

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

Purpose: Facilities can use this sample Audit Tool document as a template to develop their own audit tool specific to their endoscopes and evidence-based reprocessing practices. This sample tool is designed to be used in conjunction with the Competency Verification Tool. Facilities are encouraged to use these tools together to verify competency and audit current practice as well as to ensure that their practices are consistent with “Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee.”

Auditor: _____

Date: _____

Audit Item	Yes	No	Comments/Action
Precleaning			
Precleans the flexible endoscope at the point of use.			
Discards the cleaning solution and cloth after use.			
Transporting			
Transports the contaminated endoscope and accessories to the endoscopy processing room as soon as possible after use.			
Ensures the container or cart is labeled with a biohazard legend.			
Leak Testing			
Performs leak testing before manual cleaning if indicated.			
Manual Cleaning			
Uses a freshly prepared cleaning solution and does not add additional products to the water unless recommended by the manufacturer.			
Completely submerges the endoscope and accessories.			
Cleans exterior surfaces of the endoscope with a soft, lint-free cloth or sponge.			
Cleans all accessible channels and the end of the endoscope with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer.			
Uses a clean brush for each endoscope cleaning.			
If the endoscope has an elevator, raises and lowers the elevator throughout the manual cleaning process.			
Brushes the accessible channels until no debris appears on the brush.			
Removes debris before retracting the brush back through the endoscope.			
Flushes the channels of the endoscope with the cleaning solution.			
Manually actuates the valves during the cleaning process.			
Flushes and rinses exterior surfaces and internal channels with water until all cleaning solution and residual debris is removed.			
Dries exterior surfaces and removable parts of the endoscope and purges all channels with air.			
Reprocesses reusable parts, accessories, and cleaning implements according to the manufacturer’s instructions for use (IFU).			
Disposes of single-use parts, accessories, and cleaning implements.			

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Audit Item	Yes	No	Comments/Action
Inspection			
Inspects and evaluates endoscopes and accessories for <ul style="list-style-type: none"> • cleanliness 			
<ul style="list-style-type: none"> • missing parts 			
<ul style="list-style-type: none"> • clarity of lenses 			
<ul style="list-style-type: none"> • integrity of seals and gaskets 			
<ul style="list-style-type: none"> • physical or chemical damage 			
<ul style="list-style-type: none"> • moisture 			
<ul style="list-style-type: none"> • function 			
Uses additional illumination and magnification for inspection, as needed.			
High-level Disinfection or Sterilization			
Manually cleans the endoscope and accessories before mechanical or manual high-level disinfection or sterilization.			
<i>Mechanical methods</i>			
Checks the expiration date of the high-level disinfectant or liquid chemical sterilant before each use.			
Uses a test strip or other FDA-cleared testing device specific to the disinfectant or liquid chemical sterilant and minimum effective concentration of the active ingredient for monitoring solution potency before each use.			
Positions endoscopes and accessories within the mechanical processor to ensure contact of the processing solutions with all surfaces of the endoscope.			
Connects the endoscope to the mechanical processor correctly.			
Verifies mechanical processing cycles are completed as programmed.			
<i>Manual methods</i>			
Checks the expiration date of the high-level disinfectant before each use.			
Uses a test strip or other FDA-cleared testing device specific to the disinfectant and minimum effective concentration of the active ingredient for monitoring solution potency before each use.			
Flushes and fills lumens and ports with the high-level disinfectant.			
Completely immerses the endoscope in the high-level disinfectant solution for the designated time according to the device and high-level disinfectant solution manufacturer's IFU.			
Rinses the endoscope with water that meets the manufacturer's specification or as recommended by professional organizations after disinfection.			
<i>May be required for both mechanical and manual methods</i>			
Flushes lumens using 70% to 90% ethyl or isopropyl alcohol according to the endoscope manufacturer's IFU.			
Dries exterior surfaces and removable parts of the endoscope and purges all channels with air.			

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Audit Item	Yes	No	Comments/Action
<p>Sterilization</p> <p>Packages and sterilizes endoscopic accessories that enter sterile tissue or the vascular system per the health care facility's policy and procedure.</p>			
<p>Storage</p>			
<p>Wears clean gloves when transporting the endoscope to and from the storage cabinet.</p>			
<p>Based on the cabinet design, stores flexible endoscopes horizontally or hangs them vertically so they do not coil or touch the floor of the cabinet.</p>			
<p>Stores the flexible endoscope with all valves open and removable parts detached.</p>			
<p>Stores sterile items in a sterile storage area.</p>			
<p>Records</p>			
<p>Processing records include</p>			
<ul style="list-style-type: none"> • date and time 			
<ul style="list-style-type: none"> • identity of endoscope and endoscope accessories 			
<ul style="list-style-type: none"> • method and verification of cleaning and results of cleaning verification testing 			
<ul style="list-style-type: none"> • number or identifier of the mechanical processor or sterilizer and results of process efficacy testing 			
<ul style="list-style-type: none"> • identity of the persons performing the processing 			
<ul style="list-style-type: none"> • lot numbers of the processing solutions 			
<ul style="list-style-type: none"> • disposition of defective items or equipment 			
<ul style="list-style-type: none"> • maintenance of water systems, endoscopes and endoscope accessories, and processing equipment 			
<p>Procedural records include</p>			
<ul style="list-style-type: none"> • date and time 			
<ul style="list-style-type: none"> • identity of the patient 			
<ul style="list-style-type: none"> • procedure 			
<ul style="list-style-type: none"> • identity of the licensed independent practitioner performing the procedure 			
<ul style="list-style-type: none"> • identity of the endoscope and endoscope accessories used 			

Available from: <https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html>