelves, endoscope storage cabinets, and air intake and return ducts, should be cleaned on a regularly scheduled basis and more often if needed (AORN, 2015b). Stained ceiling tiles should be replaced, and any leaks causing the stains should be repaired. A cleaning schedule on a regular (weekly or monthly) basis should be established and followed for lighting fixtures or covers.

Care should be taken to avoid contaminating patient-ready devices such as endoscopes or compromising the integrity of packaging during cleaning. Special attention should be paid to the sequence of cleaning to avoid transferring contaminants from "dirty" to "clean" areas and surfaces. It is good practice to provide separate storage areas for environmental cleaning supplies for the decontamination and clean areas. If cleaning is contracted, written policy and procedures, IFU for products that are used, and other support information should be provided to the contractor.

Rationale: Cleaning removes soil and reduces environmental contaminants, thus reducing the risk of transmission of microorganisms.

4 Personnel

4.1 General considerations

This section provides guidelines for policies and procedures related to the processing areas, as well as education, training, and competency verification, and criteria for hand hygiene, immunizations, attire, and PPE for processing personnel.

4.2 Policies and procedures

Policies and procedures for endoscope processing, which includes processes for monitoring adherence to the policies and procedures and a chain of accountability, should include guidelines for:

a) Delineating procedures for processing of endoscopes and endoscope accessories.

b) Confirming that current versions of the manufacturer's written IFU for the endoscope models and AERs used at the facility are readily available to processing personnel.

NOTE—Processing personnel should inform manufacturers, as well as the FDA if applicable, if the IFU seem unclear or inadequate.

c) Confirming that facility processing procedures do not conflict with the written IFU of the manufacturers of the endoscopes, AERs, cleaning solutions, liquid chemical sterilants, or high-level disinfectants.

d) Verifying that processing personnel comply with processing procedures.

Policies and procedures should be disseminated and available to all processing personnel. Managerial or other designated individuals should verify that processing personnel know the location of and can access facility policies and procedures.

Policies and procedures should be reviewed and updated at regular intervals.

A policy should be developed on the reporting, treatment, and disposition of employees who are at risk of acquiring or transmitting infections in collaboration with the health care facility's infection prevention personnel.

NOTE—Exposures to blood-borne diseases should be handled in accordance with OSHA regulations and current Centers for Disease Control and Prevention (CDC) recommendations.

Rationale: The protection of patients, employees, and other individuals in the health care facility depends on the implementation of policies and procedures designed to reduce the risk of exposure to potentially pathogenic microorganisms.

4.3 Education, training, and competency verification

It is recommended that all personnel performing processing of endoscopes be certified as a condition of employment. At a minimum, personnel should complete a certification exam.

NOTE—Information concerning education, training, and/or certification of endoscopy technicians with processing duties, sterile processinging managers, and technicians can be obtained from the Certification Board for Sterile Processing and Distribution (CBSPD, www.sterileprocessing.org); the Society of Gastroenterology Nurses and Associates (SGNA, www.sgna.org); and the International Association of Healthcare Central Service Materiel Management (IAHCSMM, www.iahcsmm.org).

Personnel involved in endoscope processing should be provided education, training, and complete competency verification activities related to their duties upon initial hire; annually; at designated intervals; or whenever new endoscopic models, new processing equipment, or products such as new chemicals are introduced for processing. Processing activities should be closely supervised until competency is verified and documented for each processing task, from cleaning through storage of the endoscope.

Facility personnel providing orientation, education, training, or competency verification for processing personnel should:

a) complete facility-specific education and competency verification activities related to the role of sterile processing educator;

b) maintain competence necessary to provide education related to sterile processing activities, including the effective use of technologies to optimize practice;

c) use regulatory and evidence-based professional guidelines as the foundation for education and training activities;

d) participate in ongoing activities related to education of sterile processing personnel; and

e) periodically re-educate and reassess competency of processing personnel and document completion of education, training, and competency verification activities.

Education and training of processing personnel should include:

f) procedures for cleaning, disinfecting or sterilizing, packaging, and storing each specific endoscope make and model, including equipment connections;

NOTE—Educational, training, competency verification, and other materials and information are available from endoscope manufacturers, AER manufacturers, sterilizer manufacturers, chemical manufacturers (e.g., cleaning solutions, high-level disinfectants), professional associations, and professional journals.

g) identification of items that are single-use and discarded after use;

h) all aspects of decontamination (e.g., disassembly, manual and mechanical cleaning methods and how to monitor their effectiveness, microbiocidal processes, equipment operation, standard precautions, and engineering and work practice controls);

i) the operation of the specific manual and mechanical cleaning processes and equipment, manual and mechanical high-level disinfection processes, and, if applicable, sterilizing system(s) used by the health care facility, and the methods used to verify operation;

j) facility and processing area policies and procedures regarding sterilization and high-level disinfection, infection prevention, attire, hand hygiene, and compliance with local, state, and/or federal regulations;

k) workplace safety, including all relevant OSHA standards related to chemical use and biological hazards in that department, as well as workplace safety processes and procedures related to endoscope processing, high-level disinfection, and sterilization;

l) the process of leak testing when indicated on the manufacturer's written IFU; and

m) documentation of quality monitoring results.

Competency verification activities should include monitoring processing personnel for their:

n) compliance with facility policies and procedures and manufacturer’s written IFU for each type of endoscope reprocessed at the facility, and

o) level of proficiency in processing procedures.

Education, training, and competency verification activities should be provided and documented for all processing personnel on procedures for processing of all endoscopes, and use of all AERs and sterilizers used at the facility.

Rationale: Initial and ongoing education, training, and competency verification may decrease the possibility of operator error during processing procedures and may help to ensure that personnel are knowledgeable regarding the most current data and techniques for processing. Education, training, and competency verification are important aspects of any program intended to protect patients and employees from potential safety hazards and to help the employee recognize unsafe conditions or work practices and when, how, or why to employ protective measures. Health care facility policies and procedures are a necessary part of any education, training, and competency verification program, and personnel should be familiar with and adhere to these policies and procedures. Providing education and training introduces new information and facilitates the development of knowledge and skills related to endoscope processing. Competency verification activities measure individual performance and provide a mechanism for documentation. Documentation of education, training, and competency verification is required by regulatory and accreditation agencies.

4.4 Standard precautions

Standard precautions represent a philosophy that assumes that all patients and all body fluids and items that have contacted body fluids are potentially infectious. Standard precautions include washing hands and wearing PPE to avoid contact with contaminated items, blood, or body fluids. Because it is not possible to specify a protective barrier for every situation that can occur, a risk assessment on the potential for exposure is required by the user. The OSHA blood-borne pathogen regulation (29 CFR 1910.1030) includes the following requirements:

a) Precautions should be taken to prevent injuries from sharp objects (e.g., needles, scalpels, broken glass).

b) Sharp objects should be placed in puncture-resistant containers.

c) PPE should be used to prevent exposure to blood or body fluids.

d) Hands and other skin surfaces that are contaminated with potentially infectious fluids should be immediately and thoroughly washed.

e) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure to chemical or biological materials.

f) Food and drink should not be kept in refrigerators, freezers, or cabinets or on shelves, countertops, or benchtops where blood or other potentially infectious materials are present.

g) Employees should receive education, training, and complete competency verification activities on blood-borne pathogens.

See also CDC (2002) and CDC (2007).

Rationale: If all items are treated as infectious, then the risk of personnel exposure is reduced, especially when handling items from patients whose infectious status is unknown.

4.5 Hand hygiene

Policies and procedures on hand hygiene should be developed and communicated to employees. Such policies should be approved by infection prevention personnel or the designated employee health personnel. Considerations include, but are not limited to:

a) Fingernails should be kept short and clean and should not extend beyond the fingertips.

b) Artificial nails, including gels, extensions or tips, acrylic overlays, or other enhancements should not be worn (AORN, 2015c).

c) Each facility should develop its own policy regarding the use of nail polish, including clear nail polish; the issue remains unresolved and requires further study.

Rationale: Careful attention to hand hygiene can minimize the potential for acquiring or transmitting disease. Artificial nails can promote the growth of fungus under the nails. Careful attention to hand hygiene can minimize the potential for acquiring or transmitting disease. (Baumgardner, et al., 1993; Jeanes and Green, 2001; Porteous, 2002; Salman, et al., 2002; CDC, 2002).

4.6 Attire

4.6.1 General considerations

a) All personnel entering the processing area should change into clean uniforms that are provided by and donned at the facility.

b) Attire should be changed daily or more often as needed (i.e., when wet, grossly soiled, or visibly contaminated with blood or other bodily fluids).

c) Reusable uniforms should be laundered by a health care-accredited laundry (ANSI/AAMI ST65, AORN, 2015d).

d) All head and facial hair (except for eyebrows and eyelashes) should be completely covered with a surgical-type hair covering.

e) Jewelry and wristwatches should not be worn in the processing area.

f) Shoes worn in the processing area should be clean, have non-skid soles, and be sturdy enough to prevent injury if an item drops on the foot. Liquid-resistant shoe covers should be worn if there is potential for shoes becoming contaminated and/or soaked with blood or other bodily fluids (OSHA 29 CFR 1910.1030).

g) The use of cover apparel when employees leave the area to travel to other areas of the health care facility should be determined by each facility and should comply with state and local regulations.

h) Employees should change into street clothes when they leave the health care facility or when traveling between buildings located on separate campuses.

Rationale: Clean attire minimizes the introduction of microorganisms and lint from personnel to items being processed and to the environment. Liquids can act as vehicles for the transfer of microorganisms from soiled materials and from the skin of personnel; therefore, wet surgical attire should be considered contaminated. Controlled laundering of garments reduces the risk of transferring pathogenic microorganisms from the health care facility to the home. Jewelry should not be worn because it is not easily or routinely cleaned, it can harbor microorganisms, it can become dislodged and damage items, and it can cause holes in gloves or other barrier protection. Wristwatches and rings, in particular, can catch on equipment or instruments, injuring personnel or damaging the item or packaging. Removing wristwatches and jewelry allows for more effective hand hygiene (CDC, 2002; Graves, 2006; Trick, 2003; Field, 1996).

4.6.2 Personal protective equipment

The OSHA blood-borne pathogen regulation (29 CFR 1910.1030) requires that each facility have in place an exposure control plan that outlines the potential hazards that personnel might encounter while on the job. The plan should also identify the engineering controls, work-practice controls, and preventive and post exposure medical care

procedures that will be used to maintain the safety and health of employees. In the processing area these measures will include the use of PPE. PPE should be selected and worn based on an assessment of the potential for exposure based on the task to be performed.

a) In addition to the attire recommended in Section 4.6, personnel working in the decontamination area should wear general-purpose utility gloves and a liquid-resistant covering with sleeves (for example, a backless gown or surgical gown).

b) Processing personnel should use a style of glove that prevents contact with contaminated water. Gloves that are too short, do not fit tightly at the wrist, or lack cuffs might allow water to enter when the arms move up and down. Exam gloves should not be used for decontamination. General purpose utility gloves fitted at the wrist or above should be used.

c) In situations that require the highest level of protection (e.g., there is a possibility that attire can become soaked with blood or other potentially infectious material, as when items are being washed by hand), a Level 4 gown (as defined by ANSI/AAMI PB70) should be used.

d) PPE should also include a fluid-resistant face mask and eye protection. PPE used to protect the eyes from splash could include goggles, full-length face shields, or other devices that prevent exposure to splash from all angles.

e) Reusable gloves, glove liners, aprons, and eye-protection devices should be decontaminated, according to the manufacturer's written IFU, at least daily and between employees. If integrity is compromised, items should be discarded. Remove torn gloves and thoroughly wash hands before donning new gloves.

f) PPE worn during processing should be removed and hands should be washed.

g) Before handling disinfected endoscopes, personnel should don clean PPE.

h) Before leaving the cleaning area, employees should remove all protective attire, being careful not to contaminate the clothing beneath or their skin, and wash their hands. Designated areas, with the necessary containers, should be provided for donning and removing protective attire.

Rationale: Contaminated endoscopes and other medical devices are sources of microorganisms to which personnel could be exposed through nicks, cuts, or abrasions in skin or through contact with the mucous membranes of the eyes, nose, or mouth. PPE will minimize the potential for employee exposure to blood-borne and other disease-producing organisms. Wearing heavy-duty, waterproof gloves while handling contaminated items decreases the potential for puncture, limits the microbial burden on hands, and decreases the risk of cross-contamination. Gloves do not offer absolute protection, however, because they can develop small leaks as a result of the stresses of the cleaning process (DeGrott-Kosolcharoen and Jones, 1989). Handwashing after removal of PPE may prevent further contamination of the worker or environment. When the integrity of reusable gloves, aprons, or protective eyewear is compromised, they cease to function as a protective barrier. See also FDA (2008).

Fluid-resistant face masks help to protect personnel who are cleaning contaminated items from splash or splatter that could contain pathogens (Siegel, et al., 2007). Eye protection reduces the risk of eye contact or injury from blood, body fluids, or other potentially infectious materials or hazardous chemical agents. Liquid splashes and aerosols can contact the eyes from any direction, including settling out of the air from above.

4.7 Immunizations

Personnel who can potentially come into contact with items contaminated with blood or body fluids (occupational exposure) should be encouraged to accept hepatitis B immunization.

a) Any employee who declines immunization must sign the hepatitis B vaccine declination statement required by OSHA.

b) Information on CDC recommendations regarding exposures to blood-borne diseases can be obtained at www.cdc.gov.

Rationale: Careful attention to employee health and safety can minimize the potential for acquiring or transmitting disease. Vaccinations provide protection when there has been a failure in work practices or when an unexpected event occurs. OSHA requires that hepatitis B vaccination be offered free of charge to personnel who could come into contact with blood or other body fluids in performing their jobs (29 CFR 1910.1030).

5 Cleaning and high-level disinfection

5.1 General considerations

Meticulous attention to all steps in processing endoscopes, their removable components, and their accessories is critical to making them safe for subsequent patient use. Steps include:

a) Precleaning at the point of use

b) Transporting

c) Leak testing

d) Cleaning

e) Rinsing

f) Inspecting or testing for cleanliness, where applicable

g) Disinfection/high-level disinfection and monitoring of the process, where applicable

h) Rinsing

i) Drying and alcohol flush

j) Storage

5.2 Precleaning at the point of use

To prevent buildup of bioburden, development of biofilms, and drying of secretions, precleaning should take place at the point of use immediately following the procedure. It is imperative that the written IFU from the endoscope, AER, and cleaning solution manufacturers are followed.

Before the endoscope is detached from the light source and/or video processor:

a) Don fresh PPE, including gloves and skin and eye protection.

b) Prepare a cleaning solution according to the solution manufacturer's written IFU. Some endoscope manufacturers prescribe the use of potable water as the sole precleaning agent.

c) Wipe the insertion tube with a wet, low-linting or non-linting cloth or sponge soaked in the freshly prepared cleaning solution as soon as possible after the endoscope is removed from the patient or the procedure is completed. Ensure that all endoscope controls are in the free and unlocked position. The cloth or sponge should be single use and disposed of after use.

d) Suction the solution through the suction/biopsy channel as indicated in the endoscope manufacturer's written IFU.

e) Flush the air/water channels with solution using the endoscope's cleaning adapter or by IFU-instructed air/water flow.

f) If present, flush other channels (e.g., auxiliary water or elevator channels) with solution.

g) Flush with the minimally prescribed volume of solution and ensure that the channels are not blocked.

h) Place the distal end of the endoscope in the cleaning solution and suction the solution through the endoscope until clear.

i) Detach the endoscope from the light source and suction pump.

j) Attach a fluid-resistant cap over any electrical components, if applicable.

k) Visually inspect the endoscope for damage.

5.3 Transporting used endoscopes

Each endoscope should be isolated and transported with its components in its own closed system to the next stage of processing, as it is considered contaminated. To avoid puncture and penetration damage to the endoscope, devices such as forceps and wires used in the procedure should be transported in their own containers.

The system should be marked with a biohazard label and must meet OSHA (29 CFR 1910.1030) requirements for transporting hazardous items. The system should be large enough to accommodate a single endoscope without the need to over-coil the insertion or light guide tubes.

Transporting steps:

a) Isolate and immobilize a single endoscope in a container by naturally coiling it in large loops.

b) Separate endoscopy accessories from the contaminated endoscope to prevent puncture and penetration damage.

5.4 Leak testing

5.4.1 General considerations

Leak testing should be performed as soon as possible after the endoscope arrives in the processing area and before immersion of the endoscope into processing solutions. Leak testing can detect damage to the endoscope that may, if undetected, allow for fluid invasion into the areas not designed for fluids. These fluids can be a combination of accumulated water, chemicals, and/or biological matter that have collected from the time the endoscope's integrity was breached until the time the hole is identified. Follow the endoscope manufacturer's written IFU for the leak testing protocol.

Personnel performing the leak testing should wear PPE. Prior to leak testing, the fluid-resistant cap should be applied, if indicated in the manufacturer's written IFU. The largest surface counter or sink area available should be used to accommodate an open, minimally coiled endoscope for the test. Over-coiling can mask a hole and allow it go undetected. A well-lighted work surface should also be provided. Sufficient time should be allowed to permit a thorough water-tight exam. Environments, distractions, and or time limits can jeopardize a successful process.

NOTE—The use of nonimmersible endoscopes is not recommended as they cannot be adequately cleaned and high-level disinfected. (ASGE 2011).

Multiple types of leak testing processes are available and the one selected for use should be followed completely, addressing all steps in the required sequence.

5.4.2 Manual (dry) leak testing

Follow the written IFU from the endoscope and leak tester manufacturers. Generally, these steps are recommended:

a) Don fresh PPE, including gloves and skin and eye protection.

b) Remove all valves and biopsy port covers, keeping them with the scope throughout the process.

c) Attach the leak tester.

d) Pressurize the endoscope to the indicated pressure on the leak tester gauge.

e) Place the endoscope in a loose configuration.

f) Gently rotate each directional knob and elevator control while watching for changes in the established pressure.

g) Massage video or remote switches in a circular manner to more readily detect holes in these components.

h) Maintain pressure and inspection for a minimum of 30 seconds.

i) Release air pressure from the endoscope before removal of the leak testing unit

j) If the endoscope is water-tight, proceed with cleaning and disinfection processes.

k) Document outcome of leak test.

5.4.3 Mechanical (wet) leak testing

Follow the written IFU from the endoscope and leak tester manufacturers. Generally, these steps are recommended:

a) Don fresh PPE, including gloves and skin and eye protection.

b) Remove all valves and biopsy port covers, keeping them with the scope throughout the process.

c) Attach the leak tester.

d) Turn the air compressor on and pressurize the endoscope.

e) Establish pressurization by confirming that the bending rubber has expanded.

f) Place the endoscope in a loose configuration in a large sink with a sufficient volume of clean water to completely immerse it.

g) Completely flush all channels with water to remove trapped air.

h) Gently rotate each directional knob and elevator control, looking for bubbles at the bending rubber as well as at the knobs.

i) Massage video or remote switches in a circular manner to challenge the integrity of these components while looking for bubbles.

j) Manipulate the insertion tube and light guide tube, if applicable, to uncover hidden leaks due to the position of the coiled endoscope.

k) Perform a complete visual inspection of the endoscope for leaks. If static bubbles are attached to the endoscope, brush them away and inspect to ensure that bubbles do not return.

l) Maintain pressure and inspection for a minimum of 30 seconds.

m) Remove the entire endoscope from the test water.

n) Stop pressurization by turning off the air supply.

o) According to the manufacturer's written IFU, remove the leak tester from the air compressor and listen for the sound of evacuated air.

p) If the endoscope is water tight, proceed with cleaning and disinfection processes.

q) Document outcome of leak test.

5.4.4 Mechanical (dry) leak testing

Follow the written IFU from the endoscope and leak tester manufacturer. Generally, these steps are recommended:

a) Don fresh PPE, including gloves and skin and eye protection.

b) Prepare automated leakage tester and tubes.

c) As applicable, power on printer.

d) Power on automated leakage tester.

e) Position the endoscope(s) for leakage testing as prescribed by the manufacturer.

f) Ensure fluid-resistant caps are attached to the endoscope, as applicable.

g) Connect leakage tester tubes to endoscope(s).

h) Scan or enter user and endoscope information.

i) Select start and allow automated leakage tester cycle to complete.

j) If the endoscope receives a pass indication, proceed with cleaning and disinfection processes.

k) If the endoscope receives a failure indication, proceed with immersion leakage testing in the manual leakage testing mode as prescribed by the manufacturer to determine the leakage area. Once the leakage area is determined, follow the manufacturer’s written IFU for processing a leaking endoscope.

l) Document results upon completion of leak test or at intervals as determined by facility guidelines.

5.4.5 Mechanical leak testing using an AER

a) Don fresh PPE, including gloves and skin and eye protection.

b) Follow the endoscope and AER manufacturers' written IFU.

c) Document outcome of leak test.

5.4.6 Leak test failures

a) If a leak has been identified, follow the modified processing steps according to the endoscope manufacturer's written IFU.

b) Ensure pressure is maintained on the endoscope throughout the modified process.

c) Re-evaluate the leak testing process if fluid invasion is a reccurring problem.

5.5 Manual cleaning

Manual cleaning starts after confirming that the endoscope does not have any leaks and should be conducted as soon as possible after use to prevent soil from drying on the device. Soil that remains on the endoscope may interfere with the ability of the disinfection or sterilization process to effectively kill or inactivate microorganisms and may allow for biofilm development. If it is not possible to start the cleaning process immediately after use, the endoscope manufacturer’s written IFU for delayed processing should be followed.

Cleaning steps:

a) Don fresh PPE, including gloves and skin and eye protection.

b) Prepare fresh cleaning solution for each endoscope according to the solution manufacturer's written IFU for temperature, if applicable; concentration; and water quality. The temperature of the cleaning solution should be monitored and documented.

c) Place the endoscope in the solution, keeping it below the fluid’s surface level at all times.

d) Clean the endoscope’s exterior surfaces with a single-use lint-free cloth or sponge.

e) Clean all valve cylinders, openings, and forceps elevator housings with a cleaning brush of the length, width, and material designated in the endoscope manufacturer's written IFU.

NOTE 1—Endoscope valves need to be manually actuated to ensure coverage of all internal parts.

f) Brush all channels according to the endoscope manufacturer’s written IFU until there is no visual debris.

NOTE 2—Cleaning brushes should either be single use and disposed of or reusable and receive high-level disinfection or sterilization after each use, according to their written IFU.

g) Attach a model-specific cleaning adapter, flush channels, and allow for solution exposure according to the solution manufacturer's written IFU.

h) Flush all channels according to the endoscope manufacturer's written IFU and rinse exterior surfaces with potable water until all cleaning solution is visibly removed. Some cleaning solutions may require multiple rinses in fresh water.

i) Purge all channels with air.

j) Repeat cleaning, brushing, and rinsing steps until there is no visible debris or solution residual.

NOTE 3—Endoscopes that have been exposed to synthetic lipids or radiographic medium may require additional cleaning.

k) Soak, scrub, brush, and rinse all reusable and removable parts (valves, buttons, port covers, tubing).

NOTE 4—Discard removable parts designed for single use.

l) Clean reusable endoscopy accessories (e.g., forceps, wires, baskets) according to their written IFU.

If an automatic flushing system is used, personnel should follow the manufacturer’s written IFU and ensure that it is compatible with the endoscope being processed. Fresh solution should be used with each endoscope. All connections should be secured. The connection tubing and equipment should be cleaned and disinfected according to the manufacturer's written IFU. Any quality assurance testing recommended by the manufacturer (e.g., daily volume verification) should be performed and documented.

5.6 Manual rinsing

After cleaning the endoscope, removed components and accessories should be thoroughly rinsed with copious amounts of potable water (see AAMI TIR34) to help ensure all cleaning solutions and loosened debris are removed. Follow the endoscope manufacturer's and cleaning solution manufacturer's written IFU for the amount of water and psi and/or pressure needed to flush through each channel and number of rinses.

Rinsing steps:

a) Using the cleaning adaptors provided by the manufacturer, ensure adequate flow of potable water through each lumen.

b) Rinse all exterior endoscope surfaces with freely flowing potable water.

c) Purge channels with air using a syringe to evacuate residual rinse water. If compressed air is used, it should be oil-free and used at a pressure not to exceed that recommended by the endoscope manufacturer.

d) Rinse all valves and other removable components according to the manufacturer's written IFU.

e) Dry the exterior of the endoscope with a lint-free cloth or sponge.

f) After cleaning, all detachable valves should be kept together with the same endoscope as a unique set.

5.7 High-level disinfection and liquid chemical sterilization

5.7.1 General considerations

Liquid chemical sterilization is an important step in the reprocessing of semi-critical and, in some cases, critical heat sensitive flexible and semi-rigid endoscopes, such as upper and lower gastrointestinal endoscopes and bronchoscopes. High-level disinfection can be used in the reprocessing of semi-critical devices. Semi-critical devices can contact mucous membranes or nonintact skin and should preferably be sterilized or high-level disinfected with an FDA-cleared LCS/HLD prior to use on the next patient.

5.7.2 High-level disinfection

An HLD solution is a germicide that should inactivate all microbial pathogens, except large numbers of bacterial endospores, when used according to labeling (Spaulding, 1972). The FDA further defines an HLD as a sterilant used under the same contact conditions except for a shorter contact time. All HLD solutions are LCSs, based on passing the AOAC Sporicidal Activity Test as a sterilant. However, some HLD solutions require an extended time (e.g., 22–32 hours) to pass the AOAC Sporicidal Test as a sterilant and therefore are labeled only for high-level disinfection and are not indicated for device sterilization.

HLD solutions cleared by the FDA include those formulated with glutaraldehyde, orthophthalaldehyde, peracetic acid, chlorine, and hydrogen peroxide. Some formulations include combinations of microbicidal agents, including peracetic acid and hydrogen peroxide, glutaraldehyde and phenol/phenate, and glutaraldehyde and isopropyl alcohol. Information on HLD solutions cleared by the FDA is listed on the FDA web site at www.fda.gov.

The list, which is updated periodically, provides information on the product's clearance for high-level disinfection, the contact time and temperature required for high-level disinfection, and whether the HLD solution is limited to use in an AER. To find other HLD solutions cleared by FDA since the above listed was last updated, go to www.fda.gov.

High-level disinfection can be performed manually in a soaking tub or basin or in an AER.

The majority of HLD solutions cleared by the FDA are reusable—that is, the solution can be used repeatedly, until the solution has reached either its manufacturer-specified minimum recommended concentration (MRC) determined by testing, or its maximum reuse life prescribed by the manufacturer and determined by testing, whichever comes first. HLD solutions have been cleared by FDA for maximum reuse ranging from 5 to 30 days. Testing of the reusable HLD solution for the MRC should be performed and documented prior to each use per the manufacturer's written IFU (see ANSI/AAMI ST58).

It is unacceptable to "top off" the basin of HLD solution or AER reservoir containing the reusable HLD solution, unless the HLD solution manufacturer provides written guidance. Some volume loss of HLD solution occurs during each processing cycle. Topping off does not extend the use-life days of the solution, even if the MRC or minimum effective concentration (MEC) is still met.

Single-use HLD solution formulations are available for use with specific AERs. Some HLD solutions are formulated as a concentrate, which is metered and mixed in the AER just prior to the high-level disinfection cycle in the AER.

Examples of these types of HLD solutions include concentrated orthophthalaldehyde and peracetic acid. The MRC or MEC of the use solution for single-use HLDs that are prepared from a concentrate is determined either through use of a solution test strip or chemical monitoring device or automatically, depending on the AER.

To be effective, the HLD solution should contact all surfaces of the endoscope, including the working head and the internal lumen of all endoscope channels. Therefore, for manual processing, the endoscope and its components should be completely immersed in the HLD solution, ensuring that all channels are filled with solution and air bubbles eliminated. Nonimmersible GI endoscopes should not be disinfected in liquids. The exposure time should be precisely measured.

NOTE—Air bubbles that are on the surface of the scope could interfere with the disinfectant to function properly on that site. Use a lint-free cloth to remove the air bubbles from the surface/exterior of the scope.

5.7.3 Liquid chemical sterilants/liquid chemical sterilization

Although the terms are similar, "liquid chemical sterilization" can be different from thermal and gas (or vapor) low temperature "sterilization." The FDA recommends that liquid chemical sterilization be used for heat-sensitive, critical medical devices only when traditional sterilization methods are not feasible or not available. The FDA believes that treatment with liquid chemical sterilants may not necessarily ensure the same sterility assurance as sterilization using thermal or gas/vapor low temperature sterilization methods.

Liquid chemical sterilization involves a two-part process:

a) Devices are treated with a liquid chemical sterilant (LCS).

b) The processed devices are rinsed with water to remove the chemical residues.

It is important to be aware of the implications for use of a liquid chemical sterilant. The rinse water may be treated to reduce bioburden but may not be sterile at the point of use. If the rinse water is not sterile, the sterility of devices rinsed with this water cannot be ensured. Furthermore, devices cannot be wrapped or may not be adequately contained during processing in a liquid chemical sterilant. This means that there is no way to maintain sterility once devices have been processed. The extended time (or other specified contact conditions) may not be compatible with some types of endoscopes. Refer to the endoscope manufacturer's written IFU for compatibility information and recommended cycles and suggested LCS/HLDs. Some LCS device sterilization claims are based on the AOAC Sporicidal Test. However, others support their device sterilization claim on both the AOAC Sporicidal Test and on their ability to kill 10^6 resistant spores, such as *Bacillus subtilis,* during simulated use testing with inoculated endoscopes.

Currently, there is a system utilizing a peracetic acid-based formulation and process designed for single use in an automated system that is FDA-cleared as a liquid chemical sterilant processing system. The system is cleared for liquid chemical sterilization of manually cleaned, immersible, reusable critical and semi-critical heat-sensitive medical devices, including endoscopes and their accessories. Refer to the manufacturer’s clearance information and written IFU for details on this system.

In all cases, the manufacturer’s written IFU for each LCS/HLD should be followed. When preparing use solutions (i.e., activated, diluted, or ready-to-use), the user should follow the LCS/HLD manufacturer’s written IFU concerning the quality of the water to be used in the formulation. For some LCSs/HLDs, it might be acceptable to use tap water; for other solutions, softened water or other treated water may be needed. If a water treatment process is used, it should be monitored to ensure that the appropriate water quality is achieved. When an endoscope is to be processed in an AER using an LCS/HLD (including multi-use or single-use), the device connectors should be correct for the specific brand and model of endoscope. Personnel should ensure that all endoscope channels are connected according to the manufacturer's written IFU, and that any support tray or accessories used are for the endoscope brand and model being processed. If the sterilant is being used manually or if a reusable LCS/HLD is used, perform all quality control checks according to the manufacturer’s written IFU. (see also Section 12.5). It is important to ensure in any manual process that all internal lumens and external surfaces of the device are contacted for the entire recommended exposure time.

All items processed with LCSs/HLDs should be thoroughly rinsed with strict adherence to the manufacturer’s written IFU. This will include the quantity and quality of rinse water, as well as the number of rinses and the time required for each rinse to reduce chemical residues to safe levels. The microbial quality of the water used to rinse endoscopes processed with LCSs/HLDs is an important aspect in the sterilization or high-level disinfection process. Users should follow the recommendations of the device manufacturer and the LCS manufacturer for the microbial quality of the water to be used for rinsing (see AAMI TIR34). If the device is not rinsed adequately, the sterility of the device may be compromised.

Determine in advance whether the endoscope is to be used immediately after processing. If it is to be used immediately, it should be unloaded from any AER, transferred directly into an aseptic transport device and sent to the

intended point of use. An LCS/HLD processed endoscope will be wet and unwrapped at the end of processing. An endoscope reprocessed with LCS/HLD that will not be used immediately can become recontaminated during storage and should be handled for storage as described in 10.2. Endoscopes intended to be used in a normally sterile area, should be reprocessed with LCS/HLD immediately before use and be transferred in an aseptic transport container or device with sterile technique to the patient and used immediately. Endoscopes should not be left in the AER to complete reprocessing the next day, but should complete the entire high-level disinfection process and be properly dried and stored for next use.

5.7.4 Manual liquid chemical sterilization/high-level disinfection

5.7.4.1 Disinfection

a) Don fresh PPE, including gloves and skin and eye protection.

b) Use a closed container, labeled with a biohazard symbol or sticker that meets OSHA requirements, of sufficient capacity to completely immerse the endoscope in the LCS/HLD solution.

c) Prepare LCS/HLD solution according to the manufacturer's written IFU, noting the type, date of preparation, date of use, and expiration date.

d) Test the MRC before each use with the disinfectant-specific (by type and concentration) test strip. Follow the label directions for the test strip. Document results.

e) Immerse the prepared endoscope and its removable components into the LCS/HLD solution, maintaining a loose coil.

f) Follow the endoscope manufacturer’s written IFU for filling channels with the LCS/HLD solution.

g) Follow the LCS/HLD solution manufacturer's written IFU for contact time, and temperature. Monitor process with a timer and thermometer and document. See also Section 12.3.

h) Document operator, date, time, make, and model of endoscope placed in solution. See also Section 12.3.

i) Document operator, date, and time endoscope is removed from solution.

5.7.4.2 Manual rinsing

a) Don fresh PPE, including gloves and skin and eye protection.

b) Thoroughly rinse all surfaces and channels of the endoscope and its removed components according to the endoscope and LCS/HLD solution manufacturers' written IFU in order to remove all traces of the disinfectant.

c) Use fresh water for each rinse (do not reuse the rinse water if multiple rinses are specified in the IFU). Follow the device manufacturer's written IFU for the specified rinse water quality.

5.7.4.3 Manual drying

Effective drying of endoscopes can reduce the risk of microbial contamination following high-level disinfection (e.g., recontamination of the endoscope by waterborne microorganisms during rinsing). Certain waterborne microorganisms, such as *Pseudomonas aeruginosa,* can pose an infection risk to a portion of the endoscopy patient population, especially those receiving a bronchoscopy procedure or endoscopic retrograde cholangiopancreatography (ERCP) procedure. Further, the presence of such microorganisms in conjunction with retained moisture can lead to the development of biofilms and further patient risk. This is a particular risk when tap water is used to rinse the endoscope following high-level disinfection.

Drying can be achieved by flowing air through all endoscopes channels for a specified period of time. Drying should be facilitated by using 70–80% ethyl or isopropyl alcohol. When using alcohol, personnel should follow the manufacturer’s written IFU on the volume of alcohol and method to be used for each endoscope lumen and ensure any remaining alcohol is removed with medical-grade forced air until no visual signs of moisture remain (or as otherwise recommended by the endoscope manufacturer). Refer to the endoscope manufacturer's written IFU for guidance on correlating the force of air pressure in psi or other measure to channel size. The use of syringes to dry channels is not recommended. Thoroughly dry all removable endoscope parts. To reduce the risk of trapping liquid inside the instrument, do not attach these parts (such as valves) to the endoscope during storage. Valves (including rinsing valves) should stay with a named endoscope as a set to prevent cross-infection and enable full traceability.

6 Automated endoscope reprocessors

AERs or endoscope washer-disinfectors are machines designed for the purpose of cleaning and/or disinfecting endoscopes and components. The disinfection process uses an LCS/HLD solution to achieve high-level disinfection. The AER includes automated immersion or spraying of the endoscope and filling of the endoscope channels with the LCS/HLD solution followed by timing of the exposure period and rinsing of the endoscope internal and external surfaces with water to remove the LCS/HLD solution residues.

Following disinfection or liquid sterilization, the scope and accessories should be removed from the solution or AER, preventing recontamination. PPE that were used for decontamination should not be worn when handling a scope or any of the accessories after they have gone through the disinfection process. PPE should be removed and hands washed. Clean gloves not manufactured with natural rubber latex or dried natural rubber latex should then be worn when handling the scope and accessories.

An automated process for cleaning and disinfection may be more efficient than manual processing. It may also result in less user exposure to toxic chemicals and help ensure repeatable results.

Some AERs use high pressure and flow rates to perfuse the endoscope channels, bathe the exterior of the endoscope, and circulate the LCS/HLD solution continuously during the exposure period. Most AERs also include automated cleaning and rinse cycles. The automated cleaning cycle is not intended to replace point of use precleaning or thorough manual cleaning of the endoscope prior to placing it into the AER. The AER manufacturer's written IFU should be compared to the endoscope manufacturer's written IFU. If there are discrepencies between the two, a decision should be made based on information that can be acquired from both companies.

AERs can automatically rinse the processed endoscope with water to remove toxic LCS/HLD solution residues. Only use LCS/HLD solutions whose recommended number of rinses can be programmed into the AER. Some AERs then flush the channels with forced air or with 70–80% ethyl or isopropyl alcohol followed by forced air to aid in drying the endoscope channels and to prevent growth of waterborne pathogenic microorganisms during storage that may have recontaminated the device during rinsing.

Some AERs have reservoirs with heating elements that will bring the temperature of the LCS/HLD solution to the indicated contact temperature for liquid chemical sterilization/high-level disinfection. Some HLD solutions are indicated for use at elevated temperatures and thus can only be used with an AER with the capability to maintain LCS/HLD solution temperature at the specified temperature.

If an AER cycle is interrupted, liquid chemical sterilization/high-level disinfection of the device cannot be ensured; therefore, the cycle should be repeated.

The microbial quality of the rinse water will vary and may recontaminate the processed device (AAMI TIR34). To avoid recontaminating the device with the rinse water, the incoming AER water should be at least filtered using bacterial retentive filters as recommended in the AER manufacturer's written IFU. The water handling systems, which do not come into contact with the LCS/HLD solution, should be disinfected on a regular basis as directed by the manufacturer. Some AERs have self-disinfection cycles using either an LCS/HLD solution or thermal methods. The water filters should be changed per the manufacturer’s written IFU. In addition, the endoscopes should be flushed with alcohol and purged with pressurized air prior to storage, as described in Section 5.7.4.3.

AERs are designed to provide flow of solutions to internal channels. Quality testing devices are available for many of the AERs to ensure that the solutions are flowing. To help ensure function of this equipment, testing should be performed at least weekly, after major repairs, or whenever there is a concern about equipment function.

An unexpected endoscope or AER malfunction or previously unrecognized device incompatibilities can occur. Processing area and infection prevention personnel should routinely review FDA advisories, manufacturer alerts, and the scientific literature for reports of endoscope and AER deficiencies that may lead to infection.

Depending on the make and model of the AER, additional features may include:

a) A printer for documentation

b) Adjustable cycle times

c) Ultrasonic cleaning capabilities

d) Channel detection for obstruction

e) Leak testing

f) Automatic rinsing

g) Automatic alcohol flush

h) Automatic air purge

i) Ability to process more than one endoscope at a time, either in the same or separate chambers

Regardless of the features, when looking at an AER one should consider several questions before purchasing:

j) Is it FDA cleared?

- Review the AER manufacturer's written IFU.
- Acquire and review white papers and other literature on the specific model/type of AER.

k) Can it reprocess the types of endoscopes currently in inventory?

- Has the AER manufacturer provided a list of each make and model of endoscope it can process?
- Has the endoscope manufacturer validated the use of an AER with their endoscope(s)?
- How will the AER manufacturer provide updates for new endoscopes that are introduced to the market after the purchase of the AER, and how will the AER process the new endoscopes?
- What type and how many different connectors/adapters are needed?
- Can the endoscope and endoscope components be effectively processed with the AER (e.g., the elevator guide wire channel of some duodenoscopes may not be effectively disinfected by most AERs and this step should be performed manually)?
- Are model-specific processing protocols from both the endoscope and the AER manufacturers compatible?

l) What accessories can the AER process?

- Is the AER cleared by the FDA to process any of the peripheral endoscopy accessories currently in the inventory?

m) Is the LCS/HLD solution that is used in the AER FDA cleared?

- Can more than one type of LCS/HLD solution be used in the model?

n) Is there sufficient space in the area for the unit?

o) What utilities and specifications are needed?

p) Does the processing area need any room or air monitoring while the AER is in operation?

q) Is an air handling system, such as a fume hood, needed?

r) If the AER has cleaning claims is it clear how those claims are applied to the current practice?

s) What is the recommended preventive maintenance? Who is certified and available to perform the maintenance?

Understand the frequency for servicing and who is responsible.

Cost is important but patient safety should always be the overriding factor when choosing any type of medical device. Consider purchasing cost; cost of engineering controls such as dedicated exhaust, gas monitoring equipment, and cost of installation; costs per cycle, including expenditures for service, support, energy, disinfectants, other consumables; and costs for personnel education, training, and competency verification.

Information about an AER to be purchased for cleaning and disinfecting flexible and semi-rigid endoscopes should be reviewed by a committee that includes risk management, infection prevention, nursing, and sterile processing personnel.

Other AER considerations may include:

t) Machine should ensure that recommended pressure of fluids and air is achieved through channel sensors.

u) Rinse cycles should follow the cleaning and liquid chemical sterilization/high-level disinfection cycles and then be followed by an automatic air purge to remove any fluids.

v) Machine should have a self-disinfection cycle.

w) Drying and/or alcohol flush cycle capabilities.

x) Machine should have a clogged or dirty filter alarm.

y) Whether compatible adaptors have been validated with specific endoscopes and are indicated in the AER manufacturer's written IFU.

z) Data verification of each cycle performed, such as a print record, should be available.

7 Sterile endoscope sheaths used as protective microbial barriers

Endoscope sheaths are available for use with specified endoscopes. The instructions for endoscope processing for some of these cleared devices recommend alternative processing instructions to conventional liquid chemical sterilization/high-level disinfection when the sheath remains intact after endoscope use. For these endoscopes and sheaths, the manufacturer's written IFU should be followed. If the processing instructions from the endoscope manufacturer and the endoscope sheath manufacturer appear to differ or to conflict, health care facility personnel should contact each manufacturer to request additional information and make their own decision based on all available information in conjunction with infection prevention personnel.

Endoscope sheaths have not been cleared for all types of endoscopes.

Endoscope sheaths may fall into two categories: sheaths that are intended to reduce the level of soiling of the endoscope, and sheaths that are intended to prevent endoscope soiling and thus serve as microbial barriers. Endoscope sheaths may be used as an accessory device in conjunction with laryngoscopes, cystoscopes, esophagoscopes, and bronchoscopes. The sheath is installed over the endoscope's insertion tube, and may also contain working channels through which irrigation, suction, and/or accessory equipment can be used.

For sheaths that are only intended to reduce the level of soiling of the device, after disposal of the single-use sheath, the endoscope should be cleaned and high-level disinfected or sterilized in accordance with the endoscope manufacturer's written IFU. For sheaths that are intended to serve as a microbial barrier, after use the sheath and the endoscope should be carefully inspected for leaks or other signs of sheath failure. If after inspection the sheath is believed to be intact and the entire endoscope appears visibly clean and dry, the user may follow the sheath manufacturer's written IFU for processing the endoscope, which typically recommend surface cleaning and wiping with 70%–80% ethyl/isopropyl alcohol. If the sheath is suspected to be compromised or if any portion of the endoscope (including the endoscope handle) appears soiled or wet, the endoscope should be thoroughly cleaned and high-level disinfected or sterilized according to the endoscope manufacturer's written IFU.

If the endoscope is to be used for the next patient without the sheath installed, the endoscope should be thoroughly cleaned and high-level disinfected or sterilized even though the sheath with the previous use appeared intact and the endoscope appeared visibly clean and dry.

8 Terminal sterilization by gaseous chemical sterilization processes

8.1 General considerations

With the infection risk that endoscopes present to the patient, terminal sterilization is the preferred method of microbial inactivation and the only option in sterile environments. Terminal sterilization is recommended for flexible and semi-rigid endoscopes that enter sterile body cavities. Terminal sterilization is required for all endoscope accessories that penetrate mucosa, such as biopsy forceps, sphincterotomes, etc. Steam sterilization is often not compatible with flexible and semi-rigid endoscopes, but should be used on compatible endoscopes whenever possible. Other compatible methods are ethylene oxide (EO), hydrogen peroxide (HP) gas, and ozone sterilization.

This section outlines special considerations for the terminal sterilization of flexible and semi-rigid endoscopes using gaseous sterilization processes. The primary sources of information for terminal sterilization of endoscopes are the endoscope manufacturer's FDA-cleared labeling and written IFU, followed by the sterilizer manufacturer's FDA-cleared labeling and written IFU. Users should use FDA-cleared packaging products for the selected sterilization technology.

8.2 Packaging for terminal sterilization

8.2.1 General considerations

It is important to select packaging that allows for sterilant penetration through the packaging and onto and into the endoscope. Many packaging types are available for gaseous chemical sterilization, including Tyvek® pouches, nonwoven textile wrap material, and rigid sterilization containers that maintain sterility. Select a product that is specifically labeled by its manufacturer for use in the intended sterilization method and the specific sterilizer model/cycle to be used.

Cellulose is contraindicated for use in many gaseous chemical sterilization processes, such as hydrogen peroxide gas.

The endoscope manufacturer's written IFU should include the sterilization packaging type, manufacturer, product codes, and sizes. If there are inconsistencies between the packaging manufacturer's and the sterilizer manufacturer's written IFU, consult both manufacturers before proceeding. The endoscope manufacturer should also provide the user with any special instructions for sterilization packaging (e.g., how to stabilize an endoscope on a tray, use of pressure caps, etc.). The user should follow the endoscope and packaging manufacturers' written IFU when selecting packaging whenever possible.

8.2.2 Sterilization pouches

When pouches are selected for sterilization it is important to use pouches that are labeled for the selected sterilization method, sterilizer model, and cycle as well as lumen dimension performance when available. This information can be found in the packaging manufacturer's written IFU. Choose a size large enough to contain the endoscope/component without tightly coiling, crowding, or twisting. If double-pouching is used, the user should confirm that double-pouching has been validated by the pouch manufacturer, and the pouch manufacturer's written IFU should be followed for double-pouching procedures. If the endoscope is to be double-packaged, two sequentially-sized pouches should be used (i.e., the sealed inner pouch should fit inside the outer pouch without folding). The use of double pouching should be validated by both the pouch manufacturer and the sterilizer manufacturer.

Sterilization pouches are generally either plastic/paper or plastic/Tyvek®. For sterilization with hydrogen peroxide gas, only the latter should be used.

8.2.3 Sterilization wraps

Wrap material selected for sterilization is labeled for the sterilization method/sterilizer model and cycle and load characteristics such as lumen dimensions for which it has been shown to be effective. Some sterilization wraps contain cellulose and are contraindicated for use in many gaseous chemical sterilization processes, such as hydrogen peroxide gas. When unsure about wrap compatibility with the proposed sterilization method or load characteristics, the user should refer to the wrap manufacturer's written IFU or contact the wrap manufacturer.

The user should follow the recommended wrapping procedures outlined in ANSI/AAMI ST79.

8.2.4 Rigid sterilization containment systems

Rigid containers should be selected for the sterilization method for which they have been cleared. Containers are tested and labeled for the specific gaseous chemical sterilization methods including the process type, sterilizer model, and cycles. Endoscope manufacturers may provide recommendations for rigid containers that are compatible with the device and both the container and endoscope manufacturer's written IFU should be followed.

Some sterilization containers are available with prepositioning bracketing or organizing tray inserts. When using these types of systems, it is important to load the containers according to the manufacturer's written IFU.

8.3 Ethylene oxide gas (EO) sterilization

EO sterilization is often used for flexible and semi-rigid endoscopes due to its broad range of material compatibility and potential to penetrate complex medical devices and long lumens. The endoscope manufacturer’s written IFU should be followed to ensure that the endoscope can be successfully sterilized in a legally marketed EO sterilizer and EO cycle, including aeration time. ANSI/AAMI ST41 provides some guidance for the use of EO sterilization in health care facilities.

The endoscope and accessories should be cleaned, dried, and prepared for sterilization according to the endoscope manufacturer’s written IFU.

The endoscope should be packaged in a material that is compatible with and FDA cleared for use in the EO sterilization process and cycle being used. Follow the endoscope and packaging manufacturer’s written IFU. Acceptable packaging listed may include:

a) polyethylene plastic bags (designed for use as a sterile package and not more than 5 mm thick);

b) peel pouches made of spun-bonded olefin (Tyvek®) polyethylene-polyester laminate, paper/polyethylene-polyester laminate, and paper/polypropylene-polyester laminate;

c) woven textile, nonwoven textile, paper, coated and uncoated wraps; and

d) rigid sterilization containers systems and plastic trays with paper or Tyvek® lids.

Loading of the sterilization chamber should not exceed the recommendations of the endoscope and sterilizer manufacturer's written IFU.

The endoscope manufacturer's written IFU should be followed to ensure effective sterilization. Endoscopes may present an added challenge to the aeration procedure due to trapped gasses in the channels of the endoscope, so the specific aeration time and temperature IFU should also be followed. A single-chamber process for EO sterilization and aeration should be used according to the EPA's 2008 regulations. The endoscopes should not be unloaded until the aeration cycle is complete.

EO sterilizers and their accessories are regulated by the FDA. The EPA registers EO as an antimicrobial pesticide under FIFRA. The OSHA EO standard 29 CFR 1910.1047 must be kept on file in each area using EO. This standard specifies the requirements for employee monitoring, sterilizer installation, engineering controls, medical surveillance, emergency situations, and other measures designed to protect employees from excessive exposure to EO. Consult the EO sterilizer manufacturer's written IFU, EO Safety Data Sheet (SDS), 29 CFR 1910.1047, and ANSI/AAMI ST41 for additional information.

8.4 Hydrogen peroxide gas sterilization

The endoscope manufacturer's written IFU for compatibility with HP gas sterilization cycles should be followed.

Longer thinner lumens or mated surfaces can present challenges for successful sterilization, including for HP sterilizers. The endoscope and sterilizer manufacturer's written IFU should be followed to ensure that the endoscope can be successfully sterilized in the HP gas sterilizer. The sterilizer's FDA-cleared labeling will indicate the types of materials and the lengths and diameters of lumens that can be successfully sterilized in HP gas sterilizers. Using the incorrect HP gas sterilizer model or cycle could result in the sterilant not penetrating the lumens of an endoscope, which may create a risk to the patient. ANSI/AAMI ST58 provides guidance on the use of HP gas sterilization in health care facilities.

The endoscope and accessories should be cleaned, dried, and prepared for sterilization according to the endoscope manufacturer's written IFU. The presence of water is detrimental to a successful HP gas sterilization process and will lead to cycle cancellation, so all water should be removed from the endoscope channels. In addition, the endoscope should be prepared for sterilization according to the endoscope manufacturer's written IFU.

The endoscope should be packaged in a material that is compatible with and FDA cleared for use in the HP gas sterilization process and cycle being used. Follow the written IFU of the endoscope and packaging manufacturers. No cellulose-based product (e.g., tape, wraps, peel pouches, mats, or other accessories) should be used inside or outside of the package because these types of packaging absorb the HP and reduce the concentration of HP to a level that will not achieve sterilization. Acceptable packaging listed in ANSI/AAMI ST58 includes:

a) peel pouches made of Tyvek®-Mylar®;

b) polypropylene wrap; and

c) rigid sterilization container systems cleared for use in the specific type of HP gas sterilizer.

Loading of the sterilization chamber should not exceed the recommendations of the endoscope and sterilizer manufacturer's written IFU, and the recommendations in ANSI/AAMI ST58 should also be followed.

Care should be exercised by the sterilizer operator to avoid contact with liquid hydrogen peroxide. Liquid hydrogen peroxide used for HP gas sterilizers is very concentrated and can cause severe burns upon contact with exposed skin. Highly concentrated hydrogen peroxide is very reactive and can cause fire when it comes in contact with certain materials. The user should consult the sterilizer manufacturer's SDS prior to operation of the sterilizer. During removal from the sterilization chamber, the user should check the load contents to ensure that no liquid hydrogen peroxide remains on the packaging as this can lead to occupational injury risk for the user.

HP sterilizers and their accessories are regulated by FDA. EPA registers HP as an antimicrobial pesticide under FIFRA. While there is no specific OSHA HP standard, the OSHA permissible exposure limit (PEL) for hydrogen peroxide is 1 ppm calculated as an 8 hour time weighted average (29 CFR 1910.1000). Consult the HP gas sterilizer manufacturer's SDS and ANSI/AAMI ST58 for additional information.

8.5 Ozone sterilization

Sterilization of flexible and semi-rigid endoscopes with ozone is conducted in a sterilizer using ozone generated within the sterilizer. The endoscope manufacturer's written IFU for compatibility with different ozone sterilization cycles should be followed.

Ozone sterilization does not have the ability to penetrate as well as EO gas. Therefore, longer, thinner lumens or mated surfaces can present challenges for successful sterilization. The sterilizer's FDA-cleared labeling should indicate the lengths and diameters of lumens that can be successfully sterilized in ozone sterilizers. Again, the endoscope and sterilizer manufacturer's written IFU should be followed to ensure that the endoscope can be successfully sterilized in an ozone sterilizer. ANSI/AAMI ST58 provides guidance for the use of ozone sterilization in health care facilities.

The endoscope and accessories should be cleaned, dried, and prepared for sterilization according to the endoscope manufacturer's written IFU.

The endoscope should be packaged in a material that is compatible with and FDA cleared for use in the ozone sterilization process and cycle being used. Follow the written IFU of the endoscope and packaging manufacturers. Acceptable packaging listed in ANSI/AAMI ST58 includes:

a) peel pouches made of nonwoven material; and

b) rigid sterilization containers systems cleared for use in the specific type of ozone sterilizer.

Loading of the sterilization chamber should not exceed the recommendations of the endoscope and sterilizer manufacturer's written IFU.

The endoscope manufacturer's written IFU should be followed to ensure effective sterilization. Processed endoscopes require no aeration time at the end of the sterilization cycle.

Ozone sterilizers and their accessories are regulated by the FDA. The EPA regulates ozone as an antimicrobial pesticide under FIFRA. While there is no specific OSHA ozone standard, the OSHA PEL for ozone is 0.1 ppm calculated as an 8 hour time weighted average (29 CFR 1910.1000). Consult the ozone sterilizer manufacturer's SDS and ANSI/AAMI ST58 for additional information.

NOTE—The FDA regulation for ozone producing devices is 21 CFR 801.415, *Maximum acceptable level of ozone.* The regulation indicates that an ozone generating device will be considered adulterated and/or misbranded within the meaning of sections 501 and 502 of the act if it generates ozone at a level in excess of 0.05 ppm by volume of air circulating through the device or causes an accumulation of ozone in excess of 0.05 ppm by volume of air in the atmosphere of enclosed space intended to be occupied by people for extended periods of time.

9 Processing of endoscope accessories

Processing of certain reusable endoscope components such as air/water and suction valves, biopsy port covers, water bottles, and tubing require the same level of inspection, cleaning, and high-level disinfection or sterilization as the endoscopes themselves.

Reusable endoscopic accessories (e.g., biopsy forceps, other cutting instruments) that break the mucosal barrier should be mechanically cleaned as described previously and then sterilized between each patient use (high-level disinfection is not recommended).

Before manual or mechanical high-level disinfection, remove and clean valves, connectors, and all detachable parts. Disconnect and disassemble endoscope components and completely immerse the endoscope and components in a cleaning solution that is compatible with the accessories, according to the manufacturer's written IFU. Repeatedly actuate the valves during cleaning to facilitate access to all surfaces. Continue to brush and flush the valves until no visible soils remain. Alternately, consider the use of single-use, disposable valves.

Valves may then be immersed in a high-level disinfection solution, following the manufacturer's written IFU for disinfectant contact time and rinse requirements. Repeatedly actuate the valves during disinfection and rinsing to facilitate access to all surfaces. Alternately, valves may be placed in an AER if it has been cleared for the processing of valves and in accordance with the AER manufacturer's written IFU.

Manually clean and high-level disinfect or sterilize the water bottle (used for cleaning the lens and for irrigation during the procedure) and connecting tube according to manufacturer's written IFU, or at least daily.

Only those accessories validated for processing in the specific AER should be processed in that AER. Water bottles may not drain completely, resulting in diluted HLD solution. Irrigation tubing requires flow of disinfectant and rinse

water through the length of the tubing. Consult the manufacturer of the peripheral accessory, or consider the use of disposable water bottle connectors or irrigation tubing, which are used with bottles of sterile water.

10 Storage of reprocessed endoscopes

10.1 General Considerations

The endoscope should be hung vertically with the distal tip hanging freely in a well-ventilated, clean area, following the endoscope manufacturer's written IFU for storage. For example, make sure that the insertion tube hangs vertically and is as straight as possible (no bends). If the scope has an angulation lock, it should be in the open position while in storage. There should be sufficient space between and around scopes to prevent them hitting into one another, which can cause damage to the scopes. All removable parts (e.g., valves and caps) should be detached from the endoscope. To keep the parts together with the scope, a small bag or similar device can be used to attach the parts to the scope.

Rationale: When flexible and semi-rigid endoscopes are hung in the vertical position, coiling or kinking is prevented, allowing any remaining moisture to drain out of the endoscope and decreasing the potential development of an environment conducive to microbial growth in the endoscope. Following recommended storage practices facilitates drying and decreases potential for contamination. All valves and other accessories should be removed in preparation for drying. The scope protector may create an environment favorable for microbial growth if the endoscope is not dry and cannot hang straight (Thomas, 2005; Goldstine, 2005; Bisset et al., 2006). Storing endoscopes with valves or caps on the scope will trap residual moisture in the internal channels and provide optimal conditions for microbial growth.

AORN (2015e) recommends that flexible and semi-rigid endoscopes should be stored in a closed cabinet with venting that allows air circulation around the endoscopes, internal surfaces composed of cleanable material, adequate height to allow endoscopes to hang without touching the bottom of the cabinet, and sufficient space for storage of multiple endoscopes without touching.

Rationale: A storage area with good ventilation encourages continued air-drying of the surfaces and prevents excessive moisture buildup, thus discouraging microbial contamination. Correct storage of the endoscope will also prevent damage to the exterior of the instrument by protecting it from physical impact.

NOTE—Some flexible fiberoptic endoscopes require storage with the venting cap (for ethylene oxide) applied. Some models of videoscopes also have venting caps. The manufacturer's instructions for storage of the specific scope in use should be followed.

The CDC recommends that a policy and procedure be developed to ensure that end-users know whether a particular endoscope has been cleaned and high-level disinfected or sterilized, because when a user leaves an endoscope on a cart or other surface, the status of the scope (used or unused) might not be clear (CDC, 2008). Develop protocols to ensure that users can readily identify an endoscope that has been processed and is ready for patient use. Attach a tag or label (or other method) to document that the scope has been cleaned or high-level disinfected. The tag or label is affixed to the endoscope after it has been processed and before it is placed in the storage cabinet. For quality assurance, the tag should be labeled with the following information:

a) Date of processing

b) Name(s) of person(s) who performed the processing

c) Date of high-level disinfection

Store endoscopes in a manner that will protect them from damage or contamination.

Some endoscope storage cabinets feature HEPA-filtered air that is used to provide positive pressure in the cabinet and reduce the incidence of possible bacterial contamination. Some cabinets provide HEPA-filtered air through each endoscope channel, as well as the air in the cabinet itself.

The endoscopic personnel need to understand the role moisture plays in contributing to microbial growth after the high-level disinfection process.

To help ensure that no moisture is left on or in any part of the endoscope all channels should be flushed with 70–80% alcohol to facilitate drying (see Section 6).

All channels should be purged with filtered medical grade air at the correct psi (outlined in the manufacturer's written IFU for that specific scope) (see Section 6).

Special storage cupboards or cabinets designed for endoscopes are commercially available that assist the drying process by means of special ventilation methods, using filtered air or container systems. Regardless of whether a special cabinet is used, the temperature and humidity in the area where the scopes are stored should be monitored.

Do not use the carrying case designed to transport clean and processed endoscopes outside of the health care environment to store an endoscope or to transport the instrument within the health care environment.

10.2 Storage of high-level disinfected endoscopes

Before storage, the channel of the high-level disinfected endoscope should be dry to help prevent bacterial growth and the formation of biofilm. The endoscope should hang in a way to prevent damage to the scope and prevent the formation of moisture. Special care should be taken to avoid coiling of any part of the endoscope to reduce chances of any droplets forming within the channels. Endoscopes should be stored suspended vertically in a way to allow circulation of air. Endoscopes should hang freely. Caps, valves and other detachable components should not be installed on the endoscope during storage. Detachable parts that are to be reused (e.g., air/water and suction valves/pistons) should be processed together and stored with the specific endoscope as a unique set in order to allow traceability. Valves should be dried and lubricated according to the manufacturer's written IFU. Each scope should be identified with a tag or other means so that when it is pulled from storage, the user is able to verify that the scope has been processed and is ready for use.

10.3 Storage of sterilized endoscopes

Sterilized endoscopes should be stored in the container or packaging in which they were sterilized. Agreement should be made between the user and the sterile processing area on a maximum shelf life for the sterilized endoscope. Steps should also be taken to ensure that stock rotation occurs between all sterilized scopes. Follow ANSI/AAMI ST79 for recommended sterile storage conditions.

10.4 Hang time for high-level disinfected endoscopes

10.4.1 General considerations

The accepted time interval ("hang time" or shelf life) for the storage of processed endoscopes before they can no longer be considered safe for patient use is not well defined. There are a limited number of studies addressing this issue. The available data suggest that the risk of contamination is negligible when storage is done according to the endoscope manufacturer's written IFU and/or standards related to endoscope processing. One study concluded that contamination identified during early storage could not be found the longer the endoscope was stored. This suggests that in some cases, prolonged storage may not be associated with a risk for contamination (Vergis, et al., 2007). There are currently no known studies that have shown that prolonged "hang time" is a risk factor for adverse patient outcomes.

10.4.2 Existing guidelines

A number of guidelines and recommended practices provide recommendations as to the maximum duration of storage time before the endoscope is processed for the next use. Some of these are summarized below:

a) AORN: AORN guidelines recommend that endoscopes be reprocessed before use, if not used for more than five days. (AORN, 2015e).

b) United States Department of Veterans Affairs, Veterans Health Administration: The Veterans Health Administration currently follows a directive to process unused endoscopes after 12 days of hang time. (VA 2014).

c) Gastroenterology Association of Australia: Gastroscopes, colonoscopes, radial EUS endoscopes need to be disinfected prior to use, when the storage time of 72 hours is elapsed. Duodenoscopes, bronchoscopes and linear EUS endoscopes need to be disinfected prior to use, when the storage time of 12 hours is elapsed. Those endoscopes only used in emergency should be routinely processed every 72 hours to ensure they are ready to be used at any time. For Enteroscopes the time is 72 hours if stored with continuous flow air, 12 hours if not. If recent culture results have been positive or if adequate storage facilities are not available, endoscopes should be disinfected prior to use if the storage time has been longer than 12 hours. Extended storage is only permitted if recent (within 12 months) routine microbiological surveillance of the endoscope has shown negative culture results. (Infection Control In Endoscopy 2011)

d) West Coast District Health Board, New Zealand: The endoscope can be stored in correct storage conditions for up to 72 hours without having to be processed prior to use. (West Coast District Health Board, New Zealand, reviewed February 2013)

e) Canadian Standards Association: Endoscopes for gastrointestinal procedures should be processed if storage exceeds 7 days. (Canadian Standards Association, 2008)

f) NHS Scotland: Only use endoscopes directly from storage if stored for less than 72 hours in a purpose built cabinet providing HEPA filtered air drying. (NHS National Services Scotland, Dec 2004, amended Sep 2007)

g) HSE Standards and Recommended Practices for Endoscope Reprocessing Units, Ireland: After the drying process a conditioning process guarantees the endoscope maintains its condition for up to 72 hours or as specified by the manufacturer. (Health Service Executive Standards and Recommended Practices for Endoscope Reprocessing Units).

10.4.3 Risk assessment

A number of guidelines and recommended practices provide recommendations as to the maximum duration of storage time before the endoscope is processed for the next use. Due to the lack of consensus and evidence on the storage time, it is recommended that the health care facility conduct a risk assessment to determine the maximum storage time for an endoscope before it needs to be processed to use on the next patient. Items for consideration in the risk assessment include:

a) complexity and type of endoscope (lumened or non-lumened).

b) condition of the endoscope after processing (e.g., dry or wet; flushed with alcohol prior to storage, forced air purged, etc.).

c) method of transporting the endoscope from processing to storage (use of fresh/clean gloves, removal of the endoscope in a clean environment, whether aseptic technique was used to remove the endoscope from the AER, and whether the gloves and gown worn by personnel placing the endoscope in the AER were changed before removal).

d) conditions of storage environment (i.e., air-filtered or not air-filtered, temperature and humidity conditions, restricted access location, etc.).

e) excess handling during storage.

f) manufacturer's written IFU for storage.

g) compliance with professional organization guidelines for storage.

h) relevant research studies.

i) protective devices used to prevent contamination.

j) frequency of use.

k) patient population.

l) frequency, type, and results of quality monitoring of processing.

m) quality of final rinse water (see AAMI TIR34).

Based on the results of the risk assessment, the health care facility should develop policies and procedures to address the maximum endoscope storage time. The facility should define circumstances or conditions that may occur during storage in which an endoscope should be reprocessed before use on the next patient (i.e., likely contamination with a water source, contact with surrounding environment, etc.).

Health care facilities should address cases where processing is to be done when the established maximum storage time has been exceeded (i.e., immediate processing or processing before the next patient use). Currently, there are limited data to give a definitive answer as to best practices for this question. Health care facilities should consider the likelihood and the ease of compliance with increased processing and additional wear on the endoscopes.

Table 2—Endoscope storage risk assessment checklist

Storage of high-level disinfected endoscopes	Yes	No	Action
Endoscopes are stored so that residual fluid does not remain in the channels			
Endoscopes are stored, with their detachable parts dismantled, in a manner that keeps them secure and together with the endoscope as a unique set			
Endoscopes are stored in a vertical non-coil position			
Tracking is available for each endoscope, including last episode of HLD			
If a storage cabinet is used, all manufacturer's written IFU should be followed and documented			
Storage of sterilized endoscopes	**Yes**	**No**	**Action**
Endoscopes are rotated according to policy			
Storage conditions are monitored according to ANSI/AAMI ST79			
Endoscopes are identified and labeled			

11 Transport of high-level disinfected endoscopes

When transporting an endoscope that has been high-level disinfected, the endoscope should be protected from recontamination. Before removing the endoscope from the storage cabinet, don new exam gloves. Then transport the endoscope using an impervious barrier method that will prevent re-contamination. Examples would be a clean plastic bag, endoscope transfer system (scope in a tote bin with a cover), or similar method. The endoscope should be loosely coiled to prevent damage. The transport system should not be reused for clean transport.

Rationale: Disinfected endoscopes can become recontaminated by hands and or communication with surfaces while being handled and transported. Use of a barrier system can prevent recontamination.

12 Quality Control

12.1 General considerations

This section covers aspects of product identification and traceability, documentation and record-keeping, verification and monitoring of the cleaning process, monitoring of high-level disinfection and sterilization processes, product recalls, and quality process improvement.

Quality control is a critical aspect within endoscope processing procedures. In all cases, manufacturers' written IFU including the endoscope device, processing equipment, and other products used in processing should be followed.

NOTE 1—Quality control is usually thought of only as product and process monitoring. In its broadest sense, however, quality control involves verification and monitoring of personnel performance and work practices and adherence to established policies and procedures.

The health care facility should establish a comprehensive quality assurance and safety program for all aspects of endoscope processing. The program should:

a) Identify all personnel involved in endoscopy procedures, specifying their position descriptions and responsibilities.

b) Identify all facility areas where endoscopes are used and processed.

c) Identify all endoscopes, endoscope accessories, and endoscope processing equipment used in the facility, including manufacturer, model, serial number or facility specific identification number, and unique device identifiers (UDIs).

d) Identify the storage location, age, and status (e.g., maintenance schedule) for each endoscope.

e) Verify that the endoscopes and accessories used in the facility and new equipment are compatible with facility processing equipment and supplies based on the manufacturers' written IFU. If the labeling is unclear regarding compatibility, the manufacturer should be contacted.

f) Incorporate visual inspections and testing of the equipment to identify conditions that may affect the cleaning or disinfecting processes, such as testing for leaks, examination for cracks, and checking the integrity of fiber optic bundles. Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures.

g) Include the use of process monitors as recommended by the AER, LCS/HLD, and sterilizer manufacturers.

h) Develop and implement procedures that address specification evaluation, acquisition management, scheduled maintenance, and removal of equipment from use.

i) Verify that all manufacturer-recommended maintenance schedules and services are performed for all endoscopes and processing equipment (e.g., AERs and sterilizers) used in the facility.

j) Maintain records of the use of each endoscope, including model, serial number, and unique facility identifier or standardized UDI.

   - Records should document the patient upon whom the endoscope was used, the date and time of use, the location of use, and the type of procedure performed.

   - Records should also show the system (model and serial number of the AER or sterilizer if applicable) used to reprocess the endoscope and the identification of the person(s) responsible for processing the endoscope.

k) Assign personnel responsibilities for tracking the useful life of endoscopes and accessory equipment, including equipment and supplies for processing.

l) Document the introduction (and withdrawal from use) of all endoscopes, endoscope accessories, AERs and AER accessories such as endoscope connection devices, and sterilizers.

m) Establish and document education, training, and competency verification programs for all personnel responsible for processing endoscopy equipment and outline schedules for periodic education and training updates and competency verification.

n) Establish procedures for storage of processed endoscopes prior to patient use.

o) Establish a method for detecting clusters of infections or pseudoinfections associated with endoscopic procedures (e.g., a surveillance system).

   - If a cluster is discovered, it should be reported to the manufacturers of the endoscope and the endoscope accessories, as well as to the facility infection prevention personnel, the FDA's MedWatch, and other relevant regulatory agencies.

p) Establish a procedure to investigate lapses in processing.

q) Include the use of engineering controls such as exhausts, gas monitors, environmental controls (temperature, humidity, air flow) and records of equipment performance and maintenance as well as employee training as applicable.

NOTE 2—At the time of publication, AAMI was aware that the CDC is considering microbial sampling of endoscopes. No recommendation is made at this time.

12.2 Product identification and traceability

Each item or package intended for use should be labeled with a lot control identifier. The lot control identifier should designate:

a) the identification number or code of the sterilizer, AER, or soaking container;

b) the date chemical sterilization or high-level disinfection was performed;

c) the sterilization or high-level disinfection cycle number; and

d) the patient identifier.

The health care facility's policy should determine when the lot control information is affixed to the package or correlated to the endoscope.

Items that are processed for immediate use by means of an LCS/HLD soaking system require a means of identification of the items processed.

The lot control information is preferably affixed to the package or device (e.g., label or tag) or otherwise associated with the endoscope (e.g., logbook).

Rationale: Lot identification enables personnel to retrieve items in the event of a recall and to trace problems to their source. Quality control measures (e.g., the use of conventional BIs) might not yield results until after the processed load has been used. Quality control record-keeping is critical and relies heavily on historical data, especially where quality control measures yield conflicting evidence. Record-keeping is needed for both epidemiological tracking and ongoing assessment of the reliability of chemical sterilization and high-level disinfection processes.

12.3 Documentation and record-keeping

12.3.1 Documentation

For each chemical sterilization or high-level disinfection cycle, the following information should be recorded and maintained:

a) assigned lot number, including chemical sterilizer, AER, or soaking container identification and cycle number;

b) specific contents of the lot or load, including quantity, processing area, and a description of the items;

c) patient’s name and unique patient identifier;

d) procedure, physician, and, if applicable, serial number or other identification of the item;

e) shelf-life date, if applicable, the lot number, and the date that the original container of LCS/HLD was opened; the use-life of the open container; the date that the product was activated or diluted; the date that the activated, diluted, or ready-to-use solution was poured into a secondary container; and the reuse-life of the solution;

f) exposure time and temperature, if not provided on the physical monitors;

g) date and time of cycle;

h) LCS/HLD type and concentration; pH test results if required by facility policy or manufacturer's written IFU.

i) name or initials of the operator;

j) results of BI (terminal sterilization) or spore test strip (liquid chemical sterilization process), if applicable;

k) results of CI testing, if applicable;

l) results of MRC or MEC solution monitoring strip, if applicable;

m) results of the quality control of test strips, if applicable;

n) any reports of positive BIs or spore test strips, inconclusive or nonresponsive CIs or low MRC or MEC testing results (as indicated by solution test strips or chemical monitoring devices); and

o) any reports of positive microbial contamination testing.

The recording chart, printer, or tape, if applicable, should also be dated and maintained, and the operator should review and sign each cycle. A record of repairs and preventive maintenance should also be kept for each sterilizer, AER, and soaking container. Data on personnel exposure should also be recorded, as applicable. All recorded information may be incorporated into a paper log or, preferably, an electronic record-keeping system or may be filed as individual documentation records. All records should be retained in the GI/endoscopy or sterile processing area or another designated storage area for a period of time not less than that specified by state or local statutes and legal considerations (e.g., statutes of limitations for lawsuits). If statutes are not specific, record retention should be determined in conjunction with the facility's risk management personnel, legal counsel, and infection prevention personnel.

Rationale: Documentation helps ensure monitoring of the process as it is occurring, verifies that critical cycle parameters have been met, and establishes accountability. In addition, documentation helps personnel determine whether recalls are necessary and the extent of recalls, if evidence subsequent to lot release, such as a positive BI or spore test strip, nonresponsive CI, failed solution test strip, or chemical monitoring device suggests sterility or processing problems. Knowing the contents of the lot or load enables personnel to decide how critical a recall might be. Digitization of the process can allow quick access to load information, thus facilitating a quick response. In addition, this documentation provides evidence of a processing area's quality control program. Electronic records of process monitoring results, including specific load item identification, are recommended because of their better legibility, accuracy, traceability, security, and data integrity. The length of time to retain sterilization and/or high-level disinfection records depends on many different factors and may vary from facility to facility depending on policy and applicable regulations.

12.3.2 Expiration dating

Each packaged item in a sterilization load should be labeled with a control date for stock rotation and the following statement (or its equivalent): "Contents sterile unless package is opened or damaged. Please check before using." This information can be incorporated into the lot identification on the label or imprinted or affixed separately on the outside of the package. If the product contains material that degrades over time (e.g., latex), the product package should be labeled with a clearly identifiable expiration date that takes this degradation into account or is based on the device manufacturer's written IFU. If a time-related shelf-life system is used, the product package should be labeled with an expiration date.

Rationale: Labeling items with a lot control number and an expiration statement or (when applicable) expiration date is necessary for stock rotation.

12.4 Verification and monitoring of the cleaning process

12.4.1 General Considerations

Cleaning verification tests are performed following cleaning and are used to verify the effectiveness of a cleaning process to remove or reduce to an acceptable level the organic soil and microbial contamination that occurs during the use of an endoscope.

When developing a user verification procedure for the cleaning process, reprocessing personnel should ensure that:

a) The endoscope manufacturer has completed validation of the recommended cleaning process and provided a written IFU detailing the process.

b) The facility has established, clarified, and documented a standard cleaning process for the device (see Section 5).

c) Facilities should develop a defined program of cleaning verification that includes frequency of testing, number, and types of endoscopes to be tested.

d) Cleaning verification results are documented.

e) The facility has established, clarified and documented a process to address cleaning verification failures.

f) The facility has established an education, training, and competency assessment program that verifies personnel are consistently achieving the expected level of cleaning.

12.4.2 Cleaning verification

Cleaning verification of flexible and semi-rigid endoscopes by users should include:

a) Visual inspection combined with other verification methods (see Section 12.4.3) that allow the assessment of both external surfaces and internal housing and channels.

b) Testing of the cleaning efficacy of mechanical equipment.

c) Monitoring of key cleaning parameters (e.g., temperature).

Studies have shown that when cleaning tubular devices, the achievement of visible cleanliness and adequate microbial reduction varies greatly, depending on the type of water and cleaning solution used for cleaning. The variability of results for lumens cleaned by automated washers underscores the importance of in-use verification for manual cleaning, which is generally less efficient than mechanical cleaning (Zuhlsdorf et al. 2002).

Several methods can be used to evaluate the results of the cleaning process. The most common is visual inspection. Careful visual inspection should be conducted to detect the presence of any residual soil. Inspection using magnification and additional illumination might identify residues more readily than the unaided eye. Users should inspect every device for visible organic soil and contamination in a simple functionality test. Direct visual inspection is not always possible for the inner components of medical devices that have lumens or that are of nonsealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, and biopsy forceps). Tools such as video boroscopes of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels of some medical devices.

Residual organic soil and microbial contamination may be present on an accessible surface even though the device looks clean (Visrodia et al. 2014). Visual inspection is not possible for the inner components of medical devices that have lumens or that are of non-sealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices and biopsy forceps). The use of methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be considered and included in facility policies and procedures on device cleaning.

12.4.3 Cleaning verification tests for users

ANSI/AAMI ST79, Annex D, provides information related to user verification of cleaning procedures and cleaning equipment. Tables D.1 and D.2 summarize the currently available test methods that apply to in-use evaluation of, respectively, efficacy of cleaning of medical devices and efficacy of washer-disinfectors used for flexible and semi-rigid endoscope processing.

Several technologies are available that can be used to measure the levels of organic soil and microbial contamination on the cleaned device. The published studies that have evaluated the specific markers that can be used to determine cleaning efficacy have indicated that the following markers are useful for benchmarking purposes by the user. They include protein, carbohydrate, hemoglobin (blood), adenosine triphosphate (ATP) and an enzyme that detects specific bacteria (Alfa 2012, Alfa 2013, Alfa 2014, Visrodia 2014).

Two basic components of user verification of cleaning efficacy are:

a) Establishing a reasonable benchmark. This is the level of cleaning that can be achieved consistently using specific soil markers relevant to devices used for patients.

b) Using rapid, easy-to-perform methods that reliably demonstrate that the cleaning benchmarks have been achieved.

Realistic benchmarks depend on what can be achieved by routine cleaning and the limit of detection of the method used. Data indicate that for flexible endoscopes that have been cleaned after use on patients, the average levels of soil markers in the suction biopsy channel are as follows: protein, <6.4 µg/cm^2, carbohydrate, <1.8 µg/cm^2, hemoglobin, <2.2 µg/cm^2, sodium ion, <1 µmole/cm^2, endotoxin, <2.2 EU/cm^2, bioburden, < 4 $\log_{10}$ CFU/cm^2 and 200 RLU for ATP (Alfa 2002, Alfa 2012, Alfa 2013).

NOTE—Different ATP manufacturers use different scales. Check with the specific ATP manufacturer's written IFU for their recommended pass/fail threshold RLU values

The benchmarks for residual soil and bioburden levels after cleaning might become more definitive as more data become available and/or more efficient cleaning methods are developed. Users should review current literature along with the manufacturer's data to formulate policies and procedures for verification of cleaning efficacy. A recent study has shown that some of the above mentioned benchmarks can be significantly lowered due to the increase in cleaning efficacy achieved by automated pump-assisted cleaning. The proposed thresholds are as follows: Bioburden < 2 $\log_{10}$ CFU/cm^2, Protein, < 2 µg/cm^2 and <200 RLU for ATP (Alfa 2014).

Rationale: Benchmark levels differ between manufacturers and cleaning verification methods.

12.4.4 Testing cleaning efficacy

The facility's onsite quality assurance program should include ways to verify that the cleaning equipment used for processing of medical devices is working. Testing the equipment upon installation, during routine use (daily) and on all cycles used, after repairs, and when changing to a new type of cleaning solution allows the user to verify its continued effectiveness (ANSI/AAMI ST79; AORN, 2015a). Manufacturer's written IFU should be consulted for recommendations of types and frequency of cleaning efficacy testing.

The frequency of testing the efficacy of the manual cleaning step should occur on a regular basis, weekly or preferably daily (Drosnock 2014, Alfa 2014).

Rationale: Meticulous manual cleaning is essential for the removal of organic contamination that can interfere with high-level disinfection. The manual cleaning step is prone to error (Dirham-Langley 2013, Ofstead 2010, ASGE 2008, ASGE 2011) and therefore should be monitored on a basis at least as frequently as is recommended for the cleaning equipment (see ANSI/AAMI ST79). This testing should include at a minimum monitoring of the suction/biopsy channel (ANSI/AAMI ST58).

12.5 Monitoring processes that use liquid chemical sterilization/high-level disinfection

12.5.1 Manual processes

12.5.1.1 Use of physical monitors

Physical monitoring of manual liquid chemical sterilization/high-level disinfection processes using a thermometer and timer should be completed for each cycle. The results of physical monitoring should be documented (see 12.3.1).

Thermometers, timers, and other monitoring equipment should have their calibration verified periodically, according to facility policy, to help ensure their accuracy and precision.

The solution should be visually inspected before each use and discarded if precipitates (e.g., crystallization, particulate matter) are observed, even if the solution is within its use-life (consult the solution manufacturer's written IFU for specific guidance). Visual inspection should also ensure that the solution container is covered to prevent evaporation of the solution and exposure to light, both of which can affect the efficacy of the chemical agent. Visual observations should be documented.

If the interpretation of the physical monitors or visual inspection of the solution suggests inadequate processing, the items should not be dispensed or used. Follow-up measures should be initiated per facility policy.

Rationale: Physical monitoring is needed to help ensure that the parameters are correct for every cycle and to detect malfunctions as soon as possible so that corrective action can be taken.

12.5.1.2 Solution test strips or chemical monitoring devices

12.5.1.2.1 General considerations

Solution test strips or chemical monitoring devices are designed to determine whether the concentration of the active ingredient in the LCS/HLD solution is above or below the MRC or MEC for the LCS/HLD. These solution test strips or chemical monitoring devices assist the user in determining when the solution should no longer be used. All solution test strips or chemical monitoring devices should be used according to their manufacturer's written IFU.

12.5.1.2.2 Using solution test strips or chemical monitoring devices

Processing personnel should use the solution test strip or chemical monitoring device cleared by the FDA for use with a specific LCS/HLD product. The manufacturer's written IFU should provide information on the reliability, safety, and performance characteristics of the product, including the interpretation of the solution test strip or chemical monitoring device reaction, the MRC or MEC that the solution test strip or chemical monitoring device is designed to detect, and the shelf life and storage requirements. Any necessary efficacy testing of the solution test strip or chemical monitoring device should be performed according to their manufacturer's written IFU.

Rationale: Solution test strips or chemical monitoring devices are needed to detect inadequate concentration of the active ingredient of the LCS/HLD.

12.5.1.2.3 Frequency of use

Processing personnel should use the recommended solution test strip or chemical monitoring device to test the LCS/HLD solution. The solution should be tested before or during each use (ASGE, 2011). If the solution test strip or

chemical monitoring device indicates that the concentration of the active ingredient is inadequate, the solution should not be used. The solution test strip or chemical monitoring device manufacturer's written IFU for testing, storage of the strips and reagents, interpretation of results, and expiration should be followed.

Rationale: If the LCS/HLD has a reuse claim or is a single-use product that is prepared on site, the manufacturer should provide or identify a solution test strip or chemical monitoring device to be used with the product. The concentration of an active ingredient in the LCS/HLD solution will decrease with dilution by water, the presence of organic or other extraneous materials, and exposure of the solution to light. Checking the concentration of the active ingredient before use can reduce the risk associated with use of an ineffective LCS/HLD solution.

12.5.1.2.4 Interpretation

The solution test strip or chemical monitoring device should be read before the LCS/HLD solution is used. Processing personnel should receive education, training, and complete competency verification regarding the performance characteristics of the solution test strip or chemical monitoring device to be used.

Users should follow the manufacturer's written IFU when interpreting solution test strips or chemical monitoring devices. If the interpretation suggests that the concentration of active ingredients is inadequate, the solution should be discarded even if it is within its use life. Suppliers of solution test strips or chemical monitoring devices that change color often provide visual color interpretation reference charts. If available, these charts should be obtained and used for education of and reference by processing personnel.

Color-blind testing should be done for all processing personnel to ensure that they will be able to compare the test strip results to the interpretation reference charts.

Rationale: If the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate, the items may not have been adequately reprocessed and therefore should not be used.

12.5.1.2.5 Inadequate processing

If the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate and if items have been processed in this ineffective solution and used, the following actions should be taken to identify these items:

a) The supervisor or other designated person and the designated infection prevention personnel should be notified immediately, and this notification should be followed by a written report. The report and notification should include:

   - the time and date of the questionable processing cycles;
   - a description of the soaking or processing container and the load, including lot control numbers, product and patient names, and other identifying information;
   - the results of physical monitoring and the solution test strip or chemical monitoring device obtained from the user; and
   - any other information that could be useful in determining whether the results of the solution test strip or chemical monitoring device are valid or questionable.

b) Items processed since the last cycle for which the solution test strip or chemical monitoring device indicated an inadequate concentration should be considered unprocessed. They should be retrieved, if possible, and reprocessed. The LCS/HLD solution in question should be discarded.

c) After the cause of the processing failure has been determined and addressed, the LCS/HLD solution should be tested with a solution test strip or chemical monitoring device. If the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate, the solution should be discarded and replaced with freshly prepared solution.

d) Determine whether a product recall is necessary. Refer to Section 12.10.

Rationale: Following the recommended protocol when the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate can provide valuable data in support of corrective actions and can aid in identifying potential improvements in work practices.

12.5.2 Automated processes

12.5.2.1 General considerations

Process monitoring devices (such as BIs, spore test strips, CIs, solution test strips, or chemical monitoring devices) should be used to monitor the effectiveness of automated processing equipment that uses LCS/HLD. These devices should be defined by the manufacturer of the chemicals and/or processing equipment and should be used and interpreted according to the manufacturer's written IFU.

Solution test strips and chemical monitoring devices should be used to test automated equipment at the same frequency as for manual processes, which is before each use. The use and interpretation of these strips and chemical monitoring devices to monitor the concentration of active ingredients in LCS/HLD solutions are described in 12.5.2.2.2.

The devices to use should be determined based on the written IFU from the manufacturer of the chemicals and/or automated processing equipment, because not all process monitoring devices are commercially available for all automated processes. Furthermore, solution test strips and chemical monitoring devices are not the same as CIs used to monitor gaseous or other sterilization processes.

12.5.2.2 Use of physical monitors and process monitoring devices

Physical monitors reflect the parameters of the automated processing equipment and include displays, digital printouts, and gauges. The user should obtain information from the manufacturer of the monitoring device regarding the accuracy and precision of the monitor, what parameters are measured, and any maintenance required to ensure the continued adequate performance of the equipment.

At the end of the cycle and before items are removed from the processing equipment, the operator should examine and interpret the printout to verify that cycle parameters were met and should initial it to allow later identification of the operator. Automated processing equipment that does not have physical-monitor recording devices should not be used. Electronic software programs are also available that provide a real-time, paperless, permanent recording of physical parameters. Automated processing equipment without electronic data transfer, recording, or printing capabilities should not be used.

NOTE—It is important that any chart or printout is readable.

If the interpretation of the physical monitors or process monitoring devices (such as BIs, spore test strips, CIs, solution test strips, or chemical monitoring devices) or visual inspection of the chemical solution, as defined by the manufacturer, suggests inadequate processing, the items should not be dispensed or used. The interpreter should inform the designated supervisor or delegated individual, who should initiate follow-up measures.

Rationale: Physical monitoring provides real-time assessment of the automated processing equipment cycle conditions and provides permanent records by means of chart recordings, digital printouts, or electronic records. Physical monitoring is needed to detect malfunctions as soon as possible so that corrective actions can be taken. Process monitoring devices (such as BIs, spore test strips, CIs, solution test strips, or chemical monitoring devices) provide additional information about the effectiveness of the process and assist in determining the reasons for a process failure.

12.5.2.3 Automated processing equipment malfunction

If the physical-monitoring records or process monitoring devices (such as BIs, spore test strips, CIs, solution test strips, or chemical monitoring devices) indicate any malfunction or suspicious operation, the load should be considered inadequately processed and should not be used. The processing equipment manufacturer’s written IFU should be reviewed for troubleshooting information. After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated according to the manufacturer’s written IFU and the processing equipment removed from service. All items in the terminated cycle should be reprocessed. The health care facility engineer or maintenance contract service should then be notified and the malfunction should be corrected. Faulty processing equipment cannot be made operational without identifying and correcting the underlying problem; merely extending the cycle time, for example, is not sufficient.

Many liquid chemical sterilization/high-level disinfection automated processing equipment computer programs are designed to detect inadequate cycle conditions. Computer-controlled equipment will often abort the cycle when the required parameters for the process have not been met. Some automated equipment will also provide various types of alerts regarding equipment performance. Users of the equipment should be educated and trained to distinguish between alerts that represent fail conditions and those that do not.

A major repair is a repair outside the scope of normal maintenance, such as rebuilding or upgrading controls. When repairs involve parts that are usually replaced under preventive maintenance procedures, verification of the

processing equipment's operation to the manufacturer's specifications is sufficient to return the processing equipment to service. After a major repair, follow the manufacturer's written IFU for verification testing before the processing equipment is returned to service.

Rationale: Altering the cycle parameters of malfunctioning processing equipment may not correct a problem. Adequate processing of future loads will be jeopardized if the processing equipment continues to be used without repair and requalification. To restore processing equipment to full performance, it is necessary to identify the exact cause of the malfunction.

12.5.2.4 Inadequate processing

If any process monitoring device (such as BIs, spore test strips, CIs, solution test strips, or chemical monitoring devices) defined for use with liquid chemical sterilization/high-level disinfection indicates the concentration of the active ingredients or specific process parameter during a cycle was inadequate, the actions described below should be taken to identify the reasons for this failure:

a) Follow the manufacturer's written IFU to troubleshoot the problem.

b) If troubleshooting was not successful, a description of the processing equipment should be included in a written report and notification.

c) Any processing equipment in question should be removed from service.

d) Infection prevention, sterile processing, and facility maintenance personnel should attempt to determine the cause of the processing failure.

e) After the cause of the processing failure has been determined and corrected, the complete processing system should be tested according to manufacturer's written IFU, to include any associated diagnostic cycles and/or testing with process monitoring devices (such as BIs, spore test strips, CIs, solution test strips, or chemical monitoring devices). If the physical-monitoring results and the process monitoring devices for the cycle are satisfactory, the processing equipment can be returned to service.

Rationale: Conducting the above protocol when the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate will provide valuable data in support of any corrective action required and potential improvements in work practices.

12.5.3 Routine testing of stored endoscopes

Numerous incidents of contaminated endoscopes in storage due to a failure in processing are well documented. The sources of such failures include:

a) user errors related to disinfection procedures and drying procedures (Muscarella, 2006; Srinivasan, 2003; Allen et al. 1987; Fraser et al., 2004; Classen et al., 1988);

b) physically compromised endoscopes or AERs (DiazGranados, 2009; Alvarado et al., 1991; Nelson and Muscarella, 2006; Schelenz and French, 2000; Fraser et al., 1992);

c) contaminated water supply used during cleaning, disinfection, and the final rinse (Nelson and Muscarella, 2006; Bass et al., 1990); and

d) development of resistance to aldehyde-based disinfectants (Fisher et al., 2012; Lorena et al., 2010; Duarte et al., 2009; Tschudin-Sutter et al., 2011).

According to the Multisociety Guideline on Reprocessing Flexible Gastrointestinal Endoscopes (ASGE, 2011), microbiological surveillance testing of endoscopes after processing, during storage, or before use has not been advised in current American standards. However, this quality assurance measure is advised in processing guidelines of several international organizations, including the Gastroenterological Society of Australia and the guideline of the combined European Society of Gastrointestinal Endoscopy and the European Society of Gastroenterology and Endoscopy Nurses and Associates committee.

NOTE—At the time of publication, AAMI was aware that the CDC is considering microbial sampling of endoscopes. No recommendation is made at this time.

While currently there is no universal consensus of the value of performing testing on endoscopes that have been through a high-level disinfection process, numerous studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing (Kovaleva, et al., 2013; Aumeran, 2010; P. Corne, 2004; C. V. Sciortino, Jr, et al., 2004). These studies may provide

guidance for the design of an ongoing surveillance program of endoscopes in storage (Kovaleva, et al. 2011, Buss et al., 2008; Kovaleva et al., 2009).

Identification of non-environmental pathogens demonstrates clear evidence of a failure of the high-level disinfection process. An approach to test for the presence of these pathogens can be considered as part of a quality assurance process. This should be done in collaboration with infection prevention and risk management personnel, and, if culturing is done, with input from laboratory personnel. In the design of a surveillance program, consideration should be given to what the acceptable and unacceptable findings would be and what the action plan on those findings would be. Also if microbiological testing is undertaken the issue of how to address the delay in findings should be addressed. Studies have identified several organisms of particular concern based upon incidents of patient infections from contaminated endoscopes (DiazGranados, 2009; Bass, et al., 1990; Kovalev, et al, 2013). Organisms identified as being of concern are Gram-negative bacteria (*Pseudomonas aeruginosa, Serratia marcescens, Legionella* and *Salmonella* species). Conversely, it is important to design a quality assurance program that will limit the opportunity for false-positives. This would include being sure not to choose methods of testing that would flag positive contamination from skin-flora or other non-pathogenic environmental contaminants.

12.6 Monitoring gaseous chemical sterilization processes

12.6.1 Use of physical monitors

Physical monitors include time, temperature, and pressure recorders; displays; digital printouts; and gauges. The user should obtain information from the manufacturer of the monitoring device certifying the accuracy and precision of the monitor and describing any maintenance required to ensure the continued adequate performance of the equipment.

For sterilizers with recording charts, the operator should ensure at the beginning of the cycle that the recording chart is marked with the correct date and the sterilizer number. For sterilizers with printouts, the printout should be checked to verify that the cycle identification number has been recorded and that the pen or printer is functioning. At the end of the cycle and before items are removed from sterilizer, the operator should examine and interpret the chart or printout to verify that cycle parameters were met and initial it to allow later identification of the operator. Sterilizers without recording charts or printouts should not be used.

NOTE 1—It is important that the chart or printout is readable.

NOTE 2—Most temperature sensors indicate temperature in the sterilizer chamber, not at the center of packs. Incorrect load configuration or package composition can interfere with air evacuation and sterilant penetration, conditions that will not be revealed in the temperature recording. Therefore, physical monitoring and other indicators of sterilizer performance should never be considered a substitute for careful adherence to prescribed packaging and loading procedures.

If the interpretation of the physical monitors suggests inadequate processing, the items should not be dispensed or used. The interpreter should inform the supervisor or delegated individual, who should initiate follow-up measures.

Rationale: Physical monitoring provides real-time assessment of the sterilization cycle conditions and provides permanent records by means of chart recordings or digital printouts. Physical monitoring is needed to detect malfunctions as soon as possible, so that corrective actions can be taken in the event of failures.

12.6.2 Gaseous chemical sterilizer malfunction

If the physical-monitoring records indicate any malfunction or suspicious operation, the cycle load should be considered unsterile and not used. The supervisor or delegated individual should be notified. The manufacturer's written IFU should be reviewed for troubleshooting information. After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated according to the sterilizer manufacturer's written IFU, and the sterilizer removed from service. All items should be repackaged, all wrappers and disposable products should be replaced, and new process indicators should be used. The health care facility engineer or maintenance contract service should then be notified and the malfunction corrected. A faulty sterilizer cannot be made operational without identifying and correcting the underlying problem; merely extending the cycle time, for example, is not sufficient. After a major repair of a sterilizer, it should be requalified according to the manufacturer's written IFU (see also ANSI/AAMI ST58).

Rationale: When a sterilizer malfunctions, the load should be considered unsterile. Simply altering the cycle parameters of a malfunctioning sterilizer will not correct a problem. The sterility of future loads will be jeopardized if the sterilizer continues to be used without repair and requalification to determine the sterilizer performs to specifications after the correction of a malfunction. To restore a sterilizer to full performance, it is necessary to identify the exact cause of the malfunction.

A major repair is a repair outside of normal maintenance, such as rebuilding or upgrading controls. When repairs involve parts that are usually replaced under preventive maintenance procedures, the sterilizer is returned to service after verification of the sterilizer's operation to the manufacturer's specifications is sufficient.

Sterilizer software controls are designed to detect inadequate cycle conditions and will often abort the cycle when the required parameters for the process have not been met. Some sterilizers will also provide various types of alerts regarding equipment performance. Users of the equipment should be educated and trained to distinguish between alerts that represent fail conditions and those that do not.

Removing a load from an aborted cycle can present a risk of exposure of workers to residual sterilant. The manufacturer's written IFU should be followed, safety precautions should be observed, and personnel should wear PPE. Items from aborted cycles should be removed from packaging while wearing PPE, cleaned if needed to remove residual chemicals, repackaged, and reprocessed according to manufacturer's written IFU.

12.7 Chemical indicators

12.7.1 General considerations

Chemical indicators are sterilization process monitoring devices that are designed to respond with a chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile. The use of CIs is part of an effective quality assurance program; CIs should be used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process. All CIs should be used according to the CI manufacturer's written IFU.

12.7.2 Using chemical indicators

Health care personnel should use the CI cleared by the FDA for use with a specific gaseous sterilization system. The CI manufacturer should be consulted for information on the reliability, safety, and performance characteristics of the product. The CI manufacturer's written IFU should explain the frequency of CI use, the placement of CIs, the interpretation of CI results, the reliability of the CI in maintaining end-point response during storage of sterilized items, the sterilization conditions that the CI will detect, the shelf life of the CI, and the storage requirements for the CI before and after sterilization.

NOTE—CIs used in health care facilities are medical devices that require FDA premarket clearance. The intended-use statement in the labeling of the CI should specify the sterilization methods and systems with which it can be used.

A CI should be used on the outside of each package unless the internal indicator is visible. The CI is examined after sterilization and also before use of the item to verify that the item has been exposed to the sterilization process.

An internal CI should be used inside each package, tray, containment device (rigid sterilization container system, instrument case, cassette, or organizing tray) to be sterilized. The CI should be placed in that area of the package, tray, or containment device that creates the greatest challenge to sterilant penetration. The CI should be retrieved at the time of use and interpreted by the user.

The user should receive education, training, and complete competency verification activities about the performance characteristics of the CI and the interpretation of the results.

For general information about CIs, see ANSI/AAMI/ISO 11140-1 and ANSI/AAMI/ISO 15882.

12.7.3 Nonresponsive or inconclusive chemical indicators

If the interpretation of the CI suggests inadequate processing, the contents of the package should not be used. The interpreter should inform the designated supervisor, who should return the complete unused package, including load identification and the CI, for follow-up. The supervisor or delegated individual in the sterilizing area should then decide whether to recall that sterilized load. This decision should be based on the results of physical monitoring; the results of CIs elsewhere in the load; and, if applicable, the results of biological monitoring. If biological monitoring was performed but the results are not yet available, the remaining packages from the same load should be quarantined and should not be used until the BI results are obtained.

Rationale: If a CI is nonresponsive or inconclusive, it is possible that the entire load is nonsterile (i.e., the sterilization process failed). It is also possible that errors in loading or packaging have resulted in sterilization failures in some, but not all, packages in the load. Therefore, a single nonresponsive or inconclusive CI should not be considered definitive evidence that the entire load is nonsterile.

12.8 Biological indicators

12.8.1 General considerations

Biological indicators are sterilization process monitoring devices consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored. A negative BI does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

Process challenge devices (PCDs) are challenge test packs containing a BI or a BI and a CI. A PCD is used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed.

All BIs and PCDs should be used in accordance with the manufacturer's written IFU.

12.8.2 Using biological indicators and process challenge devices

Processing personnel should use the BIs and PCDs recommended by the manufacturer of the selected gaseous chemical sterilization system and cleared by the FDA for use with that system, or BIs and PCDs cleared by the FDA as substantially equivalent. Information should be obtained from BI and PCD manufacturers on the reliability, safety, and performance characteristics of their products. Manufacturers of BIs and PCDs should provide written IFU on the storage, handling, use, and microbiological testing of their products.

NOTE—BIs and commercially available PCDs used in health care facilities are medical devices that require FDA premarket clearance. The intended-use statement in the labeling of the BI or PCD should specify the sterilization methods and systems with which it can be used.

Processing personnel should receive education, training, and complete competency verification activities regarding the performance characteristics of the BI and PCD and the interpretation of the results.

For general information about BIs, see ANSI/AAMI/ISO 11138-1 and ANSI/AAMI/ISO 14161. For general information on PCDs, see AAMI TIR31.

12.8.3 Frequency of use of BIs and PCDs

Process challenge devices containing BIs should be used for sterilizer qualification testing during initial installation of the sterilizer; after relocation, major repairs or malfunctions of the sterilizer; and after sterilization process failures. For periodic quality assurance testing of representative samples of actual products being sterilized, BIs should be placed in actual products, not in PCDs. A PCD with a BI should also be used at least daily, but preferably in every sterilization cycle for hydrogen peroxide and ozone sterilization processes and in every load for EO sterilization processes.

Rationale: The condition of the sterilizer equipment, the expertise of the sterilizer operator, and other factors determining the success or failure of a sterilization cycle could vary from one cycle to another. The less frequently the sterilizer is used, the greater the opportunity for the occurrence of an unnoticed event that could affect the safety or sterility of the device.

12.9 Sterilizer testing

12.9.1 General considerations

All gaseous chemical sterilizers should be tested using BI PCDs upon installation, relocation, sterilizer malfunctions, major repairs, and sterilization process failures. Sterilizer testing after installation, relocation, and major repairs should be conducted in the health care facility by processing personnel in cooperation with the manufacturer. The testing should be performed between the time the sterilizer is installed, relocated, or repaired and the time it is released for use or returned to service in the health care facility. Processing personnel should follow the manufacturer's written IFU, which should include the BI and PCD to use, the placement of the BI PCD in the load or chamber, whether the chamber should be full or empty, and the number of cycles to run.

Rationale: The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. The purpose of testing a sterilizer after installation or relocation is to assess sterilizer performance in the environment in which it will be used. Satisfactory test runs verify that the sterilizer is in good working condition after shipment from the manufacturer or relocation from its previous site and that it will function effectively. Sterilizer testing after major repairs is intended to ensure that the sterilizer performs to specifications after the correction of a malfunction or a sterilization process failure.

12.9.2 Qualification test procedure with BIs

The test procedure is as follows:

a) Before being exposed to the sterilization cycle, the PCD should be labeled with sterilizer lot and load information.

b) The PCD should be positioned in the load or chamber according to the sterilizer and PCD manufacturers' written IFU, and a normal cycle should be run.

c) Upon completion of the sterilization cycle, the manufacturer's written IFU for removing the PCD from the load or chamber and the BI from the PCD should be followed. During the removal and transfer process, processing personnel should be careful to avoid contamination of the BI or injury to themselves. The BI should be identified and then incubated according to the written IFU of the BI manufacturer.

d) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the incubation temperature. Test and lot control numbers should be recorded. Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are not viable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the test should be repeated.

NOTE—If several test BIs from the same lot are run on the same day, only one control BI from that lot need be used.

12.9.3 Qualification testing acceptance criteria

Negative results from the test BIs or spore test strips, positive results from control BIs, and cycle printout records demonstrating correct and complete sterilization cycles provide verification that the sterilizer has been installed or repaired and that it will function effectively in the facility in which it is installed. All monitoring results, including results from BI controls, should be interpreted by a qualified individual and should be included in the sterilizer records.

12.9.4 Routine test procedure with BIs

The test procedure is as follows:

a) Before being exposed to the sterilization cycle, the PCD should be labeled with sterilizer and lot information.

b) The PCD should be positioned in the load according to the sterilizer and PCD manufacturers' written IFU, and the cycle should be run.

c) Upon completion of the sterilization cycle, the PCD should be removed from the load and the BI removed from the PCD according to the manufacturer's written IFU. During the removal and transfer process, processing personnel should be careful to avoid contamination of the BI or injury to themselves. The BI should be identified and then incubated according to the written IFU of the BI manufacturer.

d) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the incubation temperature. Test and lot control numbers should be recorded. Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are not viable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the test should be repeated.

NOTE—If several test BIs from the same lot are run on the same day, only one control BI from that lot need be used.

12.9.5 Routine testing acceptance criteria

An acceptable process is evidenced by negative results from all test BIs in the PCD, positive results from control BIs, and readings from physical monitors and CIs showing that the sterilization cycle was correct and complete. All monitoring results, including results from BI controls, should be interpreted by a qualified individual and should be included in the sterilizer records.

12.9.6 Positive BI results

The following actions should be taken if a BI tests positive:

a) Positive BI results (other than those from viability/positive controls) should be reported immediately to the sterile processing supervisor or other designated personnel and to infection prevention personnel. This notification should be followed by a written report. The report and notification should include

- the time and date of the questionable sterilizer cycle;
- a description of the sterilizer and load, including the lot control number, product and patient name, and other identifying information;
- the results of physical monitoring and of CIs, if applicable, as obtained from the user; and
- any other information that could be useful in determining whether the report is valid or is questionable because of human error.

b) Because a sterilization failure has occurred, items processed in that sterilizer since the sterilization cycle having the last negative BI should be considered unsterile. They should be retrieved, if possible, and reprocessed. The sterilizer in question should be taken out of service.

c) A presumptive identification of the microorganisms present on the “failed” (positive) BI should be performed in accordance with the BI manufacturer’s written IFU, and, if applicable, review the BI transfer technique. The load recall should *not* be delayed while this testing is being performed. The recalled items can be quarantined until the presumptive test results are known.

d) Microbiology, sterile processing, and facility maintenance personnel should attempt to determine the cause of the positive BI and sterilization process failure and arrange for corrective action.

e) After the cause of the sterilization process failure has been determined and corrected, the sterilizer in question should be immediately rechallenged with BI PCD(s). Processing personnel should follow the manufacturer's written IFU, which should include the BI and PCD to use, the placement of the BI PCD in the load or chamber, whether the chamber should be full or empty, and the number of cycles to run. Until the results of retesting are satisfactory, the performance of the sterilizer should be considered in question.

Rationale: Conducting the recommended protocol when positive BI results occur will provide valuable data in support of corrective actions and aid in identifying potential improvements in work practices.

12.9.7 Microbiological testing

For positive BIs, a presumptive identification should be performed according to the BI manufacturer’s written IFU to determine whether the recovered microorganism is the test microorganism from the BI or an accidental contaminant.

Rationale: Presumptive identification distinguishes accidental contamination of the BI after removal from the PCD from a true positive BI that resulted from sterilization failure. In the latter case, there would be incomplete destruction of the test microorganisms on the BI.

12.9.8 Product release

Product release should be an active decision based on evaluation of all available data from the sterilization or high-level disinfection process for the particular load. Loads that do not meet the criteria for release should be clearly identified so that they are not mistakenly distributed.

Rationale: Releasing processed devices based on all quality control measures is critical in providing safe and effective products for the care and treatment of patients.

12.10 Product recalls

12.10.1 General considerations

Written policies and procedures for the recall of issued or stored packaged items that have been processed with LCS/HLD or gaseous chemical sterilants should be developed in cooperation with the infection prevention committee and the risk management committee of the individual institution or integrated health care network. Written policies and procedures for the identification of items not packaged or stored but immediately used should also be developed. Policies and procedures should be documented, and records should be maintained. The supervisor or designated individual should decide, on the basis of the health care facility’s policies and procedures, manufacturer's written IFU, circumstances surrounding the event, or other relevant information, whether a recall of processed supplies should be implemented. Whenever there is evidence of a sterilization or high-level disinfection process failure, the infection prevention professional and other involved personnel (e.g., director of the area where the suspect items were used) should be notified so that follow-up surveillance of patients can be conducted. Written policies and procedures should

be developed for compliance with the Safe Medical Devices Act of 1990 as it pertains to failures of reusable medical devices (i.e., FDA's Medical Device Reporting [MDR] regulations of 21 CFR 803). For additional information on user facility MDR requirements, see FDA (1996).

Rationale: Establishing recall procedures can help ensure patient safety, compliance with the user facility reporting requirements of the FDA's MDR regulations, and identification and retrieval of items suspected to be unsterile or incorrectly high-level disinfected, and provide for adequate follow up actions (e.g., quarantine of the sterilizer or automated processing equipment, notification of physicians and affected areas, and surveillance of patients).

12.10.2 Recall procedure

A recall procedure should:

a) be written;

b) outline the circumstances for issuing a recall order;

c) designate the person or people authorized to issue a recall order; and

d) designate the personnel responsible for reporting on the execution of a recall order.

12.10.3 Recall order

A recall order should:

a) include all items processed back to the last negative BI (if applicable) or failed MRC indicator (if applicable);

b) be immediately communicated to affected areas and followed by a written order;

c) identify products to be recalled by lot number (if applicable), product or patient name, or other information;

d) identify the people or areas to whom the order is addressed;

e) require the recording, in terms of kind and quantity, of the products obtained in the recall; and

f) specify the action to be taken by the people receiving the order (e.g., destruction or return of product).

12.10.4 Recall summary report

A summary report of a recall order should:

a) identify the circumstances that prompted the recall order;

b) specify the corrective actions taken to prevent a recurrence;

c) state, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall; and

d) provide verification that the recalled items were reprocessed or destroyed.

12.10.5 Outbreak report

The people responsible for the health care facility's infection prevention program and risk management function should report any outbreaks associated with chemical sterilization or high-disinfection processes to the FDA, the local health department and the State Board of Health, the CDC, the medical device manufacturer, and the manufacturer of the chemical sterilant or chemical sterilization system (ASGE, 2003).

12.11 Quality process improvement

12.11.1 General considerations

This section identifies performance measures and process monitors that can be used for Continuous Quality Improvement (CQI) programs. CQI programs are recognized as an effective means of improving the performance of any process. For chemical sterilization and high-level disinfection, a CQI program encompasses the entire process: decontamination, preparation, packaging (if applicable), chemical sterilization or high-level disinfection, quality control, storage (if applicable), and product distribution.

Procedures for cleaning, high-level disinfection, and chemical sterilization should be based on all of the manufacturers' written IFU (endoscope, cleaning solution, LCS/HLD, AER, and/or sterilizer, as applicable) as part of a documented quality process that measures objective performance criteria. This quality process should be developed

in conjunction with designated personnel and integrated into the overall quality process in the health care facility. Variables in the system can be controlled to achieve assurance of product quality and process efficacy. Monitoring frequency will vary, depending on the quality improvement goals, health care facility policies and procedures for the handling of unfavorable or unplanned events, and type of process variable.

A root cause analysis should be completed for any problem relating to any aspect of cleaning, high-level disinfection, or chemical sterilization processing that could pose a risk to personnel or patients. The root cause analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected.

There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Quality processes can be enhanced by audits that are conducted on a regular basis. The information from these activities should be summarized and made available to designated individuals or groups.

According to FDA, a quality audit "means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives" (21 CFR 820.3[t]).

Rationale: Measurements of process performance allow cleaning, high-level disinfection, and chemical sterilization processes to be monitored against a predetermined level of quality. Evaluation of findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data essential to assessing the effectiveness of the processes and making improvements in performance.

12.11.2 Risk analysis

Risk analysis = risk assessment + risk management + risk communication

Disinfection is not sterilization, but a high-level disinfected device is one that should be free of viable pathogens, excepting spores such as those of *C. difficile.*. The Spaulding Classification of the device will define the level of disinfection or sterilization required. Devices that require at a minimum high-level disinfection with a chemical disinfectant are usually classified as semi-critical devices as they are in contact with mucous membranes or non-intact skin. As with sterilization, it is recognized that the effectiveness of these processes cannot be fully verified by subsequent inspection and testing of the product. For this reason, high-level disinfection processes are validated for use and the performance of the process is monitored routinely, including any associated equipment. This is also the case for sterilization processes.

A quality system for processing medical devices in health care facilities is based on a validated system. This should include manual or automated steps in the process. For automated equipment, this will include the AER or sterilization process manufacturer and designated representatives of the health care facility, who will conduct installation qualification and operational qualification testing. The individual device manufacturer and the AER manufacturer recommend validated means of cleaning and/or disinfecting or sterilizing the specific devices to be reprocessed, in lieu of a formal performance qualification.

NOTE—The "validated cycle" provided by the medical device manufacturer is often based on the assumption that the device is to be processed alone.

In health care facilities, a processing risk analysis, in its broadest sense, includes risk assessment, risk management, and risk communication:

a) **Risk assessment** involves identifying the source of a failure, estimating the likelihood that such a failure will occur, assessing the consequences if that failure does occur, and assessing how prepared the facility is to manage the failure. It should be assumed that at some time a failure will occur.

b) **Risk management** entails determining which of the failures identified in the risk assessment process require management and selecting and implementing the plans or actions that are needed to ensure that those high-level disinfection failures are controlled.

c) **Risk communication** involves an interactive dialogue between sterile processing personnel, operating room personnel, endoscopy personnel, and infection prevention professionals that actively informs the other concerned parties, including patients. This process is the facility's recall procedure.

The processing risk analysis should be part of the health care facility's overall infection prevention and risk control analysis in accordance with accreditation agency requirements. It should be performed at least annually and should be reevaluated whenever significant changes occur.

12.11.3 Decontamination

Procedures for decontamination should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in collaboration with designated personnel and should be integrated into the overall quality process in the health care facility. Written policies and procedures should take into account federal, state, and local regulations; CDC recommendations; national voluntary standards and recommended practices; and the recommendations of medical device and processing equipment manufacturers. Variables in the system should be controlled to achieve assurance of quality and process efficacy. Performance measures should be developed to monitor environmental, performance, and process factors, including tests for monitoring and verifying the parameters of the cleaning process. Monitoring frequency will vary, depending on the quality improvement goals, on the health care facility's policy and procedures for the handling of untoward events, and on the type of performance measure.

A root cause analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The root cause analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected. There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Auditing results should be routinely summarized and submitted to the infection prevention personnel for review.

Rationale: Measurements of process performance allow the system to be monitored and the results compared with a predetermined level of quality. Evaluation of the findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data that can be used to assess the effectiveness of the process and make ongoing improvements in performance.

12.11.4 Liquid chemical sterilization, high-level disinfection, and gaseous chemical sterilization

Procedures for liquid chemical sterilization, high-level disinfection, and gaseous chemical sterilization should be based on a documented quality process that measures objective performance criteria. The quality process should be developed in conjunction with the designated personnel and integrated into the overall quality process in the health care facility. Monitoring frequency will vary depending on the quality improvement goals, on the health care facility's policy and procedures for the handling of untoward events, and on the type of performance measure.

a) **Use of liquid chemical sterilization/high-level disinfection.** Performance measures should include, but are not limited to, verification of training and continuing education; correct choice of and use of LCSs/HLDs and PPE; correct loading of items into the solution container or automated processing equipment; selection of LCS/HLD cycle parameters; selection and use of CIs, spore test strips, and solution test strips or chemical monitoring devices; accurate load records; documentation of physical and chemical monitoring; and adherence to device, LCS/HLD, and automated processing equipment manufacturers' written IFU.

b) **Gaseous chemical sterilization processes.** Performance measures should include, but are not limited to, verification of training and continuing education; correct loading of items into the sterilizer chamber; selection of chemical sterilization cycle parameters; selection and use of CIs and BIs; accurate load records; documentation of physical, chemical, and biological monitoring; and adherence to device and sterilizer manufacturers' written IFU.

c) **Handling and transfer.** Performance measures should include, but are not limited to, selection and use of attire; correct techniques for unloading the sterilizer, automated processing equipment, or solution container; and correct techniques for transferring items to the point of use.

A root cause analysis should be completed for any problem with any aspect of liquid chemical sterilization, high-level disinfection, gaseous chemical sterilization, or aseptic transfer that could pose a risk to patients. The root cause analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected. There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Auditing results should be routinely summarized and submitted to the infection prevention personnel for review.

Rationale: Controlling variables in the system can help to ensure quality and process efficacy. Ensuring that liquid or gaseous chemical sterilization or high level-disinfection has been achieved will minimize the potential risk to patients. Measurements of process performance allow the system to be monitored and the results compared with a predetermined level of quality. Analysis of this information provides a method of identifying problems or shifts in activities and making improvements in the system.

12.11.5 Functional areas for product and process improvement

12.11.5.1 Workplace design

Optimization of product and process performance relies on efficient workplace design. Problems such as cross-contamination, excessive processing costs, product failures, inefficient time usage, and so on can be created or exacerbated by poor workplace design. Workplace design encompasses the physical layout of the processing area; the functional work flow patterns; the physical facilities (e.g., the mechanical and electrical systems, lighting, plumbing, ventilation, environmental controls); and the types and locations of processing equipment and supplies.

12.11.5.2 Processing policies and procedures

Evaluating and monitoring the effectiveness of the process should be an ongoing effort and is critical to maintaining control over and determining methods for improvement of the product and process. The review of records and of documented quality control procedures that have been implemented should serve as the basis for monitoring and evaluating the process. Written procedures should be reviewed, and current practices should be audited for compliance in the areas included in the CQI program. Examples of CQI program areas include

a) training, continuing education, and competency verification;

b) product identification and traceability (i.e., lot control numbers and load records);

c) monitoring cleaning effectiveness;

d) monitoring manual processes that use LCSs/HLDs;

e) monitoring automated processes that use LCSs/HLDs;

f) monitoring gaseous chemical sterilization processes;

g) product testing;

h) product recalls; and

i) workplace safety training (including safe use of chemicals and safe handling of biohazards).

12.11.5.3 Product use

Evaluating the performance of products that have been or will be used can offer important feedback on the effectiveness of the process and the products selected. Performance measures can come from internal evaluations, end-user feedback, supplier testing, and repair records:

a) **Internal evaluations.** Internal evaluations can be used to audit the quality of finished products. For example, instruments can be checked for functionality, packaging, and delivery. Preprocessing decontamination can be evaluated by visually examining instruments for contamination. Product recalls can be evaluated by reviewing records of actions following documented chemical sterilization or high-level disinfection process failures. Periodic product monitoring can be evaluated on the basis of the loads or cycles tested and the actions taken as a result of failures.

b) **End-user feedback.** A formal documented system to log, investigate, and resolve complaints and product failures should be established. Issues such as patient infections, PPE failures, malfunctioning instruments and equipment, and dispensing of incorrect products should be documented, monitored, and tracked over time. A procedure should be established for investigation and remediation of serious and repeat problems.

c) **Supplier testing.** The manufacturer should thoroughly analyze concerns relative to the performance of products or supplies through testing or other means. Processing personnel should make a written request to and receive a response from any vendor whose products, supplies, or services are in question. All correspondence should be filed with the corresponding complaint, including details of the investigation, the findings, and any actions taken by the vendor to resolve the problem.

d) **Repair records.** Review of instrument repair records might show a pattern. Once identified, the cause for the repair can be reviewed, corrected, then monitored to ensure the problem has been resolved.

12.11.5.5 Implementation of product and process improvements

There is no single right way to implement a CQI program. The program should be customized to the individual facility. However, a team approach has been proven to be successful, because it allows direct input from multiple employees and results in a superior program.

Employees who are actively involved in and responsible for the day-to-day functions outlined in the plan should be members of the team. This approach should generate input from those most knowledgeable in methods of effectively improving the program. Additionally, such involvement may promote a sense of ownership that may lead to a higher degree of commitment on those endoscope processing team members implementing the program.

The single most important issue for those charged with implementing a CQI program is the accurate collection of data using the facility plan for documenting process monitoring and product performance (developed as part of the CQI program). The frequency and type of information generated will vary depending on the level of control established in the documentation plan. Facilities with processes that are uncontrolled or highly variable will require increased process monitoring and documentation, which can be reduced over time as the program brings these processes under improved control.

Occupational safety is symbiotic with patient safety and is a key part of the quality system. Occupational safety records that should be kept as part of the quality system include maintenance records such as exhaust air flow checks; exposure records from gas monitors; employee safety training (chemical used onsite, OSHA Hazcom standard; emergency procedures, work instructions for safe use of equipment): and medical evaluation for personnel using respirators.

The CQI program should assess all components of chemical sterilization and high-level disinfection processes for the ongoing ability to achieve the desired outcome of consistently delivering an efficacious product to the user. Performance improvement plans, when needed, should be implemented to enhance chemical sterilization and high-level disinfection processes on the basis of this assessment. Examples of measures to be considered when assessing chemical sterilization and high-level disinfection processes include trending data over a defined time period related to

a) the number of items processed;

b) the number of failed cleaning verification tests, if applicable;

c) the number of BI tests, if applicable;

d) the number of BI failures for each chemical sterilization process, if applicable;

e) the number of physical parameter failures;

f) the number of failed CIs, if applicable;

g) the number of spore test strips, if applicable;

h) the number of spore test strip failures, if applicable;

i) the number of solution test strip or chemical monitoring device failures for processes that use LCSs/HLDs;

j) competency verification (the percentage of endoscope processing team members successfully completing education, training, and competency verification activities).

k) timing and completeness of preventive maintenance of gaseous chemical sterilizers and automated processing equipment;

l) ability to locate all items during recalls;

m) completeness of test records; and

n) occupational safety records.

Annex A
(informative)

Bibliography

Allen JI. Pseudomonas aeruginosa infection during endoscopy: Reply. *Gastroenterology,* 93:1451, 1987.

Allen JI, Allen MO, Olson MM, Gerding DN, Shanholtzer CJ, Meier PB, Vennes JA, Silvis SE. Pseudomonas infection of the biliary system resulting from use of a contaminated endoscope. *Gastroenterology,* 759-763, 1987.

Alfa M, Iram F, Olson N. The adenosine triphosphate test is a rapid and reliable audit tool to assess manual cleaning adequacy of flexible endoscope channels. *Am J Infect Control,* 41(3): 249-253, 2013.

Alfa MJ, Olson N, and Murray B.. Comparison of clinically relevant benchmarks and channel sampling methods used to assess manual cleaning compliance for flexible gastrointestinal endoscopes. *Am J Infect Control* 42(1), pp e1-e5, 2014.

Alfa MJ, Olson N, DeGagne P, and Jackson M. A survey of reprocessing methods, residual viable bioburden and soil levels in patient-ready endoscopic retrograde choliangiopancreatography duodenoscopes used in Canadian centers. *Infect Control Hosp Epidemiol,* 23:198–206, 2002.

Alfa, MJ, Olson N, DeGange P, Simmer. Development and validation of rapid use scope tests to determine the efficacy of manual cleaning for flexible endoscope channels. *Am J Infect Control,* 4:2012 (NEED MORE CITE)

Aleccia J. Undisclosed superbug sickened dozens at Virginia Mason. *Seattle Times,* 21-Jan-2015.

Alvarado CJ, Stolz SM, Maki DG. Nosocomial infections from contaminated endoscopes: a flawed automated endoscope washer. An investigation using molecular epidemiology. *Am J Med,* 91:272S–80S. 1991.

American National Standards Institute. *Emergency eyewash and shower equipment.* ANSI Z358.1:2009. New York: ANSI, 2009.

ASGE Standards of Practice Committee, Banerjee S, Shen B, Nelson DB, Lichtenstein DR, Baron TH, et al. Infection control during GI endoscopy. *Gastrointest Endosc* 2008;67:781-90.

American Society for Gastrointestinal Endoscopy. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointestinal Endoscopy*, 73(6):1075–1084, 2011.

American Society for Gastrointestinal Endoscopy. *Endoscope repair by original equipment manufacturers and independent service organizations:* 2003.

American Society of Heating, Refrigerating, and Air-Conditioning Engineers. *Ventilation for acceptable indoor air quality.* Standard 62.1-07. Atlanta: ASHRAE, 2007a.

American Society of Heating, Refrigerating, and Air-Conditioning Engineers. *2007 ASHRAE handbook.* Atlanta: ASHRAE, 2007b.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological indicators—Part 1: General requirements.* ANSI/AAMI/ISO 11138-1:2006/(R)2010. Arlington (VA): AAMI, 2006. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Part 1: General requirements.* ANSI/AAMI/ISO 11140-1:2005/(R)2010. Arlington (VA): AAMI, 2005. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Biological indicators—Guidance for the selection, use, and interpretation of results.* ANSI/AAMI/ISO 14161:2009. Arlington (VA): AAMI, 2009. American National Standard.

Association for the Advancement of Medical Instrumentation. *Sterilization of health care products—Chemical indicators—Guidance for selection, use and interpretation of results.* ANSI/AAMI/ISO 15882:2008. Arlington (VA): AAMI, 2008. American National Standard.

Association for the Advancement of Medical Instrumentation. *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.* ANSI/AAMI PB70:2003/(R)2009. Arlington (VA): AAMI, 2003. American National Standard.

Association for the Advancement of Medical Instrumentation. *Ethylene oxide sterilization in health care facilities: Safety and effectiveness.* ANSI/AAMI ST41:2008. Arlington (VA): AAMI, 2008. American National Standard.

Association for the Advancement of Medical Instrumentation. *Chemical sterilization and high-level disinfection in health care facilities.* ANSI/AAMI ST58:2013. Arlington (VA): AAMI, 2013. American National Standard.

Association for the Advancement of Medical Instrumentation. *Processing of reusable surgical textiles for use in health care facilities.* ANSI/AAMI ST65:2008. Arlington (VA): AAMI, 2008. American National Standard.

Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* ANSI/AAMI ST79:2010, A1:20120, A2:2011, A3:2012, & A4:2013. Arlington (VA): AAMI, 2010. American National Standard.

Association for the Advancement of Medical Instrumentation. *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.* AAMI TIR30:2003. Arlington (VA): AAMI, 2003. AAMI Technical Information Report.

Association for the Advancement of Medical Instrumentation. *Process challenge devices/test packs for use in health care facilities.* AAMI TIR31:2008. Arlington (VA): AAMI, 2008. AAMI Technical Information Report.

Association for the Advancement of Medical Instrumentation. *Water for the reprocessing of medical devices.* AAMI TIR34:2014. Arlington (VA): AAMI, 2014. AAMI Technical Information Report.

Association of periOperative Registered Nurses. Guideline for cleaning and care of surgical instruments. In: *Guidelines for Perioperative Practice.* Denver: AORN, 2015a.

Association of periOperative Registered Nurses. Guideline for environmental cleaning. In: *Guidelines for Perioperative Practice.* Denver: AORN, 2015b.

Association of periOperative Registered Nurses. Guideline for hand hygiene. In: *Guidelines for Perioperative Practice.* Denver: AORN, 2015c.

Association of periOperative Registered Nurses. Guideline for surgical attire. In: *Guidelines for Perioperative Practice.* Denver: AORN, 2015d.

Association of periOperative Registered Nurses. Guideline for cleaning and processing flexible endoscopes and endoscope accessories. In: *Guidelines for Perioperative Practice.* Denver: AORN, 2015e.

Aumeran C, Poincloux L, Souweine B, et al. Multidrug-resistant *Klebsiella pneumoniae* outbreak after endoscopic retrograde cholangiopancreatography. *Endoscopy,* 42: 957–9, 2010.

Aumerana C, Thiberta E, Chapellea FA, Hennequinc C, Lesensb O, and Traoréa O. Assessment on experimental bacterial biofilms and in clinical practice of the efficacy of sampling solutions for microbiological testing of endoscopes. *J Clin Microbiol,* 50(3):938-942, 2012.

Bass DH, Oliver S, Bornman PC. Pseudomonas septicaemia after endoscopic retrograde cholangiopancreatography—an unresolved problem. *S Afr Med J,* 77: 509-511, 1990.

Baumgardner CA, et al. Effects of nail polish on microbial growth on fingernails. *AORN J,* 58:84–88, 1993.

Beilenh, U et al., and the ESGE Guidelines Committee. ESGE-ESGENA guideline: *Cleaning and disinfection in gastrointestinal endoscopy.* European Society for Gynological Endoscopy: 2008.

Bisset L, Cossart YE, Selby W, West R, Catterson D, O'Hara K, Vickery K. A prospective study of the efficacy of routine decontamination for gastrointestinal endoscopes and the risk factors for failure. *Am J Infect Control* 2006; 34(5):274.

Bommarito M, Thornhill G, Morse D. Multi-site field study evaluating the effectiveness of manual cleaning of the flexible endoscopes with an ATP detection system. *AJIC,* 41 (6): S24, 2013.

British Society of Gastroenterology. Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy. London: BSG: 2013.

Buss AJ. Endoscope disinfection and its pitfalls—requirement for retrograde surveillance cultures. *Endoscopy*, 40(4): 327-332, 2008.

Carbonne A. Thiolet JM, Fortineau N, et al. Control of a multi-hospital outbreak of CPC—producing *klebsiella pneumonia* type 3 in France, Sept–Oct 2009. *Euro Surveill,* 15(48): 1-6, 2010.

Centers for Disease Control and Prevention. Notes from the field: New Delhi metallo-β-lactamase-producing Escherichia coli associated with endoscopic retrograde cholangiopancreatography. 3 Jan 2014.

Centers for Disease Control and Prevention. National Hospital Discharge Survey: 2009 table, procedures by selected patient characteristics. Available from: http://www.cdc.gov/nchs/fastats/insurg.htm. Accessed November 1, 2013.

Centers for Disease Control and Prevention. *Basic Infection Control and Prevention Plan for Outpatient Oncology Settings.* Atlanta (GA): CDC, 2011.

Centers for Disease Control and Prevention. Guideline for hand hygiene in health-care settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *Morbidity and Mortality Weekly Report (MMWR),* 51(RR16):1–44, 2002.

Centers for Disease Control and Prevention. *Guidelines for isolation precautions: Preventing transmission of infectious agents in healthcare settings.* Atlanta (GA): CDC, 2007.

Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *Guideline for disinfection and sterilization in healthcare facilities.* Atlanta (GA): CDC, 2008.

Classen DC, Jacobson JA, Burke JP, Jacobson JT, Evans RS. Serious Pseudomonas infections associated with endoscopic retrograde cholangiopancreatography. *Am J Med,* 84: 590-596, 1988.

Cowen A, Jones D, Wardle E, editors. *Infection control in gastrointestinal endoscopy*, 2nd ed. Sydney (Australia): Gastroenterological Society of Australia; 2003.

Cullen KA, Hall MJ, Golosinsky A. *Ambulatory surgery in the United States*, 2006. Natl Health Stat Rep 2009;11:1-25.

DeGrott-Kosolcharoen J, and Jones JM. Permeability of latex and vinyl gloves to water and blood. *Am J Infect Control*, 17(4):196–201, 1989.

Department of Veterans Affairs. Reprocessing Flexible Endoscopes, Memorandum dated 25-Nov-2014.

DiazGranados. Outbreak of pseudomonas aeruginosa infection associated with contamination of a flexible bronchoscope. *Infect Control Hosp Epidemiol,* 30(6), 2009.

Dirlam-Langley A, et al. Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg. *Am J Infect Control,* 41(12): 1188–1194, 2013.

Donlan RM. Biofilms: Microbial life on surfaces. *Emerging Infectious Diseases*, 8(9):881–90, 2002.

Drosnock M. Endoscope Reprocessing: Avoiding Complacency. http://www.endonurse.com. Posted on 08/21/2014.

ECRI Institute. Top 10 health technology hazards list. Published annually. https://www.ecri.org/2014hazards.

Environmental Protection Agency. ETO reregistration eligibility Decision (RED), docket number EPA-HQ-OPP-2005-0203. Federal Register Notice, April 16, 2008 (Volume 73, Number 74) at http://www.epa.gov/fedrgstr/EPA-PEST/2008/April/Day-16/p7997.htm.

Facility Guidelines Institute. *Guidelines for Design and Construction of Health Care Facilities*. Chicago: FGI, 2014.

Favero M, and Bond W. Chemical disinfection of medical surgical material. In: Block SS. (ed.). *Disinfection, sterilization, and preservation.* 5th ed. Philadelphia: Lippincott, Williams & Wilkins, 2001, pp. 881–917.

Field EA, McGowan P, Pearce PK, Martin MV. Rings and watches: should they be removed prior to operative dental procedures? *J Dent,* 24(1-2): 65-69, 1996.

Fraser TG, Reiner S, Malczynski M, et al. Multidrug resistant *Pseudomonas aeruginosa cholangitis* after endoscopic retrograde cholangiopancreatography: failure of routine endoscope cultures to prevent an outbreak. *Infect Control Hosp Epidemiol,* 25(10): 856-9, 2004.

Fraser VJ, Jones M, Murray PR, et al. Contamination of flexible fiberoptic bronchoscopes with Mycobacterium chelonae linked to an automated bronchoscope disinfection machine. *Am Rev Respir Dis,* 145:853–5, 1992.

Garner JS, and Healthcare Infection Control Practice Advisory Committee (HICPAC). Guideline for isolation precautions in hospitals. *Am J Infec Control*, 24:24–52, 1996.

Goldstine S. Endoscopy storage: Preventing distal tip protector contamination. *Gastroenterol Nurs* 28(1), 45-46, 2005.

Gonzalez-Candelas F, Guiral S. et al. Patient-to-patient transmission of hepatitis C virus (HCV) during colonoscopy diagnosis. *Virol J,* 217, 2010.

Graves PB, Twomey CL. Surgical hand antisepsis: an evidence-based review. *Perioperative Nursing Clinics,* 1(3): 235-246, 2006.

Herve R, Keevil C. Current limitations about the cleaning of luminal endoscopes. *J Hosp Infect,* 83: 22-9, 2013.

Holodny M, Oda G, Schirmer P, et al. Results from a large-scale epidemiologic look-back investigation of improperly reprocessed endoscopy equipment. *ICHE,* 33(7): 649–656, 2012.

Jeanes A, and Green J. Nail art: A review of current infection control issues. *J Hosp Infect*, 249:139–142, 2001. Joint Commission. *2010 Comprehensive accreditation manual for hospitals: The official handbook (CAMH).* Chicago: Joint Commission, 2009.

Kimmery, M, et al. ASGE technology assessment position paper: Transmission of infection by gastrointestinal endoscopy. *Gasteroin Endoscop,* 39: 885–8, 1993.

Kovaleva, J. Is bacteriologic surveillance in endoscope reprocessing stringent enough? *Endoscopy,* 41(10): 913-916, 2009.

Kovaleva J, Frans T, Peters M, and Degener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clin Microbiol Rev,* 26(2): 231–254, 2013.

Leffler D, Kheraj R, Garud S, et al. The incidence and cost of unexpected hospital use after scheduled outpatient endoscopy. *Arch Intern Med,* 170(19): 1752-1757, 2010.

McCool S, et al. Carbapenem-resistant Enterobacteriaceae (CRE) Klebsiella pneumonia (KP) Cluster Analysis Associated with GI Scopes with Elevator Channel. University of Pittsburgh Medical Center, Pittsburgh, PA 2012 (http://www.myendosite.com/articles/UPMC1.pdf).

Muscarella, LF. Inconsistencies in endoscope-reprocessing and infection-control guidelines: The importance of endoscope drying. *Am J Gastroenterol,* 101:2147-54; 2006.

National Institutes of Health. *The Burden of Digestive Diseases in the United States.* US Government Printing Office, 2008; NIH Publication No. 09-6443.

Nelson DB and Muscarella LF. Current issues in endoscope reprocessing and infection control during gastrointestinal endoscopy. *R World J Gastroenterol,* 12(25), 2006.

Occupational Safety and Health Administration. Access to employee exposure and medical records. *Code of Federal Regulations,* Title 29, Part 1910.20.

Occupational Safety and Health Administration. Toxic and hazardous substances. *Code of Federal Regulations,* Title 29, Part 1910.1000.

Occupational Safety and Health Administration. Occupational exposure to blood-borne pathogens. *Code of Federal Regulations,* Title 29, Part 1910.1030.

Occupational Safety and Health Administration. Occupational exposure to ethylene oxide. *Code of Federal Regulations,* Title 29, Part 1910.1047.

Ofstead C, Dirlam Langlay AM, Mueller NJ, Tosh PK, Wetzler HP. Re-evaluating endoscopy-associated infection risk estimates and their implications. *Am J Infect Control,* 41(8):734-6, 2013.

Ofstead C, Wetzler H, Snyder A. Endoscope reprocessing methods: A prospective study on the impact of human factors and automation. *Gastroenterology Nursing,* 33(54): 3-10, 2010.

Osborne S, Reynolds, George N, Lindemayer F, Gill A, Chalmers M. Challenging endoscopy reprocessing guidelines: A prospective study investigating the safe shelf life of flexible endoscopes in a tertiary gastroenterology unit. *Endoscopy* 2007; 39(9): 825.

Parente DM. Could biopsy port valves be a source of potential flexible endoscope contamination? *EndoNurse,* 2006; 6:24–28.

Porteous J. Artificial nails: Very real risks. *Canad OR Nurs J,* 20(3):16–17, 20–21, 2002.

Public Health Agency of Canada. *Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy.* Ontario, Canada: 2010.

Rea MS. (ed.). *Lighting handbook: Reference and application.* 8th ed. New York: Illuminating Engineering Society of North America, 1993.

Rejchrt S, Cermak P, Pavlatova L, McKova E, Bures J. Bacteriologic testing of endoscopes after high-level disinfection. *Gastrointest Endosc* 2004;60(1):76.

Riley R, Beanland C, Bos H. Establishing the shelf life of flexible colonoscopes. *Gastroenterol Nurs* 2002; 25(3):114.

Rutala WA, Weber DJ. Gastrointestinal Endoscopes: A Need to Shift From Disinfection to Sterilization? *JAMA* 2014;312(14):1405-1406.

Rutala WA., Weber DJ. How to Assess Risk of Disease Transmission to Patients when There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines. *Infect Control Hosp Epidemiol* 2007; 28:146-155.

Rutala WA. APIC guideline for selection and use of disinfectants. *Am J Infect Control,* 1990;18:99-117.

Salman L, et al. Banning artificial nails from health care settings. *Am J Infect Control*, 30:252–4, 2002.

Sanderson R. An Outbreak of carbapeneum-resistant *klebsiella* pneumonia infections associated with endoscopy retrograde cholangiopancreatogrphy (ERCP) procedures at a hospital. New Orleans (LA): APIC Conference, July 2010.

Schelenz S, French G. An outbreak of multidrug-resistant Pseudomonas aeruginosa infection associated with contamination of bronchoscopes and an endoscope washer-disinfector.. *J Hosp Infect,* 46:23-30, 2000.

Seoane-Vazquesz E, Rodriguesz-Monuio R, Visaria J, et al. Exogenous endoscopy-related infections, pseudo-infections, and toxic reactions: Clinical and economic burden. *Curr Med Res Opin,* 22: 2007-21, 2006.

Shimono N1, Takuma T, Tsuchimochi N, et al. An outbreak of Pseudomonas aeruginosa infections following thoracic surgeries occurring via the contamination of bronchoscopes and an automatic endoscope reprocessor. *J Infect Chemother,* 14:418-423, 2008.

Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. *2007 Guideline for isolation precautions: Preventing transmission of infectious agents in healthcare settings.* Atlanta (GA): Centers for Disease Control and Prevention, June 2007.

Society of Gastroenterology Nurses and Associates, Inc. *Standards of infection control in reprocessing of flexible gastrointestinal endoscopes.* Chicago [IL]: Society of Gastroenterology Nurses and Associates, Inc; 2012.

Society of Gastroenterology Nurses and Associates. Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes (2012). Available at: http://www.sgna.org/Portals/0/Infection%20Prevention/Professional%20Society/5_InfectionControlStandard_2012.pdf

Spaulding EH. Chemical disinfection and antisepsis in the hospital. *J Hosp Res*, 9:5–31, 1972.

Srinivasan A. Epidemiology and prevention of infections related to endoscopy. *Curr Infect Dis Rep,* 5:467-472, 2003.

Thomas L A. Essentials for endoscopic equipment. Recommended care and handling of flexible endoscopes: Endoscope storage. *Gastroenterol Nurs* 2005; 28(1):45.

Trick WE, Vernon MO, Hayes RA, et al. Impact of ring wearing on hand contamination and comparison of hand hygiene agents in a hospital. *Clin Infect Dis,* 36(11): 1383-1390, 2003.

U.S. Food and Drug Administration. Labeling. *Code of Federal Regulations,* Title 21, Part 801.

U.S. Food and Drug Administration. General hospital and personal use devices: Classification of liquid chemical sterilants/high level disinfectants and general purpose disinfectants. Federal Register, 65(111):36324-26, June 8, 2000a.

U.S. Food and Drug Administration. Quality system regulation. *Code of Federal Regulations,* Title 21, Part 820.

U.S. Food and Drug Administration. Medical device reporting for user facilities. Rockville (MD): FDA, 1996. FDA Guidance. Available at: www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidance Documents/ UCM095266.pdf.

U.S. Food and Drug Administration. *Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers.* 12 March 2000b. Available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm073746.htm.

U.S. Food and Drug Administration. *Guidance for industry and for FDA staff—Enforcement priorities for single-use devices reprocessed by third parties and hospitals*. FDA, August 14, 2000c. FDA Guidance. Available at: www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM107172.pdf.

U.S. Food and Drug Administration. *Guidance for industry and FDA staff: Medical glove guidance manual*. Rockville (MD): FDA, 22 January 2008. Available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM428191.pdf.

U.S. Food and Drug Administration. Sterilization process indicator. *Code of Federal Regulations,* Title 21, Part 880.2800.

Vergis AS, Thomson D, Pieroni P, Dhalla S. Repro-cessing flexible gastrointestinal endoscopes after a period of disuse: Is it necessary? *Endoscopy* 2007; 39(8):737.

Visrodia K, Ofstead C, Yellin H, Wetzler H, Tosh P, and Barron T. The Use of Rapid Indicators for the Detection of Organic Residues on Clinically Used Gastrointestinal Endoscopes with and without Visually Apparent Debris. *Infection Control and Hospital Epidemiology* Vol. 35, No. 8. pp. 987-994, 2014.

Zuhlsdorf B, Emmrich M, Floss H, and Martiny H. Cleaning efficacy of nine different cleaners in a washer-disinfector designed for flexible endoscopes. *J Hosp Infect,* 52:206–11, 2002.