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

## Section 3: Observation Form - High-level Disinfection and Sterilization

**High-level Disinfection and Sterilization.** This form is intended to guide observations of medical device reprocessing performed by the healthcare facility.

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 pages 2-6).
- 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 pages 7-10).
- 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 <u>Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)</u> 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.

High-level Disinfection and Sterilization ICAR Interview Questions (Section 2 Module 5) and Observation Forms for other IPC topics (Section 3) are available on the ICAR web page: <a href="https://www.cdc.gov/hai/prevent/infection-control-assessment-tools.html">https://www.cdc.gov/hai/prevent/infection-control-assessment-tools.html</a>



#### **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

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

**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				

	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	<ul> <li>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</li>             Not observed and not endorsed by reprocessing staff  </ul>
	<ul> <li>"Meticulously clean patient-care items with water and detergent, or with water and enzymatic cleaners before high-level disinfection or sterilization procedures.</li> <li>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.</li> <li>Perform either manual cleaning (i.e., using friction) or mechanical cleaning (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers).</li> <li>Category IB."</li> <li>Ensure appropriately sized cleaning brushes are selected for cleaning device channels and lumens.</li> <li>Source: Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)</li> </ul>
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)
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5. Do HCP engaged in sterilization activities wear appropriate PPE to prevent exposure to infectious agents or chemicals?

Yes

<ul> <li>9. Are disposable cleaning brushes discarded after use or, if reusable, cleaned and high-level disinfected or sterilized (per manufacturer's instructions) after use?</li> <li>Yes</li> <li>No</li> <li>Not observed but endorsed by reprocessing staff</li> <li>Not observed and not endorsed by reprocessing staff</li> </ul>	
"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 contrarydevices 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)	
<ul> <li>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         </li> </ul> <li>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?</li>	
"Use biologic indicators to monitor the effectiveness of sterilizers at least weekly with an FDA-cleared commercial preparation of sporesintended 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)	
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<ul> <li>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?</li> <li>Yes</li> <li>No</li> <li>Not observed but endorsed by reprocessing staff</li> <li>Not observed and not endorsed by reprocessing staff</li> </ul>
"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)
<ul> <li>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?</li> <li>Yes</li> <li>No</li> <li>Not observed but endorsed by reprocessing staff</li> <li>Not observed and not endorsed by reprocessing staff</li> </ul>
"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)
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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)	
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### **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)

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

**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

Nο

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)

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." <b>Source:</b> 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.
<ul> <li>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.     </li> <li>Yes         No         Not observed but endorsed by reprocessing staff         Not observed and not endorsed by reprocessing staff     </li> </ul>
"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
<ul> <li>"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:</li> <li>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</li> <li>2. designed and intended by the manufacturer for horizontal storage of flexible endoscopes."</li> <li>Source: Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC (cdc.gov)</li> <li>*While specific to endoscopes, many of the essential elements in this guidance are more broadly applicable to other semi-critical instruments.</li> </ul>
Notes

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

Yes No