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ANSI/AAMI ST91:2021 Content Changes and New Emphasis: What Every CER Must Know

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Certified Endoscope Reprocessor (CER) lessons provide members with ongoing education focusing on the maintenance and handling of endoscopes. These lessons are designed for CER recertification but can be of value to any CRCST.

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LEARNING OBJECTIVES

1. Identify substantive changes made to the updated ST91
2. Review areas of emphasis within the steps of endoscope reprocessing
3. Understand the emphasis on endoscope inspection, cleaning verification, storage, and handling

In the previous issue of *PROCESS*, the CER lesson plan introduced areas of new or increased focus for ANSI/AAMI ST91:2021. *Note: This updated version replaces the 2015 standard and is not an addendum to it; therefore, healthcare organizations, management and staff members will need to reference this guidance moving forward.* This lesson identifies substantive changes made to the standard and reviews the recommendations for best practice within the steps of endoscope processing.

The foreword of the updated document includes (as did the 2015 version) definitions for key words that are used to differentiate levels of requirement for the guidance given. This is important when reading and interpreting any standard or guidance document.

Used within the context of this document:

- "Must" represents obligatory requirements [e.g., as dictated by regulations. Occupational Safety and Health Administration (OSHA) regulations are examples].
- "Shall" denotes strict requirements based on subscribing to this document.
- "Should" directs reference to one practice, in particular, when other options may be available to consider.
- "May" indicates acceptance of (or permission for) a particular practice.
- "Can" signals possible practice.

It is essential to understand that the entire document (not just the "musts," "shalls" and "shoulds") speaks to recommendations for best practices—and that is what should always drive the work of endoscope processing.

Objective 1: Identify substantive changes made to the updated ST91

As stated in the March/April 2022 CER lesson, a distinct definition is given for high-risk endoscopes (those known

to have been involved with outbreaks and those that are more difficult to process). These include elevator channel endoscopes [duodenoscopes and linear endoscopic ultrasound (EUS) scopes], bronchoscopes, ureteroscopes, cystoscopes, and endobronchial ultrasound scopes (EBUS)]. Additionally, an organization can opt to classify any other type of endoscope as "high risk" based on its own multidisciplinary risk assessments. In making this definition, increased attention and consideration are given to endoscope complexity as well as known issues identified through clinical investigations and research.

The principal consideration for high-risk endoscopes involves increased quality control, especially for the steps of focused inspection and cleaning verification. There is now an expectation of cleaning verification testing each time a high-risk endoscope is processed. Remaining "non-high-risk" endoscopes would still undergo cleaning verification (minimally, as endoscopes arrive new) and at pre-established intervals (determined through a facility risk assessment). Example guidance is provided to help users determine the most appropriate frequency intervals (high-risk endoscopes should always receive prioritization in risk assessments).

ST91:2021 sets an expectation of endoscope processing certification within two years for any staff performing this work (example certification organizations are included in the standard). ST91:2021 further directs that frontline staff should receive training and competency assessments before being considered independent, and those training and competencies should be provided annually (at minimum) and whenever devices, equipment or processes change. The updated standard includes key elements to consider for staff training, responsibilities for those providing training, and competency verification activities.

A weakness and risk for many healthcare organizations lies in the actual physical space and design of endoscope processing areas. To assist with facility assessments and/or when renovations are being considered, direction is provided in the updated standard, along with space requirements for each area of processing. Infection prevention and unidirectional flow from dirty to clean is emphasized, as are patient and staff safety. Reference is made to commonly existing one-room designs; however, the standard states that two separate rooms are preferred. Focused content is provided regarding traffic control; sinks and accessories; physical surfaces; heating, ventilation and air conditioning (HVAC); electrical and lighting; and water quality.

A cornerstone of the 2021 standard involves embedding quality monitoring throughout the steps of processing. The expectation for staff certification and maintaining training and competency are certainly part of this foundation, as is enhanced visual inspection and cleaning verification. The new standard also emphasizes monitoring of both manual and automated cleaning processes, with a focus also on water quality. Reference is given to evaluate water quality upon installation, as well as when repairs and modifications occur. Quality control also involves policies and procedures, traceability, documentation requirements, and record keeping. Throughout the standard, recommendations are given for decisions to be made by a multidisciplinary team; this includes establishing policies and procedures and an implementing an ongoing quality assurance program. Detailed content in the standard provides a roadmap for embedding quality control measures.

Objective 2: Review areas of emphasis within the steps of endoscope processing

One fundamental for ongoing quality monitoring is ensuring each step of processing occurs according to the manufacturer's instructions for use (IFU) and that written policies are based on nationally recognized standards and guidelines. Therefore, the core of ST91:2021 details best practice guidance from point of clinical use through processing and back to storage.

An intentional reset of terminology includes the term "point-of-use treatment" as opposed to "precleaning" to describe what should happen to an endoscope at the bedside immediately following the procedure. Adopting the "point of use" terminology helps prevent misinterpretation that this practice replaces or is part of manual cleaning, and it recognizes other necessary tasks in this step. Aside from the actual wiping and flushing of the endoscope, accessories are to be removed, the endoscope should then be readied for transport and communication should be initiated for "handoff" to processing professionals.

To limit drying of residual bioburden, the endoscope is to remain moist for transport. This can be achieved by placing a moistened towel inside the container, using an approved pretreatment solution or placing the endoscope inside a package designed to maintain humid conditions. The endoscope should not be transported submerged in solution. OSHA regulations essentially drive the remaining expectations and direct the need for (and type of) containment. Clear biohazard labeling is required. The

endoscope should be transported within a container large enough to safely hold that model of endoscope. The container should be nonporous, puncture-proof, and leakproof on its sides and bottom.

From there, the endoscope arrives in the processing area and undergoes leak testing. Leak testing is to be performed every processing cycle, before the endoscope is exposed to fluids. Endoscopes discovered to have leaks should be labeled, removed from clinical rotation and sent for repair. Quality control for leak testers is stressed in ST91:2021 to include pressure output verification each day the testers are in use. This is a new concept for many. The main operator-controlled quality control that could occur for leak testers is electrical safety testing. The intent is to ensure adequate pressure is being delivered to discover any size leak.

Point-of-use treatment should be done as soon as possible after clinical use and handoff communication. This handoff involves transfer of information to processing staff and denotes time procedure was completed, time point of use treatment occurred, and identification of procedural area and patient identifier. Aside from operational value, this also serves to allow (if necessary) delayed processing protocols, as directed by endoscope manufacturers – which need to be followed.

For manual cleaning performed at the sink, reinforcement is given to those delayed processing principles, and utility water rinsing after the detergent wash. Additionally, in preparation for visual inspection, drying the exterior and purging accessible channels with air should be performed. For automated cleaning [e.g., automated endoscope reprocessors (AERs)], recognition is given that some current generation AERs have cleaning cycles that are validated and U.S. Food and Drug Administration (FDA)-cleared; however, ST91:2021 emphasizes that automated cleaning cycles do not replace or abbreviate point-of-use treatment. The standard also emphasizes that when considering replacing full manual cleaning with automated cleaning, a multidisciplinary team should be convened to conduct a risk assessment. Further, when it comes to duodenoscopes, the FDA recommendations are reinforced (AER cleaning cycles should only be a supplement to thorough manual cleaning).

Objective 3: Understand the emphasis on endoscope inspection, cleaning verification, storage and handling

Inspection is a critically important next step in endoscope reprocessing—and one that is commonly missed by processing staff. This presents an opportunity to ensure the endoscope is clean enough to proceed, even before automated processes, and to also ensure the endoscope is inspected for damage. Best practices includes enhanced visual inspection, with lighted magnification. Borescope inspection can also be included, especially for endoscope channels, port openings, and distal tips. Cleaning verification occurs during this step also to test for residuals that may not be seen. As stated previously, high-risk endoscopes are to undergo cleaning verification testing every cycle. ST91:2021 reinforces the importance of sending any endoscope for repair that repeatedly fails cleaning verification tests or has damage.

As stated in the previous CER lesson, ST91:2021 recommends against manual high-level disinfection (HLD), as automated processes have shown to be more consistent and efficient and presents less staff exposure risk. Still, direction is provided for manual disinfection, which needs to be available as a backup (but preference is still for automated disinfection). For manual disinfection, ST91:2021 highlights the need to use critical water for the post-processing rinse (unless sterile water is specified by the endoscope manufacturer's IFU). Examples of critical water are deionized and reverse osmosis water.

Whether automated or manual processes are used (after exposure to a high-level disinfectant), the endoscope is to be rinsed and then manually dried—even when an automated process has a drying cycle. Generally, the drying cycle in an AER is a purge only. The exterior is to be dried with a non-linting cloth, and accessible channels should undergo "a minimum of 10 minutes with pressure-regulated forced instrument air or a minimum of HEPA-filtered air." Endoscopes are to be dried, regardless of whether they are to be placed in storage or used for the next clinical procedure. Drying cabinets may be used to facilitate drying; however, adherence to cabinet manufacturer's IFU is critical. Drying verification tests can aid in screening for residual moisture.

For storage, drying cabinets are preferred, but at minimum, conventional endoscope storage cabinets need to have HEPA-filtered air circulating within them. With this declaration in ST91:2021, the days of passive ventilation for endoscope storage are over. Endoscopes should not be stored in procedure rooms or within soiled areas of processing rooms.

Hand hygiene and clean gloves are required when handling patient-ready endoscopes (including when placing the devices into storage cabinets or when removing them from the

cabinets). Following the HLD process, endoscopes are not to be packaged like sterilized endoscopes; it is not possible to determine by sight whether the devices have undergone processing. Instead, clear visual identification is needed to indicate post-HLD, patient-ready status. This means a label or tag should be attached to the processed endoscope that includes the processing date, name(s) of the individual(s) who performed the processing, and the expiration date. The storage expiration ("hang time") is based on the facility's established risk assessment. ST91:2021 provides guidance for what to consider in such an assessment.

Conclusion

As noted in this lesson plan, ST91:2021 includes numerous significant changes that impact endoscope reprocessing professionals. It is recommended that all endoscope reprocessing areas have a copy of ST91:2021 available to staff members, so they can begin understanding and applying the updates. One's facility can compile a multidisciplinary team to begin working through those changes and identify areas of noncompliance. From there, an implementation strategy with assigned due dates for different topics can be created. With a regimented plan in place, facilities will be better able to institute these best practices and improve quality and patient safety.