

## Sterilization & Infection Control

# Verification, validation: What's the difference?

**T**here are many reasons you may want to change how you organize or package an instrument set or the sterilization cycle for a set. Maybe the set weighs more than the 25 pounds recommended for containerized instrument sets. Perhaps the original container has sharp edges that tear the wrappers, and you want to containerize the set. Maybe your facility doesn't want to use the extended cycle in the device manufacturer's instructions because the cycle takes too long, requires more cycles to be run, and affects efficiency and output.

Those all may seem like good reasons. But if you make such a change without having validated, Food and Drug Administration-cleared instructions for use (IFUs) from the device or container/packaging manufacturer, you can't assume the instruments are safe for patient use. That's because the facility has not validated the change and submitted the data to the FDA in a 510(k) submission. Though your facility may have performed product testing to verify the changes, that is not the same as validation testing by the medical device manufacturer.

It's important to understand the difference.

### Validation versus verification

What is the difference between validation and verification? The

*Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* from the Association for the Advancement of Medical Instrumentation (AAMI) defines the 2 terms:

**Validation:** "Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications" (Section 2.129). Validation covers 3 activities: installation qualification, operational qualification, and performance qualification. AAMI also says that validation is performed by the device manufacturer.

**User verification:** "Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met" (Section 2.128).

### User verification

User verification is product testing to determine if a health care facility can sterilize a medical device based on the predetermined specifications (eg, packaging, cycle parameters) that the medical device manufacturer provides as a result of its validation testing. Product testing involves placing self-contained biological indicators (BIs) and chemical indicators (CIs) in the most challenging areas of the containment device or other packaging and running a standard load with the sterilization parameters provided in the IFUs.

Not all products need to be tested. Instead, products can be tested by families, usu-



ally designated by the manufacturer, such as orthopedic or neurological instruments. In that family, the most challenging product is chosen as the master product for testing. If a new instrument or container set is a greater challenge than the master product previously tested from that family, then product testing needs to be performed.

If a new instrument or container set is not as great a challenge as the previous master product tested, product testing does not need to be performed. Medical device manufacturers can assist in identifying product families and a master product.

### **Manufacturer validation**

Manufacturer validation testing is expensive and time-consuming. AAMI's standard for containment devices (ANSI/AAMI ST77:2006) states that manufacturers shall demonstrate through validation testing that the contents of a container or other packaging can be processed to a sterility assurance level (SAL) of  $10^{-6}$  under the conditions recommended in their IFU. This means there is less than or equal to 1 chance in 1 million that a single viable microorganism is present on a sterilized item.

Depending on the sterilization method, according to AAMI, testing shall be performed with either one-half cycle, fractional cycles, or a cycle based on predetermined increments of critical process parameters such as sterilant concentration, volume of sterilant, or sterilization time.

AAMI provides detailed recommendations for how containment devices are to be selected for testing and how the testing is to be conducted. These recommendations are difficult if not impossible for most health care facilities to carry out. They require, among other things, microbiological challenges with a BI spore strip or inoculated carriers (not self-contained BIs); internal mapping of sterilant penetration with multiple, calibrated temperature sensors; and sterility maintenance and physical integrity tests.

The manufacturer must then submit this testing information to the FDA for clearance before it can be provided in the IFU. The clearance process also takes time.

The FDA requires that all medical device manufacturers maintain a detailed record of any changes in the device, called the design history file. This file includes what change was made, what the risks were, and how those risks were satisfied. Based on these changes, the manufacturer may decide to repeat the validation testing and file a new or amended 510(k).

### **Can your facility perform validation testing?**

If you are considering performing validation testing, answer these questions. If any of the answers are no, don't attempt to perform validation testing. Does your facility have:

- the personnel expertise or the ability to change the sterilization equipment cycles to perform half cycles, fractional cycles, or incremental critical process parameter cycles using spore strips, inoculated threads, or liquid spore suspensions?
- a laboratory capable of aseptically retrieving the BI samples, placing them in the appropriate media, and incubating them at the correct temperature?
- expertise or multiple calibration temperature sensors to do internal temperature mapping inside the containers or other packaging?
- expertise and required equipment to perform sterility maintenance testing and microbial challenge testing?
- resources to maintain contact with the original device manufacturers to ensure you know when design changes are made on devices so you can determine if you need to repeat validation testing?

## **Why should I care if validation testing was done?**

Validation testing is performed by medical device manufacturers, and the results are cleared by the FDA to ensure the product is safe for patient use. Once a device and its up-to-date IFU are in your health care facility, your goal is to ensure the product is safe for patient use. The only way you can do that is by following the manufacturer's IFU and monitoring the sterilizers according to the recommended practices from ANSI/AAMI.

Because of the differences in the validation testing performed by manufacturers and the verification testing performed by health care facilities, facilities cannot make changes from the original manufacturer's IFU, such as packaging and cycle parameters, based on the facility's user verification or product testing.

Do not allow a sales representative, delivery person, or your personnel to make any of the following changes to a manufacturer's original instrument/container set unless those are addressed in validated FDA-cleared IFU from that manufacturer. If changes are made, the medical devices may no longer be safe for patient use.

Do not:

- remove or add instruments to the set
- remove the set and add it to a generic rigid container
- add the original instruments with container to a generic rigid container
- take instruments from several vendor trays and add them together in a vendor-provided tray or rigid container system to create a new set.

In addition, do not change the original validated wrapping material or change the validated sterilization cycle parameters.

Contact the corporate headquarters of the medical device manufacturer to ensure changes you want to make in packaging or sterilization cycles are validated and FDA-cleared. Patients are depending on you to follow medical device manufacturers' IFU and provide them with a safe product. ❖

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## **References**

- Association for the Advancement of Medical Instrumentation. *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. ANSI/AAMI ST79:2010 & A1:2010 (Consolidated Text). Arlington, VA: AAMI, 2010. [www.aami.org](http://www.aami.org)
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