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: May 2022

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 (e.g., magnification, flexible inspection scopes [FIS/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 process for *enhanced visual inspection* (e.g., hand-held magnifier and/or borescope), to inspect medical devices for defects:

- functionality
- pitting
- stains
- imperfections on the item during its processing cycle
- Rejecting medical devices, according to their instructions for use (IFU)s, 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. *Be aware that 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 ST91:2021, Flexible and semi-rigid endoscope processing in health care facilities

   According to AAMI ST91[1], "Healthcare facilities should establish a multidisciplinary, comprehensive written quality assurance and safety program for all aspects of endoscope processing. The program should include procedures visual inspection and testing of the equipment and ancillary parts to identify conditions that could affect the cleaning or disinfecting process."

   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 will identify residues and/or more readily than the unaided eye."
   - Tools, such as video borescopes of an appropriate dimension (length and diameter), can be used to visually inspect the accessible internal channels and document their condition.
   - Methods able to quantitatively or chemically detect organic residues that are undetectable using visual inspection should be implemented.
   - 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]

3. 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).

4. Also, the HSPA Endoscope Reprocessing Manual[4] 2022 states,
"Endoscopes have many internal components. The lumens (channels) that run through the endoscope are important areas for inspection. Lumens pose a challenge because their narrow structure prevents visualization during cleaning; it is important therefore, 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."

5. 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 [Mfr.'s] guideline."

6. 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.
    - Section 3.A.6 states, "Flexible endoscopes are inspected for damage and leak tested as part of each reprocessing cycle." [6]
    - 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. Visibly dirty endoscopes will get sent back to be recleaned, according to the manufacturer'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 (as a quality monitoring tool) *after* the reprocessing is complete. 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 inspectable with a borescope, including:

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

Additionally, (Fig. 1) there are some other suggested areas that might be considered for inspection on a flexible endoscope.

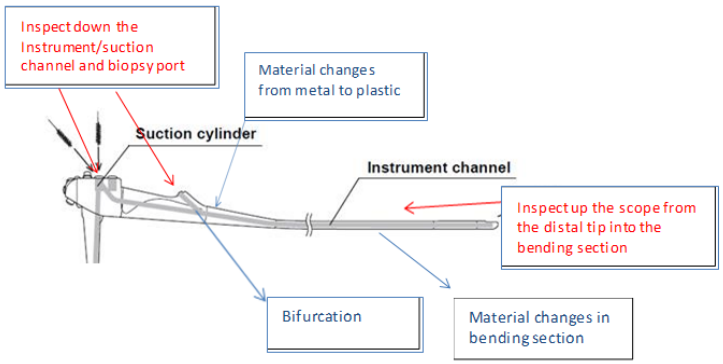

Figure 1.

Responsibility:

The Endoscope Processing Manager (or designee) is responsible for assuring a) staff training, b) initiation, c) completion, d) documentation, and e) 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 (e.g., handheld, bench magnifier, borescope, etc.) should be used to inspect endoscopes within their process.

An example of a log sheet 'Inspection Table (Results of Visual Inspection' 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.

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 inspected endoscope is found visually dirty (unclean), it must be recleaned and then re-inspected until visually clean to proceed to the next step in its reprocessing cycle.
**If an endoscope is found to be damaged, 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. Asks 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 (i.e., FIS, 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, reclean it according to its specific IFU.			
If the policy states to use enhanced inspection beyond the unaided eye (e.g., lighted magnified, etc.) use it to inspect the endoscope. If the device is found to be: • Clean- follow the IFU for the next step in the process. • Dirty- send back to be recleaned 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/in good condition, follow the IFU for the next step in the process. • Dirty, send back to be recleaned according to the IFU. • 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. Documentation may entail recording the serial and model number of the device checked with enhanced visual inspection.			

**Follow the healthcare facility policy on enhanced visual inspection of medical devices and always follow Mfr.'s 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. Asks 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 FIS. 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 FIS.			
Read/review the specific instructions for the Healthmark FIS.			
Gathers supplies/equipment to perform internal inspecting of the endoscopes with the FIS.			
Selects appropriate endoscopes for inspection with FIS (i.e., the borescope will fit down the channel of the endoscope).			
First, visually inspect the medical device with your natural eyesight and light. If the device is visually dirty, reclean 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 FIS on the medical device, you must demonstrate the following: • Scope is plugged in to a USB 2.0 plug before opening software. • Flexible Inspection Scope short cut icon is on the computer desktop screen. • Double click on Healthmark software icon to run program. • Software recognizes a FIS is properly connected to continue. • Clicking on software interface or scope buttons make the a) illumination feature, b) photo capture, c) record, and d) review feature work.			
Inserts scope tip into lumens to demonstrate 100 degree (100°) view by maneuvering scope through lumen, while 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. • Dirty- send back to be recleaned according to the IFU. • In a state of disrepair- pull from service and assess the condition further to determine if repair is needed. Note: • Some facilities may choose to inspect scopes in storage (after reprocessing is completed) with a borescope as a quality monitoring tool. Other facilities use the borescope 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 FIS 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 system. Documentation may entail recording the serial and model number of the endoscope checked with the FIS. Follow your facilities policy on documentation.			

References:

1. AAMI. (2021). *ANSI/AAMI ST91:2021. Flexible and semi-rigid endoscope processing in health care facilities*. Association for the Advancement of Medical Instrumentation (AAMI).

2. AORN. (2016). *Guideline for Processing Flexible Endoscopes. Guidelines for Perioperative Practice* [section VI]. The Association of periOperative Nurses (AORN).

3. AAMI. (2017). *ANSI/AAMI ST79:2017. Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Association for the Advancement of Medical Instrumentation (AAMI).

4. HSPA. (2022). Endoscope Reprocessing Manual (2nd ed.). Healthcare Sterile Processing Association (HSPA).

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

6. Centers for Medicare & Medicaid Services (CMS). (2015, July 17). *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]. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf.

7. Centers for Medicare & Medicaid Services (CMS). (2014, September). *Hospital Infection Control Worksheet*. CMS Survey and Cert Letter 15 12. https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf.