HEALTHCARE PURCHASING NEWS

April 2022
The self-study lesson on this central service topic was developed by 3M Health Care. The lessons are administered by Endeavor Healthcare Media.

Earn CEUs

After careful study of the lesson, complete the examination at the end of this section. Mail the completed test and scoring fee to *Healthcare Purchasing News* for grading. We will notify you if you have a passing score of 70% or higher, and you will receive a certificate of completion within 30 days. Previous lessons are available at www.hpnonline.com.

Certification

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this in-service for one (1) contact hour for a period of five (5) years from the date of original publication. Successful completion of the lesson and post-test must be documented by facility management and those records maintained by the individual until recertification is required. DO NOT SEND LESSON OR TEST TO CBSPD. For additional information regarding certification, contact CBSPD - 148 Main Street, Suite C-1, Lebanon, NJ 08833 • www.cbspd.net.

HSPA (Healthcare Sterile Processing Association, https://myhspa.org)) has pre-approved this in-service for 1.0 Continuing Education Credits for a period of three years, until March 8, 2025. The approval number for this lesson is **3M-HPN 220803**.

For more information, direct any questions to *Healthcare Purchasing News* (941) 259-0832.

LEARNING OBJECTIVES

1. *Review the principles of sterilization quality control.*
2. *Discuss the basic requirements of validation.*
3. *Examine the requirements and application of routine monitoring.*

Sponsored by:
3M Health Care

SELF-STUDY SERIES

Sterilization quality control

Validation, routine monitoring go hand in hand

Craig Wallace, President, Wallace Sterilization Consulting, LLC

Proper sterilization of medical and surgical instruments is a critical piece of any infection prevention program. The very best aseptic technique will not be able to compensate for contaminated instruments. The equipment and processes used in the sterile processing department are complex, and the success or failure of a sterilization process is not easily determined. The sterile processing team must rely on a comprehensive quality system approach to ensure that instruments are safe and ready for use on patients.

Introduction to sterilization quality control

You can't see sterility. A sterile instrument looks identical to a nonsterile instrument. Thus, the decision on whether processed instruments are safe for patient use must be based upon other information. A sterilization quality control (QC) system must be in place to provide a process testing framework that will provide this necessary information. A QC system can be loosely defined as a system that maintains the quality of a product (in this case, the product is safe surgical instruments) by testing the product against a set of specifications. In this context, sterilization QC systems do not test the instruments themselves because instrument sterility testing is not practical in a hospital setting. Instead, the sterilization process conditions are tested using an array of different types of tests that provide a comprehensive picture of the quality of the sterilization process.

The QC system should cover every aspect of instrument reprocessing (e.g., cleaning, inspection), with tests designed to provide information specific to each step in the process. This article will focus on the sterilizer and the sterilization process, and the QC approach that supports the final decision on whether to release the instrument load for use on patients. In addition, the focus will be on steam sterilization, as this process is used for the majority of surgical instruments. However, the principles discussed can be applied to low temperature sterilization processes as well.

Approaches to quality control

There are two different approaches to quality control for sterilization processes (also called sterility assurance). The first approach is called process validation, the second approach is called verification. In some situations, the validation approach can enable the use of parametric release for

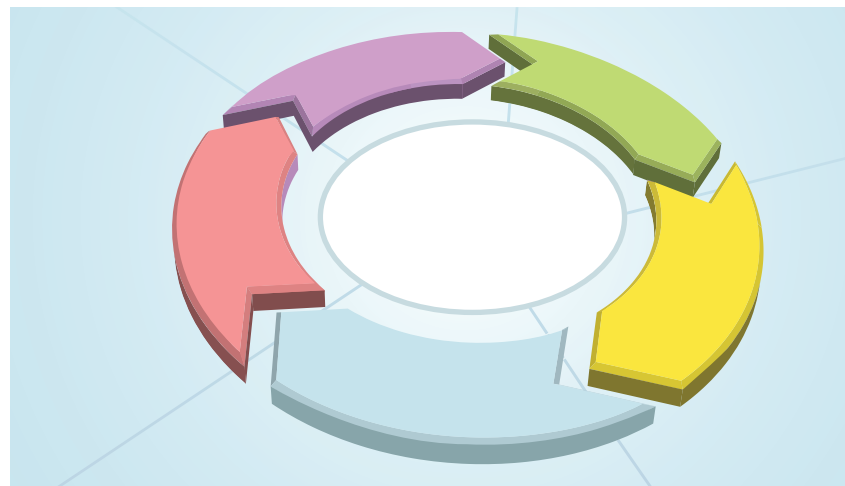

Photo credit: Michael Brown | stock.adobe.com

the final load release decision. Verification relies on individual process testing and is often called routine monitoring. In this approach the load release decision will be based on the results of an array of tests on that specific sterilization process and load. The validation and routine monitoring approaches are quite different, however, there are ways they can be compatible. We'll start with a detailed review of each approach.

Validation

The term validation is defined as a "confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled"[1]. The "provision of objective evidence" refers to testing that produces data on the performance of a process, in this case, a sterilization process. This data is analyzed to determine if "the requirements . . . have been fulfilled," in other words, if the sterilization process met its expected performance parameters. For steam sterilizers used in healthcare, validation is typically performed by the sterilizer manufacturer to define and control the selected cycle. To really understand the details of the validation approach we can look at how validation is used by medical device and pharmaceutical manufacturers. The larger scale of their sterilization processes and required compliance with healthcare regulations makes validation the preferred sterility assurance approach for these companies. Substantial technical and financial resources are required to support the validation programs. Let's take a closer look.

The validation approach starts with testing and documentation that verifies that the equipment is installed and operating correctly. Process development begins with physical testing to confirm the critical variables of the process, and also determine the process parameters of the process. Critical variables are process variables such as exposure time or temperature that have a direct effect on the efficacy, or killing power, of the sterilization process. A process parameter is the actual numerical setting for a variable. For example, temperature is considered a critical variable for steam sterilization. A specific setting of 132°C would be the process parameter for the temperature variable. In the healthcare setting the sterile processing team will "choose" process parameters by selecting from pre-programmed cycles on the sterilizer. For an industrial setting that is using the validation approach the parameters must be established by testing. This testing can be quite extensive and complex. This process development testing will include establishing the limits of the process, that is, how much the parameters can be varied and still provide the required process lethality. Sometimes called "worst case" testing, these process tests will include physical measurements from multiple cycles using complex instrumentation that is placed in several locations inside the chamber and load. Process efficacy is typically evaluated through microbial inoculation of the most difficult to sterilize locations within the most challenging surgical devices, followed by culturing in a microbiological laboratory.

Once the required sterilization process parameters are established, the rest of the validation approach is focused on ensuring that those parameters are controlled and achieved on every single cycle. The core of the validation approach is the data-driven establishment of the process parameters followed by active control of the process and parameters to ensure that the process achieves it's expected efficacy. Active control means taking steps to ensure that the equipment is always capable of delivering the required process parameters. This will include rigorous on-going calibration of all testing equipment and sensors, and strict adherence to preventative maintenance procedures for the sterilizer and any ancillary equipment. A major challenge for steam sterilization is assurance that the steam quality does not vary from cycle to cycle. Steam quality is a critical process variable, as problems with steam quality (e.g., too wet, too dry, superheated, contaminated with non-condensable gasses) will adversely affect the efficacy of the process. Variations in steam quality can be difficult to detect and require significant investment to control. Validated steam sterilization processes typically require dedicated steam generation equipment, strict control of feedwater quality, and a rigorously maintained delivery system. The steam quality is carefully monitored to ensure it continually meets the requirements established in the process development and validation testing.

Another general requirement of the validation approach is change control. Again, the overall philosophy of the validation approach is establishment of the conditions necessary to achieve a successful sterilization process, then active control of those conditions for all routine sterilization processes. Change control requires an assessment of the possible effects of any change from the original validated conditions, with subsequent revalidation of the process to accommodate the change, if needed. Changes can include intended changes to process parameters as well as any changes in cleaning processes, process or testing equipment, packaging or containers, instruments in the load, and even changes in load size or configuration. Sterility assurance by validation requires complete documentation of all materials processed, all process conditions, and the results of all change control assessments. Periodic re-validation of the process is required even if there are no substantive changes.

A final aspect of the validation approach is possibility of the use of parametric release. Parametric release is defined as "declaration that product is sterile, based on records demonstrating that the process parameters were delivered within specified tolerances."[1] In this system the decision to release a load of instruments for use on patients is based on assessment of the critical process parameters for that load, to see if all of the parameters were within the ranges established during the validation work. While this sounds straightforward, in reality it is quite complex. The parameter measurements require sophisticated instrumentation. A typical sterilizer cycle printout generated by a single sensor in the sterilizer chamber would not meet this requirement. In addition, the use of parametric release assumes the full critical parameter control system is in place for this cycle, and for all cycles. Parametric release is an efficient tool and well suited for industrial applications that are capable of the high level of process control and documentation required to utilize it.

Verification and routine monitoring

The term verification is defined as "confirmation, through the provision of objective evidence, that specified requirements have been fulfilled"[1]. The definition is similar to that of validation, but verification is a bit narrower. It is not defined as a process and focuses on "specified requirements" instead of the broader "intended use." For

Self-Study Test Answers: 1. A, 2. A, 3. B, 4. A, 5. B, 6. A, 7. A, 8. A, 9. A, 10. A

sterility assurance, a practical way to look at verification is routine monitoring, where the specified requirements would be the expected results of physical, chemical, and biological testing of a process. For steam sterilizers used in healthcare, verification is performed by the sterilize processing department personnel on each cycle.

The fundamental assumption behind the routine monitoring approach to sterility assurance is that total control over all process parameters coupled with a rigid system that does not allow variation is not possible in many situations. Healthcare facilities are typically not staffed, equipped, or funded to be able to implement the full validation process. The size, weight, and composition of healthcare sterilization loads are known to vary widely based on the cases scheduled in the operating room.[3] The validation approach operates under the assumption that, through rigorous engineering and controls, every sterilization cycle and load is identical. The routine monitoring approach operates under the assumption that variability is inherent in the system and, for load release, treats each sterilization cycle as a distinct, independent event. In this system each sterilization cycle is tested with independent monitors, and the load release decision is based on the test results for that specific cycle.

The testing tools used for routine testing load release are physical monitors, chemical indicators, and biological indicators. Physical monitoring is accomplished by sensors in the steam sterilizer chamber that measure temperature and pressure and record the readings on the cycle printout. Physical monitoring helps ensure that the intended cycle was selected and provides a printed record of the cycle. Chemical indicators placed on the outside of packages are used to provide visual confirmation of exposure to the process, while chemical indicators placed inside of packaged items will provide information on the physical process parameters occurring inside of the load. Biological indicators, typically placed inside of process challenge devices, challenge the sterilization process with a large number of highly resistant bacterial spores. Biological indicators provide the only direct measurement of process lethality because they measure the process' ability to kill microorganisms rather than evaluating physical parameters.[2] The results of all tests are considered for the final load release decision.

While the routine monitoring approach considers each sterilization cycle as a unique event regarding load release, there is still a need for a broader QC program. Documented standard operating procedures should be in place that define the requirements for all processing steps. An example of a broader QC program for steam sterilization is provided in AAMI ST79:2017 (*Comprehensive guide to steam sterilization and sterility assurance in health care facilities)* [4]. This standard defines different types of tests for the sterilizer and sterilization process that go beyond load release testing and provide a much broader picture of the overall quality of the sterilization process. In addition to Routine Load Release, AAMI ST79 recommends Routine Sterilizer Efficacy Monitoring (routine monitoring of the process with process challenge devices), Sterilizer Qualification Testing (a special testing regime to be used to return a sterilizer to service), and Periodic Product Quality Assurance Testing (to verify instrument manufacturer's Instructions for Use). This matrix of quality control tests provides a breadth of information about the sterilization process while accommodating the realities of the flexibility required in health care sterilization.

Routine monitoring with validation

The validation and routine monitoring approaches to sterility assurance are quite different, and at first glance would seem to have little or no overlap. The validation approach seems to be best suited for industrial sterilization or sterilizer manufacturers, and not really applicable to the health care environment. However, while a full-blown validation system is typically not suited to healthcare, there are elements of the validation approach that can complement and strengthen a routine monitoring program. From a higher level, a general philosophy of more control and consistency in all processes can help reduce variability and improve quality. Careful attention to sterilizer sensor calibration and sterilizer preventative maintenance of testing and process equipment can also reduce variability. Some healthcare facilities already do quarterly or annual testing of sterilizer process parameters and such things as varied load configurations as part of their quality program. Though sometimes called validation, this type of testing should not be confused with a full validation program that requires on-going control of all process parameters, a full change control system, etc. In a general sense, any additional quality control steps taken beyond normal routine monitoring are helpful and can improve the quality of the overall process. In this way validation and routine monitoring can go hand in hand.

Summary

Sterility assurance programs are required to ensure that processed instruments are safe and ready for patient use. The full validation approach is effective but requires significant resources and is typically only used in industrial settings. The routine monitoring approach accommodates variability and the flexibility required in health care settings. Elements of the validation approach can augment and strengthen the routine monitoring approach in healthcare facilities. **HPN**

References:

1. International Organization for Standardization. Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards. ISO 11139:2018. Geneva, Switzerland. ISO, 2018

2. Rutala, WE et al. Guideline for Disinfection and Sterilization in Health Care Facilities, 2008. Update May 2019. HICPAC/CDC.

3. Lapanaitis et al. Case Study: Correlation between the duration of a steam sterilization process and the weight of the processed load. Zentralsterilization 26: 2018.

4. ANSI/AAMI ST79:2017 & 2020 Amendments A1, A2, A3, A4. , Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Association for the Advancement of Medical Instrumentation.

3M Health Care sponsored this article.

Craig Wallace, president of Wallace Sterilization Consulting, LLC, has over 28 years of experience in the field of medical device disinfection and sterilization. Craig is the Convenor of the ISO TC198 Working Group 4, the ISO committee responsible for international biological indicator performance standards, as well as a U.S Technical Expert for Chemical Indicators (ISO WG 6). He is also the Co-Chair of the United States (AAMI) Biological Indicator Working Group, and an active member of several other AAMI working groups including chemical indicators and vaporized hydrogen peroxide sterilization.

CONTINUING EDUCATION TEST • APRIL 2022

Sterilization quality control

Validation, routine monitoring go hand in hand

Circle the one correct answer:

1. **Since you can't determine if an instrument is sterile just by looking at it, you need to rely on other information to decide if a load of instruments is safe for patient use.**
   A. True B. False

2. **The process validation approach to sterility assurance is primarily used by medical device and pharmaceutical manufacturers.**
   A. True B. False

3. **A process variable is a specific value of a process parameter.**
   A. True B. False

4. **Validation and routine monitoring are two approaches to sterility assurance.**
   A. True B. False

5. **Parametric release relies on the results of physical, chemical, and biological indicators.**
   A. True B. False

6. **The validation approach assumes each sterilization cycle is the same as the previous cycle.**
   A. True B. False

7. **Routine monitoring relies on the results of physical, chemical, and biological indicators.**
   A. True B. False

8. **For load release, routine monitoring treats each sterilization cycle as a unique event.**
   A. True B. False

9. **The routine monitoring approach to sterility assurance is the typical approach used in health care facilities.**
   A. True B. False

10. **Elements of the validation approach can be used to strengthen the routine monitoring approach.**
    A. True B. False

HSPA HEALTHCARE STERILE PROCESSING ASSOCIATION

The approval number for this lesson is **3M-HPN 220803**.

CBSPD

HEALTHCARE PURCHASING NEWS EDUCATION HUB

You can now read and take the test online in our new **Education Hub**:

https://educationhub.hpnonline.com/

Request for Scoring

❑ *I have enclosed the scoring fee of $10 for EACH test taken — **Payable to Healthcare Purchasing News.** We regret that no refunds can be given. (It is not neccessary to submit multiple tests separately.)*

Detach exam and return to:
Continuing Education Division
Healthcare Purchasing News
2477 Stickney Point Road, Suite 315B
Sarasota, FL 34231
PH: 941-927-9345 Fax: 941-927-9588

Please print or type. Return this page only.	
Name	
Title	
Hospital Name	
Mailing Address	
Apt/Suite	
City, State, Zip	
Daytime Phone	
Email	