

# Standards and Guidelines for Flexible Endoscope Reprocessing

John Whelan BSN, RN  
Clinical Education Coordinator  
Healthmark Industries

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LIACS/MACSA

# Disclosure

- I am an employee of Healthmark Industries Fraser, Michigan USA.
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals.
- No compensation has been received for this presentation or for travel to and from the seminar.
- All opinions are those of the presenter.
- This presentation reflects the techniques, approaches and opinions of the individual presenter. This sponsored presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).

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# Objectives

- Discuss the key provisions and competency recommendations from ANSI/AAMI **ST 91**, SGNA, AORN guidelines, ECRI and FDA.
- Outline ANSI/AAMI **ST90** national standard for Quality Systems for Reprocessing.
- Discuss a process for implementing standards/guidelines – incl. AAMI ST91.

# CLEANR Study—Direct observation:

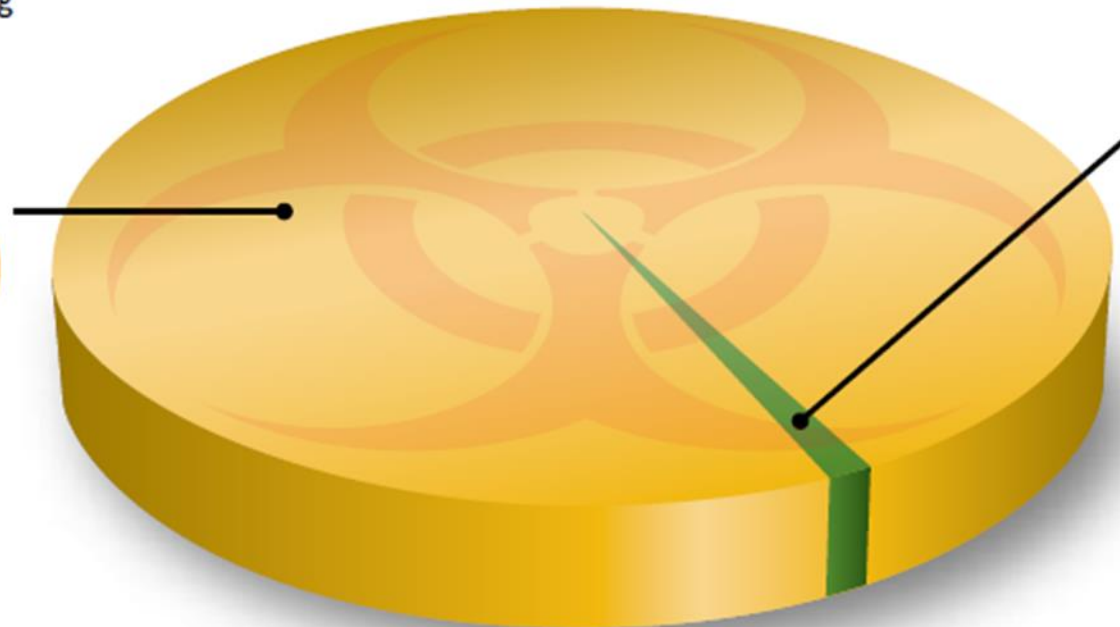
Only *half* of the 183 scopes were reprocessed properly;

manual cleaning was almost always inadequate

Reprocessing using manual cleaning

**99%**

1 or more steps  
skipped or done  
incorrectly



**1%**  
All steps  
completed

Manual cleaning n = 69; p = 0.001

# US Senate Report - 01/12/2016

Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients



- At least **25 separate incidences** and **over 250 patients infected**.
- Traced antibiotic-resistant infections directly to duodenoscopes.
- Hospitals generally did not raise alarms about these infections with federal regulators.
  - Lack of reporting of the required adverse event form to the device manufacturers.

<http://www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf>

# UCLA study identifies risk factors for bacteria transmission from tainted scopes

Phil Hampton | May 20, 2016

**O**ver the past few years, medical scopes contaminated with antibiotic-resistant bacteria have caused hundreds of patients who underwent a specific gastrointestinal procedure to become sick. Now, UCLA physicians have identified factors that increase the likelihood of these infections.

Full-screen View

In [research published](#) in the journal *Gastrointestinal Endoscopy*, the physicians report that patients face an increased risk of infection from exposure to a contaminated scope if they had a stent placed in the bile duct using a tainted scope, had a history of bile duct cancer, or were hospital inpatients at the time of the procedure.

The study was based on data from a 2015 bacterial outbreak at Ronald Reagan UCLA Medical Center that sickened eight patients, three of whom later died. Among its authors were physicians who were directly involved in reporting the outbreak, tracking down its source and halting it. UCLA's actions helped educate the public about risks posed by contaminated scopes, whose complicated design makes them difficult to clean and implicates them in several outbreaks.

"Our interest is in protecting public health," said the study's lead author, Dr. Stephen Kim, a clinical instructor in the division of digestive disease in the David Geffen School of Medicine at UCLA. "We feel a professional and academic responsibility to learn from our experience and add our findings to the limited body of research on this topic."

The senior author was Dr. Raman Muthusamy, a UCLA clinical professor of digestive diseases and director of endoscopy. A co-author was Dr. Zachary Rubin, UCLA Health's medical director of clinical epidemiology and infection prevention.

Rubin and others identified the bacterial outbreak at the UCLA hospital after detecting an increase in the number of patients infected with carbapenem-resistant Enterobacteriaceae, or CRE, a family of virulent bacteria that are resistant to antibiotics and can be fatal. They traced the infections to two duodenoscopes. (A duodenoscope is a flexible tube with a tiny camera at its tip that is passed down the throat to help diagnose and treat diseases of the liver, bile ducts and pancreas.)

At UCLA, a single patient with an active CRE infection had undergone two separate procedures with a different scope each time, and all UCLA patients with CRE infections had subsequently undergone procedures with one of the two reusable scopes, Rubin and his colleagues found.

County public health officials and UCLA Health determined that the hospital had followed the manufacturer's guidelines for cleaning the scopes. UCLA removed the two tainted scopes from use and added a rigorous sterilization regimen for duodenoscopes and certain other scopes.

Shortly after UCLA reported its findings of the outbreak, federal regulators issued several safety alerts about duodenoscopes to all U.S. hospitals. The manufacturer ultimately recalled the device after additional outbreaks elsewhere were linked to the device's design, which includes crevices that can harbor bacteria even if they are cleaned according to federal guidelines. Unlike an endoscope, a duodenoscope has a side-viewing camera and a mechanism that guides devices such as stents from the side — rather than the front — of the scope's tip.

BUSINESS



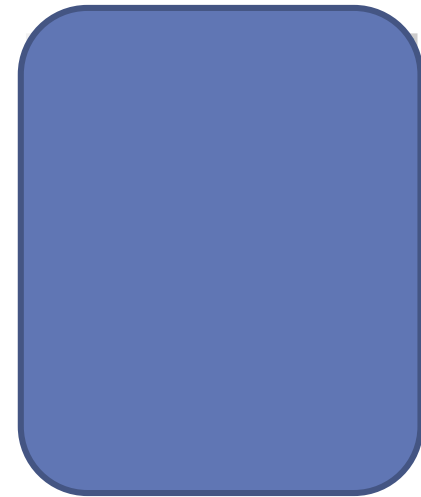
# 11 deaths at Huntington Hospital among patients infected by dirty scopes, city report says



## Crozer-Chester cited for using dirty scope on patient

by [Don Sapatkin](#), **STAFF WRITER**, Posted: March 28, 2017

Full-screen Skip



**f** POST

**t** TWEET

**o** SUBMIT

**e** EMAIL

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**in** LINKEDIN

A state health inspector cited Crozer-Chester Medical Center for allowing an improperly cleaned endoscope to be used in a surgical procedure, exposing the elderly patient to possible infection.

Endoscopes — a group of tubular instruments used to look at various organs inside the body during procedures — are [notoriously hard to clean](#) and have been [linked to infections](#), some fatal, at hospitals around the country in recent years. The American Journal of Infection Control reported last month that microbes grew on 60 percent of endoscopes in [a small study](#) even after rigorous cleaning.

The Crozer investigation noted that the hospital's endoscopy suite was closed for the weekend when the incident occurred on Saturday, Jan. 7. A Pennsylvania Health Department inspector's interview determined that an employee involved with the surgery "did not know that an endoscope could not be reused if it had only been pre-cleaned and did not understand that it required high level disinfection before reuse," according to the investigative report, which determined that the hospital had failed to follow its own policies.

[In a statement](#) Wednesday morning, Crozer Keystone Health System said that it "encourages the immediate reporting of potential safety risks that may occur during patient care. As such, in this case, health system became aware that an employee may not have completely followed



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## Air Force notifies patients of possible risks associated with scope procedure

By Air Force Surgeon General Public Affairs, Air Force Surgeon General Public Affairs / Published June 19, 2017



[PRINT](#) | [E-MAIL](#)

**FALLS CHURCH, Va. --** A review conducted by the Air Force Medical Service has found that endoscopes used for upper and lower gastrointestinal procedures at AI Udeid Air Base were cleaned in a manner inconsistent with sterilization guidelines from April 2008 to April 2016.

The review determined 135 patients had procedures during this period and may have been exposed to blood-borne diseases when an alternate cleaning method was used rather than the manufacturer's recommended cleaning process.

"Providing quality health care to our Airmen and their families is our top priority," said Brig. Gen. Robert Miller, Air Force Medical Operations Agency commander. "We apologize to our patients and assure them that appropriate actions have been taken to address and mitigate the causes that led to this problem."

Miller said several preventive measures have been taken starting with a Service-wide patient safety alert to confirm compliance with endoscope cleaning, decontamination, inspection, and sterilization processes. Air Force military treatment facility commanders were also directed to complete the same review of all reusable medical instruments and devices. In addition, experts are reviewing current best practices to develop and implement standard processes in an attempt to prevent this issue from recurring.

Analysis by infectious disease experts shows the risk of contracting diseases is very low. However, medical officials are encouraging patients to be tested as a precaution.

"The risk of exposure to patients is low," said Miller. "It's important, though, for anyone who receives a notification to contact us to discuss the situation and if they desire to pursue diagnostic testing. Our medical team is here to address concerns and help patients throughout this entire process."

The Air Force Medical Service is in the process of notifying the patients and providing contact information for Healthcare Resolution Specialists who will answer questions and help identify locations for medical counseling and diagnostic testing.

"Our patients put their trust in us when they step into any of our medical facilities," said Miller. "We take potential risk to patient safety very seriously and are committed to informing those under our care of any increased risk."



HEALTH NEWS AUGUST 30, 2019 / 7:28 PM / 9 DAYS AGO

# Oklahoma hospital used dirty gastroscopes on almost 1,000 patients; no infections reported

Chad Terhune

6 MIN READ



(Reuters) - An unnamed hospital in Oklahoma used contaminated gastroscopes in procedures performed on nearly a thousand patients in recent months, device maker Pentax Medical told U.S. regulators last month, putting the patients at risk of exposure to bacteria that can cause infections.

In a July 22 report [here](#) that only recently became public and was reviewed by Reuters, Pentax told the Food and Drug Administration that a hospital used up to four gastroscopes contaminated with bacteria in 998 procedures performed sometime last year through June 2019, when the problem was discovered. Pentax, a unit of Tokyo-



# Regulations/Standards/Guidelines

- Regulations

- A rule or directive made and maintained by an authority
- Mandatory

- Standards

- Requirements and specifications to ensure consistency and fit for purpose
- Voluntary, but can become mandatory

- Guidelines, Recommended Practices, Technical Information reports

- Technical guidance, information or preferred procedures regarding a given topic
- Voluntary but with interpretation



# For **ENDOSCOPE REPROCESSING**, what are standards & guidelines based on?

- All the major groups support in principal
  - Quality improvement
  - Quality assurance
  - Monitoring of processes
- Clinically relevant & evidence-based practices
- Peer reviewed literature
- Other articles and research.
- Manufacturer's IFUs
- This is, and has been, a dynamic process

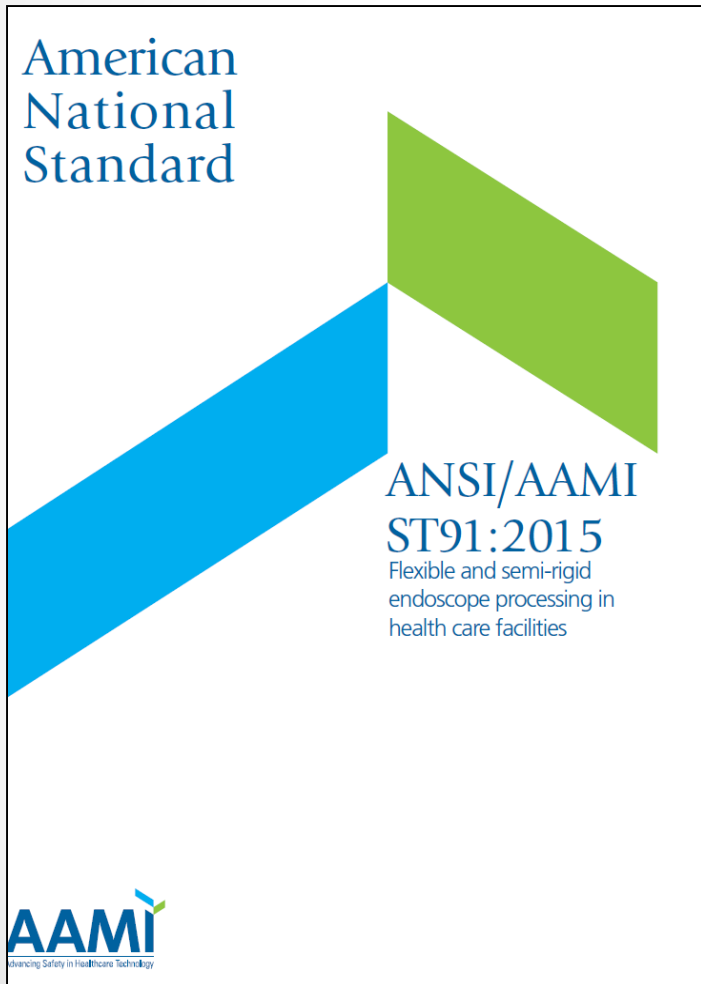


# Highlights within guidelines

Recommendations for:

- **Certifications and training frequency** for staff performing reprocessing
- **Process monitoring:**
  - the manual cleaning process
  - automated cleaning processes
  - water quality
  - temperature of detergents and disinfectant solutions
- **Traceability.** After processing, all detachable valves and buttons should be kept together with the endoscope as a unique set.
- **Risk Assessments**
- **Documentation and quality assurance** parameters

# What is ANSI/AAMI ST 91?



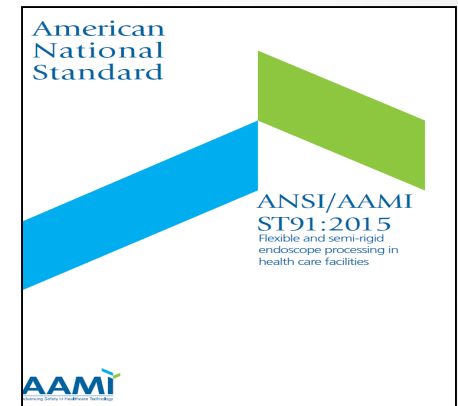
- Flexible and semi-rigid endoscope reprocessing in health care facilities
- Contains best practices for endoscope reprocessing in ANY setting
- Excludes TEE/ultrasound probes



# AAMI ST91 - Education, Training and Competency Recommendations

- All personnel performing processing are **certified** as a condition of employment.
- At a minimum, personnel should complete a **certification exam**.
- **Frequencies** of training/competency:

Initial hire; annually; at designated intervals; or whenever new endoscopic models, new processing equipment, or products such as new chemicals are introduced for processing.



# What are the SGNA Standards and Practice Guidelines?

- Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes (2018)
- Standard of Infection Prevention in the Gastroenterology Setting (2019)
- Management of Endoscopic Accessories, Valves, and Water and Irrigation Bottles in the Gastroenterology Setting (2018)
- Guidelines for the Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting (2017)

Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes

Standards of Infection Prevention  
in  
Reprocessing Flexible Gastrointestinal  
Endoscopes

**SGNA**  
Society of Gastroenterology Nurses and Associates, Inc.

Society of Gastroenterology Nurses and Associates, Inc.

<https://www.sgna.org/Practice/Standards-Practice-Guidelines>

# SGNA - Education, Training and Competency Recommendations

- Strengthen training and educating reprocessing staff. In addition to observing for staff competency and compliance, consider reprocessing certification.
- Undergo more frequent validation of competency for specialty endoscopes that are used infrequently;
- Temporary personnel should *not* be allowed to clean or disinfect instruments in either a manual or an automated reprocessing system until competency has been established (Peterson et al., 2017).
- All staff involved in endoscope reprocessing are identified, trained, and demonstrate initial and continued competency based on the manufacturer's IFU (Armellino, 2016).

# ASGE – Multisociety Guidelines



Prepared by: REPROCESSING GUIDELINE TASK FORCE

Bret T. Petersen, MD, FASGE, Chair, Jonathan Cohen, MD, FASGE, Ralph David Hambrick, III, RN, Navtej Buttar, MD, David A. Greenwald, MD, FASGE, Jonathan M. Buscaglia, MD, FASGE, James Collins, RN, Glenn Eisen, MD, MPH, FASGE

This article was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

*The beneficial role of GI endoscopy for the prevention, diagnosis, and treatment of many digestive diseases and cancer is well established. Like many sophisticated medical devices, the endoscope is a complex, reusable instrument that requires meticulous cleaning and reprocessing in strict accordance with manufacturer and professional organization guidance before being used on subsequent patients. To date, published episodes of pathogen transmission related to GI endoscopy using standard end-viewing instruments have been associated with failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment. Recent reports pertaining to transmission among patients undergoing specialized procedures using side-viewing duodenoscopes with distal tip elevators have raised questions about the best methods for the cleaning and disinfection or sterilization of these devices between patient uses.*

*In 2003 the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Healthcare Epidemiology of America collaborated with multiple physician and nursing organizations, infection prevention and control organizations, federal and state agencies, and industry leaders to develop evidence-based guidelines*

*for reprocessing GI endoscopes.<sup>1,2</sup> Since then, high-level disinfectants, automated reprocessing machines, low-temperature sterilization methods, endoscopes, and endoscopic accessories have evolved.<sup>3-7</sup>*

*Additional outbreaks of infections related to suboptimal infection prevention practices during endoscopy,<sup>8,9</sup> lapses in endoscope reprocessing, contamination or malfunction of automated reprocessing machines, and transmission during ERCP have been well publicized. A cluster of cases of hepatitis C virus infection was attributed to grossly inappropriate intravenous medication and sedation practices.<sup>10</sup> In other instances, risk of infection transmission has been linked to incorrect reprocessing as a result of unfamiliarity with endoscope channels, accessories, and the specific steps required for reprocessing of attachments.<sup>9</sup> On-site ambulatory surgery center surveys confirm that gaps in infection prevention practices are common.<sup>10</sup> Given the ongoing occurrences of endoscopy-associated infections attributed to lapses in infection prevention, an update of the 2003 multisociety guideline was published in 2011.<sup>11,12,13</sup> Now, after the recent experience with transmission by duodenoscopes despite appropriate reprocessing practices, an update to incorporate evolving information is again warranted.*

*This update of the 2011 multisociety guideline retains the expanded details related to critical reprocessing steps of cleaning and drying and incorporates recent guidance that is specific to those endoscope models with movable*

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0016-5107/\$36.00  
<http://dx.doi.org/10.1016/j.gie.2016.10.002>

282 GASTROINTESTINAL ENDOSCOPY Volume 85, No. 2 : 2017

[www.giejournal.org](http://www.giejournal.org)

# AORN – Guideline for Processing Flexible Endoscopes



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## Flexible Endoscopes

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### Introduction

The Guideline for Processing Flexible Endoscopes has been approved by the AORN Guidelines Advisory Board. It was presented as a proposed guideline for comments by members and others. The guideline is effective February 1, 2016. The recommendations in the guideline are intended to be achievable and represent what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the guideline can be implemented. AORN recognizes the many diverse settings in which perioperative nurses practice; therefore, this guideline is adaptable to all areas where operative or other invasive procedures may be performed.

### Purpose

This document provides guidance to perioperative, endoscopy, and sterile processing personnel for processing all types of reusable flexible endoscopes and accessories. Recommendations are provided for design and construction of the endoscopy suite as well as for controlling and maintaining the

# AORN - Education, Training and Competency Recommendations

- Flexible endoscopes and endoscope accessories should be cleaned and processed by individuals who have received education and completed competency verification activities related to endoscope processing.
- Personnel with responsibility for processing flexible endoscopes should receive initial and ongoing education and complete competency verification activities related to processing flexible endoscopes.
- The health care organization should establish education and competency verification activities for its personnel and determine intervals for education and competency verification related to processing flexible endoscopes and accessories.
- Personnel should receive education and complete competency verification activities before new flexible endoscopes, accessories, cleaning and processing solutions, equipment, or procedures are introduced.

# Other foundational resources to guide best practices for endoscope reprocessing

- Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC  
<https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html> Page last reviewed: December 27, 2018. Accessed 09-03-2019.
- FDA Safety Communications: <https://www.fda.gov/medical-devices/medical-device-safety/safety-communications>
- Manufacturer’s IFUs for endoscopes, automated reprocessing equipment, and reprocessing accessories.
- TJC HLD & Sterilization BoosterPak:  
[https://www.jointcommission.org/assets/1/6/TJC\\_HLD\\_BoosterPak.pdf](https://www.jointcommission.org/assets/1/6/TJC_HLD_BoosterPak.pdf)



## 2019 Top 10 Health Technology Hazards Executive Brief

ECRI Institute is providing this abridged version of its 2019 Top 10 list of health technology hazards as a free public service to inform healthcare facilities about important safety issues involving the use of medical devices and systems. The full report—including detailed problem descriptions and ECRI Institute’s step-by-step recommendations for addressing the hazards—is available to members of ECRI Institute programs through their membership web pages.

### The List for 2019

1. Hackers Can Exploit Remote Access to Systems, Disrupting Healthcare Operations
2. “Clean” Mattresses Can Ooze Body Fluids onto Patients
3. Retained Sponges Persist as a Surgical Complication Despite Manual Counts
4. Improperly Set Ventilator Alarms Put Patients at Risk for Hypoxic Brain Injury or Death
5. Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections
6. Confusing Dose Rate with Flow Rate Can Lead to Infusion Pump Medication Errors
7. Improper Customization of Physiologic Monitor Alarm Settings May Result in Missed Alarms
8. Injury Risk from Overhead Patient Lift Systems
9. Cleaning Fluid Seeping into Electrical Components Can Lead to Equipment Damage and Fires
10. Flawed Battery Charging Systems and Practices Can Affect Device Operation



# ECRI Institute - Endoscope Processing Recommendations

- Cleaning and disinfecting flexible endoscopes between uses is known to be a challenging process. Failure to precisely follow a robust reprocessing protocol can lead to debilitating or even fatal infections. Less well known is that **improper handling and storage practices** can recontaminate **previously disinfected scopes**, heightening the risk of patient infections.
- If endoscopes are not completely dried after being subjected to high-level disinfection, any remaining viable microbes can rapidly proliferate and colonize the instruments. **To promote drying**, ECRI Institute and relevant professional societies recommend **purging endoscope channels with clean air at the end of the reprocessing process**.
- The disinfected status of endoscopes can also be compromised if the instruments are handled with unclean gloves—a practice that ECRI Institute has observed. **Endoscopes that have been cleaned but not yet high-level disinfected are still contaminated with viable microbes; thus gloves used to handle an endoscope** at that stage must not be used to remove the scope from the reprocessing machine.
- Recontamination can also occur when transporting and storing endoscopes. **Disinfected and dried endoscopes should be transported in a clean enclosed container, dedicated to that purpose**, and should be prevented from contacting potentially unclean surfaces.

## REPORT A DEVICE PROBLEM

Reporting a device problem can help you and the whole healthcare community. When you report a problem, we investigate. If we believe a specific device hazard exists, we notify the manufacturer and encourage them to correct it, and then let you know what we learn. To prevent it from happening again, we'll add your report to our databases and may follow up with publication in *Health Devices Alerts*. All reports are kept strictly confidential, and this service is free.

An asterisk (\*) denotes a required field.

### Problem Description

\* Please use the following text box to describe the hazard or problem in detail.

Date  📅

Title

Name

Organization



# FDA recommendations

- Follow manufacturer's IFUs.
- Adhere to professional reprocessing guidelines.
- Have a comprehensive QC program.
- Required documentation:
  - Training
  - Competencies
  - Quality monitors



# FDA Safety Communications

## Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication - August 4, 2015

<http://wayback.archive-it.org/7993/20170722150658/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm>

Provides a list of supplemental duodenoscope reprocessing measures that facilities can use in addition to current IFUs for additional risk mitigation.

- Microbiological Culturing
- Ethylene Oxide Sterilization
- Use of a Liquid Chemical Sterilant Processing System
- ~~Repeat High-Level Disinfection~~



# FDA Safety Communications

## The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication – August 29, 2019

[https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication?utm\\_campaign=2019-08-29%20CDRH%20Safety%20Comm%20-%20%20Recommendations%20and%20Updates%20to%20Help%20Improve%20Duodenoscope%20Reprocessing&utm\\_medium=email&utm\\_source=Eloqua](https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication?utm_campaign=2019-08-29%20CDRH%20Safety%20Comm%20-%20%20Recommendations%20and%20Updates%20to%20Help%20Improve%20Duodenoscope%20Reprocessing&utm_medium=email&utm_source=Eloqua)

- “Now recommending that hospitals and endoscopy facilities transition away from fixed endcap duodenoscopes to those with newer design features that facilitate or eliminate the need for reprocessing.
- Consider using duodenoscopes that have disposable components, if available.
- Ensure staff are meticulously following reprocessing instructions.
- Institute a quality control program that includes sampling and microbiological culturing, and other monitoring methods.
- Develop schedules for routine inspection and periodic maintenance in accordance with the duodenoscope manufacturer's instructions.”

## ATP Confusion: from FDA notice

“One potential method to monitor the effectiveness of duodenoscope reprocessing is the **use of test strips that detect adenosine triphosphate (ATP), an indicator of the presence of live microbes.** While some manufacturers of ATP test strips are promoting ATP test strips for assessing duodenoscope cleaning, as of August 29, 2019, we are not aware of any ATP test strips legally marketed for this use. The FDA premarket review is necessary to assess whether ATP test strips for this use are adequately validated and properly labeled. We have contacted manufacturers of ATP test strips advising them of our requirements for manufacturing, testing and labeling for medical devices promoted for assessing duodenoscope cleaning.”

# AAMI ST90

## Processing of health care products—Quality management systems for reprocessing

- This standard specifies the **minimum requirements for a quality management system** that can be used by healthcare organizations that process medical devices.
- It was developed to help healthcare professionals more effectively, efficiently, and consistently reprocess reusable medical devices in order to prevent infections, pyrogenic reactions, or other adverse events.

# AAMI ST90

- This document specifies minimum requirements for quality management systems (QMS) to effectively, efficiently, and consistently process (transport, clean, decontaminate, disinfect, inspect, package, sterilize, and store) medical devices to prevent adverse patient events and non manufacturer-related device failures.



# AAMI ST90 - Inclusions

This standard addresses the major elements of a quality management system as it applies to the processing of health care products performed in a sterile processing area or similar location with the same responsibility.

The major elements of a quality management system are as follows:

- **General objectives and documentation requirements**
  - objectives, policies & procedures, record keeping
- **Management responsibility**
  - communication to staff, management reviews, ensuring adequate resources, complete and adequate quality policies, responsibility and authority,
- **Resource management**
  - competency requirements, education, training, physical space, equipment, and supplies
- **Product realization**
  - Planning for new devices/equipment/materials, determining customer requirements, developing and monitoring processes, purchasing, traceability
- **Measurement, analysis, and improvement**
  - Customer satisfaction, auditing, process monitoring, data analysis, quality improvement, corrective and preventative actions

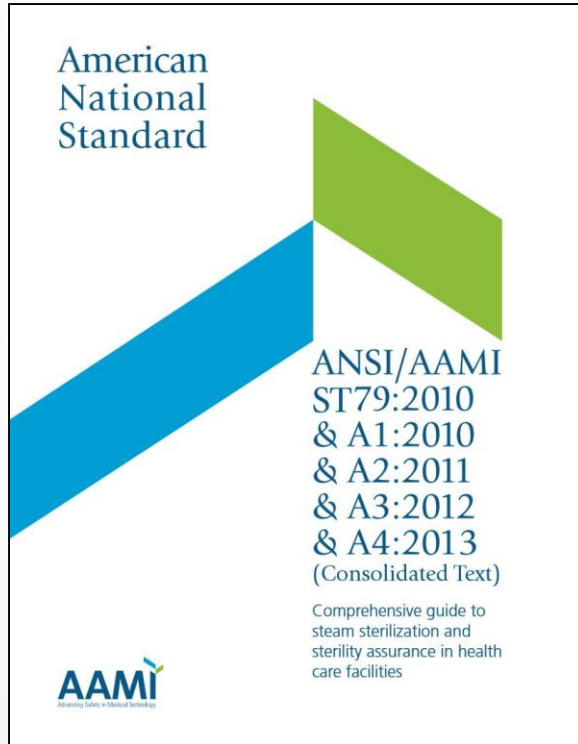
# AAMI ST90 - Exclusions

This standard does **NOT** cover

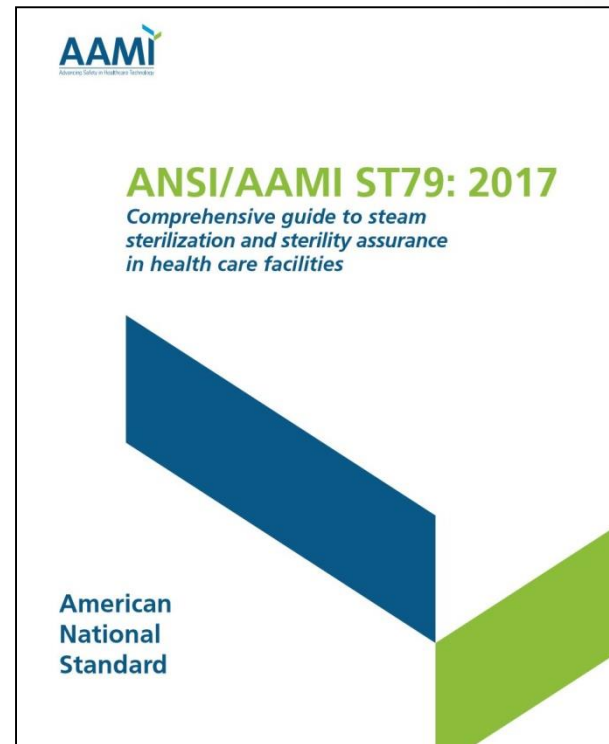
- the implementation of any specific AAMI standard, recommended practice, or guideline supporting a **particular process**;
- the development or implementation of any specific system instruction, work instruction, or policy supporting a **particular process and/or piece of equipment**;
- the development or implementation of any specific education, training, or competency test supporting a **particular process and/or piece of equipment**;
- the development or implementation of any specific audit process or tool supporting a **particular process and/or piece of equipment**; or
- the **reprocessing of single-use devices** by a health care facility.

# AAMI ST79 updates

Out with the old, in with the NEW



...



# AAMI ST79 (2017) –

## New Format, new sections, expanded sections

### Previous Version

- 1) Scope
- 2) Definitions and abbreviations
- 3) Design Considerations
- 4) Personnel Considerations
- 5) Receiving
- 6) Handling, Collection and transport of contaminated items
- 7) *Cleaning and other decontamination processes*

### New Version

- 1) Scope
- 2) Definitions and abbreviations
- 3) Design Considerations
- 4) Personnel Considerations
- 5) Receiving
- 6) Handling, Collection and transport of contaminated items
- 7) **Cleaning, disinfection (microbicidal processes), and other decontamination steps**

# AAMI ST79 (2017) –

## New Format, new sections, expanded sections

### Previous Version

8) *Packaging, preparation, and Sterilization*

9) *Installation, care, and maintenance of sterilizers*

10) *Quality control*

11) **Quality process improvement**

12) **New product evaluation**

### New Version

8) Preparation and assembly of instruments

9) Packaging

10) Sterilization

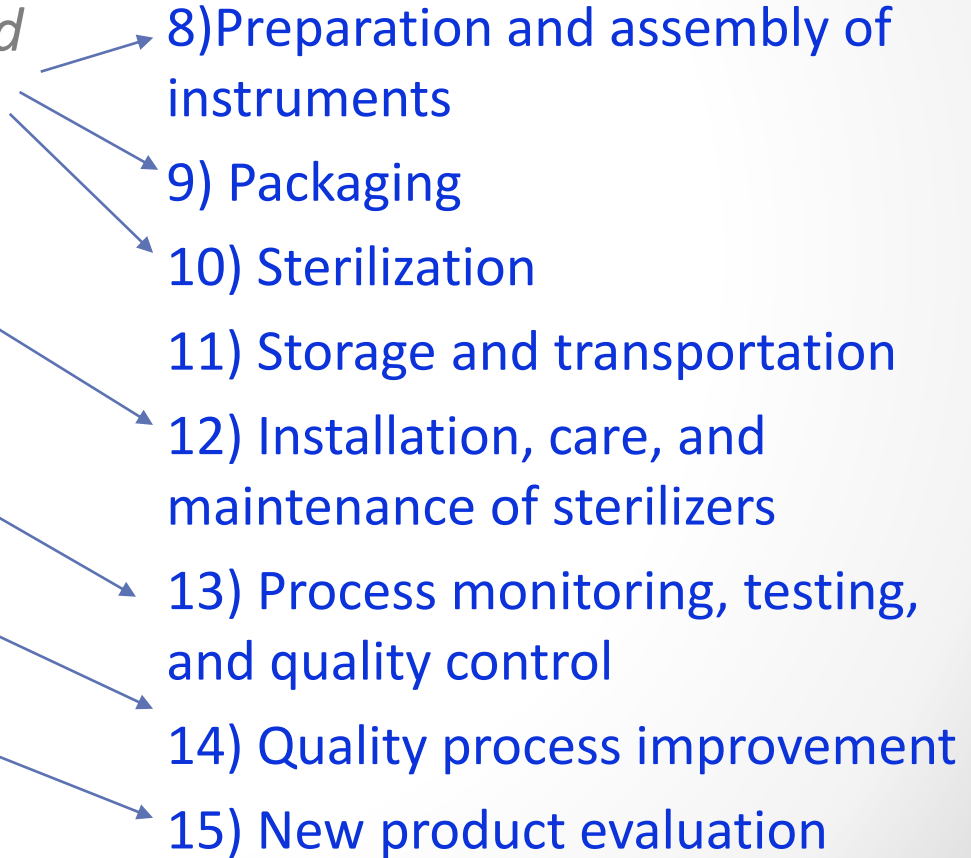
11) Storage and transportation

12) Installation, care, and maintenance of sterilizers

13) Process monitoring, testing, and quality control

14) Quality process improvement

15) New product evaluation



## AAMI ST79 (2017) –

- Section 3.3.5.5: Big **changes in Temperature requirements**.
  - The health care organization should identify which version of ANSI/ASHRAE/ASHE 170 will be used based on when the HVAC system was initially installed or last upgraded.
  - **No more AAMI specific temperature or humidity guidance.**
- New Annex Q (informative): **Alternatives for keeping cool in the sterile processing environment.**
- Section 7.6.4.5 and 13.2: **Cleaning verification of mechanical processes is now daily and should be documented.** (changed from weekly, preferably daily).
- Section 7.6.4.4.1: **Ultrasonic cleaning should be...performed with fresh cleaning solution; solution should be changed after each use** (a “use” should be defined in the health care facility’s policies and procedures).

## AAMI ST79 (2017) –

- Section 7.6.4.4.1: In addition to following the manufacturer’s written IFU, the following actions should be taken: **Perform cavitation testing daily whenever the equipment is in use.**
- **“Standard” sterilizer exposure times and temps table removed.**
- There are now **“Types”** of indicators/integrators/emulators. Old verbiage was **“Class”**
- Most **graphics have been updated.**

# Implementation of standards

...



# Disciplined Approach

1. Assemble Multidisciplinary Stakeholder Team.
  - e.g. Endo, CSPD, Infection Prevention, Safety, Risk Management, Accreditation, clinical customers
2. Agree on Guidelines and Recommendations.
  - Standardize across the institution
3. Develop Gap Analysis, Audit Tool and Timelines.
4. Examine Current State of Affairs.
5. Conduct Mock Tracer/Gap/Risk Analysis
6. Present and Analyze Results.
7. Prioritize Issues.
8. Change/modify practices where needed.
9. Follow up Improvement Plans.
10. Evaluate Actions.
11. Conduct Regular Risk Assessments/Mock Tracer/Gap/Risk Analysis

## Step 2: Agree on Current Guidelines and IFU

- Review current guidelines for reprocessing flexible endoscopes – wherever they are clinically used.
- Have the latest version of guidelines available.
- Review supplemental FDA guidance – safety communications.
- Resolve conflicts if not in harmony!
- When evidence is lacking, expert opinion, independent guidelines, or standards for accreditation may differ.
- Always refer to FDA labeling and manufacturers' instructions for device-specific reprocessing guidance.
- Accrediting bodies will typically survey for performance in accordance with this guidance.

## Step 2: Agree on Current Guidelines and IFU

Issue	SGNA	AAMI ST91	APIC	AORN	MSG
Storage Interval after which endoscopes must be reprocessed before use	7 days	Risk assessment	No recommendation	Multidisciplinary team conduct a risk assessment	Address at the facility level in conjunction with the IP department or consultants
Cleaning verification	Pre-established interval	Weekly, preferably daily	No recommendation	With each reprocessing cycle or daily	Monitor as part of a quality program

# Step 3: Develop Gap Analysis Audit Tool and Timelines

Can use or modify available templates.

Needs to pointedly be reflective of institution's written policies/procedures.

“Basics” address P & P and assessment of:

- Reprocessing steps
- Reprocessing staff
- Reprocessing equipment and supplies
- Reprocessing OEM IFU readily available and followed
- Adequate physical space and HVAC
- Appropriate endoscope storage
- Documentation
- Traceability
- AER validation
- Frequency of Gap Analysis

# Available Audit Tools

The screenshot shows the CMS.gov homepage. At the top, there is a navigation bar with links for Home, About CMS, Newsroom, Archive, Share, Help, and Print. Below this is the CMS.gov logo and the text "Centers for Medicare & Medicaid Services". A row of yellow buttons provides quick access to various sections: Medicare, Medicaid/CHIP, Medicare-Medicaid Coordination, Private Insurance, Innovation Center, Regulations & Guidance, Research, Statistics, Data & Systems, and Outreach & Education. A secondary navigation bar includes a Home button, the CMS.gov logo, a description of the website as a federal government site managed by the U.S. Centers for Medicare & Medicaid Services, and the agency's address. A "Full-screen Snip" button is visible. The main content area is divided into three columns: "CMS & HHS Websites" with links to Medicare.gov, MyMedicare.gov, Medicaid.gov, InsureKidsNow.gov, HealthCare.gov, and HHS.gov/Open; "Tools" with links to Acronyms, Contacts, Glossary, and Archive; and "Helpful Links" with a list of various policy and informational links. A "Receive Email Updates" form with a "Submit" button is also present.

**CMS encourages HOPD and ASC to use worksheet as part of self assessment tools to help promote quality and patient safety.**

Accessed 09-03-2019:

- Hospital: <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf>
- Amb. Surg. Ctr: [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107\\_exhibit\\_351.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf)

# Convert Guidelines/Recommendations into Your Own Yes/No Document



## Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC

<https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html>

Page last reviewed: December 27, 2018. Accessed 09-03-2019.

Board Font Paragraph Styles Editing

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

### HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

**Purpose:** Facilities can use this sample Audit Tool document as a template to develop their own audit tool specific to their endoscopes and evidence-based reprocessing practices. This sample tool is designed to be used in conjunction with the Competency Verification Tool. Facilities are encouraged to use these tools together to verify competency and audit current practice as well as to ensure that their practices are consistent with “Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee.”

**Auditor:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Audit Item	Yes	No	Comments/Action
<b>Precleaning</b>			
Precleans the flexible endoscope at the point of use.			
Discards the cleaning solution and cloth after use.			
<b>Transporting</b>			
Transports the contaminated endoscope and accessories to the endoscopy processing room as soon as possible after use.			
Ensures the container or cart is labeled with a biohazard legend.			
<b>Leak Testing</b>			
Performs leak testing before manual cleaning if indicated.			
<b>Manual Cleaning</b>			
Uses a freshly prepared cleaning solution and does not add additional products to the water unless recommended by the manufacturer.			
Completely submerges the endoscope and accessories.			
Cleans exterior surfaces of the endoscope with a soft, lint-free cloth or sponge.			
Cleans all accessible channels and the end of the endoscope with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer.			
Uses a clean brush for each endoscope cleaning.			
If the endoscope has an elevator, raises and lowers the elevator throughout the manual cleaning process.			
Brushes the accessible channels until no debris appears on the brush.			
Removes debris before retracting the brush back through the endoscope.			
Flushes the channels of the endoscope with the cleaning solution.			
Manually actuates the valves during the cleaning process.			
Flushes and rinses exterior surfaces and internal channels with			

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

Audit Item	Yes	No	Comments/Action
<b>Inspection</b>			
Inspects and evaluates endoscopes and accessories for			
• cleanliness			
• missing parts			
• clarity of lenses			
• integrity of seals and gaskets			
• physical or chemical damage			
• moisture			
• function			
Uses additional illumination and magnification for inspection, as needed.			
<b>High-level Disinfection or Sterilization</b>			
Manually cleans the endoscope and accessories before mechanical or manual high-level disinfection or sterilization.			
<b>Mechanical methods</b>			
Checks the expiration date of the high-level disinfectant or liquid chemical sterilant before each use.			
Uses a test strip or other FDA-cleared testing device specific to the disinfectant or liquid chemical sterilant and minimum effective concentration of the active ingredient for monitoring solution potency before each use.			
Positions endoscopes and accessories within the mechanical processor to ensure contact of the processing solutions with all surfaces of the endoscope.			
Connects the endoscope to the mechanical processor correctly.			
Verifies mechanical processing cycles are completed as programmed.			
<b>Manual methods</b>			
Checks the expiration date of the high-level disinfectant before each use.			
Uses a test strip or other FDA-cleared testing device specific to the disinfectant and minimum effective concentration of the active ingredient for monitoring solution potency before each use.			
Flushes and fills lumens and ports with the high-level disinfectant.			
Completely immerses the endoscope in the high-level disinfectant solution for the designated time according to the device and high-level disinfectant solution manufacturer's IFU.			
Rinses the endoscope with water that meets the manufacturer's specification or as recommended by professional organizations			

**FLEXIBLE ENDOSCOPES**  
Guideline at a Glance



**PROCESSING ROOM**

- Perform endoscope processing activities in a physically separate care activities take
- Wear personal protective equipment including a surgical mask with gown, general pur beyond the cuff of shoe covers.
- Maintain a unidirectional airflow in the contamination area workroom and the
- Keep processing room
- Maintain relative humidity between 40% and 60% the heating, ventilation, and air conditioning design parameters
- Monitor performance of the room and report a variance in health care organization so that designated assessment to data sources should be taken

★ Processing flexible endoscopes in a room where temperature, humidity, and air are managed may improve the functionality of flexible endoscopes and reduce cross contamination, and



**TRANSPORTING**

- Transport contaminated endoscopes to the decontamination area as soon as possible.
- Keep endoscopes moist with liquid during transport.
- Transport endoscopes in a closed transport cart.
- The container must be leak resistant and should be labeled with the endoscopes and accessories.
- Label the transport cart with a hazard legend.
- Keep accessories with the endoscopes stored separately.
- Process endoscopes and accessories as soon as possible after the copy processing room or as recommended time
- When it is not possible to process within the endoscopes' recommended time to the manufacturer's instructions for decontamination
- Implement a process for endoscopes when the procedure is initiated.
- Clean and disinfect transport

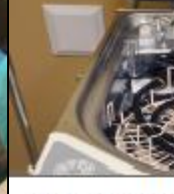
★ Transporting the contaminated endoscopes to the decontamination area as soon as possible facilitates the cleaning process and prevents the material from drying on the endoscopes. Keeping accessories with the endoscopes prevents them from being lost or damaged and reduces the risk of damage to the endoscope and accessories as a single unit.



**MANUAL CLEANING**

- Manually clean the flexible endoscope after leak testing.
- Follow the endoscope and processor manufacturer's IFU.
- Use a freshly prepared cleaning solution with the endoscope and do not reuse the cleaning solution unless the manufacturer's instructions allow.
- Completely submerge the endoscope in the cleaning solution.
- Clean the exterior surfaces of the endoscope with a soft, lint-free cloth or sponge.
- Clean all accessible channels of the endoscope with a cleaning solution with a length, width, and material as recommended by the endoscope manufacturer.
- Actuate the endoscope valve.
- Clean and brush the elevator recesses surrounding it.
- Raise and lower the elevator to clean the channels.
- Use a clean brush for each endoscope channel.
- Brush the accessible channels until no debris appears on the brush.
- Remove debris from the brush by rinsing the brush back through the channels.
- Flush the endoscope channels with a cleaning solution and residual water.
- Dry the exterior surfaces and the elevator recesses with instrument air.
- Clean, brush, and rinse reusable parts and cleaning implements.
- Use only single-use parts, accessories, and cleaning implements that are compatible with the endoscope manufacturer's instructions.

★ The effectiveness of the cleaning process is based on a number of factors including the number of devices being cleaned, the design of the device, and the ability of the endoscope and accessories as a single unit.



**HIGH-LEVEL DISINFECTANT OR PACKAGING**

- Mechanically clean endoscopes and accessories before high-level disinfection or mechanically clean endoscopes and accessories before high-level disinfection.
- Follow both the endoscope and processor manufacturer's instructions for high-level disinfection.
- Position endoscopes and accessories to prevent contact of the processor with the endoscopes.
- Ensure all contact surfaces are covered by the high-level disinfectant.
- Perform mechanical cleaning of endoscopes using critical cleaning solutions.
- Use cleaning, disinfection, and chemical agents and mechanical processing.
- If recommended by the manufacturer, use a test strip to verify high-level disinfection.
- After disinfection, mechanically rinse endoscopes and accessories with deionized water.
- Form a multidisciplinary team to assess the need for decontamination of decontamination solutions.
- Dry the exterior surfaces of the endoscope.
- Dry the endoscope instrument air or mechanical processing.
- Package and store endoscopes in a sterile tissue

★ The Spaulding semicritical endoscopes that come in contact with nonintact skin or mucous membranes are considered to be semicritical and should be processed with high-level disinfection or sterilization.



**RECORDING**

- Keep records related to flexible endoscope processing that include:
  - date and time
  - identity of the endoscope and endoscope accessories
  - method and verification of cleaning and of cleaning verification testing
  - number or identifier of the mechanical processor and results of processor efficacy testing
  - identity of the persons performing the procedure
  - lot numbers of processing solutions
  - disposition of defective items or equipment
  - maintenance of water systems, endoscope accessories, and processing equipment
- Keep records related to flexible endoscope processing that include:
  - date and time
  - identity of the patient
  - procedure
  - identity of the licensed independent practitioner performing the procedure
  - identity of the endoscopes and accessories used during the procedure
- Specify in your policy and procedures how records should be kept.

★ Records provide data for the identification of trends and demonstrate compliance with regulatory requirements and accreditation standards.



**PERSONNEL**

- Ensure cleaning and processing is conducted by individuals who have received education and completed competency verification activities related to endoscope processing.
- Implement procedures to verify that processing of flexible endoscopes is performed in the same manner in all processing locations.
- Ensure sufficient time and numbers of personnel are provided to permit thorough cleaning and processing of flexible endoscopes.
- Schedule endoscopy procedures to allow sufficient time for cleaning and processing flexible endoscopes.
- Maintain an inventory of flexible endoscopes and accessories sufficient to meet the anticipated demand.
- Establish policies and procedures requiring that flexible endoscopes used for procedures performed at the bedside or outside of normal operating hours are processed in the same manner as endoscopes used during normal operating hours.

★ Having individuals who have received education and demonstrated competency process flexible endoscopes and accessories helps reduce the risk for errors and cross contamination.

processing flexible endoscopes.

damage and reduces contamination to help ensure devices are safe for patient use.



# Infection Prevention Toolkit

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## Infection Prevention Resources

The SGNA Infection Prevention Task Force created the framework for the Infection Prevention Champions Program and toolkit. The goal of the **Infection Prevention Champions Program** is for each facility/setting across the country to have a team member enroll as a Champion who acts as the link to the most current infection prevention news, helping ensure the most current and safe practices are followed.

The Infection Prevention Toolkit contains resources for Champions and others who seek to advance their infection prevention knowledge. Champions have access to additional resources and discussion forums.

Full-screen Snip

### Publicly accessible resources include:

- [Professional Society Guidelines](#)
- [Manufacturer Guidelines](#)
- [Educational Resources](#)
- [Employer Resources](#)
- [Best Practice Tools](#)
- [Photo Gallery](#)

### SGNA Infection Prevention Work Group

Term: January 2015 - Present

**Chair:** Karen Zervopoulos, RN CFER CGRN

### Members:

Dianna Burns, BS RN CGRN



## Step 4: Examine Current State of Affairs

- Who? What? When? Where?
- Inventory information:
  - Endoscope make and model.
  - Clinical site using.
  - Number of procedures performed.
  - Location of OEM IFUs.
  - Location for reprocessing.
  - Equipment used for HLD and / or sterilization.
  - Endoscope inventory tracking: in-use versus out for repair versus “retired”.
- Current P & P, Competency records, Guidelines and Reference documents.



## Step 5: Conduct Mock Tracer / Gap Analysis

- Have multiple disciplines tour together.
- Hit all areas that use flexible endoscopes.
  - Common: GI Endo., ORs, Respiratory, ICU, ED, Anesthesia, Urology, ENT, OB/GYN
- Identify deficiencies in practice as compared to policies.
- Ensure compliance with all current federal and local regulatory requirements, as well as applicable accrediting organizations.

# Step 11: Conduct Regular ONGOING

## Risk Assessments/Mock Tracers/Gap & Risk

### Analyses

Example –

TJC

HLD & Sterilization

BoosterPak:

[https://www.jointcommission.org/assets/1/6/TJC\\_HLD\\_BoosterPak.pdf](https://www.jointcommission.org/assets/1/6/TJC_HLD_BoosterPak.pdf)

High-Level Disinfection (HLD) and  
Sterilization BoosterPak



## GENERAL →

### CHECKLIST FOR CLEANING, HIGH-LEVEL DISINFECTION, AND/OR STERILIZATION OF INSTRUMENTS AND FLEXIBLE SCOPES

- ❑ Copy of manufacturers' current instructions for cleaning, disinfection, and/or sterilization available for each instrument or scope
- ❑ Copy of manufacturers' current instructions for use of sterilizer/automated endoscopic reprocessor (AER)
- ❑ Cleaning instructions for scopes posted in cleaning area
- ❑ Copy of manufacturers' instructions for each cleaning product, disinfectant, high-level disinfectant, and designated test strips for the high-level disinfectant
- ❑ Appropriate personal protective equipment (PPE) available and used during processing- (Head/hair covering, mask/face shield, goggles, utility gloves, and fluid resistant gown)
- ❑ Flow of instruments is from dirty to clean with no cross-contamination (from clean to dirty or dirty to clean)
- ❑ Staff should know by the clearly designated location what stage of the HLD process a scope or instrument is in, whenever there is doubt if a step has been conducted or completed, reprocess the device (start over)
- ❑ Instruments, equipment, and supplies labeled "single use disposable" are not reprocessed or reused (ex. brushes)
- ❑ Written policies and procedures for HLD of scopes and probes are to include preventative maintenance and storage, must be current, and front-line staff must have knowledge of and access to these documents
- ❑ Competency evaluations should be completed for each employee on hire and considerations for annual review as recommended by evidence-based guidelines; also include random observations. Determine frequency of competency and training based on staff turnover, purchasing new equipment or products, or a breach in the process has been identified
- ❑ Processing log maintained: scope #, test strip results, immersion, initialed, and dated; may refer to and use HLD manufacturer provided log form

## ENDOSCOPIC REPROCESSING →



### POINT-OF-USE



### TRANSPORT



### DECONTAMINATION



### High-level Disinfection (HLD) – Manual Process:

- ❑ **Point-of-Use:** Scope immediately wiped down at point of use (in the procedure room) and channels flushed with enzymatic, detergent
- ❑ **Transport:** Scope is safely transported to the cleaning area/decontamination room in a leak-proof, puncture resistant container/device labeled as biohazardous which is based on evidence-based guidelines, manufacturer instructions for use
- ❑ **Decontamination:**
  - Scope is leak tested; if fails, finish processing, remove from service, and send for repair
  - All accessories are removed for cleaning or discarded if disposable – following manufacturer's instructions-for-use
  - Scope and accessories immersed in measured enzymatic detergent
  - Cleaning solution is changed after each scope is cleaned, based on manufacturer instructions for use
  - All channels and accessories thoroughly brushed with manufacturer recommended brushes

Date Solution Opened	Date Solution Expires	Date Solution Tested	Time Solution Tested	Test Results (circle one)	Tested by (Initials)	Temp. Before Use	Comments
				Pass Fail			



## REVIEW QUESTIONS

### Q&A

- Q.** What is meant by “flow of instruments or devices,” and in which direction should this always occur?
- A.** The term “flow of instruments or devices” pertains to the cleaning of instruments; the flow is always from dirty to clean, with no risk of cross contamination.
- Q.** What are the steps involved when decontaminating scopes using the manual HLD process?
- A.** Scope is leak tested; if fails, follow manufacturer instructions for a failed leak test, remove from service, and send for repair.
- All accessories are removed for cleaning or discarded if disposable – following manufacturer’s instructions-for-use
  - Scope & accessories are fully immersed in measured enzymatic, detergent
  - Cleaning solution changed after each scope is cleaned per manufacturer
  - All channels and accessories thoroughly brushed with manufacturer brush(es)
- Q.** When using an AER, how many rinses should scopes go through?
- A.** The AER should be set for triple rinses based on manufacturer’s instructions-for-use and evidence-based guidelines.

### Important Takeaways

- **Become familiar with the Spaulding Classification and understand which instruments or devices fall within the semi-critical category. When you know this and follow the manufacturer instructions for use, you will be able to determine which instruments/devices undergo HLD**
- **When transporting a “dirty” scope from the procedure room, always make sure that it is safely moved to the cleaning area/decontamination room in a leak proof, puncture resistant container/device labeled as biohazardous as per evidence-based guidelines**
- **Always change the cleaning solution after each scope. DON'T re-use the solution. When changing the solution always measure accurately, don't approximate**

# Objectives

- Discuss the key provisions and competency recommendations from ANSI/AAMI **ST 91**, SGNA, AORN guidelines, ECRI and FDA.
- Outline ANSI/AAMI **ST90** national standard for Quality Systems for Reprocessing.
- Discuss a process for implementing standards/guidelines – incl. AAMI ST91.

**“If you don't know what you don't know until you know you don't know it, how can you be certain of anything?”**



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# Stay positive and stay informed!

John Whelan BSN, RN  
Clinical Education Coordinator  
Healthmark Industries  
[jwhelan@HMARK.COM](mailto:jwhelan@HMARK.COM)

Healthmark: <https://www.hmark.com/>

