Example Policy for Enhanced Visual Inspection for Flexible Endoscopes

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Note: This document is an example of a policy that may be instituted in a health-care facility for enhanced visual inspection of flexible endoscopes. The actual policy in a facility must be based on variables, logistics and risk-assessments that are specific to your facility.

Subject: Enhanced Visual Inspection of Flexible Endoscopes

Department: Endoscopy Reprocessing Area or GI department

Approved By: [Name of Department Supervisor]

Effective: [Enter date when this will take effect]

Revised: June 2021

Purpose: The purpose of this example policy is to provide a means of inspecting the condition of flexible endoscopes with an enhanced visual inspection method (i.e.: magnification, flexible inspection scopes [borescopes], and cameras), as part of a departmental quality improvement process to ensure items are clean, functional, and can proceed to their next step in their reprocessing cycle.

Policy: The endoscopy reprocessing manager (or their designee) shall be responsible for selecting the type of endoscopes and the frequency of the monitoring of those products by enhanced visual inspection.

Rationale: Inspecting an item for it to be visually clean is the minimum standard for processing flexible endoscopes. If an item is identified as being dirty, then it must be sent back through the cleaning process and inspected again. Endoscope processing professionals must make sure all endoscopes are clean and functional before they are high-level disinfected (HLD) or sterilized.

Using some form of magnification to enhance the visual inspection process (*enhanced visual inspection)*, such as a hand-held magnifier and/or borescope to inspect medical devices for defects:

- functionality
- pitting
- stains
- imperfections on the item during its processing cycle

and rejecting medical devices, according to their IFUs, if any imperfections are found. These things are essential to providing a clean and functional endoscope.

National processing standards, professional society guidelines, and regulatory bodies recommend the use of visual and enhanced inspection of flexible endoscopes at all steps in the process, but a thorough inspection with lighted magnification should be performed after manual cleaning prior to HLD or sterilization. The term *visual clean* will be defined by referencing the IFU of the endoscope being inspected. *Note: this could be different for each endoscope being inspected.*

It is important to document whether magnification was used in the endoscope reprocessing record as a task performed to ensure the endoscope is clean and functional.

Standards And Professional Society Recommendations:

1. **ANSI/AAMI ST91:2015, Flexible and semi-rigid endoscope processing in health care facilities**

   According AAMI ST91 [1], healthcare facilities should establish a comprehensive quality assurance and safety program to monitor all aspects of endoscope processing. This program should incorporate both visual inspections and testing of the equipment to identify conditions that may affect the cleaning or disinfecting processes.

   Simply viewing with the naked eye may not be enough to rate the efficacy of cleaning processes. Enhanced visualization methods, including inspection with a borescope (i.e.: Flexible Inspection Scope [FIS]), are being incorporated into current standards and recommendations.

   Visual inspection of the equipment should include the following:
   - Residual organic soil
   - Cracks and other damage to the instrument
   - Integrity of fiber optic bundles
   - Use of magnification

2. Both ST91 [1] and AORN Endoscope Reprocessing Guidelines [2] state to consider inspection with borescope. According to ST91, inspection using magnification and additional illumination might identify residues more readily than the unaided eye.
   - Tools, such as video borescopes of an appropriate dimension (length and diameter), may be used to visually inspect the internal channels of some medical devices.
   - Methods able to quantitatively or chemically detect organic residues, undetectable using visual inspection, should be considered and included in facility policies and procedures on device cleaning.

3. According to AORN VII.c.1., "Internal channels of flexible endoscopes may be inspected using an endoscopic camera or borescope. [2: High Evidence] Endoscopic cameras and borescopes penetrate the lumen and allow for improved visual inspection."[2]

4. In AAMI ST79 [3], *visual inspection* is described as a verification of the cleaning process. Section 7.6.4.5 states the following:

    - After completing the cleaning process, personnel should visually inspect each item carefully to detect any visible soil
    - Inspection using enhanced visualization tools such as lighted magnification and video borescopes might identify residues not observable by the unaided eye
    - Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure or detect organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures (see Annex D for available methods).

5. Also, the IAHCSMM Endoscope Reprocessing Manual [4] 2017 states the following:

    - "The most important areas for inspection are the lumens that run through the endoscope. Lumens pose a cleaning challenge because of their narrow structure that prevents visualization during the cleaning; 'therefore, it is important to always check lumens for cleanliness after cleaning. Visual inspection of lumens can be accomplished using a borescope, a small flexible fiberoptic device that enables visualization of otherwise inaccessible areas within endoscope lumens."

6. According to the SGNA Position Statement on Management of Endoscopic Accessories, Valves, and Water and Irrigation Bottles in the Gastroenterology Setting[5], "A comprehensive quality control program for reusable medical devices should be implemented and include, but not limited to the following:
    - "Visual inspection and equipment testing to identify conditions that may affect the cleaning or disinfection process. Damaged reusable items should be removed from use. Follow facility protocol for returning device.
    - "Procedures for monitoring the useful life of medical devices that include visual inspection, scheduled maintenance, and removal of equipment from use based on manufacturer's guideline."

7. The CMS ASC Infection Control Surveyor Worksheet [6] and the CMS Survey and Cert Worksheets [7] state that surveyor should be looking for the following steps to be performed in facilities.

    a. Section 3.A.6 states, "Flexible endoscopes are inspected for damage and leak tested as part of each reprocessing cycle." [6]

b. Section 3.B.5's worksheet reads, "Items are thoroughly pre-cleaned according to the manufacturer's instructions and visually inspected for residual soil prior to sterilization." [7]

Procedure:

The Endoscopy Reprocessing Manager (or designee) determines the type of endoscopes to be visually inspected using enhanced magnification and the frequency at which inspection should occur. Dirty endoscopes pose a potential risk not only to patients but to processing staff. Endoscopes visibly dirty will be sent back to be re-cleaned according to the manufacture's IFU. All inspection results are recorded to give data to the Processing staff to monitor and improve their cleaning process (problem analysis).

While many facilities use a borescope for endoscope inspection after manual cleaning, and prior to disinfection or sterilization, some facilities periodically choose to inspect endoscopes with a borescope *after* the reprocessing is complete—as a quality monitoring tool. If this is the case, then the endoscope must go back through the reprocessing cycle.

After each inspection, the FIS (borescope) is to be cleaned and disinfected/sterilized between uses. *(Note: Different models of borescopes have different reprocessing compatibilities. Consult the IFU or supporting documentation, respectively*.). Place the protective cap over the borescope lens when not in use to protect the distal tip from damage.

Areas to inspect:

According to AORN [2], visual inspection is described as a verification of the manual cleaning process. Endoscopes, accessories, and equipment should be visually inspected and evaluated for:

- Cleanliness
- Missing parts
- Clarity of lenses
- Integrity of seals and gaskets
- Moisture
- Physical or chemical damage
- Function.

Visual inspection and evaluation help detect the presence of residual soil and identify items in need of repair.

External: The entire endoscope should be visually inspected externally with the naked eye and lighted magnification in accordance with national standards and professional society guidelines.

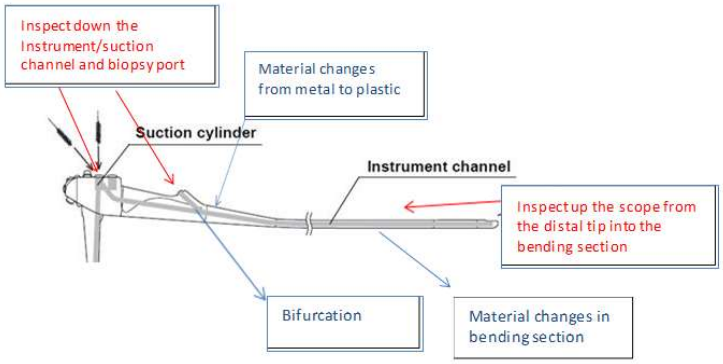
- Note any debris or damage
- Reclean the endoscope if debris is found

- Assess the condition of the endoscope in accordance with facility policy to determine if repair is needed.
- Do not use a damaged endoscope

Internal: There are many areas in an endoscope, which can be inspected with a borescope including the:

- Instrument suction channel through the biopsy channel
- Channel openings/valve housings
- Distal tip
- Forceps elevator recess on duodenoscopes.

Additionally, as shown below, there are some other suggested areas that might be considered for inspection on a flexible endoscope:



An example of a log sheet to record enhanced visual inspection is included with this policy. This can also be done if you have a computer system and considered a task to be completed before going on to the next task.

Responsibility:

The Endoscope Processing Manager (or designee) is responsible for assuring staff training, initiation, completion, documentation, and analysis of the enhanced visual inspection policy for the department.

The manager of the Endoscopy Reprocessing Area will determine when and what type of magnification (handheld, bench magnifier, borescope, etc.) that should be used to inspect endoscopes within their process.

Inspection Table (Results of Visual Inspection)

Date of Inspection	Inspector initials	Endoscope model / serial number	Visual Clean * Yes / No Damage ** Yes / No	Comment
			Visual Clean Yes / No Damage Yes / No	
			Visual Clean Yes / No Damage Yes / No	
			Visual Clean Yes / No Damage Yes / No	
			Visual Clean Yes / No Damage Yes / No	
			Visual Clean Yes / No Damage Yes / No	
			Visual Clean Yes / No Damage Yes / No	
			Visual Clean Yes / No Damage Yes / No	

*If an endoscope is found to be visually dirty (unclean) by inspection, it must be sent back to be re-cleaned and then re-inspected until visually clean to proceed to the next step in its reprocessing cycle.
**If an endoscope is found to be damage, it must be taken out of use and assessed to determine if it must be sent out for repair.

Comments:

_____
_____
_____

Example: General Competency Record for Visual Inspection of Endoscopes

Name:

Competency Statement: Complies with policy and procedure for "List name of specific policy here"

Key
1 = Performs independently and consistently. Ask for assistance in new situations.
2 = Performs with minimal guidance and direction. Asks for assistance when necessary.
3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

Comments:

_____
_____
_____
_____
_____
_____

Competency Achieved: _____ Date:_____

Evaluator: _____

Learner: _____

Note: Because there are different methods/equipment that can be used to visually inspect medical devices this is a generic competency, and the user must select the correct inspection device for that specific medical device that will need enhanced visual inspection

Critical Behaviors Table

Critical Behaviors	1	2	3
Review Hospital Policy on visual inspecting endoscopes and the enhanced visual method of inspecting.			
Describes the purpose of visually inspecting endoscopes.			
Gather appropriate supplies and equipment to perform the task of visually inspecting endoscopes (flexible inspection scope, magnifying glass with illumination, etc.).			

Read the specific instructions for use on the endoscope you are going to inspect.			
First, visually inspect the endoscope with your natural eyesight and light. If the scope is visually dirty, re-clean it according to its specific IFU.			
If the policy states to use enhanced inspection beyond the unaided eye, such as a lighted magnified, use it to inspect the endoscope. If the device is found to be clean, follow the IFU for the next step in the process; if found dirty send back to be re-cleaned according to the IFU.			
If the policy states to inspect with a borescope, use it to inspect the internal channel of the endoscope. If the device is found to be clean and in good condition, follow the IFU for the next step in the process; if found dirty send back to be re-cleaned according to the IFU. If the device is found in a state of disrepair, pull from service, and assess the condition further to determine if repair is needed. NOTE: Some facilities choose to inspect with a borescope after the reprocessing is complete as a quality monitoring tool. If this is the case, the endoscope must go back through the reprocessing cycle.			
Document all results of the inspection on a log sheet, record book or electronic system. Sometimes this documentation entails the serial and model number of the device checked with enhanced visual inspection is recorded.			

*****_Follow Healthcare Facility Policy on enhanced visual inspection of medical devices and always follow manufactures guidelines (IFU) on inspecting medical devices._

Sample Competency Record for the Healthmark Flexible Inspection Scope (Borescope)

Name:

Competency Statement: Complies with policy and procedure for "…list policy here"

Key
1 = Performs independently and consistently. Ask for assistance in new situations.
2 = Performs with minimal guidance and direction. Asks for assistance when necessary.
3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

Comments:
_____
_____
_____
_____
_____

Competency Achieved: _____ Date: _____

Evaluator: _____

Learner: _____

This is a general competency that can be used for training staff on the proper use of the Healthmark Flexible Inspection Scope. This competency can be adjusted according to each facility specific requirement.

Critical Behavior Table

Critical Behaviors	1	2	3
Review Hospital Policy on visual inspecting endoscopes using the Flexible Inspection Scope			
Describes the purpose of visually inspecting endoscopes using the Flexible Inspection Scope			
Read / review the specific instructions for the Healthmark Flexible Inspection Scope			
Gather appropriate supplies/equipment to perform the task of internally inspecting the endoscopes with the Flexible Inspection Scope			

Selects appropriate endoscopes for inspection with flexible inspection scope (i.e., the borescope will fit down the channel of the endoscope).			
First visually inspect the medial device with your natural eyesight and light. If the device is visually dirty, re-clean it according to its specific IFU.			
If medical device is visually clean by natural eyesight and light proceed to the form of enhanced visual inspection.			
Before using the Flexible Inspection Scope on the medical device, you must demonstrate the following.			
Ensures scope is plugged in to a USB 2.0 plug before opening software.			
Ensure that the icon for the Flexible Inspection Scope short cut is on the computer screen			
Double clicks on Healthmark software icon to run program.			
The program will than recognize that a Flexible Inspection Scope is properly hooked up and you can than proceed.			
Demonstrates illumination feature, photo capture, record, and review feature by clicking on software icons or scope buttons.			
Inserts scope tip into lumens and demonstrates 100-degree view of lumen by maneuvering scope through lumen, avoiding any restrictive areas that may damage the scope tip.			
Use the FIS borescope to inspect the internal channel of the endoscope. If the device is found to be clean and in good condition, follow the IFU for the next step in the process; if found dirty send back to be re-cleaned according to the IFU. If the device is found in a state of disrepair, pull from service, and assess the condition further to determine if repair is needed. Note: While some facilities choose to inspect with a borescope after reprocessing is complete and the scope is in storage as a quality monitoring tool, other facilities use it after the manual cleaning process prior to disinfection or sterilization. Use			

the borescope at the step in the process that your facility has designated as appropriate. If the borescope is used on processed endoscopes, the endoscope must go back through the reprocessing cycle.			
After each inspection, clean and disinfect/sterilize the Flexible Inspections Scope in accordance with its IFU. Note: different models of borescopes have different reprocessing compatibilities. Place the protective cap over the lens when not in use to protect the distal tip from damage			
Document all results of the inspection on a log sheet/record book/electronic. This documentation may entail the serial and model number of the endoscope checked with the Flexible Inspection Scope. Follow your facilities policy on documentation.			

References:

1. ANSI/AAMI ST91:2015. Flexible and semi-rigid endoscope processing in health care facilities.

2. AORN GUIDELINE FOR PROCESSING FLEXIBLE ENDOSCOPES, Revised February 2016 for publication in Guidelines for Perioperative Practice, 2016 edition.

3. ANSI/AAMI ST79:2017. Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

4. IAHCSMM Endoscope Reprocessing Manual, 1st Edition. 2017.

5. SGNA POSITION STATEMENT: Management of Endoscopic Accessories, Valves, and Water and Irrigation Bottles in the Gastroenterology Setting. 2018. Available at: https://www.sgna.org/Portals/0/Management%20Endoscopic%20Accessories%20Valves%20Water%20Irrigation%20bottles.pdf?ver=2018-08-20-141307-367

6. CMS audit worksheet: Exhibit 351 Ambulatory Surgical Center (ASC) INFECTION CONTROL SURVEYOR WORKSHEET (Rev: 142, Issued: 07-17-15, Effective: 07-17-15, Implementation: 07-17-15).

7. Centers for Medicare & Medicaid Services. Hospital Infection Control Worksheet. CMS Survey and Cert Letter 15 12.