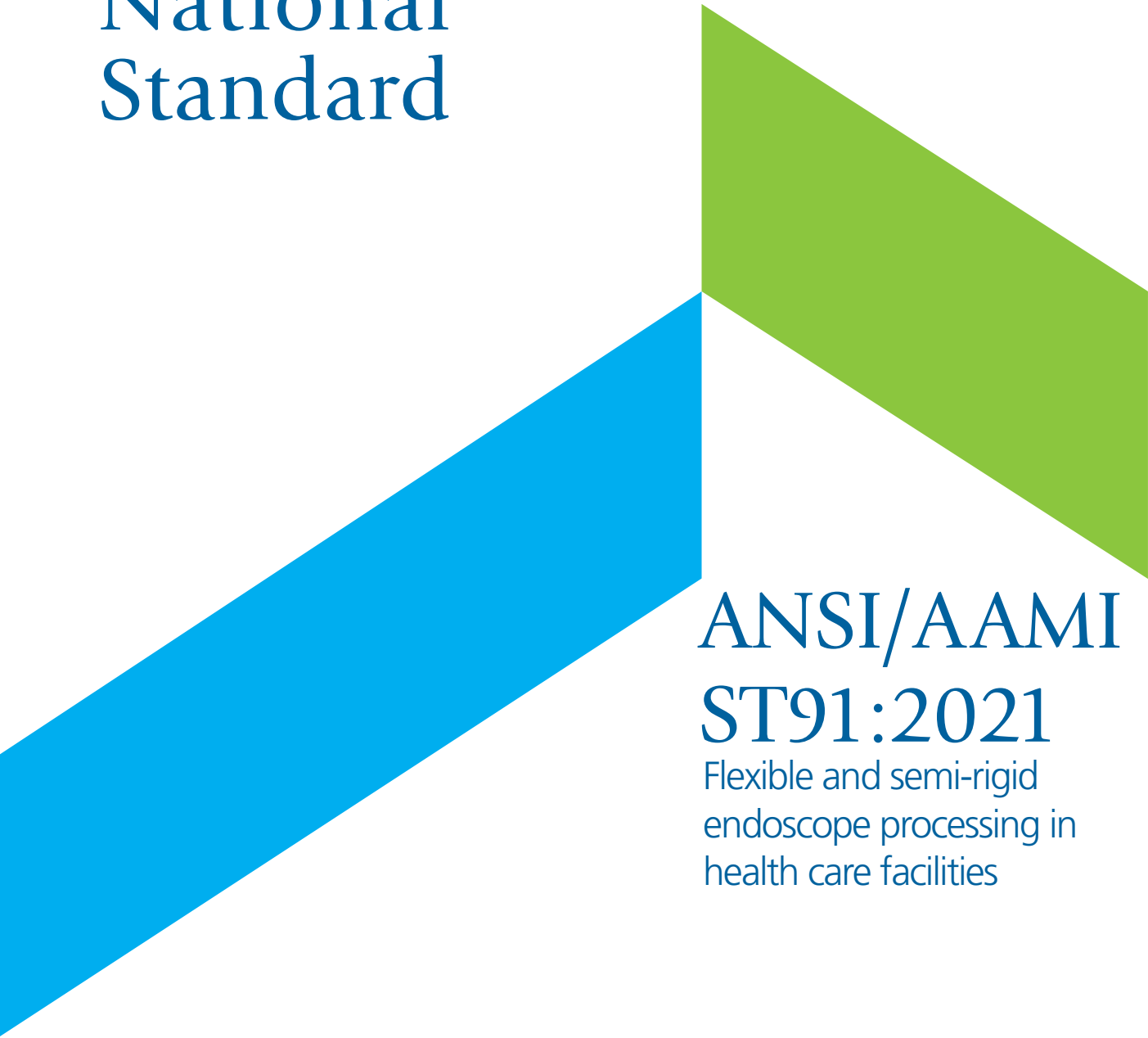


American National Standard



ANSI/AAMI ST91:2021

Flexible and semi-rigid
endoscope processing in
health care facilities

Flexible and semi-rigid endoscope processing in health care facilities

Approval 1 October 2021 by
AAMI

Approved 21 December 2021 by
American National Standards Institute, Inc.

Abstract: Provides guidelines for point of use treatment, transporting, leak testing (where indicated), cleaning, packaging (where indicated), high-level disinfecting and/or sterilizing, storage, and quality control procedures of flexible gastrointestinal (GI) endoscopes, flexible bronchoscopes, flexible ear, nose, and throat endoscopes, flexible urology endoscopes, and other types of reusable flexible endoscopes used in procedural and surgical settings, and semi-rigid operative endoscopes (e.g., choledochoscopes) used in health care facilities. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these reusable devices and accessories to render them safe for patient use.

Keywords: endoscope processing, endoscope storage, flexible endoscopes, semi-rigid endoscopes, high-level disinfection, sterilization, leak testing, endoscope inspection

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CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time.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 can obtain current information on all AAMI documents 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

AAMI
901 N Glebe Rd, Suite 300
Arlington, VA 22203
www.aami.org

© 2022 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this draft should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, et seq.) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violator's risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, visit the Copyright Clearance Center.

Printed in the United States of America

ISBN 978-1-57020-830-0

Contents

Page

Committee representation	v
Acknowledgments	x
Foreword	xi
Introduction	xii
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 Design of endoscope processing area	11
5 Environmental cleaning	21
6 Personnel	22
7 Decontamination processes	28
8 High-level disinfection, liquid chemical sterilization, and terminal sterilization systems for flexible endoscopes	40
9 Sterile endoscope sheaths used as protective microbial barriers	51
10 Processing of endoscope accessories	51
11 Storage of processed endoscopes	52
12 Transport of processed endoscopes	57
13 Quality control	57
14 Device repair and loaned endoscopes	82
15 New product evaluation	85
Annex A (informative) Alternatives for keeping cool in the processing environment	87
Annex B (informative) Purchase considerations in selecting AERs and LCSPSs	90
Annex C (normative) Reference material for repairs	92
Annex D (informative) Manufacturer's written instructions for use (IFU) conflict management	94
Annex E (informative) Endoscope visual inspection	95
Annex F (informative) User verification of cleaning processes	105
Annex G (informative) Effects of simethicone on flexible endoscopes	112
Annex H (informative) Safety considerations for high-level disinfectants and liquid chemical sterilants	113
Annex I (informative) Endoscope microbiocidal methods	148
Annex J (informative) Endoscope storage risk assessment	150
Annex K (informative) Endoscope drying	151
Bibliography	155

Tables

Table 1—IES-recommended illuminance levels for work environments*	19
Table 2—Barrier Gown liquid barrier performance class	27
Table 3—Microbiological culture surveillance sampling advantages and disadvantages*	69
Table H.1—Examples of labeled contact conditions for high-level disinfection by FDA-cleared glutaraldehyde products	114

Table I.1—Characteristics of microbicidal methods for endoscope processing	148
Table K.1—Summary of endoscope drying studies and methods of evaluation	152

Figures

Figure E.1—Inspection of an endoscope using the unaided eye or magnification	95
Figure E.2—Anatomy of endoscope elevator mechanism of duodenoscope distal end.....	96
Figure E.3—Areas to inspect for damage on endoscope.....	97
Figure E.4—Control body (including valves and switches)	98
Figure E.5—Examples of insertion tube peeling and scratching	98
Figure E.6—Additional example of insertion tube defects.....	99
Figure E.7—Examples of denting and crush marks	99
Figure E.8—Examples of buckling	100
Figure E.9—Biopsy port.....	100
Figure E.10—Examples of cracked or damaged distal c-cover.....	101
Figure E.11—Examples of cracked or chipped objective or light guide lens	101
Figure E.12—Examples of residue buildup or staining.....	101
Figure E.13—Examples of residue buildup or staining.....	102
Figure E.14—Examples of bending section rubber glue joint separation	102
Figure E.15—Examples of cracks in glue joints	103
Figure E.16—Examples of cuts or punctures.....	103
Figure E.17—Examples of articulation	104
Figure E.18—Examples of moisture.....	104
Figure H.1—Endoscope markings example.....	115

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:

Cochairs: Mary Ann Drosnock
Garland-Rhea Grisby

Members: Cheri Ackert-Burr, Cantel Inc
Anas Aljabo, CMC Sterilization Ltd
Edward Arscott, NAMSA
Melissa Austin, United Health Services
Rebecca Bartles
Marcia Benedict, STERIS Corporation | Healthcare
Melinda Benedict, Olympus America Inc
Damien Berg
Lisa Berus
Holger Biering, Holger Biering Consulting
Marie Brewer
Deborah Bunn
Jonathan Burdach, Nanosonics Limited
Jennifer Burrell
Ruth Carrico
Lori Chabot
Shanaun Chavez, Intuitive Surgical Inc
Nancy Chobin
Jacqueline Cink, Mayo Clinic
Horlando Cintron
James Collins
Linda Condon, Condon Healthcare Consulting
Edward Conklin
Jeri Culbertson
Jacqueline Daley
Frank Daniels
Mary Ann Drosnock, Healthmark Industries Company Inc
Loraine Durigan
Michelle Eppes, WuXi AppTec Inc
Christine Estep, Fractyl Laboratories Inc
David Etzioni, American Society of Colon and Rectal Surgeons
Jon Fish, Endoscopy Repair Specialist Inc
Christopher Franklin
Sarah Friedberg, Stryker Instruments Division
Marcia Frieze, Case Medical Inc
Jeremy Gibson-Roark, Det Notske Veritas Region
Prerna Gopal, American Dental Association
David Greenwald, American College of Gastroenterology
Garland-Rhea Grisby
Michael Gudejko
Barbara Ann Harmer
Emily Hildebrand, Research Collective
Rachel Hill, Becton Dickinson & Company
Samantha Hodge, Medtronic Inc Campus
Julie Hoover, Johnson & Johnson
Charles Hughes, HIGHPOWER Validation Testing & Lab Services Inc
Timothy Hurtado
Sheri King, Henry Ford Health System

Susan Klacik, HSPA
 Theresa Klein
 Karla Klueber
 Michael Kochman, American Gastroenterological Association
 Margaret (Marcy) Konja, SpecialtyCare
 Marcelo Kugelmas, AASLD-American Association for Study of Liver Diseases
 Erin Kyle, Association of Perioperative Registered Nurses (AORN)
 Mary (MK) Lane
 Angela Lewellyn, Advantage Support Services Inc
 Ann Mangskau, Ecolab
 Regina Manning
 Jason Marosi
 Albert (Ted) May, Andersen Products Inc
 Elaine Mayhall, FDA/CDRH
 Josha McCarthy
 Kathleen McMullen, Association for Professionals in Infection Control & Epidemiology
 Terrence Mistalski, Germitec
 Emily Mitzel, GE Healthcare
 Frank Myers
 Karen Nauss
 Brian Newton, Parametrik Holdings, LLC
 Jake Nordaas
 Gerry O'Dell, Gerry O'Dell Consulting
 Cori Ofstead, Ofstead & Associates
 Adam Okada
 Mary Olivera, Quality Processing Resource Group LLC
 Navid Omidbakhsh, Advanced Sterilization Products (ASP)
 Kia Parker
 Alpa Patel, Sotera Health LLC
 Suzanne Patterson, CIVCO Medical Solutions
 Deanna Pedeville, Bausch & Lomb Inc
 Christopher Pennucci
 Bret Petersen, American Society for Gastrointestinal Endoscopy
 Michael Polozani, Case Medical Inc
 Janet Prust, 3M Health Care
 Natalie Reece, Key Surgical Inc
 Vincent Reed, VHA-National Office of Clinical Consultation & Compliance
 Wayne Rogers, Wayne J Rogers Enterprises
 Vicki Sage
 Jessica Schmidt, Analytical Lab Group
 Anne Schuler, LexaMed Ltd
 Harry Shaffer, Sterilization Consulting Services
 Frank Smith
 Donald Socha, Getinge USA
 Alison Sonstelie
 Joan Spear, Joan M. Spear (Independent Expert)
 Suzanne Stefanik
 Christopher Strafaci, Cogentix Medical
 Grace Thornhill, Boston Scientific Corporation
 James Treharn
 Cindy Turney Smith
 Sunny Vestal
 Marjorie Wall
 Richard Warburton, ChemDAQ Inc
 James Wiggs
 Nicole Williams, Sterilucent Inc
 Jo Wood
 Zheng Xue, Germitec
 Jarl Yeager
 Jennifer Zeck
 Roberto Zumbado, Philips

Alternates: Jennifer Ayscue, American Society of Colon and Rectal Surgeons
 Jhmeid Billingslea, Advantage Support Services Inc
 Matthew Chitester, ChemDAQ Inc

Stephanie Cole, FDA/CDRH
 Brad Conway, American College of Gastroenterology
 Jeffery Daniels, Olympus America Inc
 Lukejohn Day, American Society for Gastrointestinal Endoscopy
 Shawn Engberg, MD Furniture & Supply
 Christian Escobar, Cogentix Medical
 Bill Facemire, Boston Scientific Corporation
 Nancy Fellows, Advanced Sterilization Products (ASP)
 Daniel Fowler, WuXi AppTec Inc
 Ann Hewitt, Cantel Inc
 Meredith Hotchkiss
 Erin Huber, LexaMed Ltd
 Henri Hubert, Quality Processing Resource Group LLC
 Peter Kalkbrenner, Sterilucent Inc
 Marcus Keller, Getinge USA
 Nikki Kluck (Einerson), 3M Health Care
 Philippe Labrie, STERIS Corporation | Healthcare
 Jean-Luc Lemyre, Stryker Instruments Division
 Alisha Loy
 Courtney Mace Davis
 Jacob Manthey, American Gastroenterological Association
 Betty McGinty, Boston Scientific Corporation
 Derek Mortisen, Intuitive Surgical Inc
 Lia Moshkanbaryans, Nanosonics Limited
 Michael Neilson, Becton Dickinson & Company
 Konstantin Petrov
 Bethany Phillips, Association for Professionals in Infection Control & Epidemiology
 Lionel Pineau, Germitec
 Erin Romens, Analytical Lab Group
 Klaus Roth, Quality Processing Resource Group LLC
 Don Rotter, Ecolab
 Christopher Sczublewski
 Benjamin Sims, Sotera Health LLC
 Ryan Swartz, CIVCO Medical Solutions
 Jania Torreblanca
 Brandon VanHee, Key Surgical Inc
 Rebecca Washburn, Henry Ford Health System
 Cheryl Weisbrod
 John Whelan, Healthmark Industries Company Inc
 Jon Wood, HSPA
 Daryl Woodman, Andersen Products Inc

NOTE Participation by federal agency representatives in the development of this standard 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:

Cochairs: Janet Prust
 Patrick Weixel

Members: Gregory Aldrich
 Anas Aljabo, CMC Sterilization Ltd
 Eseosa Amenaghawon
 Brett Anderson, Cochlear Ltd
 Jennifer Asleson, Quality, Microbiology & Sterilization Services LLC
 Richard Bancroft, STERIS Corporation
 Marie Brewer
 Trabue Bryans, BryKor LLC
 Jonathan Burdach, Nanosonics Limited
 Charles Cogdill, Medtronic Inc Campus
 Emily Craven, Boston Scientific Corporation
 Jacqueline Daley
 Gordon Ely, LexaMed Ltd
 Nicole Felderman, CIVCO Medical Solutions

Brian Fortier, Aorta Medical Inc.
 Lisa Foster, Aduvo QS & SA Consulting
 Daniel Fowler, WuXi AppTec Inc
 Joel Gorski, NAMSA
 Magnus Graham, BSI Healthcare
 Ashley Hammer
 Joyce Hansen, Johnson & Johnson
 Douglas Harbrecht, Sterility Assurance LLC
 John Harper, Sterile Edge
 Deborah Havlik, DA Havlik Consulting
 Mollie Holter, MicroBio Consulting LLC
 Clark Houghtling, Cosmed Group Inc
 Susan Klacik, HSPA
 Erin Kyle, Association of Perioperative Registered Nurses (AORN)
 Byron Lambert, Abbott Laboratories
 Patrick McCormick, Bausch & Lomb Inc
 Leslie Nichols, Mayo Clinic
 Gerry O'Dell, Gerry O'Dell Consulting
 Tarika Onishi, DexCom Inc
 Ken Paddock, Baxter Healthcare Corporation
 Kia Parker
 Suzanne Patterson, CIVCO Medical Solutions
 Kimberly Patton, Becton Dickinson & Company
 Janet Prust, 3M Health Care
 Nancy Rakiewicz, IUVO BioScience
 Joan Rickard
 Linda Schultz
 Kristen Singleton, Getinge USA
 Joan Spear, Joan M. Spear (Independent Expert)
 Sopheak Srun, Quality Tech Services LLC
 Mark Swanson, Quality and Regulatory Expert Partners (QRX)
 Julie TerWee, Pfizer Parenteral Center for Excellence
 James Treharn
 Marjorie Wall
 Sean Weir
 Patrick Weixel, FDA/CDRH
 James Wiggs
 Martell Winters, Sotera Health LLC
 Roberto Zumbado, Philips

Alternates: Jennifer Benolken, DuPont Tyvek Medical and Pharmaceutical Protection
 Stacy Bohl, Boston Scientific Corporation
 Carolyn Braithwaite-Nelson, Philips
 Richard Burgess, BSI Healthcare
 Greg Crego, IUVO BioScience
 Kimbrell Darnell, Becton Dickinson & Company
 Aaron DeMent, Sotera Health LLC
 Eric Einwalter, CIVCO Medical Solutions
 Chad Geiger, DexCom Inc
 Anna Grayson, Grayson Associates
 David Kelman, Sterile Edge
 Michelle (Shelly) Luebke, Baxter Healthcare Corporation
 Gerald McDonnell, Johnson & Johnson
 David McGoldrick, Abbott Laboratories
 Nicole McLees, 3M Health Care
 Shane Pinkston, Getinge USA
 Christine Render, Cosmed Group Inc
 Jimmy Reyes, Alcon Laboratories Inc
 Molly Swanson, Quality Tech Services LLC
 Lisa Ward, STERIS Corporation
 Jon Wood, HSPA
 Shelley Zimmerman, WuXi AppTec Inc

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

Acknowledgments

The Endoscope Reprocessing Working Group would like to thank Cori Ofstead and Jon Fish for their contributions to the content, and in particular, supplying figures for use in the annexes of this document.

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, transport, leak testing, cleaning, high-level disinfection, liquid chemical sterilization, packaging, sterilization, and storage of flexible and semi-rigid endoscopes. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these devices and accessories.

The first edition of this standard was published as an American National Standard in 2015. This edition technically revises and replaces the first edition.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall.”

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 standard are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the ANSI/AAMI ST91, *Flexible and semi-rigid endoscope processing in health care facilities* (ANSI/AAMI ST91:2021), but it does provide important information about the development and intended use of the document.

Introduction

Reusable flexible and semi-rigid endoscopes are used in various body cavities for diagnostic and therapeutic procedures. All endoscopy procedures pose risks to patients. The introduction of pathogens through use of contaminated endoscopes is an appreciable risk that can be mitigated. Pathogens can be introduced when there are breaches of host barriers, person-to-person transmission of pathogens (e.g., *Escherichia coli*), or transmission of environmental pathogens (e.g., *Pseudomonas aeruginosa*). Further consequences of inadequate device processing can include device damage and adverse reactions in patients.

Of greatest concern is the multiple and growing number of reports of multi-drug-resistant organism (MDRO) transmission resulting in patient infection (Galdys, 2019 [158]; Kumarage, 2019 [203]; Jørgensen, 2016 [192]) and in some cases high rates of mortality (FDA MDR 8379810, 2019 [322]; Humphries, 2017 [177]; Ross, 2015 [270]; FDA, 2015c [335]). These outbreaks have led to Food and Drug Administration (FDA) safety alerts (FDA, 2018a [332]; FDA, 2015a [333]; FDA, 2015b [334]; FDA, 2015c [335]), Centers for Disease Control and Prevention (CDC) statements (CDC/FDA, 2015 [110]; CDC, 2015 [111]; FDA/CDC, 2018 [341]), professional guidelines and position statements updates, and heightened awareness by the public. Additional outbreaks have been reported related not only to duodenoscopes (Rauwers, 2019 [262]; Bourigault, 2018 [96]; Potron, 2017 [257]; Epstein, 2014 [145]), but also to gastroscopes (Bajolet, 2013 [74]), ureteroscopes (Kumarage, 2019 [200]; Chang, 2013 [102]), cystoscopes (Sorbetes, 2019 [296]; Ottawa Public Health, 2019 [250]; Jimeno, 2016 [184]; Wendelboe, 2008 [374]), colonoscopes (Reddick, 2017 [264]; Gonzalez-Candelas, 2017 [165]) and bronchoscopes (Galdys, 2019 [158]; Alipour, 2017 [64]; Jørgensen, 2016 [192]; Guy, 2014 [169]; Kovaleva, 2013 [202]). What is very concerning regarding outbreaks related to MDROs is that failures in the processing or the equipment could not always be identified. The facilities were following the guidelines and manufacturers' written instructions for use (IFU) (Galdys, 2019 [158]; Humphries, 2017 [177]).

Endoscopic transmission of infection

Although flexible endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine, as illustrated above, numerous healthcare-associated infections (HAIs) have been linked with the use of contaminated endoscopes. Prior to the multiple documented outbreaks in the last few years, the risk of endoscope-related patient infection was considered to be relatively rare. Now there are multiple published reports of endoscope processing lapses, including tens of thousands of patient exposures both in the United States and other countries (Dirlam-Langlay, 2013 [135]; Ottawa Public Health, 2019 [250]; Galdys, 2019 [158]; FDA MDR 8811666, 2019 [346]; Ross, 2014 [270]; Epstein, 2014 [145]; US Department of Veterans Affairs, 2009 [131]). In addition, there are other reports of potential patient exposures to contaminated endoscopes in the media and other public databases that have not been published in peer-reviewed literature (U.S. Senate Report, 2016 [364]; CMS, 2015a [120]; CMS, 2015b [121]).

Health care facilities and manufacturers are 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 reprocessor) has caused or contributed to a death, injury, or serious illness of a patient. The MAUDE database contains numerous references to infections suspected to have occurred after lapses in processing or as a result of ineffective processes (e.g., FDA MDR 8683917, 2019 [319]; FDA MDR 8524645, 2019 [321]; FDA MDR 8379810, 2019 [322]; FDA MDR 8242610, 2019 [323]).

Multiple peer-reviewed publications in several countries, including the United States, have documented breaches in processing that have led to patient exposure to improperly processed flexible and semi-rigid endoscopes and have caused serious infections (Gonzalez-Candelas et al., 2010 [165]; Carbonne et al., 2010 [101]; Aumeran et al., 2010 [72]; Robertson, 2017 [268]; Reddick, 2017 [264]; Kumarage, 2019 [203]; FDA MDR 8379810, 2019 [322]; Kovaleva et al., 2013 [202]; Rubin et al., 2018 [271]).

In many reports of patients being exposed to contaminated endoscopes, the patients were not tested for all pathogenic organisms but only HIV or hepatitis B viruses, despite documented outbreaks of non-viral pathogens. Published reports support the conclusion that current risk estimates are outdated and inaccurate (Ofstead et al., 2013 [243]; Dirlam-Langlay et al., 2013 [135]). The true risk of patient infection related to flexible endoscopy procedures has recently been reported to be higher than previously believed (Wang, 2018 [371]). In addition, there are many reports of outbreaks related to contaminated endoscopes (Seoane-Vazquez, 2006 [289]; Kovaleva et al., 2013 [202];

Rubin et al., 2018 [271]; Galdys 2019 [158]; Kumarage, 2019 [203]; Sorbets, 2019 [296]). The FDA provided interim results from mandated post market surveillance studies on duodenoscope contamination. These results indicate that up to 5.4 % of duodenoscopes sampled after appropriate processing were contaminated with high-concern organisms (FDA, 2019a [325]; FDA, 2019b [326]; FDA, 2019c [327]; FDA, 2019d [336]). These results led the FDA to recommend adoption of new technologies and designs of duodenoscopes to address the problem.

Audits conducted of facilities that perform GI endoscopic procedures have found widespread lapses in infection prevention and control, including endoscope processing, and in some cases, endoscopes were not processed in accordance with guidelines (Dirlam-Langlay et al., 2013 [135]; The Joint Commission, 2017 [186]; Armellino, 2018 [70]; Ofstead, 2018(a) [237]; Ofstead, 2018(b) [242]; Ofstead, 2017 [238]).

A 2013 northeastern Illinois infectious outbreak of 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 39 patients were identified as infected (Epstein et al, 2014 [145]). Further outbreaks were similarly linked to duodenoscopes in Boston (Shenoy et al., 2019 [291]), Pittsburgh (McCool et al., 2012 [209]), Seattle (Wendorf et al., 2015 [375]), and Los Angeles (Rubin and Murthy, 2016 [273]; Smith et al., 2015 [294]; Humphries, 2017 [177]) known through media and FDA reporting.

Effects of endoscopy-related infection outbreaks and other adverse events can include the following:

- Spread of microorganisms from patient to patient by contaminated or improperly processed flexible and semi-rigid endoscopes or by malfunctioning equipment or between patients and endoscopy personnel (exogenous infections).
- Spread of microorganisms during an endoscopy procedure from the GI tract through the bloodstream to susceptible organs or spread of microorganisms to adjacent tissues that are breached as a result of the endoscopic procedure.
- Patient or healthcare worker injury related to chemical residue remaining on devices after the procedure or processing.
- Patient injury or delay in treatment related to damaged devices that are difficult to use because of mishandling or inadequate processing.

Mitigating these risks begins with the correct handling procedures in preparation for processing, including precleaning 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 required to remove clinical soil and other materials prior to the antimicrobial processes of high-level disinfection or sterilization. Growth of gram-negative bacteria and other potential pathogens can be prevented by complete drying after high-level disinfection (Alfa, 1991 [53]; Ofstead et al., 2018 [242]; Perumpail, 2019 [254]).

Cleaning is a multi-step process and is critical not only to ensure that subsequent processing steps can be effective but also to remove materials that can lead to adverse patient reactions. Cleaning, which reduces clinical soil, is then followed by disinfection or sterilization to inactivate microbial contaminants. Critical devices are devices that are introduced directly into the bloodstream, or which contact a normally sterile tissue or body space during use and for which sterilization is required. Semi-critical devices come in contact with mucous membranes or non-intact skin. These items should be thoroughly cleaned and then sterilized. If sterilization is not possible, high-level disinfection is the minimum advised processing method (FDA, 2015 [334]). Historically, because of cost and logistic needs, the standard of care for gastroenterology and other endoscopes used in procedures performed outside of operating rooms has been high-level disinfection (SGNA, 2018 [297]; ASGE, 2017 [28]). It is advised that flexible and semi-rigid endoscopes to be used in semi-critical applications be sterilized prior to use (Spaulding, 1972 [301]; FDA, 2015 [334]; AORN, 2018 [367]).

Evidence to support sterilizing all flexible endoscopes (semi-critical and critical) includes:

- a) high microbial load after patient procedure (Alfa, 2014 [56]; Ofstead, 2015 [235]; Fushimi, 2013 [157]);

- b) complex design of flexible endoscopes;
- c) risk for biofilm formation (Alfa, 2017 [51], [62]; Herve, 2016 [173]).

These risk factors can lead to residual clinical soil in endoscopy channels and outer surfaces (i.e., distal end, elevator mechanism) after cleaning procedures (Visrodia, 2014 [369]; Ofstead, 2015 [235]; Ofstead, 2017 [238]; Ofstead, 2018a [237]; Alfa, 2014a [56]). Effective cleaning followed by routine sterilization of flexible endoscopes is preferred because of the significant public health risk. Sterilization of endoscopes can reduce this risk because of the greater margin of safety in the overkill process, and terminal sterilization provides a sterile packaged endoscope (Rutala and Weber, 2016a [279]; McCool et al., 2012 [209]; Wendorf et al., 2015 [375]; Rubin and Murthy, 2016 [273]; Smith et al., 2015 [294]). 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.

Transition from high level disinfection to sterilization as the standard of care may be accelerated by identifying and addressing key technical and compatibility obstacles and defining priorities and key steps.

Contribution of reusable medical device manufacturer is essential (FDA 2015, updated 2017 [338]). Partnerships between sterilizer and medical device manufacturers are encouraged.

Although endoscopes play a vital role in the effective delivery of health care and offer patients many benefits, the risks associated with iatrogenic transmission via endoscopes continue to be of significant concern. Endoscope design complexity presents a substantial challenge to achieving consistent and effective processing. Although risk mitigation steps, such as inspection prior to every use, are detailed in manufacturers' instructions, these steps fail to account for the high-risk design elements, such as long, internal lumens and recessed spaces that either cannot be visualized or are difficult to visualize.

The process of improving patient safety in flexible endoscopy is multi-factorial, needing clear guidance on endoscope processing, effective training and competency verification of personnel, comprehensive quality control systems, validated methods for ensuring adequate processing, and designing processes with margins of safety that account for the level of risk associated with use of these devices (FDA, 2019 [337]). As part of this process, continued research, and partnership between endoscope, reprocessor and sterilizer manufacturers to support elevating the standard of endoscope processing from high-level disinfection to sterilization is encouraged.

Flexible and semi-rigid endoscope processing in health care facilities

1 Scope

This standard provides guidelines for point of use treatment, transporting, leak testing (where indicated), cleaning, packaging (where indicated), high-level disinfecting and/or sterilizing, storage, and quality control procedures of flexible gastrointestinal (GI) endoscopes, flexible bronchoscopes, flexible ear, nose, and throat endoscopes, flexible urology endoscopes, and other types of reusable flexible endoscopes used in procedural and surgical settings, and semi-rigid operative endoscopes (e.g., choledochoscopes) used in health care facilities. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these reusable devices and accessories to render them safe for patient use.

NOTE For purposes of this standard, "health care facilities" include, but are not limited to, hospitals, ambulatory surgery facilities, physicians' offices, cardiac catheterization laboratories, endoscopy suites and centers, respiratory therapy clinics, urology clinics, and other areas where reusable medical devices are processed, stored, and used.

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) care and inspection of endoscopes;
- e) maintenance of processing equipment;
- f) facility risk management considerations;
- g) quality control;
- h) quality process improvement.

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

1.2 Exclusions

This standard does not cover:

- a) the processing of rigid endoscopes (see ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* [17]; ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities* [14]; and ANSI/AAMI ST41, *Ethylene oxide sterilization in health care facilities: Safety and effectiveness*) [12];
- b) the processing of transesophageal echocardiogram (TEE) probes, or endocavity ultrasound probes;
- c) specific construction and performance criteria for steam sterilizers (see ANSI/AAMI ST8, *Hospital steam sterilizers* [10], and ANSI/AAMI ST55, *Table-top steam sterilizers*) [13], 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*) [11], rigid sterilization container systems (see ANSI/AAMI ST77, *Containment devices for reusable medical device sterilization*) [16], or rigid, protective organizing cases that require wrapping before sterilization (see ANSI/AAMI ST77); or

- d) the processing of devices labeled for single use only and not intended to be processed by the healthcare facility prior to use.

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

2 Normative references

There are no normative references in this document.

3 Terms and definitions

3.1

automated endoscope reprocessor

AER

<endoscope washer–disinfector>

machines designed for the purpose of cleaning and/or disinfecting or liquid chemically sterilizing endoscopes and components.

Note to entry: The process can use a cleaning agent, and always uses a high-level disinfectant (HLD) or liquid chemical sterilant (LCS) solution.

3.2

bioburden

population of viable microorganisms on a product and/or a sterile barrier system

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

3.3

biofilm

accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily (Donlan, 2002) [136]

Note to entry: 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 extracellular polymeric substance), and prevents antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells.

3.4

biological indicators

BIs

test systems containing viable microorganisms providing a defined resistance to a specified sterilization process

Note 1 to entry: According to the 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)] [329]

Note 2 to entry: Biological indicators are intended to demonstrate whether or not the conditions were adequate to achieve sterilization. A negative Biological Indicator (BI) does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

Note 3 to entry: See ISO 11138-7 for information on the selection, use, and interpretation of biological indicators.

3.5

borescope

device used for visual inspection of areas that are inaccessible by other means

Note to entry: Some borescopes are equipped with cameras that provide still images or video of inaccessible areas within endoscope lumens.

3.6

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 sterile barrier system suitable for specified sterilization method(s) to maintain sterility

3.7

certification

process by which a non-governmental agency or association certifies that an individual has met certain predetermined standards specified by that profession for specialty practice

3.8

challenge test pack

pack used in qualification, installation, and routine quality assurance testing of health care sterilizers

Note to entry: See also process challenge device.

3.9

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 used in specific tests of sterilization equipment

Note 1 to entry: ANSI/AAMI/ISO 11140-1:2014, *Sterilization of health care products—Chemical indicators—Part 1: General requirements* [2], defines six types of CIs and specifies performance requirements for them:

Type 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.

Type 2 (Bowie-Dick test indicators): 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).

Type 3 (single critical process 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.

Type 4 (multicritical process 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.

Type 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 ANSI/AAMI/ISO 11138 series for BIs.

Type 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. ANSI/AAMI/ISO 11140-1 refers to these indicators as cycle verification indicators. [2]

Note 2 to entry: FDA recognition of chemical indicators is limited to Type 1 process indicators; Type 2 indicators for use with special tests; and Type 6 emulating indicators (ANSI/AAMI/ISO 11140-1:2014) [2].

Note 3 to entry: The International Standards Organization published a revised version of ISO 11140-1, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, in 2014 [2]. The ISO document was adopted by the Association for the Advancement of Medical Instrumentation (AAMI) and subsequently approved as an American National Standard, ANSI/AAMI/ISO 11140-1:2014. A key change in the 2014 version of the standard is the use of the term “type” rather than the term “class” of chemical indicator. As chemical indicator manufacturers update their device labeling to reflect the new standard, there will be a transition period during which end-users will observe some chemical indicators labeled as “Class X” and others labeled with the new term “Type X” in the marketplace.

3.10 chemical monitoring device

non-traditional indicator or LCS/HLD concentration measurement method

3.11 cleaning

removal of contamination from an item to the extent necessary for further processing or for the intended use

Note to entry: In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent clinical 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.

3.12 clinical soil

residues on medical instruments after patient use

3.13 competency

an expected level of performance that integrates knowledge, skills, abilities, and judgment.

Note to entry: Certification in reprocessing of endoscopes does not mitigate the need for orientation, ongoing education training/education and competency assessments (CDC, 2017 [108]).

3.14 competency verification

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

3.15 CQI

continuous quality improvement

3.16 critical device

device that is introduced directly into the bloodstream or which contacts a normally sterile tissue or body space during use

3.17 critical water

water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, deionization [DI], and reverse osmosis [RO] or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process

Note 1 to entry: This water is mainly used for the final rinse or for steam generation.

Note 2 to entry: See AAMI TIR34 [23] for specifications.

3.18 decontamination

process of removing pathogenic microorganisms from objects so they are safe to handle, use, or discard (CDC, 2008 [107])

3.19 decontamination area

area of a health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items

3.20

education

knowledge, comprehension, and insight acquired by an individual after studying a specific subject

3.21

endoscope sheath

sterile, single-use protective barrier for various types of endoscopes, intended to cover the entire insertion tube of the endoscope and which might contain air, water, or suction channels but most often is single channel (FDA, 2000b) [340]

3.22

engineering controls

concept that, to the extent feasible, the work environment and the job itself are designed to eliminate or reduce exposure to hazards

3.23

ethylene oxide (EO) sterilization

validated process used to render a device free of viable microorganisms that utilizes ethylene oxide gas as the active sterilant

3.24

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

3.25

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

3.26

exposure control plan

according to OSHA, “a written [plan] designed to eliminate employee exposure to bloodborne pathogens” (29 CFR 1910.1030(C)(1)) [231]

3.27

exposure time

period for which sterilization or high-level disinfection process parameters maintain their specific tolerances

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

3.28

gaseous and vapor chemical sterilization

validated process employing gaseous and/or vapor chemical sterilants (e.g., ethylene oxide [EO], hydrogen peroxide, ozone)

3.29

high-level disinfectant

HLD

germicide that inactivates all microbial pathogens except for bacterial endospores when they are present in large numbers, when used according to labeling (Rutala, 1990 [280])

Note to entry: According to the FDA, an HLD is a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass the AOAC International sporidical activity test as a sterilant.

3.30

high-level disinfection

process that kills all microbial pathogens but not necessarily high numbers of bacterial spores

Note to entry: 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.

3.31

high-risk endoscopes

endoscopes that have been associated with infectious outbreaks including those that are difficult to process and increase the risk of incomplete clearance of contaminating infectious organisms, including bronchoscopes, cystoscopes, duodenoscopes, endobronchial ultrasound endoscopes, linear ultrasound endoscopes, ureteroscopes, and others as determined by the facility

3.32

hydrogen peroxide sterilization

validated process used to render a device free of viable microorganisms that utilizes a formulation of vaporized hydrogen peroxide as the active sterilant and might or might not include a plasma phase to help break down hydrogen peroxide

3.33

hydrogen peroxide–ozone sterilization

validated process used to render a device free of viable microorganisms that utilizes a formulation of vaporized hydrogen peroxide–ozone as the active sterilant

3.34

iatrogenic

relating to illness caused by medical examination or treatment

3.35

inspect

to assess a medical device carefully and visually, typically to evaluate the condition or to discover any residual debris or damage, using the unaided eye, lighted magnification and/or a borescope

3.36

installation qualification

IQ

process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

3.37

instrument air

medical gas that falls under the general requirements for medical gases as defined by NFPA 99, *Health care facilities code*) [216], is not respired, is compliant with ANSI/ISA S-7.0.01 (*Quality standard for instrument air*), and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40 °F (-40 °C)

{SOURCE: ANSI/AAMI ST79:2017, 2.56} [17]

3.38

labeling

any literature, including instructions for use, provided with a device as well as all advertising claims published by the manufacturer (21 CFR 801) [328]

3.39

liquid chemical sterilant

LCS

solution of a chemical that passes the AOAC Sporicidal Activity Test as a sterilant

3.40

liquid chemical sterilant processing system LCSPS

specific category of AER that uses a liquid chemical sterilant to achieve liquid chemical sterilization of the medical device load, which is frequently an endoscope and its accessories

3.41

liquid-resistant material

material that inhibits the penetration of liquids

Note to entry: According to ANSI/AAMI PB70 [9], a liquid-resistant material would be defined as a Level 1, 2, or 3 barrier material.

3.42

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

3.43

magnification

use of a tool to enhance the visual inspection of a device by enlarging the image

3.44

manufacturer's written instructions for use

IFU

written directions developed, validated, and provided by the manufacturer of a device that provide instructions for operation, safe and effective processing

3.45

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

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.

3.46

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) [339]

3.47

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 to entry: 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.

3.48

occupational exposure

contact, through inhalation, ingestion, skin contact, or absorption, with a potentially hazardous material during the course of employment

Note 1 to entry: Occupational exposure to hazardous materials, including chemical and biological agents and potentially infectious materials, is regulated by OSHA (29 CFR Part 1910).

Note 2 to entry: The OSHA bloodborne pathogens regulation (29 CFR 1910.1030 [231]) 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.”

3.49

operational qualification

OQ

process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

3.50

OSHA

United States Department of Labor Occupational Safety and Health Administration

3.51

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

3.52

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) [231]

3.53

point of use treatment

the collective activities that the user of a medical device performs at the point of use (where the procedure using the endoscope was performed) to prepare it for processing, occurring immediately after patient use and including precleaning (to prevent biofilm formation and drying of soil), disconnecting accessories, preparing handoff communication, and preparing the endoscope for transport to the decontamination by attaching required caps and placing in an appropriately-labeled container

Note to entry: For purposes of this standard, precleaning and point of use care have the same meaning as point of use treatment.

3.54

preventive maintenance

routine servicing of equipment for the purpose of maintaining it in good working condition

3.55

process challenge device

PCD

item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process

Note to entry: For purposes of this standard, a PCD is a challenge test pack containing a BI or a BI and a CI. See AAMI TIR31 [22].

3.56

processing

process carried out on a device to allow its subsequent safe use, which can include cleaning, disinfection, sterilization, and related procedures

3.57

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

3.58

pseudoinfection

laboratory evidence of the presence or activity of pathogenic microorganisms in the absence of infection, which can result from colonization of the site without infection, contamination of the specimen, or laboratory error or misinterpretation yielding a false-positive test result for an infectious disease

3.59

reprocessing

see *processing* (3.56)

3.60

reusable 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

3.61

reusable medical device

device intended for repeated use on different patients, with decontamination and other processing between uses

Note to entry: Examples include surgical instruments, endoscopes, basins, and electromedical equipment.

3.62

rigid sterilization container system

sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents

Note to entry: 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.

3.63

safety data sheet

SDS

previously referred to as MSDS (material safety data sheet), this document is required to be provided by the manufacturer of chemicals used in the workplace, such as disinfectants

3.64

semi-critical device

device that contacts intact mucous membranes or non-intact skin but does not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body

3.65

shelf life

when the term is used with respect to a processed or sterilized medical device, the period of time during which the item is considered safe to use

3.66

solid container

container that maintains its shape is puncture resistant and is intended to protect its contents

3.67

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

3.68

Spaulding classification

strategy for determining the level of processing needed for contaminated medical devices, which is comprised of a system that classifies a medical device as critical, semi-critical, or noncritical based on risk to patient safety from contamination on a device and establishes three levels of germicidal activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semi-critical, and noncritical)

3.69

spore test strip

test system containing a known number of bacterial spores (at least 10^5 per strip) of known resistance to a liquid chemical sterilant and used in a defined liquid chemical sterilant processing system

3.70

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 CDC 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) [104]

3.71

steam sterilization

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

3.72

sterile

free from viable microorganisms

3.73

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

3.74

sterilization

validated process used to render a product free from viable microorganisms

3.75

sterilization cycle

defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber

3.76

sterilizer

apparatus used to sterilize medical devices, equipment, and supplies by direct exposure to the sterilizing agent

3.77

terminal cleaning

thorough environmental cleaning that includes, but is not limited to walls, floors, horizontal surfaces, movable equipment, non-movable equipment, utility sinks, hand hygiene sinks, air vents, storage cabinets and racks

3.78

terminal sterilization

process whereby product is sterilized within its sterile barrier system that permits storage for use at a later time

3.79

training

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

Note to entry: The specific goals of training are to improve capability, capacity, productivity, and performance.

3.80

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

3.81

utility water

water that comes from the tap for flushing, washing, or rinsing

Note to entry: See AAMI TIR34 [23] for specifications.

3.82

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 to entry: Validation is performed by the manufacturer.

4 Design of endoscope processing area

4.1 General considerations

The processing area should be physically separated from the patient care areas and procedure rooms. The processing area should be designated 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, including:

- a) receipt of devices, leak testing;
- b) cleaning (decontamination);

- c) inspection;
- d) storage; and
- e) disinfection and drying or packaging and sterilization.

In all cases, facilities should ensure a unidirectional flow from dirty to clean; conduct an analysis to identify risks; and minimize these risks by policies, procedures, 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 (see 6.3.2).

The design of the endoscope processing area should facilitate the highest level of infection prevention and patient and employee safety. An area designed with environmental needs such as solid, nonporous horizontal surfaces, lighting, and utility support of electricity should be provided in areas used for endoscope processing. When designing an endoscope processing area based on applicable regulations, considerations include, but are not limited to:

- a) ability of work surfaces to withstand frequent cleaning and disinfection;
- b) workflow;
- c) patient volume (current and anticipated);
- d) number and types of endoscopes and equipment;
- e) quantity and types of processing equipment (e.g., sterilizers, AERs, washer-disinfectors);
- f) scope and equipment storage requirements;
- g) supply and chemical storage requirements;
- h) number of people anticipated to be working in the area;
- i) traffic flow;
- j) required utilities (e.g., instrument air with a regulator, if necessary, source of water of appropriate quality, lighting, electricity, data drops, heating, ventilation, air conditioning (HVAC), negative air flow and adequate air exchange rates, suction capabilities);
- k) ergonomics and human factors;
- l) clean space required for visual inspection and cleaning verification tests; and
- m) area for employees to take breaks as food and drink are not permitted in the endoscope processing area.

4.2 Workflow

4.2.1 General considerations

Workflow should be unidirectional from the decontamination area to the clean area and then to the storage area. Workflow patterns should be designed to contain contaminants, prevent damage to endoscopes, and minimize employee exposure to pathogens and toxic chemicals.

Ergonomic factors affecting worker safety and comfort should be considered when designing work areas. For example:

- Counters, sinks and work surfaces should be:

- height-adjustable or positioned at heights that accommodate the average height of employees and the tasks to be performed at each location; and
 - sufficient to accommodate the endoscope length.
- Anti-fatigue mats should be:
- used in areas where prolonged standing is required; and
 - 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 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 workflow and to provide adequate space for necessary equipment can enhance efficiency and reduce the potential for cross-contamination. Considering ergonomic factors during the design phase can help prevent worker injury. A pass-through window that can be closed is convenient for devices that have been manually decontaminated to be passed over to the clean side for processing. Having a window that can be closed maintains the air pressure requirements as well as maintaining the integrity of the clean side.

4.2.2 Physical separation

Facilities should have two separate rooms for processing endoscopes. Until such time (major renovations or new construction) that two separate processing rooms can be provided, strict unidirectional processing procedures should be in place to reduce risks of cross-contamination. After cleaning, PPE should be changed, and hand hygiene performed before any disinfection or sterilization activities. The endoscope processing area should also include a designated drying area, when applicable, to dry the device with forced instrument air prior to patient use, storage, or in preparation for packaging and terminal sterilization.

Adequate space shall be provided to allow for the manual cleaning and rinsing of devices during decontamination. It is optimal that the manual cleaning area is physically separated by walls or partitions in a two-room configuration to control contaminants generated during manual cleaning. Doors that open in the direction of the one-way workflow and closeable pass-through windows separating the decontamination area from the adjoining disinfection/sterilization area should remain closed when not in active use. An endoscopy processing room with a one-room design should provide a minimum of 4 feet between the decontamination area and the clean work area and either a separating wall or a barrier that extends a minimum of 4 feet above the sink rim to separate soiled work areas from clean work areas (FGI, 2018 [146]; AORN, 2018e [39]).

An area should be defined for disinfection/sterilization that is separate from the manual cleaning/processing area. For manual processing, this area should 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. Sufficient space and utilities for the units should be provided along with adequate space for storage of chemicals near the AER. Strict unidirectional processing procedures should be in place to reduce risks of cross-contamination following an antimicrobial process. A pass-through AER is another option to fulfill these requirements. This should include a designated drying area to dry the device prior to patient use, storage, or in preparation for packaging and gaseous sterilization.

Flexible endoscopes should be stored in a clean, secure location but not within the endoscopy procedure room (AORN, 2018e [39]). Physical separation of this area from the main processing area is preferred to minimize risk of cross-contamination during storage.

Rationale: Physical enclosure of the decontamination area is necessary because contaminated aerosols, droplets, 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 (e.g., AERs, storage equipment) can help protect processed flexible and semi-rigid endoscopes from recontamination. A study (Johnston et al., 2019 [185]) determined that contaminants during a gastroenterology procedure could travel significant distances in the procedure room, contaminating items hanging on the wall, not used during the procedure.

4.2.3 Traffic control

Traffic in the processing area should be restricted to authorized personnel wearing appropriate attire. 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 might be necessary for visitors 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 and potentially hazardous chemicals used in the decontamination area.

4.3 Physical facilities

4.3.1 General 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:

- a) operational systems;
- b) equipment; and
- c) the anticipated workload in each functional work area.

Space requirements should be based on:

- a) the volume of work anticipated;
- b) the amount of product that will be routinely stored;
- c) disposal needs; and
- d) the degree of mechanization, the product mix (e.g., reusables vs. disposables), and the storage methods used, which might change over time.

There should be adequate space for:

- a) maneuvering, queueing, and unloading carts or other transportation systems at times of average daily peak workload; and
- b) record-keeping, either manual or computerized.

4.3.1.1 Space requirements in the decontamination area

In the decontamination area, sufficient space should be allocated for:

- a) decontamination sink for manual cleaning;

- b) workspace to perform inspection by unaided eye and/or use of tools such as lighted magnification and/or a borescope;
- c) cleaning verification/equipment counterspace;
- d) trash bins;
- e) laundry bins;
- f) separate sink designated for hand hygiene;
- g) an emergency eyewash station that is separate from the decontamination sink;
- h) storage of cleaning chemicals;
- i) storage of cleaning implements;
- j) storage of PPE;
- k) sink and/or counterspace for leak testing;
- l) leak testing equipment;
- m) automated flushing systems;
- n) suction machines;
- o) drying (instrument air, adapters, connectors);
- p) servicing of the equipment;
- q) water treatment for critical water; and
- r) documentation manual or electronic and method to dispose of patient labels.

NOTE It is permissible to combine handwashing sink and emergency eyewash station.

According to NFPA 99, *Health care facility code* [216], a separate vacuum system for performing suction in processing is needed.

Allocate sufficient space for filtration system and utilities for the AER. Adequate space for storage of detergents and disinfectants near the AER should also be considered.

4.3.1.2 Space requirements in the preparation area

The preparation area should be adjacent to the area used for sterilization or disinfection. Sufficient space should be allocated for:

- a) inspection and inspection equipment such as lighted magnification and/or a borescope;
- b) workspace to fully lay out an endoscope for inspection;
- c) instrument air, adapters, and connectors;
- d) documentation manual or electronic which may include computer, printer, and label maker;
- e) storage for all packaging supplies (i.e., quality monitors, tape wrappers); and
- f) separate sink designated for hand hygiene (i.e., sink with soap and paper towels).

4.3.1.3 Space requirements for terminal sterilization

Sufficient space should be designed for:

- a) the appropriate sterilization equipment;
- b) the capacity of the sterilizer (i.e., number of endoscopes per sterilization cycle) combined with the cycle time of the sterilization process to accurately determine the number of sterilizers required in the space to meet turnaround expectations;
- c) space for sterilization supplies (e.g., BIs, CIs, test packs, pouches, wraps, rigid containment system, etc.); and
- d) servicing area for sterilizer.

4.3.1.4 Space requirements for manual high-level disinfection or manual liquid chemical sterilization

If a facility anticipates using manual high-level disinfection or manual liquid chemical sterilization, sufficient space should be allocated in the clean area for:

- a) manual containers placed close to a sink (AORN, 2019a [35]);
- b) separate sinks for rinsing;
- c) ventilation hoods, if needed;
- d) storage of HLD chemicals, sterilant chemicals, spill kits, PPE, instrument air, alcohol, adapters, connectors, and filters;
- e) water treatment for critical water;
- f) drying;
- g) documentation;
- h) sink designated for hand hygiene; and
- i) emergency eye wash station.

NOTE It is permissible to combine handwashing sink and emergency eyewash station.

Rationale: Space requirements can vary significantly depending upon the specific processing needs of the facility and are often underestimated during the planning process. Adequate space is needed for effective and safe endoscope processing. Mechanical processing improves effectiveness, increases efficiency, minimizes personnel exposure to biohazardous materials and chemicals, and can be more successfully monitored for quality and consistency.

4.3.1.5 Space requirements for automated high-level disinfection or liquid chemical sterilization

If automated high-level disinfection is anticipated, sufficient space should be designed for:

- a) the appropriate high-level disinfection or liquid chemical sterilization equipment;
- b) the capacity requirements;
- c) filtration system and utilities for the AER;
- d) servicing area for automated equipment;
- e) storage of LCS/HLD chemicals, spill kits, PPE instrument air, alcohol, connectors, or filters;

- f) drying; and
- g) documentation.

4.3.2 Sinks and accessories

Processing areas should have dedicated plumbing and drains that meet the needs of the facility for volume and capacity.

NOTE Some jurisdictions have regulations that apply to plumbing. Uniform Plumbing Code (UPC) can be useful to reference.

Provisions for chemical disposal should be integrated into the design of the decontamination space as described in the manufacturer's written IFU and in accordance with local, state, and federal regulations.

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., a minimum of 16 inches x 30 inches) to ensure that the endoscope can be positioned without tight coiling. Sinks should be height-adjustable so that personnel do not have to bend over to clean endoscopes. An ideal decontamination sink is height-adjustable, 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. Consideration should be given for additional space for delayed processing protocol. 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 the endoscope while attaching it to the leak tester, detach and separate removable components, and to inspect the endoscope for physical damage and cleaning effectiveness.

Lighting of the recommended illuminance should be placed above the sink and counter area so that personnel can adequately perform inspection activities as the endoscope is processed (see 4.3.8 and Table 1). A lighted magnifier should be available for inspection.

Instrument air along with a pressure regulator should be provided in the processing area. Instrument 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.

Critical water for final rinsing should be provided in necessary locations (see 4.3.11 and AAMI TIR34 [23]).

A hand hygiene sink, which is separate from utility sinks, should be located in the decontamination area (see also 4.3.9).

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. Height-adjustable sinks enable personnel to avoid bending over to perform cleaning. Sinks located too high or too low increase the risk of back injury or strain. Current medical technology could require complex equipment and systems to inspect, maintain, or verify device performance.

4.3.3 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 informed of the work performed in the processing area and should be provided a detailed list of specific equipment used and installation specification specific to this equipment. Electric engineers should collaborate with managerial or other designated personnel when determining electrical system requirements. For some equipment, uninterruptible power sources are recommended. The equipment manufacturer's

installation and site-planning requirements should be reviewed and met. The need for data drops/lines should be reviewed.

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

4.3.4 Floors and walls

Floors in the processing areas should be level (i.e., should have no ridges or bumps), non-slip, monolithic or joint-free, and constructed of materials that will withstand daily or more frequent wet cleaning and the application of cleaning and disinfecting 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 could 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 could harbor microorganisms. 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 and prevent effective cleaning.

4.3.5 Ceilings

Processing area ceilings should:

- a) be constructed to create a flush surface with recessed, enclosed fixtures;
- b) enclose pipes and duct work above work areas;
- c) be constructed of materials that are not of a particulate- or fiber-shedding composition; and
- d) be durable, smooth, and cleanable.

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

4.3.6 Doors

A door should provide access to the decontamination area from the corridor, and any door that provides access to the decontamination area must have a hazard warning sign (29 CFR 1910.1030) [231].

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 and disinfected frequently. Doors should not have thresholds and should open easily following the one-way directional workflow. Doors 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 might damage the door surface and expose porous materials that could harbor bacteria and other contaminants and are difficult to clean. Bumping against a threshold can cause carts to spill and might necessitate picking up the cart to traverse the threshold.

4.3.7 Heating, ventilation, and air conditioning (HVAC) operating parameters

Requirements for HVAC in the endoscope processing area should conform with the specifications of ANSI/ASHRAE/ASHE 170 [34] that were in effect when the HVAC system was initially installed or last upgraded. The health care facility should establish and implement systematic processes for monitoring HVAC performance parameters

and a mechanism for identifying and resolving variances within the rooms throughout the facility where processing occurs.

Facility engineering personnel or designated responsible personnel should establish policies and procedures for monitoring and maintaining HVAC parameters within the processing areas. Procedures should include maintaining records of monitoring results that are retrievable either from a central system or a local log.

If a variance in the HVAC parameters occurs, processing personnel in combination with a multidisciplinary team (e.g., facility engineer, infection preventionist, risk manager, endoscopy personnel, perioperative personnel, sterile processing manager or other designated personnel) should conduct a risk assessment. The processing department is defined by ANSI/ASHRAE/ASHE 170 [34] as a critical area.

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.

See also Annex A.

Rationale: The effect of the HVAC system parameters falling out of range is variable. A risk assessment provides necessary information to guide appropriate response measures. A small variance for a short period of time as defined in the risk assessment might not be of clinical concern, whereas a large variance for a longer period could have clinical significance. A risk assessment provides necessary information to guide appropriate response measures.

4.3.8 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.

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

- 1) the illumination needed varies from person to person, and with age, and so adequate illumination should be provided for all employees;
- 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).

The correct illuminance for each workspace within the processing area should be determined (see 4.3.2 and Table 1). 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.

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)

*Source: Illuminating Engineering Society of North America (IES), Rea, 1993 [263]

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.

4.3.9 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 process endoscopes (AORN, 2018e [39]). 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 or existing facilities under renovation. 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 handwashing soap and bacteria on the endoscopes or contaminate personnel's hands (AORN, 2018e [39]). 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 might 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.

4.3.10 Emergency eyewash/shower equipment

Suitable eyewash units must be available for immediate emergency use in all places where chemicals are used (29 CFR 1910.151) [228]. The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units (ANSI Z358.1 [32]). 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;
- 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 Z358.1 [32]); and
- c) in an area that does not require flushing of the eyes in the decontamination sink.

It is prudent to consider the stress and potentially compromised vision of the person and the availability of assistive personnel in the immediate area when determining the location of eyewash stations (ANSI Z358.1 [32]).

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 ANSI Z358.1, health care personnel should consult the standard to familiarize themselves with all its provisions [32].

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 110 °F]) (ANSI Z358.1 [32]). 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 Annex H. See also OSHA's Eye and Face Protection Standard (29 CFR 1910.133) [227], OSHA's Medical and First Aid Standard (29 CFR 1910.151) [228], and ANSI Z358.1 [32].

4.3.11 Water quality

Water quality is an important consideration in all stages of endoscope processing. It is important that the water quality that is identified in the manufacturer's written IFU is used during each stage of endoscope processing. To ensure that the correct water quality is used in each stage of processing, the user should review the manufacturers' written IFU for all equipment and supplies used, including:

- a) endoscope and accessories;
- b) AER; and
- c) processing chemicals used.

Using the correct water quality helps to prolong the life of medical devices, facilitates their effective functioning, and, importantly, reduces the risk of medical device contamination.

The health care facility should monitor and control the water supply quality to endoscope processing sinks and equipment.

Major repairs of or changes to the water utility system should be treated as major repairs to the endoscope processing equipment (e.g., AERs), and equipment qualification testing should be performed before use.

Water quality evaluation should be conducted on installation of water-consuming equipment or the water supply, after repairs to water-consuming equipment or the water supply, after modification of water routing infrastructure, and during investigation of endoscope processing cycle failures.

See AAMI TIR34 [23].

5 Environmental cleaning

A multidisciplinary team should:

- a) define roles and responsibilities for environmental cleaning;
- b) select cleaning chemicals, materials, tools, and equipment for use in the endoscope processing setting;
- c) establish cleaning frequencies for high-touch objects and surfaces (e.g., decontamination area work surfaces and sinks);
- d) establish cleaning frequencies for all other surfaces including, but not limited to, storage shelves, endoscope storage cabinets, and similar objects;
- e) establish terminal cleaning frequency for endoscope processing areas, at a minimum daily if the space is used and more often as needed (e.g., large biohazardous spill, known MDRO contamination of the environment); and

- f) define an area outside of the processing area where food and beverage are permitted.

Cleaning logs should be maintained for the cleaning of the endoscope storage cabinet.

Environmental cleaning verification tools such as ultraviolet light visible markers, protein tests and ATP bioluminescence tests can be used to measure the adequacy of environmental cleaning. Environmental cleaning and disinfection procedures should be performed routinely or as needed in areas used for any aspect of decontamination, preparation, high-level disinfection, or sterilization. Contaminated work surfaces shall be decontaminated after completion of procedures, immediately or as soon as feasible when surfaces are overtly contaminated, or after any spill of blood or other potentially infectious material. Floors and horizontal work surfaces should be cleaned and disinfected at least daily. Other surfaces, such as walls, storage shelves, endoscope storage cabinets, and registers and duct diffusers, should be cleaned and disinfected on a regularly scheduled basis and more often if needed (AORN, 2018e [63]). Stained ceiling tiles should be replaced, and any leaks causing the stains should be repaired. There should not be any rust in the processing area. If rust is identified, it should be removed, and the cause remediated. A cleaning schedule should be established and followed for lighting fixtures or covers, based on a facility needs assessment to reduce the collection of dust particles and other potential contaminants.

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 environmental 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. Food and beverage contaminate the processing area as well as the items being processed. The OSHA Bloodborne pathogen regulation forbids food and drink in the decontamination room (29 CFR 1910.1030) [231]. Measurement with cleaning verification tools provides a mechanism for feedback to improve the thoroughness of cleaning.

6 Personnel

6.1 General considerations

This section provides guidelines for policies and procedures related to the processing areas, as well as processing time requirements, education, training, and competency verification, and criteria for hand hygiene, immunizations, attire, and PPE for processing personnel. Studies have shown that most endoscope reprocessing technicians are under pressure to complete steps rapidly, and some acknowledge skipping steps to save time (Ofstead, 2010 [245]; Ofstead, 2019a [240]). Non-adherence to recommended steps has been documented in several studies where personnel reported cutting corners to save time (Ofstead, 2018a [237]; Ofstead, 2018b [242]). A multisite study found that completing all of the reprocessing steps required at least 90-minutes (Ofstead, 2019b [241]). Institutions should ensure that reprocessing personnel are provided sufficient time to complete steps in accordance with regulations, standards, guidelines, and manufacturer IFU.

6.2 Policies and procedures

Policies and procedures for endoscope processing (see 13.2), which include 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 manufacturers' written IFU for the endoscope models, processing equipment, sterilizers, and all other devices are readily available to processing personnel;
- c) confirming that facility processing procedures are consistent with the written IFU of the manufacturers of the endoscopes, processing systems, and accessories and consumables used (see Section 15); and
- d) verifying processing personnel competency and consistent compliance with processing procedures.

Policies and procedures should be disseminated and readily available and used by all processing personnel. Managerial or other designated individuals should verify that processing personnel know the location of and can access facility policies and procedures. Processing personnel should inform manufacturers, as well as the FDA if applicable, if the IFU seems unclear or inadequate or are unable to be performed due to technical incompatibilities.

Policies and procedures should be reviewed by a multidisciplinary group (e.g., personnel representing GI, sterile processing, operating room, infection prevention and control, risk management, etc., as applicable to the facility) and updated at regular intervals established by the health care facility and/or local regulations.

Policies and procedures should be developed for the protection of processing personnel. These policies and procedures should include safety measures to protect personnel from exposure to pathogens and chemicals. In addition, policies and procedures should detail the exposure control plan. All policies and procedures designed for personnel protection should be developed in collaboration with the organization's infection prevention and employee/occupational health personnel.

NOTE Exposures to bloodborne 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.

6.3 Education, training, and competency verification

6.3.1 General considerations

All personnel performing endoscope processing shall complete formal training and competency verification in all aspects of endoscope processing prior to first assignment to perform these tasks independently. All personnel performing processing of endoscopes should be certified in flexible endoscope processing within two years of employment and should maintain that certification throughout their employment.

NOTE Information concerning education, training, and/or certification of endoscopy technicians with processing duties, sterile processing managers, and technicians can be obtained from the Certification Board of Sterile Processing and Distribution (CBSPD) (www.cbspd.net), the Healthcare Sterile Processing Association (HSPA) (www.myhspa.org), and the Society of Gastroenterology Nurses and Associates (SGNA) (www.sgna.org).

6.3.2 Frequency of education, training, and competency verification

Personnel involved in endoscope processing shall be provided education, training, and complete competency verification activities related to their duties upon initial hire; annually; at designated intervals; or whenever new endoscope 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 point of use through storage of the endoscope and transport to the next point of use.

Rationale: Breaches in processing related to insufficient model-specific training and competence have resulted in patient exposures (FDA MDR 8811666, 2019 [346]; McFeeters, 2016 [210]; Bauman, 2014 [83]; Washington State, 2014 [373]; Minnesota Department of Health, 2010 [212]; Haluska and Kiszle v. Forbes, 2005 [170]).

6.3.3 Responsibilities of personnel providing training

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

- a) maintain the competence necessary to provide education, including the effective use of technologies to optimize practice and adherence to hand hygiene practices;
- b) use regulatory and evidence-based professional guidelines as the foundation for education and training activities; and

- c) periodically, at least annually, re-educate and reassess the competency of processing personnel and document completion of education, training, and competency verification activities.

6.3.4 Education and training

6.3.4.1 Personnel handling flexible endoscopes at the point of use

Education and training of personnel handling flexible endoscopes at the point of use should include:

- a) proper endoscope handling;
- b) point of use treatment after the procedure for precleaning the endoscope;
- c) information to include in transport handoff, such as the completed procedure time and patient identifier, date and time of use, location, and time point of use treatment was completed (see 7.2.2);
- d) removal of single-use items; and
- e) transport of the endoscope and reusable accessories to the decontamination area as described in 7.3.2.

Rationale: Inadequate point of use treatment has contributed to processing failures (Ofstead, 2017 [246]; Ofstead, 2018a [237]) and patient exposure and infection (Kumarage, 2019 [203]; Ottawa Public Health, 2019 [250]).

6.3.4.2 Endoscope processing personnel

Education and training for endoscope processing personnel should include:

- a) proper endoscope handling;
- b) procedures for leak testing, cleaning, inspecting, disinfecting, sterilizing, packaging, and storing each specific endoscope make and model, including equipment and equipment connections;

NOTE Educational, training, competency verification, and other materials and information are available from endoscope manufacturers, AER manufacturers, sterilizer manufacturers, chemical solution and HLD manufacturers, professional associations, and professional journals.

- c) identification of items that are single use and intended to be discarded after use;
- d) all aspects of decontamination (e.g., disassembly, manual and mechanical cleaning methods and how to monitor their effectiveness, microbicidal processes, equipment operation, inspection, standard precautions, and engineering and work practice controls);
- e) the operation of the specific manual and mechanical cleaning processes and equipment, manual and mechanical HLD processes, and sterilizing systems used by the health care facility, and the methods and equipment used to verify operation;
- f) facility and processing area policies and procedures regarding high-level disinfection and sterilization, infection prevention and control, attire, hand hygiene, and compliance with local, state, and/or federal regulations;
- g) workplace safety related to chemical use and biological hazards (see also 6.4);
 - OSHA standards and requirements;
 - Applicable personnel exposure monitoring specific to chemicals used;
 - Recognizing and responding to exposure-related symptoms (e.g., difficulty breathing, skin irritation, eye tearing, mucous membrane irritation);
 - Location and correct use of PPE;

- Location and use of SDS;
 - Location and use of chemical spill kit(s); and
 - Workplace-specific policies and procedures related to endoscope processing, high-level disinfection, and sterilization;
- h) the process of leak testing when indicated in the manufacturer's written IFU;
 - i) the process of obtaining and documenting quality control monitoring results;
 - j) the process for visual inspection of endoscopes using lighted magnification and the use, care, and handling of a borescope;
 - k) the process for cleaning verification procedures, including method(s) for conducting the testing and interpreting the results; and
 - l) the process for removing a damaged endoscope from service and sending it for repair.

6.3.5 Competency verification

Competency verification activities should include monitoring processing personnel for their:

- a) compliance with facility policies and procedures and manufacturers' written IFU, and adherence to regulatory requirements, for each type of endoscope processed at the facility; and
- b) level of proficiency in processing procedures.

6.3.6 Documentation

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

Rationale: Initial and ongoing education, training, and competency verification can decrease the possibility of operator error during processing procedures and 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. 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.

6.4 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 hand hygiene 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 necessary. The OSHA bloodborne pathogen regulation (29 CFR 1910.1030) [231] includes the following requirements:

- a) Precautions should be taken to prevent injuries from sharp objects (e.g., needles, scalpels, broken glass).
- b) Sharp objects must be placed in puncture-resistant, leak-proof on the sides and bottom, closeable containers, and labeled with an OSHA-compliant label.
- 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 bloodborne pathogens.

See also CDC (2002) [105] and CDC (2007) [106].

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.

6.5 Hand hygiene

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

- 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.
- c) Each facility should develop its own policy regarding the use of nail polish, including clear nail polish, as the issue remains unresolved and requires further study.
- d) Hands should be cleaned according to CDC or WHO guidelines (CDC, 2002 [105]; WHO, 2009 [377]).
- e) Hand hygiene with soap and water should be performed whenever the hands are visibly soiled.
- f) Alcohol-based hand sanitizers are the preferred method for hand hygiene when hands are not visibly soiled.
- g) Hand hygiene should be performed before and after glove use.

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 (AORN, 2018c [37]; Baumgardner et al., 1993 [83]; Jeanes and Green, 2001 [183]; Porteous, 2002 [256]; Salman, et al., 2002 [285]; CDC, 2002 [105]).

6.6 Attire

6.6.1 General considerations

General considerations for attire to be worn in the processing area include the following:

- 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 [15]; AORN, 2018d [38]).
- d) All head and facial hair (except for eyebrows and eyelashes) should be completely covered (AORN, 2018d [38]).

- e) Jewelry and wristwatches should not be worn in the processing area (AORN, 2018d [38]).
- f) Shoes worn in the processing area must 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 (29 CFR 1910.1030) [231].
- 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 (AORN, 2018d [39]). Reusable cover apparel should be laundered daily and changed when soiled.
- h) Remove uniform before leaving the health care facility unless the facilities are connected by an internal walkway (AORN, 2019a [35]).

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 [105]; Graves, 2006 [166]; Trick, 2003 [313]; Field, 1996 [148]).

6.6.2 Personal protective equipment

The OSHA bloodborne pathogen regulation (29 CFR 1910.1030) [231] and the OSHA Hazard Communication Standard (29 CFR 1910.1200) require 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 risk of exposure during the task to be performed and compliant with OSHA's Personal Protective Equipment Standards (29 CFR 1910.132 to 1910.138).

- a) In addition to the attire recommended in 6.6.1, personnel working in the decontamination area should wear general-purpose utility gloves and a liquid-resistant covering with long sleeves to the wrist (for example, a protective gown).
- b) Processing personnel should use a style of glove that prevents contact with contaminated water. For this purpose, exam gloves should not be used for decontamination. General-purpose utility gloves fitted at the wrist or above should be used.
- c) When performing decontamination duties, the highest level gown should be worn (ANSI/AAMI PB70 [9]).

Table 2—Barrier Gown liquid barrier performance class

ANSI/AAMI PB70 barrier performance	Test	Result	Anticipated risk of exposure: Fluid amount, spray or splash, pressure on gown or drape
Level 1	AATCC 42:200	≤ 4.5 g	Minimum
Level 2	AATCC 42:2000 AATCC 127:1998	≤ 1.0 g ≥ 20 cm	Low
Level 3	AATCC 42:2000 AATCC 127:1998	≤ 1.0 g ≥ 50 cm	Moderate
Level 4	ASTM F1671:2003 (surgical gowns and other protective apparel) ASTM F1670:2003 (surgical drapes and drape accessories)	Pass Pass	High

NOTE 1 The barrier performance class may be stated on the label as the barrier level or test method. Reprinted from AORN Guidelines.

NOTE 2 AATCC=American Association of Textile Chemists and Colorists and ASTM=American Society for Testing and Materials.

NOTE 3 Using TIR11:2005/(R)2015, *Selection and use of protective apparel and surgical drapes in health care facilities* [19], you can make your own table that reflects the AORN table. The first and last columns are taken from Table 3 and the second and third are from Table 2.

- d) PPE should also include a fluid-resistant face mask, liquid-resistant shoe covers (if there is potential for shoes to become contaminated and/or soaked with blood or other bodily fluids), 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. If noise levels exceed OSHA permissible levels for the OSHA-designated time duration, hearing protection should be available (29 CFR 1910.95 g).
- 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 their integrity is compromised, items should be discarded. Torn gloves should be removed, and hands should be thoroughly washed before donning new gloves.
- f) When PPE worn during processing is removed, hand hygiene should be performed immediately.
- g) PPE should be changed between performing decontamination and handling disinfected endoscopes.
- h) Before leaving the cleaning area, employees should remove all protective attire, being careful not to contaminate the clothing beneath or their skin and perform hand hygiene. 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 bloodborne and other disease-producing organisms and chemicals used in the processing of endoscopes. 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 [130]). 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. Hand hygiene performed after removal of PPE can 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) [342].

Fluid-resistant face masks are an OSHA requirement and help to protect personnel who are cleaning contaminated items from splash or splatter that could contain pathogens (29 CFR 1910.1030) [231]. 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.

7 Decontamination processes

7.1 General considerations

Cleaning is the most critical step in effective processing of flexible and semi-rigid endoscopes, beginning with point of use treatment, followed by meticulous manual cleaning in the endoscope processing area; all of which precedes the disinfection or sterilization process. Cleaning is intended to remove the clinical soil so that the subsequent disinfection or sterilization process is effective. Thorough attention to cleaning is crucial for overall processing effectiveness and patient safety. Failure to perform effective cleaning can result in disinfection failure (Kumarage, 2019 [203]; Ofstead, 2018a [237]; Ofstead, 2018b [242]; Ofstead, 2017 [246]; Ofstead, 2016 [247]; Ofstead, 2015 [235]) or sterilization failure (Ofstead, 2017 [246]) and outbreaks of infection can occur (Kumarage, 2019 [203]; Galdys, 2019 [158]; FDA MDR 8379810, 2019 [322]). Cleaning consists of manual and mechanical processes that include wiping, brushing, and

flushing all external surfaces and internal channels using detergent solutions and cleaning accessories. Thorough rinsing of all detergents is important to remove detergent residuals.

The cleaning process begins at the point of use. When allowed to dry, soils become more difficult to remove. Soils are also known for their corrosive effects on material. Risk of biofilm formation is also increased by surface damage. To help prevent formation of biofilm or endoscope damage, cleaning should occur as soon as possible after the endoscope is used. Biofilm consists of accumulated biomass of bacteria and extracellular materials that tightly adhere to a surface and are difficult to remove. Biofilm effectively protects microorganisms from ordinary cleaning methods. It can form on many surfaces but is particularly problematic on devices with lumens, such as endoscopes. Prompt cleaning reduces or eliminates the population of biofilm-forming microorganisms and thus can help prevent the formation of biofilm (ANSI/AAMI ST79 [17]). Failure to promptly and properly initiate cleaning of endoscopes after use can increase the difficulty of cleaning and decrease the effectiveness of disinfection and/or sterilization.

Effective processing, including cleaning, is a challenging task and prone to human error (Joint Commission, 2018 [187]; Ofstead, 2010 [245]; Ofstead, 2018a [237]; Ofstead, 2018b [242]; Ofstead, 2017 [246]; Armellino, 2018 [70]; Ofstead, 2019 [240]; California Health and Human Services Agency, 2017 [100]; CMS, 2015a [120]; CMS, 2015b [121]; CMS, 2015c [122].

7.1.1 The appropriate cleaning methods for flexible endoscopes are based on:

- a) the device manufacturer's written IFU;
- b) the type of cleaning solutions, accessories and equipment used to clean the device;
- c) the cleaning solution manufacturer's written IFU; and
- d) any processing equipment manufacturer's written IFU.

7.1.2 Endoscope, cleaning equipment, and cleaning solution IFU should be followed during the cleaning process for endoscopes. In the event of conflict, the endoscope manufacturer should be contacted for clarification. Cleaning steps include the following:

- a) point of use treatment;
- b) transporting the endoscope from the point of use to the processing area as soon as possible;
- c) leak testing;
- d) manual and/or FDA-cleared automated cleaning (see 7.6 and 7.7);
- e) thorough rinsing;
- f) exterior drying and channel purge; and
- g) inspection and testing for cleanliness.

Nonimmersible endoscopes should not be used, as they cannot be adequately processed.

7.2 Point of use treatment

7.2.1 General considerations

To prevent buildup of bioburden, development of biofilms, and drying of secretions, point of use treatment is performed immediately after completion of use of the device. It is imperative that the written IFU from the endoscope, cleaning equipment, and cleaning solution manufacturers are followed. When labelled for this purpose, commercially available sponges or wipes can be used for point of use treatment.

7.2.2 Procedure

The steps listed below are typical of the overall process for point of use treatment of a flexible or semi-rigid endoscope. Actual instructions for cleaning an individual endoscope will vary based on manufacturers' written IFU. Before the endoscope is detached from the light source and/or video processor:

- a) Don PPE. Personnel performing point of use treatment and handling contaminated flexible endoscopes should wear PPE that includes
 - 1) fluid-resistant surgical masks in combination with eye protection devices, such as goggles, glasses with solid side shields, or chin-length face shields;
 - 2) fluid-resistant gowns (see ANSI/AAMI PB70 [9]);
 - 3) general purpose utility gloves fitted at the wrist or above; and
 - 4) liquid-resistant shoe covers (if there is potential for shoes becoming contaminated and/or soaked with blood or other bodily fluids, see 6.6.1 and ANSI/AAMI ST79 [17]).
- b) Prepare a cleaning solution. The endoscope manufacturer's written IFU should be referenced for types of compatible cleaning agents, and the solution manufacturer's written IFU should be referenced for preparation of the chosen cleaning solution.
- c) Wipe the insertion tube according to the manufacturer's written IFU with a clean, non-linting cloth or wipe or a non-abrasive sponge soaked in water or 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) Place the distal end of the endoscope in the cleaning solution and suction the solution through the instrument/suction channel as indicated in the endoscope manufacturer's written IFU.
- e) During point of use treatment of an endoscope with an elevator mechanism, while continuing the immersion and the aspiration, raise and lower the forceps elevator three times by turning the elevator control level or as per the manufacturer's written IFU for the endoscope.
- f) Flush the air/water channels with solution using the endoscope's cleaning adapter or by IFU-instructed air/water flow.
- g) Flush any other channels (e.g., auxiliary water or elevator channels) with solution.
- h) Flush each lumen as directed in the manufacturer's written IFU and until clear.
- i) Detach the endoscope from the light source and suction pump.
- j) Remove disposable accessories, if used.
- k) Attach a fluid-resistant cap over any electrical components, if applicable.
- l) Visually inspect the endoscope. If there is any evidence of damage, refer to the manufacturer's written IFU for further processing instructions. Tag the endoscope for further review. Refer to Section 14.
- m) Sinks should be cleaned, disinfected, and rinsed between uses with a disinfectant approved by a multidisciplinary team (see Section 5) and in accordance with the IFUs for the disinfectant and the sink.

Hand-off communication from point of use to the decontamination area shall include at minimum, patient identifier, date of procedure, and time of point of use treatment was completed. Other information that may be helpful is the completed procedure time, location of the procedure, and employee contact.

When there is a delay and/or failure to perform point of use treatment, the endoscope should be processed using delayed processing protocols described in the device manufacturer's IFU.

Rationale: Flushing helps to remove excess soil and ensures that the channels are not blocked, debris is removed, and channels are moistened for further processing.

7.3 Transport of contaminated endoscopes

7.3.1 General considerations

Improper containment and transport of contaminated endoscopes represents a potential risk of infection transmission to staff and patients. Precleaned endoscopes are still considered contaminated and appropriate precautions and procedures should be followed. Endoscopes should be transported immediately after point of use treatment to the decontamination area.

The manufacturer's written IFU should be reviewed to determine any necessary point of use treatment, 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.

7.3.2 Procedure

Each endoscope should be isolated and transported with its components in a closed container or closed transport cart to the next stage of processing, as it is considered contaminated. The transport cart or container must be labeled with a visible fluorescent orange, orange-red, or red label containing a biohazard legend and must meet OSHA requirements (29 CFR 1910.1030) [231] for transporting hazardous items. The closed container or closed transport cart must be nonporous, leak-proof on its sides and bottom, puncture-resistant, and large enough to accommodate a single endoscope without the need to over-coil the insertion or light guide tubes. When endoscopes are transported on cart tops, a bag with an affixed biohazard label and designed for containment and transportation of soiled endoscopes may be used.

Soils on endoscopes and accessories should be kept moist, e.g., by applying a pretreatment solution, placing a towel moistened with water (not saline) over the items or placing items inside a package designed to maintain humid conditions, but not submerged in a solution. Keeping the endoscopes and accessories moist is not intended to extend time before processing.

Flexible endoscopes should be transported in a horizontal position, not suspended. When no other option is available and a dumbwaiter elevator or lift is used to transport both clean/sterile and contaminated supplies, they should be separated, and the transport carts should be covered or enclosed. All items, clean or soiled, should be contained in transport containers, and must be labeled biohazard.

Steps in the transport of endoscopes are as follows:

- 1) Separate endoscopy accessories from the contaminated endoscope to prevent puncture and penetration damage.
- 2) Place endoscopes and accessories in a container to prevent damage, including by naturally coiling each in large loops.
- 3) Hand-off communication from the transporter to the processing location should include:
 - a) confirmation that the endoscope was transported correctly, and all accessory parts are present;
 - b) the date and time of completion of use of that device;
 - c) the time of point of use treatment; and
 - d) patient identifier.

Rationale: Keeping the endoscope and accessories moist helps dilute, soften, and ease removal of organic soils (AORN, 2018e [39]). Allowing organic material to dry on the surface and in the channels of the endoscope makes the cleaning process more difficult. Fluid might leak from the contaminated endoscope if transported vertically. When suspended, the endoscope might become damaged because of compression on dependent components. Including completion of use time and point of use treatment time in the hand-off communication determines workflow for processing personnel.

7.4 Leak testing

7.4.1 General considerations

Leak testing, when applicable, should be performed as soon as possible after the endoscope arrives in the processing area and before immersion of the endoscope into processing solutions. Follow the endoscope manufacturer's written IFU for acceptance criteria of the leak testing protocol, including quality controls. Flexible endoscopes that cannot be leak tested should not be used. Automated leak testers should be placed on a calibration schedule to verify the leak tester is producing the correct pressure. Manual handheld leak testers and leak tester tubing should be inspected for damage, leakage, and pressure output (kPa). Pressure verification should be performed for each type of leak tester in the facility each day that endoscopes are used; calibration ensures that an endoscope will be challenged with the proper pressure each time when being tested for leaks. Documentation of testing results should be recorded. The manufacturer's written IFU for testing each type of leak tester (manual or mechanical) used in the facility should be followed to ensure they are properly functioning.

Rationale: Leak testing can detect damage to the endoscope that could, if undetected, allow for fluid invasion into the areas not designed for fluids and pose a potential risk of cross-contamination. 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. Over-coiling can mask a hole and allow it to go undetected.

7.4.2 Leak testing procedures

Multiple types of leak testing processes are available.

- a) Wet leak tests require immersion of the pressurized endoscope in clean water and inspection for bubbles emanating from the device, which signal a leak from the endoscope.
- b) Dry leak tests also pressurize the endoscope and detect a decrease in pressurization, which can signal a leak.
- c) Manual testing requires the user to select and maintain the selected pressure, whereas mechanical leak tests automatically achieve the selected pressure.

The manufacturer's written IFU for the selected leak test should be followed. General considerations include the following:

- a) Personnel performing the leak testing should wear PPE.
- b) Prior to leak testing, the fluid-resistant cap should be applied, if indicated in the manufacturer's written IFU.
- c) The largest surface counter or sink area available should be used to accommodate an open, minimally coiled endoscope for the test.
- d) At a minimum, the manufacturer's recommended time for pressurization should be followed to achieve an accurate test.
- e) Wet leak testing requires a clean sink with clean water without detergent.
- f) Leak testers shall be cleaned and decontaminated according to the facility's policy and the manufacturer's written IFU.

7.4.3 Manual (dry) leak testing

The endoscope and leak tester manufacturers' written IFU should be followed. Unless otherwise specified by the manufacturer's written IFU, the following steps are recommended:

- a) Remove all detachable parts from the endoscope (e.g., single-use valves and biopsy port covers).
- b) Ensure that the fluid-resistant cap is attached, if applicable.
- c) Attach the leak tester securely at the connector.
- 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) Manipulate video or remote switches in a circular manner to detect holes more readily in these components.
- h) Manipulate the insertion tube and light guide tube, if applicable, to uncover hidden leaks due to the position of the coiled endoscope.
- i) Maintain pressure and inspection for a minimum of 30-seconds.
- j) Release air pressure from the endoscope before removal of the leak testing unit. In the event of a failure, see 7.4.8.
- k) If the endoscope passes the dry leak test, proceed to the next step of processing.
- l) Document the outcome of the leak test.
- m) Detach the leak test connector from the endoscope.

7.4.4 Manual (wet) leak testing

The endoscope and leak tester manufacturers' written IFU should be followed. Unless otherwise specified by the manufacturer's written IFU, the following steps are recommended:

- a) Remove all detachable parts from the endoscope (e.g., single-use valves and biopsy port covers).
- b) Ensure that the fluid-resistant cap is attached, if applicable.
- c) Attach the leak tester securely at the connector.
- d) Pressurize the endoscope to the indicated pressure on the leak tester gauge.
- e) Place the endoscope in a loose configuration in a large sink with a sufficient volume of clean water to completely immerse it.
- f) Using a new syringe, completely flush all channels with water to remove trapped air.
- g) Gently rotate each directional knob and elevator control, looking for bubbles at the bending rubber as well as at the knobs. Also watch for changes in the established pressure.
- h) Manipulate video or remote switches in a circular manner to detect holes more readily in these components.
- i) Manipulate the insertion tube and light guide tube, if applicable, to uncover hidden leaks due to the position of the coiled endoscope.

- j) 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 the bubbles do not return.
- k) Maintain pressure and inspection for a minimum of 60-seconds.
- l) Remove the entire endoscope from the test water.
- m) Depressurize according to the endoscope manufacturer's written IFU before removing the leak tester. Release air pressure from the endoscope before removal of the leak testing unit. In the event of a failure, see 7.4.8.
- n) If the endoscope is water-tight, proceed with cleaning and disinfection processes.
- o) Document the outcome of the leak test.
- p) Detach the leak test connector from the endoscope.

7.4.5 Mechanical (dry) leak testing

The endoscope and leak tester manufacturers' written IFU should be followed. Unless otherwise specified by the manufacturer's written IFU, the following steps are recommended:

- a) Prepare automated leakage tester and tubes.
- b) As applicable, power on the printer.
- c) Power on the automated leak tester.
- d) Position the endoscope(s) for leak testing as prescribed by the manufacturer's written IFU.
- e) Ensure that fluid-resistant caps are attached to the endoscope, as applicable.
- f) Connect the leak tester tubes to the endoscope(s).
- g) Scan or enter user and endoscope information.
- h) Select the "start" and allow the automated leak tester cycle to complete the test.
- i) If the endoscope receives a pass indication, proceed with the next step of processing.
- j) If the endoscope received a fail result, check connections and repeat the test. If failure occurs again, proceed with a wet leak test in the manual leak testing mode, as prescribed by the manufacturer's written IFU, to determine the leakage area. Once the leakage area is determined, see 7.4.8 for recommendations on processing a leaking endoscope.
- k) Document the outcome of the leak test.
- l) Detach the leak test connector from the endoscope.

7.4.6 Mechanical (wet) leak testing

The endoscope and leak tester manufacturers' written IFU should be followed. Unless otherwise specified by the manufacturer's written IFU, the following steps are recommended:

- a) Remove all valves and biopsy port covers.
- b) Ensure that the fluid-resistant cap is attached prior to immersion, if applicable.
- c) Attach the leak tester.