Standards, sterilization and quality control

Raising the standard of care for flexible endoscopes

by Jason Bean, BS, MBA

This era of heightened infection risk has become a major challenge to healthcare providers, and no one is taking it lightly. In the United States and around the world, concern is regularly expressed about the dangers of antibiotic-resistant, life-threatening healthcare-associated infections, and the need to reduce or eliminate them wherever possible. U.S. and international agencies meet regularly to discuss and gain consensus around the priorities for healthcare providers. By the time written reports, standards and guidelines are published, they need to be correct and in accordance with standards of care and practice. Our latest issue provides the most recent best practices for endoscopy reprocessing, the three authoritative levels of documentation and the latest regulatory requirements. There is a mountain of information available to healthcare providers to guide them in creating and updating their own endoscope reprocessing policies and procedures. The challenge is to prioritize the information so that it can help providers write compliant programs that follow the best current practices. For endoscopy reprocessing, the three authoritative levels of documentation are depicted in Table 1, top of next page.

The most currently relevant U.S. standards for processing reusable medical devices are: ANSI/AAMI ST79 and its four amendments (A1-A4, 2010-2013), which address the specifics of steam sterilization; ANSI/AAMI ST58, third edition, 2013, which addresses chemical sterilization and high-level disinfection; ANSI/AAMI ST41, fourth edition, 2010, which provides details on ethylene oxide (EO) sterilization; Society of Gastroenterology Nurses and Associates (SGNA): Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes (2012); and ANSI/AAMI ST91, “The Comprehensive Guide to Flexible and Semi-rigid Endoscope Reprocessing in Health Care Facilities.” This last standard provides the most recent best practices for reprocessing thermosensitive flexible endoscopes in a manner that is safest for both person-
nel and patients. Although the standards differ in some respects, and some cover additional topics, all of them discuss work area design, personnel considerations, proper cleaning and preparation of devices, selecting the appropriate process and/or chemistries, using the process safely, device storage and/or transport, and quality control and improvement.

In addition to these, there are numerous guidelines available from professional and governmental agencies that provide detailed process and procedure recommendations to healthcare providers. The following documents are among the most relevant and useful at this time: CDC Guideline for Decontamination and Sterilization in Healthcare Facilities, (2008); ASGE/Shea/SGNA/APIC: Multi-society guidelines on reprocessing flexible gastrointestinal endoscopes (2011); SGNA Guidelines for Use of High Level Disinfectants and Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes (2013); AORN Recommended Practices for Cleaning and Processing Flexible Endoscopes and Endoscope Accessories (2014); and AAMI TIR34: Water for the Reprocessing of Medical Devices (2014).

Moving the standard toward sterilization
Currently, flexible endoscopes are reprocessed in a number of ways designed to achieve either high-level disinfection or sterilization. A high-level disinfectant (HLD) is a product that, when used as directed, should inactivate all microbial pathogens, except large numbers of bacterial endospores. An HLD is often a liquid chemical sterilant that is being used for a shorter exposure time than is required to pass an FDA-defined spore inactivation test.

High-level disinfection requires controlled and correct use of the HLD, including proper rinsing. In fact, any liquid-based disinfection or sterilization process requires controlled, timed rinses with purified water to assure that scopes are not re-contaminated with microorganisms or chemicals commonly found in potable rinse water. AAMI TIR34 provides valuable information on the biological and chemical contamination risks associated with potable water, and ways to assure the quality of rinse water for liquid disinfection and sterilization processes.

Sterilization is a validated process used to render an item free from viable microorganisms, including bacterial spores. The liquid chemical sterilant process uses a peracetic acid-based product that is validated to provide a microbial kill adequate to obtain FDA clearance for a device sterilization label claim. This means that the product has passed the required spore inactivation testing, and has demonstrated effective liquid chemical sterilization of the intended types of medical devices in simulated use and in-use studies.

In order to align with the CDC Gastroenterology/Urology Devices Panel recommendation (that the healthcare community move toward sterilization as the standard of care for duodenoscopes and other thermosensitive flexible endoscopes), facilities will need to evaluate the available low-temperature sterilization options and determine which are compatible with their particular devices. Each option has helpful and challenging aspects for reprocessing departments. They are explained in Table 2, right.

Typically, a department needs more than one of these technologies in order to sterilize all the endoscopes they currently own. As new devices are evaluated for purchase, consideration should be given to how the new device will be sterilized, so that where it makes sense or improves compliance, the department can work toward streamlining the inventory and the number of different sterilization systems being used.

Essentials of liquid chemical sterilant processing
Ethylene oxide sterilizers have been in use for many decades, and hydrogen peroxide gas and plasma sterilizers have been cleared in recent literature, so this module will focus on the most recently cleared technology: the liquid chemical sterilant processing system. The components of the cleared system include: the processor with interchangeable trays to accommodate different device types, a three-part water treatment system, single-use sterilant cups for each cycle, and connectors designed for different types of critical and semi-critical endoscopes, including flexible multi-channel devices and endoscopic retrograde cholangiopancreatography (ERCP) scopes (see figure 1 on next page). Liquid chemical sterilization with peracetic acid has a long history. In a 1998 study by MJ Alfa et al., titled, “Comparison of liquid chemical sterilization with peracetic acid and ethylene oxide sterilization for long, narrow lumens,” the peracetic acid process was shown to be “more effective for sterilizing narrow flexible lumens in the presence of residual inorganic and organic soil. This effectiveness was achieved through a combination of organism wash-off and peracetic acid sterilant killing of organisms.”

Table 1: Authoritative levels of documentation

<table>
<thead>
<tr>
<th>Regulations - Mandatory</th>
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<tbody>
<tr>
<td>Rules or directives made and maintained by an authority, such as the Occupational Safety and Health Administration (OSHA) or the Centers for Medicare &amp; Medicaid Services (CMS)</td>
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<tr>
<td>Mandatory for the affected parties – must be compliant in related policies and procedures</td>
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<tr>
<th>Standards - Voluntary/Mandatory</th>
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<tbody>
<tr>
<td>Provide requirements and specifications that can be used to assure consistency and fitness for a purpose</td>
</tr>
<tr>
<td>Maintained by national and international guidance bodies such as: International Organization for Standardization (ISO); Association for the Advancement of Medical Instrumentation (AAMI); American National Standards Institute (ANSI)</td>
</tr>
<tr>
<td>Although they are not typically mandatory, they can become so through an act of legislation, or if you claim compliance to them in your policies and procedures</td>
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<tr>
<th>Guidelines, Recommended Practices, Technical Information Reports - Voluntary, with interpretation</th>
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<tr>
<td>Technical guidance, information or preferred procedures for a given practice or process</td>
</tr>
<tr>
<td>Examples: Association of periOperative Registered Nurses (AORN) recommended practices, or AAMI technical information reports (TIRs)</td>
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Table 2: Types of Low-Temp Sterilization

<table>
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<tr>
<th>Ethylene oxide gas sterilizers</th>
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<tbody>
<tr>
<td>Benefits</td>
</tr>
<tr>
<td>Challenges</td>
</tr>
<tr>
<td>Aeration required</td>
</tr>
<tr>
<td>Endoscopes may require repair after 15-20 cycles</td>
</tr>
<tr>
<td>“Not routinely recommended” by FDA (Dr. William Maisel, FDA deputy director, chief scientist)</td>
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<tr>
<th>Hydrogen peroxide gas and plasma</th>
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<tbody>
<tr>
<td>Benefits</td>
</tr>
<tr>
<td>Typical sterilization cycle is approx. 30 minutes</td>
</tr>
<tr>
<td>Processes some critical endoscopes</td>
</tr>
<tr>
<td>Some systems have claims for single and multiple-lumened devices, and for bronchoscopes</td>
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| Challenges |
| Endoscopes may have a cleared claim to process flexible gastrointestinal scopes |
| Sterilization claims are for specific critical flexible endoscopes and specific lumen lengths and diameters – must consult manufacturer IFU for each device |

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<tr>
<th>Liquid chemical sterilization</th>
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<tbody>
<tr>
<td>Benefits</td>
</tr>
<tr>
<td>23-minute cycle time</td>
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<tr>
<td>Employs multi-stage water treatment system for extensively treated water for rinsing</td>
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<tr>
<td>Challenges</td>
</tr>
<tr>
<td>Processed items cannot be stored – they must be used immediately</td>
</tr>
<tr>
<td>There is no drying cycle</td>
</tr>
<tr>
<td>Requires water supply</td>
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This system was designed to align with numerous recommendations from current guidance. For example, it enables the user to treat duodenoscopes as critical devices regardless of their classification by applying a validated liquid chemical sterilant process to these devices and a growing number of other flexible endoscope models. In addition, guidance about rinse water quality has been addressed with a three-step treatment process involving pre-filtration, UV irradiation, and a second dual-layer 0.1-micron filtration to remove bacteria, fungi and protozoa. Also, to provide robust quality control for flexible endoscopes, numerous automated monitoring and documentation functions are built into the system to assure process integrity, and testing strips and biological tests have been designed for use in system cycles.

The key stages/functions in the liquid chemical sterilant process, and their purposes, are:

1. **Device preparation**: includes leak testing, cleaning, and rinsing per the medical device manufacturer’s IFU. This removes all visible soils from device surfaces and facilitates the liquid sterilant process. Note: Drying is not required, which significantly reduces prep time.

2. **Device placement**: involves selecting the correct support tray and appropriate connector, loading the device and tray into the processor, loading the sterilant cup, and placing a chemical indicator in the chamber. This prepares all internal and external surfaces of the scope, including contact parts, for exposure to the flow of sterilant, and provides an independent quality control measure for the process.

3. **Connections**: involves aligning and locking the connector at all appropriate junctures of the specific scope, per the liquid chemical process manufacturer’s IFU. This prepares the scope for proper, complete sterilant flow during the cycle.

4. **Sterilization**: involves shutting and locking the lid and pressing the cycle activation button. This initiates the 23-minute automated sterilant processing cycle, which includes:
   a. Filling and equilibration of the sealed chamber
   b. Six-minute exposure to the sterilant at 46-55°C at a controlled flow and temperature
   c. Two rinses with extensively treat water (via a three-step automated treatment process during the cycle)
   d. A filtered air purge, which removes most of the remaining liquid in the channels

5. **Quality control**: numerous control functions and tools, including: automated time, temperature and concentration monitoring during the cycle; water treatment monitoring (a filter integrity test at the end of every cycle, and monitoring of the ultraviolet light dose); chemical indicators to assure the correct concentration of the sterilant; and spore test strips to demonstrate that the antimicrobial process has been applied. The system can also perform a diagnostic cycle as needed, to verify proper functions of the electromechanical systems.

6. **Transport** for patient use: Processed scopes are ready for immediate use after processing. Devices are transported in their trays to the site of use.

As new endoscopes are developed, many are undergoing individual laboratory and clinical testing in this liquid chemical sterilant processing system. Validation of each scope includes meeting specific regulatory requirements, demonstrating antimicrobial efficacy, confirming connection and material compatibility, and verifying biocompatibility (lack of toxicity).

**Improving quality control**

A repeated call to action in recent guidance has been to improve the overall quality of every facility’s reprocessing functions. As stated in ANSI/AAMI ST91: 2015, “Quality control is usually thought of only as product and process monitoring. In its broadest sense, however, quality control involves continuous supervision of personnel performance and work practices, and ongoing verification of adherence to established policies and procedures...” The key to a robust and effective quality control plan is to monitor and verify process, product and people. The ANSI/AAMI ST 91 standard is a rich and detailed resource that healthcare professionals can use to establish thorough quality control policies, procedures and practices for flexible endoscope reprocessing.

In general, a thorough quality control plan should contain the following activities:

- Create a written policy to stay current on all applicable standards and guidelines. Watch for updates and areas of statement conflict to address
- Review the facility’s reprocessing policy, including:
  - At the facility level: patient, personnel and process safety, work area design, and essential requirements of the work
  - At the individual department level: detailed work instructions on how to use all tools and equipment, and specific safety procedures
- Develop an effective staff training program that teaches all necessary skills and requires individuals to demonstrate their competence
  - Provide training for new staff and refreshers for current personnel
  - Audit personnel practices periodically
  - Update practices and add training as new equipment and devices enter the facility

**Protect patients one scope at a time**

Providers and patients continue to appreciate the value of minimally invasive therapies made possible by flexible endoscopes. New devices continue to enter the healthcare market at such a pace that it challenges providers to keep up. It’s time to slow down and rethink how these complex instruments are being managed and reprocessed in U.S. healthcare facilities, for the safety and benefit of everyone involved. Each device deserves the staff’s full attention and thorough understanding, and with improved policies, procedures and practices, this can be achieved.

**References**


Jason D. Bean, BS, MBA, is the senior global product manager for endoscopy at STERIS Corporation. He began his career at STERIS as a microbiologist in the device testing group, where he spent more than five years conducting testing for FDA submissions. He then transitioned to a marketing career with an emphasis on low temperature sterilization modalities. Bean holds a BS in Biology with an emphasis on microbiology, from Lake Erie College in Painesville, Ohio, and a master of Business administration also from Lake Erie College. He is a professional member of AORN and SGNA.
1. Three high-profile regulatory and guidance organizations issued warnings and concerns about flexible endoscope reprocessing that were discussed in this module. They were:
   a. FDA, OSHA, CDC
   b. AORN, CDC, AAMI
   c. CDC, FDA, ECRI
   d. None of the above

2. Among the relevant standards related to reprocessing flexible endoscopes, the most recent and specific document is:
   a. ANSI/AAMI ST79
   b. ANSI/AAMI ST58
   c. ANSI/AAMI ST41
   d. ANSI/AAMI ST91

3. Guidelines, technical information reports and recommended practices are mandatory requirements.
   a. True
   b. False

4. The liquid chemical sterilant process uses a peracetic acid-based product that is validated to provide a microbial kill adequate to obtain FDA clearance for a medical device sterilization label claim. This means that:
   a. The product is a sterilant
   b. The product has demonstrated its effectiveness for liquid chemical sterilization in simulated use and in use with clinically used medical devices.
   c. a and b
   d. None of the above

5. The liquid chemical sterilant processing system was designed to align with numerous recommendations from current guidance, including:
   a. Improving rinse water quality
   b. Improving quality control
   c. Moving towards sterilization of flexible endoscopes
   d. None of the above
   e. a, b and c

6. Validation of new endoscopes that undergo laboratory and clinical testing in the liquid chemical sterilant processing system includes:
   a. Demonstrating antimicrobial efficacy and verifying biocompatibility
   b. Confirming connection and material compatibility
   c. Meeting specific regulatory requirements
   d. All of the above
   e. b and c

7. The key stages or functions in the liquid chemical sterilant process are:
   a. Leak testing, drying, loading the sterilant cup, closing the lid, starting the cycle
   b. Testing the water, testing the chemistry, testing the filters, testing the electromechanics
   c. Device preparation, device placement, connection, sterilization, quality control, transport
   d. None of the above

8. The 26-minute automated liquid sterilant processing cycle includes:
   a. Filling and equilibration
   b. Six-minute exposure to the sterilant at 46-55°C at a controlled flow and temperature
   c. Two rinses with extensively treated water and a filtered air purge
   d. A drying phase
   e. a, b, and c

9. Quality control involves continuous supervision of personnel performance and work practices, and ongoing verification of adherence to established policies and procedures.
   a. True
   b. False

10. The key to a robust and effective quality control plan is to monitor and verify process, product and people.
    a. True
    b. False

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