# HICPAC Sample Gap Analysis and Risk Assessment Tools: Reprocessing Flexible Endoscopes

**Purpose:** Facilities can use these sample Gap Analysis and Risk Assessment Tools as templates to develop their own quality improvement tools to be used in conjunction with a complete facility flexible endoscope inventory and the manufacturer’s instructions for use (IFU) for each flexible endoscope. These sample tools are intended to be modified to align with facilities’ specific needs. When combined, they will assist facilities in determining if their flexible endoscope reprocessing practices are high-quality and reliable, minimize infection risk, and are consistent with “Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee.” If reprocessing practices are found to have gaps, the tools will help facilities determine where those gaps are and help them create a prioritized plan of action to address and ameliorate them. A Gap Analysis and Risk Assessment should be conducted periodically and:

1. whenever new flexible endoscopes are purchased;
2. when manufacturer’s IFU change; and
3. when guidance from professional and regulatory organizations changes.

## Gap Analysis

A gap analysis is a way for facilities to determine if facility endoscope reprocessing practices are aligned with best practices and manufacturer’s IFU and to determine if a plan of action should be created to move from current practices to implementation of best practices for scope processing. Gap analyses have also been called need-gap analyses, needs analyses, and needs assessments.

A gap analysis consists of:

1. A list of best practices for endoscope reprocessing and the supporting facility structure necessary to execute these practices.
2. Determination if the facility practice meets the identified best practice.
3. If current facility practice differs from the cited best practice, note any documentation (professional organization, federal agency, or certifying body) supporting the current facility practice.
4. An assessment of whether the facility practice is insufficient to assure high-quality, reliable reprocessing of flexible endoscopes that minimizes infection risk.
5. A list of barriers to implementation of the best practice, if any.

This gap analysis supports the HICPAC Essential Elements of Endoscope Reprocessing, so it identifies the Essential Elements as best practices. However, this gap analysis is modifiable to encourage a facility to add in the individual manufacturer’s IFU and, if necessary, to adapt this template to reflect the different best practice resources a facility may already have in use.

To use the gap analysis below:

1. Analyze how current process matches up with all manufacturer recommendations for cleaning, processing, transporting and storage for each type of scope currently used.
2. Identify deficiencies: How do current practice differ from best practices and manufacturer recommendations?
3. Determine if sufficient resources exist within the facility to comply with all manufacturer recommendations.
4. Determine what additional resources are needed in order to comply with manufacturer recommendations. (This may mean updating equipment, purchasing new equipment, purchase of proper storage or transport containers).
5. Seek input from staff doing the processing to be sure all information is obtained.
6. Determine which areas of the process need improvement.

## Sample Gap Analysis Tool: Reprocessing Flexible Endoscopes

### Essential Steps for Flexible Endoscope Reprocessing

Completed by: Date completed:

| **Essential Elements of Endoscope Reprocessing** | **Practice Meets Element (Y/N)** | **Facility Practice & Supporting Documentation (if any)** | **Deficiency Identified? (Y/N)** | **Barriers to Implementing Essential Element** |
| --- | --- | --- | --- | --- |
| Pre-cleaning |  |  |  |  |
| Is pre-cleaning performed at point-of-use, immediately following completion of the endoscope procedure? |  |  |  |  |
| Are flexible endoscopes and reusable accessories pre-cleaned following the device manufacturer’s instructions for use (IFU)?  |  |  |  |  |
| Are the pre-cleaned endoscopes placed in rigid container labeled as BIOHAZARD for transport to the reprocessing area? |  |  |  |  |
| **Leak Testing (for endoscopes** that require leak **testing)** |  |  |  |  |
|  Is the leak test performed using manufacturer’s IFU after each use and prior to manual cleaning? |  |  |  |  |
| Manual Cleaning |  |  |  |  |
| Is meticulous manual cleaning performed according to manufacturer's IFU before performing high-level disinfection (HLD) or sterilization? |  |  |  |  |
| Does manual cleaning include brushing and flushing channels and ports consistent with the manufacturer’s IFU?  |  |  |  |  |
| Is manual cleaning performed within the timeframe specified in the manufacturer’s IFU? |  |  |  |  |
| Visual Inspection  |  |  |  |  |
| Are the endoscope and its accessories visually inspected after manual cleaning?  |  |  |  |  |
| Disinfection or Sterilization |  |  |  |  |
| Is HLD or sterilization performed in accordance with the manufacturer’s IFU following cleaning and visual inspection? |  |  |  |  |
| Are the endoscope manufacturer’s reprocessing instructions for disinfection and sterilization carefully reviewed and adhered to?  |  |  |  |  |
| Are the IFU for chemicals or sterilants used for reprocessing carefully reviewed and adhered to? |  |  |  |  |
| Are the manufacturer's IFU for any equipment used for reprocessing (e.g., automated endoscope reprocessors) carefully reviewed and adhered to? |  |  |  |  |
| When conducting the risk assessment or gap analysis, if an AER is used, is there documentation that the AER has been validated for reprocessing the endoscope and endoscope components?  |  |  |  |  |
| Is compatibility verified for the model-specific reprocessing protocols for both the endoscope and AER? |  |  |  |  |
| Storage |  |  |  |  |
| Are endoscopes and accessories stored in a manner that prevents recontamination, protects the equipment from damage, and promotes drying?  |  |  |  |  |
| Is the endoscope storage cabinet of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without touching the bottom of the cabinet? |  |  |  |  |
| If the answer to the storage cabinet question is no, is the cabinet designed and intended by the manufacturer for horizontal storage of flexible endoscopes? |  |  |  |  |
| Documentation |  |  |  |  |
| Is documentation of adherence to these essential steps maintained for each time an endoscope is reprocessed? |  |  |  |  |

### Essential Elements of a Reprocessing Program for Flexible Endoscopes

| **Essential Elements of Endoscope Reprocessing** | **Practice Meets Element (Y/N)** | **Facility Practice & Supporting Documentation(if any)** | **Deficiency Identified? (Y/N)** | **Barriers to Implementing Essential Element** |
| --- | --- | --- | --- | --- |
| Administrative |  |  |  |  |
| Has leadership allocated sufficient human and material resources to ensure that the selection, use, and reprocessing of endoscopes and related accessories are managed in a manner that minimizes infection risk and supports patient and healthcare worker safety? |  |  |  |  |
| Is leadership supporting and empowering the authority of those responsible for managing infection prevention practices to ensure effectiveness of the program? |  |  |  |  |
| Does leadership ensure that the essential elements of an endoscope reprocessing program are followed and that endoscopes are reprocessed according to manufacturers’ IFU?  |  |  |  |  |
| Are gap analyses and risk assessments conducted periodically and whenever new endoscopes are purchased, manufacturer’s IFUs change, and when changes occur in guidance from professional and regulatory organizations? |  |  |  |  |
| Policies  |  |  |  |  |
| Have endoscope reprocessing policies been developed by a multidisciplinary team that includes physicians, nurses, endoscope reprocessing personnel, infection preventionists, and other personnel who are involved in the use and reprocessing of endoscopes? |  |  |  |  |
| For facilities with limited personnel where formation of a multidisciplinary team is not possible, was external expertise sought to obtain multidisciplinary input into the development of endoscope reprocessing policies? |  |  |  |  |
| Do policies address the selection, use, transport, reprocessing, and storage of endoscopes and accessory devices?  |  |  |  |  |
| Do policies ensure that the facility's reprocessing procedures are in compliance with endoscope and reprocessing equipment manufacturers’ IFU?  |  |  |  |  |
| Do policies clearly include requirements for documentation of adherence to essential reprocessing steps?  |  |  |  |  |
| Do policies clearly include requirements for parameters regarding the physical setting where endoscope reprocessing occurs?  |  |  |  |  |
| Do policies clearly include requirements for staff education, training, and assessment of competency? |  |  |  |  |
| Do policies clearly include requirements for ongoing quality assurance procedures?  |  |  |  |  |
|  Do endoscope reprocessing policies clearly include requirements for protocols for responding to equipment and HLD/sterilization failures or breaches? |  |  |  |  |
| Do policies include the management of “loaner” endoscopes (i.e., endoscopes that are not owned by the healthcare facility but are provided for temporary use by manufacturers, equipment suppliers or other healthcare facilities)? |  |  |  |  |
| Do loaner endoscope policies include requiring adherence to the same reprocessing standards as for facility-owned equipment? |  |  |  |  |
| Do loaner endoscope policies include assessing the condition (i.e., visual inspection, leak testing) of loaner endoscopes prior to use? |  |  |  |  |
| Do loaner endoscope policies include requiring cleaning and high level disinfection or sterilization of loaner endoscopes supplied by the manufacturer or another healthcare facility prior to use? |  |  |  |  |
| Are policies in compliance with all federal and local regulatory (e.g., FDA, CMS, OSHA, state health departments)?  |  |  |  |  |
| Are policies in compliance with relevant accrediting organization (e.g. AAAASF, AAAHC, DNVGL Healthcare, TJC) standards and requirements? |  |  |  |  |
|  Do policies take into consideration the standards and recommendations from professional organizations (e.g., AAMI, AGA, AORN, ASGE, SGNA)? |  |  |  |  |
| Does management ensure that policies related to the reprocessing of endoscopes are in place and are reviewed on a regular basis as required by the facility governing body and any applicable regulatory organization?  |  |  |  |  |
| Does management regularly update policies when new equipment/products are purchased and when new information is published? |  |  |  |  |
| Does management ensure that single-use devices are not reprocessed?  |  |  |  |  |
| If the facility chooses to reprocess a single use device, does management ensure that FDA regulations for reprocessing of single use devices are followed? |  |  |  |  |
| Does management ensure that occupational health needs are addressed including, but are not be limited to, the provision of hepatitis B vaccine, prevention of exposure to infectious agents (e.g., bloodborne pathogens, enteric pathogens) and availability of post-exposure prophylaxis when indicated, convenient access to and appropriate use of personal protective equipment (PPE), and monitoring for exposure to chemicals used for reprocessing when applicable?  |  |  |  |  |
| Does management ensure patient scheduling and staffing levels are adequate to allow for enough time to consistently perform adequate reprocessing of endoscopes and to avoid delays between completion of an endoscopic procedure and initiation of reprocessing of the endoscope used for that procedure?  |  |  |  |  |
| Is management knowledgeable about the manufacturer’s IFU related to delayed reprocessing to ensure that appropriate steps are taken if a reprocessing delay occurs? |  |  |  |  |
| Does management ensure that staff has access to personnel with infection prevention knowledge and training to support the development and implementation of infection prevention policies and procedures? |  |  |  |  |
| Does management ensure that personnel involved in the reprocessing of endoscopes, including the supervisors and managers of reprocessing personnel, receive ongoing education, training and assessment of competency? |  |  |  |  |
| If personnel are responsible for reprocessing more than one type of endoscope, is reprocessing competency verified for each type of endoscope, including the appropriate use of all equipment required for reprocessing? |  |  |  |  |
| Do personnel with current endoscope reprocessing certification also receive ongoing competency assessments? |  |  |  |  |
| Does the water used for reprocessing of endoscopes at a minimum meet the specifications that are recommended by the device and reprocessing equipment manufacturer? |  |  |  |  |
| Are professional society guidelines that recommend more stringent water specifications considered for implementation by the facility? |  |  |  |  |
| Are all the essential elements of an effective endoscope reprocessing program met and maintained? |  |  |  |  |
| Documentation |  |  |  |  |
| Does facility documentation meet the requirements of the chosen reprocessing methods and the products that are used for HLD or sterilization? |  |  |  |  |
| Are endoscope and patient identifiers documented for all methods of reprocessing using HLD or sterilization? |  |  |  |  |
| Is there a process in place to record the procedure end time and the start time for manual cleaning?  |  |  |  |  |
| Is documentation maintained for the effectiveness of the products used for cleaning and disinfection (e.g., document the results of testing for effective concentrations of the chemical disinfectant, expiration dates for test strips and chemical disinfectants)? |  |  |  |  |
| Are records maintained of preventive maintenance and repair of endoscopes and reprocessing equipment (e.g., leak testers, automated endoscope reprocessors [AERs], sterilizers)? |  |  |  |  |
| Does documentation include the investigation of critical or potential critical events such as HLD or sterilization process failures or equipment failures? |  |  |  |  |
| Does management retain documentation as designated by the facility record retention policy to include documentation for AERs and retired endoscopes? |  |  |  |  |
| Are periodic audits of facility reprocessing protocols and the completeness of documentation performed to monitor compliance?  |  |  |  |  |
| Inventory |  |  |  |  |
| Do frontline personnel maintain an endoscope inventory to identify all endoscopes and method of reprocessing in use by the facility? |  |  |  |  |
| Does information reviewed for each endoscope include but is not limited to the: |  |  |  |  |
| Endoscope manufacturer and model |  |  |  |  |
| Location of use |  |  |  |  |
| Number of procedures performed  |  |  |  |  |
| Location of the endoscope manufacturer’s IFUs |  |  |  |  |
| Location for reprocessing |  |  |  |  |
| Equipment used for HLD and/or sterilization  |  |  |  |  |
| Status of the endoscope (i.e., retired, out for repair, in use) |  |  |  |  |
| Does each endoscope have a unique identifier to facilitate tracking?  |  |  |  |  |
| Does the method of tracking include the ability to determine when specific endoscopes were used for specific patients, loaned to other units or facilities, reprocessed, or repaired? |  |  |  |  |
| Physical Setting |  |  |  |  |
| Is the reprocessing area in a space that is separate from the patient procedural area? |  |  |  |  |
| Does the physical setting ensure a “one way” work flow that separates contaminated work spaces from clean work spaces? |  |  |  |  |
| If a separate room is used for manual cleaning of endoscopes, does the space have a directional airflow that maintains negative pressure within that room relative to adjoining spaces? |  |  |  |  |
| Are heating, ventilation, and air conditioning parameters appropriate for the chemicals and equipment in use? |  |  |  |  |
| Does staff have access to a handwashing sink that is separate from the reprocessing sink(s)? |  |  |  |  |
| Are either plumbed or self-contained eyewash stations installed within the endoscopy reprocessing room where chemicals that are hazardous to the eyes are used?  |  |  |  |  |
| Are manufacturer’s IFU for reprocessing of the endoscopes and for use of the AERs and associated chemicals readily available? |  |  |  |  |
| Is designated space provided 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? |  |  |  |  |
| Education, Training, and Competencies |  |  |  |  |
| Does education and training include the rationale for each of the seven essential steps of reprocessing outlined in this document?  |  |  |  |  |
| Are training and competency assessments based upon the endoscope manufacturer’s IFU as well as the reprocessing equipment and chemicals used?  |  |  |  |  |
| If more than one type/model of endoscope is used, is staff able to demonstrate they are competent to reprocess each specific type of endoscope? |  |  |  |  |
| Are model-specific competency assessment check lists used to ensure competency? |  |  |  |  |
| Are visual educational aids and standard operating procedures posted to reinforce best reprocessing practices? |  |  |  |  |
| Do education and training address decontamination, cleaning and sterilization of reusable accessories that breach the mucosal barrier (e.g., biopsy forceps)? |  |  |  |  |
| Are trainers and managers competent to reprocess endoscopes? |  |  |  |  |
| Are trainers and managers able to adequately train and verify the competency of their staff? |  |  |  |  |
| Are staff competencies conducted initially upon hire and periodically as required by facility policy?  |  |  |  |  |
| Does this competency include an educational update followed by direct observation of staff performing endoscope reprocessing? |  |  |  |  |
| Are staff competencies conducted whenever a new model of endoscope, reprocessing equipment (e.g., AER, leak tester), or chemical is purchased? |  |  |  |  |
| Are staff competencies conducted when there are updates to the manufacturer’s IFU? |  |  |  |  |
| Do staff competencies include essential steps of reprocessing from pre-clean to storage and documentation? |  |  |  |  |
| Do staff competencies 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 alternative automated reprocessor that is validated for the endoscope)? |  |  |  |  |
| Do staff competencies include how and when to perform supplemental testing or other assessments of endoscope cleaning if those tests are used by the facility (e.g., tests that measure residual organic material or adenosine triphosphate)? |  |  |  |  |
| Are staff orientation, ongoing education/ training, and competency assessments conducted even if personnel are certified in reprocessing of endoscopes? |  |  |  |  |
| Disinfection/Sterilization Breach or Failure |  |  |  |  |
| Is each breach evaluated to determine the risk of disease transmission?  |  |  |  |  |
| Is each event carefully reviewed by a multi-disciplinary team (including infection prevention, risk management, and endoscopy personnel) to determine the necessary corrective steps and the need for patient notification? |  |  |  |  |
| Does the multi-disciplinary team use one or more of the available resource documents to guide their breach investigation? |  |  |  |  |
| When a breach involves a suspicion of patient exposure to an improperly reprocessed endoscope, is the decision to notify patients of their potential exposure made in consultation with an infection preventionist and state and local health departments? |  |  |  |  |
| If a healthcare provider suspects persistent bacterial contamination of an endoscope following reprocessing, either because of an increase in infections after endoscopic procedures or because of the results of microbiological culturing of endoscopes, is a voluntary report filed through MedWatch, the FDA Safety Information and Adverse Event Reporting program? |  |  |  |  |

## HICPAC Sample Risk Assessment and Action Plan

A risk assessment is a way for facilities to identify potential problems that could occur based upon the findings of the gap analysis and to create a prioritized plan of action to improve deficiencies.

A risk assessment consists of:

1. A list of deficiencies in practice identified via a gap analysis or other quality assurance methods and consideration of the potential harm associated with the deficiencies.
2. A plan of action to improve facility practices.
3. The timeline for implementation of action plan. This timeline is based on a prioritization of actions based upon the likelihood of potential harm.
4. The person responsible for executing the plan of action.

This risk assessment and action plan is modifiable to encourage a facility to adapt this template to reflect the different quality assurance procedures a facility may already use.

To use the risk assessment tool below to create a prioritized action plan from the results of the gap assessment:

1. Seek input from staff doing the processing to be sure all information is obtained for each deficiency.
2. Determine which areas of the process needs improvement and define the necessary actions to take to ameliorate the risk.
3. Prioritize the order in which deficiencies are addressed, and how quickly they are addressed.
4. Assign staff responsible for implementing the action plan in the allotted timeframe.

## HICPAC Sample Risk Assessment and Action Plan Tool

Completed by: Date completed:

| **Deficiency Identified** | **Action Plan** | **Timeline for Implementation of Action Plan** | **Person Responsible** |
| --- | --- | --- | --- |
| Deficiencies imported from Gap Analysis | Actions to be taken to improve deficiency |  | Person responsible for action plan and maintaining timeline |
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Available from: <https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html>