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Quality Assurance for Vaporized Hydrogen Peroxide (VH_2O_2) Sterilizers

Planning to update your facility's VH_2O_2 Sterilization Quality Assurance Policy and Procedure? Healthcare accreditation organizations are paying close attention to medical device processing. To ensure the best possible patient outcomes, it is important to have a robust quality assurance program in place for all sterilization modalities. Be sure your policy is aligned with current published standards and guidelines. Two useful references for VH_2O_2 sterilization are:

- ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities.[1]
- 2016 Edition AORN Guidelines for Perioperative Practice, Guideline for Sterilization.[2]

A summary of the quality assurance recommendations included in these documents is provided below.

Monitoring Tools

As with other sterilization modalities, a variety of monitoring tools are used as part of an effective VH_2O_2 sterilizer quality assurance program. These include physical monitors, chemical indicators and biological indicators.

Monitoring Tool	What do the Standards and Guidelines say?
Physical Monitors	**Section 9.5.2.1 of AAMI ST58 states:** "Physical monitors include time, temperature and pressure recorders; displays; digital printouts; and gauges." **The Rationale statement for this section goes on to explain:** "Physical monitoring provides real-time assessment of the sterilization cycle conditions and provides permanent records by means of chart recordings or digital printouts. Physical monitoring is needed to detect malfunctions as soon as possible, so that appropriate corrective actions can be taken in the event of failures."
Chemical Indicators (CIs)	**Section 9.5.3.1 of AAMI ST58 states:** "Chemical indicators are sterilization process monitoring devices that are designed to respond with a chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer or malfunctions of the sterilizer."
Biological Indicators (BIs)	**Section 9.5.4.1 of AAMI ST58 states:** "Biological indicators are sterilization process monitoring devices consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored. Biological indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization." **AORN's Guideline for Sterilization** recommends the use of BIs containing *Geobacillus stearothermophilus* for both low-temperature hydrogen peroxide gas plasma sterilizers (Recommendation XX.h.4) and hydrogen peroxide vapor sterilizers (Recommendation XX.h.5).

AAMI recommends that users be appropriately trained and knowledgeable about the performance characteristics and the interpretation of the indicator results.

In the U.S., chemical and biological indicators are medical devices regulated by the FDA. Monitoring tools used in U.S. healthcare facilities should be FDA-cleared for the particular VH_2O_2 sterilizer(s) and cycle(s) used at your facility.

Qualification Testing

As with other sterilization modalities, sterilizer qualification testing should be performed on VH_2O_2 sterilizers after installation, relocation, major repairs and sterilization process failures. Successful qualification testing verifies the sterilizer is fit to process instruments for patient use.

AORN recommends that for each type of cycle enabled, one BI PCD should be run in three consecutive empty cycles (AORN Guideline for Sterilization, Recommendations XX.h.4 and XX.h.5).

AAMI ST58 recommends: "Sterilizer testing after installation, relocation and major repairs should be conducted in the health care facility by health care personnel in cooperation with the manufacturer. The testing should be performed between the time the sterilizer is installed, relocated, or repaired and the time it is released for use or returned to service in the health care facility. Health care personnel should follow the manufacturer's written IFU, which should include the appropriate BI and PCD to use, the placement of the BI PCD in the load or chamber, whether the chamber should be full or empty, and the number of cycles to run."

Routine Efficacy Testing

In typical facilities, VH_2O_2 sterilizers are used many times each day and instruments are quickly returned to patient use. A robust quality assurance program includes routine efficacy testing using the monitoring tools described on the previous page.

Physical Monitors: Section 9.5.1 of AAMI ST58 discusses the use of physical monitors for monitoring gaseous chemical sterilization processes. Two key quotes are: "At the end of the cycle and before items are removed from the processing equipment, the operator should examine and interpret the printout to verify that cycle parameters were met and should initial it to allow later identification of the operator." (Section 9.4.2) and, "If the interpretation of the physical monitors suggests inadequate processing, the items should not be dispensed or used." (Section 9.5.1).

External Chemical Indicators: "A CI should be used on the outside of each package unless the internal indicator is visible. The CI is examined after sterilization and also before use of the item to verify that the item has been exposed to the sterilization process." (AAMI ST58:2013, Section 9.5.3.2)

Internal Chemical Indicators: An internal CI should be used inside each package, tray and containment device to be sterilized. (AAMI ST58:2013, Section 9.5.3.2)

Biological Indicators: AAMI ST58 states: "A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle" (Section 9.5.4.3). AAMI ST58 goes on to state in Section 9.5.4.5.2 that the PCD should be labeled before use and then positioned in the load according to the sterilizer manufacturer's written IFU. AORN's Guideline for Sterilization is slightly more specific and states, "Routine sterilizer efficacy monitoring should be performed at least daily on each cycle type, preferably with each load" (Recommendations XX.h.4 and XX.h.5). In U.S. hospitals, end-users typically place a BI and an internal CI in a peel-pouch indicated for use in VH_2O_2 sterilizers and then position the pouched BI in the sterilizer chamber as recommended by the sterilizer manufacturer. As a best practice and to provide optimal patient safety, 3M recommends that every sterilization load be monitored with a biological indicator.

Positive BI Results

A positive result for a test BI indicates a sterilization process failure. AAMI ST58 provides guidance on handling positive BI results in Section 9.5.4.6. This section states: "Because a sterilization failure has occurred, items processed in that sterilizer since the sterilization cycle having the last negative BI should be considered non-sterile. They should be retrieved, if possible, and reprocessed. The sterilizer in question should be taken out of service."

Traceability and Cycle Documentation

To ensure traceability of load items, AAMI ST58 recommends that each pack be labeled with a lot control identifier which specifies the sterilizer, cycle number and date of sterilization. For each sterilization cycle, the user should record: the assigned lot number; the specific contents of the load; the date and time of the cycle; the time, temperature, and chemical concentration of the exposure phase of the cycle; the name or initials of the operator; and the results of BI testing, if applicable. (AAMI ST58, Section 9.2)

Summary

For routine sterilizer efficacy testing, your VH_2O_2 Quality Assurance Program should include the elements in the table below. To document compliance with your policy, ensure staff knows how to complete the necessary record keeping, either on paper or using an electronic software program.

Routine Efficacy Testing of VH_2O_2 Sterilizers

Monitoring Tool	Frequency	Acceptance Criteria	Record Keeping
Physical Monitor	Every load	Printout is examined to verify cycle parameters were met	Printout is initialed and included in cycle documentation
Chemical Indicators (CI)	External CI placed on outside of each package unless internal CI is visible	External CI examined after sterilization to verify that the package has been exposed to the VH_2O_2 sterilization process	—
	Internal CI used inside each package, tray or containment device	Internal CI retrieved and interpreted at time of use to verify it has met its end-point response	Document any reports of internal CIs which did not meet their end-point
Biological Indicator (BI)	Test BI is run daily, preferably in every sterilization cycle (AAMI ST58, Section 9.5.4.3) *– or –* Test BI is run daily on each cycle type, preferably with each load (AORN Guideline for Sterilization, Recommendations XX.h.4 and XX.h.5)	Negative result from test BI	Test BI results and lot codes are documented
	Control BI with matching lot code is incubated each day	Positive result from control BI	Control BI results and lot codes are documented

References

1. ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities.

2. 2016 Edition AORN Guidelines for Perioperative Practice. Guideline for Sterilization.

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