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# Review of Updated ANSI/AAMI ST91:2021, *Flexible and semi-rigid endoscope processing in health care facilities*

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**LEARNING OBJECTIVES**

1. Explain the impetus for and development of the new version of ANSI/AAMI ST91
2. Provide an overview of recommendations in the updated ANSI/AAMI ST91

The updated version of ANSI/AAMI ST91:2021, *Flexible and semi-rigid endoscope processing in health care facilities* was approved on December 31, 2021.

This national standard applies to the processing of all types of flexible and semi-rigid endoscopes in all healthcare settings—holding all facilities to the same standard of care. Although flexible endoscopes are valuable diagnostic and therapeutic tools used in a wide variety of applications, there are risks involved with their use and their processing, particularly when improperly performed. In fact, there have been many outbreaks of healthcare-associated infections (HAIs) related to the use of contaminated or damaged endoscopes. There is, therefore, a great need for improvements in quality and endoscope processing steps to help alleviate the risks associated with the use of these devices.

This CER lesson plan is the first in a series to outline the changes to ANSI/AAMI ST91:2021 and its implications on endoscope processing within healthcare facilities. We encourage all Sterile Processing (SP) leaders to purchase the updated version and thoroughly review the document to familiarize themselves with the new standard, create a crosswalk of non-compliance topics, and formulate a plan to strategically implement the changes.

## Objective 1: Explain the impetus for and development of the new version of ANSI/AAMI ST91

The first edition of ST91 was published in 2015 after three years of effort by AAMI Workgroup 84. As the foreword of the inaugural version indicates, the

document was initially "proposed as a technical information report"; over time, however, it was decided "more extensive guidance" was needed.[1] The document also forewarned that the standard could be reviewed and revised if or when new information was available and as technology changed.

As the document was headed to publication, the endoscope processing landscape was shifting. Coincidentally, around 2015, there were increasing reports of infections, deaths and exposures linked to contaminated flexible endoscopes. Additionally, reports of endoscope processing lapses and breaches in processing were coming forth. Combined with new research and evolving technologies, it became obvious that this standard could not remain static; and the decision was made for the committee to continue its work, so content could be added and recommendations strengthened. After six years and multiple in-person and virtual meetings, the 2021 edition came to fruition.

The updated standard reflects the combined participation and input not just from industry leaders and clinical users but increased contributions from professional societies, researchers, accreditation bodies and governmental agencies. Indirectly, the significance of—and interest in—this work is exemplified by the increased committee membership. For 2015, the Workgroup included 46 primary and six alternate members.[1] The 2021 edition was born of 109 primary members and 44 alternates.[2] Since its existence, ST91 has increasingly become a reference point and benchmark for endoscope processing best practices; and the inclusive contributions for the 2021 edition further strengthen the multidisciplinary guidance provided.

The comprehensive group discussions and overarching goal were to focus on best practices for endoscope processing in any setting but with coincidental recognition that an increasing number of endoscopy procedures are occurring in ambulatory settings. As in the previous version, this standard applies to reusable flexible and semi-rigid endoscopes of any kind. Meanwhile, technological advances for flexible endoscopes meant that the committee also needed to consider more recent devices—for example, those with disposable end caps. Endoscope drying technology has also evolved and needed to be referenced.

A significant driver for updated or new recommendations were the cited clinical investigations and research that have called increasing attention to the inherent risks present when processing these complicated reusable devices. The inclusion of data from the U.S. Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database adds sobering relevance.[3] Multiple peer-reviewed research studies serve as further foundational support. The addition of these research studies and FDA MAUDE database citations provides the references needed to help facilities implement updated policies and procedures and gives leadership the proof that these changes are needed to remain compliant and increase the quality of care given to our patients.

A concerted effort was made to ensure that the updated ST91 was be a user-focused document (i.e., for frontline processing staff and management). It was important to remain conscious of, for example, the clarity of definitions, the quality of rationale provided, if or when guidance was purposefully repeated, and the ability of a reader to navigate the content. A purposeful goal was to include several informative annexes to be used to guide discussions and risk assessments within healthcare institutions. Example annexes include reference material for repairs, instructions for use (IFU) conflict management, visual inspection, cleaning verification, and endoscope storage risk assessment.

Throughout the updated standard, embedding quality control measures into processing protocols was reinforced. This includes monitoring of physical processes, managerial oversight, multidisciplinary review as well as focused education, training and certification. Time and care were taken to differentiate requirements from recommendations—through detailed discussions of whether "shall" or "should" would be used in the guidance document for each topic. Keep in mind that a "shall" is a standard requirement, whereas a "should" is a strong recommendation.

## Objective 2: Provide an overview of recommendations in the updated ANSI/AAMI ST91

As previously stated, there are numerous revisions to the updated standard. Remember, this is a *replacement* of the 2015 version, not an addendum to it, as has been seen with other AAMI documents. Areas of new or increased focus for ST91 include sterilization of endoscopes, identification of high-risk endoscope types, point-of-use treatment, recommendations to keep endoscopes moist for soiled transport, enhanced visual inspection, cleaning verification, a recommendation against manual disinfection, enhanced endoscope drying and storage considerations. Brief descriptions of each of these updated content areas follow. *Note: More details will also be provided in the next lessons in the CER series.*

### Transition to sterilization

In stating that sterilization of endoscopes is preferred, recognition is given that technology needs to catch up. New advancements must be made to allow for more endoscopes to be designed as compatible with existing sterilization technologies or to have additional low-temperature sterilization methods that can effectively allow sterilization as an option. Thus, further research and development are needed. Distinct direction is given that endoscopes used as critical devices need to be sterilized. Also, all endoscopes that are currently compatible with sterilization modalities (e.g., most bronchoscopes with vaporized hydrogen peroxide systems) should be moved to sterilization—if that sterilization method is available in the facility—because sterilization is the preferred method for those devices, according to the Spaulding Classification System.

### High-risk endoscopes

Facilities will need to identify their inventory of high-risk endoscopes. Based on information from published clinical investigations and research, the definition of high-risk endoscopes is "those known to have been involved with outbreaks and those that are more difficult to process."[2] These include elevator channel endoscopes (endoscopic retrograde cholangiopancreatography [ERCP] and endoscopic ultrasound [EUS]), bronchoscopes, ureteroscopes, cystoscopes and endobronchial ultrasound scopes (EBUS). This definition also allows for a facility to classify any other endoscope(s) as high risk based on its own risk assessment. An example could be endoscopes used on at-risk individuals, such as pre- or post-transplant patients.

### Point-of-use treatment

Within ST91, there has been a transition to the term "point-of-use treatment" (as opposed to point-of-use cleaning or simply "pre-cleaning"). This gives recognition to the fact that more is required immediately post-procedure than the act of wiping or flushing the endoscope. Point-of-use treatment includes pre-cleaning but also emphasizes the removal of all accessories, preparation for transport, and hand-off communication for processing staff. Use of the term "point-of-use treatment" also removes the misconceptions of having to use a cleaning brush and that the device is completely cleaned after this step (one does not need to use a brush; thorough cleaning is still required). The term point-of-use treatment also aligns with the terminology in ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*

### Keeping endoscopes moist for soiled transport

To limit drying of residual soils, the new standard calls for keeping endoscopes moist—but not submerged—for post-procedure transport. Examples can include applying a pre-treatment solution, using a towel moistened with water or placing the endoscope inside a package designed to maintain humid conditions (i.e., a humidity chamber bag). Keeping soils moist assists with the subsequent manual cleaning process.

### Enhanced visual inspection

Visual inspection needs to occur at every step of the process, including before use in a procedure; however, it should also occur as a unique step following manual cleaning. This allows for repeat manual cleaning, as needed, as well as identification of endoscopes that need to be sent out for repair. Enhanced visual inspection (preferably using lighted magnification) is needed and can include the use of a borescope for internal inspection.

### Cleaning verification

Any endoscope classified as "high risk" shall undergo cleaning verification (CV) testing after each use. Endoscopes not identified as high risk should have CV performed when new devices arrive and at pre-established intervals, established through a facility risk assessment (i.e., a statistically significant portion of cycles based on the number of procedures performed). Additional guidance is given in an annex to help users determine the proper frequency.

### Recommendations against manual disinfection

Focused guidance includes a recommendation against performing manual disinfection of endoscopes. Automated processes, such as those performed in an automated endoscope reprocessor (AER), offer safety, efficiency and standardization of processes and limit human error. Understanding that facility or resource limitations or interruptions can occur, the revised standard includes best practices for manual disinfection. But, under normal circumstances, standard endoscope processing should occur in an AER, even in off-site and ambulatory settings.

### Endoscope drying

Endoscopes must be completely dry before going into storage or being used again clinically. Both manual HLD and automated (AER) processing shall be followed by a minimum 10-minute active, pressure-regulated, filtered-air drying or per the validated cycle of the drying unit being used. For quality

control, drying verification tests or borescopes may be used to check that drying practices are adequate.

### Storage considerations

After HLD, each endoscope requires a clear visual identification on the device itself to indicate post-processing and patient-ready status. A label or tag should be used that includes an employee identifier (who processed that item), date of processing and expiration date. The facility should perform a multidisciplinary risk assessment to determine post-processing expiration ("hang time") protocols. Active drying cabinets are preferred but, minimally, an endoscope storage cabinet requires high-efficiency particulate air (HEPA)–filtered air circulating through the cabinet.

## Conclusion

The new ANSI/AAMI ST91:2021 provides updated and more stringent guidelines related to pre-cleaning, transport, leak testing, cleaning, high-level disinfection, sterilization, drying and storage of flexible and semi-rigid endoscopes. Within the numerous changes found in the new standard are new requirements and many updated recommendations related to processing. Understandably, it will be a challenge for facilities to implement all of these changes in a timely manner. It is hoped that this series of CER lesson plans will help readers digest the major changes found within the document and create an implementation plan. There is no timeline listed for how quickly these updates need to be instituted.

Creating a list of non-compliance topics (i.e., those areas where your current practices do not align with the new standard) and an implementation strategy for each will help operationalize the standard into manageable, actionable parts. Invariably, implementation of some changes found in ANSI/AAMI ST91:2021 will cause increased costs and processing cycle times, but these investments are worth the reward of improved quality of patient care and a reduction in HAIs.

### REFERENCES


1. Association for the Advancement of Medical Instrumentation, ANSI/AAMI ST91:2015, *Flexible and semi-rigid endoscope processing in health care facilities*.
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3. U.S. Food and Drug Administration, "Manufacturer and User Facility Device Experience Database (MAUDE)," https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacturer-and-user-facility-device-experience-database-maude.