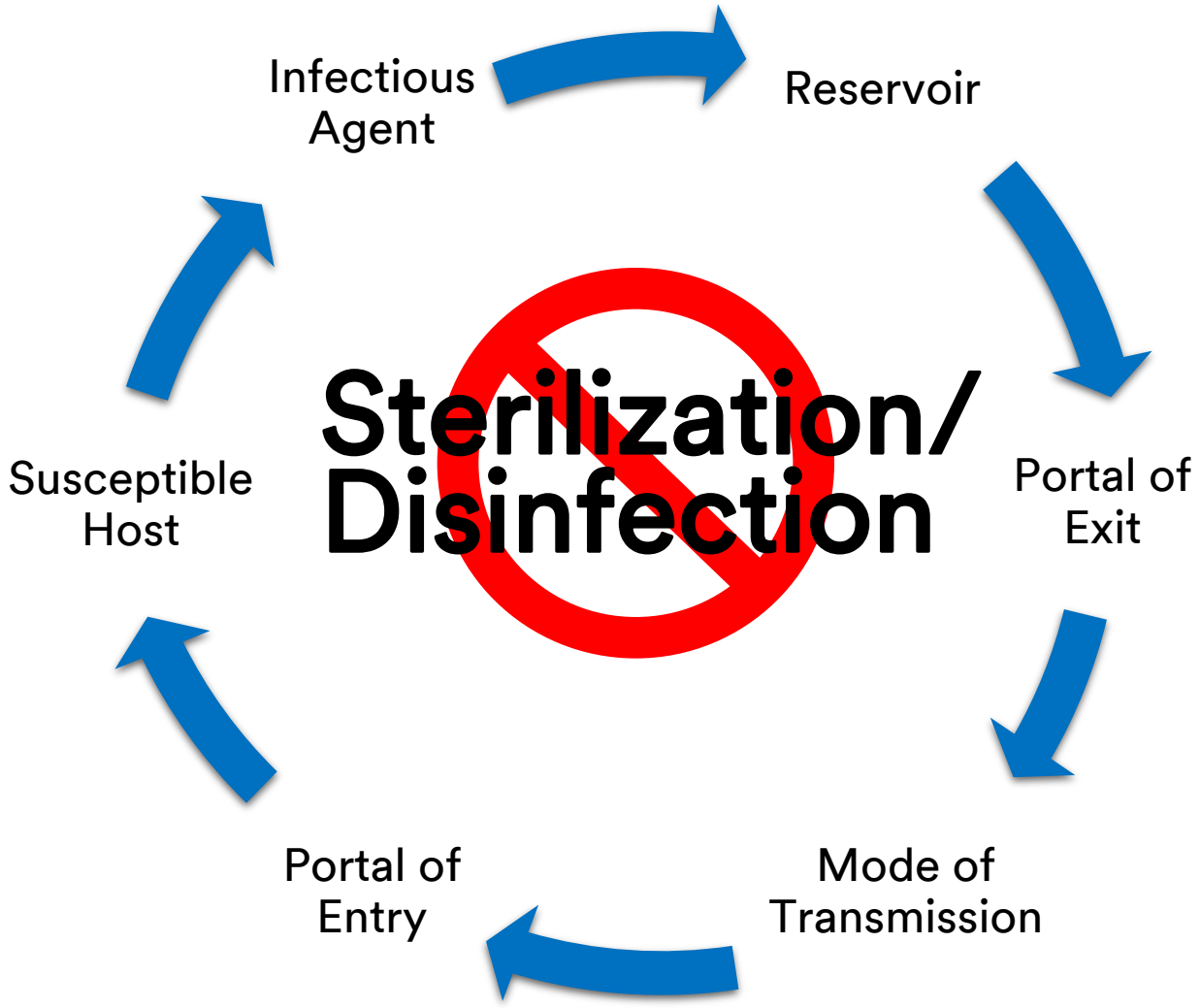
3M℠ Health Care Academy

Sterilization Quality Control for the ASC

NJHCSA

January 13, 2024

Disease Transmission Cycle



Accreditation Bodies Care!

The Joint Commission (TJC)

Most Challenging Ambulatory Health Care Standard for 2020

- **IC.02.02.01 – The organization reduces the risk of infections associated with medical equipment, devices, and supplies.**

Joint Commission Online May 12, 2021. Top 5 most challenging requirements for 2020.

https://www.jointcommission.org/-/media/tjc/newsletters/jc-online-may-12-2021.pdf 2 2021.

Accreditation Bodies Care!

Accreditation Association *for* Ambulatory Health Care (AAAHC) Infection Prevention & Control Program Surveyor Findings - 2020

- *Guidelines on Immediate Use Steam Sterilization (IUSS) not being followed*
- *No written policies addressing the identification and processing of medical equipment and instruments that failed to meet sterilization parameters*
- *Insufficient (or no) monitoring and documentation of cleaning, HLD and sterilization; failure to follow national guidelines and/or manufacturer's instructions for use*
- *The Certified Surgical Technician responsible for sterilization was unable to describe use of spore testing for autoclave sterilizer function monitoring and indicated that this was not used*

2021 AAAHC Quality Roadmap A report on accreditation survey results
https://www.aaahc.org/quality-institute/quality-roadmap/

Learning Objectives

- Review sterilization modalities typically used in the ASC setting
- Describe available sterilization monitoring tools
- Discuss current guidelines and recommended practices for quality control monitoring of steam and vaporized hydrogen peroxide sterilization processes

Sterilization: Guidelines/Standards

AORN

- Guidelines for Perioperative Practice, 2023 Edition

AAMI

- ANSI/AAMI ST79:2017 with Amendments A1, A2, A3 & A4:2020 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ANSI/AAMI ST58:2013 (R2018) Chemical sterilization and high-level disinfection in health care facilities

Basic Definitions

Cleaning

- **Removal** of organic soil
- Microbes and soil can still be present
- Device can still be infectious

High-Level Disinfection (HLD)

- Microbial **kill** under defined conditions
- Not all spores are killed
- Effectiveness dependent on meticulous cleaning

Sterilization

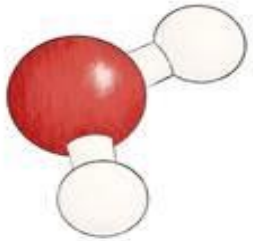
- **Kills** all living organisms including spores
- Effectiveness dependent on meticulous cleaning

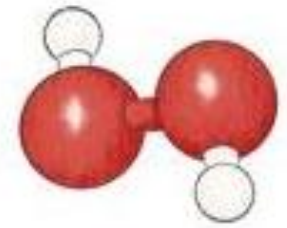
Review sterilization modalities typically used in the ASC setting

Sterilization Processes Used in ASCs

- Steam

- Vaporized hydrogen peroxide





"Use saturated steam under pressure to sterilize heat- and moisture-stable items unless otherwise indicated by the device manufacturer."*

*AORN 2021, *Guideline for Sterilization*, Recommendation 5.1

Steam Sterilization

- Fast
- Effective
- Inexpensive
- Technologically well understood
- Relatively easy to use
- Items can be packaged and maintained sterile
- No hazardous residues after sterilization

Steam Sterilization

Three critical variables for steam sterilization to be effective:

Time

Temperature

Steam

Steam Quality: NCGs

Non-condensable gases (NCGs) in the steam or chamber will prevent uniform and effective condensation, resulting in inadequate sterilization conditions.

What is the most common non-condensable gas?

AIR!!

Steam Sterilization Cycle Types
Goal: Air removal

Gravity displacement

- Steam into the top of the chamber drives air out the bottom

Dynamic air removal

- Pre-Vacuum

  Series of vacuum pulls/pressure pulses to drive air out

- Steam Flush Pressure Pulse (SFPP)

  Positive pressure steam pulses with gravity flush

Loading the Steam Sterilizer: Instrument Sets

Place instrument sets and rigid containers horizontally

- To maintain distribution of metal mass
- Allow air removal
- Sterilant penetration
- Condensate drainage
- Drying
- Prevents shifting of set contents

ANSI/AAMI ST79:2017, Section 10.1.3

Loading the Steam Sterilizer: Paper-Plastic Pouches

- Used for small, lightweight, low-profile items
- Closed so that seals are smooth
- Double pouch only if validated by manufacturer

ANSI/AAMI ST79:2017, Sections 9.5.4 and 10.1.2
Sketch reprinted from ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 &A3:2012 with permission of Association for the Advancement of Medical Instrumentation, Inc. © 2012 AAMI

Loading the Steam Sterilizer: Solid-Bottom Pans and Basins

Place items tilted on edge and oriented in the same direction for:

- Condensate drainage
- Displacement of air
- Rapid, even distribution of steam throughout the load

ANSI/AAMI ST79:2017, Section 10.1.5

Loading the Steam Sterilizer: Rigid Sterilization Container Systems

- Inspect before each use
  - Latching mechanism, valves, gasket, etc.
- Place flat on shelf below absorbent items
- Stack only if indicated by manufacturer
- Do not stack containers from different MDMs

ANSI/AAMI ST79:2017, Sections 9.8 and 10.1.6

Unloading the Steam Sterilizer

- Verify sterilization parameters
- Remove cart and place in a low traffic area, no air-conditioning or cold-air-vents
- Allow items to cool to room temp before handling
  - May use infrared thermometer
- Do not touch items during the cooling process
  - Could wick bacteria from hands into packaging
- Do not transfer warm items to a cool metal rack or shelving (could cause condensate to form → contamination)

ANSI/AAMI ST79:2017, Section 10.3; AORN 2021 Guideline for Sterilization, RP 5.4

Vaporized Hydrogen Peroxide Sterilizers

- Utilize vaporized hydrogen peroxide (VH2O2) as sterilant
- Operate at lower temperatures than steam
- Kills by oxidation after direct contact with microorganisms

Types:

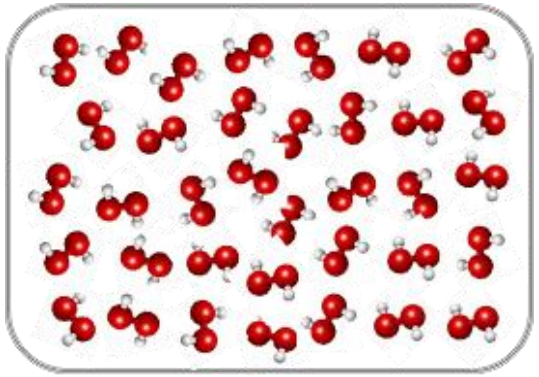
Vaporized Hydrogen Peroxide
Vaporized Hydrogen Peroxide with plasma
Vaporized Hydrogen Peroxide with ozone

VH2O2 Sterilization Critical Variables

Variable identified as being essential to the attainment of sterilization

Time

Temperature



Hydrogen Peroxide Concentration

ISO 11140-1:2014. *Sterilization of health care products — Chemical indicators — Part 1: General Requirements*

Safe and Effective Use of VH2O2 in ASCs

- Adhere to the sterilizer chamber loading weight limits
  - Limits on weight and device types per models and cycles is complex!
  - Always refer to the sterilizer manufacturer's instructions for use
- Adhere to loading weight limits for rigid containers
- Assure packaging and devices are adequately dry
- Double check the packaging is labelled for VH2O2 sterilization
- Double check device is labeled for VH2O2 sterilization
- Reduce or stop the use of extraneous materials in VH2O2

How Does an ASC Determine Which Sterilization Processes to Run?

Sterilization Modality?

- Steam
  - Method of air removal
  - Temperature
- VH2O2
  - Sterilizer Make/Model
  - Cycle Type

By consulting the device manufacturers' Instructions for Use (IFU)
Online resource: oneSOURCEdocs.com

ANSI/AAMI ST79:2017, Section 10.2.2

Healthcare Facility Responsibility

- Sterilize according to manufacturers' instructions for use
  - Reusable device, packaging, and sterilizer
- IFUs should be accessible to staff performing sterilization
- Reconcile sterilization method and cycle parameters recommended by device and packaging manufacturer with sterilizer manufacturer's written instructions

AORN 2021, Guideline for Sterilization, 1.4

Describe available sterilization monitoring tools

Sterilization Process Monitoring

Goal of the sterilization process?

- To kill microorganisms!
  - You can't see sterility!
  - You can't test sterility of processed devices in your ASC in any practical way!

We use several monitoring tools to gather information about the process to demonstrate the process was effective

Sterilization Process Monitoring Tools

Biological Indicators

Chemical Indicators

Physical Monitors

Physical Monitors

- Information from sensors in the sterilizer chamber wall (e.g., temperature, pressure)
- Can confirm that the correct cycle was selected
- Provides a record of the cycle

Chemical Indicators for Sterilization Monitoring

Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment

Primary Applications

- Exposure Indicators (outside every pack)
- Internal Chemical Indicators (inside every pack)
- Sterilizer Test Indicators

ANSI/AAMI/ISO 11140-1:2014
ANSI/AAMI ST79:2017 Section 13.5.2
ANSI/AAMI ST58:2013 (R2018) Section 9.5.3

Types of Chemical Indicators

Type 1	Process Indicators (external)
Type 2	Indicators for use in specific tests (e.g., Bowie-Dick test)
Type 3	Single variable Indicators (internal)
Type 4	Multi-variable Indicators (internal)
Type 5	Integrating Indicators (internal)
Type 6	Emulating Indicators (internal)

Internal

There is no hierarchical significance to the types

ANSI/AAMI/ISO 11140-1: 2014
ANSI/AAMI ST79:2017 Section 13.5.2

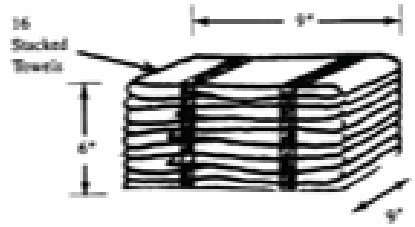
Biological Indicators for Sterilization Monitoring

- Test systems containing viable microorganisms providing a specified resistance to a specified sterilization process

ISO 11139:2018, 3.29

BI Process Challenge Device (BI PCD)

"Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process."



© AAMI used with permission

- User assembled PCD
  - Challenge test pack or tray (e.g., AAMI 16-towel pack, gravity IUSS containment device, representative table-top PCD)
- Pre-assembled, commercially available PCD
  - FDA cleared
  - Note: not available for table-top sterilizers

ANSI/AAMI ST79:2017, Sections 2.9 and 13.5.4

Discuss current guidelines and recommended practices for quality control monitoring of steam sterilization processes

ANSI/AAMI ST79 Section 13 Steam Sterilization Process Monitoring

Four levels of testing . . .

1 Routine load release	Testing of each non-implant and implant load
2 Routine sterilizer efficacy monitoring	Establishing a regular pattern of testing the efficacy of the sterilization process
3 Sterilizer qualification testing	Testing of the sterilizer after events occur which could affect the ability of the sterilizer to perform
4 Periodic product testing	Testing of routinely processed items to ensure the effectiveness of the sterilization process and to avoid wet packs

ANSI/AAMI ST79:2017, Section 13

Routine Load Release Non-Implants

- Physical monitor
- External process indicator (Type 1) on every package
- Internal CI (preferably Type 5 or 6) inside every package
- Optional monitoring of load with a PCD containing a
  - BI
  - BI & Type 5 CI
  - Type 5 integrating indicator
  - Type 6 emulating indicator
- Evaluation of all data by an experienced, knowledgeable person
- Do not distribute load if any concern for a process failure

ANSI/AAMI ST79:2017, Table 2 and Sections 13.5 and 13.6

Physical Monitors

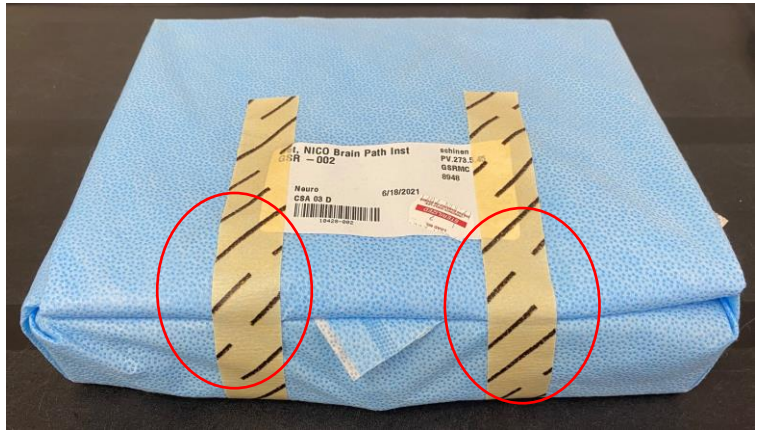
- Physical monitor checked for every cycle to verify correct cycle was selected and cycle parameters were met

- “Sterilizers that do not have recording devices should not be used, with the exception of sterilizers used together with accessory recording devices or printouts.”

ANSI/AAMI ST79:2017, Section 13.5.1

Exposure Indicators (External CIs)

- For visual confirmation that the pack or package was exposed to the process
- Every packaged item should have an external process indicator (Type 1)
- Do not provide information on the quality of the sterilization process



ANSI/AAMI ST79:2017, Section 13.5.2.2.1

Internal Chemical Indicators (CI)

- Place a chemical indicator inside every package
  - Can be Type 3, 4, 5, or 6 but **preferably** a Type 5 or Type 6 CI

ANSI/AAMI ST79:2017, Section 13.5.2.2.2

Steam Sterilization Quality Control

Implants vs Non-Implants

- AAMI & AORN place the highest level of quality control test requirements on loads that contain an implant
- Rationale is that implants present the highest level of risk

Routine Load Release Implants

- Physical monitor
- External process indicator (Type 1) on every package
- Internal CI (preferably Type 5 or 6) inside every package
- A PCD containing a BI and a Type 5 integrating indicator
- Evaluation of all data by an experienced, knowledgeable person
- Do not distribute load if any data suggests a sterilization process failure

- The load should be quarantined until the results of the BI testing are available
- Type 5 integrating indicator used to release implant in emergency situations

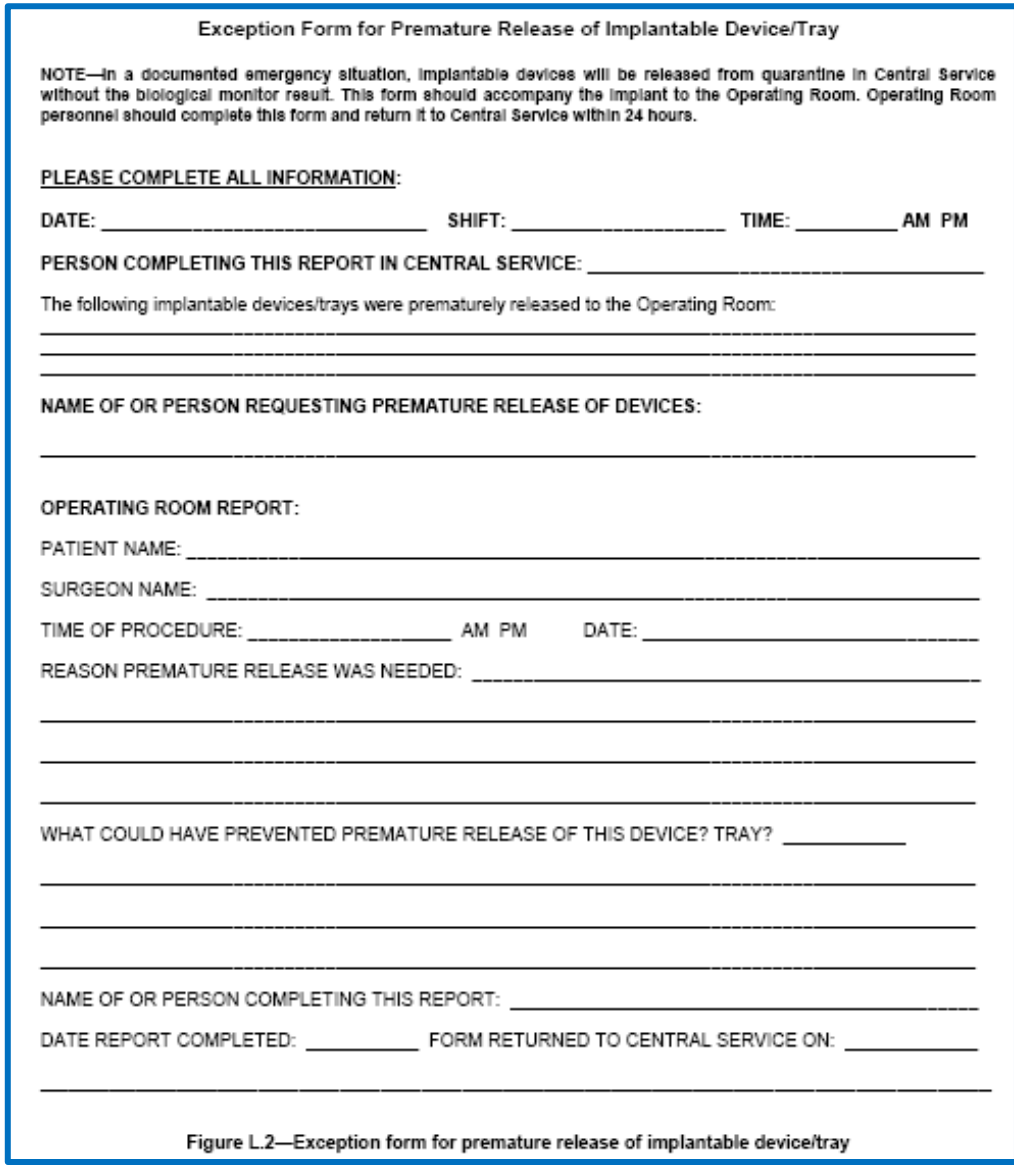
ANSI/AAMI ST79:2017, Sections 13.6.3, Table 2

Early Release of Implants

- If medical exceptions dictate release of implant before BI result is known, document using *Exception Form for Premature Release of Implantable*
  - Name of implant
  - Name of patient
  - Name of surgeon
  - Reason for premature release
  - **What could have prevented the premature release**

ANSI/AAMI ST79:2017 13.6.3 and Annex K

Annex K



Exception Form for Premature Release of Implantable Device/Tray

NOTE—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. Operating Room personnel should complete this form and return it to Central Service within 24 hours.

PLEASE COMPLETE ALL INFORMATION:

DATE: _____ SHIFT: _____ TIME: _____ AM PM

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

The following implantable devices/trays were prematurely released to the Operating Room:

_____

_____

_____

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:

_____

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ AM PM DATE: _____

REASON PREMATURE RELEASE WAS NEEDED: _____

_____

_____

_____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE? TRAY? _____

_____

_____

_____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ FORM RETURNED TO CENTRAL SERVICE ON: _____

_____

Figure L.2—Exception form for premature release of implantable device/tray

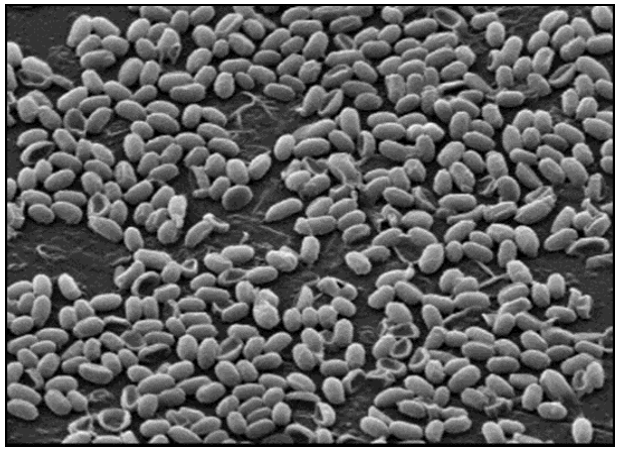
Routine Steam Sterilizer Efficacy Monitoring

- **Divided into sections**
  - Sterilizers larger than 2 cubic feet
  - Table-top sterilizers
  - Gravity-displacement cycles

ANSI/AAMI ST79:2017, Section 13.7

Routine Steam Sterilizer Efficacy Monitoring

- Biological indicators containing *Geobacillus stearothermophilus* spores
- Select a BI that is suitable for use in the specific sterilization cycle
- Frequency: BI PCD should be used for routine sterilizer efficacy monitoring at least weekly, but preferably every day that the sterilizer is in use



Geobacillus stearothermophilus spores (ATCC 7953)

ANSI/AAMI ST79:2017, Section 13.5

Routine Efficacy Monitoring With a BI PCD

Frequency of Monitoring with a BI PCD: Weekly, preferably daily

Sterilizers larger than 2 cubic feet

- AAMI 16 towel pack or commercially available disposable, FDA cleared BI PCD
- Commercially available PCDs recommended
- Full load on bottom shelf over drain
- Each cycle type should be tested

ANSI/AAMI ST79:2017, Sections 13.7,1, 13.7.2

Routine Efficacy Monitoring With a BI PCD
Dynamic-air-removal IUSS

- Use a pre-assembled, commercially available BI PCD
- Monitoring of IUSS cycles may be done in an empty chamber (Table 2)

AAMI ST79:2017 Table 2 and Sections 13.7.2.1

Routine Efficacy Monitoring With a BI PCD

Frequency of Monitoring with a BI PCD: Weekly, preferably daily

Gravity Displacement Sterilizers

- Representative BI PCD
- Test each type of tray configuration used
- Placed on bottom shelf over the drain
- Otherwise, empty chamber

ANSI/AAMI ST79:2017, Sections 13.7.1, 13.7.4

Routine Efficacy Monitoring With a BI PCD

Frequency of Monitoring with a BI PCD: Weekly, preferably daily

Table-top sterilizers

- BI PCD should be representative of the package or tray routinely processed, and most difficult to sterilize
- Contains items normally present during routine sterilization
- BI PCD placed in full load in cold point (check with sterilizer manufacturer)

ANSI/AAMI ST79:2017, Sections 13.7.1, 13.7.3

Biological Indicators - Positive Control

- Incubate a control BI each day that a test BI is incubated in each incubator or auto-reader
  - Control BI should have same lot number as test BI
  - Document test and control lot numbers and results
- Purpose is to verify the test system is working and to ensure:
  - Correct incubation conditions
  - Viability of spores
  - Capability of medium to promote growth
  - Proper functioning of auto-reader and incubator

ANSI/AAMI ST79:2017, Section 13.7.2.4 and ANSI/AAMI ST79:2017/A4:2020

Routine Sterilizer Efficacy Monitoring

- Bowie-Dick Testing: Evaluate efficacy of the vacuum system to remove residual air from the chamber
  - 270-275°F dynamic-air removal sterilizers (e.g., Pre-vacuum or vacuum-assisted sterilizers)
  - Run Bowie-Dick test pack:
    - Empty chamber
    - Performed each day the sterilizer is used, before the first processed load

ANSI/AAMI ST79:2017, Section 13.7.6

BD test sheet with uniform color change

ANSI/AAMI ST79:2017
Recall

“13.7.5 Actions to take when BIs, CIs, or physical monitors indicate a sterilization process failure”

“c) If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible, and reprocessed (see 13.7.5.2). The sterilizer in question should be taken out of service until the cause of the failure is identified and corrected.”

ANSI/AAMI ST79:2017, Section 13.7.5

ANSI/AAMI ST79:2017
Recall

“13.7.5 Actions to take when BIs, CIs, or physical monitors indicate a sterilization process failure”

“c) If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible, and reprocessed (see 13.7.5.2). The sterilizer in question should be taken out of service until the cause of the failure is identified and corrected.”

ANSI/AAMI ST79:2017, Section 13.7.5

Considerations for Monitoring Every Steam Sterilization Load With a BI PCD:

- Uniform standard of care
- Highest level of quality control
- Reduce risk of monitoring mistakes
- Simplifies staff training
- Minimize impact of a recall
- Fast readout BIs facilitate frequent monitoring

Discuss current guidelines and recommended practices for quality control monitoring of vaporized hydrogen peroxide sterilization processes

AAMI ST58:2013 (R2018)
Section 9 Quality Control

9.5 monitoring gaseous chemical sterilization processes

- Physical Monitors
- Chemical Indicators
- Biological Indicators

VH2O2 Sterilizer Monitoring: Physical Monitors

9.5 monitoring gaseous chemical sterilization processes

... physical monitoring and other indicators of sterilizer performance should never be considered a substitute *for careful adherence to prescribed packaging and loading procedures ... (AAMI ST58)*

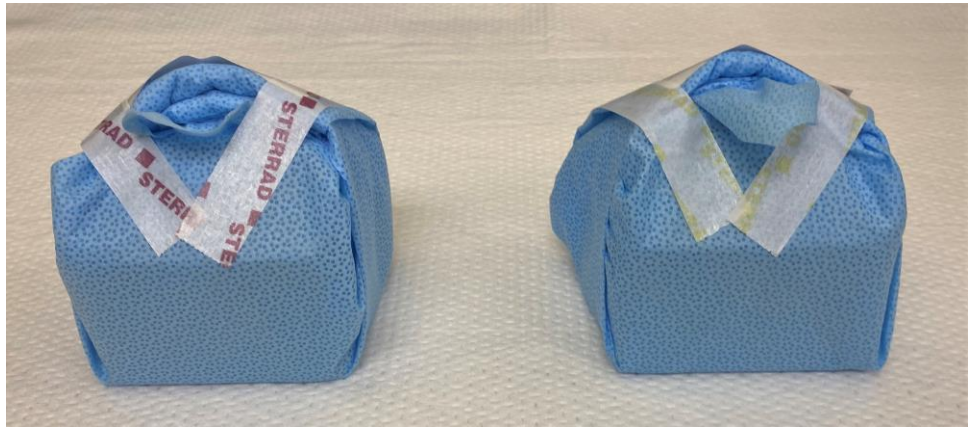
- printout should be verified
- cycle identification number
- verify cycle parameters met and initial

ANSI/AAMI ST58: 2013 (R2018) Section 9.5

VH2O2 Sterilizer Monitoring: Recommended Chemical Indicator (CI) Usage

- Exposure Control: External CI on every package

"Using chemical indicators
.....A CI should be used on the outside of each package unless the internal indicator is visible..."



ANSI/AAMI ST58:2013 (R2018), Section 9.5.3.2

VH2O2 Sterilizer Monitoring: Recommended (CI) Usage

- Internal CI inside every package, tray, containment device, cassette, instrument tray

"Using chemical indicators

.... The CI should be placed in that area of the package, tray, or containment device that creates the greatest challenge to sterilant penetration..."

ANSI/AAMI ST58:2013 (R2018), Section 9.5.3.2

VH2O2 Sterilizer Monitoring: Recommended Biological Indicator (BI) Usage

- ***9.5.4.1 General considerations***

  "…Biological indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization."

- ***9.5.4.3 Frequency of use…***
  - *"A PCD with the appropriate BI should also be used at* ***least daily, but preferably in every sterilization cycle*** *(see 9.5.4.5)"*
  - *Each load containing implantable.."*

ANSI/AAMI ST58:2013 (R2018), Section 9.5.4.3

AAMI ST58:2013 Section 9 Quality Control

- Incubate control BI daily
  - From same lot as test BI
- Routine testing acceptance criteria:
  - Negative result from test BI
  - Positive result from control BI
  - Appropriate readings from physical monitors
  - CIs with acceptable end-points

ANSI/AAMI ST58:2013 (R2018), Section 9.5.4.5.2 and 9.5.4.5.3

Key Learnings

- Accreditation surveyors continue to focus on device reprocessing
- Consult device manufacturers' Instructions for Use (IFU) for validated sterilization parameters
- Quality control monitoring, according to current standards and evidence-based guidelines, is an important element of all sterilization processes

Questions?

THANK YOU!

References

Association for the Advancement of Medical Instrumentation

- ANSI/AAMI ST79:2017 with 2020 Amendments A1, A2, A3, A4 (Consolidated Text). *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*
- ANSI/AAMI ST58:2013 (R2018). *Chemical sterilization and high-level disinfection in health care facilities.*

Association of periOperative Registered Nurses. *Guidelines for Perioperative Practice* 2022 Edition. Denver, CO. © 2021.

- Guideline for Sterile Technique
- Guideline for Sterilization

Thank you