Sterilization Quality Control: Your Path to Protecting Your Patients

BY CRAIG WALLACE

Protecting the patient is the objective of all infection prevention programs. Safe and effective processing of medical devices that have been used in surgery and patient care is a critical element of every healthcare infection prevention program. The sterilization processes used in healthcare are designed to kill all microorganisms on the medical devices, rendering them sterile. The problem, of course, is that you can't see sterility. You can't just look at the instruments after processing and decide if they are sterile and safe for use on a patient. You need a quality testing system designed to provide you with the information you need to decide if the instruments are safe for patient use.

Learning Objectives

1. **Discuss the key elements of sterilization quality control.**
2. **Review the information provided by sterilization monitoring tests.**
3. **Examine the current best practice recommendations for sterilization monitoring.**

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Introduction to quality control

Quality control in manufacturing is a process that relies on a test or combination of tests to ensure that a product meets its required performance or quality standard. Sterilization quality control is a set of procedures and tests intended to ensure that the sterilized devices have been properly processed and are then safe for patient use. The quality control plan should address all stages of the process, from the time soiled instruments are received for cleaning and decontamination until they are sterilized and ready for patient use. The quality tests used through the process may include visual or functional inspections, or specific tests on the device or process to demonstrate that the latest step in the process was completed correctly. For this article we will focus on quality control testing during the last step in the process: the complex and critical sterilization step. Sterilization quality control processes will generally be based on frequent testing of the sterilizer with different types of monitoring devices that are designed to provide information on different aspects of each sterilization process. These monitoring products are typically placed in different locations within the loaded sterilizer (load control) or inside the packs (pack control) to provide a complete view of the process. The information provided by these monitors is reviewed and the final decision about the quality of the cycle (and hence safety of the instruments) is made based on the results of all the tests. This fundamental QC approach is applied to both of the primary sterilization processes used in healthcare today – steam sterilization and vaporized hydrogen peroxide sterilization (VH2O2).

Sterilization quality control testing

Variations in a sterilization process could significantly impact the effectiveness of that process. Each type of sterilization process has critical process variables, or process variables that must be within their validated range or they can have a negative impact on the effectiveness of the process. For steam sterilization the critical process variables are exposure time, temperature, and the presence of saturated steam. For VH2O2 sterilization, the critical process variables are exposure time, temperature, and the concentration of hydrogen peroxide. Sterilization quality control testing uses tests that are sensitive to these critical process variables. The best practice is to monitor the process with different types of tests and include the results of each of the tests in the final load release decision. The three types of tests typically used in sterilization quality control are physical tests, chemical indicator tests, and biological indicator tests.

Table 1: Types of Chemical Indicators		
Type	**Term**	**Description and use**
1	Process indicators	Used on the outside of packages to differentiate processed from unprocessed items.
2	Indicators for specific tests	Indicators used for specific sterilizer tests such as Bowie-Dick tests for pre-vacuum steam sterilizers.
3	Single critical process variable indicators	Intended to react to a single critical process variable. Placed inside of packages.
4	Multicritical process variable indicators	Intended to react with one or more critical process variables. Placed inside of packages.
5	Integrating indicators Used inside of packages or inside a PCD.	Intended to react with all critical variables and relate to a calculated biological response. Used inside of packages or inside a PCD.
6	Emulating indicators	Intended to react with all critical variables. Used inside of packages or inside a PCD.

Physical testing

Physical monitors are electromechanical sensors located in the sterilizer chamber walls that measure physical variables such as temperature and pressure in the sterilizer chamber. Cycle time is also recorded as part of the cycle record. Information from these sensors is transmitted to a display and a printer, which produces a paper record of the cycle.

Physical monitors provide important information and should be reviewed by qualified personnel after every cycle. The physical monitors provide information on any major malfunctions that may have occurred in the cycle and are also used to confirm that the correct cycle was run. The printed record is a valuable tool for record keeping. Since physical sensors are located in the sterilizer chamber walls, they cannot provide information on the physical environment within the load or inside of packages or containers.

Chemical indicators

Chemical indicators (CIs) are defined as a "test system that reveals change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process" 1. Chemical indicators will either change color or have a visible chemical move along a window in response to exposure to one or more of the critical process variables.

Chemical indicators are categorized based on how they respond to the sterilization process. Six different types are defined in the ISO international standard for chemical indicators2. Different types of chemical indicators may have different applications. The chemical indicator types and applications are summarized in Table 1. It should be noted that chemical indicator Types are not hierarchical; that is, higher numbers do not mean better or more robust indicators.

Chemical indicators play a broad and important role in a sterilization quality control program. Indicator chemicals undergo a readily identifiable physical or chemical change when exposed to certain levels of some or all of the critical process variables. The indicator type, and the manufacturer's instructions regarding the capabilities of the chemical indicator should be understood so the indicator result can be correctly interpreted.

Process indicators such as tapes and labels use color change chemistry to make it easy to distinguish sterilized from non-sterilized items to prevent accidental use of instruments that have not been processed. Process indicators do not, however, provide information on the quality of the sterilization process; rather, they simply

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

demonstrate that the item has been exposed to the process by a change in indicator color.

Bowie-Dick tests provide important information on the function of the vacuum system on steam sterilizers that use dynamic air removal processes. These tests are done in an empty chamber to assess the worst-case conditions (maximum amount of air to be removed). Bowie-Dick tests are specific to steam sterilizers.

Chemical indicator types 3, 4, 5, and 6 are designed to be placed inside each package or container to provide information on the sterilization conditions at the location of the surgical instruments themselves. Internal or pack indicators provide a cost-effective way to obtain information on the status of each package and are particularly useful in finding errors in packaging or sterilizer loading. The amount of information provided by the indicator will depend on the type of indicator selected.

Finally, for steam loads that don't contain an implant (more on this below), Type 5 or Type 6 chemical indicators can be placed inside a process challenge device (PCD) and used as part of a load release decision.

Biological indicators

Biological indicators (BIs) are defined as a "test system containing viable microorganisms providing a defined resistance to a specified sterilization process."[1] BIs contain a large number of bacterial spores that are highly resistant to the sterilization process. After exposure to the process, the BI is incubated to determine if the spores produce any biological activity, which would indicate a sterilization process failure. Technological advancements have reduced BI readout times (incubation time required to determine that the BI is negative) from days to minutes or seconds.

BIs are generally contained inside PCDs, which are placed in the chamber with the instrument load and are designed to challenge the sterilization process and directly demonstrate that the sterilization process was effective in killing microorganisms. BI will be able to detect problems with steam quality or VH2O2 concentration that are not detected by the other indicators, as poor sterilant quality will reduce the cycle lethality and result in a positive BI.

Table 2: Load Release Testing – Vaporized Hydrogen Peroxide (VH2O2) Sterilization

	Loads containing implants	Loads without implants
Physical monitoring	Every cycle	Every cycle
External (process) CI	On the outside of every package	On the outside of every package
Internal (pack) CI	Inside every package	Inside every package
Load challenge	BI/PCD or FDA-cleared BI containing quality monitoring device in each load	Optional monitoring with BI/PCD or FDA-cleared BI containing quality monitoring device in each load

Table 3: Load Release Testing – Steam Sterilization

	Loads containing implants	Loads without implants
Physical monitoring	Every cycle	Every cycle
External (process) CI	On the outside of every package	On the outside of every package
Internal (pack) CI	Inside every package	Inside every package
PCD (load challenge)	PCD with BI and Type 5 CI: In every load.	Optional use: PCD with Bi, BI/Type 5 CI, BI Type 6 CI

Process challenge devices

Process challenge devices (PCD) are defined as an "item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process."[2] PCD contain a barrier system and a biological or chemical indicator (or both) that provide information about the quality of the sterilization process. The PCD barrier system restricts the access of the sterilization process to the indicator during routine processing. It is intended to mimic the effect of placement of the indicator inside one of the sterilization load's packages or medical devices, where the load and packaging would also restrict access of the sterilization process to the indicator. The PCD is easily retrieved from the sterilizer after the cycle is completed, and the indicator can be removed and evaluated without compromising any of the load contents.

Quality control testing plans

The key U.S. recommended practice standards for VH2O2 and steam sterilization are AAMI ST58[3] and AAMI ST79,[4] respectively. These standards recommend using all three monitors (physical, chemical, biological) and combining the information they provide to decide if the instruments and packages were processed correctly and are safe for patient use. Table 2 reviews the recommended testing plan for load release for VH2O2 sterilization:

Table 3 reviews the recommended testing plan for load release for steam sterilization:

Current quality testing recommendations for VH2O2 and steam sterilization are quite similar. Both standards recommend a quality control plan that uses a combination of physical, chemical, and biological

testing. And, both standards set higher testing standards for loads with implants, because of the higher infection risk that could be posed by an implanted device.

Summary

Sterilization quality control is important to patient safety. The use of physical monitors, CIs, and BIs provides a comprehensive picture of the quality of a sterilization process to help decide whether instruments should be released for use on patients. Industry standards such as AAMI ST79 and AAMI ST58 provide guidance on how to perform quality control testing on sterilization processes. **HPN**

Article references can be found at hpnonline.com

Craig Wallace, President of Wallace Sterilization Consulting, LLC, has over 26 years of experience in the field of medical device disinfection and sterilization. Craig is the Convenor of the ISO Biological Indicator Working Group (TC 198, 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) and Moist Heat Sterilization (WG 3). 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, vaporized hydrogen peroxide sterilization, and ethylene oxide sterilization.

Sterilization Quality Control: Your Path to Protecting Your Patients - Practice Quiz

1. **A robust sterilization quality control program is needed because:**
   - A. you can't tell if an instrument is sterile just by looking at it
   - B. unexpected variations in a sterilization process could make the process less effective
   - C. a non-sterile instrument can pose a threat to a patient
   - D. you need to ensure that the critical process variables were within their expected range
2. **The critical variables for steam sterilization are:**
   - A. exposure time
   - B. temperature
   - C. cycle pressure
   - D. presence of saturated steam
3. **The critical variables for vaporized hydrogen peroxide sterilization are:**
   - A. concentration
   - B. exposure time
   - C. elevation
   - D. temperature
4. **The primary tools in sterilization quality control are:**
   - A. physical monitors
   - B. peel pouches
   - C. chemical indicators
   - D. biological indicators
5. **Physical monitors...**
   - A. provide information for the cycle printout
   - B. can replace biological and chemical indicators
   - C. can confirm if the proper cycle was run
   - D. can provide information on the environment within the load
6. **Chemical process indicators:**
   - A. help distinguish between processed and unprocessed items
   - B. often use color change chemistry
   - C. are often in the form of a tape or label
   - D. provide information on the quality of the sterilization process
7. **Chemical indicators**
   - A. provide information on the critical process variables
   - B. are categorized based on the type of information they provide
   - C. contain large numbers of bacterial spores
   - D. are never placed inside a PCD
8. **Biological indicators:**
   - A. directly determine if the sterilization process can kill microorganisms
   - B. contain a large number of resistant bacterial spores
   - C. can detect problems with sterilant quality
   - D. require at least 2 days of incubation to provide results
9. **Process challenge devices**
   - A. are placed inside of loads or packages
   - B. make it easier for the sterilant to reach the indicator
   - C. provide a barrier to the sterilant to mimic what happens inside the load
   - D. must contain a chemical indicator
10. **Recommended practices for sterilization quality control**
    - A. differentiate between loads with implants and loads without implants
    - B. recommend combined use of physical monitors, CIs, and BIs
    - C. recommend use of chemical process indicators on all packages
    - D. recommend the use of a chemical indicator inside of every package

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