Navigating AAMI ST91: Enhancing Patient Safety in Endoscope Processing

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AAMI's ST91 standard for endoscope processing covers design, cleaning, personnel, decontamination, storage, transport, quality control, repair, new product evaluation, and more.



AAMI on a computer's display

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In 2021, AAMI released its updated standard, ST91, on flexible and semi-rigid endoscope processing. The standard is truly comprehensive and aimed at helping mitigate the risks of endoscopy procedure infections. Understanding the standard's intent, recommendations, and requirements is critical for successful endoscope processing and positive outcomes. While this article covers some of the standard's message, important changes, and recommendations, it is advised to purchase, read, and digest the entire standard to fully understand the requirements.

Design of Endoscope Processing Area

Sections 1, 2, and 3 cover the standard's *Scope, Normative references*, and *Terms and definitions*. **Section 4**, *Design of endoscope processing area*, is where the new standard's impact is first felt. The new standard reaffirms design recommendations for unidirectional flow with additional statements that the processing area should be designated for processing only and have 2 separate rooms for processing endoscopes. While the standard states, "Until such a time (major renovations or new construction) that two separate processing rooms can be provided, strict unidirectional processing should be in place"[1], the intent is to prevent cross-

contamination and maintain separation between clean and dirty through appropriate room designs. Further recommendations are provided for single-room processing areas that cannot be renovated to the preferred 2-room design.

Additional design recommendations include utilizing a closable pass-through window or pass-through automated endoscope reprocessors (AER) to fulfill the dirty and clean separation requirements while maintaining air pressure differentiation. Guidance is provided on suitable endoscopy storage, including separation from the procedure room. A designated drying area with pressure-regulated forced instrument air or a minimum of HEPA-filtered air is recommended and covered in more detail in Section 8.

Additional design recommendations cover sink basins, general inspection lighting with magnification based on the Illuminating Engineering Society of North America (IES) recommendations, procedures for monitoring and maintaining the HVAC system, and monitoring of water supply quality (see new AAMI standard ST108:2023).

Environmental Cleaning

Section 5, *Environmental cleaning*, provides recommendations for routine cleaning and disinfection of the reprocessing area with the intent that a clean environment reduces the transmission of microorganisms. This is also the first use of "multidisciplinary team" language that is utilized throughout the standard to bring together personnel with vested interests in processing outcomes to ensure adequate action is taken to meet the standard's recommendations, identify and minimize risks, document policies and procedures, and improve the reprocessing quality.

The standard provides recommendations for the multidisciplinary team to ensure effective environmental cleaning is performed and verified.

Personnel

Section 6, *Personnel*, highlights that "institutions should ensure that reprocessing personnel are provided sufficient time to complete steps in accordance with regulations, standards, guidelines, and manufacturer IFU (instructions for use)."[2] While this statement may seem straightforward and common knowledge, every facility should ensure endoscopy staff and leadership understand the regulations, standards, guidelines, and IFU requirements, the time needed to properly perform the necessary reprocessing tasks, and ensure staff has the time

required to perform the tasks properly. This section includes information on *Standard precautions, Hand hygiene, and Attire*, and considerable time on *Policies and procedures recommendations, plus Education, training, and competency verification*.

The *Policies and procedures* section provides content recommendations, such as being consistent with available and current IFUs, for processing activities and ensuring adherence to the policies and procedures is monitored. They should also be reviewed by the multidisciplinary team and updated regularly.

For *Education, training, and competencies*, the standard confirms the common understanding that all endoscope processing personnel shall complete formal training and competency verification before performing the tasks independently. The use of "shall" is important here as that denotes a requirement versus a recommendation. Additionally, the standard supports the benefit of certification by stating staff be certified in flexible endoscope processing within 2 years of employment and maintain their certification.

ST91 also clarifies a critical point in staff competencies by stating they should include each specific endoscope make and model, equipment, equipment connections, and cleaning verification procedures. This requirement means that if the company has 8 different endoscopes, each employee performing tasks on those endoscopes must demonstrate training and competencies specific to each make and model.

Decontamination Processes

Section 7, Decontamination processes, begins the standard's recommendation on actual scope reprocessing. The standard provides general comments and procedures for point-of-use treatment, transport of contaminated endoscopes, leak testing, manual and automated cleaning, rinsing, drying, inspection, and cleaning verification. Actual facility procedures should be based on written IFUs, with ST91's procedures providing a starting point to ensure the inclusion of necessary areas.

New to the standard is a required hand-off communication from the point of use to the decontamination area, including the patient identifier, date of procedure, and time at which point of use treatment was completed. Recommendations for proper transport of dirty endoscopes are provided, as well as stating that cleaning should start within one hour of point-of-use treatment unless otherwise stated in the manufacturer's IFU. Remember that leak testing must be done before actual

cleaning starts, so the 1 hour includes transportation, leak testing, and any waiting time before cleaning must begin.

The standard covers leak testing recommendations for calibration and maintenance, with 3 acceptable options for handling detachable parts and valves, reviews sink cleaning solution management, and brush usage recommendations.

Subsection 7.8 clarifies the difference and need for visual inspection with lighted magnification recommendations and cleaning verification. The most significant change and impact is the requirement to perform a cleaning verification test on all high-risk endoscopes (examples provided in the standard) after each use. Additionally, cleaning verification tests are required for all non–high-risk endoscopes on established intervals based on the number of uses.

High-Level Disinfection (HLD) and Sterilization

Section 8, *High-level disinfection, liquid chemical sterilization, and terminal sterilization systems for flexible endoscopes*, focuses on 3 critical aspects: high-level disinfection versus sterilization, water quality, and drying requirements. This section opens with the statement, "All flexible endoscopes that are introduced directly into the bloodstream or that contact a normally sterile tissue or body space during use are critical devices and shall be sterilized."[3] Each facility must determine which scopes this applies to. The section also provides general comments and procedures for high-level disinfection, liquid chemical sterilization processing, automated high-level disinfection, manual disinfection, and terminal sterilization modalities.

For water quality, ST91 makes multiple mentions of the microbial quality of the rinse water while following the endoscope and processing equipment manufacturer's IFUs. With the release of AAMI's new standard ST108:2023, Water for reprocessing medical devices, ST108 should now be referenced for endoscope processing water quality instead of TIR34:2014 (R2021).
ST108 defines tap, utility, critical, and steam water quality measurements based on the processing use and requires testing at the point of generation and point of use. ST108 also references a multidisciplinary committee responsible for water quality and water management programs, including risk analysis and water quality monitoring.

Drying of endoscopes also receives considerable attention in the new
ST91 standard. A minimum 10-minute dry time is recommended using pressure-regulated forced instrument air

or HEPA-filtered air. If moisture is still observed, active drying should be continued until no moisture is visible. The standard also discusses how to detect moisture and recommended procedures for manual drying.

Storage of Processed Endoscopes

Sections 9 and 10 are short sections on *Sterile endoscope sheaths used as protective microbial barriers* and *Processing of endoscope accessories*. **Section 11**, *Storage of processed endoscopes*, provides recommendations for storing high-level disinfected, liquid chemically sterilized, and terminally sterilized endoscopes. For example, storage cabinets should be designed to allow air circulation as described by the endoscope manufacturer's IFU, and valves and accessories shall be removed during storage. This section also complements Section 8's comments on drying by stating that scopes should be dried before being placed into HEPA-filtered storage cabinets that do not have drying capabilities. Definitions, differences, and recommended use of endoscope drying cabinets versus conventional cabinets are provided.

The standard provides recommendations for the identification of endoscopes during storage. As for expiration dates, ST91 states that "The accepted maximum safe storage time (previously referred to as 'hang time' or shelf life) for processed endoscopes before they can no longer be considered safe for patient use is not well defined."[4] The standard recommends that the health care facility's multi-disciplinary team conduct a risk assessment to determine the maximum storage time for an endoscope before processing.

Section 12, *Transport of processed endoscopes*, provides brief recommendations on handling and transporting endoscopes. **Section 13**, *Quality control*, is a lengthy 24-page section that covers multiple aspects of quality control and process improvement. The standard states a multidisciplinary quality assurance program for all aspects of endoscope processing should be created and then lists the 20 areas that should be included. Full traceability of the endoscope use and processing documentation should be maintained (instrument tracking systems often meet this requirement).

Endoscope visual inspection and cleaning verification are reaffirmed and stated as part of the quality control process. Methods to verify cleaning equipment is working and effective should be established, including routine testing of automated cleaning equipment. Process monitoring and quality process improvement recommendations are provided for continuous improvement programs. Lastly, there should be a systematic

and ongoing process for verifying compliance with procedures, risk analysis should be performed annually, and root cause analysis should be completed for any problem identified.

Section 14, *Device repair and loaned endoscopes*, covers general considerations and recommendations for detecting repair needs, communication, handling, and documenting endoscope repairs. Routine preventive maintenance should be addressed in the facility's policy and procedures, including a thorough inspection of all channels and working mechanisms. **Section 15**, *New product evaluation*, shares considerations associated with conducting product evaluations.

Following the standard's 15 sections are 11 informational annexes that share additional information, reasoning, and background for the standard that provide more understanding. Overall, ST91 is a thorough and well-written standard that provides numerous requirements and recommendations to effectively process endoscopes in a manner that will help mitigate the risks of endoscopy procedure infections. To purchase your copy of the standard, go to AAMI's website.[6]

REFERENCE

1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST91:2021: Flexible and semi-rigid endoscope processing in health care facilities. 2021.

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