Building Quality into Flexible Endoscope Reprocessing: Compliance with AAMI ST91

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Objectives

• Discuss the key provisions and competency recommendations of the standard
• To identify best practices in reprocessing of flexible endoscopes
• Discuss methods of cleaning verification and surveillance testing to determine if an endoscope is patient ready
What is ANSI/AAMI ST 91?

- Flexible and semi-rigid endoscope reprocessing in health care facilities
- Contains best practices for scope reprocessing in ANY setting
- Available for purchase at the www.aami.org
Risk of Endoscopy Related infection or Other Adverse Patient Reactions

- Spread on infections related to endoscopy:
  - Exogenous infections = Microorganisms spread from patient to patient by contaminated or malfunctioning scopes or equipment
    - Microorganisms may be transmitted from patients to endoscopy personnel and/or from endoscopy personnel to patients
  - Endogenous infections = Microorganisms spread from the GI tract through the bloodstream during an endoscopy procedure to susceptible organs, or may spread to adjacent tissues that are breached as a result of the endoscopic procedure

- Other risks related to endoscopy:
  - Chemical burns, colitis, anaphylaxis, death
  - Devices may be damaged or rendered difficult to use due to mishandling or inadequate processing.
Objective – ST91

• Provide guidelines for processing of flexible endoscopes
  • Includes all stages of reprocessing HLD and sterilization of scopes and accessories
  • Include flexible gastrointestinal (GI) endoscopes; bronchoscopes; ENT scopes; surgical flexible endoscopes (e.g., ureteroscopes); and semi-rigid operative scopes (e.g., choledochoscopes)
• Exclusions
  • Rigid endoscopes and probes (e.g., TEE probes)
ST91 Scope – What’s contained in this standard?

- Definitions
- Design of endoscope processing areas
- Personnel considerations
- Cleaning
- High level disinfection
- Automated endoscope reprocessors (AERS)
- Liquid chemical sterilization
- Gaseous chemical sterilization
- Processing accessories
- Storage and Transportation to site of use
- Quality Control including cleaning verification
- Quality Process Improvement
- Informational Annexes
Best practices for processing flexible endoscopes

• Meticulous attention to all steps in processing endoscopes, their components and accessories is critical making them safe for subsequent patient use

• Steps are outlined in the document in detail and include the following categories
  • Precleaning, transportation, leak testing, cleaning, rinsing, inspection or testing for cleanliness, high-level disinfection & sterilization and monitoring of the process, rinsing, drying, alcohol flush, & storage
Highlights of AAMI ST 91

- Gives recommendations for:
  - Certifications for technicians performing reprocessing
  - Monitoring the manual cleaning process
  - Monitoring the automatic cleaning process
  - Monitor water quality
  - Monitor temperature
  - After cleaning, all detachable valves should be kept together with the same endoscope as a unique set

- Risk Assessment
- Proper documentation and quality assurance parameters
Processing / Reprocessing

Processing (or reprocessing) is a process carried out on a device to allow its subsequent safe use, which can include cleaning, disinfection, sterilization, and related procedures.
Best practices in Precleaning

• Prevents buildup of bioburden, development of biofilms, drying of patient secretions
• Occurs at point of use immediately after the procedure
• Don fresh PPE
• Prepare a cleaning solution (or water if validated) according to the solution manufacturer's written IFU.
• Wipe insertion tube with a low or non-linting cloth/sponge soaked in the freshly prepared cleaning solution.
  • Note: cloth/sponge is single-use only

Remember to follow the IFU for the endoscope and detergent!
Best practices in precleaning

- Ensure that controls are in the free/unlocked position.
- Suction solution through the suction channel as per manufacturer's written IFU.
- Flush the air/water channels with solution using the cleaning adapter per manufacturer’s IFU.
- Flush all other channels (e.g., auxiliary water or elevator channels) with solution, if present.
- Suction the solution through the endoscope until clear.
- Detach the endoscope from the light source and suction pump.
- If applicable, attach the fluid-resistant cap.
- Visually inspect the endoscope for damage.
Contaminated Transport

• From procedure room to reprocessing area:
  • Closed, labeled transport containers
• Place a single endoscope in a container by naturally coiling it in large loops.
• Separate endoscopy accessories from the endoscope to prevent puncture and damage.
• Labelled appropriately as biohazard
Best practices for Leak Testing

- Occurs in processing area prior to immersion in cleaning solution.
- Serves to detect damage that would allow for fluid-invasion
- Wear PPE
- Ensure fluid-resistant cap is on prior to submersion
- Use a basin of water or surface large enough to ensure that the endoscope is not coiled too tightly to mask holes.
- Allow for sufficient time to observe the endoscope for leaks, manipulate knobs and buttons
- Outlines different methods for performing leak testing
- Refer to manufacturer’s IFU for detailed steps and what to do in the even of a failure
Best practices for manual cleaning

• Soil remaining on the endoscope may interfere with the ability of the disinfection or sterilization process to effectively kill or inactivate microorganisms

• If process is not initiated immediately, follow written IFU for delayed reprocessing from manufacturer

• General process is outlined including
  • Don fresh PPE, use fresh detergent solution, monitor the temperature of the cleaning solution
Best practices for manual cleaning

• Cleaning steps:
  • Clean with a single-use lint-free cloth/sponge
  • Submerge scope to prevent splashing contaminated fluids
  • Use a cleaning brush with specifications per manufacturer’s IFU
  • Brush all channels, cylinders, openings and forceps elevators per IFU
Best practices for manual cleaning

Cleaning steps (continued):

• Use recommended cleaning adapters
• Flush all channels, rinse all channels, air purge all channels
• Repeat until there is no visible debris
• Soak, scrub, brush & rinse all reusable/removable parts
• Automated flushing pumps may be used during manual cleaning
Cleaning Solutions (Detergents)

- Designed for endoscope cleaning
- Typically neutral detergents
  - May or may not contain enzymes
  - Numerous products available
- Essential features
  - Optimum cleaning performance
    o Manufacturers’ labeling
  - Device protection
  - Water quality control
  - Toxicity validation
Automated flushing systems

• If a flushing pump is used, follow manufacturer’s written IFU
• Ensure compatibility of endoscope with model of flushing system
• Use fresh solution with each endoscope
• Clean and disinfect tubing and equipment according to manufacturer’s IFU
• Perform any other QA testing as recommended (e.g. daily volume verification)
Rinsing after cleaning

• Thoroughly rinse with copious volumes of potable water
  • AAMI TIR34
• Follow IFU of endoscope & cleaning solution to determine the amount of water needed for rinsing, psi/pressure, and number of rinses
• Use recommended cleaning adapters
• Rinse all external and internal surfaces
• Perform an air purge of all channels
• Dry exterior with a lint-free cloth/sponge
• **Keep detachable valves together with the same endoscope as a unique set**
Best practices for cleaning verification and process monitoring

• Cleaning verification is performed following cleaning to verify the effectiveness of a cleaning process PRIOR TO DISINFECTION

• Cleaning verification should include:
  • Visual inspection
  • Testing of the cleaning efficacy of mechanical equipment
  • Monitoring of key cleaning parameters

• Use of methods to detect organic residue should be considered

• Use of a borescope should be considered
Endoscope visual inspection
ST 91 - Cleaning Verification – 12.4.2

“...Inspection using magnification and additional illumination might identify residues more readily than the unaided eye... tools such as video borescopes of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels of some medical devices...the use of methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be considered and included in facility policies and procedures on device cleaning...”
Examination by borescope

Instrument suction channel

The crack in the weld at the water jet nozzle not picked up by a leak test
Verifying Clean

- Visual inspections and testing of the equipment
  - Inspecting organic residues
  - Testing for any cracks in the devices
  - Checking integrity of fiber optic bundles

- Methods to measure organic and other residues found on scopes
  - Protein
  - Hemoglobin
  - Carbohydrates
  - ATP
Cleaning verification

- Technologies for monitoring cleaning are discussed including residual protein, carbohydrate & hemoglobin markers and ATP systems.

- Facilities QA program should include ways to verify cleaning equipment is working AND the efficacy of manual cleaning steps in endoscope reprocessing should be monitored on a regular basis, weekly or preferably daily.
Cleaning verification recommendations

- Current recommendations support testing of the manual cleaning process at pre-established regular intervals:
  - AAMI ST91: Regular intervals, i.e. **Weekly or preferably daily**
  - AORN: Regular intervals such as with **EACH reprocessing cycle** or daily
  - SGNA: Confirm the adequacy of manual cleaning by using a rapid cleaning monitor. If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection. **Frequency determined by facility.**
Manual Cleaning Verification Monitors

Channel Sample

Flush methods

Combination test strips

Swab methods

Protein swabs
Hemoglobin swabs

ATP Systems

Dectes ATP
Flush and swab methods
Many systems available

Carbohydrate, protein
& hemoglobin
Which Organic Parameters to monitor?

Flexible endoscope biopsy channel: (Alfa et al 2002)

- Protein; < 6.4 µg/cm²
- Carbohydrate; < 1.8 µg/cm²
- Hemoglobin; < 2.2 µg/cm²
- Endotoxin; <2.2 EU/cm²
Best practices for High-Level Disinfection

- Standard of care for reprocessing semi-critical instruments
  - Those devices which contact mucous membranes
  - Sterilization preferred or HLD with an FDA-cleared HLD prior to next use
- HLD defined as a germicide that inactivates all microbial pathogens, except large numbers of bacteria endospores when use in accordance with labeling
- HLD can be performed manually or with an automated endoscope reprocessor (AER)
High-level Disinfection

- Fully immerse in HLD
- Fill all channels with HLD
- Soak for time and at temperature specified by HLD manufacturer
- After soak, purge channels of HLD
- Rinse (follow manufacturer’s instructions) and air purge.
- Follow air with 70% isopropyl alcohol flush
Best practices for High-Level Disinfection

• Reusable HLDs must be monitored to ensure that it is above the Minimum recommended concentration (MRC)
  • Test prior to each use per IFU
  • Solution is used repeatedly until it fails test strip or meets its maximum use life, whichever comes first
  • Do not “top off” HLD unless instructed by HLD manufacturer

• HLD’s need to contact ALL surfaces
  • Internal channels and external surfaces
  • Complete immersion
  • Monitor exposure times precisely
  • Remove air bubbles from surfaces of endoscope
Remember to Rinse!

- Rinsing is often overlooked and underestimated
  - Removal of chemicals and residual soil such as protein (e.g., enzymes used during cleaning)
  - Devices should not present a toxic risk to patients
  - Water quality/purity can impact this
  - Number of rinses and rinsing method using fresh water with each rinse
Use of Automated Endoscope Reprocessors (AER)

- Machines designed to clean and/or disinfect endoscope and components using an LCS/HLD solution
- Use of AER’s may be more efficient and leads to less user exposure and helps to ensure repeatable results
- Section has detail on types of AER available and features of their cycles
- If AER cycle is interrupted, it should be repeated
- Purchase considerations are outlined
Manual Drying and Alcohol Flush

- Effective drying reduces the risk of microbial contamination post HLD
- Waterborne organisms can pose an infection control risk to some patients
  - Bronchoscopy and ERCP patients
- Presence of such organisms in conjunction with retained moisture can lead to biofilms and patient risk
  - Especially true if tap water is used for final rinse
  - Hanging to dry' or ‘drip dry’ is NOT effective
  - Most AERs ‘purge’ water from the endoscope lumens not ‘dry’
Manual Drying and Alcohol Flush

• Drying is achieved by flowing air through the endoscope channels
  • Facilitate drying with alcohol flush (70-80% ethyl or isopropyl alcohol)
  • Follow endoscope IFU for amount to be used
  • Follow with instrument quality forced air to ensure residual alcohol is removed
  • Refer to endoscope IFU for psi recommendations
  • Dry all removable parts and do not reattach
  • Keep valves with the endoscope to ensure traceability
Liquid Chemical Sterilization (LCS)

- Liquid chemical sterilization system is used for heat-sensitive, critical medical devices when traditional methods are not feasible or available
- Devices are treated with LCS & rinsed with water
- Rinse water is treated but may not be sterile
- Can not maintain sterility
  - Immediate use, no storage
- System is currently available
- Follow written IFU’s of LCS system for proper use
Best practices for Sterilization

• Sterilization processes for flexible and semi-rigid scopes is discussed in detail
• Recommended for devices entering sterile body cavities
• Section outlines special considerations for terminal sterilization with primary source of info being endoscope’s IFU
• More modalities compatible with surgical flexible endoscopes
Storage of reprocessed endoscopes

- Endoscope should be hung vertically with the distal tip hanging freely in a well-ventilated, clean area following endoscope manufacturer’s IFU for storage
- Angulation locks in the free position
- Sufficient space between endoscopes
- All removable parts should be detached, but kept together with the endoscope
  - (small bag or similar device)
- Have policies and procedures in place regarding storage
Storage of reprocessed endoscopes

• Ensure that endoscopes are adequately dry prior to placing in storage to prevent bacterial growth and biofilm
• Sterilized endoscopes should be stored in their container or packing in which they were sterilized
• “Hang time” guidance
  • Current recommendations are outlined
  • Policies & procedures should be developed based on a risk assessment outlined in document
Storage

• General considerations
  • Prevent coiling or kinking (hanging preferred)
  • Closed cabinets recommended
  • Tracking and traceability

• Hang time
  • Importance of risk assessment (facility-specific)
  • Policy and procedure development

• Liquid chemical disinfection or sterilization
  • Drying is essential
  • Reduce risks of recontamination
  • Transportation to point of use

• Gaseous sterilization
  • Correct storage conditions/methods
Risk assessment recommendations

- Risk assessment should be performed to address **length of storage (hang-time)**
  
- Considerations should be given to the following:
  - Complexity of instrument, condition after processing (wet/dry, alcohol flush), transportation methods, conditions of storage environment, handling during storage, manufacturer’s recommendations for storage, professional society guidelines, current research studies, protective devices to prevent
  
- **Now in alignment with AORN recommendations to conduct a risk assessment**

- Develop protocols to ensure that users can readily identify an endoscope that has been processed and is ready for patient use.
Current recommendations for length of storage “hang time”

- AAMI ST91: Due to lack of consensus it is recommended to perform a risk assessment to establish maximum length of storage.
- AORN: Perform a risk assessment with a multi-disciplinary team to establish a policy for maximum storage time that processed flexible endoscopes are considered safe to use without reprocessing.
- SGNA: 7 days based on a systematic review, if scopes are effectively reprocessed and stored in a way that keeps them completely dry and free from environmental and human contamination.
Guidance on culturing

- **AAMI** - No recommendation is made in the current version because of the timing of release.
  - Studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing.

- **CDC**
  - Interim Guidance on culturing duodenoscopes updated 4/3/15
  - Sites to be cultured?
    - Instrument channel (suction/biopsy channel)
    - Distal end (elevator mechanism, elevator recess)
    - Elevator channel (on older, unsealed)
  - Every 30 days or 60 cycles

What about surveillance of scopes in storage/prior to use?

- Options include:
  - Traditional culturing
  - Gram negative test kits
- Not ATP or cleaning verification tests
NOW!™ Working Principle:

- The NOW! Kit is used to screen flexible endoscopes, which have been processed and stored.
- The kit offers a quick test that can detect the presence of Gram-negative bacteria in 10 minutes after a 12 hour incubation period.
- The NOW! Kit works by detecting an enzyme mechanism typical to the Gram-negative bacteria.

- Through the use of fluorescence technology a reading is produced on a fluorometer that relates directly to the number of Gram-negative bacteria which are present in the sample.
- Readings above “300” are considered positive for bacteria.
Microbial Surveillance Kit

FLEXIBLE ENDOSCOPE SAMPLING KIT

Surveillance tool for the random testing of duodenoscopes in compliance with CDC guidelines - In association with Nelson Laboratories

A simple and complete kit. After flushing and brushing the lumen and elevator mechanism of a duodenoscope, simply follow the procedure to have the sample solution & brush heads quickly sent to Nelson Laboratories - the leader in independent testing of flexible endoscopes. All tools are included for testing and shipment.

- Mail back service for endoscope samples
- Includes items needed to take samples, a protocol based on CDC recommendations, shipper, etc.
- Sent to Nelson labs to grow out the cultures
- Identifications performed by the lab
- Allows for independent verification of scope reprocessing
Summary

• With heightened public concern and documented cases of improper reprocessing endoscopes, it is imperative that we must reducing the risk of exposure to improperly reprocessed medical devices.
• This is a shared responsibility among the healthcare facilities responsible for cleaning, disinfecting or sterilizing the devices.
• ST91 is your go-to guide for national standards in endoscope reprocessing and highlights best practices and quality control measures for each step along the way. Available at [www.aami.org](http://www.aami.org)
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