

Comparison of ANSI/AAMI ST-91 Standards, SGNA Standards and AORN Guidelines on Processing Endoscopes March 9, 2017

Process or Equipment Change	SGNA Recommendation	ANSI/AAMI ST-91 Standard	AORN 2017 Endoscopy Guideline	CDC Essential Elements of a reprocessing program 2016	Health System Implementation	Deadline for compliance
New guidelines for processing endoscopes, published May 2015 ANSI/AAMI ST-91	N/A	Review	N/A			
Processing Steps						
	<ol style="list-style-type: none"> 1. Precleaning; 2. Leak testing; 3. Manual cleaning; 4. Rinse after cleaning; 5. Visual inspection; 6. High-level disinfection (manual or automated); 7. Rinse after high level disinfection; 8. Drying (alcohol and forced air); and 9. Storage. 	<ol style="list-style-type: none"> a) Precleaning at the point of use b) Transporting c) Leak testing d) Cleaning e) Rinsing f) Inspecting or testing for cleanliness, where applicable g) Disinfection/high-level disinfection and monitoring of the process, where applicable h) Rinsing i) Drying and alcohol flush j) Storage 	<ol style="list-style-type: none"> 1. Precleaned at the point of use. 2. Transported to the endoscopy processing room. 3. Leak Test 4. Manual cleaning 5. Rinse 6. Dry 7. Visual inspection 8. high-level disinfection (critical water) or sterilization 9. Rinse, flush, critical water 10. alcohol flush and drying 11. Storage 	<p>Pre-clean Leak-test Manual clean Visual inspection Disinfection or Sterilization Storage</p>		
Precleaning	<p>Precleaning removes organic material (e.g., blood, body fluids, body soil) and decreases the bioburden, making it much more likely that subsequent reprocessing steps will be successful. Precleaning occurs in the procedure room immediately after removal of the insertion tube from the patient and prior to disconnecting the endoscope from the power source. Precleaning should be performed at point of use, before bioburden has an opportunity to dry and before complete decontamination (Miner, 2013; Petersen et al., 2011).</p>	<p>To prevent buildup of bioburden, development of biofilms, and drying of secretions, precleaning should take place at the point of use immediately following the procedure. It is imperative that the written IFU from the endoscope, AER, and cleaning solution manufacturers are followed.</p> <p>Before the endoscope is detached from the light source and/or video processor:</p> <ol style="list-style-type: none"> a) Don fresh PPE, including gloves and skin and eye protection. b) Prepare a cleaning solution according to the solution manufacturer's written IFU. Some endoscope manufacturers prescribe the use of potable water as the sole precleaning agent. c) Wipe the insertion tube with a wet, low-linting or non-linting cloth or sponge soaked in the freshly prepared cleaning solution as soon as possible after the endoscope is removed from the patient or the procedure is completed. Ensure that all endoscope controls are in the free and unlocked position. Cloth or sponge should be single use and disposed of after use. 	<p>The collective evidence supports precleaning of flexible endoscopes at the point of use as a mechanism for moistening, diluting, softening, and removing organic soils (eg, blood, feces, respiratory secretions) and reducing the formation of biofilm. If organic soil and biofilm are not removed completely, the subsequent HLD or sterilization process might not be effective.</p> <p>The need for precleaning at the point of use is emphasized in numerous clinical practice guidelines.</p>	<p>a.Pre-clean flexible endoscopes and reusable accessories by following the device manufacturer’s instructions for use (IFU). Perform pre-cleaning immediately following completion of the endoscope procedure to help prevent the formation of biofilm.</p>		

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Precleaning (Cont.)		<p>d) Suction the solution through the suction/biopsy channel as indicated in the endoscope manufacturer's written IFU.</p> <p>e) Flush the air/water channels with solution using the endoscope's cleaning adapter or by IFU-instructed air/water flow.</p> <p>f) If present, flush other channels (e.g., auxiliary water or elevator channels) with solution.</p> <p>g) Flush with the minimally prescribed volume of solution and ensure that the channels are not blocked.</p> <p>h) Place the distal end of the endoscope in the cleaning solution and suction the solution through the endoscope until clear.</p> <p>i) Detach the endoscope from the light source and suction pump.</p> <p>j) Attach a fluid-resistant cap over any electrical components, if applicable.</p> <p>k) Visually inspect the endoscope for damage.</p>				
Transporting	<p>Transport the soiled endoscope to the reprocessing area in a closed container that prevents exposing staff, patients, or the environment to potentially infectious organisms (Petersen et al., 2011). The transport container must be labeled to indicate biohazardous contents (ASGE, 2011; AAMI, 2015). Containers should be large enough to prevent damage to the endoscope by being coiled too tightly.</p>	<p>Each endoscope should be isolated and transported with its components in its own closed system to the next stage of processing, as it is considered contaminated. To avoid puncture and penetration damage to the endoscope, devices such as forceps and wires used in the procedure should be transported in their own containers.</p> <p>The system should be marked with a biohazard label and must meet OSHA (29 CFR 1910.1030) requirements for transporting hazardous items. The system should be large enough to accommodate a single endoscope without the need to over-coil the insertion or light guide tubes.</p>	<p>Contaminated flexible endoscopes and accessories should be transported to the endoscopy processing room as soon as possible after use.</p> <p>Endoscopes and accessories should be kept wet or damp but not submerged in liquid during transport. Using containers of sufficient size to fully contain</p> <p>Contaminated endoscopes and accessories must be transported to the decontamination area in a closed container or closed transport cart. The container or cart must be</p> <ul style="list-style-type: none"> • leak proof, • puncture resistant, • large enough to contain all contents 	Not mentioned		

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Leak testing	Leak testing detects damage to the interior or exterior of the endoscope. The leak test is done before immersion of the endoscope in reprocessing solutions to minimize damage to parts of the endoscope not designed for fluid exposure. Leak testing can be performed by manual (dry), mechanical (wet), mechanical (dry), and mechanical in AER means (AAMI, 2015). Follow the manufacturer's instructions to ensure endoscope and leak tester compatibility.	<p>Leak testing should be performed as soon as possible after the endoscope arrives in the processing area and before immersion of the endoscope into processing solutions. Leak testing can detect damage to the endoscope that may, if undetected, allow for fluid invasion into the areas not designed for fluids. These fluids can be a combination of accumulated water, chemicals, and/or biological matter that have collected from the time the endoscope's integrity was breached until the time the hole is identified. Follow the endoscope manufacturer's written IFU for the leak testing protocol.</p> <p>Personnel performing the leak testing should wear PPE. Prior to leak testing, the fluid-resistant cap should be applied, if indicated in the manufacturer's written IFU. The largest surface counter or sink area available should be used to accommodate an open, minimally coiled endoscope for the test. Over-coiling can mask a hole and allow it go undetected. A well-lighted work surface should also be provided. Sufficient time should be allowed to permit a thorough water-tight exam. Environments, distractions, and or time limits can jeopardize a successful process.</p> <p>*Document outcome of leak test.</p>	Leak testing detects openings in the external surfaces and internal channels of the endoscope that could permit water, chemicals, or organic material to enter portions of the endoscope not intended for fluids. These materials may accumulate from the time the integrity of the endoscope is breached until the time the leak is identified. Leak testing may be accomplished by manual or mechanical methods and may be performed using a wet (ie, under water) or dry process.	For endoscopes that require leak testing, perform the leak test using manufacturer's IFU after each use and prior to manual cleaning. Leak testing detects damage to the external surfaces and internal channels of the endoscope that can lead to inadequate disinfection and further damage of the endoscope.		
Manual Cleaning	Manual cleaning of endoscopes is necessary prior to automated/manual high-level disinfection or sterilization. This is the most important step in removing the microbial burden from an endoscope. Retained debris contributes to biofilm development (Fang et al., 2010) and interferes with the HLD capability to effectively kill and/or inactivate microorganisms (Roberts, 2013). Manual cleaning and thorough	Manual cleaning starts after confirming that the endoscope does not have any leaks and should be conducted as soon as possible after use to prevent soil from drying on the device. Soil that remains on the endoscope may interfere with the ability of the disinfection or sterilization process to effectively kill or inactivate microorganisms and may allow for biofilm development. If it is not possible	The collective evidence indicates that cleaning is the most important step in the processing of flexible endoscopes. Because of the body cavities they enter, some flexible endoscopes acquire high levels of microbial contamination. Some flexible endoscopes contain multiple channels and ports that can easily collect organic material. The environment in which flexible endoscopes are used	a. Perform meticulous manual cleaning including brushing and flushing channels and ports consistent with the manufacturer's IFU before performing high-level disinfection (HLD) or sterilization. Perform manual cleaning within the timeframe specified in the manufacturer's IFU. Manual cleaning is the most critical step in the disinfection process since		

<p>Manual Cleaning (Cont.)</p>	<p>brushing of channels are required even when AER manufacturers claim that manual cleaning is unnecessary (FDA, 2009). The composition of soil found on endoscopes includes proteins, fats, carbohydrates, and the various chemical salts that exist in blood and other body fluids. Ideally, a cleaning solution should have a broad spectrum of effectiveness against these various contaminants and not harm the device being cleaned. Enzymatic cleaning solutions use surfactants to break down and digest bioburden.</p>	<p>to start the cleaning process immediately after use, the endoscope manufacturer's written IFU for delayed processing should be followed.</p> <p>Cleaning steps: a) Don fresh PPE, including gloves and skin and eye protection. b) Prepare fresh cleaning solution for each endoscope according to the solution manufacturer's written IFU for temperature, if applicable; concentration; and water quality. The temperature of the cleaning solution should be monitored and documented. c) Place the endoscope in the solution, keeping it below the fluid's surface level at all times. d) Clean the endoscope's exterior surfaces with a single-use lint-free cloth or sponge. e) Clean all valve cylinders, openings, and forceps elevator housings with a cleaning brush of the length, width, and material designated in the endoscope manufacturer's written IFU. NOTE 1—Endoscope valves need to be manually actuated to ensure coverage of all internal parts. f) Brush all channels according to the endoscope manufacturer's written IFU until there is no visual debris. NOTE 2—Cleaning brushes should either be single use and disposed of or reusable and receive high-level disinfection or sterilization after each use, according to their written IFU. g) Attach a model-specific cleaning adapter, flush channels, and allow for solution exposure according to the solution manufacturer's written IFU. h) Flush all channels according to the endoscope manufacturer's written IFU and rinse exterior surfaces with potable water until all cleaning solution is visibly removed. Some cleaning solutions may require multiple rinses in fresh water. i) Purge all channels with air.</p>	<p>provides optimal conditions for contamination and growth of biofilm. When inadequately cleaned, contaminated endoscopes may be vectors of normal bacterial flora as well as pathogenic bacteria. When endoscopes are effectively cleaned, bioburden is reduced to a level that does not present a challenge to subsequent disinfection or sterilization.</p>	<p>residual organic material can reduce the effectiveness of HLD and sterilization.</p>		
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<p>Manual Cleaning (Cont.)</p>		<p>j) Repeat cleaning, brushing, and rinsing steps until there is no visible debris or solution residual. NOTE 3—Endoscopes that have been exposed to synthetic lipids or radiographic medium may require additional cleaning. k) Soak, scrub, brush, and rinse all reusable and removable parts (valves, buttons, port covers, tubing). NOTE 4—Discard removable parts designed for single use. l) Clean reusable endoscopy accessories (e.g., forceps, wires, baskets) according to their written IFU.</p>			
<p>Rinse</p>	<p>RINSE AFTER MANUAL CLEANING a. Thoroughly rinse the endoscope and all removable parts with clean water to remove residual debris and detergent. b. Purge water from all channels using forced air. Dry the exterior of the endoscope with a soft, lint-free cloth to prevent dilution of the HLD used in subsequent steps. c. Rinsing may be performed in AER's that provide this feature.</p>	<p>After cleaning the endoscope, removed components and accessories should be thoroughly rinsed with copious amounts of potable water (see AAMI TIR34) to help ensure all cleaning solutions and loosened debris are removed.</p> <p>Follow the endoscope manufacturer's and cleaning solution manufacturer's written IFU for the amount of water and psi and/or pressure needed to flush through each channel and number of rinses.</p> <p>Rinsing steps: a) Using the cleaning adaptors provided by the manufacturer, ensure adequate flow of potable water through each lumen. b) Rinse all exterior endoscope surfaces with freely flowing potable water. c) Purge channels with air using a syringe to evacuate residual rinse water. If compressed air is used, it should be oil-free and used at a pressure not to exceed that recommended by the endoscope manufacturer. d) Rinse all valves and other removable components according to the manufacturer's written IFU.</p>	<p>The exterior surfaces and internal channels of the endoscope should be flushed and rinsed with utility water until all cleaning solution and residual debris is removed.</p> <p>Thorough flushing of the channels and rinsing of the endoscope with utility water helps remove residual debris and cleaning solutions and prevents dilution of the high-level disinfectant or liquid chemical sterilant. If not adequately rinsed, enzymatic cleaning solutions may contribute to protein buildup within the endoscope channels.</p>	<p>Not specifically mentioned separately</p>	

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Dry	Not specifically mentioned	Dry the exterior of the endoscope with a lint-free cloth or sponge.	<p>The exterior surfaces of the endoscope should be dried with a soft, lint-free cloth or sponge and all channels purged with instrument air.</p> <p>Moisture remaining on the surface or in the endoscope lumens may dilute the high-level disinfectant or interfere with the sterilization process, potentially reducing its effectiveness. Hydrogen peroxide vapor and hydrogen peroxide gas plasma sterilization cycles may abort in the presence of excess moisture. Ethylene oxide combines with water to form ethylene glycol (ie, antifreeze), which is toxic and not removed during aeration</p>	Not specifically mentioned		
Visual Inspection	<p>Safety Stop Visual inspection is recommended to make sure the endoscope is visibly clean (AAMI, 2015; Rutala et al., 2008). It is not a guarantee that decontamination from manual cleaning is complete, but it can be considered a safety stop or “time out” to ensure the endoscope is visually clean before proceeding to the next step of HLD.</p> <p>a. Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion, discoloration, retained debris) (FDA, 2009; AAMI, 2015).</p> <p>b. Use magnification and adequate lighting to help assist in visual inspection (AAMI, 2015).</p> <p>c. Repeat manual cleaning step(s) if not clean.</p> <p>Note: It is impossible to visualize internal channels. Literature suggests that, to confirm the adequacy of manual cleaning, a rapid cleaning monitor (or rapid audit tool) for</p>	Not specifically mentioned	<p>Flexible endoscopes, accessories, and associated equipment should be visually inspected for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization.</p> <p>The collective evidence supports visual inspection of endoscopes, accessories, and equipment after cleaning and throughout use and processing as a method to help identify residual organic material and defective items in need of repair</p>	a. After manual cleaning, visually inspect the endoscope and its accessories. Visual inspection provides additional assurance that the endoscope and its accessories are clean and free of defects. Complex devices such as flexible endoscopes may require the use of lighted magnification or additional methods to assist with the inspection process.		

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Visual Inspection (Cont.)	al., 2014). If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection. The frequency of the testing should be determined by the individual institutions (Alfa et al., 2013, 2014; AAMI, 2015; ASGE, 2014).					
High level disinfection	The effectiveness of the high-level disinfectant depends on: 1. Effective precleaning, manual cleaning, and rinsing to decrease the organic load and microbial content of the endoscope; 2. Drying after rinsing to avoid diluting the HLD; and 3. Proper preparation and use (in accordance with the manufacturer's directions).	Depending on the make and model of the AER, additional features may include: a) A printer for documentation b) Adjustable cycle times c) Ultrasonic cleaning capabilities d) Channel detection for obstruction e) Leak testing f) Automatic rinsing g) Automatic alcohol flush h) Automatic air purge i) Ability to process more than one endoscope at a time, either in the same or separate chambers	After manual cleaning and inspection and when compatible with the endoscope manufacturer's IFU, flexible endoscopes and accessories should be either mechanically cleaned and mechanically processed by exposure to a high-level disinfectant or a liquid chemical sterilant or should be mechanically cleaned and sterilized.	a. Following cleaning and visual inspection perform HLD or sterilization in accordance with the manufacturer's IFU. Carefully review and adhere to the endoscope manufacturer's reprocessing instructions and to the IFU for chemicals or sterilants and any equipment (e.g., automated endoscope reprocessors) used for reprocessing to help ensure that effective disinfection occurs.		
Storage	Endoscopes must be stored in an area that is clean, well-ventilated and dust-free in order to keep the endoscopes dry and free of microbial contamination. An endoscope that is not dry must be reprocessed before use. Endoscopes should also hang freely so that they are not damaged by physical impact. Endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers' IFU. Two major types of storage cabinets exist: conventional cabinets and drying cabinets. Conventional cabinets are favored in the United States, and drying cabinets are used mainly in Europe and Australia. Drying cabinets are designed to control air quality and humidity, and access to endoscopes (Courné & Geyssens, 2011; Foxcroft, Monaghan, & Faoagali, 2008; Grandval,	The endoscope should be hung vertically with the distal tip hanging freely in a well-ventilated, clean area, following the endoscope manufacturer's written IFU for storage. For example, make sure that the insertion tube hangs vertically and is as straight as possible (no bends). If the scope has an angulation lock, it should be in the open position while in storage. There should be sufficient space between and around scopes to prevent them hitting into one another, which can cause damage to the scopes. All removable parts (e.g., valves and caps) should be detached from the endoscope. To keep the parts together with the scope, a small bag or similar device can be used to attach the parts to the scope. Rationale: When flexible and semi-rigid endoscopes are hung in the vertical position, coiling or kinking is prevented,	Cabinets used for storage of flexible endoscopes should be situated in a secure location in the clean workroom of the endoscopy processing room in a two-room design or in a separate clean area close to, but not within, the endoscopy procedure room Storage cabinets should have doors, and be located at least 3 ft (0.9 m) from any sink. Flexible endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers' IFU. Flexible endoscopes should be stored in a drying cabinet If a drying cabinet is not available, flexible endoscopes may be stored in a closed cabinet with HEPA-filtered air that provides positive pressure and	a. After reprocessing is complete, store endoscopes and accessories in a manner that prevents recontamination, protects the equipment from damage, and promotes drying. Store processed flexible endoscopes in a cabinet that is either: i. of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without touching the bottom of the cabinet OR ii. designed and intended by the manufacturer for horizontal storage of flexible endoscopes		

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Storage (Cont.)	Hautefeuille, Marchetti, Pineau, & Laugier, 2013; Pineau, Villard, Luu & Marchetti, 2008). They have bacteria-free air under pressure to keep surfaces dry. High efficiency particulate air (HEPA) filters provide microbial-free air that is blown through the endoscope channels to ensure that they remain dry.	allowing any remaining moisture to drain out of the endoscope and decreasing the potential development of an environment conducive to microbial growth in the endoscope. Following recommended storage practices facilitates drying and decreases potential for contamination. All valves and other accessories should be removed in preparation for drying. The scope protector may create an environment favorable for microbial growth if the endoscope is not dry and cannot hang straight (Thomas, 2005; Goldstine, 2005; Bisset et al., 2006). Storing endoscopes with valves or caps on the scope will trap residual moisture in the internal channels and provide optimal conditions for microbial growth. AORN (2015e) recommends that flexible and semi-rigid endoscopes should be stored in a closed cabinet with venting that allows air circulation around the endoscopes, internal surfaces composed of cleanable material, adequate height to allow endoscopes to hang without touching the bottom of the cabinet, and sufficient space for storage of multiple endoscopes without touching.	allows air circulation around the flexible endoscopes			
Avoiding cross contamination by utilizing a uni-directional workflow	The reprocessing work flow should be from dirty to clean to avoid cross-contamination	Work flow should be unidirectional from the decontaminated area to the clean area and then to the storage area. Work flow patterns should be designed to contain contaminants, prevent damage to endoscopes, and minimize employee exposure to blood-borne and other disease-producing organisms.	“The endoscopy processing room should be designed to facilitate a unidirectional workflow from the decontamination area or decontamination room to the clean area or clean workroom, and then to clean storage in a separate location.”	<ol style="list-style-type: none"> 1. The reprocessing area should be in a space that is separate from the patient procedural area. 2. Review the physical setting to ensure a “one way” work flow that separates contaminated work spaces from clean work spaces. 3. If a separate room is used for manual cleaning of endoscopes, ensure a directional airflow that maintains negative pressure within that room relative to adjoining spaces. 4. Ensure that heating, ventilation, and air conditioning parameters are 	<ol style="list-style-type: none"> 1. Review workflow design to ensure process is uni-directional 2. Ensure there are no processes that could contaminate a processed endoscope 	

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Avoiding cross contamination by utilizing a uni-directional workflow (Cont.)				<p>appropriate for the chemicals and equipment in use.</p> <p>5. Ensure that manufacturer’s IFUs for reprocessing of the endoscopes and for use of the AERs and associated chemicals are readily available.</p> <p>6. Provide designated space to enable access to files electronically (e.g., computer) or hard copy (e.g., in binders for IFUs and Safety Data Sheets for chemicals used to reprocess flexible endoscopes.</p>		
Separate sink dedicated for hand-washing	The room must have more than one sink and separate hand-washing facilities.	Hand hygiene facilities (i.e., sink, soap dispenser, towel dispenser, or alcohol-based hand rub dispensers) should be conveniently located and designed to allow good hand hygiene practices. The hand hygiene sink should be separate from the sink used to clean endoscopes.	Hand-washing sinks should not be used to clean flexible endoscopes. Decontamination sinks should not be used for hand washing.	Staff should have access to a handwashing sink that is separate from the reprocessing sink(s).	Review with facilities to ensure proper handwashing sinks are available.	Ongoing with each facility.
Decon Sinks	Leak testing, Detergent step, and rinsing are mentioned in step by step description under “manual cleaning steps”.	<p>Sinks should be deep enough to allow complete immersion of the endoscope to minimize aerosolization. The size of the sink should be adequate (i.e., 16 inches x 30 inches) to ensure the endoscope can be positioned without tight coiling. Sinks should not be so deep that personnel have to bend over to clean instruments. An ideal decontamination sink is approximately 36 inches (91 centimeters [cm]) from the floor and 8 to 10 inches (20 to 25 cm) deep, enabling a person of average size to work comfortably without undue strain on the back; foot stools should be readily available to accommodate shorter personnel.</p> <p>At a minimum, two sinks or one sink with two separate basins should be used, One sink or sink basin should be designated for leak testing and manual cleaning, and the other only for rinsing. Optimally, three sinks or one sink with three separate</p>	<p>A minimum of two decontamination sinks (or one sink with two divisions) should be provided in the endoscopy processing room.</p> <p>When two decontamination sinks (or one sink with two divisions) are provided, one sink or division should be designated for leak testing and manual cleaning, and the other for rinsing.</p> <p>Three decontamination sinks (or one sink with three divisions) may be provided in the endoscopy processing room. When three decontamination sinks (or one sink with three divisions) are provided, one sink or division should be designated for leak testing, the second for manual cleaning, and the third for rinsing.</p> <p>•a minimum of 3 ft (0.9 m) between the decontamination area and the clean work area and</p>	Not specifically mentioned		

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Emergency Eyewash	Eye wash stations for immediate emergency use must be available in the GI Lab no greater than 10 seconds from the location of chemical use or storage (AORN, 2015; AAMI, 2015). The eye wash station must be activated weekly to ensure proper use during a potential chemical exposure. Refer to the eye wash manufacturer for proper maintenance of the device.	<p>basins should be used, with each function in a separate sink or basin.</p> <p>Suitable eyewash units must be available for immediate emergency use in all places where chemicals are used. The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units (ANSI Z358.1).</p> <p>ANSI Z358.1 requires that eyewash units provide a minimum of 0.4 gallons per minute continuously for at least 15 minutes, that they be designed to flush both eyes simultaneously, and that they have a "hands-free, stay open" feature once activated. Under the ANSI standard, drench hoses or eyewash bottles are not acceptable emergency eyewash units.</p> <p>Eyewash stations should be located:</p> <p>a) so that travel time is no greater than 10 seconds from the location of chemical use or storage, or immediately next to or adjoining the area of chemical use or storage, if the chemical is caustic or a strong acid; and</p> <p>b) on the same level as the hazard with the path of travel free of obstructions (e.g., doors) that may inhibit immediate use of the eyewash station (ANSI Z358).</p>	<p>•either a separating wall or a barrier that extends a minimum of 4 ft (1.2 m) above the sink rim to separate soiled work areas from clean work areas.</p> <p>Eyewash stations, either plumbed or self-contained, must be provided where chemicals that are hazardous to the eyes are located.</p> <p>It is a regulatory requirement that emergency eyewash stations or showers be immediately accessible in locations where the eyes or body of any person may be exposed to injurious corrosive materials.</p> <p>Plumbed eyewash stations are connected to a continual source of water that is safe to drink. Self-contained eyewash stations are stand-alone devices that contain flushing fluid.</p>	Install eyewash stations, either plumbed or self-contained, within the endoscopy reprocessing room where chemicals that are hazardous to the eyes are used. Eyewash stations should not be installed in a location that requires flushing of the eyes in the decontamination sink.		
Traceability of all endoscope and accessories to the Patient	Literature suggests that reusable buttons and valves should be reprocessed and stored together with the endoscope as a unique set for tracking purposes.	<p>Items that are processed for immediate use by means of an LCS/HLD soaking system require a means of identification of the items processed.</p> <p>Identify all endoscopes, endoscope accessories, and endoscope processing equipment used in the facility, including manufacturer, model, serial number or facility specific identification number, and</p>	<p>•identity of the endoscope and endoscope accessories used during the procedure.</p> <p>Records enable traceability in the event of a processing failure.</p> <p>Records related to flexible endoscope processing should include the identity</p>	For all methods of reprocessing using HLD or sterilization, document endoscope and patient identifiers. Tracking is essential in the event of a disinfection failure and for responding to device or product recalls.		

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Transporting Contaminated Endoscopes	<p>Transport the soiled endoscope to the reprocessing area in a closed container that prevents exposing staff, patients, or the environment to potentially infectious organisms (Petersen et al., 2011). The transport container must be labeled to indicate biohazardous contents.</p> <p>(ASGE, 2011; AAMI, 2015). Containers should be large enough to prevent damage to the endoscope by being coiled too tightly</p>	<p>unique device identifiers (UDIs).</p> <p>of endoscope and endoscope accessories,</p> <p>Each endoscope should be isolated and transported with its components in its own closed system to the next stage of processing, as it is considered contaminated. To avoid puncture and penetration damage to the endoscope, devices such as forceps and wires used in the procedure should be transported in their own containers.</p> <p>The system should be marked with a biohazard label and must meet OSHA (29 CFR 1910.1030) requirements for transporting hazardous items. The system should be large enough to accommodate a single endoscope without the need to over-coil the insertion or light guide tubes.</p> <p>Transporting steps: a) Isolate and immobilize a single endoscope in a container by naturally coiling it in large loops. b) Separate endoscopy accessories from the contaminated endoscope to prevent puncture and penetration damage.</p>	<p>Contaminated endoscopes and accessories must be transported to the decontamination area in a closed container or closed transport cart. The container or cart must be</p> <ul style="list-style-type: none"> •leak proof, •puncture resistant, and •large enough to contain all contents. <p>Transporting items in leak-proof, puncture-resistant containers and in a manner that prevents exposing personnel to blood, body fluids, and other potentially infectious materials is a regulatory requirement</p> <p>The container should be of sufficient size to accommodate the endoscope when the endoscope is coiled in large loops</p>	Not specifically mentioned		
Transporting Clean Endoscopes	Could not find a recommendation.	<p>When transporting an endoscope that has been high-level disinfected, the endoscope should be protected from recontamination. Before removing the endoscope from the storage cabinet, don new exam gloves. Then transport the endoscope using an impervious barrier method that will prevent re-contamination. Examples would be a clean plastic bag, endoscope transfer system (scope in a tote bin with a cover), or similar method. The endoscope should be loosely coiled to prevent damage. The transport system should not be reused for clean transport.</p>	<p>Personnel should wear clean gloves when transporting processed flexible endoscopes to and from the storage cabinet.</p> <p>Wearing clean gloves may prevent contamination of processed flexible endoscopes by the hands of personnel.</p>	Not specifically mentioned		

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Process or Equipment Change	SGNA Recommendation	ANSI/AAMI ST-91 Standard	AORN 2016 Endoscopy Guideline	CDC Essential Elements of a reprocessing program 2016	Health system Implementation	Deadline for compliance
Documentation of cleaning time	Could not find recommendation	Could not find recommendation	A procedure should be developed and implemented for recording the times that the procedure is completed and cleaning is initiated.	1. Ensure that there is a process in place to record the procedure end time and the start time for manual cleaning. Recording these times enables reprocessing personnel to ascertain how long the endoscope has been awaiting reprocessing, to prioritize reprocessing of specific endoscopes, and to determine whether routine reprocessing within the manufacturer's recommended time to cleaning is achievable, and if not, to implement the manufacturer's procedures for delayed processing.		
Cleaning solution changes	1) Freshly prepared detergent solution should be used for each endoscope to prevent cross-contamination. 2) Low-foaming detergents are recommended such that the device can be clearly visualized during the cleaning process, preventing personnel injury and allowing for complete cleaning of lumen surfaces.	Prepare fresh cleaning solution for each endoscope according to the solution manufacturer's written IFU for temperature, if applicable; concentration; and water quality. The temperature of the cleaning solution should be monitored and documented.	Cleaning solutions should be changed when the temperature of the solution does not meet the temperature specified in the manufacturer's IFU. A digital temperature measuring device may be used to monitor the temperature of the cleaning solution.	Not specifically mentioned		
Reusable water bottle decontamination	Did not find recommendation.	Did not find recommendation.	Water and irrigation bottles should be high-level disinfected or sterilized at least daily. There should be no residual water or moisture remaining in the water-bottle assembly. Water bottles consist of the water container, cap, and tubing used for insufflation of air and lens washing. Irrigation bottles consist of the water container, tubing, and accessories used to flush water through the endoscope	Not specifically Mentioned		

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Process or Equipment Change	SGNA Recommendation	ANSI/AAMI ST-91 Standard	AORN 2016 Endoscopy Guideline	CDC Essential Elements of a reprocessing program 2016	Health System Implementation	Deadline for compliance
			Sterile water should be used to fill water and irrigation bottles.			
Final Rinse	<p>1. Thoroughly rinse the endoscope and all removable parts with clean water to remove residual debris and detergent.</p> <p>2. Purge water from all channels using forced air. Dry the exterior of the endoscope with a soft, lint-free cloth to prevent dilution of the HLD used in subsequent steps.</p> <p>3. Rinsing may be performed in AER's that provide this feature.</p> <p>* No residual water should remain in hoses and reservoirs.</p> <p>* Cycles for alcohol flushing and forced air drying are desirable.</p> <p>* The machine should also feature a self-contained or external water filtration system.</p>	<p>Manual rinse - Use fresh water for each rinse (do not reuse the rinse water if multiple rinses are specified in the IFU). Follow the device manufacturer's written IFU for the specified rinse water quality.</p> <p>AER - Rinse cycles should follow the cleaning and liquid chemical sterilization/high-level disinfection cycles and then be followed by an automatic air purge to remove any fluids.</p> <p>AER - The microbial quality of the rinse water will vary and may recontaminate the processed device (AAMI TIR34). To avoid recontaminating the device with the rinse water, the incoming AER water should be at least filtered using bacterial retentive filters as recommended in the AER manufacturer's written IFU.</p> <p>The water handling systems, which do not come into contact with the LCS/HLD solution, should be disinfected on a regular basis as directed by the manufacturer. Some AERs have self-disinfection cycles using either an LCS/HLD solution or thermal methods.</p> <p>The water filters should be changed per the manufacturer's written IFU. In addition, the endoscopes should be flushed with alcohol and purged with pressurized air prior to storage, as described in Section 5.7.4.3.</p>	<p>Following disinfection, the endoscope and endoscope channels should be mechanically rinsed and flushed with critical or sterile water.</p> <p>Critical water meets the following parameters:</p> <ul style="list-style-type: none"> • hardness: < 1 mg/L calcium carbonate,119 • pH: 5 to 7,119 • chloride: < 1 mg/L,119 • bacteria: < 10 CFU/mL,119 and • endotoxin: < 10 endotoxin units (EU)/mL. 	At minimum, water used for reprocessing of endoscopes meets the specifications that are recommended by the device and reprocessing equipment manufacturers. Professional society guidelines that recommend more stringent water specifications should be considered		
Visual Inspection	VISUAL INSPECTION Visual inspection is recommended to make sure the endoscope is visibly clean (AAMI, 2015; Rutala et al., 2008). It is not a guarantee that	Incorporate visual inspections and testing of the equipment to identify conditions that may affect the cleaning or disinfecting processes, such as testing for leaks, examination for cracks, and	Flexible endoscopes, accessories, and associated equipment should be visually inspected for cleanliness, integrity, and function before use, during the procedure, after the	a. After manual cleaning, visually inspect the endoscope and its accessories. Visual inspection provides additional assurance that the endoscope and its accessories are		

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<p>Visual Inspection (Cont.)</p>	<p>decontamination from manual cleaning is complete, but it can be considered a safety stop or “time out” to ensure the endoscope is visually clean before proceeding to the next step of HLD. a. Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion, discoloration, retained debris) (FDA, 2009; AAMI, 2015). b. Use magnification and adequate lighting to help assist in visual inspection (AAMI, 2015). c. Repeat manual cleaning step(s) if not clean.</p>	<p>checking the integrity of fiber optic bundles. Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures.</p>	<p>procedure, after cleaning, and before disinfection or sterilization. Lighted magnification should be used to inspect endoscopes and accessories for cleanliness and damage. Internal channels of flexible endoscopes may be inspected using an endoscopic camera or borescope.</p>	<p>clean and free of defects. Complex devices such as flexible endoscopes may require the use of lighted magnification or additional methods to assist with the inspection process.</p>		
<p>Storage “Hang Time”</p>	<p>SGNA supports a 7-day storage interval for reprocessed endoscopes but only if they were reprocessed and stored according to professional guidelines and manufacturer instructions.</p>	<p>A number of guidelines and recommended practices provide recommendations as to the maximum duration of storage time before the endoscope is processed for the next use. Some of these are summarized below: a) AORN: AORN guidelines recommend that endoscopes be reprocessed before use, if not used for more than five days. (AORN, 2015e). b) United States Department of Veterans Affairs, Veterans Health Administration: The Veterans Health Administration currently follows a directive to process unused endoscopes after 12 days of hang time. (VA 2014). c) Gastroenterology Association of Australia: Gastrosopes, colonoscopes, radial EUS endoscopes need to be disinfected prior to use, when the storage time of 72 hours is elapsed. Duodenoscopes, bronchoscopes and linear EUS endoscopes need to be disinfected prior to use, when the storage time of 12 hours is elapsed. Those endoscopes only used in emergency should be routinely processed every 72 hours to ensure they are ready to be used at any time. If recent culture results have been positive or if adequate storage facilities are not</p>	<p>The multidisciplinary team should establish a policy for removing and reprocessing the endoscope before use if the maximum storage time has been exceeded. The collective evidence regarding the maximum safe storage time for processed endoscopes is inconclusive. Recommendations from professional organizations for maximum storage times for flexible endoscopes are not in agreement; recommended storage times range from three hours to one month. (2015 recommended 5 days)</p>	<p>•The available data on the maximum interval of endoscope storage before reprocessing is required prior to use is inconclusive. The length of time may depend on multiple factors as identified on organizational risk assessment that may include endoscope usage/turnover of endoscopes used and manufacturer’s instructions-for-use.</p>		

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Process or Equipment Change	SGNA Recommendation	ANSI/AAMI ST-91 Standard	AORN 2016 Endoscopy Guideline	CDC Essential Elements of a reprocessing program 2016	Health system Implementation	Deadline for compliance
Storage “Hang Time” (Cont.)		<p>available, endoscopes should be disinfected prior to use if the storage time has been longer than 12 hours. Extended storage is only permitted if recent (within 12 months) routine microbiological surveillance of the endoscope has shown negative culture results. (Infection Control In Endoscopy 2011)</p> <p>d) West Coast District Health Board, New Zealand: The endoscope can be stored in correct storage conditions for up to 72 hours without having to be processed prior to use. (West Coast District Health Board, New Zealand, reviewed February 2013)</p> <p>e) Canadian Standards Association: Endoscopes for gastrointestinal procedures should be processed if storage exceeds 7 days. (Canadian Standards Association, 2008)</p> <p>f) NHS Scotland: Only use endoscopes directly from storage if stored for less than 72 hours in a purpose built cabinet providing HEPA filtered air drying. (NHS National Services Scotland, Dec 2004, amended Sep 2007)</p> <p>g) HSE Standards and Recommended Practices for Endoscope Reprocessing Units, Ireland: After the drying process a conditioning process guarantees the endoscope maintains its condition for up to 72 hours or as specified by the manufacturer. (Health Service Executive Standards and Recommended Practices for Endoscope Reprocessing Units).</p>				
Endoscope labeling for storage	Did not find a recommendation.	<p>The tag should be labeled with the following information:</p> <p>a) Date of processing</p>	Did not find recommendation.	Maintain documentation of adherence to these essential steps each time an endoscope is reprocessed. Documentation is		

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Process or Equipment Change	SGNA Recommendation	ANSI/AAMI ST-91 Standard	AORN 2016 Endoscopy Guideline	CDC Essential Elements of a reprocessing program 2016	Action Item/Responsible Party	Evaluation of Effectiveness
Storage Cabinets	<p>Endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers' IFU. Drying cabinets are designed to control air quality and humidity, and access to endoscopes</p> <p>They have bacteria-free air under pressure to keep surfaces dry. High efficiency particulate air (HEPA) filters provide microbial-free air that is blown through the endoscope channels to ensure that they remain dry.</p> <p>Key considerations in storage include:</p> <p>a. Use storage cabinets that are made of a material that can be disinfected.</p> <p>b. In conventional storage, hang endoscopes in a vertical position (with caps, valves, and other detachable components removed) to prevent moisture accumulation and subsequent microbial growth. Make sure that they hang freely so they are not damaged by contact with one another.</p> <p>c. When using drying cabinets, follow the cabinet manufacturer's instructions. Since drying does not rely on gravity, the endoscopes can be stored horizontally or vertically depending on the design of the cabinet.</p> <p>Endoscopes must be stored in an area that is clean, well-ventilated and dust-free in order to keep the endoscopes dry and free of microbial contamination. An endoscope that is not dry must be reprocessed before use. Endoscopes should also hang</p>	<p>b) Name(s) of person(s) who performed the processing c) Date of high-level disinfection</p> <p>The endoscope should hang in a way to prevent damage to the scope and prevent the formation of moisture.</p> <p>Special care should be taken to avoid coiling of any part of the endoscope to reduce chances of any droplets forming within the channels.</p> <p>Endoscopes should be stored suspended vertically in a way to allow circulation of air.</p> <p>Endoscopes should hang freely.</p> <p>Caps, valves and other detachable components should not be installed on the endoscope during storage.</p>	<p>Flexible endoscopes and endoscope accessories should be stored in a manner that minimizes contamination and protects the device or item from damage</p> <p>Flexible endoscopes should be stored in a drying cabinet</p> <p>If a drying cabinet is not available, flexible endoscopes may be stored in a closed cabinet with HEPA-filtered air that provides positive pressure and allows air circulation around the flexible endoscopes</p>	<p>essential for quality assurance purposes and for patient tracing in the event a look back is necessary.</p> <p>After reprocessing is complete, store endoscopes and accessories in a manner that prevents recontamination, protects the equipment from damage, and promotes drying. Store processed flexible endoscopes in a cabinet that is either:</p> <p>i. of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without touching the bottom of the cabinet OR</p> <p>ii. designed and intended by the manufacturer for horizontal storage of flexible endoscopes</p> <p>•The storage cabinet features that are optimal for prevention of contamination have not been determined (e.g., cabinet ventilation parameters, capacity to store accessories).</p>		

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Process or Equipment Change	SGNA Recommendation	ANSI/AAMI ST-91 Standard	AORN 2016 Endoscopy Guideline	CDC Essential Elements of a reprocessing program 2016	BHS Implementation	Deadline for compliance
	freely so that they are not damaged by physical impact.					
Environmental Cleaning	<p>A well-established housekeeping plan should involve staff from infection prevention, environmental services, and the GI department to establish the appropriate frequency, cleaning, disinfection, and maintenance of the unit (Seavey, 2010). The development of guidelines and policies should include manufacturers' guidelines, infection prevention principles, and current, accepted evidence-based practice (Day & Kelsey, 2013).</p> <p>Facilities are responsible for developing written policies or protocols which outline the responsibilities of endoscopy staff for routine and non-routine cleaning and/or disinfection of the environment. Staff should use appropriate PPE when performing any cleaning or disinfection. Supervisors or designee(s) should be responsible for ensuring that proper cleaning procedures are being followed. Consult your facility policies for terminal cleaning requirements. Blood and other potentially infectious materials should be promptly cleaned up.</p>	<p>Floors and horizontal work surfaces should be cleaned at least daily. Other surfaces, such as walls, storage shelves, endoscope storage cabinets, and air intake and return ducts, should be cleaned on a regularly scheduled basis and more often if needed (AORN, 2015b).</p> <p>Stained ceiling tiles should be replaced, and any leaks causing the stains should be repaired. A cleaning schedule on a regular (weekly or monthly) basis should be established and followed for lighting fixtures or covers.</p>	<p>Structural surfaces (eg, doors, floors, walls, ceilings, cabinets, shelves, work surfaces), furniture (eg, tables), and equipment in the endoscopy processing room, procedure rooms, and patient care areas should be smooth and made of materials that are water resistant, stain resistant, and able to withstand frequent cleaning.</p> <p>Structural surfaces that are smooth and able to withstand frequent cleaning ease the cleaning process. A clean environment will reduce the number of microorganisms present.</p> <p>Processes and procedures for environmental cleaning in the endoscopy suite should be carried out in accordance with the AORN Guideline for Environmental Cleaning</p>	Not specifically mentioned		
Certification of Personnel/ Competency	<p>Demonstrate competency for all steps of endoscope reprocessing, including proper use of automatic endoscope reprocessing systems and other equipment at least annually</p> <p>Undergo more frequent validation of competency for specialty endoscopes that are used infrequently;</p>	<p>It is recommended that all personnel performing processing of endoscopes be certified as a condition of employment. At a minimum, personnel should complete a certification exam.</p> <p>NOTE—Information concerning education, training, and/or certification of endoscopy technicians with processing duties, sterile processing managers, and technicians can be obtained from the</p>	<p>Personnel with responsibility for processing flexible endoscopes should receive initial and ongoing education and complete competency verification activities related to processing flexible endoscopes.</p>	<p>Certification in reprocessing of endoscopes does not mitigate the need for orientation, ongoing education training/education and competency assessments.</p> <p>1. Education and training should include the rationale for each of the seven essential steps of reprocessing outlined in this document. Training and competency assessments should</p>		

<p>Certification of Personnel/ Competency (Cont.)</p>	<p>□ Complete reprocessing training with documented competency for new models of endoscopes, accessories, valves, and automatic endoscope reproprocessors as soon as they are introduced in the facility (AAMI, 2015; AORN, 2015);</p>	<p>Certification Board for Sterile Processing and Distribution (CBSPD, www.sterileprocessing.org); the Society of Gastroenterology Nurses and Associates (SGNA, www.sgna.org); and the International Association of Healthcare Central Service Materiel Management (IAHCSMM, www.iahcsmm.org).</p>		<p>be based upon the endoscope manufacturer’s IFUs as well as the reprocessing equipment and chemicals used. If more than one type/model of endoscope is used, staff should be able to demonstrate they are competent to reprocess each specific type of endoscope.</p> <ul style="list-style-type: none"> •Model-specific competency assessment check lists may be required. •Post visual educational aids and standard operating procedures to reinforce best reprocessing practices. <p>2.Education and training should also address decontamination, cleaning and sterilization of reusable accessories that breach the mucosal barrier (e.g., biopsy forceps).</p> <p>3.Ensure that trainers and managers are competent to reprocess endoscopes and are able to adequately train and verify the competency of their staff.</p> <p>4.Perform staff competencies:</p> <ol style="list-style-type: none"> a.Initially upon hire and periodically as required by facility policy. An educational update followed by direct observation of staff performing endoscope reprocessing is recommended. b.Whenever a new model of endoscope, reprocessing equipment (e.g., AER, leak tester), or chemical is purchased. c.Whenever there are updates to the manufacturer’s IFUs. d.That include essential steps of reprocessing from pre-clean to storage and documentation. e.That include a review of procedures to be followed in the case of equipment failure (e.g., use of manual reprocessing methods as per manufacturer’s IFU or use of an 		
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				alternative automated reprocessor that is validated for the endoscope). f. That include how and when to perform supplemental testing or other assessments of endoscope		
Process or Equipment Change	SGNA Recommendation	ANSI/AAMI ST-91 Standard	AORN 2016 Endoscopy Guideline	CDC Essential Elements of a reprocessing program 2016	Health system Implementation	Deadline for Compliance
Certification of Personnel/ Competency (Cont.)				cleaning (e.g., tests that measure residual organic material or adenosine triphosphate) when those tests are used by the facility.		
Culturing of Duodenoscopes and other elevator type scopes.	<p>Routine culturing of endoscopes following reprocessing is not currently recommended in the United States but may be considered in the event of an identified outbreak (Petersen et al., 2011). Surveillance cultures can be used as a method for assessing reprocessing quality (Frohlich, Leiss, & Muller, 2013; Kovaleva, Peters, van der Mei, & Degener, 2013; Rutala & Weber, 2015) and aid in identifying particular endoscope defects that hamper effective reprocessing (Buss et al., 2007; Rutala & Weber, 2015).</p> <p>Facilities should be aware of recent interim guidelines and consider culturing duodenoscopes to validate the cleaning process of these particular scopes (CDC, 2015).</p>	<p>Cleaning verification of flexible and semi-rigid endoscopes by users should include:</p> <p>a) Visual inspection combined with other verification methods (see Section 12.4.3) that allow the assessment of both external surfaces and internal housing and channels.</p> <p>b) Testing of the cleaning efficacy of mechanical equipment.</p> <p>c) Monitoring of key cleaning parameters (e.g., temperature).</p> <p>Studies have shown that when cleaning tubular devices, the achievement of visible cleanliness and adequate microbial reduction varies greatly, depending on the type of water and cleaning solution used for cleaning. The variability of results for lumens cleaned by automated washers underscores the importance of in-use verification for manual cleaning, which is generally less efficient than mechanical cleaning (Zuhlsdorf et al. 2002).</p> <p>Several methods can be used to evaluate the results of the cleaning process. The most common is visual inspection. Careful visual inspection should be conducted to detect the presence of any residual soil. Inspection using magnification and additional illumination might identify residues more readily than the unaided eye. Users should</p>	<p>A multidisciplinary team that includes infection preventionists, endoscopists, endoscopy processing personnel, microbiologists, laboratory personnel, risk managers, and other involved individuals should evaluate the need to implement a program for regular microbiologic surveillance cultures of flexible endoscopes and mechanical processors.</p> <p>A program of regular microbiological surveillance culturing of flexible endoscopes and mechanical processors is advised in the processing guidelines of several international organizations, including the combined Gastroenterological Society of Australia (GESA), Gastroenterological Nurses College of Australia (GENCA), and Australian Gastrointestinal Endoscopy Association (AGEA), the combined ESGE and European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) committee, and the Steering Group for Flexible Endoscope Cleaning and Disinfection (SFERD).</p> <p>Routine surveillance microbiological culturing is supported in the literature as an effective method for monitoring the effectiveness and quality of processing, reinforcing best practices,</p>	<p>Microbiological culturing and quarantine until negative culture</p>		

<p>Culturing of Duodenoscopes and other elevator type scopes. (Cont.)</p>		<p>inspect every device for visible organic soil and contamination in a simple functionality test.</p> <p>Direct visual inspection is not always possible for the inner components of medical devices that have lumens or that are of nonsealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, and biopsy forceps). Tools such as video boroscopes of an appropriate dimension (length and diameter) may be used to visually inspect the internal channels of some medical devices.</p>	<p>evaluating the effectiveness of corrective interventions, and detecting endoscopes requiring service</p>			
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