

April 2007

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## Learning Objectives

1. Discuss the four essential elements of an effective sterility assurance program.
2. Briefly describe biological performance qualification of steam sterilizers as it is conducted by sterilizer manufacturers.
3. Discuss development of medical device reprocessing guidelines as described in AAMI TIR 12:2004.
4. Discuss how to conduct product testing.

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# Why do we need to conduct product testing?

by Susan Flynn, BESC

By now you've probably heard the news that the Association for the Advancement of Medical Instrumentation (AAMI) published new recommended practices for steam sterilization in the fall of 2006. This document, ANSI/AAMI ST79:2006, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, is a must-have for all sterile processing departments. In fact, it was AAMI's best selling standard in 2006!

Chapter 10 of ANSI/AAMI ST79:2006 discusses four essential elements of an effective sterility assurance program:

- Routine load release for both implant and nonimplant loads;
- Routine sterilizer efficacy monitoring;
- Sterilizer qualification testing;
- Periodic product quality assurance testing.

February's self-study article discussed routine sterilizer efficacy monitoring and sterilizer qualification testing in detail.<sup>2</sup> This article will explore the details of the fourth element, periodic product quality assurance testing.

Let's briefly review the first three essential elements as they provide the foundation for a solid monitoring program.

**Routine load release** is divided into two sections: nonimplants and implants. The sterilization monitoring tools used to release a nonimplant load include the sterilizer's physical monitors, external and internal chemical monitoring of packages, and the optional use of a Process Challenge Device (PCD or test pack) containing one of: a biological indicator (BI); a BI and a Class 5 integrating indicator; a BI and an enzyme-only indicator; or an enzyme-only indicator. It's important to remember that the criteria for releasing implant loads are more stringent. Monitoring tools recommended to release implant loads are the sterilizer's physical monitors, external and internal chemical monitoring of packages, and a PCD containing either a BI and a Class 5

integrating indicator or a BI and an enzyme-only indicator. Except in defined emergency situations, the implant should not be released until the results of the BI are available.

**Routine sterilizer efficacy monitoring** is establishing a regular pattern of testing the efficacy of the sterilizer to ensure medical devices are effectively sterilized. ST79 recommends monitoring a full load weekly, preferably daily, with a BI PCD for sterilizers larger than 2 cubic feet and table-top sterilizers. For sterilizers larger than 2 cubic feet, the PCD is the AAMI 16-towel pack or an FDA cleared, commercially available disposable BI PCD. For table-top sterilizers, the PCD is a representative package or tray that is routinely processed and considered difficult to sterilize. Flash sterilizers are monitored at the same frequency but the BI is placed inside each type of tray (perforated, mesh-bottomed open surgical tray; rigid sterilization container system; a protective organizing case; or a single wrapped surgical tray) routinely processed and placed in an empty load. A BI PCD should be run in each type of cycle for which the sterilizer is designed (i.e. prevacuum, gravity displacement, flash, etc.). In addition, routine sterilizer efficacy monitoring includes the use of a Bowie-Dick (BD) PCD to evaluate the efficacy of air removal and steam penetration in dynamic-air-removal steam sterilizers. This testing is conducted each day the sterilizer is used, before the first processed load.

**Sterilizer qualification testing** is testing of the sterilizer "after sterilizer installation, relocation, malfunction, major repairs, and sterilization process failures."<sup>3</sup> For sterilizers larger than 2 cubic feet, three consecutive empty cycles should be run, one right after the other, with a BI PCD (AAMI 16-towel pack or FDA cleared commercially available disposable BI PCD) followed by three consecutive empty cycles with a Bowie-Dick PCD in dynamic-air-removal sterilizers.

In table-top sterilizers the BI PCD is run in three consecutive cycles in a fully loaded chamber and the load quarantined until the BI results are available. A representative package or tray that is routinely processed and considered difficult to sterilize should be used as the PCD. Like sterilizers larger than 2 cubic feet, flash sterilization cycles are qualified by running a BI PCD in three consecutive empty cycles followed by three consecutive empty cycles with a Bowie-Dick PCD in dynamic-air-removal sterilizers. The user selects a tray configuration (for example, a perforated, mesh-bottomed, open surgical tray or a rigid sterilization container system) as the PCD.

So provided your facility has qualified your steam sterilizers after installation, conducts routine efficacy monitoring according to agency recommendations and releases loads based on defined criteria, why is periodic product testing necessary?

To address this question, let's explore the standards used by sterilizer manufacturers in the validation of steam sterilization cycles and by device manufacturers in the development of reprocessing guidelines for reusable medical devices. One term common to both documents is Sterility Assurance Level (SAL). SAL is defined as the probability of a viable microorganism being present on a product after sterilization. Items intended to come in contact with compromised tissue are generally expected to have a SAL of  $10^{-6}$ , meaning that there is less than or equal to one chance in a million that a single, viable microorganism is present on a sterilized item.<sup>4</sup>

### Performance qualification of hospital steam sterilizers by sterilizer manufacturers

ANSI/AAMI ST8:2001, *Hospital steam sterilizers*, provides guidance on the minimum construction and performance requirements for hospital steam sterilizers larger than 2 cubic feet in volume. The document is not a user document, it is intended "for use by equipment manufacturers in the performance and design qualification of steam sterilizers intended for use in health care facilities."<sup>4</sup>

Section 4 of the standard lists the requirements and corresponding parts of Section 5 provide test methods and procedures for manufacturers to verify compliance with the various requirements. An extensive list

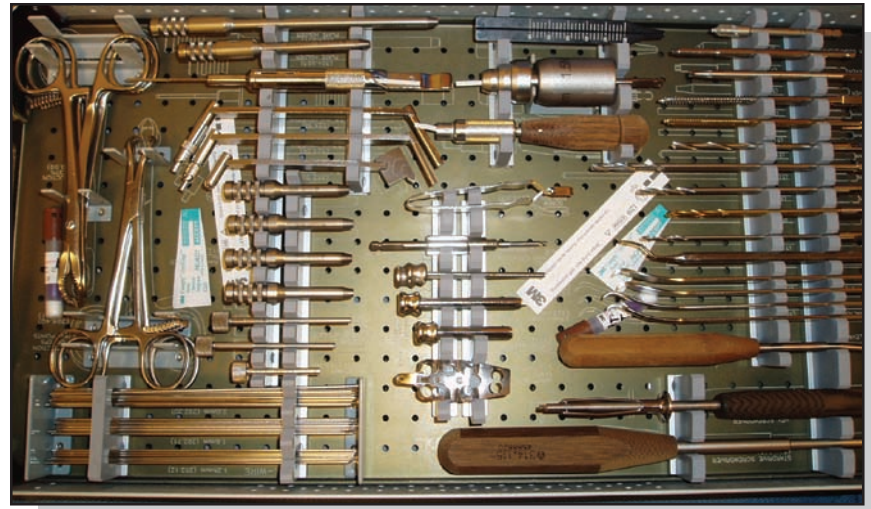


Figure 1: Example of instrument set with multiple BIs and CIs

of requirements, including minimum labeling, safety, information and service manuals, pressure vessel test certification, etc., are specified in the standard. For the purposes of this self-study article, we'll focus on the "Biological performance of sterilizers" requirement. Section 4.5 states:

When the sterilizer is tested according to 5.5, the manufacturer's recommended cycle or cycles shall have sufficient lethality to reduce a biological-indicator (BI) population to a  $10^{-6}$  probability of a surviving organism, and the test results shall otherwise meet the acceptance criteria defined in 5.5.<sup>4</sup>

This means manufacturer's testing must demonstrate that there is less than or equal to one chance in a million that a single, viable microorganism is present on a sterilized item.

Guidance on conducting tests to support this requirement is provided in Section 5.5, Biological performance of sterilizers. Manufacturers conduct the tests as part of initial design qualification and periodically (at least every 24 months or whenever a design change that could affect performance occurs) on production units. Manufacturers must conduct biological performance tests, using BIs containing *Geobacillus stearothermophilus* spores, on the following types of loads:

- a. Fabric test pack;
- b. Liquid loads (if applicable);
- c. Wrapped instrument test pack;
- d. Abbreviated (flash/emergency) cycles for nonporous items, either unwrapped or in a single wrapper (if applicable).

Tests for the non-liquid loads (i.e. a, c, and d) should produce acceptable results when performed with separate loads on three consecutive half cycles. For the purposes of this self-study, let's explore the details of biological performance testing for fabric and wrapped instrument test packs in more detail.

The fabric test pack is the standard AAMI 16-towel test pack, with BI(s) and a temperature sensor placed in the geometric center of the pack. The test pack is placed in the "cold point" and run in a chamber fully loaded with test packs (without BIs) for gravity-displacement sterilizers and in an otherwise empty chamber for dynamic-air removal (e.g. pre-vacuum) sterilizers. Note that the test loads vary for gravity displacement sterilizers vs. dynamic-air-removal sterilizers because of the different effects of chamber air content on steam penetration. ST8 states: "Dynamic-air-removal sterilizers are subject to the "small-load effect," whereas gravity-displacement cycles are more challenged by a large load that inhibits the air-displacement process". After running a normal sterilization cycle, including drying time, the BIs are incubated to determine the appropriate sterility assurance level (SAL) was achieved and the packs are inspected for moisture retention which includes verifying that the packs have not gained more than 3% in weight and do not exhibit wet spots.

For wrapped instrument test packs, manufacturers must use a test pack with a total weight of 16 pounds. The pack is com-

See **SELF-STUDY SERIES** on page 42

## SELF-STUDY SERIES from page 41

posed: of a perforated or wire-mesh-bottom tray lined with a cotton surgical towel, miscellaneous metal surgical instruments; two BIs placed among the instruments; two cotton wrappers. The test pack is run in a full load, with simulated instrument packs making up the balance of the load contents. A sterility assurance level (SAL) of at least  $10^{-6}$  and appropriate moisture retention (no wet spots on outer wrappers or more than 3% gain in weight) are the acceptance criteria.

The points key to this discussion are that sterilizer manufacturers use a 16-towel test pack and 16 pound instrument test pack to verify biological performance of fabric and wrapped instrument loads, respectively. The use of rigid containers and complex instrument sets containing large heat sinks and/or lumen challenges is not required.

## Reprocessing reusable medical devices

We know that the Medical Device Manufacturer (MDM) should always be consulted for reprocessing instructions for reusable medical devices. So how do MDMs develop their reprocessing instructions? One of their guides is AAMI TIR12: 2004, *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*.

"This AAMI Technical Information Report (TIR) covers design consideration that medical device manufacturers should take into account to help ensure that their products can be safely and effectively reprocessed."<sup>5</sup> Manufacturers are obligated by the FDA to conduct testing to validate their reprocessing instructions. They have the responsibility to provide comprehensive written instructions for the handling, cleaning, disinfection, testing, packaging, sterilization, and, if necessary, aeration of their products. As health care professionals, it is our responsibility to obtain, review and ensure we have the resources necessary to follow manufacturers' device reprocessing instructions. While the AAMI TIR includes discussion on design considerations, decontamination, disinfection, and sterilization, this self-study focuses on steam sterilization reprocessing guidance.

Section 6.5 of AAMI TIR12:2004 discusses sterilization efficacy testing. Efficacy testing must show that the recommended cycle parameters are capable of producing the desired SAL for

the device (typically  $10^{-6}$ ). Device manufacturers are encouraged to test commonly available hospital sterilization cycles. The good news: for steam sterilization, the available cycles provided to manufacturers in Annex B of the TIR are essentially the same cycles listed in Tables 5 and 6 (minimum cycle times for gravity-displacement and dynamic-air-removal, respectively) in AAMI ST79:2006. Should the available cycles be insufficient to achieve the desired SAL, the TIR suggests manufacturers adjust those parameters that can be controlled by health care personnel (e.g. exposure time in the case of steam sterilization).

Manufacturers demonstrate the desired lethality of a cycle by using the overkill sterilization method. An example would be the successful inactivation of a microbiological challenge in one-half the cycle exposure time. The microbiological challenge used to qualify steam sterilization processes is *Geobacillus stearothermophilus*. The challenge should be placed in the most difficult-to-sterilize, accessible locations of the medical device. If placing a biological indicator in this area of the device isn't possible, the manufacturer can inoculate the device using a liquid spore suspension.

Device manufacturers can then demonstrate cycle lethality by performing three sterilization cycles at one-half the exposure time. During these qualification runs, the device should be packaged in a manner appropriate to the device and available to health care personnel.

Understanding that device manufacturers may now be inoculating complex medical devices with spores, determining the exposure time necessary to achieve the desired SAL and then doubling this time to arrive at a recommended sterilization exposure time gives us a better understanding of the science behind the extended cycle times being recommended by some device manufacturers.

## Product testing in health care facilities

Now that you know your steam sterilizers were validated by the manufacturer using test loads that may be less challenging than those routinely processed in your department and that MDM instructions for reprocessing medical devices are increasingly recommending cycles different than those you may have routinely used in the past, hopefully you have a better appreciation of the need for product testing.

The "Rationale" sections of ANSI/AAMI ST79:2006 help to clarify the justification for specific recommended practices. In the case of Product Testing, the rationale states: "The standardized PCD (BI challenge test pack) presents a known challenge to the sterilization process. However, this pack does not reflect the items routinely processed in a health care facility. Therefore, product testing is recommended as part of a complete quality assurance program to ensure the effectiveness of the sterilization process and to avoid wet packs."<sup>3</sup>

So, now if we accept the need to conduct product testing, how is it done? Turning to ST79, Section 10.9 provides guidance on periodic product quality assurance testing. With respect to frequency, the document states: "A program should be established to periodically test routinely sterilized products. Product testing should always be performed when major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper."<sup>3</sup> Additionally, you may choose to conduct product testing when adding new instrument sets, including loaner instrument sets.

To conduct the testing, place biological indicators (BIs), and chemical indicators (CIs) and/or enzyme only indicators within the test sample (see Figure 1). The number of BIs and CIs used will depend on the size and configuration of the pack sample being tested. Place the indicators in the area(s) that presents the greatest challenge to the sterilization process (e.g. in the corners and center of containment devices, between layers of a folded surgical gown within a fabric pack, next to a heat sink in an instrument set). Wrap/close the product test sample as you normally would, label the product test sample(s) and process in a routine load along with other items. Always consult with the medical device manufacturer for recommended sterilization parameters and, when conducting product testing, group items/containers that have similar recommended sterilization cycles. Place the test samples at the most difficult to sterilize points in the chamber.

After sterilization, retrieve the BIs and CIs, inspect the pack for moisture, and either reprocess or discard the contents of the test sample. Investigate any unacceptable test results (positive BIs, CIs that haven't reached their endpoint, or evidence of moisture) and implement correc-

See **SELF-STUDY SERIES** on page 44

