ANSI/AAMI ST91: 2015

Flexible Endoscope Reprocessing and the Importance of 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

Risk of Endoscopy Related infection or Other Adverse Patient Reactions

- Other risks related to endoscopy:
  - Chemical substances can remain on devices from various chemicals used during the procedure or processing that can cause toxic reactions in subsequent patients.
    - 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**

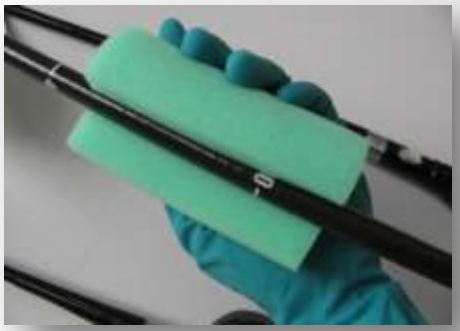
- Risk Assessment
- Proper documentation and quality assurance parameters

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

Best practices for Leak Testing

- Outlines 4 general methods for performing leak test:
  - Manual (dry) leak testing
  - Mechanical (wet) leak testing
  - Mechanical (dry) leak testing
  - Mechanical AER leak testing
- Refer to manufacturer's IFU for detailed steps
- For failures, refer to manufacturer's IFU for modified processing steps being sure to maintain positive pressure throughout

Best practices for manual cleaning

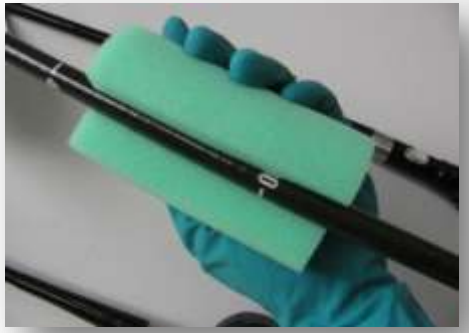
- Soil remaining on the endoscope may interfere with the ability of the disinfection or sterilization process to effectively kill or inactivate microorganisms
- If process is not initiated immediately, follow written IFU for delayed reprocessing from manufacturer
- General process is outlined including
  - 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
        - 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 & 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

Verifying Clean through Inspection

- Visual inspections and testing of the equipment
  - Inspecting organic residues
  - Testing for any cracks in the devices
  - Checking integrity of fiber optic bundles
- Use lighted magnification and inspect throughout process
- Consider inspection with borescope
  - ST91 and AORN recommendations
- SGNA – Treat as a **"Time out"**
- Methods to measure organic & other residues found on scopes
  - Protein
  - Hemoglobin
  - Carbohydrates
  - ATP

Optical & Enhanced Inspection

AORN Recommendations:

- Visually inspect with lighted magnification for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization.
- Inspection helps to identify residual organic material and defective items and remove from service soiled/defective items that might put patients at risk for infection or injury.
- An endoscope that appears clean may harbor debris that cannot be seen without magnification. Lighted magnification may increase the ability to identify residual soil or damage.
- Internal channels of endoscopes may be inspected using a borescope. Borescopes penetrate the lumen and allow for improved visual inspection.

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

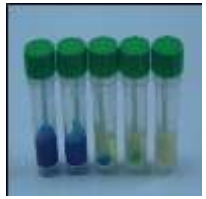
Combination test strips

Carbohydrate, protein & hemoglobin

Swab methods

Protein swabs

Hemoglobin swabs



ATP Systems

Detects ATP

Flush and swab methods

Many systems available

Which Organic Parameters to monitor?

Flexible endoscope biopsy channel: (Alfa et al 2002)

- Protein; < 6.4 µg/cm^2
- Carbohydrate; < 1.8 µg/cm^2
- Hemoglobin; < 2.2 µg/cm^2
- Endotoxin; <2.2 EU/cm^2

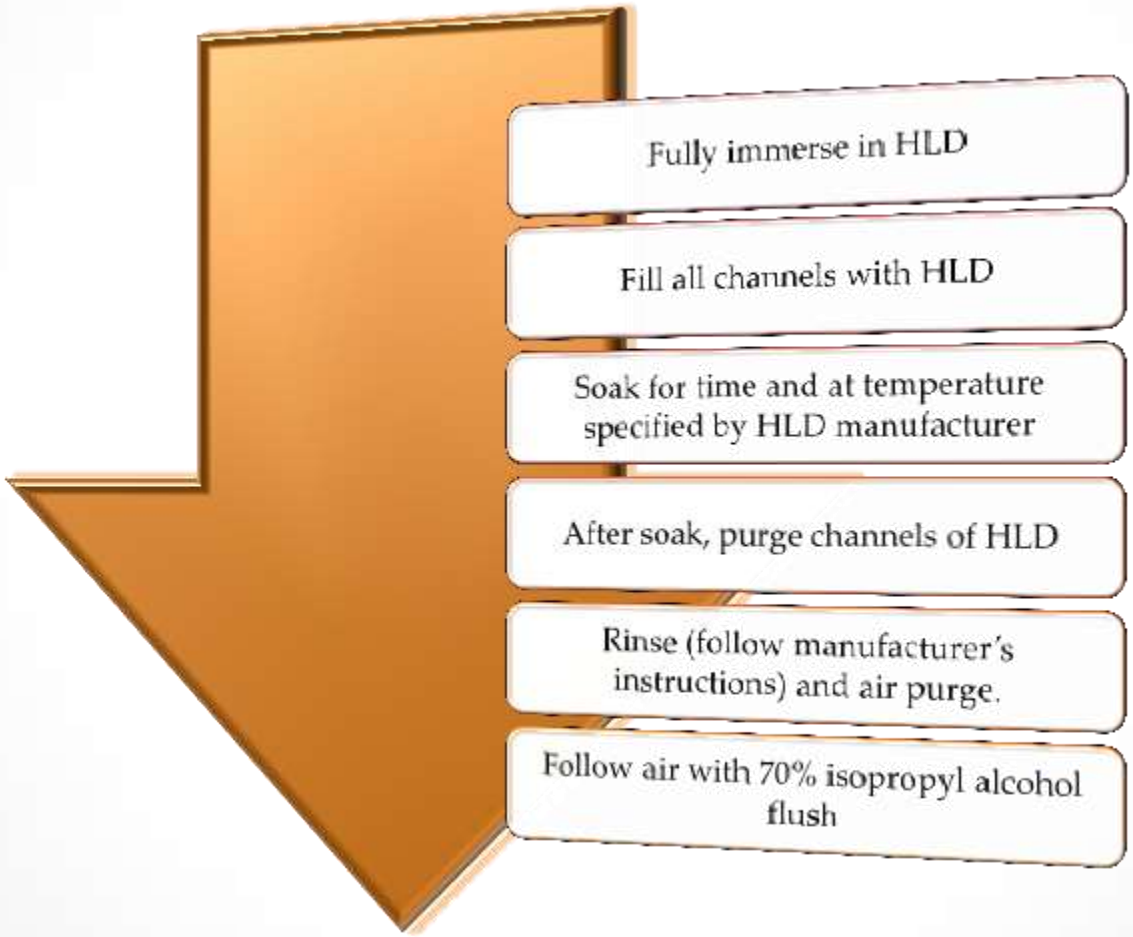
Best practices for High-Level Disinfection

- 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

Best practices for High-Level Disinfection

- HLD types include:
  - Glutaraldehyde
  - OPA
  - Peracetic Acid
  - Chlorine
  - Hydrogen Peroxide
  - Combination products
- Refer to www.fda.gov for a list of cleared HLDs
- HLD can be performed manually or with an automated endoscope reprocessor (AER)

High-level Disinfection



Best practices for High-Level Disinfection

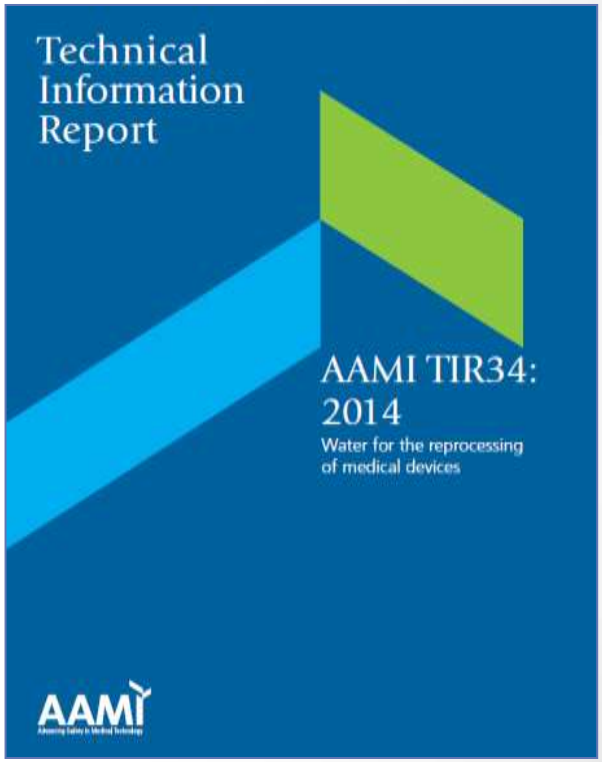
- Reusable HLDs must be monitored to ensure that it is above the Minimum recommended concentration (MRC)
  - Test prior to each use per IFU
  - Solution is used repeatedly until it fails test strip or meets it maximum use life, which ever comes first
  - Do not "top off" HLD unless instructed by HLD manufacturer
    - Can not be used to extend the use life of HLD

Best practices for High-Level Disinfection

- Single-use HLD's:
  - Used with specific AER's
  - Can be concentrated or ready to use
    - Examples concentrated OPA and peracetic acid
  - MRC is tested through either test strip of chemical monitoring by the AER
- 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



Key Points with Disinfection

- Label claims can vary
  - Safety, preparation, contact time, numbers or rinsing etc
  - Request specifics from manufacturers (e.g., 'rinse thoroughly')
- Single use or multiple use
  - Use of solution test strips to verify minimum recommended concentra (MRC)
- Multiple use disinfectants
  - Closely reuse label claims, including maximum reuse life
  - 'Topping off' of solutions
- All parts of the device should be contacted
- Importance of rinsing
  - Correct water quality (bacteria-free; AAMI TIR34)
  - Fresh water for every rinse (by immersion)
  - Correct number of rinses
- Device inspection prior to use

Use of Automated Endoscope Reprocessors (AER)

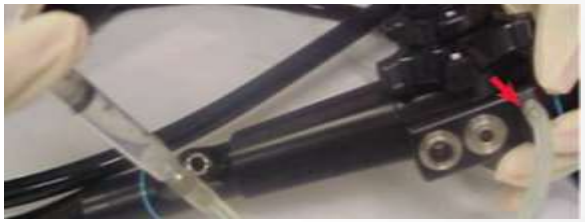
- Machines designed to clean and/or disinfect endoscope and components using an LCS/HLD solution
- Use of AER's may be more efficient and leads to less user exposure and helps to ensure repeatable results
- Section has detail on types of AER available and features of their cycles
- If AER cycle is interrupted,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

Automated Endoscope Reprocessors (AERs)

- Review claims and instructions for use carefully
  - FDA clearance
  - Note any limitations such as disinfection of connector contact sites on endoscopes, device preparation, flushing capabilities for all lumens, drying capabilities etc
- Correct use of cleaning detergents (when applicable) and disinfectants
- Rinse water control
- Routine maintenance

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

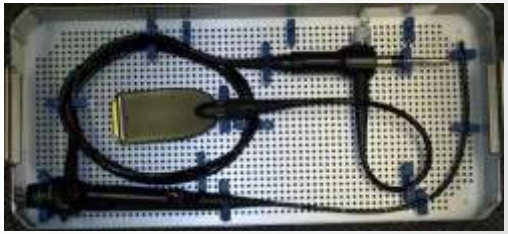
- Drying is achieve by flowing air through the endoscope channels
  - Facilitate drying with alcohol flush (70-80% ethyl or isopropyl alcohol)
  - Follow endoscope IFU for amount to be used
  - **Follow with instrument quality forced air to ensure residual alcohol is removed**
  - Refer to endoscope 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 not 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



Best practices for Sterilization

- Packaging considerations are outlined
  - Pouches, wraps, rigid containers
- Guidance for different sterilization modalities is given:
  - Steam
  - Ethylene Oxide
  - Hydrogen Peroxide gas
  - Ozone
- Sterilization is dependent on adequate **cleaning,** rinsing and device preparation
  - Drying is also essential
  - Packaging requirements (if applicable)

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)

Storage of reprocessed endoscopes

- Have policies and procedures in place regarding storage
- 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

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**

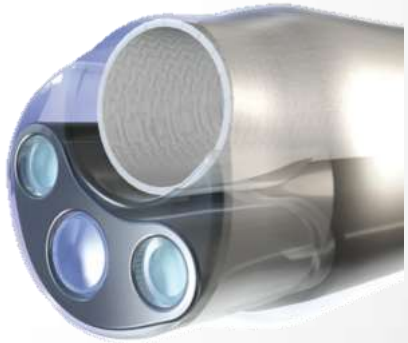
- Develop protocols to ensure that users can readily identify an endoscope that has been processed and is ready for patient use.

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

Use of sterile endoscope sheaths

- Available for use with specified endoscopes
- Instructions for endoscope reprocessing for cleared devices recommend alternative processing instructions when the sheath remains intact after endoscope use
- Sheaths are not cleared for all types of endoscopes
- Two categories of sheaths:
  - Those intended to reduce the level of soiling of the endoscope
  - Those intended to prevent endoscope soiling and serve as microbial barriers
  - There are different processing instructions dependent on which type is being used
  - Refer to sheath manufacturer IFU and endoscope IFU



Processing of endoscope accessories

- Processing of certain endoscope components (valves) requires the same level of inspection, cleaning, and HLD or sterilization as the endoscope itself
- Process for manual cleaning & HLD of accessories is outlined
- Water bottle processing should occur according to manufacturer's IFU and at least daily

ST91

Education, Training and Competency Recommendations

Education, Training and Competency Recommendations

- All personnel performing processing be **certified** as a condition of employment.
- At a minimum, personnel should complete a certification exam.
- Frequencies of training/competency:
  - initial hire; annually; at designated intervals; or whenever new endoscopic models, new processing equipment, or products such as new chemicals are introduced for processing.

Education, Training and Competency Recommendations

- Processing activities should be closely supervised until competency is verified for each processing task.
- Identification of items that are single-use
- Facility policies regarding sterilization and high-level disinfection, infection prevention, attire, hand hygiene, and compliance with local, state, and/or federal regulations

What Should The Education Include?

- Procedures for cleaning, leak testing, disinfecting or sterilizing, packaging, and storing each specific endoscope make and model, including equipment connections
- All aspects of decontamination (e.g., disassembly, manual and mechanical cleaning methods and how to monitor their effectiveness, microbiocidal processes, equipment operation, standard precautions, and engineering and work practice controls)
- Documentation of quality monitoring results.

What Should The Education Include?

- The operation of the specific cleaning processes & equipment, high-level disinfection processes, sterilizing systems and the methods used to verify operation

- Workplace safety, including OSHA standards for chemical use and biological hazards as well as workplace safety processes and procedures related to endoscope processing, high-level disinfection, and sterilization.

Quality Control Procedures

- Quality control is critical within endoscope reprocessing procedures
- Topics covered are product identification, traceability, documentation, record-keeping, verification and monitoring of HLD and sterilization process, product recalls and quality process improvement
- Facilities should develop comprehensive quality assurance and safety programs
- Each section outlines what parameters should be documented, tested, and/or maintained

Product Recalls

- Written policies should be in place for a recall event (HLD or sterilization failure)
- Policies developed in cooperation with infection prevention and risk management
- Establishing recall procedures helps to ensure patient safety, compliance with user facility reporting requirements to the FDA & allows for adequate follow-up actions

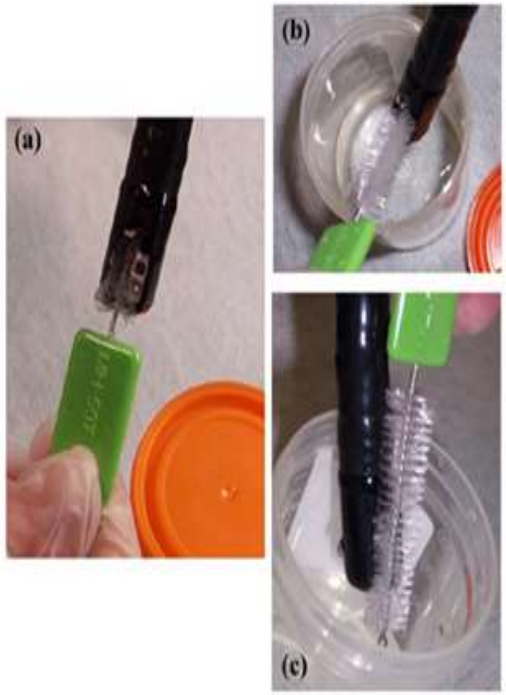
Microbial Surveillance

- Options include:
  - Traditional culturing
  - Gram negative test kits
- 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
- AORN: Base decision on a risk assessment
- Not ATP or cleaning verification tests

Guidance on culturing

- 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)
    - **Frequency: Every 30 days or 60 cycles**

- Mail back service for endoscope samples are now available



http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html

Monitoring for Gram-negative organisms in reprocessed scopes

- Enzymes specific to Gram-negative bacteria hydrolyze the substrate in the reagent vial
  - This generates fluorescence, which is read by the fluorometer, which then gives a reading.

- ST91: Types of verification testing may include enzyme based tests
  - Such as the gram negative test kit

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

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