Reprocessing safely in all settings

Procedures requiring sterilized or high-level-disinfected instruments are performed daily in a variety of settings—hospitals, freestanding and hospital-affiliated ambulatory surgery centers (ASCs), physicians’ offices, clinics, endoscopy suites, and dental facilities.

Accreditation surveyors are looking closely at reprocessing in these facilities.

Medicare’s new ASC interpretive guidelines for surveyors issued in May 2009 have detailed guidelines on infection control, supporting the updated ASC Conditions for Coverage (CfCs). Also, the Joint Commission recently said it will scrutinize the entire process of steam sterilization rather than focusing mainly on flash sterilization.

This article includes observations about how ambulatory facilities can adapt the major sterilization standards and recommended practices to their settings. We also offer considerations based on our consulting experience.

Two constants

Like hospitals, many ambulatory facilities have been designed to facilitate efficiency and comply with standards and recommended practices. They may have state-of-the-art instrument processing equipment and be staffed with experienced and competent sterile processing personnel.

Others are converted offices, homes, or apartments that have limited space, and staff have little or no experience in instrument processing. Cleaning is done manually, sterilization is usually accomplished in a tabletop gravity steam sterilizer, and high-level disinfection is not automated.

Two factors, however, are constant regardless of the setting:

• Personnel want to provide safe patient care using instruments that have been properly processed.

• The standards and recommended practices for high-level disinfection and sterilization do not differentiate by practice setting but are adaptable to facility resources.

That is true for the Association of PeriOperative Registered Nurses (AORN) Standards and Recommended Practices and the Association for the Advancement of Medical Instrumentation (AAMI) Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. For example, AORN’s Recommended Practices for Sterilization state, “Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented.”

Adapting your facility

For instance, a facility with space for only one instrument processing area will not be able to dedicate one room under negative pressure to decontamination processes and another under positive pressure for packaging and
sterilization. But it is possible to separate the decontamination and disinfection or sterilization functions by time and space.

Separation by time is accomplished by not decontaminating and sterilizing or disinfecting at the same time. Instruments should be sterilized or high-level disinfected during a time when decontamination is not being done.

To separate these functions by space, the work flow should flow from dirty or contaminated to clean; eg, cleaning followed by packaging followed by sterilization. For example, if there are 2 countertops in the instrument processing area, one should be dedicated to decontamination and the other to packing and sterilization. If there is only one countertop, the end near the sink should be dedicated to decontamination, and the other end should be dedicated to packaging and sterilization. Ideally, the sterilizer should be located at the end of the counter farthest from the sink and after the packaging area.

To separate the decontamination area from the clean area, a Plexiglas partition may be installed on the countertop. Decontamination can be carried out on one side of the partition, and instruments can be packaged and sterilized on the other side.

**Key areas to check**

These are the more common knowledge deficits and areas needing improvement or education this consultant has observed. They are not all-inclusive. Consult the AAMI and AORN documents for a thorough understanding of standards and recommended practices.

Key considerations:

- Personnel cleaning instruments should wear personal protective equipment; ie, a liquid-resistant covering, utility gloves, and eye protection. This applies when cleaning even one instrument.
- The sink used for cleaning instruments should not be used for hand-washing.
- Contaminants should be contained—used instruments should be transported or carried to the decontamination area in a covered container marked with a biohazard label or at least contained in a towel or drape.
- Instruments should be disassembled where appropriate and washed as soon as possible. If unable to clean immediately after a procedure, spray instruments with presoak solution and store them in a covered metal tray or other closed container also marked with a biohazard label.
- Wiping instruments or containment devices with a germicidal wipe is not a substitute for cleaning. Instruments and containment devices should be washed with a detergent intended for this purpose, and the detergent should be prepared strictly according to manufacturer’s instructions.
- Household cleaners are not suitable for instrument cleaning.
- Instruments should be thoroughly dried before they are packaged.
- A chemical indicator should be placed inside all packages. If the inside indicator is not visible from the outside, a chemical indicator should be affixed to the outside as well. The external and internal indicators are different. The external indicator should be a Class 1 indicator. The internal one should be either a Class 3 or 4 indicator or preferably a Class 5 integrating indicator or a Class 6 emulating indicator. The AAMI standard has detailed recommendations on indicators.
• Chemical indicators do not demonstrate sterility. Class 1 indicators are designed to indicate that the package was processed. Class 3, 4, 5, and 6 indicators are designed to indicate that some or all of the parameters have been met.

• Packages should be labeled with the date of sterilization. When a marking pen is used on a peel pouch, the writing should be on the plastic side only.

• The efficacy of the sterilizer should be monitored at least weekly using a biological indicator (BI) appropriate for the sterilizer and cycle. A BI is different from a chemical indicator. A BI is a test system containing viable microorganisms providing a defined resistance to a specified sterilization process (eg, steam sterilization). The test system is subject to a sterilization cycle and then incubated. No growth indicates the sterilizer is effective. Instructions for use guide the user through the process of monitoring.

• A biological indicator must be used with all loads containing an implant.

• Companies that sell chemical indicators and BIs can be located on the internet. Some ambulatory facilities contract with an outside company that will incubate the BI and provide the results.

• BI monitoring results should be documented.

• There should be a written policy and procedure describing actions to take when a BI test indicates sterilization failure.

• High-level disinfection is not the same as sterilization. It should not be referred to as “cold sterilization.” High-level disinfection kills all microorganisms (except prions) but does not kill high numbers of spores. Sterilization kills all microorganisms (except prions) and kills high numbers of spores.

• High-level disinfection is appropriate for flexible GI endoscopes but not for surgical instruments used in a sterile procedure or for instruments that are intended to contact normally sterile areas of the body.

• Processing of GI endoscopes is a complex process. Instructions for processing should be readily available—preferably with an instructional DVD and a laminated poster in the processing area.

• Personnel responsible for processing must have demonstrated competency.

• High-level disinfectant solutions should be labeled with the date the solution was activated or poured into the container and the date it expires.

• High-level disinfectant solutions should be tested before each use to determine that the minimum effective concentration is present.

• Strips used for testing must match the product being tested. Strips are not interchangeable. Some test strips require that a quality control test be performed on each package/bottle of strips prior to using them. Results of the quality control testing should be documented.

• Although a high-level disinfectant may pass the minimum effective concentration test after the expiration date, the solution should be discarded once the expiration date is reached.

• Results of high-level disinfectant testing should be documented.

• An eye-wash station should be present and an eye-wash station sign posted in any facility using high-level disinfectants.

• Processed GI endoscopes should be stored by themselves in a closet or other closed-off area. They should be stored hanging, not coiled.
Sterilized packages/items should be stored only with other sterile items. If storage space is extremely limited, sterile items may be stored on one shelf of a cabinet and clean supplies stored on another shelf.

Supplies should be stored away from potential sources of contamination such as sinks, pipes, and window sills. Nothing should be stored on the floor. Sterile items should be stored at least 8 inches above the floor and at least 18 inches below the ceiling or sprinkler heads.

Reviewing these areas as well as the complete standards and recommended standards will help ambulatory managers not only to prepare for surveyors but also to confirm that their practices for sterilization and disinfection are state of the art.

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References


