SESSION TITLE: Sterilization Process Failures: Investigation and Prevention

SPEAKER NAME: Rose E. Seavey, MBA, BS, RN, CNOR, CRCST

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CONTACT HOURS: 1.0 CH

OVERVIEW:

Those responsible for sterilization in health care facilities must understand that sterilization process failures may place patients at risk. Sterilization process failures occur for many reasons: a malfunctioning sterilizer, user error (e.g., incorrect packaging or loading procedures, incorrect cycle selection), poor steam quality, and others. All process failures should be investigated and the root cause of the failure identified. This presentation will cover the possible causes of sterilization process failures and walk through the action steps necessary for investigation of a failed load. We will discuss the steps necessary to re-challenge the sterilizer after a major repair and before putting the machine back into service.

OBJECTIVES

1. Discuss sterilization process monitoring.
2. Describe correct actions to take to address sterilization process failures.
3. Identify ways to help prevent sterilization process failures.

CONTACT INFORMATION:

Rose E. Seavey, MBA, BS, RN, CNOR, CRCST
President/CEO Seavey Consulting, LLC
Seavey Healthcare Consulting, Inc.
Arvada, Colorado
E-mail: rose@seaveyhealthcareconsulting.com

FACULTY DISCLOSURE:

Rose Seavey 7. No conflict.

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REFERENCES:

- CDC Guideline for Decontamination and Sterilization in Healthcare Facilities 2008
TJC National Patient Safety Goals – Goal 7: Reduce Risk of Healthcare-associated Infections

NPSG.07.05.01
- “Implements policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (for example, the Centers for Disease Control and Prevention [CDC] and/or professional organization guidelines).”

Disinfection and Sterilization Standards, Recommendations and Evidence-Based Guidelines

AORN Perioperative Standards and Recommended Practices, 2012

AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

CDC Guideline for Decontamination and Sterilization in Healthcare Facilities, 2008
Essential Elements of Sterility Assurance
ANSI/AAMI ST79

• Quality assurance means monitoring all sterilization processes including:
  • Every package and every sterilization load (10.6)
  • Periodic product quality assurance testing (10.9)
  • Sterilizer Qualification testing:
    ➢ Installation,
    ➢ Relocation, and
    ➢ Sterilizer malfunction (10.6.4 and 10.8)

Sterilization Process Monitoring Devices
Types and Applications (Table 6 and 7)
Physical Monitors (10.5.1)

Physical (mechanical) monitors
- Displays,
- Gauges, and
- Digital printouts

Verify and record parameters
- Time,
- Temperature, and
- Pressure

Records
- Must be readable, and initialed

Chemical Indicators (10.5.2)

- External CI on the outside of each package
  - Examined after sterilization and before use
  - Must be visible
- Internal CI within each package, tray, or rigid sterilization container system
  - Placed in area considered least accessible to sterilant penetration
- Class 5 or Class 6 within a PCD to monitor each load
  - AAMI and AORN - Class 5 CIs be included in BI PCDs for implant loads.
Nonresponsive or Inconclusive CI

A single nonresponsive or inconclusive CI should not be considered definitive evidence that the entire load is nonsterile.

Professional judgment should be used in determining whether to recall the entire load.

Check all performance indicators:
- Physical monitors,
- CI, and
- BI responses

Biological Indicators (10.5.3)

Only process monitoring device that provides a direct measure of lethality of the process

- BIs should be used within PCDs (10.5.4):
  - Routine sterilizer monitoring
  - Implant loads
    - Quarantine until BI results available
  - Qualification testing (10.8)
    - Instillation,
    - Relocation,
    - Malfunction and major repairs, and
    - After sterilization process failures
Sterilization Process Failures - Actions to Take (10.6.4)

- Notify department head & investigative procedures –
  - Physical monitors – malfunction or suspicious
  - External CIs or PCD monitor (BI or CI challenge test pack) – questionable

If malfunction cannot be identified or corrected immediately:
- Consider load nonsterile
- Quarantine items
- Remove sterilizer from service
- Notify hospital engineer or maintenance contract service
  » Identify root cause
  » Correct failure

Faulty Sterilizer (10.6.4)

Identify and correct the problem
- Extending the cycle or increasing the cycle temperature not appropriate

Ask for copy of the report to determine testing required
- Minor or major repair?
  » Weld repairs,
  » Replacement of the chamber door, vacuum pump, or major piping assembly, or
  » Rebuilds or upgrades of controls
- Re-qualify sterilizer
Qualification testing (10.8)

- Three (3) consecutive BI PCDs  
  » One right after the other
- Three (3) Bowie-Dick tests for prevacuum cycle
- Acceptance criteria (10.8.2.4)
  » Demonstrate correct and complete sterilization cycles  
    – 3 negative BI test results,
    – Appropriate CI results,
    – 3 satisfactory Bowie-Dick tests (prevacuum cycle), and
    – Cycle printout records

Actions to take when BI, CI or physical monitors indicate failure (10.7.5)

Failed PCD (BI or CI) or failed physical monitor
- Demonstrated failure for the entire load
- Report immediately to supervisor and Infection Prevention and Control (IPC)

Followed up by a written report which includes:
- Date and time of cycle,
- Description of the sterilizer and load, (lot control number),
- Results of physical and CI monitoring ,
- Other useful information that could help determine if valid failure
Cause of Failure

- If immediately identified (operator error) and confined to one load or a single item
  - Correct the cause and reprocess

- Cause NOT readily known
  1. Quarantine entire load,
  2. Remove sterilizer from service, and
  3. Recall all items back to the last negative BI (Product recalls 10.11)
  4. Investigate cause of failure
     ➢ Figure 12 - Decision Tree for conducting investigations process failures
     ➢ Table 8 – Checklist for identifying reasons for process failures

Product Recalls (10.11)

- P&P for recall of issued items or stored loads
  - Developed in cooperation with Infection Prevention and Control and Risk Management

- Department head (or delegate) makes the decision to recall

- Evidence of sterilization failure
  - IPC notified ASAP
    - Follow-up surveillance of patients
Product Recalls - 3 Parts (10.11)

- Written recall **procedure**
  - Outline circumstances and responsible persons

- Sterilization recall **order**:
  - Include all items processed back to last negative BI,
  - Communicated to all areas,
  - Identify lot number,
  - Identify departments involved,
  - Record all items obtained, and

- Recall written **report** should:
  - Identify the circumstances,
  - Specify corrective action(s) taken to prevent a recurrence,
  - State percentage of products located, and
  - Provide verification that the recalled items were reprocessed or destroyed

**Failed or Positive BI**

- Microbiology lab - presumptive identification
  » Test – specific microorganisms or other growth
  » Micro lab test instructions (10.7.5.2)
- Do not delay recall
- Determine root cause
  » Review transfer technique (BIs not self-contained)
  » Arrange for corrective action
    - Training education (review)
    - Return demonstration
Guidance on How to Conduct an Investigation

- AAMI ST79 Figure 12 (2009 amendment)
  - Decision Tree is a visual aid for conducting investigations of steam sterilization process failures
  - BI, CI and physical monitors
  - Clarify steps and provides additional guidance
  - Appropriate for any type of process failure (steam or low temp)

Variables Affecting the Outcome of Steam Sterilization Process

- Human error: 85%
- Equipment malfunction: 10%
- Utilities: 5%
- Low temperature
- Inadequate air removal
- Poor quality steam

Personal Communication, Charles Hancock, President, Charles O. Hancock Associates, Inc.

- Incorrect packaging, loading
- Incorrect Biological Indicator (BI) Process Challenge Device (PCD) for load
- Incorrect BI/PCD placement in load
- Incorrect cycle parameters for load
Operator Errors

Four categories of possible human errors

1. Incorrect use and interpretation of monitoring tools

2. Selection of incorrect cycle for load contents

3. Use of inappropriate packaging materials or packaging technique

4. Incorrect loading of sterilizer

Incorrect Use and Interpretation of Monitoring Tools

• Examples include:
  • Incorrect placement of the PCD
  • Incorrect incubation of BI
  • Incorrect use of internal indicators
  • Incorrect storage of CIs or BIs
  • Use of broken media ampoule or missing spore strip
Incorrect Use and Interpretation of Monitoring Tools

Use of defective CI
- Expired
- Faded, partial color change
  » Incorrect storage, or
  » Previously exposed

Use of Inappropriate Packaging Materials or Technique
- Incorrect packaging for cycle parameters
- Incorrect preparation of containment device
  - (e.g. incorrect filters, valves or bottom tray)
- Tray that does not allow air removal
- Wrapper too large
- Textile packs too dense
- Incorrect placement of basins in set
- Failure to use absorbent material between nested basins
- Inadequate preconditioning of packaging materials
Human Error

Use of Inappropriate Packaging Materials or Technique

• Folded paper–plastic pouch
• Paper–plastic pouch inside set

Human Errors

Sterilization Errors

• Selection of incorrect cycle for load contents
  – Container or medical device manufacturer’s IFU not followed
• Incorrect loading
  • Stacking
    • Containment devices
    • Perforated trays
  • Incorrect placement
    • Trays not flat
    • Pouches flat on shelf
    • Basins not tilted
    • Textile packs not on edge
    • Packages too close
Sterilizer or Utility Malfunctions

Four categories of possible malfunctions
1. Poor steam quality or quantity
2. Incomplete air removal
3. Inadequate cycle temperature
4. Insufficient time at temperature

Steam Quality

• Significantly contributes to process failures

• Assessment of the entire steam delivery system

• Annex M - How to achieve and maintain adequate steam quality
  » Critical variables
    – Dryness of the steam (97 -100%)
    – Level of noncondensable gases (such as air) that does not impair steam penetration
Poor Steam Quality or Quantity

**Wet steam** (overly saturated with moisture)
- Steam lines
  » Improper insulation
  » Malfunction or no trap
- Malfunction of drain check valve
- Steam contact with cold load
- Too much water in produced steam at boiler

Poor Steam Quality or Quantity

**Superheated steam**
- Improper chamber heatup
- Desiccated packaging materials (dry packaging) (8.3)
  » Freshly laundered – rehydrates the fabric
- Excessive reduction of steam pressure too close to sterilizer
- Control valve or pressure reducer is faulty
Poor Steam Quality or Quantity

- Variations in pressure
  - Clogged filter,
  - Poorly engineered piping, or
  - Excessive demands

- Pressure gauges out-of-calibration

- Clogged
  - Steam lines
  - Steam strainer
  - Drain line or screen

- Malfunction of valves

Steam Quality Problems

Steam quality problems may be difficult to replicate in a given situation.

Steam quality varies with total system load throughout the work day and is not constant.
Incomplete Air Removal

- Inadequate vacuum or other air removal systems

- Clogs:
  - Chamber drain line, strainer, drain screen, or vent lines

- Leaks:
  - Faulty door gaskets, or other areas of the chamber

- Control valves:
  - Plugged, faulty, or incorrectly adjusted

Incomplete Air Removal

- Low steam pressure

- Water:
  - Temperature too high
  - Pressure inadequate
  - Supply strainer clogged

- Air trapped by the load

- Incorrect cycle parameters
Inadequate Cycle Temperature

- Temperature gauge, out-of-calibration
- Heat lag - long heatup time for large loads
- Clogs
  - Drain line,
  - Strainer, or
  - Drain screen

Inadequate Cycle Temperature

- Steam pressure variations
  - Clogged filters,
  - Poorly engineered piping, or
  - Excessive steam demands
- Presence of noncondensable gases
- Inadequate pressure for steam supply
- Clogged steam supply strainer
Personal Experience – Process Failures

- Repeated positive BIs
- Six days of investigation
- Clogged drain screen
- Now remove and check drain screen every shift

Insufficient Time at Temperature

- Control timer out-of-calibration
- Inappropriate cycle parameters
  - Not following Manufacturer’s IFU
- Come-up time less than 1.5 minutes in a 270°-275°F gravity-displacement cycle
- Oversized load
Efficacy of Sterilization

Four phases significantly dependent on each other to produce and maintain a sterile product.

1. Lowering and limiting bioburden
2. Appropriately preparing devices
3. Selecting the correct sterilization parameters
4. Maintaining the sterility of sterilized items until used

Decreasing Risks
Sterilization Process Failure

Best Practices
- Use evidence based published practices (AAMI ST 79)
  » Competent personnel (section 4)
  » Packaging, preparation and sterilization (section 8)
  » Quality control (section 10)
  » Quality process improvement (section 11)
    – Risk analysis (11.2.2)
  » New product evaluation (section 12)
- Let’s review some of the highlights from these sections
Personnel Considerations (Section 4)

Guidelines for qualifications (4.2)

• Minimum criteria for training, education, personnel health, hygiene and attire

• Supervisory personnel (4.2.1)
  » Prepared for responsibility by education, training and experience

• Sterile processing personnel (4.2.2)
  » Qualified individuals
    - Initial orientation
    - On-the-job-training
    - Competency-based knowledge
      ✓ Demonstrated and documented competencies in all aspects

Sterile Processing Certification

• Training and continuing education (4.3)
  – At a minimum - all staff should be certified within 2 years
    • Supervisor (level of responsibility)
    • Technicians
  – Certification develops
    • Basic level of understanding and knowledge,
    • Consistencies and standardization,
    • Professional element to the department, and
    • Boosts self-esteem, confidence and authority
Packaging, Preparation and Sterilization (Section 8)

• Selection of packaging material (8.2)
  – Wraps, peel packs and rigid container systems
  – Obtain and keep on hand
    • MFG test data,
    • Instructions for use (IFU), and
    • Care and handling instructions

• Package configuration and preparation (8.3)
  – Materials held at room temp and relative humidity (30-60%) for minimum of 2 hours

Package Configuration and Preparation

• Packaging illustrations (Figures 4-7)
  • Wrappers
    » Snug – prevent low spots,
    » Not to tight – strike-through

  • Rigid containers systems
    • Validated suitable for specific cycle used
    • No stacking in sterilizer (unless validated by MFR)
Paper-Plastic Pouches

Paper-plastic pouches (8.3.4)
- Only used for small, lightweight, low-profile items
- Double peel pack
  » Not recommended unless validated from manufacturer
    - Two sequentially sized pouches
    - Do not fold
- Not appropriate for use within wrapped sets or containment devices

Packaging, Preparation & Sterilization (Section 8)

Preparation and assembly of instrumentals
- Multiple parts – disassembled
- Excessive moisture removed
- Maximum weight limit – 25 pounds

Loading the sterilizer
- Pouches on edge and loosely loaded
- Textiles loosely loaded and on edge
- Tilt items capable of holding water
- Heavy metal items below wrapped items

Sterilization parameters – same for all items per IFU
Installation, Care and Maintenance of Sterilizers (Section 9)

Maintaining equipment helps prevent malfunctions
- Proper installation
- Routine care
  » Inspect and clean daily according to Manufacturer’s IFU
  » Preventative maintenance (by a qualified individual)
  » Periodic calibrations performed and documented

Record-keeping
- Maintenance record for each sterilizer
- Sufficient information to establish a history of service repairs

Periodic Product Testing (Section 10.9)

- BI PCD presents a known challenge however, it doesn’t necessarily reflect same challenge as inside various sets.

- QA product testing performed:
  - Routinely processed items, and
  - Before new or loaner items placed into use
    - Product family - group of products characterized by similar attributes (mass, material, construction, set weight, shapes, lumens and packaging system).
    - Master Product – product with the most attributes of the product family designated as the representative.
Product Testing (Section 10.9)

Place multiple BIs and CIs into area of packages determined to be the greatest challenge (master product)
- Corners,
- Different layers, and
- Next to the heat sink (metal mass)

Document product testing
- Date,
- Name of set, tray or item,
- Placement of all BIs and CIs (photo) and,
- Test results

Quality Process Improvement (Section 11)

- CQI programs –improves performance measures and process monitors
  - Sterilization CQI encompasses the entire process (decontam through distribution) for verifying compliance with procedures
    » Planned, systematic, and ongoing process
The Joint Commission (TJC)

Standard IC.01.03.01
“The hospital identifies risks for acquiring and transmitting infections.”

Element of Performance # 4
“The hospital reviews and identifies its risks at least annually and whenever significant changes occur with input from, at a minimum, infection control personnel, medical staff, nursing, and leadership.”

Quality Process Improvement

- **Risk analysis** (11.2.2) =
  Risk assessment + Risk management + Risk communication

- Objective is to identify the risks & reduce the likelihood of a sterilization process failure
New Product Evaluation (Section 12)

Systematic process of product evaluation
- Product evaluation committee - Multidisciplinary
  » Infection Prevention and Control,
  » Operating Room,
  » Sterile Processing,
  » Risk Management, and
  » Staff Development/Education

- Considerations include:
  » Contribution to patient safety,
  » Cost/value analysis (ROI)
  » Ability to reprocess
  » Necessary education to implement
  » Ease of use
  » Standardization – (helps to prevent errors)

Sterilization Process Errors - Summary

Competent staff
Effective process monitoring devices
Be proactive - prevention
- Stay current – evidence-based guidelines
- Follow manufacturer’s IFU
- Maintain equipment
- Perform annual risk analysis (don’t wait for a process failure)
- Standardization – monitoring and new products etc.