Infection Control Assessment and Response (ICAR) Tool for General Infection Prevention and Control (IPC) Across Settings

Module 5: High-level Disinfection and Sterilization Facilitator Guide

High-level Disinfection and Sterilization. This form is intended to aid an ICAR facilitator in the review of the types of medical device reprocessing performed by the healthcare facility (Part A) and guide observations (Parts B and C).

Practices should ideally be assessed in all areas of the facility where high-level disinfection and sterilization of medical devices is performed, which could include areas outside of the main central reprocessing area (e.g., endoscopy suite, bronchoscopy suite). The observation sections address the main steps that should be occurring but likely are not sufficient for a full assessment of practices in a central sterile reprocessing department and are not intended for these settings. For the most accurate assessment, particularly if the ICAR is being performed in response to an outbreak, the ICAR facilitator should use the reprocessing instructions for the device(s) being reprocessed to guide observations.

Categories of Medical Devices:

- Critical items (e.g., surgical instruments) are objects that enter sterile tissue or the vascular system and must be sterile prior to use (see Part B).
- Semi-critical items (e.g., endoscopes for upper endoscopy and colonoscopy, vaginal probes) are objects that contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse (see Part C).
- Non-critical items (e.g., blood pressure cuffs) are objects that may come in contact with intact skin but not mucous membranes and should undergo cleaning and low- or intermediate-level disinfection depending on the nature and degree of contamination (See ICAR Module 4: Environmental Services).
- Single-use devices (SUDs) are labeled by the manufacturer for a single use and do not have reprocessing instructions. They may not be reprocessed for reuse except by entities which have complied with FDA regulatory requirements and have received FDA clearance to reprocess specific SUDs.

Note: The Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov) is referenced in the rationale and relevant guidance section. While specific to endoscopes, many of the essential elements in this guidance are more broadly applicable to other semi-critical instruments.

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Part A. High-level Disinfection and Sterilization Interview Questions

1. What types of reprocessing are performed onsite or offsite? *(select all that apply)*

1a. High-level disinfection

- ☐ Onsite
- ☐ Offsite
- ☐ Unknown
- ☐ Not assessed
- ☐ Not performed

1b. List all areas where onsite high-level disinfection is performed (e.g., endoscopy suites, bronchoscopy suite):

1c. Sterilization (by any method)

- ☐ Onsite
- ☐ Offsite
- ☐ Unknown
- ☐ Not assessed
- ☐ Not performed

1d. List all areas where onsite sterilization, including immediate use steam sterilization, is performed (e.g. operating room area, central processing):

Understanding the types of medical device reprocessing and locations where it is performed will allow the ICAR facilitator to ensure observations and assessments are performed in all relevant areas of the facility.

2. Does the facility use devices or instruments/instrument trays that are supplied by a vendor?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

*If **YES**:*

2a. Prior to use do all vendor devices undergo the appropriate level reprocessing at the facility?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

Some equipment or instruments may be on-loan from a vendor (e.g., specialized orthopedic equipment). There should be a process in place to ensure such equipment has been sterilized or high-level disinfected (as appropriate) prior to use at the facility.

"Policies should 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) to ensure adherence to the same reprocessing standards described above required for facility-owned equipment. This includes:

1. Assessing the condition (i.e., visual inspection, leak testing) of loaner endoscopes prior to use.

2. Cleaning and high level disinfection or sterilization of loaner endoscopes supplied by the manufacturer or another healthcare facility prior to use."

Source: Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)

Notes

3. Does the facility ever use single-use devices for more than one patient?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

*If **YES**:*

3a. Prior to reuse do they undergo the appropriate level reprocessing?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

If the facility elects to reuse single-use devices, these devices must be reprocessed prior to reuse by a third-party reprocessor that it is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. The facility should have documentation from the third party reprocessor confirming this is the case.

Note: The individual responding to questions may not know that HCP are reusing single-use devices. Even if the answer is no, the ICAR facilitator should watch for such practices while performing observations.

4. Does the facility have policies and procedures (e.g., logging the cleaning and use of individual devices and patients in whom they were used) outlining facility response (i.e., risk assessment and recall of device) in the event of a reprocessing error or failure?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

*If **YES**:*

4a. How are potentially contaminated devices identified/recalled?

4b. How are potentially exposed patients identified?

4c. Who is involved in the process of assessing potential risks to patients on whom the equipment was used?

Facilities should have policies and procedures addressing how they will respond to reprocessing errors or failures, particularly if such errors are not detected until after equipment has been released and used on a patient.

"Each breach is a result of unique circumstances and should be evaluated to determine the risk of disease transmission. A multi-disciplinary team that includes infection prevention, risk management, and [reprocessing] personnel should review each event carefully to determine the necessary corrective steps and the need for patient notification…. the decision to notify patients of their potential exposure should be made in consultation with an infection preventionist and state and local health departments."

In addition to engagement with the health department, potential errors or failures of medical devices should be reported to the device manufacturer and FDA MedWatch.

Source: Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)

Information that can aid in these situations include a mechanism to determine:

- Dates the reprocessing error/failure occurred.
- Which equipment/trays were potentially impacted by the failure (e.g., if only one autoclave was affected, which equipment was sterilized in that autoclave)
- Which patients were exposed to the potentially contaminated equipment. Having a log system that records the equipment trays or endoscopes used during the procedure can help facilitate this process.

Notes

5. Is there a process for reporting suspected device-associated infections to public health officials?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

*If **YES**:*

5a. Does this process include reporting to the manufacturer?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

5b. Does this process include reporting to FDA MedWatch?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

6. Is routine maintenance for reprocessing equipment (e.g., automated washers, steam autoclaves, automated endoscope reprocessors) and endoscopes regularly performed?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

*If **YES**:*

6a. Who performs this maintenance?

- ○ The facility
- ○ The device manufacturer
- ○ Unknown
- ○ Not Assessed
- ○ Other (specify): _____

6b. Does the facility maintain records of all maintenance?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

"Maintain records of preventive maintenance and repair of endoscopes and reprocessing equipment (e.g., leak testers, automated endoscope reprocessors [AERs], sterilizers)."

Source: Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)

If possible, confirm that maintenance records are available. If the ICAR is being performed in response to an outbreak or reprocessing error/failure, these records can sometimes help with determining how long such errors/failures might have been occurring.

Device representatives can also be an important resource to ensure the equipment is currently functioning as intended.

Notes

Part B. Sterilization Observations

Ideally, observations should be conducted in each area of the facility where sterilization is performed. If direct observations cannot be gathered, then information can be obtained by asking staff.

1. Are policies, procedures, and manufacturer reprocessing instructions available in the reprocessing area?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Manufacturer's instructions for reprocessing reusable medical equipment should be readily available and used to establish clear operating procedures and training content for the facility. Instructions should be posted at the site where equipment reprocessing is performed."

"Compare the reprocessing instructions (e.g., for the appropriate use of endoscope connectors, the capping/noncapping of specific lumens) provided by the instrument manufacturer and the sterilizer manufacturer and resolve any conflicting recommendations by communicating with both manufacturers. Category IB"

Sources: https://www.cdc.gov/hicpac/recommendations/core-practices.html

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

2. Is there an appropriate supply of equipment for the volume of procedures performed to allow adequate time for all reprocessing steps, including drying, to be correctly performed?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Do not use immediate-use steam (flash) sterilization for convenience, as an alternative to purchasing additional instrument sets, or to save time. Category II"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

If the facility is routinely having to flash sterilize trays (immediate-use steam sterilization) in order to meet procedural needs, this could be a sign that they do not have an appropriate supply of equipment.

3. Is there a clear separation between soiled and clean workspaces?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"The reprocessing area should be in a space that is separate from the patient procedural area."

"Review the physical setting to ensure a "one way" work flow that separates contaminated work spaces from clean work spaces."

"Maintain separation between clean and soiled equipment to prevent cross contamination."

Sources: https://www.cdc.gov/hicpac/recommendations/core-practices.html

Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)

4. Do HCP have access to a handwashing sink that is not used for cleaning devices?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Staff should have access to a handwashing sink that is separate from the reprocessing sink(s)."

Source: Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)

Notes

5. Do HCP engaged in sterilization activities wear appropriate PPE to prevent exposure to infectious agents or chemicals?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Ensure that workers wear appropriate PPE to preclude exposure to infectious agents or chemicals through the respiratory system, skin, or mucous membranes of the eyes, nose, or mouth. PPE can include gloves, gowns, masks, and eye protection. The exact type of PPE depends on the infectious or chemical agent and the anticipated duration of exposure. The employer is responsible for making such equipment and training available. Category II, IC."

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

6. Is a precleaning step performed as soon as practical after use (e.g., at the point of use)?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Clean medical devices as soon as practical after use (e.g., at the point of use) because soiled materials become dried onto the instruments. Dried or baked materials on the instrument make the removal process more difficult and the disinfection or sterilization process less effective or ineffective. Category IB."

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

Such observations can be made by observing precleaning at the point of care (e.g., endoscopy suite) or looking at how items are packaged when they arrive at the reprocessing area (e.g., appropriately soaking in detergent/cleaner in a biohazard container).

7. Are devices thoroughly cleaned according to manufacturer instructions and visually inspected for residual soil prior to sterilization?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Meticulously clean patient-care items with water and detergent, or with water and enzymatic cleaners before high-level disinfection or sterilization procedures.

i. Remove visible organic residue (e.g., residue of blood and tissue) and inorganic salts with cleaning. Use cleaning agents that are capable of removing visible organic and inorganic residues. Category IB.

Perform either manual cleaning (i.e., using friction) or mechanical cleaning (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers). Category IB."

Ensure appropriately sized cleaning brushes are selected for cleaning device channels and lumens.

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

8. Is the enzymatic cleaner or detergent used for cleaning discarded according to manufacturer's instructions (typically after each use)?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Discard enzymatic cleaners (or detergents) after each use because they are not microbicidal and, therefore, will not retard microbial growth. Category IB"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

Notes

9. Are disposable cleaning brushes discarded after use or, if reusable, cleaned and high-level disinfected or sterilized (per manufacturer's instructions) after use?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Use cleaning brushes appropriate for the size of the endoscope channel or port (e.g., bristles should contact surfaces). Cleaning items (e.g., brushes, cloth) should be disposable or, if they are not disposable, they should be thoroughly cleaned and either high-level disinfected or sterilized after each use. Category II"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

10. After cleaning, are instruments appropriately wrapped/packaged for sterilization?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Ensure that packaging materials are compatible with the sterilization process and have received FDA 510[k] clearance. Category IB."

"Place items correctly and loosely into the basket, shelf, or cart of the sterilizer so as not to impede the penetration of the sterilant. Category IB"

"…hinged instruments should be opened; items with removable parts should be disassembled unless the device manufacturer or researchers provide specific instructions or test data to the contrary…devices with concave surfaces should be positioned to facilitate drainage of water; heavy items should be positioned not to damage delicate items;"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

11. Is a chemical indicator (process indicator) placed correctly in the instrument packs in every load?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Monitor each load with mechanical (e.g., time, temperature, pressure) and chemical (internal and external) indicators. If the internal chemical indicator is visible, an external indicator is not needed. Category II."

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

12. Is a biological indicator, intended specifically for the type and cycle parameters of the sterilizer, used at least weekly for each sterilizer and with every load containing implantable items?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Use biologic indicators to monitor the effectiveness of sterilizers at least weekly with an FDA-cleared commercial preparation of spores…intended specifically for the type and cycle parameters of the sterilizer. Category IB"

"Use biologic indicators for every load containing implantable items and quarantine items, whenever possible, until the biologic indicator is negative. Category IB"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

Notes

13. For dynamic air removal-type sterilizers (e.g., prevacuum steam sterilizer), is an air removal test (Bowie-Dick test) performed in an empty dynamic-air removal sterilizer each day the sterilizer is used?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"An air-removal test (Bowie-Dick Test) must be performed daily in an empty dynamic-air-removal sterilizer (e.g., prevacuum steam sterilizer) to ensure air removal."

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

14. Are sterile packs labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date. Category IB"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

15. Are sterilization logs current and complete (include results from each load)?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"For each sterilization cycle, record the type of sterilizer and cycle used; the load identification number; the load contents; the exposure parameters (e.g., time and temperature); the operator's name or initials; and the results of mechanical, chemical, and biological monitoring. Category II"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

16. Is immediate-use steam sterilization only done in circumstances in which routine sterilization procedures cannot be performed?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Do not use flash sterilization for convenience, as an alternative to purchasing additional instrument sets, or to save time. Category II"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

17. Are instruments that undergo immediate-use steam sterilization used immediately and not stored?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"When using flash sterilization, make sure the following parameters are met: 1. clean the item before placing it in the sterilizing container (that are FDA cleared for use with flash sterilization) or tray; 2. prevent exogenous contamination of the item during transport from the sterilizer to the patient; and 3) monitor sterilizer function with mechanical, chemical, and biologic monitors. Category IB"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

Notes

18. After sterilization, are medical devices stored so that sterility is not compromised?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Ensure the sterile storage area is a well-ventilated area that provides protection against dust, moisture, insects, and temperature and humidity extremes. Category II.

Store sterile items so the packaging is not compromised (e.g., punctured, bent). Category II."

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

19. Are sterile packages inspected for integrity and compromised packages reprocessed prior to use?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Evaluate packages before use for loss of integrity (e.g., torn, wet, punctured). The pack can be used unless the integrity of the packaging is compromised. Category II.

If the integrity of the packaging is compromised (e.g., torn, wet, or punctured), repack and reprocess the pack before use. Category II"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

Notes

Part C. High-level Disinfection Observations

Ideally, observations should be conducted in each area of the facility where high-level disinfection is performed. If direct observations cannot be gathered, then information can be obtained by asking staff.

1. Are policies, procedures, and manufacturer's reprocessing instructions available in the reprocessing area?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Manufacturer's instructions for reprocessing reusable medical equipment should be readily available and used to establish clear operating procedures and training content for the facility. Instructions should be posted at the site where equipment reprocessing is performed."

"Compare the reprocessing instructions (e.g., for the appropriate use of endoscope connectors, the capping/noncapping of specific lumens) provided by the instrument manufacturer and the sterilizer manufacturer and resolve any conflicting recommendations by communicating with both manufacturers. Category IB"

Sources: https://www.cdc.gov/hicpac/recommendations/core-practices.html

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

2. Is there an appropriate supply of equipment for the volume of procedures performed to allow adequate time for all reprocessing steps, including drying, to be correctly performed?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"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. "

Source: Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)

**While specific to endoscopes, many of the essential elements in this guidance are more broadly applicable to other semi-critical instruments.*

3. Is there a clear separation between soiled and clean workspaces?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"The reprocessing area should be in a space that is separate from the patient procedural area."

"Review the physical setting to ensure a "one way" work flow that separates contaminated work spaces from clean work spaces."

"Maintain separation between clean and soiled equipment to prevent cross contamination."

Sources: Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)

https://www.cdc.gov/hicpac/recommendations/core-practices.html

4. Do HCP have access to a handwashing sink that is not used for cleaning devices?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Staff should have access to a handwashing sink that is separate from the reprocessing sink(s)."

Source: Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)

Notes

5. Do HCP engaged in high-level disinfection activities wear appropriate PPE to prevent exposure to infectious agents or chemicals?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Ensure that workers wear appropriate PPE to preclude exposure to infectious agents or chemicals through the respiratory system, skin, or mucous membranes of the eyes, nose, or mouth. PPE can include gloves, gowns, masks, and eye protection. The exact type of PPE depends on the infectious or chemical agent and the anticipated duration of exposure. The employer is responsible for making such equipment and training available. Category II, IC."

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

6. Is a precleaning step performed as soon as practical after use (e.g., at the point of use)?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Clean medical devices as soon as practical after use (e.g., at the point of use) because soiled materials become dried onto the instruments. Dried or baked materials on the instrument make the removal process more difficult and the disinfection or sterilization process less effective or ineffective. Category IB."

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

Such observations can be made by observing precleaning at the point of care (e.g., endoscopy suite) or looking at how items are packaged when they arrive at the reprocessing area (e.g., soaking in detergent/cleaner in a biohazard container).

7. Are devices thoroughly cleaned according to manufacturer instructions and visually inspected for residual soil prior to high-level disinfection?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Meticulously clean patient-care items with water and detergent, or with water and enzymatic cleaners before high-level disinfection or sterilization procedures.

ii. Remove visible organic residue (e.g., residue of blood and tissue) and inorganic salts with cleaning. Use cleaning agents that are capable of removing visible organic and inorganic residues. Category IB.

Perform either manual cleaning (i.e., using friction) or mechanical cleaning (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers). Category IB."

Ensure appropriately sized cleaning brushes are selected for cleaning device channels and lumens

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

8. Is the enzymatic cleaner or detergent used for cleaning discarded according to manufacturer's instructions (typically after each use)?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Discard enzymatic cleaners (or detergents) after each use because they are not microbicidal and, therefore, will not retard microbial growth. Category IB"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

Notes

9. Are disposable cleaning brushes discarded after use or, if reusable, cleaned and high-level disinfected or sterilized (per manufacturer's instructions) after use?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Use cleaning brushes appropriate for the size of the endoscope channel or port (e.g., bristles should contact surfaces). Cleaning items (e.g., brushes, cloth) should be disposable or, if they are not disposable, they should be thoroughly cleaned and either high-level disinfected or sterilized after each use. Category II"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

10. Are flexible endoscopes inspected for damage and leak tested as part of each reprocessing cycle?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"To detect damaged endoscopes, test each flexible endoscope for leaks as part of each reprocessing cycle. Remove from clinical use any instrument that fails the leak test, and repair this instrument. Category II"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

11. For chemicals used in high-level disinfection, are manufacturer's instructions followed for:

11a. Preparation

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

11b. Testing for appropriate concentration

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

11c. Replacement (i.e., upon expiration or loss of efficacy)

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"Routinely test the liquid sterilant/high-level disinfectant to ensure minimal effective concentration of the active ingredient. Check the solution each day of use (or more frequently) using the appropriate chemical indicator (e.g., glutaraldehyde chemical indicator to test minimal effective concentration of glutaraldehyde) and document the results of this testing. Discard the solution if the chemical indicator shows the concentration is less than the minimum effective concentration. Do not use the liquid sterilant/high-level disinfectant beyond the reuse-life recommended by the manufacturer (e.g., 14 days for ortho-phthalaldehyde). Category IA"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

12. If automated reprocessing equipment (e.g., automated endoscope reprocessor) is used, are proper connectors used to assure that channels and lumens are appropriately disinfected?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"If using an automated endoscope reprocessor (AER), place the endoscope in the reprocessor and attach all channel connectors according to the AER manufacturer's instructions to ensure exposure of all internal surfaces to the high-level disinfectant/chemical sterilant. Category IB"

Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

13. Are devices disinfected for the appropriate length of time as specified by the manufacturer instructions?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"When using FDA-cleared high-level disinfectants, use manufacturers' recommended exposure conditions."
Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

14. Are devices disinfected at the appropriate temperature as specified by the manufacturer instructions?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"When using FDA-cleared high-level disinfectants, use manufacturers' recommended exposure conditions."
Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

15. After high-level disinfection, are devices appropriately rinsed as specified by the manufacturer?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

Review the manufacturer's instructions to determine recommended practices, including need for a final alcohol rinse.

16. Are devices thoroughly dried prior to use?
Note: *For lumened instruments (e.g,. endoscopes) this includes flushing all channels with alcohol and forcing air through the channels.*

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"After flushing all channels with alcohol, purge the channels using forced air to reduce the likelihood of contamination of the endoscope by waterborne pathogens and to facilitate drying. Category IB"
Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)

17. Are devices stored in a manner to protect from damage or contamination?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by reprocessing staff
- ○ Not observed and not endorsed by reprocessing staff

"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:

1. of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without touching the bottom of the cabinet OR
2. designed and intended by the manufacturer for horizontal storage of flexible endoscopes."

Source: Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)
**While specific to endoscopes, many of the essential elements in this guidance are more broadly applicable to other semi-critical instruments.*

Notes