Product testing: The overlooked 4th pillar of a robust sterilization process monitoring program

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Has a new loaner tray ever given you pause because of its size, complexity, or density? Concerned about processing a new brand of container in your facility's older sterilizers? Installing a new low temperature sterilizer? While the responsibility for validating sterilization parameters for reusable surgical instruments and packaging rests squarely with the device manufacturer, sterile processing professionals can and should perform product testing.

Learning Objectives

1. **Review the four elements of a comprehensive sterilization monitoring program.**
2. **Discuss approaches to streamline periodic product testing.**
3. **Discuss AAMI and AORN guidance on the prepurchase evaluation of rigid containers.**

Product testing can give you confidence that a particular instrument set or container can be successfully processed in your facility in your sterilizers. In fact, product testing is one of the four pillars of a comprehensive sterilization quality assurance program, albeit the one that is probably the least often practiced. This article will review the recommendations on product testing provided in national standards and guidelines.

ANSI/AAMI ST79:2017/(R)2022, *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities*, is the 'go to' document for steam sterilization. This resource describes the four pillars of a robust quality assurance program: routine load release; routine sterilizer efficacy testing; sterilizer qualification testing; and periodic product testing.[1]

Qualification testing, which includes three consecutive cycles with a biological indicator (BI) process challenge device (PCD), should be done after installing a new sterilizer or performing major repairs on an existing sterilizer. Healthcare facilities should have defined policies for routine release of both non-implant and implant loads and implants should be quarantined until the BI result is available. Routine efficacy testing of both steam and vaporized hydrogen peroxide (VH2O2) sterilizers should be conducted at least daily on each cycle type, if not every load, and internal and external chemical indicators (Cis) should be included in and on each item.

Adherence to the recommended quality assurance program tends to be inconsistent, however, on the 4th recommended element: performing periodic product testing of routinely processed load items. Intuitively, departments sometimes perform product testing when investigating a sterilization product failure, often uncovering a surprise in an IFU related to load size, container placement, and/or validated sterilization modality. Rather than being a reactive exercise, product testing can be a proactive method of verifying the ability to achieve sterilization parameters in your facility with your sterilizers and associated utilities. But sometimes the ambiguity of the requirements makes it easy to push product testing to the back burner. How often should we do it? How do we do it? Haven't the device and packaging manufacturers already validated sterilization parameters for their products? Why should we repeat their work in our department?

This last question leads us to review two definitions provided in ANSI/AAMI ST77:2013®2018, *Containment devices for reusable medical device sterilization*:

- Verification: "Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met."[2]
- Validation: Documented procedure performed by the device manufacturer for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications."[2]

Product testing (i.e., verification) is not a replacement for the more extensive validation testing performed by device manufacturers. Product testing cannot be used, for example, to justify a shortened steam sterilization exposure time or a different VH2O2 cycle type than has been validated by the medical device manufacturer. It is used to demonstrate that the device manufacturer's validated IFU can be successful in the sterilizers in your health care facility.

VH2O2 Sterilization

The recommendation to conduct periodic product testing is not unique to steam sterilization standards. Indeed, because VH2O2 sterilization is technique-sensitive, one could argue that if you are not yet performing product testing, this low-temperature modality might be the place to start! Luckily, ANSI/AAMI ST58:2013/(R)2018 *Chemical sterilization and high-level disinfection in health care facilities*, includes good suggestions on this topic in Section 9.7.[3] For example, the concept of a 'product family' is discussed. Medical devices may be grouped into a product family sharing the same basic design, materials, and reprocessing instructions. From the product family, a 'master product', considered the most challenging in the family to process, is selected. Product testing conducted on the master product thus covers the entire product family. The good news? If you purchase a new item that fits into an established product family and is less challenging to process than the master product, there is no need to conduct product testing on the new item. How often should master products be tested? ANSI/AAMI ST58 suggests testing one master product each month. It could be daunting to test all master products at the same time each year, so adopting a system of testing one master product per month may be a more achievable plan. What might trigger a repeat master product test? ANSI/AAMI ST58 suggests in Section 9.7.1, "Product testing could be repeated whenever changes are made to a product family's composition, designated master product or written IFU or if a new sterilizer or other piece of processing equipment is purchased."[3]

Steam sterilization Section 13.9 in ANSI/AAMI ST79:2017/(R)2022 provides recommendations on conducting periodic product testing of items that are routinely processed using steam sterilization. The same product family and master product concepts reviewed above are discussed in this section. When establishing a product family, AAMI recommends considering several product characteristics including:

- Design configuration
- Number of components
- Materials of construction
- Size and/or surface area
- Need for disassembly
- Surface finish or texture
- Presence of cannulations, lumens, or mated surfaces
- Written reprocessing instructions provided by the manufacturers".[1]

After establishing a product family, a master product (the most difficult to sterilize device) is designated. Performing product testing on this master product is much less burdensome than testing every single device or set in a product family.

Lesson:

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Quiz Answers:
1. A, 2. B, 3. B, 4. A, 5. A, 6. B, 7. A, 8. B, 9. A, 10. A

Like AAMI ST58, AAMI ST79 also suggests testing one master product each month as a good starting point for a periodic product testing program. Perhaps you even have extra control BIs that could be used for a monthly master product verification test. And exactly how is product testing done? Multiple biological indicators and chemical indicators are placed within the test sample; the sample is labeled as a test item; and the test sample is run in a routine sterilizer load using the cycle parameters recommended in the manufacturer's written IFU. After sterilization: the test sample is opened and inspected for evidence of moisture; the BIs are incubated and the CIs are inspected to verify they have reached their endpoint. Any unexpected result should be investigated. The test protocol and results should be documented, and the test sample reprocessed before patient use. Loaned items can include complex instruments packaged in multilayered sets, representing a challenge to sterilization. Does your facility's loaner policy specify that loaners arrive 48 hours before the scheduled case? When a new loaned item arrives at the facility, AAMI ST79 recommends performing product testing unless the item fits into an established product family.[1]

Rigid containers

Manufacturers of rigid sterilization containers are required to validate the sterilization efficacy of their products in sterilization cycles commonly available in healthcare facilities.[2] They cannot possibly, however, perform validation testing in all brands, models, and sizes of sterilizers. As the chamber size, vintage, steam quality, maintenance history, etc. can vary widely out there in the real world, it is recommended that healthcare facilities perform prepurchase evaluation of rigid containers.

AAMI provides detailed guidance on performing prepurchase evaluation of rigid containers in ANSI/AAMI ST79:2017(R)2022, Section 13.10.[1] Prepurchase evaluation is recommended so that users can verify, before purchase, that the specific design of the container system will perform as expected in the health care facility's sterilizers. Although the container manufacturer has conducted sterilization validation studies, the user is responsible for verifying that the containers are compatible with the sterilizers in their facility. In the case of steam sterilizers, the user needs to verify the rigid containers will permit complete air removal, adequate steam penetration and adequate drying.

As a first step, assess the rigid container manufacturer's written IFU to verify the FDA-cleared indications for use are consistent with cycles available on your sterilizer(s). To perform the prepurchase evaluation, place multiple BIs and CIs throughout the container. Consult the container manufacturer for advice on the appropriate (i.e., area of greatest challenge to air removal and steam penetration) placement of BIs and CIs in the rigid container. The BIs, CIs, and instruments are placed in the test rigid container system, along with any required filters. Worst case testing is simulated by using the largest instrument sets recommended by the container manufacturer and testing both a maximum and small load. Any absorbent material, if typically used, should also be included in the container. After running the cycle recommended by the container manufacturer, open the container and check for retained moisture, examine all CIs and incubate the BIs. There should be no visible condensed moisture in or on the container, the CIs should have reached their endpoint, and all BIs should be negative. Any unacceptable results should be investigated and resolved before purchase of the rigid container system. The instruments used to conduct the test need to be reprocessed before use.

Product testing isn't just for the sterile processing department. AAMI ST79 recommends placing items to be sterilized for immediate use in a rigid sterilization container. Thinking of switching brands? Don't forget to conduct a prepurchase evaluation of any rigid sterilization containers being considered for immediate-use steam sterilization (IUSS). Verify your OR sterilizers can run the cycle validated by the container manufacturer. In the case of prevac containers, check whether both a pre-assembled BI PCD and the container will fit in the IUSS sterilizer chamber. Positive biological indicators or failed internal chemical indicators can be caused by a rigid container/sterilization cycle mismatch that could have been caught had product testing been performed. For example, running a rigid container validated for pre-vacuum steam sterilization in an "express" (2-pulse pre-vac) IUSS cycle can result in a failed product test, with a potential corrective action of removing the express cycle option from the sterilizer to prevent future inadvertent use errors.

AORN perspective

The Association of perioperative Registered Nurses routinely updates their Guidelines for Perioperative Practice. As in previous editions, the 2024 edition includes guidelines focusing on device reprocessing. In general, these guidelines are consistent with recommendations found in AAMI end user sterilization standards. The Guideline for Sterilization Packaging Systems includes the recommendation that packaging systems and packaging materials should be evaluated before purchase and use.[4] AORN reminds us that a critical first

step before switching to a new packaging method is to review the product's FDA clearance and the packaging manufacturer's IFU to verify the packaging is suitable for the method(s) of sterilization and the specific equipment at your facility. The guidelines further suggest conducting product testing before major changes in packaging, e.g., before switching to the use of rigid containers. AORN recommends conducting product testing by lacing the set or container with BIs and CIs, running the item in a full load, and evaluating the monitoring products for pass or fail results. The procedure and all test results, including an assessment of moisture for steam-sterilized items, should be documented.

Summary

Contemplating switching to a new method of packaging? Borrowing or purchasing a new, complex orthopedic set? Installing a new model VH2O2 sterilizer? Sitting on an accumulation of leftover control BIs? Perhaps it's time to incorporate product testing into your sterilization quality control program. This could be a great assignment for a team member looking to take on some additional responsibility. Tackle the project in manageable pieces, perhaps by testing one master product in each sterilization modality each month. As part of the process, remember to obtain the current IFU for both the master product, the associated packaging, and any ancillary items placed in the set. **HPN**

References

1. Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2017(R)2022. Arlington (VA): AAMI, 2017.

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3. Association for the Advancement of Medical Instrumentation. Chemical sterilization and high-level disinfection in health care facilities. ANSI/AAMI ST58:2013/(R)2018. Arlington (VA): AAMI, 2013.

4. Association of periOperative Registered Nurses. Guideline for Selection and Use of Packaging Systems for Sterilization in Guidelines for Perioperative Practice 2024 Edition. © 2024 AORN Inc, Denver, CO.

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Product testing: The overlooked 4th pillar of a robust sterilization process monitoring program - Practice Quiz

1. **Routine load release is one element of a robust sterilizer quality assurance program.**
   A. True
   B. False
2. **It is not necessary to perform product testing for items processed in low temperature methods of sterilization**
   A. True
   B. False
3. **Health care facilities are responsible for validating sterilization parameters for medical devices.**
   A. True
   B. False
4. **AORN suggests conducting product testing before major changes in packaging.**
   A. True
   B. False
5. **A 'product family' is a group of products that have similar design, materials, and processing instructions.**
   A. True
   B. False
6. **A 'master product' is considered the least challenging item in a product family to process.**
   A. True
   B. False
7. **Product testing of a master product should be repeated if a new sterilizer is purchased.**
   A. True
   B. False
8. **It is not necessary to document product testing activities.**
   A. True
   B. False
9. **Checking the processed test sample for evidence of moisture is part of the product testing procedure for steam sterilized items.**
   A. True
   B. False
10. **Testing both a maximum and small load is recommended when conducting prepurchase evaluation of rigid sterilization containers.**
    A. True
    B. False

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