Quality assurance for low-temperature sterilizers

by Susan Flynn, BESc, CSPDT

Sterile processing staff play an essential role in minimizing the risk of surgical site infections by meticulously cleaning and sterilizing reusable medical devices. Sterilization of critical items is done to ensure these items are free of viable microorganisms when used in surgery. Healthcare accreditation organizations are paying close attention to medical device processing. One accreditation agency, The Joint Commission, continues to see an increasing number of citations for both hospitals and ambulatory facilities for noncompliance with the Infection Prevention and Control Standard IC.02.02.01. This particular standard requires healthcare facilities to reduce the risk of infections associated with medical equipment, devices, and supplies.1

To deliver the best possible patient outcomes, it is important to have a robust quality assurance program in place for all sterilization modalities. As a component of a facility’s risk assessment for sterilization and disinfection, The Joint Commission recommends that current evidence-based guidelines be available and accessible for the use of front-line staff.1 And while staff in many facilities are very familiar with the quality control recommendations for steam sterilization found in ANSI/AAMI ST79, they may be less well-versed in the corresponding AAMI standards for low-temperature sterilization:

- ANSI/AAMI ST58: 2013 Chemical sterilization and high-level disinfection in health care facilities.3

Another key resource is AORN’s Guidelines for Sterilization.4 This self-study article provides a summary of the quality assurance recommendations for low-temperature sterilization included in these documents.

**Background**

Low-temperature sterilization is used for medical devices that cannot tolerate the temperature and/or moisture encountered during steam sterilization. Terminal sterilization results in a dry, packaged product that can be stored for later use. The two most commonly available terminal low-temperature sterilization modalities used in U.S. hospitals are ethylene oxide (EO) sterilizers and vaporized hydrogen peroxide (VH2O2) sterilizers. Manufacturers of reusable medical devices are responsible for validating cleaning and sterilization method(s) for their products and provide reprocessing guidance to the end-user in a device’s Instructions for Use (IFU). Healthcare facilities, in turn, are expected to ensure staff has access to and follows current IFUs, which for low-temperature sterilization may stipulate the use of specific sterilizer models and/or cycle types, and in the case of EO, sterilization and aeration temperatures and times.

ANSI/AAMI/ISO 11140-1:2014 specifies the performance requirements and test methods for chemical indicator manufacturers.5 This standard also contains some useful information for end-users responsible for the quality assurance of low temperature sterilizers. This information includes the symbols used as abbreviated descriptions of the various sterilization modalities and the critical process variables for each process. Table 1 below summarizes this information for low-temperature sterilizers.

**Monitoring tools**

As with steam sterilization, a variety of monitoring tools are used as part of an effective low-temperature sterilization quality assurance program. These include physical monitors and chemical and biological indicators. See table 2.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Sterilization modality</th>
<th>Critical process variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>EO</td>
<td>Ethylene oxide</td>
<td>Time, temperature, relative humidity and ethylene oxide (EO) concentration</td>
</tr>
<tr>
<td>VH2O2</td>
<td>Vaporized hydrogen peroxide</td>
<td>Time, temperature, and hydrogen peroxide concentration</td>
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</table>
In the United States, chemical and biological indicators are regulated as Class 2 medical devices by the FDA. Monitoring tools used in U.S. healthcare facilities should be FDA-cleared for the particular low temperature sterilizer(s) and cycle(s) used at your facility. AAMI recommends that users be appropriately trained and knowledgeable about the performance characteristics and the interpretation of the indicator results.

**Routine efficacy testing**

A robust quality assurance program includes routine efficacy testing using the monitoring tools described above as follows:

- **Physical Monitors**: Section 9.5.1 of AAMI ST58 discusses the use of physical monitors for monitoring gaseous chemical sterilization processes. Two key quotes are: “At the end of the cycle and before items are removed from the processing equipment, the operator should examine and interpret the printout to verify that cycle parameters were met and should initial it to allow later identification of the operator” (3, Section 9.4.2) and, “If the interpretation of the physical monitors suggests inadequate processing, the items should not be dispensed or used.” (3, Section 9.5.1).

- **External chemical indicators**: Both AAMI ST41 and AAMI ST58 recommend the use of a chemical indicator on the outside of each package unless the internal indicator is visible. This external chemical indicator, typically indicator tape in the case of wrapped packs and external process indicators on locks or cards for rigid containers, is examined immediately after the sterilization cycle by sterile processing staff to verify that the load item has been exposed to sterilant.

- **Internal chemical indicators**: An internal CI should be used inside each package, tray, and containment device to be sterilized (AAMI ST41, Section 10.5.2.2.2 and AAMI ST58, Section 9.5.3.2). The internal CIs are retrieved at the time of use and interpreted by the user. It is therefore important that Sterile Processing staff educate their OR colleagues about the interpretation of any new internal CIs.

**Table 2 - Types of monitors**

<table>
<thead>
<tr>
<th>Monitor Type</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Physical Monitors</td>
<td>Section 9.5.2.1 of AAMI ST58 states, “Physical monitors include time, temperature, and pressure recorders; displays; digital printouts; and gauges.” The Rationale statement for this section goes on to explain, “Physical monitoring provides real-time assessment of the sterilization cycle conditions and provides permanent records by means of chart recordings or digital printouts. Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective actions can be taken in the event of failures.”</td>
</tr>
<tr>
<td>Chemical Indicators (CIs)</td>
<td>Section 9.5.3.1 of AAMI ST58 states, “Chemical indicators are sterilization process monitoring devices that are designed to respond with a chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer.”</td>
</tr>
<tr>
<td>Biological Indicators (BIs)</td>
<td>Section 10.5.3.1 of AAMI ST41 states, “Biological indicators consist of viable spores in or on a carrier, sometimes (as in the case of self-contained BIs) accompanied by incubation media. Biological indicators provide the only direct measure of the lethality of the sterilization process.” This section goes on to state, “All BIs should be used in accordance with the BI manufacturer’s instructions.” Similar language is used in Section 9.5.4.1 of AAMI ST58, “Biological indicators are sterilization process monitoring devices consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored. Biological indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization.”</td>
</tr>
</tbody>
</table>

**Table 3 - Biological indicators**

<table>
<thead>
<tr>
<th>Spore Type</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Bacillus atrophaeus</td>
<td>Daily load</td>
</tr>
<tr>
<td>Geobacillus stearothermophilus</td>
<td>Daily, preferably in every sterilization cycle</td>
</tr>
</tbody>
</table>

**Figure 1** Biological indicators: Table 3 below summarizes the spore and recommended frequency of routine BI testing for low temperature sterilizers.

AAMI ST58 states in Section 9.5.4.5.2 that the BI Process Challenge Device (PCD) should be labelled before use and then positioned in the load according to the sterilizer manufacturer’s written IFU. In U.S. hospitals, end-users typically place a BI and an internal CI in a peel-pouch indicated for use in V/H2O2 sterilizers (see Figure 1) and then position the pouched BI in the sterilizer chamber as recommended by the sterilizer manufacturer.

The BI PCD used for routine monitoring of EO sterilizers may be either a facility-assembled routine BI test pack (as described in Section 10.7.2 of AAMI ST41) or a commercially available product that is equivalent in challenge to the routine test pack. The BI PCD is placed in the area of the chamber considered least favorable to sterilization, generally in the center of the load. See Figure 2.

While both AAMI ST41 and AAMI ST58 recommend that any implants be quarantined until the BI result is available, device manufacturers typically validate steam sterilization for implantable items.

A positive result for a test BI indicates a sterilization process failure. AAMI ST58 provides guidance on handling positive BI results in Section 9.5.4.6. This section states, “Because a sterilization failure has occurred, items processed in that sterilizer since the sterilization cycle having the last negative BI should be considered nonsterile. They should be retrieved, if possible, and reprocessed. The sterilizer in question should be taken out of service.” Similar guidance for EO sterilizers in provided in AAMI ST41, Section 10.7.6.1.

**Traceability and cycle documentation**

Traceability of sterilized items is another key component of a QA program. To ensure traceability of load items, AAMI recommends that each pack be labeled with a lot control identifier which specifies the sterilizer, cycle number, and date of sterilization. For each sterilization cycle, the user should record: the assigned lot number; the specific contents of the load; the date and time of the cycle; the time, temperature, and chemical concentration of the exposure phase of the cycle; the name or initials of the operator; the results of BI testing, if applicable; and, in the case of EO cycles, the aeration time and temperature (AAMI ST41, Section 10.3 and AAMI ST58, Section 9.2).
Qualification testing

While routine testing is done daily, preferably with each cycle, qualification testing is done less frequently and one often needs to refer to the applicable standard for a refresher on how to conduct it. Successful qualification testing verifies a sterilizer is fit to process instruments for patient use. Sterilizer qualification testing should be performed after installation, relocation, and major repairs. Qualification testing of EO sterilizers is discussed in Section 10.8.1 of AAMI ST41: “For qualification testing after installation or relocation of the sterilizer, one or more PCDs (the challenge BI test pack of 10.8.2) should be run in three consecutive cycles in simulated loads. A simulated load should contain additional PCDs without BIs, not packaged patient care items.” Note that the challenge BI test pack is different than the routine BI PCD used for routine efficacy testing of EO sterilizers. As qualification testing is not an everyday occurrence, it is important to have a copy of AAMI ST41 on hand to reference on those occasions when qualification testing is necessary.

For vaporized hydrogen peroxide sterilizers, AORN recommends that for each type of cycle enabled, one BI PCD should be run in three consecutive empty cycles (4, Recommendations XX.h.4 and XX.h.5). AAMI ST58 recommends, “Sterilizer testing after installation, relocation, and major repairs should be conducted in the health care facility by health care personnel in cooperation with the manufacturer. The testing should be performed between the time the sterilizer is installed, relocated, or repaired and the time it is released for use or returned to service in the health care facility. Health care personnel should follow the manufacturer’s written IFU, which should include the appropriate BI and PCD to use, the placement of the BI PCD in the load or chamber, whether the chamber should be full or empty, and the number of cycles to run.” See table 4, next page.

Summary

If both ethylene oxide and vaporized hydrogen peroxide sterilizers are in use at your facility, staff should have access to AAMI ST41 (EO) and AAMI ST58 (VH2O2). For routine sterilizer efficacy testing, your low-temperature sterilization Quality Assurance program should include the elements in the table above. Scan the table to ensure your facility’s policies reflect current standards and guidelines. To document compliance with your policy, ensure staff knows how to complete the necessary record keeping, either on paper or using an electronic software program.

References

1. The Joint Commission. High-Level Disinfection (HLD) and Sterilization BoosterPak. December 2015.

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Susan Flynn is a Technical Service Specialist with 3M Infection Prevention Division. She is routinely involved in troubleshooting and addressing questions about sterilization processes. Susan’s role at 3M includes providing education for customers and sales personnel on improving the performance of the sterilization process and implementing best practices. Susan is certified Central Sterile Processing and Distribution Technician. In addition, she is a member of several AAMI working groups.
Quality assurance for terminal low-temperature sterilizers

Circle the one correct answer:

1. Quality assurance guidance for all sterilization modalities used in healthcare facilities is provided in ANSI/AAMI ST79.
   A. True  B. False

2. The chemical indicator (CI) standard that provides the symbols used to represent the method of sterilization is ANSI/AAMI/ISO 11140-1:2014 Sterilization of healthcare products-Chemical Indicators-Part 1: General requirements.
   A. True  B. False

3. The critical variables for the vaporized hydrogen peroxide sterilization process are:
   A. Time, temperature, and hydrogen peroxide concentration
   B. Time, temperature and the presence of saturated steam
   C. Time, temperature, relative humidity and EO concentration
   A. True  B. False

4. AORN’s Guideline for Sterilization recommends that vaporized hydrogen peroxide sterilizers be tested with a BI daily on each cycle type, preferably with each load.
   A. True  B. False

5. ANSI/AAMI ST41 recommends that ethylene oxide sterilizers be monitored with a BI PCD in each load.
   A. True  B. False

6. AAMI recommends that an external process indicator be used on every item.
   A. True  B. False

7. Biological indicators (BIs) that contain spores of Bacillus atrophaeus are used to monitor vaporized hydrogen peroxide sterilizers.
   A. True  B. False

8. To ensure traceability, AAMI recommends that each pack be labeled with a lot control identifier which specifies the sterilizer, cycle number, and date of sterilization.
   A. True  B. False

9. Sterilization of critical items helps ensure these items are free of viable microorganisms at the time of use.
   A. True  B. False

10. An effective low-temperature sterilization quality assurance program includes the use of physical monitors, chemical indicators, and biological indicators.
    A. True  B. False

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### Table 4 - Routine efficacy testing of low-temperature sterilizers

<table>
<thead>
<tr>
<th>Monitoring Tool</th>
<th>Frequency</th>
<th>EO</th>
<th>VH2O2</th>
<th>Acceptance Criteria</th>
<th>Record Keeping</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Monitor</td>
<td>Every load</td>
<td>Every load</td>
<td>Printout is examined to verify cycle parameters were met.</td>
<td>Printout is initialed and included in cycle documentation.</td>
<td></td>
</tr>
<tr>
<td>Chemical Indicators (CI)</td>
<td>External CI placed on outside of each package unless internal CI is visible.</td>
<td>Internal CI used inside each package, tray, or containment device.</td>
<td>External CI examined after sterilization to verify that the package has been exposed to the sterilization process.</td>
<td>Document any reports of internal CIs which did not meet their end-point response.</td>
<td></td>
</tr>
<tr>
<td>Biological Indicator (BI)</td>
<td>Routine BI PCD is run in every load.</td>
<td>Test BI is run daily on each cycle type, preferably with each load.</td>
<td>Negative result from test BI.</td>
<td>Test and control BI results and lot codes are documented.</td>
<td></td>
</tr>
</tbody>
</table>

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