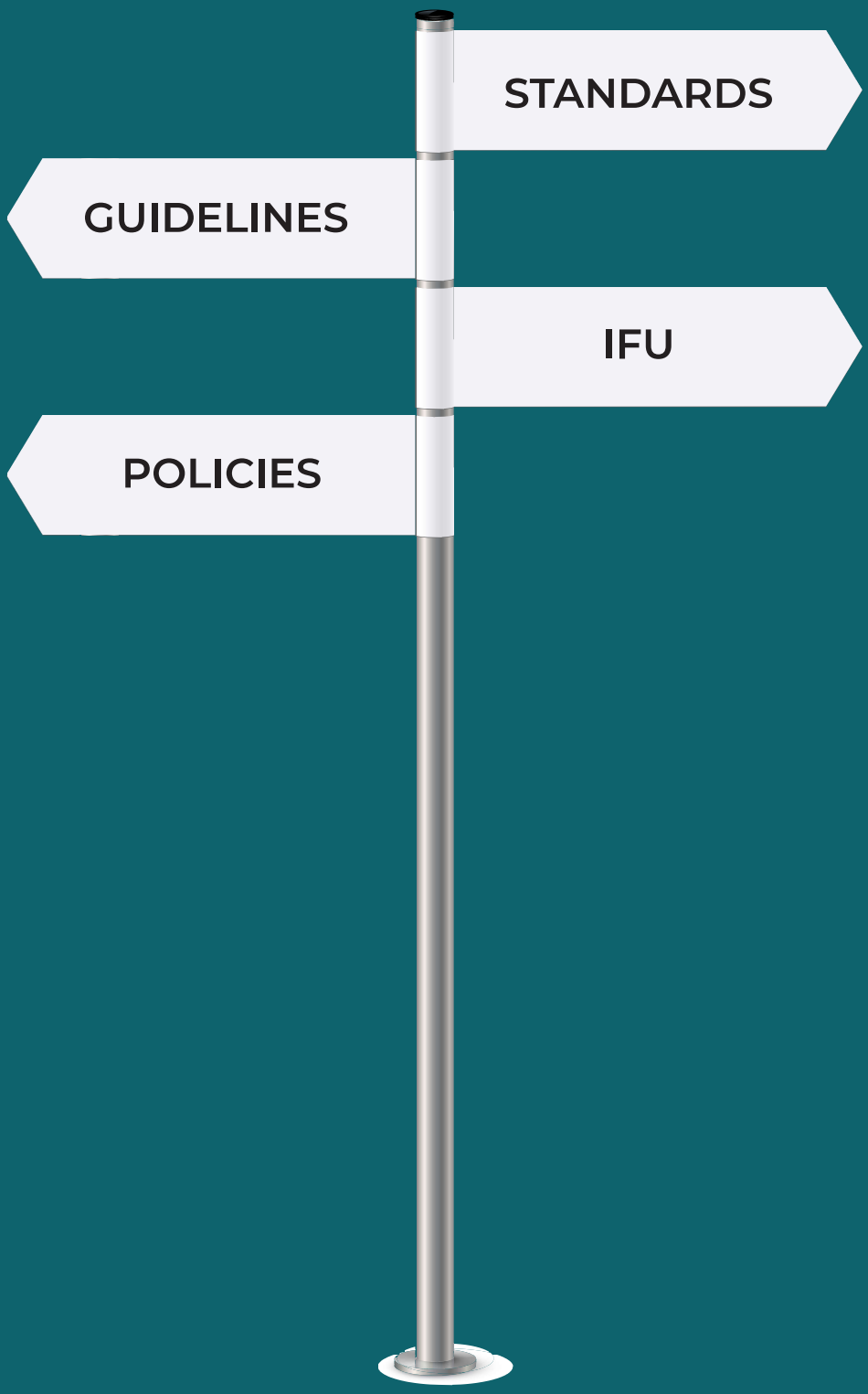
STANDARDS
GUIDELINES
IFU
POLICIES

Crosswalk of Current Standards & Guidelines for Flexible Endoscope Processing

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LEARNING OBJECTIVES

1. Identify training and personal protective equipment recommendations for employees who process endoscopes
2. Learn the recommendations for the transport, testing, manual cleaning and inspection of soiled endoscopes
3. Understand recommendations for high-level disinfection (HLD), post-automated endoscope reprocessor drying, device handling and transport, post-HLD labeling and storage
4. Understand current recommendations for sterilization, microbial surveillance and quality management

To guide best practices in the processing of reusable medical devices, cleaning and disinfection/sterilization practices should be based on manufacturers' instructions for use (IFU), national guidelines and standards, and institutional policies. Within the last three years, the four major organizations that direct processing of flexible endoscopes have all published new guidelines. This includes (in order of publication): the American Society for Gastrointestinal Endoscopy (ASGE), the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN) and, most recently, the Society of Gastroenterology Nurses and Associates (SGNA). It is vital to understand that each of these documents replace existing publications; they are not simply updates or addendums.

It is critical for healthcare organizations, leaders and frontline staff, including Sterile Processing (SP) professionals, to have access to the most current version of these guidance documents and ensure that institutional policies and practices reflect the latest recommendations. Accreditation and surveying agencies commonly reference the latest standards and guidelines and survey to them; therefore, it is useful for SP professionals to know which guidelines, standards and best practices are referenced and followed by their organization.

This lesson compares and highlights the latest endoscope processing recommendations from ASGE, AAMI, AORN and SGNA and provides an at-a-glance crosswalk of the related guidance documents. (See **Figure 1**) It serves as only a brief overview of some of the key points in these new guidance

Organization	SGNA – Society of Gastroenterology Nurses and Associates	AORN – Association of periOperative Registered Nurses	AAMI – Association for the Advancement of Medical Instrumentation	ASGE - American Society for Gastrointestinal Endoscopy
Most recent year of publication	2023	2022	2021	2021
Standard/Guideline title	Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes	Guidelines for Perioperative Practice: Flexible Endoscopes	ANSI/AAMI ST91:2021 *Flexible and semi-rigid endoscope processing in health care facilities*	"Multisociety guideline on reprocessing flexible GI endoscopes and accessories"
Replaces previous publication year	2018	2019	2015	2016

Figure 1

documents; therefore, it is prudent to individually review each in full.

Objective 1: Identify training and personal protective equipment recommendations for employees who process endoscopes

ASGE, AAMI, AORN and SGNA all reinforce the importance of ongoing focused training and competencies for all staff performing endoscope processing.[1,2,4,6] Not only should processing staff receive education and competency verification before initial independent practice, they should also receive refresher training and competency verification at least annually.[1,2,6] Training and competency verification are also necessary whenever processes change (e.g., if IFU are updated or new endoscopes, equipment or chemistries are acquired and put into use) and anytime a process breach occurs.[1,2,6]

When it comes to certification specific to endoscope processing, ANSI/AAMI ST91:2021 *Flexible and semi-rigid endoscope processing in health care facilities* is the most prescriptive in stating that processing staff "should be certified . . . within two years of employment and should maintain that certification throughout their employment."[1] SGNA recommends to "consider certification,"[6] and SGNA, AORN and AAMI all highlight the need for education and training staff members to be competent as well.[1,2,6]

Performing various endoscope processing roles and responsibilities consistently, safely and appropriately hinges on the availability and proper use of personal protective equipment (PPE). PPE is essential for all endoscope processing areas, and each staff member should be individually fit-tested for PPE to ensure optimal protection. SGNA, AORN and AAMI identify that the minimum requirements for PPE for the processing area include gloves, eye protection, a fluid-resistant gown, and a face shield or mask.[1,2,6] AAMI and AORN additionally call for fluid-resistant shoe covers and the "highest-level gown" (level 3 or 4) for technicians working in the decontamination area.[1,2]

Objective 2: Learn the recommendations for the transport, testing, manual cleaning and inspection of soiled endoscopes

Harmony exists across the guidance documents regarding soiled transport recommendations, and this is largely because Occupational Safety and Health Administration (OSHA) regulations provide the foundational expectations that endoscopes be transported in closed, covered, leak-proof and puncture-resistant containers with biohazard labeling.[1,2,4,6] Both AORN and AAMI recommend keeping endoscopes moist for transport[1,2] (e.g., with an enzymatic point-of-use product or a towel moistened with water[2]) or inside a package designed to maintain humid conditions to limit drying of bioburden. Further, all four organizations identify the need to communicate to processing staff the time point-of-use treatment occurred so delays and process gaps can be addressed as needed.[1,2,4,6]

AORN and AAMI recommend performing quality control measures and documenting pressure output from leak testers to help ensure all leaks are identified.[1,2] This should be done for both automated and manual leak testers. Per AAMI, this should be performed "each day that endoscopes are used."[1] Any endoscope that fails leak testing or is found to be damaged should be individually labeled/tagged and managed per the facility's repair policies.[1,2,6]

All four organizations consider manual cleaning as essential for successful processing outcomes. SGNA refers to manual cleaning as "the most critical step in removing bioburden."[6]

ASGE states to "meticulously clean the entire endoscope"[4] and AAMI stresses that "thorough attention to detail is crucial for overall processing effectiveness and patient safety."[1] They each stress the need to follow manufacturer's IFU for delayed processing protocols. Brushing during manual cleaning "using a brush size compatible with each channel"[6]—either "the endoscope manufacturer's brush or equivalent"[1]—is recommended, even with automated endoscope reprocessors (AERs) that have automated cleaning claims. AAMI and AORN recommend performing a risk assessment anytime forgoing some or all manual cleaning is being considered.[1,2]

All the organizations encourage the use of lighted magnification as part of focused inspection following manual cleaning.[1,2,4,6] AORN directly promotes the use of borescopes for accessible channels.[2] SGNA indicates borescopes "may be useful,"[6] and AAMI states that "a borescope can be used periodically . . . at a frequency determined by the facility."[1]

Further, AAMI, AORN and SGNA recommend that cleaning verification (CV) testing be performed as part of inspection after manual cleaning.[1,2,6] SGNA states to "consider a method of manual cleaning verification . . . visual inspection and verification testing . . . [which] play an important part in evaluating the effectiveness of manual cleaning."[6] AAMI and AORN recommend every-cycle CV testing for "high-risk endoscopes," including bronchoscopes, elevator channel endoscopes, cystoscopes, ureteroscopes and endobronchial ultrasound (EBUS) scopes.[1,2] For non–high-risk endoscopes (e.g., colonoscopes and gastroscopes), CV tests should be performed when new endoscopes are purchased and at regular intervals as established by the facility.[1]

Objective 3: Understand recommendations for high-level disinfection (HLD), post-automated endoscope reprocessor drying, device handling and transport, post-HLD labeling and storage

SGNA allows for manual or automated HLD whereas the other three organizations stress that automated processing is preferred. Specifically, ASGE states that "HLD should be performed in an automated endoscope reprocessor."[4] AAMI states that "manual processing is not recommended" but provides direction for manual processing, recognizing that manual processing needs to be available as a backup when automated processes fail and also that there are situations where facility or resource limitations affect the availability of automated options.[1]

Among the more notable changes to all four guidance documents is the emphasis on active channel drying following use of an AER, regardless of whether the endoscope will be reused for another procedure or placed into storage.[1,2,4,6] This recommendation is the result of clinical investigations and research over the past several years that clearly revealed remaining moisture inside endoscope channels, even days after processing. The risks associated with residual moisture include bacterial contamination and biofilm development. All four organizations now recommend drying processed endoscopes with automated filtered air for at least 10 minutes.

SGNA recommends the use of a channel alcohol flush,[6] while ASGE states to follow the endoscope manufacturer's IFU for that step.[4] AAMI and AORN recommend a risk assessment to determine whether alcohol flushes should be used.[1,2]

There has been an increased focus on active channel drying post-processing, and the four organizations call for endoscopes to be dry prior to conventional hanging storage or being placed in active drying cabinets for the duration stated in the drying cabinet manufacturer's IFU. AORN and AAMI state that conventional storage cabinets should have HEPA-filtered forced air circulating in the cabinet.[1,2] AAMI states that drying cabinets are preferred, but "at a minimum, conventional cabinets with HEPA filtration should be used to store flexible endoscopes."[1]

SGNA is the only organization still referencing a distinct number of days (seven) for endoscope storage expiration ("hang time"), citing a research study from 2015.[6] The other three organizations recommend basing hang time on a multidisciplinary discussion and review of available clinical investigations and research.[1,2,4]

Each organization also states that hand hygiene and clean gloves should be used when handling endoscopes post-processing.[1,2,4,6] Neither SGNA nor ASGE address containerized transport post-processing; however, both AAMI and AORN identify the need for protection "from contamination and damage."[1,2]

It is also important to note that a post-HLD endoscope can look similar to an endoscope that has undergone bedside point-of-use treatment, so it is important to "ensure that a system exists for identifying" patient-ready endoscopes.[6] SGNA and ASGE reference "tagging" as one possible system[4,6] whereas AAMI and AORN call for a "distinct visual cue"[2] (e.g., a label or tag attached to the processed endoscope).[1]

Objective 4: Understand current recommendations for sterilization, microbial surveillance and quality management

In recent years, reports of infections and deaths attributed to contaminated flexible endoscopes have generated increased discussion and scrutiny about whether endoscopes should be sterilized instead of high-level disinfected. These discussions have included whether the Spaulding classification of flexible endoscopes should be adjusted to consider them as critical devices.[7] SGNA states that "since the environment in which endoscopes are introduced and used is not sterile (and thus each time that the endoscope enters the digestive tract sterility is immediately broken), SGNA does not recommend reclassification of endoscopes within Spaulding."[6]

The current reality is that some but not all endoscopes can be sterilized. Both AORN and AAMI promote the routine use of existing sterilization modalities for all endoscopes "that are manufacturer validated for sterilization when possible."[2] AAMI notes that the industry needs to move in the direction of sterilization and this "may be accelerated by identifying and addressing key technical and compatibility obstacles and defining priorities and key steps."[1]

None of the organizations require routine post-processing surveillance, but when it is performed, it is necessary to follow the established U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC) and American Society for Microbiology (ASM) culturing protocol.[5] AAMI notes that "surveillance sampling and culturing is a time- and resource-intensive process" and that healthcare facilities should consider their own needs and available resources when implementing this type of procedure."[1] AORN further advises to "convene an interdisciplinary team that includes laboratory personnel to evaluate the need to implement a program for routine microbiological surveillance cultures."[2]

ASGE, AAMI, AORN and SGNA all recommend having a systematic multidisciplinary quality management program in place that provides oversight and support for endoscope processing within any organization. Endoscopic clinicians and SP professionals are encouraged to work closely with Infection Prevention and Control, Risk Management, Administration and Quality toward process standardization, compliance and adherence to best practices.

Conclusion

All four guidance-writing organizations—ASGE, AAMI, AORN and SGNA—have unique processes for developing their standards and presenting their written recommendations, but each standard and guideline is rooted in a focus of quality assurance, best practices and patient safety.

It is important to realize that standards and guidelines take time to develop and update. As Figure 1 demonstrates, there has been anywhere from five to seven years between standards updates. Staying connected with professional societies and standards organizations is very important to ensure that flexible endoscopes are processed according to the latest guidance. Similarly, it is important to stay informed as new developments occur—in between publishing of new or updated standards and guidelines. The FDA's Safety Communications and the CDC's Health Alert Network (HAN) are free options that can help facilities access the timeliest information.[3,8] Sustained best practices come from constant vigilance and adherence to the latest guidance documents, IFU, peer-reviewed literature and research. P

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