Sterilization Quality Control

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LEARNING OBJECTIVES

1. Review the principles of sterilization quality control
2. Discuss information provided by physical monitors and biological and chemical indicators
3. Review current best practice recommendations for monitoring steam and vaporized hydrogen peroxide sterilization processes

Effective sterilization of surgical instruments is critical for patient safety and essential to any infection prevention program. The problem, of course, is that one cannot see sterility. It is impossible to simply look at the instruments after processing and determine whether they are sterile and safe for patient use. Sterile Processing (SP) technicians must have a way of testing the sterilization process to ensure the process was effective. Testing the sterilization process is the heart of a sterilization quality control program. This lesson reviews sterilization quality control basics, explores the testing tools available, and reviews best practices for sterilization quality control.

Objective 1: Review the principles of sterilization quality control

Quality control for sterilization involves procedures and tests intended to ensure that sterilized devices are correctly processed and safe for patient use. Sterilization quality control procedures are based on frequent sterilizer testing with different monitoring devices designed to provide information on various aspects of each sterilization process. These monitoring devices 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 then reviewed, and the final decision about the quality of the cycle (and the safety of the instruments) is made based on the results of the tests.

Sterilization process effectiveness can be diminished if there are undetected variations in the critical process variables; critical process variables must be correct for the process to work properly. For steam sterilization, the critical variables are exposure time, temperature and the presence of saturated steam. The critical variables for vaporized hydrogen peroxide sterilization (VH2O2) are exposure time, temperature and the concentration of hydrogen peroxide.

Monitors sensitive to the critical process variables must be used for

sterilization quality control testing. The best practice is to test the process with different types of monitoring products and include the results of each type of monitor in the final load release decision. The three types typically used in sterilization quality control are physical monitors, chemical indicators (CIs) and biological indicators (BIs).

Objective 2: Discuss the information provided by physical monitors and biological and chemical indicators

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 printer, which produces a paper record of the cycle.

Physical monitors provide essential information and should be reviewed by qualified personnel after every cycle. 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.

Temperature sensors are located in the sterilizer chamber walls and cannot provide information on the physical environment within the load or inside packages or containers. Therefore, physical monitors will not detect problems associated with improper loading, air removal, or sterilant (steam) penetration. Also, physical monitors will not typically detect issues with steam quality or hydrogen peroxide concentration.

CIs are defined as a "test system that reveals a change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process."[1] In simpler terms, CIs will change color or have a chemical move along a window in response to exposure to one or more of the critical process variables.

CIs are categorized based on how they respond to the sterilization process. Six different types are defined in the ISO international standard for CIs.[2] (See **Table 1**). However, it should be noted that CI types are not hierarchical; higher numbers do not mean better or more robust indicators.

CIs are also categorized by their intended use. The four main uses of CIs are described in **Table 2**.

CIs play a broad and vital role in a sterilization quality control program. The 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 manufacturer's instructions regarding the capabilities of the CI used should be understood so the indicator result can be correctly interpreted.

Process indicators 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. Instead, they demonstrate that the item has been exposed to the process by changing the indicator color. Process indicators are used in steam and VH2O2 processes, but the correct indicator must be chosen for each sterilization method.

Type	Term	Description and use
1	Process indicators	Intended for use on individual items to visually demonstrate exposure to the process
2	Indicators for specific tests	Intended for use in specific sterilizer tests (e.g., Bowie-Dick tests)
3	Single critical process variable indicators	Intended to react to a single critical process variable
4	Multicritical process variable indicators	Intended to react with one or more critical process variables
5	Integrating indicators	Intended to react with all critical variables and relate to a calculated biological response
6	Emulating indicators	Intended to react with all critical variables

Table 1: Types of chemical indicators. Source: *Sterilization of health care products – Chemical indicators – Part 1: General requirements*. ISO 11140-1:2014.

Application	Description	Indicator Type	Sterilization process
Process indicator	Placed outside packages to differentiate processed from unprocessed items	1	Steam, VH2O2
Equipment tests	Bowie-Dick tests	2	Steam
Pack indicators	Placed inside each package to test conditions inside of packs	3,4,5,6	Steam, VH2O2
Load indicators	Placed inside a PCD to test chamber conditions	5,6	Steam

Table 2 – Chemical indicator applications

	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

Table 3: Load release testing – steam sterilization. Source: ANSI/AAMI ST79: 2017 ***Comprehensive guide to steam sterilization and sterility assurance in health care facilities.***

	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)	BI/PCD in every load	BI/PCD daily, preferably every load

Table 4 – Load release testing – vaporized hydrogen peroxide sterilization. Source: ANSI/AAMI ST58:2013 ***Chemical sterilization and high-level disinfection in health care facilities***

Bowie-Dick tests provide important information about 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.

Certain types of CIs are designed to be placed inside each package or container to provide information on the sterilization conditions at the location of the surgical instruments. Internal or pack indicators offer a cost-effective way to obtain information about 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 depends on the type of indicator selected (Type 3 single critical process variable indicators offer the least information because they respond to only one variable). For steam processes, Type 5 integrating indicators provide the most information, as they respond to all critical variables and must have a relationship to a theoretical biological response. For VH2O2 processes, Type 4 multicritical process parameter indicators provide the most information because Type 5 indicators are not defined for VH2O2 processes.

Finally, for steam processes that don't contain an implant, Type 5 or Type 6 CIs can be placed inside a process challenge device (PCD) and used as part of a load release decision. *Note: How these fit into the overall quality control scheme will be addressed later in this lesson.*

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. As the Centers for Disease Control and Prevention (CDC) states, "Biological indicators are recognized by most authorities as being closest to the ideal monitors of the sterilization process because they measure the sterilization process directly by using the most resistant microorganisms (i.e., Bacillus spores), and not by merely testing the physical and chemical conditions necessary for sterilization."[3]

BIs inside PCDs are placed in the chamber with the instrument load and are used to challenge the entire sterilization process and demonstrate that the process had the intended lethality. BIs can detect problems with steam quality or VH2O2 concentration that are not detected by the other indicators because poor sterilant quality reduces the cycle lethality and results in a positive BI.

Objective 3: Review current best practice recommendations for monitoring steam and vaporized hydrogen peroxide sterilization processes

Best practices in sterilization quality control recommend using all three tools (physical, chemical and biological) and combining the information they provide to decide whether the instruments and packages were processed correctly and are safe for patient use. The key recommended practice standards for steam and VH2O2 sterilization are ANSI/AAMI ST79[4] and ANSI/AAMI ST58[5], respectively. **Table 3** reviews the recommended testing plan for load release for steam sterilization:

ANSI/AAMI ST79 differentiates the level of information required to release implant loads versus loads without implants. There is a higher standard for implant loads (every load monitoring with a PCD containing a BI and Type 5 CI) because of the higher risk to the patient posed by an implanted device.

Many healthcare facilities have chosen to monitor all steam loads (with and without implants) with a BI/PCD to achieve a uniform standard of care and reduce recall costs and monitoring errors.

The recommendations for VH2O2 testing are similar to steam. Again, many facilities test every VH2O2 load with a BI for the same reasons as steam. **Table 4** summarizes the recommended testing plan for VH2O2 processes.

Conclusion

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

REFERENCES

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