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Learning Objectives:

1. Discuss the objective(s) of ANSI/AAMI ST91 as it applies to the guidance for reprocessing steps typically employed in a healthcare facility.
2. Identify the reprocessing stages associated with the reprocessing of flexible endoscopes.
3. Understanding how and why specific tools and products are necessary to clean, disinfect, test and verify proper endoscope reprocessing.

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Complying with AAMI ST91: Key recommendations for your facility

by Mary Ann Drosnock, MS, CIC, CFER, RM (NRCM)

Although you are most likely very familiar with AAMI ST79, which is used by the majority of facilities to support the day-to-day decision making regarding best practices for steam sterilization of medical instruments, what you may not be familiar with is the new AAMI Standard that was published in April 2015 regarding flexible and semi-rigid endoscope reprocessing.

This new AAMI Standard, ANSI/AAMI ST91:2015, is titled, “Flexible and semi-rigid endoscope processing in health care facilities” and is applicable to all healthcare facilities regardless of the setting. In essence it applies the same rigorous reprocessing standards of care for flexible and semi-rigid endoscopes whether they are performed in the hospital setting, an ambulatory surgery center (ASC), or an office-based setting. Due to the ever-changing landscape of information and regulatory guidance, the criticality of the risk of infection associated with these devices, and the scientific studies coming to light recently, this document will be reviewed by the AAMI work group on a continual basis and updated to provide end users with the most current information and guidance.

The objective of ST91 is to provide comprehensive guidance to achieve best practice for each stage of the processing of flexible endoscopes as well as staff education, design of reprocessing facilities, selection of equipment, and more. The guidance for reprocessing steps typically employed in a healthcare facility covered within this document are precleaning, leak testing, manual cleaning, rinsing, drying, packaging (where indicated), high-level disinfection and rinsing, storage, and/or sterilization of flexible endoscopes (e.g., bronchoscopes) and surgical flexible endoscopes (e.g., flexible ureteroscopes) and semi-rigid operative endoscopes.

As we all know, meticulous attention to all steps in reprocessing of flexible endoscopes and accessories is critical to ensure that they are rendered safe for subsequent patient use. With that in mind, each subcategory of reprocessing is discussed in detail within the ST91 document along with an emphasis on the importance of

demonstrating a high-level of competence for those individuals reprocessing flexible endoscopes. What follows discusses some of the best practices discussed within ST91 for each subcategory with particular attention paid to those recommendations which may be new or noteworthy to your facility. Note that this merely is an overview of steps that may be new and considered best practice. There are many more specific recommendations made in ST91 for each subcategory of reprocessing.

Reprocessing stages

Pre-cleaning occurs immediately after the patient procedure and helps to prevent buildup of bioburden, development of biofilm, and drying of patient secretions. It is recommended to wipe the insertion tube with a wet, low-linting cloth or sponge soaked in freshly prepared cleaning solution. The cloth or sponge needs to be single-use and should be discarded promptly. There are a variety of single-use sponges and low-linting wipes on the market to implement this practice if your facility is not already doing this. Visual inspection of the endoscope at this stage is recommended in ST91 to ensure that it is not damaged. Optical inspection products, such as magnifiers, can be used to help aid the naked eye with this inspection step. See figure 1.

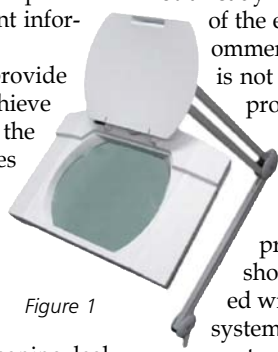


Figure 1

For transportation to the reprocessing area, the endoscope should be isolated and transported with its components in a closed system labeled as a biohazard. This must meet OSHA requirements for transport of a hazardous item. In order to prevent damage to the endoscope, be sure that the endoscope is not coiled too tightly in the transport bin/container. I recommend a hard closed bin labeled as biohazard for transportation as the best method to protect employees and the endoscope.

Once the endoscope is received in the reprocessing area, leak testing should begin without time delay. In the section regarding leak testing in ST91, it is recommended to use a basin or surface large enough to ensure that the endoscope is not coiled too tightly to mask holes or to damage the endoscope.

Manual cleaning is a critical step in reprocessing endoscopes because any soil remaining may interfere with the ability of the disinfection or sterilization process to effectively kill or inactivate microorganisms. Within this section of ST91 it is recommended to don fresh personal protective equipment (PPE), use fresh detergent solution with each endoscope, closely monitor the temperature of the cleaning solution, and clean with a single-use, low-linting cloth/sponge. It is also recommended that the endoscope is inspected for visible debris after cleaning and that the manual cleaning process is repeated until no debris remains on the endoscope. Again at this stage, use of visual inspection tools (Figure 2), such as lighted magnification, may be warranted to help identify any remaining debris. Given the difficulty of directly inspecting the internal channels of an endoscope, it is also suggested to use chemical reagent tests, such as for protein or blood, to check for any residual contamination inside the scope.

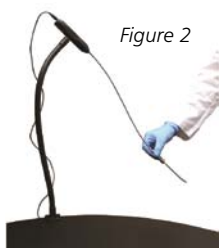


Figure 2

High-level disinfection remains the standard of care for reprocessing semi-critical instruments that contact mucous membranes, namely flexible endoscopes. Within ST91 it is recommended to don fresh PPE for high-level disinfection and to perform the process in a closed sealed container (Figure 3), labeled appropriately. Chemical exposure times must be monitored precisely (i.e., with a timer). The proper temperature during this process is also critical to achieve successful disinfection. If done manually, the temperature of the disinfection bath should be monitored.



Figure 3

Rinsing after high-level disinfection is another critical step as it removes residual disinfectant from the endoscope and its channels. There is a recommendation within this section of ST91 to don fresh PPE again and to use fresh water of an appropriate quality (see AAMI TIR34 for further guidance on water quality) for each separate rinse as multiple rinses may be required. Refer to your disinfectant IFU for more information on appropriate rinsing.

Effective drying after disinfection reduces the risk of microbial contamination post high-level disinfection. The document outlines that drying can be achieved by flowing air through the endoscope channels. It is recommended to facilitate drying with an



Figure 4

alcohol flush. Follow the alcohol flush with medical-grade forced air to ensure residual alcohol is removed. Refer to endoscope IFU for pressure recommendations that should not be exceeded. All removable parts must be adequately dried and must not be reattached to the endoscope during storage. In this section it is recommended to keep valves together with the endoscope to ensure traceability. There are many products available (mesh bags, valve storage cages (Figure 4) that will keep the valves and

adapters with the endoscope as a unique set.

For storage of high level disinfected endoscopes, it is recommended that the endoscopes hang freely with caps, valves, and other detachable components removed for storage. Detachable parts that are reusable (i.e., air/water and suction valves) should be processed together and stored with the respective endoscope as a unique set in order to allow traceability. Each scope should be identified with a tag (Figure 5), label or other means so that when it is removed from storage, the user is able to verify that the scope has been processed and is ready for use. As mentioned earlier, there are many products commercially available to meet these requirements.

Quality system implementation critical

An area of critical importance discussed in great detail within ST91 is the implementation of a Quality Assurance Program within reprocessing. Facilities should develop comprehensive quality assurance and safety programs to ensure that they are adequately reprocessing endoscopes and to build quality into their procedures. Each section of the document outlines the parameters that should be documented, tested, and/or maintained as part of a quality process.

As part of a quality system, it is recommended to institute some form of cleaning verification testing. The implementation of cleaning verification tests for users is a new recommendation for endoscopy in general. According to ST91, a facility's on-going quality assurance program should

include ways to verify that mechanical cleaning equipment is working and that the efficacy of manual cleaning steps should be tested on a regular basis, at least weekly but preferably daily. Cleaning verification tests are performed following manual cleaning to verify the effectiveness of a cleaning process and should also include a visual inspection. This should be considered part of quality management in any processing area, which is not unlike how verification of other processes such as sterilization does occur. This may be even more critical with flexible GI endoscopes, because as recent outbreaks associated with duodenoscopes have demonstrated, these devices are not only a challenge to clean, but because they are not typically sterilized, the margin for safety is much less.

For an indication of appropriate cleaning, visual inspection of the device is still very important, but the use of cleaning verification technologies is recommended and can be extremely useful. Currently, several technologies are available that can be used to measure the levels of organic soil and other markers after cleaning. Available options include swab testing for protein, hemoglobin, and ATP as well as flushing methods that test for residual protein, carbohydrate and hemoglobin. AAMI ST91 states that use of methods to detect organic residue should be considered and further explains that these technologies include those for protein, carbohydrate & hemoglobin markers as well as ATP. See figure 6 and photos below.



Figure 5



Figure 6



Photo Courtesy of Healthmark Industries.

Checking for protein



See **SELF-STUDY SERIES** on page 28

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Complying with AAMI ST91: Key recommendations for your facility

Circle the one correct answer:

Within ST91 education, training and competency of reprocessing staff are discussed in great detail. There are recommendations that personnel involved in endoscope reprocessing be provided education, training, and complete competency verification related to their duties upon initial hire; annually; at designated intervals; or whenever new endoscopic models, new processing equipment, or products such as new chemicals are introduced. Additionally, certification of reprocessing staff is a recommendation contained within ST91. It states that all personnel performing processing of endoscopes should be certified as a condition of employment and at a minimum successful completion of a certification exam.

If reprocessing of flexible or semi-rigid endoscopes occurs within your facility, then it is of critical importance that you obtain a copy of this AAMI standard and begin a gap analysis to determine what areas your facility needs to concentrate on. Create an implementation strategy for these changes and begin the process of building quality into your reprocessing procedures. This may involve evaluating new products and technology that will allow your facility to become compliant with the AAMI ST91.

Let us not forget the recent headlines that demonstrate that trusting established process may no longer be enough. Each facility must ask if its endoscopes are patient-ready and how do they know that. We must "trust but verify." This document provides an excellent road map for each facility to start down the path of providing the best outcome for their patients. After all, patient safety is the endpoint that we are all striving for and implementation of these reprocessing best practices will help to get us there. **HPN**

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References:
1. AANSI/AAMI ST91: 2015, "Flexible and semi-rigid endoscope processing in health care facilities."

- Which AAMI Standard is titled, "Flexible and semi-rigid endoscope processing in health care facilities"?
A. ANSI/AAMI ST58
B. ANSI/AAMI ST79
C. ANSI/AAMI ST90
D. ANSI/AAMI ST91
- The objective of ST91 is to provide comprehensive guidance to achieve best practice for each stage of the processing of flexible endoscopes, what else is included?
A. Staff education
B. Design of reprocessing facilities
C. Selection of equipment
D. All the above
- Which reprocessing step for flexible and semi-rigid endoscope is not covered within ANSI/AAMI ST91?
A. Pre-cleaning, leak testing, manual cleaning, rinsing.
B. Drying, packaging, high-level disinfection and rinsing, storage.
C. High temperature steam sterilization of flexible endoscopes, and chemical sterilization.
D. None of the above.
- ANSI/AAMI ST91 places an emphasis on the importance of demonstrating a high-level of competence for those individuals reprocessing flexible endoscopes.
A. True
B. False
- Pre-cleaning occurs immediately after...?
A. Arrival into the decontamination area.
B. Patient procedure.
C. Leak testing the device.
D. Disinfecting the device.
- Transportation of the flexible endoscope to the reprocessing area is best achieved by
A. Keeping the devices isolated.
B. Transporting with its components.
C. Transporting in a closed system.
D. Labeling as a biohazard.
E. All the above.
- Identify which step is critical in the reprocessing of endoscopes in order to prevent any soil remaining on the device whereby interfering with the ability to disinfect or sterilize the device.
A. Pre-cleaning of the device.
B. Manual cleaning of the device.
C. Inspection of the device.
D. Packaging of the device.
- According to ANSI/AAMI ST91, it is appropriate to don fresh personal protective equipment (PPE), when...?
A. Prior to manual cleaning.
B. Prior to high-level disinfection.
C. Prior to rinsing after high-level disinfection.
D. All the above.
E. Only A and B.
- As part of a quality system, it is recommended to institute some form of cleaning verification testing, which method is not recognized in ANSI/AAMI ST91?
A. Use of Geobacillus stearothermophilus biological indicators.
B. Swab testing for protein.
C. Swab testing for hemoglobin.
D. Flushing methods for residual protein.
- Storage of high-level disinfected endoscopes should hang freely with caps, valves, and other detachable components removed for storage; what else should be done to help verify the scope has been processed?
A. Each scope should be visually inspected.
B. Each scope should be identified with a tag, label or other means to assist verifying the scope is ready for use.
C. Each scope should be placed in a reusable dust cover.
D. Both A and B.



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