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Flexible and semi-rigid endoscope processing in health care facilities

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Advancing Safety in Health Technology

Flexible and semi-rigid endoscope processing in health care facilities

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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

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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

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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;
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- "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 (Sorbets, 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