Cleaning, Disinfecting, and Sterilization of Medical Devices and Equipment

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Cleaning, disinfection, and sterilization of medical devices and equipment has emerged as a serious, widespread challenge for many health care organizations. These organizations include inpatient settings such as acute care and long term care and outpatient settings such as ambulatory surgery, outpatient clinics, pain clinics, hemodialysis centers, and dental and physician offices. Inadequate management of devices and equipment has led to multiple outbreaks of infection, causing morbidity and mortality among patients.[1–7] Each step of cleaning, disinfection, and sterilization is critical to reduce the risk of infection. Risks for transmission of infection related to use, cleaning, disinfection, and sterilization failures include the following[8–12]:

- Reprocessing in a manner inconsistent with the intended use of the instrument or equipment
- Not following standard reprocessing procedures
- Not following manufacturer's instructions for use
- Inadequate or ineffective manufacturer's instructions for use
- Use of expired detergents or disinfectants
- Design flaws in the device or equipment
- Continued use of devices despite integrity, maintenance, and mechanical issues
- Lack of adequate training and competency of personnel responsible for using or reprocessing medical devices and equipment

Health care–associated infections (HAIs) can be prevented when facilities do the following:

- Use instruments as intended by manufacturer
- Explicitly follow manufacturer's instructions
- Implement clear policies and procedures for use and processing that include evidence-based infection prevention practices
- Implement stringent quality controls on use and reprocessing
- Ensure that staff are trained and competent to use each instrument or device
- Ensure that staff are trained and competent to reprocess each instrument or device
- Provide appropriate space, supplies, and equipment to support use and reprocessing

The US Centers for Medicare & Medicaid Services (CMS) and The Joint Commission have recognized these problems and are intensifying their survey processes to better address and improve care related to the processing of instruments and equipment. This chapter will (1) identify the Joint Commission Infection Prevention and Control (IC) standards and Environment of Care (EC) standards that relate to medical devices and equipment and (2) provide guidance for complying with recommendations and requirements that can lead to best practices for managing devices and equipment used for patient care.

EXPLORING STANDARD IC.02.02.01

The [organization] reduces the risk of infection associated with medical equipment, devices, and supplies.

Requirements for managing medical equipment, devices, and supplies are included in both the IC and EC Joint Commission standards. This chapter explains key elements and proposed strategies to meet these standards. The Joint Commission standards related to cleaning and disinfection of the environment are covered in Chapter 7.

Disinfection and sterilization is also a focus area by CMS. Because The Joint Commission has deeming authority, all surveyors must ensure that the minimum CMS requirements are met—therefore, current CMS references are included for related discussions. Infection preventionists should review the most current CMS Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and the CMS surveyors' infection control worksheets for hospitals and ambulatory surgery centers on a regular basis, as they change periodically. Links to these documents are found in the Tools section of this chapter.

The most common approach to disinfection and sterilization was described by Spaulding more than 30 years ago and, with some exceptions for more recent discoveries, such as prion disease, they still apply today.[13] Spaulding classified medical devices to be reprocessed as critical, semicritical, and noncritical according to risk of infection as follows:

- Items that enter the vascular system or have contact with sterile tissues or fluids create a high risk of infection and are categorized as critical. These items require sterilization.
- Mucous membranes like those of the gastrointestinal tract and nonintact skin are generally more resistant to infection by common bacteria. Therefore, items that come in contact with mucous membranes (for example, eyes, mouth, nose, vagina, gastrointestinal tract) and nonintact skin are categorized as semicritical. These items require at least high-level disinfection.
- Items that come in contact with intact skin are categorized as noncritical and require cleaning with or without low- or intermediate-level disinfection depending on intended use.

Table 8-1 below summarizes how items should be reprocessed based on the risk of infection for the patient.

TABLE 8-1: Categorization of Items to Be Reprocessed Based on Risk of Infection*

Level	Risk of infection	Description	Examples of items	Reprocessing methods
Critical	High	Item comes in contact with or enters sterile tissue, sterile body cavity, or the vascular system	Surgical and dental instruments, inner surfaces of hemodialyzers, urinary catheters, biopsy forceps, implants, intravascular devices, and needles	Sterilization
Semicritical	Moderate	Item comes in contact with mucous membrane or nonintact skin	Respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades, esophageal manometry probes, vaginal ultrasound probes and specula, and diaphragm fitting rings	Minimum: high-level disinfection (when practical, sterilization preferred)
Noncritical	Low	Item comes in contact with intact skin	Patient care items: bedpans, blood pressure cuffs, crutches, incubators, and computers Environmental surfaces: bed rails, bedside tables, patient furniture, counters, and floor	Low and intermediate disinfection*

* Note: Because of new developments in disinfection and sterilization technologies, some changes to the Spaulding classification are being considered by experts in the field.

This table follows the Spaulding Classification. Sidebar 8-1, below, provides references to help infection preventionists meet the requirements of Standard IC.02.02.01.

IC.02.02.01, Element of Performance (EP) 1: The [organization] implements infection prevention and control activities when doing the following: Cleaning and performing low-level disinfection of medical equipment, devices, and supplies.
Note: *Low-level disinfection is used for items that come in contact with intact skin such as stethoscopes, glucometers, and pulse oximetry devices. Additional cleaning and disinfecting is required for medical equipment, devices, and supplies used by patients or residents who are isolated as part of implementing transmission-based precautions.*

Low-Level Disinfection
The risk of infection from medical equipment and devices that have contact with intact skin, such as stethoscopes, pulse oximetry sensors, and blood pressure cuffs, is low.[13] However, because these items readily become contaminated during use and are potential sources for transmission, organizations should implement cleaning and disinfecting procedures using at least a low-level disinfection protocol that follows the equipment or the device's manufacturer instructions for reusable items. Care should be taken to ensure that single-use devices are not being cleaned, disinfected, or reused unless regulatory requirements are met.

SIDEBAR 8-1: Key Documents to Help Meet Requirements of Standard IC.02.02.01

Association for the Advancement of Medical Instrumentation (AAMI)

- ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ST91: Comprehensive guide to flexible and semi-rigid endoscope processing in health care facilities
- ST58: Chemical sterilization and high-level disinfection in health care facilities
- ST41: Ethylene oxide sterilization in health care facilities: Safety and effectiveness

Note: AAMI standards must be reaffirmed, revised, or withdrawn no later than five years from the date of publication and may be revised or withdrawn at any time, so check for updates regularly.

Note: These references are available for purchase.

Association of periOperative Registered Nurses (AORN) Recommended Practices

- Guideline for Selection and Use of Packaging Systems for Sterilization
- Guideline for High-level Disinfection
- Guideline for Processing Flexible Endoscopes
- Guideline for Cleaning and Care of Surgical Instruments
- Guideline for Sterilization

Note: These guidelines must be purchased.

US Centers for Medicare & Medicaid Services (CMS) State Operations Manual: Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf

CMS Infection Control Worksheets for Ambulatory Surgical Centers and Hospitals
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-1.pdf

US Centers for Disease Control and Prevention Guidelines (CDC)
Disinfection and Sterilization in Healthcare Facilities, 2008
http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
Environmental Infection Control in Health-Care Facilities, 2003
http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

US Food and Drug Administration (FDA) Guidance—Medical Devices Section
http://www.fda.gov/MedicalDevices/default.htm

Facility Guidelines Institute (FGI)
http://www.fgiguidelines.org/guidelines/2010-edition/read-only-copy/http://www.fgiguidelines.org/guidelines/2014-hospital-outpatient/read-only-copy/ (accessed Jan 3, 2017)

In general, as per standard precautions and because a patient may have an undiagnosed infection, personnel should clean and disinfect equipment and devices using a method that ensures that equipment used on any patient is rendered safe for use on the next patient. However, for those patients known or suspected of being infected or colonized with organisms that are resistant to routine disinfection methods (for example, *Clostridium difficile* or norovirus), additional cleaning or disinfection or alternative products may be necessary.[14]

Manufacturers should provide cleaning, disinfection, and sterilization instructions, as appropriate, for reusable devices, equipment, and supplies used in health care facilities or on patients if cleared by the US Food and Drug Administration (FDA).[15] Particular care should be taken to follow manufacturer's instructions, as failure to do so could cause damage to the devices and/or result in increased infection risk to the patient or staff.[16,17]

The facility must confirm that a manufacturer's instructions achieve the level of cleaning, disinfection, or sterilization outlined by the Spaulding classification. If a manufacturer's instructions for equipment or device cleaning does not meet the required processing level outlined in the Spaulding classification, it should not be used unless the level of disinfection or sterilization associated with its intended use can be achieved.

Tool 8-1 can be used as a basis for ensuring assessment of equipment. It assists users in taking the item's intended use, manufacturer's instructions for use, and the facility's ability to perform disinfection into account. Failure to follow manufacturer's instructions or apply the Spaulding classification is a frequent reason for noncompliance with this Joint Commission standard. Infection preventionists should always be aware of new evidence that may require a change in practice.

The CDC Disinfection and Sterilization Guideline can assist the infection preventionist in evaluating cleaning, disinfection, and sterilization issues to be considered. For example, this guideline notes that despite the CDCs recommendation *prior* to 2008 to use 3% hydrogen peroxide and 70% isopropyl alcohol to disinfect tonometer tips (used to measure intraocular pressure), new data suggest that these disinfectants are not effective against adenovirus and similar viruses that can cause epidemic keratoconjunctivitis, and they should not be used for disinfecting applanation tonometers.[13]

TIP

The US Centers for Disease Control and Prevention Disinfection and Sterilization Guideline will assist the infection preventionist in addressing cleaning, disinfection, and sterilization issues and provides an excellent overview of the following:

- Active ingredients used in disinfectants and their spectrum of effectiveness in killing specific organisms that have been linked to outbreaks.
- Evidence-based cleaning, disinfection, and sterilization methods, including mode of action and potential uses and recommended practices.

Evolving research findings and standards that will affect practice must be integrated into policies and procedures with updated references so that the organization is using best practices for patient protection and surveyors can be assured that the most recent knowledge is being applied. Infection preventionists have a responsibility to maintain currency about new or revised evidence-based guidelines to accomplish this task.

Manufacturer's instructions for the devices and equipment used as well as the cleaning and disinfection products must be available to staff assigned to clean and disinfect them. The purchasing process should include a formal review of the manufacturer's recommended or required cleaning and disinfection or sterilization instructions for the device. This can help ensure that the product can be processed and that the compatible cleansers and or disinfectants are available. If the cleanser or disinfectant manufacturer's instructions indicate that a product is compatible but the equipment or device manufacturer's instructions do not indicate compatibility, the organization should contact the device manufacturer for written clarification or confirmation so the items can safely be processed. Accreditation and regulatory agencies and other surveyors can request this documentation.

Cleaning and disinfection chemicals can create health hazards to employees who use them. Facilities should evaluate each product to ensure that it can be used safely and should include a review of dilutions, storage, shelf-life, personal protective equipment (PPE) needed, and disposal and ventilation requirements. For example some products can cause blindness if splashed in an eye or cause a fire if improperly disposed. During cleaning, personnel must wear appropriate PPE to prevent exposure to infectious agents or chemicals.[14] The US Occupational Safety and

Health Administration (OSHA) Bloodborne Pathogens Standard, as well as material safety data sheets, provide guidance for the correct PPE to be worn to protect the employees.

TIP

Facilities should evaluate each product to ensure that it can be used safely.

CMS requires that the facility establish and follow a schedule for regular cleaning and disinfecting reusable medical devices and equipment (for example, blood glucose meters, pulse oximeters). Facilities must decide the frequency of cleaning or disinfection based on their risk assessment for patient safety and the ability to maintain cleanliness based on their defined schedule. There must be a clear designation of responsibility for cleaning and disinfection of reusable noncritical patient care devices.[14]

In order to meet the CMS and other requirements for cleaning of noncritical devices and equipment, organizations should establish and implement policies and procedures that are consistent with manufacturer recommendations and that include the following:

- *Who* (for example, central service worker, nursing assistant, nurse) is responsible for cleaning and disinfecting items?
- *What* cleaning and disinfecting products should be used (for example, quaternary ammonium compound, bleach)?
- *Where* should cleaning and disinfecting efforts occur (for example, patient room, soiled utility room, central processing)?
- *When* should cleaning and disinfecting occur (for example, after each use, prior to removing from a patient room, daily)?
- *How* should cleaning and disinfecting be done (for example, following manufacturer's instructions for use)?

A best practice is to create a chart or table of frequently used equipment or devices that includes the item description, the job role responsible for cleaning, the product(s) that should be used, and the frequency of cleaning. An example is provided as Table 8-2, below.

TABLE 8-2: Guideline for Cleaning Frequently Used Equipment

Item	Location	Role responsible for cleaning	Frequency of cleaning	Product used to clean
Blood pressure machine	Clinics	Person using machine (e.g., medical assistant, nurse, MD)	After every patient use	Pop-up wipe (specify compatible product name)
Blood pressure machine	Inpatient units: portable	Person using machine (e.g., nursing assistant, nurse)	After every patient use	XYZ wipes
Blood pressure machine	Pre- and Postprocedure units	Person using machine (e.g., nurse, anesthesiologist	After every patient use	XYZ wipes
Installed monitors	Inpatient units	Environmental Services (EVS)	After each discharge	XYZ wipes
Installed monitors	Pre- and Postprocedure units	Nurse	After each discharge	XYZ wipes
Pill crusher	Medication rooms	(EVS)	Every Friday 1st shift	Soap and water
Procedure table: Radiology	Scanning rooms	Radiology tech (RT); (EVS)	Patient surface after every patient (RT), entire table every Friday evening shift (EVS)	ABC disinfectant

IC.02.02.01, EP 2: The [organization] implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. (*See also* EC.02.04.03, EP 4.)
Note: *Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes.*

Medical devices that come into contact with mucous membranes or nonintact skin are known as semicritical items and must receive at least high-level disinfection.[13] Examples are endoscopes, endocavity probes (for example, vaginal ultrasound and transesophageal echocardiography probes), vaginal and nasal specula, and some reusable portions of ventilator circuits. Medical instruments or devices that contact, enter or go through normally sterile areas of the body, or enter the vascular system are known as critical items and must be sterilized.[13] These items include surgical and dental instruments, implants, and ultrasound probes used in sterile body cavities.

High-level disinfection results in a product that is rendered free of all microbial contamination, except for a small number of bacterial spores. Sterilization results in a product that is free of all forms of microbial life. Items to be high-level disinfected or sterilized must be thoroughly cleaned prior to disinfection, because failure to clean the item could interfere with the disinfection and sterilization processes. All manufacturer's instructions for use must be followed, as cleaning and disinfection with the incorrect products or use of an incorrect disinfection or sterilization process could result in damage to the equipment and a piece of equipment that is unsafe for use on a patient.

TIP
Items to be high-level disinfected or sterilized must be thoroughly cleaned prior to disinfection, because failure to clean the item could interfere with the disinfection and sterilization processes.

The infection preventionist must be aware that some manufacturer's instructions for use are not always consistent with the intended use and the Spaulding classification. In order to ensure the safety of patients, infection preventionists and those who process reusable instruments and devices must critically review and question instructions that do not conform to the Spaulding classification. If, for example, an item will enter a sterile area and the manufacturer's instruction indicates that high-level disinfection is the accepted method for disinfecting the item, the manufacturer should be contacted for corrected instructions or the item should not be used, as this clearly does not follow current standards of practice or the Spaulding classification. Infection preventionists may find Section 1 of Tool 8-1 helpful in this evaluation.

TIP
In order to ensure the safety of patients, infection preventionists and those who process reusable instruments and devices must critically review and question instructions that do not conform to the Spaulding classification.

To ensure that personnel are properly processing and handling medical devices and instruments, organizations should do the following:

- Identify all medical devices and equipment used in the facility.
- Identify those items that require high-level disinfection or sterilization and the areas where they are used and reprocessed.
- Ensure that manufacturer's cleaning and disinfection instructions for each item are readily available to staff performing any step of the reprocessing procedures.
- Give careful attention to each step of manufacturer's instructions to ensure that the correct environment, equipment, and supplies are available to reprocess the item.
- Implement programs for training and testing to ensure competence of all personnel who reprocess medical devices and equipment.
- Ensure consistent quality control and documentation in all areas performing high-level disinfection and sterilization so that the processes can be audited for compliance.

Centralized oversight is strongly encouraged to ensure consistent application of facility and best-practice standards. Decentralized reprocessing is acceptable as long as all areas can meet the elements discussed above.

The reprocessing procedure should always move from dirty to clean. Appropriate functional design of the physical space makes it possible for staff to perform procedures in the correct order without skipping steps and minimizes risk of cross-contamination by facilitating flow from dirty to clean. For example, barriers are recommended between the clean and dirty areas of the space.

The physical space should be built to standards that make it possible for staff and equipment to be protected during decontamination, for equipment to be taken through a one-way flow from dirty to clean, and, as applicable, to achieve disinfection or be packaged and sterilized and be

held for further distribution. Adequate supplies of PPE should be available to make it easy for staff to follow the clean-to-dirty flow. Hand hygiene facilities that are separate from reprocessing sinks should be provided. Figure 8-1, below, demonstrates the recommended movement of equipment and staff from dirty to clean.

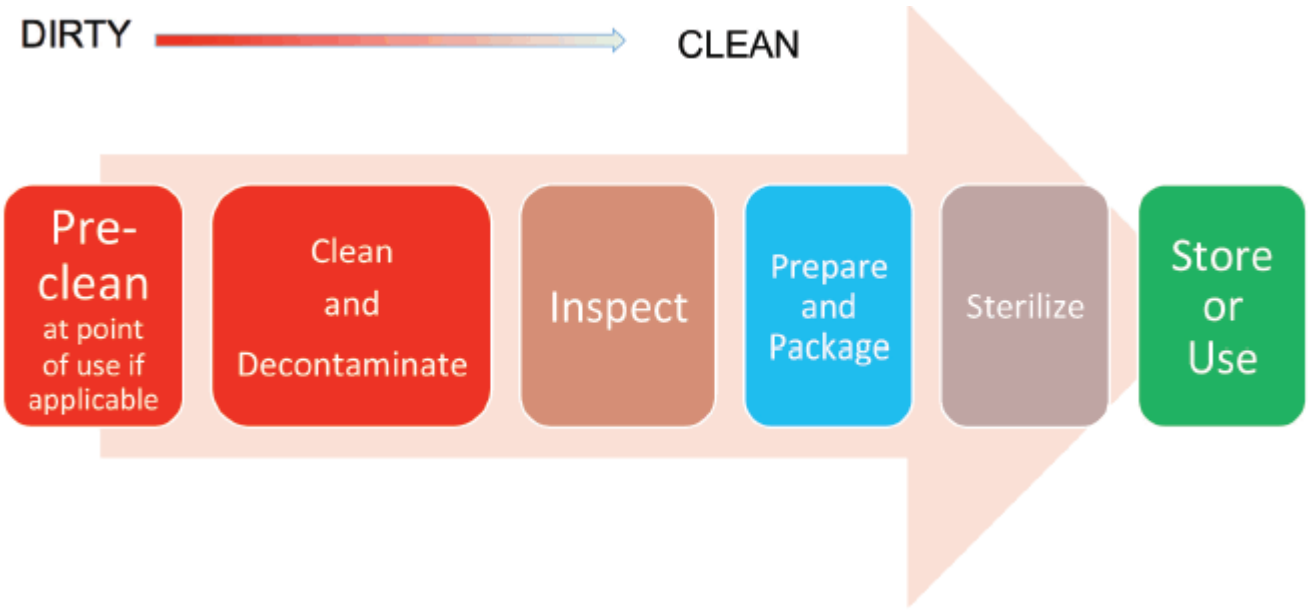
Many physical factors can affect the disinfection and sterilization process, and surveyors will expect that all areas where reprocessing occurs meet local building code requirements and specific requirements established by manufacturers of equipment and supplies used in these locations. These factors include the following:

- Temperature
- Humidity
- Air exchanges
- Ventilation exhaust
- Adequate space
- Equipment

The Association for the Advancement of Medical Instrumentation (AAMI) guidelines18 provide the rationale for many of the requirements, and surveyors will refer to AAMI and the applicable version of the Facility Guidelines Institute (FGI) 2010 Guidelines for Design and Construction of Health Care Facilities.[14,19,20] Surveyors generally use the most current version of a guideline but may accept a variance if the area was designed to the applicable standard of the year the building was built or renovated. There may be differences between FGI, AAMI, and manufacturer's instructions that facilities must resolve through careful analysis and their own risk assessment. For example, AAMI currently recommends that sterilization supplies should be kept at 30% humidity because drier supplies may lead to sterilization failure, but the FGI 2010 Table 7-1 indicates the maximum relative humidity for central medical and surgical supply clean workroom is 60% and does not provide a lower limit.[18,19] At the request of The Joint Commission, the FGI clarified room configuration, layout, and ventilation requirements for endoscopy equipment processing rooms. These requirements were published in the March 2012 edition of *The Joint Commission Perspectives*.[21] Association of periOperative Registered Nurses (AORN) has published a summary of ventilation and humidity requirements in the 2015 Guideline for Sterilization.[22] See Table 8-3, page 120.

Water quality affects the decontamination and processing of equipment and instruments. All areas should have potable (suitable for drinking) water available if staff will be performing high-level disinfection. Treated (deionized or reverse osmosis) water should be available for final rinsing of instruments. Sterile water is recommended for the final rinse of ophthalmology instruments to prevent toxic anterior segment syndrome.[23]

FIGURE 8-1: Recommended Movement of Equipment and Staff



Staff performing reprocessing must be trained and demonstrate competence to perform reprocessing procedures regardless of facility type or location. Recommendations regarding training content varies, but all recommendations emphasize the need for a comprehensive, intensive, and redundant training program for reprocessing staff along with a process for demonstrating specific competencies. When job roles include high-level disinfection, documentation of model-specific competency is expected. Most manufacturers can provide step-by-step instructions or training documents that can be used to assess competence. The box on page 17 includes key points to consider for high-level disinfection.

HIGH-LEVEL DISINFECTION

The most commonly used devices that undergo high-level disinfection in health care facilities are endoscopes, such as colonoscopes, bronchoscopes, laryngoscopes, and endocavity probes (vaginal and rectal ultrasound probes, transesophageal echocardiography probes).

Endoscopes

All endoscopes must be trackable from the reprocessing procedure through use on a patient.[16,17,24–26] In order to ensure that all endoscopes can be tracked, facilities should create a master list of all endoscopes available in the facility. The process for taking endoscopes off the list (for example, if an endoscope is taken out of service or sent out

TABLE 8-3: Parameters for Controlled Environments During Sterilization[1,2]

Functional area	Airflow	Minimum number of air exchanges per hour	All air exhausted directly to the outdoors	Temperature	Relative humidity
Soiled/ decontaminated	Negative (in)	10* (6)	Yes	60°F to 65° F (16°C to 18°C)	20% to 60%
Sterilizer equipment access	Negative (in)	10	Yes	75°F to 85°F (24°C to 29°C)	20% to 60%
Sterilizer loading/unloading	Positive (out)	10	Yes	68°F to 73°F (20°C to 23°C)	20% to 60%
Restrooms/ housekeeping	Negative (in)	10	Yes	68°F to 73°F (20°C to 23°C)	20% to 60%
Preparation and packaging	Positive (out)	10 (downdraft type)	No	68°F to 73°F (20°C to 23°C)	20% to 60%
Textile packaging room	Positive (out)	10 (downdraft type)	No	68°F to 73°F (20°C to 23°C)	20% to 60%
Clean/sterile storage	Positive (out)	4 (downdraft type)	No	$\leq$ 75°F ($\leq$ 75°C)	$\leq$ 70%

* The Facility Guidelines Institute recommends a minimum of 6 air exchanges an hour in decontamination. The Association for the Advancement of Medical Instrumentation (AAMI) recommends 10 exchanges. Regulatory agencies may enforce the American Society for Healthcare Engineering (ASHE) or AAMI recommendations listed in Table 8-3. They also may enforce other recommendations, such as the 2000 NFPA [National Fire Protection Association] 101, which states the relative humidity should be at 35%. As stated in the ASHE document, these parameters are intended to be used for the design of the heating, ventilation, and air-conditioning systems, and there may be daily fluctuations based on the environmental conditions.

REFERENCES

1. Association for the Advancement of Medical Instrumentation (AAMI). ANSI/AAMI ST79:2010, A1:2010 & A2:2011, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Arlington, VA: AAMI, 2010/2011. Adapted and reprinted with permission. Further reproduction or distribution is prohibited.
2. American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE). ANSI/ASHRAE/ASHE Addendum D to ANSI/ASHE Standard 170-2008. Atlanta: ASHRAE, 2010.

Source: Graybill-D'Ercole P. Implementing AORN recommended practices for sterilization. *AORN J*. 2013 May;97(5):521–533. Used with permission.

KEY POINTS TO CONSIDER FOR HIGH-LEVEL DISINFECTION

- Facilities should develop and implement policies and procedures for disinfection and sterilization, including use of PPE or other dress code requirements in accordance with manufacturers' instructions for use, evidence-based practices (for example, AAMI, AORN), and regulatory requirements (such as OSHA).
- Personnel should be trained in the correct use, donning, removal, limitations, and indications for PPE to prevent biological and/or chemical exposure.
- Procedures should include following the recommended dilution of cleaning chemicals and soak times.
- If an automated dilution system is not used, signage should indicate how much product (for example, two pumps) is added to a specified amount of water (such as two gallons, which is designated by the line in the sink or container).
- Periodic validation of automated dilution systems should be performed as recommended by the manufacturer.
- Items should be rinsed according to the manufacturer's instructions for using the cleaning agent.
- When brushes are used, the brushing should be done underwater to prevent aerosolization during cleaning. Brushes must be the correct diameter, length, bristle type, and material for the instrument or equipment to be cleaned.
- Manufacturer's instructions should be followed to ensure that the correct brush is used. Brushes are labeled as single- or multiple-use items and should be used accordingly.
- If reusable brushes are used, CMS requires that they be disinfected or sterilized in accordance with manufacturer's instructions and at least daily.

for repair) or putting endoscopes on the list (such as loaner endoscopes) should be consistent throughout the facility. An example of an endoscope inventory form is provided as Tool 8-2 on page 24.

Most manufacturers indicate that initial cleaning of flexible endoscopes should take place next to the bedside or exam table with an enzymatic detergent or other cleaner recommended by the manufacturer. The Joint Commission supports this approach. This process is known as precleaning and should not be confused with the thorough cleaning that is necessary prior to disinfection. Some manufacturers instruct customers to perform precleaning with a brush and/or sponge. Staff should be wearing PPE that is recommended by the manufacturer while performing precleaning. After precleaning has been performed, the soiled item should be transported to the reprocessing area in a container that is leak-proof, puncture resistant, and labeled as biohazardous. This transport container may be a special designated box or leak-proof bag.

Surveyors will identify issues with compliance based on the manufacturer's instruction for use and facility policy and procedure.

The routine reprocessing of endoscopes normally includes the following steps[16,17,25]:

At Point of Use

- Precleaning

In Reprocessing Area

- Leak testing
- Manual cleaning
- Rinse after cleaning
- Visual inspection
- High-level disinfection (manual or automated)
- Rinse after high-level disinfection
- Drying (alcohol and forced air)

In Storage Area

- Storage

Precleaning and Cleaning

Precleaning at the point of use should be followed by manual cleaning and visual inspection (steps 1–5) and should occur even if an automated endoscope reprocessor (AER) is used.[25] AAMI ST91 states:

The automated cleaning cycle is not intended to replace point of use precleaning or thorough manual cleaning of the endoscope prior to placing it into the AER.[25(p. 26)]

The Joint Commission High-Level Disinfection (HLD) Sterilization BoosterPak states:

All the steps of precleaning, leak testing, cleaning, and rinsing must occur to prepare the endoscope for either a manual or automated disinfection process.[27]

Personnel should take care to ensure that the cleaning and disinfection process occurs within the time frame specified by the endoscope manufacturer. At least one endoscope manufacturer specifies that reprocessing should occur within one hour, or an alternative reprocessing procedure that includes extended soaking may be required. In addition, detergents used to clean endoscopes should be changed after each endoscope.

Endoscopes may be manually disinfected or disinfected in an automated reprocessor in accordance with the endoscope and AER manufacturer's instructions for use. If issues or discrepancies are identified between the two, AORN states that the endoscope manufacturer's instructions should be followed, while AAMI ST91 states that a decision should be made based on information that can be acquired from both companies if there are discrepancies between the two.[25,28] Surveyors from CMS and other agencies may ask to review the process used to resolve any discrepancies and how risks were addressed in the facility or departmental risk assessment.

The cleaning chemicals and disinfectants must be compatible with the endoscope and must be used in compliance with manufacturer's instructions. Personnel should test the high-level disinfectant in accordance with manufacturer's instructions. This would include ensuring that the test strips for the disinfectant have undergone quality-control testing, have not expired, and have been used in accordance with manufacturer's instructions. Failure to follow test strip instructions has been a frequent finding by surveyors. Figure 8-2, below, shows a technician using the test strip to check the dilution of the disinfectant agent.

Every channel of the endoscope must be reprocessed each time the endoscope is used, even if the channel was not used in the preceding procedure. **Each step of the appropriate process must be applied to every channel.** If an AER is used it is essential that the model-specific connectors are used to ensure that every channel is disinfected. After being disinfected and rinsed, channels must be dried. This usually involves injecting air through each channel followed by an alcohol flush and then additional air to purge the alcohol. The outside of the endoscope should also be dried; some manufacturers recommend a clean, dry cloth, while others recommend wiping with alcohol.

Final Inspection and Storage

The endoscope should undergo final inspection and be stored. The Society of Gastroenterology Nurses and Associates (SGNA) recommends that unless the reprocessor has a dedicated space for accessories, such as a basket or "nook" for accessories such as buttons, these items should be reprocessed separately.[24] However, ST91 states that the detachable endoscope parts that are to be reused (for example, air/water and suction valves/pistons) should be processed together and stored with the specific endoscope as a unique set in order to allow traceability.[25]

FIGURE 8-2: Testing the Disinfectant with Test Strip

Photo by Sylvia Garcia-Houchins, RN, MBA, CIC

Each organization will determine what process it will use. The infection preventionist can help guide the decision.

In the United States surveyors will expect to see endoscopes stored in a designated vented cabinet in the vertical position without the tip of the endoscope touching the bottom of the cabinet. Scopes should not be touching each other. Storage of endoscopes and specific accessories are controversial because of discrepancies between regulatory requirements and endoscope reprocessing standards. ST91 states that each facility must determine and implement the policy and procedure that is least likely to lead to patient harm.[25]

Future Reprocessing Options for Endoscopes

Some disinfection and sterilization experts are now recommending that endoscopes be sterilized instead of receiving high-level disinfection. This is based on evidence that high-level disinfection does not always adequately destroy organisms in the scope (such as duodenoscopes), which has resulted in serious infections and multidrug-resistant organism outbreaks. Contamination of both duodenoscopes and flexible bronchoscopes has been found even after the manufacturer's instructions and professional guidelines were followed correctly.[8–10] Infection preventionists should follow this issue carefully and work with the reprocessing personnel and others in order to advise their organization about which strategy is appropriate for the organization. In addition to those in the References list, Sidebar 8-2, upper right, lists two helpful sources. Sidebar 8-3, lower right, lists key areas requiring high-level disinfection.

Laryngoscopes

These devices should undergo at least high-level disinfection regardless of where it has been used in a facility. Care should be taken to ensure compliance with manufacturer's instructions for use. Prior to use, each item must be handled in a way that prevents contamination. Most facilities accomplish this by placing the laryngoscope blade in a clean towel, clean bag, or back into a peel pouch after testing the light. In general, keeping laryngoscopes uncovered or unprotected in drawers where they are frequently accessed by potentially contaminated personnel hands would not be considered appropriate. If peel pouches are used to protect laryngoscopes after high-level disinfection, care should be taken to ensure that the laryngoscope is completely dry, and the packaging label should clearly identify that the laryngoscope is high-level disinfected and not sterile. This topic is covered on the Joint Commission website under "Standards FAQ Details.". (*See* the Websites section at the end of this chapter.)

Endocavity Probes

Many facilities use endocavity probe covers to prevent gross contamination of the probe (for example, for vaginal probes). Because many probe covers have high in-use leak rates, use of a probe cover does not negate the need for high-level disinfection.[29] Probes must be cleaned—following manufacturers' instructions—prior to high-level disinfection. Similar to endoscopes, automated high-level disinfection is available. The choice of a high-level disinfection process should be made in accordance with manufacturer instructions and the facility risk assessment.

SIDEBAR 8-2: Resources on Reprocessing Options for Endoscopes

https://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062282.htm

SIDEBAR 8-3: Key Areas Requiring High-Level Disinfection

Key areas where devices requiring at least high-level disinfection can be found include the following:

- Emergency department: Endoscopes, endocavity probes
- OB/GYN clinic: Endocavity probe, diaphragm fitting rings
- Sleep study units: Reusable sleep study masks and tubing
- GI or pulmonary procedure units and clinics: Colonoscopes, duodenoscopes, bronchoscopes
- ICUs: Endoscopes, transesophageal echocardiography probes
- Radiology: Endocavity probes
- Urology clinic: Endoscopes, endocavity probes
- Operating and procedure rooms and sterile processing: Endoscopes, transesophageal echocardiography probes
- Ambulatory surgery centers, office-based surgery practice: Endoscopes, laryngoscopes
- Cardiac procedure areas: Transesophageal

Sterilization

To ensure that devices and instruments are properly sterilized and safe for care on patients, organizations should focus on the following key issues, which include some or all of the following steps.

- **Precleaning at the point of use:** Start the process of cleaning instruments at point of use (for example, in the procedure room) by flushing lumens with sterile water and/or wiping gross tissue and blood on instruments with a moistened sponge during the procedure. If instruments cannot be transported to the decontamination area for immediate reprocessing after the procedure, cover used instruments with an enzymatic spray, gel, or foam, compatible detergent, or a cloth moistened with water in order to prevent drying and then transport as soon as possible to the reprocessing location. Both the instrument manufacturer's and the precleaning product manufacturer's instructions should be consulted and followed. Facilities should ensure compliance with removal of gross debris and prevention of drying, as these procedures are needed to avoid biofilm formation.[18]
- **Transport the item(s) to the reprocessing area:** Contain all items contaminated with blood or body fluids in a leak-proof container from point of use to the decontamination area. Use a puncture-resistant, leak-proof, closable, and labeled container that meets OSHA standards for items that are sharp. Additional requirements may be necessary if transporting offsite for reprocessing, such as maintaining separation between clean and dirty in the transport vehicle and ensuring that items are secured at all times.[25]
- **Disassembly:** Gaskets should be removed, stopcocks opened, and instruments should be completely disassembled as specified by the instrument manufacturer's instruction during the cleaning and sterilization process.[18]
- **Cleaning and disinfection or decontamination:** All items must be cleaned before they can be disinfected or sterilized. This is in addition to removal of gross contamination at the point of use. Thorough cleaning is always required prior to sterilization to remove dirt and organic matter to ensure that the sterilant can reach the surfaces of the items processed. This cleaning must be done in accordance with the manufacturer's instructions. If automated equipment is used for cleaning it must be compatible with the item being cleaned.[18]
- **Refer to manufacturer's instructions, law, and regulation:** Automated cleaning equipment must be operated and quality controlled according to manufacturer's instructions, regulatory requirements, and facility procedures. For example, most manufacturers of automated cleaning equipment have specific loading instructions, cleaning chemicals and rinse water requirements, as well as daily (for example, grate cleaning) and weekly (such as soil challenge tests) checks that must be completed in order to ensure that the equipment is functioning properly. Instruments should be processed as soon as possible after use and should not be held overnight or over a weekend.
- **Rinsing:** Most cleaning or disinfection chemicals include specific instructions for rinsing or not rinsing between steps and the number of rinses that are required.
- **Drying:** Depending on the manufacturer's instructions some items may require drying prior to further processing, while others may not. In all circumstances, items should not be placed in storage until they are completely dry.
- **Physical inspection:** During and after completing the cleaning process, items should be inspected for visible soil or damage. Visual inspection can be facilitated by ensuring that there is adequate light, and use of a magnifier may provide additional assistance.
- **Lubrication:** Some instruments require lubrication to prevent stains and corrosion and to keep the moving parts from rubbing and sticking. Immersion baths are generally not recommended because of the risk of microbial contamination.
- **Wrapping or containers:** All packaging and must be validated for use with the sterilization process and parameters that will be used. Care should be taken to use wrapping supplies, including pouches and rigid containers, in accordance with manufacturer's instructions. Cleaning recommendations and filters for rigid containers are manufacturer specific.
- **Labels:** Labeling that allows the item to be tracked back to the sterilization load must be on the package from the time of sterilization until use. Labeling should not compromise the barrier (for example, mark the plastic side of a peel pouch instead of the paper side and write on sterilization tape rather than on the wrap). The label should include the contents, the date sterilized, and an identifier that allows the item to be tracked back to the sterilization load.
- **Sterilization:** The choice of sterilant must be in compliance with manufacturer's instructions for both the device or instrument and the sterilizer. The sterilization process must be monitored using chemical, biological, and physical indicators as outlined by the manufacturer.
  - Chemical indicators are specific to the sterilization process. Examples include the sterilization tape affixed to the outside of packs and the strips placed within the sterilization container that change color after processing. External and internal indicators should be used for every item sterilized regardless of type of container or packaging. Indicators should be placed in the location specified by the indicator and container manufacturer. Staff must know what

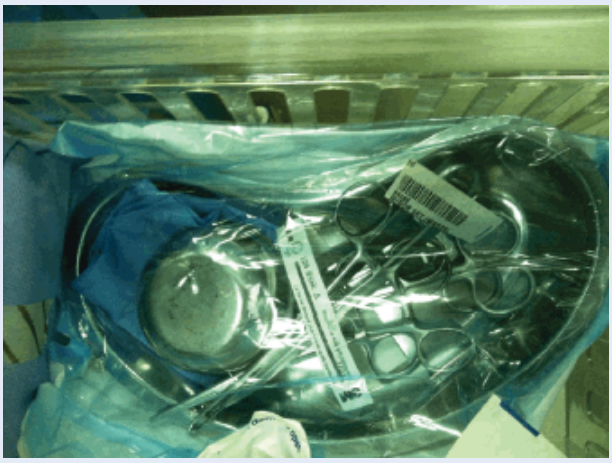
color changes are expected for the indicator used at the facility. Care should be exercised, as there are no standardized color changes among products that are available.

- Biological indicators are specific to the sterilization process and should be included in at least one sterilizer load per week and every load that includes an implant. Clear and complete documentation of the results of biologic indicators is required.
- Physical indicators such as time, temperature, and pressure must be monitored in accordance with the sterilizer manufacturer's instructions. Verification that parameters were met (for example, initials or signature) are usually required as part of the quality-control process prior to removing the item from the sterilizer. Clear and complete documentation of these indicators is also required.

Surveyors will focus on many of these issues. Infection preventionists should work closely with the central processing staff to ensure that the policies and procedures reflect best practice. As one example, Sidebar 8-4, at right, reviews issues associated with peel pouches.

If used, pouches should be sized to prevent tearing during movement or storage. Items should be packaged to ensure that sterilant can contact all surfaces. Facilities can provide safe medical equipment and devices for patients, protect health care workers from exposure, and demonstrate compliance with Standard IC.02.02.01 by following evidence-based guidelines such as those from the CDC, AAMI, and AORN.[13,18,22,25,28,30] These standards are comprehensive and provide concrete recommendations to guide an organization's identification, development, and implementation of appropriate practices related to cleaning, disinfections, and sterilization. Following these standards will ensure maximum patient safety and minimize risk associated with reprocessing. Joint Commission surveyors have been trained on these standards and use them as reference for identifying compliance and noncompliance with this EP. It is highly recommended that all facilities have at least one copy of each recommended reference. Placing these documents on the organization's intranet can provide easy access to personnel who need them. In addition, organizations should be aware that the CMS worksheets for hospitals and ambulatory surgery centers[14,31] address the management of medical devices and equipment.

SIDEBAR 8-4: Common Issues with Peel Pouches



Third peel pouch is too small for container and items.

Photo by Sylvia Garcia-Houchins, RN, MBA, CIC

If double pouching is performed, it must be validated by the manufacturer.

Photo by Sylvia Garcia-Houchins, RN, MBA, CIC

TIP

Each facility should have at least one copy of the relevant and current references for cleaning, disinfection, and sterilization of medical devices and equipment, including those from the following:

- AORN
- AAMI
- CDC
- SGNA

Placing these documents on the organization's intranet can provide easy access to personnel who need them.

A summary of key points for best practices for high-level disinfection and sterilization is provided below.

To help ensure that key best practices for cleaning, disinfection, and sterilization are used, an organization should perform the following:

- Classify all reusable medical equipment, instruments, and devices as noncritical, semicritical, or critical.
- Confirm that all single-use equipment is either discarded r reprocessed by an FDA–approved third-party reprocessing facility.
- Confirm that all reusable equipment is reprocessed according to manufacturer's instructions for use.
- Use multidisciplinary teams to develop and implement standardized policies and procedures for handling, cleaning, disinfecting, sterilizing, and disposing of or storing medical equipment, devices, and supplies. Include the following key participants:
  - Managers and supervisors of any area performing reprocessing
  - Central sterile processing management
  - Infection preventionist
- Ensure that cleaning, disinfection, and sterilization practices are standardized and implemented consistently throughout the organization regardless of location.
- Provide orientation, training, and competency programs for staff involved in cleaning, disinfecting, and sterilizing medical equipment, devices, and supplies.
- Develop, implement, and monitor quality assurance protocols for high-level disinfection and sterilization processes. For example, such protocols must address the use of chemical indicators, administrative controls, and biological monitors for sterilizers and chemical test strips to evaluate the concentration of high-level disinfectants such as glutaraldehyde or peracetic acid.
- Conduct quality assurance monitoring for high-level disinfection and sterilization processes in accordance with manufacturer recommendations and recognized standards and recommendations, such as those from AORN, AAMI, and the CDC.
- Develop a recall policy and procedure that can be activated if performance monitoring or other findings indicate that the sterilization process fails.
- Ensure adequate staffing levels and supervision of personnel who process medical equipment, devices, and supplies. For example, if the average time to clean an endoscope is 15–20 minutes, the average endoscope reprocessing technician can clean approximately 20 to 28 scopes if doing nothing but cleaning during an 8-hour shift (assuming standard breaks). Additional time for high-level disinfection, required documentation, storing, and so on would need to be calculated.
- Develop and implement a system for assessing personnel adherence to cleaning, disinfection, and sterilization protocols and providing the findings to these personnel.
- Ensure availability of policies and procedures for repair or disposal and, if indicated, replacement of damaged equipment and devices.

An infection preventionist should work with facility staff to ensure that a risk assessment of all areas performing high-level disinfection and/or sterilization is performed and that there is consistency among all areas that perform medical device and instrument cleaning, disinfection, sterilization, and/or disposal or storage procedures. In addition, an infection preventionist should be an active participant in the quality review of all areas performing high-level disinfection and sterilization.

IC.02.02.01, EP 3: The [organization] implements infection prevention and control activities when doing the following: Disposing of medical equipment, devices, and supplies.

An organization can demonstrate compliance with IC.02.02.01, EP 3, when health care workers dispose of used medical equipment, devices, and supplies according to federal, state, and local requirements. Rules for managing hazardous waste can vary from state to state, as discussed in Chapter 7. In general, potentially infectious medical waste must be segregated from other waste and packaged according to applicable requirements for transportation to disposal sites. Facilities should establish clear policies and procedures to meet these requirements, educate staff, and ensure compliance.

IC.02.02.01, EP 4: The [organization] implements infection prevention and control activities when doing the following: Storing medical equipment, devices, and supplies.

To prevent supplies from becoming contaminated or compromised during storage, medical equipment, devices, and patient care items should be stored appropriately in protected areas with controlled traffic flow. Key points related to storage include the following:

- Storage areas should meet FGI requirements adopted by CMS and should be clean and in good repair.[19]
- Sterile items should be stored at least 8 inches off the floor, 2 inches from outside walls, and 18 inches from ceilings[8] (FGI section 8.9.2, page 87).
- All items in clean storage rooms should be clean (no soiled items), and clean items should not be stored in soiled rooms.
- Clean and sterile items should be removed from their external shipping containers before they enter storage areas, because the containers may have been exposed to unknown and potentially high microbial contamination during shipping, and may serve as generators of and reservoirs for dust and vermin18 (FGI section 8.9.2, page 88).
- Clean and sterile items may be stored in the same room but it should be clear to staff which items are clean and which are sterile. It may therefore be helpful to group clean items separately from similar sterile items (for example, sterile and nonsterile gauze on separate shelves). Practitioners should determine specific temperature and humidity requirements by reviewing current standards, recommendations, and guidelines.
- Expired items and items in damaged packaging (for example, torn, soiled, wet) should be discarded or reprocessed in accordance with manufacturers' instructions.
- If open shelving is used for sterile or clean storage, the bottom shelf should be solid to protect items from contamination.[18]
- •AMI recommends closed or covered cabinets for storage of items that are seldom used,[18] whereas AORN recommends that sterile items be stored in a controlled environment.[22]
- Supplies, including those in rigid containers, should not be stored next to or under sinks, under exposed or open water or sewer pipes, or in any location where they could become wet.[18]
- Outside shipping containers and corrugated boxes should not be used as containers in sterile storage areas.[18]

IC.02.02.01, EP 5: When reprocessing single-use devices, the [organization] implements infection prevention and control activities that are consistent with regulatory requirements and professional standards.

Inappropriate reprocessing of single-use devices (SUDs) can compromise patient safety. The FDA has strict requirements for reprocessing devices labeled for single-use under the Federal Food, Drug, and Cosmetic Act.31 The FDA requires that reprocessors of these devices provide validation information that includes cleaning and sterilization and functional performance data demonstrating that each SUD will remain substantially the same after the maximum number of times the device is reprocessed. (Third-party reprocessors can be used to meet these requirements.) In other words, before a device that is intended for one use or use on a single patient during a single procedure can be reprocessed and reused, a third party or a health care facility must comply with the same requirements that apply to original equipment manufacturers.

To comply with IC.02.02.01, EP 5, the infection preventionist should collaborate with personnel in patient care and reprocessing areas to ensure that SUDs, particularly those used in invasive procedures, are not reprocessed and reused unless the organization can meet the FDA requirements.[26] Because most health care organizations cannot meet these rigorous requirements, the majority should either use a third-party reprocessor that can meet the requirements or choose not to reprocess and reuse SUDs. The organization would benefit from a clearly written policy, and the infection preventionist can be a valuable collaborator in developing the policy.

Additional information about reprocessing SUDs can be found on the FDA website using the search term "single-use device" (http://www.fda.gov) and in the Further Resources section of this chapter.

EC.02.04.03, EP 4: The [organization] conducts performance testing of and maintains all sterilizers. These activities are documented. (*See also* IC.02.02.01, EP 2)

The machinery used to sterilize devices, equipment, and supplies used for patient care must work effectively so that the organization can ensure that each item processed is safe for patient care. Like Standard IC.02.02.01, Standard EC.02.04.03 illustrates the importance of medical equipment maintenance and testing in infection prevention and control efforts, specifically the maintenance and testing of sterilizers. To comply with EC.02.04.03, EP 4, an organization must have documentation that performance testing, including physical, chemical, and biological

monitoring, and routine maintenance are performed on all sterilizers in accordance with manufacturer recommendations and standardized, accepted practices. In collaboration with the staff members who use sterilizers, infection preventionists should review sterilizer performance monitoring and maintenance records to ensure that maintenance is occurring and that sterilizers are working properly. Staff members who use the sterilizers should have a clear process to follow when the sterilizer is not working properly.

SUMMARY

Inappropriate or inadequate cleaning, disinfection, and sterilization practices have resulted in the transmission of infections to patients. These HAIs can be prevented when facilities implement appropriate infection prevention practices. Effective cleaning, disinfection, and sterilization requires meticulously detailed processes and controls. From initial evaluation of an item for intended use through implementation and quality control of reprocessing procedures, extreme care and oversight is needed. Organizations must provide facilities and equipment that promote proper procedures. Infection preventionists must be aware of current evidence-based infection prevention practices, regulations, and other requirements; new sterilization and disinfection products and technologies; and outbreaks and clusters of infection related to medical devices and equipment. These affect use and reprocessing of devices and equipment at their facility. No matter where in the facility the reprocessing happens or the type of services being provided, the expectations are the same—the safest possible devices and equipment for the patient.

FURTHER RESOURCES

Tools

The following can be found on the flash drive:

- Tool 8-1: Sample Form: Assessment of Item for Reprocessing
- Tool 8-2: Sample Form: Endoscope Inventory
- Tool 8-3: Evaluation Steps for Instruments and Equipment
- Tool 8-4: Sample Manager Rounding Sheet for High-Level Disinfection
- Tool 8-5: Sample Audit Tool for Internally Sterilized Items
- Tool 8-6: CMS Infection Control Worksheet for Ambulatory Surgery Centers
- Tool 8-7: CMS Infection Control Worksheet for Hospitals

This toolkit is available online: ASC Quality Collaboration. Endoscope Reprocessing Toolkit. Accessed Jan 3, 2017. http://www.ascquality.org/endoscopereprocessingtoolkit.cfm

Websites

- Helpful website for practical information about disinfection and sterilization—slides and resources. http://www.disinfectionandsterilization.org.
- The Joint Commission Standards FAQ Details: Laryngoscopes, Blades, and Handles—How to clean, disinfect, and store these devices. Accessed Jan 3, 2017 https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=1201&ProgramId=46.
- US Centers for Medicare & Medicaid Services. CfCs and CoPs for various health care organizations are available at the following: https://www.cms.go/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html.
- US Center for Medicare & Medicaid Services: State Operations Manual Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals is used to survey hospitals for compliance with CoPs and is available at the following site (accessed Jan 3, 2017): https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_a_hospitals.pdf.
- US Food and Drug Administration. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Accessed Jan 3, 2017. http://www.fda.gov/Safety/MedWatch/. Infection preventionists should consider signing up for e-mail Safety Alerts concerns and recalls related to medical devices and medication.

Guidelines

Sidebar 8-1 provides a list of documents and guidelines hat are recommended or required for use by health care facilities when developing their cleaning, disinfection, and sterilization protocols and practices. This section provides additional information.

***Facility Guidelines Institute (FGI)* Guidelines for Design and Construction of Health Care Facilities**

Although the FGI Guidelines were updated in 2014, some states still require compliance with the 2010 edition of the FGI Guidelines. To ensure compliance with state requirements, organizations must identify which guidelines edition their state(s) uses.

- Facility Guidelines Institute (FGI). 2010 FGI *Guidelines for Design and Construction of Health Care Facilities*. Accessed Jan 3, 2017. Available at http://www.fgiguidelines.org/guidelines-main/.

- Facility Guidelines Institute (FGI). FGI 2014 *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*. Provides minimum standards for clinical and support areas of hospitals, rehabilitation facilities, and ambulatory health care facilities. Accessed Jan 3, 2017. http://www.fgiguidelines.org/guidelines-main/.

Additional Reading

- US Food and Drug Administration (FDA). Devices for which a 510(k) should contain validation data (Reprocessing Final Guidance Appendix E). This document provides a list of items that must have validation of reprocessing instruction as part of their FDA 510(k) submission. Accessed Jan 3, 2017. http://www.fda.gov /MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm436512.htm
- Proper Maintenance of Instruments—also known as the "red book"—is an excellent practical reference for specific issues with reprocessing surgical instruments and is available for free download at http://www.lrinstruments.com.au/assets/docs/Proper-Maintenance-of-Instruments_Red-Book_v8-2005.pdf. Accessed Jan 3, 2017.

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