The Role of the SPD in Breaking the Chain Of Infection

Prevention Surgical Site Infections (SSIs)

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Learning Objectives

- Review the role of the Joint Commission in the Central Sterile Department as it relates to Infection Prevention
- Discuss infection risks associated with therapeutic and diagnostics devices
- Discuss best practices for monitoring the sterilization process and why biological indicators are considered the most effective method for monitoring the sterilization process
- Understand the importance of procedures for recall of potentially contaminated equipment and supplies
- List the issues of concern in the Central Sterile Department (CSD) that impacts infection prevention

Disclosures

- Speaker's Bureau
  - 3M
  - Sage

According to the CDC…

"In the United States, approximately 46.5 million surgical procedures and even more invasive medical procedures – including approximately 5 million gastrointestinal endoscopies-are performed each year."[1]

Surgical Site Infections are the most common adverse event for surgical patients.

1. Rutala, Weber and HICPAC. CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008

Burden of Surgical Site Infections (SSI)

Outcomes Associated with SSI

- Approx. 7-10 additional post-op hospital days (deep and organ-space infection much longer)
- Are 5 times more likely to be re-admitted
- Have a 60% increase in ICU admissions
- 2-11 times higher risk of death
- 77% of deaths among patients with SSI are directly attributable to SSI.
- Attributable cost estimates range from $3,000-$29,000 (maybe more for deep and organ-space infections)
- SSIs are believed to account for up to $10 billion annually in healthcare expenditures.

Anderson, DJ, Kaye, KS et al. Strategies to Prevent Surgical Site Infections in Acute Care Hospitals. SHEA/IDSA Practice Recommendations Prevention Compendium 2008

Evidence-based Practices – Pre-Op

- Hair removal as close to surgery as possible
  - Option for depilatory or clippers
- Antiseptic showering – night before and morning of surgery
  - Decrease bioburden on skin at time of surgery
  - Clean linen and clean clothing
- Patient skin prep in the OR
  - Use according to manufacturer's instructions and allow prep to dry
- Pre-op nasal decontamination

Mangram, AJ, Horan, TC et al. Guideline for Prevention of Surgical Site Infection, 1999

Perioperative Strategies

- Antibiotic Prophylaxis
  - re-dose cases >2-3 hours
- Proper insertion of central lines
- Aseptic technique during Foley placement
- Glycemic control
- Prevent wound contamination by practicing the principles of aseptic technique
- Decrease the length of surgery
- Prevent hypothermia
- Use closed drainage system when needed

Mangram, et al. The Hospital Infection Control Practices Advisory Committee (HIPAC). Guideline for the Prevention of Surgical Site Infection. *Infect Control Hosp Epidemiol* 1999;20:247-80.

Perioperative Strategies

- Environmental Factors
  - Maintain OR at positive pressure with respect to corridor and adjacent areas.
  - Air changes should be a minimum of 20 air changes per hour (3 or 20% must be fresh air)
  - Introduce air at the ceiling and exhaust near the floor.
  - Keep OR doors closed except as needed for passage of equipment, personnel and patient.
  - Limit the number of personnel in the operating room to necessary personnel.

AORN Perioperative Standards and Recommended Practices For Inpatient and Ambulatory Settings. 2011 Edition

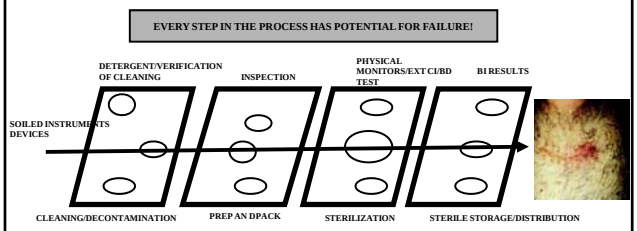
System Design – How is your system designed?

Every system is perfectly designed to get results it consistently achieves.

***Donald* M. *Berwick*, MD, MPP, FRCP, President and CEO, Institute for Healthcare Improvement (IHI)**

Is your system/process designed to consistently break the chain of infection? Prevent infections?

Is Your System/Process Designed for Infection Control?



It is a flawed system that will allow a problem at the beginning to progress all the way through to adversely affect patient safety.

Based on James Reason's Swiss Cheese Model

Image from Gordon, Steven New Surgical Techniques and Surgical Site Infections. EID 2001; 7 (2):217-219

15 patients in 3 states possibly exposed to fatal brain disease

Fifteen people in three states now have been warned that they may have been exposed to a rare and fatal brain disease through potentially contaminated surgical equipment, health officials said Friday.
In addition to eight patients in New Hampshire, five in Massachusetts and two in Connecticut have received the news that they may have shared tainted equipment with a patient who died from apparent Creutzfeldt-Jakob Disease, *…* ***Hospitals frequently share high-cost neurosurgery equipment on a fee-for-use or rental basis.***
The problem arose because standard hospital sterilization techniques cannot eradicate the prion that causes s CJD. …

http://www.nbcnews.com/health/15-patients-3-states-possibly-exposed-fatal-brain-disease-8C11097250 NBC News Health September 6, 2013

Dentist's office a 'perfect storm' for HIV, hepatitis exposure, health official says

About ***7,000 patients*** *who visited a suburban Tulsa, Oklahoma, dentist in the past six years may have been* ***exposed to HIV and hepatitis,*** *health investigators say. Investigators were left grasping for words to describe what they found inside W. Scott Harrington's dental practice: Assistants did techniques that only a dentist should, and* ***sterilization procedures and needles were handled improperly.***

http://www.cnn.com/2013/03/29/health/oklahoma-dental-warning/index.html
CNN Health March 29, 2013

Report: Dirty surgical tools in hospitals putting patients at risk

*When **63-year-old John Harrison had surgery to repair his rotator cuff in 2009***, he assumed the ordeal would be quick and relatively painless.

Instead, Harrison, who had the surgery performed at The Methodist Hospital in Houston, ***developed an infection that ate away at his shoulder bone and rotator cuff***. The infection led to a lengthy recovery time, and he became dependent on nurses to help him dress and shower. Harrison was one of seven patients who developed an infection after having surgery at Methodist within a two-week timeframe. As a result, the hospital voluntarily closed its operating room and asked the U.S. Centers for Disease Control and Prevention (CDC) to investigate.

"Evidence from the investigation suggests the Methodist infection outbreak was most likely caused by retained tissue," said Dr. Pritish Tosh, a former investigator at the CDC's Epidemic Intelligence Service, in a 2011 issue of Control and Hospital Epidemiology.

In Harrison's case, ***the likely causes of infection were the two surgical tools – an arthroscopic shaver and an inflow/outflow cannula – which, when inspected using tiny video cameras, were found to have traces of human tissue and blood caked onto them.***

...

Source: NBC Today Show
Fox News

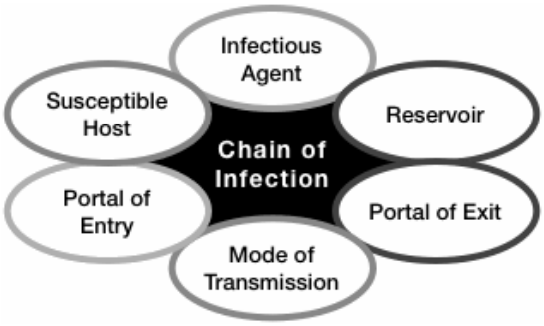
Report: Dirty surgical tools in hospitals putting patients at risk

Methodist is not the only hospital where dirty surgical tools have led to health problems. Also in 2009, the Department of Veterans Affairs admitted more than 10,000 patients in Florida, Tennessee and Georgia had colonoscopies and endoscopies with contaminated tools between 2002 and 2009. Some of these patients have tested positive for HIV, hepatitis C and hepatitis B. Lawsuits ensued.

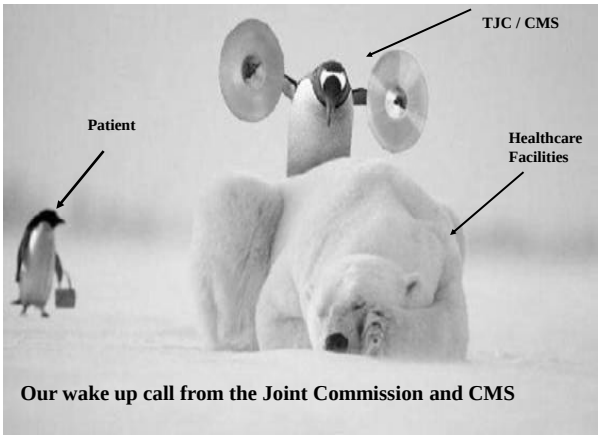
In 2008, an outpatient surgical center in Las Vegas found six patients had been sickened with hepatitis C after it reused biopsy forceps.

Source: NBC Today Show
Fox News

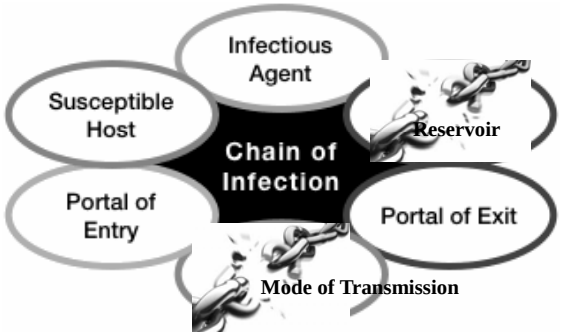
Chain of Infection – Remains Intact



Graphic from Google Images

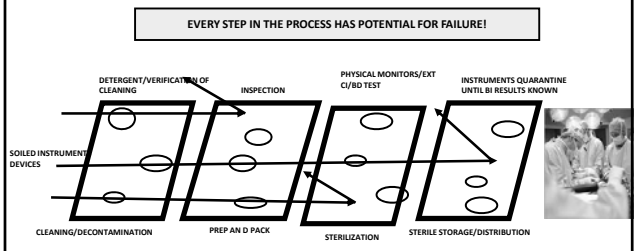


Breaking the Chain of Infection



Graphic from Google Images

… Or Is Your System/Process Designed for Infection Prevention?



Based on James Reason's Swiss Cheese Model

http://consumerist.com/368325/california-hospital-takes-botched-operations-seriously from Google Images

The Joint Commission National Patient Safety Goals

- ***NPSG.07.05.01*** - Implement evidence-based practices for preventing surgical site infections.
- ***EP3:***
  - 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 Center for Disease Control and Prevention [CDC] and/or professional organization guidelines).

The Joint Commission. 2012 Hospital Accreditation Standards

The Joint Commission

- ***LD.04.01.01, EP2***
  - The hospital provides care, treatment, and services in accordance with licensure requirements, laws and regulations
- ***LD.04.03.07***
  - Patients with comparable needs receive the same standard of care, treatment, and services throughout the hospital
- ***LD.04.04.07***
  - The hospital considers clinical practice guidelines when designing or improving processes.
- ***IC.02.02.01*** - The organization reduces the risk of infections associated with medical equipment, devices and supplies.
  - The hospital implements infection prevention and control activities when doing the following:
    - **EP1**- Cleaning and performing low-level disinfection of medical equipment, devices, and supplies.
    - **EP2** - The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.

The Joint Commission: 2013 Hospital Accreditation Standards

The Joint Commission Survey

- The Joint Commission will survey for:
  - Orientation, training and competency of the health care worker (HCW) who process medical equipment, devices and supplies
  - Levels of staffing and supervision of the HCW who process medical equipment, devices and supplies
  - Standardization of the process regardless of whether it is centralized or decentralized
  - Ongoing quality monitoring
  - Observation against the manufacturers guidelines and the organization procedures.

The Joint Commission Perspectives. October 2009 Vol 29 (10)

TJC – Challenging Standards

- First half of 2013
  - Ambulatory Care, Critical Access Hospital, Hospital and Office-based Surgery
  - IC.02.02.01 The organization reduces the risk of infections associated with medical equipment, devices, and supplies.

Role of Central Sterile Department (CSD/SPD)

"The importance of this [CSD/SPD] role in the prevention of nosocomial [HAIs] is clear: *reusable medical devices improperly handled, disinfected, or sterilized provide a source of contamination and increase the risk of transmission of infection to both patients and the staff involved in reprocessing procedures."*

Pugliese, Gina and Hunstiger. Central Services, Linens and Laundry. In Hospital Infections. Edited by John V. Bennett and Philip S. Brachman. 3rd ed.

Role of the CSD/SPD

Direct healthcare providers (such as physicians, nurses,...) and ancillary personnel (such as housekeeping and ***equipment-processing personnel) are responsible for ensuring the appropriate infection prevention and control practices are used at all times*** (including hand hygiene; strict adherence to aseptic technique; cleaning and disinfection of equipment and the environment; ***cleaning, disinfection, and sterilization of medical supplies and instruments and appropriate surgical prophylaxis protocols).***

Strategies to Prevent Surgical Site Infections in Acute Care Hospitals. SHEA/IDSA Practice Recommendations

Sterilization Risk Analysis

Risk analysis = risk assessment + risk management + risk communication

"The sterilization risk analysis should be part of the overall infection prevention and control risk analysis in accordance with accreditation agency requirements."
- Risk assessment (FMEA)
- Risk management (ANSI/AAMI ST79, Root cause analysis)
- Risk communication (Recall procedure)

"It should be performed annually and should be reevaluated whenever significant changes occur."

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 11.2.2

Sterilization Risk Analysis

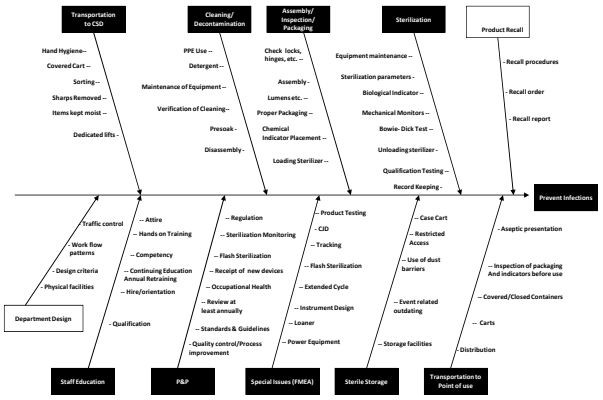
- **Risk assessment**
  - Identify sources of potential sterilization failures
  - Estimate likelihood that each failure will occur
  - Assess the consequences if that failure does occur
- **Risk management**
  - Determine which of the potential sterilization failures identified require management
  - Select and implement the plans or actions needed to ensure those failures are controlled
  - AAMI ST79 describes the accepted means of managing these risks

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 11.2.2

Breaking the Chain of Infection Focus on the Patient

Graphic from Google Images

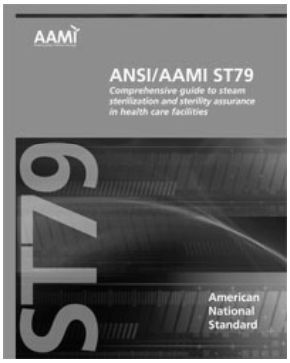
Central Sterile Process - Ishikawa (Fishbone) Diagram



What are the parts of the process?

- Cleaning and Decontamination
- Preparation and Packaging
- Sterilization
- Sterile Storage and Distribution
- Record Keeping
- Recall Procedures

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 (Consolidated Text)



Under continuous review and maintenance.

Manual or Mechanical? If you can't clean it, you can't sterilize it!

CLEANING AND OTHER DECONTAMINATION PROCESSES

The purpose of decontamination is to prevent the spread of infection.

Personal Protective Equipment

PROPER ATTIRE

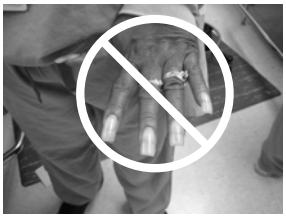
Personal Protective Equipment (PPE) – Portal of Exit/Entry

- Liquid-resistant covering with sleeves
- Heavy-duty latex free or plastic gloves
- Surgical face mask (impervious to fluid and high filtration)
- Safety glasses that wrap around the eye or face shield
- Disposable hair covering
- Proper footwear

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 4.5.1

Personal Protective Equipment (PPE) – Portal of Exit/Entry

- Fingernails and Artificial Nails
  - Natural nail tips should be kept to ¼ inch or less in length (CDC II; WHO II)
  - Artificial nails or extenders are not be worn when having direct contact with high-risk patients (e.g., ICU, OR) (CDC 1A; WHO 1A)
- Especially important in Assembly / Prep and Pack



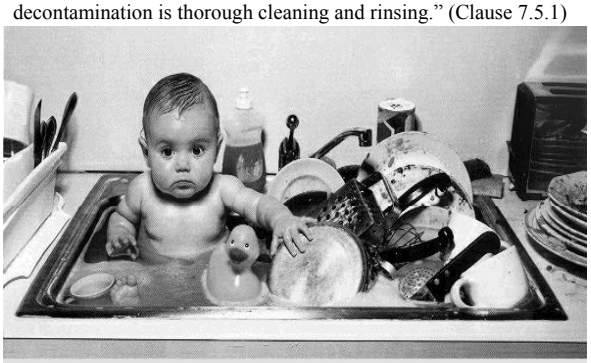
Guideline for Hand Hygiene in Health-care Settings. *MMWR 2002*; vol. 51, no. RR-16.

Cleaning and other Decontamination Processes

- "To be rendered safe to handle, some medical devices require only thorough cleaning; others, because of occupational exposure considerations, must be cleaned and subjected to a microbicidal process. Some devices can be prepared for patient reuse following the decontamination process, whereas others must be prepared and subjected to terminal sterilization (e.g., steam sterilization of surgical instruments)." (Clause 7.1)
- "The type of decontamination required for a particular contaminated device depends on the biohazard that the device presents." (Clause 7.1)
- "The written [instructions for use] IFU of the device manufacturer should always be followed." (Clause 7.2.2)
- "Surgical instruments and other items composed of more than one part or piece (e.g., metal tracheostomy tubes, procedure needles, dental handpieces, laparoscopic instrumentation, trumpet valves) should be disassembled to expose all surfaces to the cleaning process." (Clause 7.4.1)

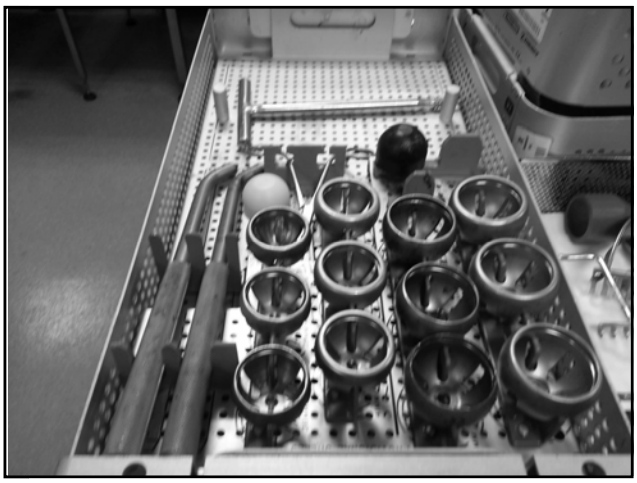
Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Sec. 7.1 & 7.2.2 & 7.4.1

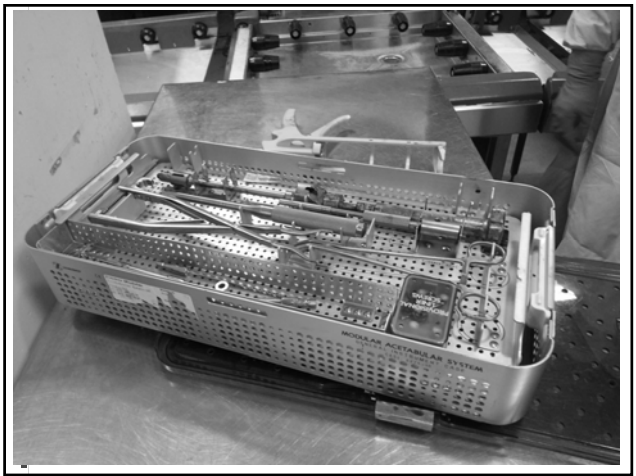
"For all reusable, the first and most important step in decontamination is thorough cleaning and rinsing." (Clause 7.5.1)



What are you doing to save time?

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 7.5.1





Manual Cleaning

"Manual cleaning is often recommended for delicate or complex medical devices, such as microsurgical instruments, lensed instruments, and air-powered drills. Immersible devices should be cleaned under water to minimize aerosolization; devices that cannot be immersed should be cleaned in a manner that will not produce aerosols and should be rinsed and dried according to the device manufacturer's written IFU."

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 7.5.3.2

Mechanical Cleaning

- "Mechanical cleaning equipment removes soil and microorganisms through an automated cleaning and rinsing process. Some types of equipment incorporate thermal disinfection processes and/or chemical disinfectant rinses capable of destroying various numbers and types of microorganisms. Mechanical cleaning equipment includes utensil washers and cart washers, washer-sanitizers, pasteurization equipment, washer-disinfectors, washer-decontaminators, and washer-sterilizers." (Clause 7.5.3.3)
- Ultrasonic cleaners used for fine cleaning

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 Clause 7.5.3.3

PACKAGING

"The primary functions of a package containing a medical item are to allow the sterilization of the contents, to maintain the sterility of the contents until the package is opened, and to provide for the removal of the contents without contamination."

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A:2012 Clause 8.2 Rationale

Effective Packaging Materials

- Allow adequate air removal and steam penetration
- Adequate barrier to microorganisms or their vehicles
- Resist tearing or puncture
- Allow a method of sealing that results in a complete seal that is tamper-evident and provides seal
- integrity
- Allow for ease of aseptic presentation
- Be free of toxic ingredients and nonfast dyes
- Be non-linting
- Be shown by value analysis to be cost-effective

- **Reusable woven textile**
- **Disposable nonwoven materials**
- **Peel pouches**
- **Reusable rigid sterilization containers**

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 8.2

Packaging Concerns

Paper-Plastic Pouches – "The plastic laminate used in paper–plastic pouches is impervious to the sterilant and, therefore, might prevent the sterilant from reaching the surface of anything with which the plastic side is in physical contact. Therefore, paper–plastic pouches should not be used within wrapped sets or containment devices unless the practice has been validated by the packaging manufacturer and verified by product testing in the health care facility.

- **ANSI/AAMI ST77:2006 Rigid Container Systems (Manufacturer Standard)**
- Ergonomic issue
  - "The combined weight of the containment device, the instruments, and any accessories or wrappers shall not exceed **25 pounds**…"
  - When containment devices, including their contents and any accessories or wrappers, are too heavy, **sterilization and/or drying could be compromised** in commonly available hospital sterilization cycles.

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 8.3.4 & 8.4.2 Rationale

Packaging Concerns

100% medical grade paper bags

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 8.3.4 & 8.4.2 Rationale

Packaging Concerns

- **Wet packs should not be released for use**
  - Repackage, replace chemical indicators (CIs)
    - Disposable products (e.g. gauze or cotton balls) should be discarded
  - Review the sterilizer cycle conditions
    - Drying cycle length and temperature
    - Set contents, weight, & density (especially metal mass)
    - Loading of the sterilizer and position of wet pack
  - Reprocess after detecting the error or probable cause of the wet pack
- Perform process audits to ensure adherence to packaging procedures

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 8.3.1

The first step in being able to monitor the steam sterilization process is to know the type of steam sterilizer that is used.

STEAM STERILIZATION

Steam Sterilization

Approximately 85% of medical item sterilization in healthcare facilities is achieved with saturated steam under pressure

- Fast
- Highly effective
- Reliable
- Relatively low cost
- Easy to use
- Readily available
- Technology well understood
- No toxicity or hazardous residues

Steam Sterilization – Critical Parameters

- Time
- Temperature
- Saturated Steam

Types of Steam Sterilization Processes

- ✓Gravity Displacement
- ✓Dynamic-Air-Removal Prevacuum
- ✓ Steam-flush pressure-pulse (SFPP)

Gravity Displacement - Cycle Time Examples

Load Contents	Time (Min)
Wrapped instruments	30
Textile packs	30
Wrapped utensils	30

Dynamic-Air-Removal

- Prevacuum
  - Series of pressure and vacuum excursions
- Steam-flush pressure-pulse (SFPP)
  - Series of steam flushes and pressure pulses above atmospheric pressure

Cycle Time Examples

Load Contents	Temp	Time (Min)
Wrapped instruments	132°C/270°F 135°C/275°F	4 3
Textile packs	132°C/270°F 135°C/275°F	4 3
Wrapped utensils	132°C/270°F 135°C/275°F	4 3

Table Top Gravity Steam Sterilizers

Load Contents	Temp	Time (Min)
Unwrapped instruments on tray or glassware	132°C/270°F 135°C/275°F	≥3
Wrapped trays of instruments, instruments in peel pouches	132°C/270°F 135°C/275°F	≥5
Packs, wrapped	121°C/250°F	≥30

Immediate Use Steam Sterilization (Formerly Flash Sterilization)

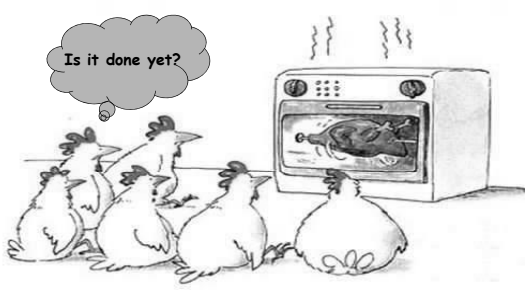
- Process designed for the steam sterilization of patient care items for immediate use
  - High temperature (132-135°C / 270-275°F)
    - Gravity or dynamic-air-removal
    - No dry time
    - No storage

Cycle Time Examples

Load Contents	Temp	Time (Min)
Unwrapped instruments (non-porous items)	270°F/132°C 275°F/135°C	3 3
Unwrapped non-porous and porous items in mixed load	270°F/132°C 275°F/135°C	4 3

Cycle Time Examples

Load Contents	Temp	Time (Min)
Unwrapped non-porous items (e.g., instruments)	132°C/270°F 135°C/275°F	3 3
Unwrapped non-porous and porous items in mixed load	132°C/270°F 135°C/275°F	10 10



Sterilization Monitoring - not as simple as it looks!

Continuous Quality Improvement (CQI)

- CQI programs are used to assess and improve all components of the sterilization process
  - Desired outcome of improving patient care by consistently delivering sterile product to the user
    No single "right way" to implement CQI
  - Team approach

Design the sterilization process to prevent error and break the chain of infection? (SCARR)

- Standardize the process
- Checklists - outline all the steps
- Automate the process
- Reduce the number of steps and handoffs
- Redundancy (double checks)

Quality Control

- Monitoring and verifying the cleaning process
- Sterilization process monitoring
  - monitoring of every package and sterilization load
  - routine monitoring of sterilizer efficacy
  - qualification testing of the sterilizer after installation, relocation, sterilizer malfunction, major repairs, and sterilization process failures
  - periodic product quality assurance testing

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.4, Table 6, 10.6 – 10.9

Sterilization Process Monitoring Devices

- *Each monitoring tool "plays a distinct and specific role in sterilization process monitoring, and each is indispensable to sterility assurance."*
- Physical monitors
  - time, temperature and pressure recorders, displays, digital printouts and gauges
- Chemical indicators (CIs)
  - external/internal Cis
  - Bowie-Dick (BD) type tests
- Biological indicators (BIs)

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.4, Table 6 & 7

Reasons for Testing the Sterilization Process

- ✓ Ensure probability of sterility of processed medical devices
- ✓ Detect sterilization failure ASAP: quarantine medical devices until final BI result known
- ✓ Verify a corrected failure ASAP…… get sterilizer back into service
- ✓ Control costs
- ✓ Remove medical devices involved in failures before patient use
- ✓ Helps determine if events during sterilization process met parameters
- ✓ Provides verification of adherence to policies/procedures
- ✓ Promote patient safety and improve outcomes

Sterilization Assurance

- Probability
- Assurance level of 10^{-6}
- Individual sterilization monitors does not indicate sterility
- Need the combination of all monitors to give an assurance of sterility
- ***Physical + Chemical + Biological = Probability of sterility (1 in a million chance that an item is not sterile)***

Physical Monitors

- Verify that parameters of sterilization cycle are met
  - Recording charts
  - Gauges
  - Tape
  - Printouts
  - Digital displays
- Limitations
  - Generally only monitor one location in the sterilizer
  - Conditions not revealed in the temperature recording, such as:
    - Improper packaging
    - Improper loading procedures

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.1

Chemical Indicators AAMI

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 10.5.2.1 & A3:2012

- **Class 1** Process Indicators
- **Class 2** Indicators for use in Specific Tests
- **Class 3** Single Variable Indicators
- **Class 4** Multi-variable Indicators
- **Class 5** Integrating Indicators
- **Class 6** Emulating Indicators

Reprinted from ANSI/AAMI/ISO 11140-1:2005/ (R)2010 Sterilization of health care products-Chemical indicators - Part 1: General requirements, 2ed

Class 1: Process Indicators (External Indicators)

- Tapes, labels, printed legends
- Designed to react to one or more of the critical process variables
- Placed on each hospital assembled package or rigid sterilization container system intended for sterilization
- Identifies processed from unprocessed packages
  - if not changed, do not use

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.2.2.1, Table 6 & 7

Class 2: Indicators for Specific Tests

- Equipment Control
- Testing sterilizer performance
  - Bowie-Dick Test monitors efficacy of air removal and steam penetration in 132-135ºC (270-275°F) dynamic-air removal sterilizers (i.e., vacuum assisted sterilizers)

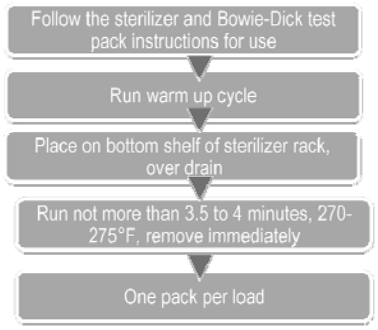
Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.2.1, Table 7 & 10.7.6

Class 2: Indicators for Specific Tests

- Bowie-Dick tests can detect:
  - Air leaks
  - Inadequate air removal
  - Inadequate steam penetration
  - Presence of non-condensable gases: air or gases from boiler additives

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.2.1, Table 7 & 10.7.6

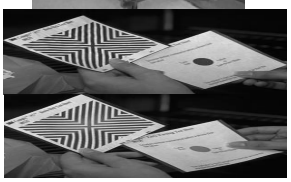
Bowie-Dick Test



ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.2.1, Table 7 & 10.7.6

Class 2: Indicators for Specific Tests

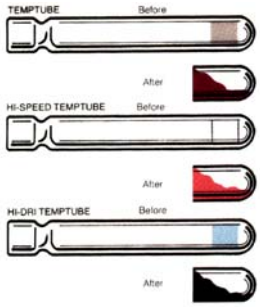
- Bowie-Dick Test
  - Uniform color change – Use
  - Not uniform color change – Retest
  - If not uniform, shut down and call repair person
  - Re-qualify if major repair



Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.2.1, Table 7 & 10.7.6

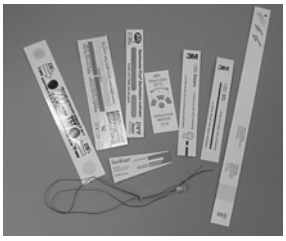
Class 3: Single Variable Indicators

- Responds to one critical variable for sterilization
- Usually temperature
- Indicates exposure to a sterilization process at a stated value (SV) of the chosen variable



Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.4, 10.5.2.1, 10.5.2.2.2, Table 6 & 7

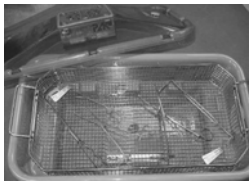
Internal Chemical Indicators



- Class 4 – Multi-variable
  - Measures 2 or more of the critical variables of the sterilization process
- Class 5 – Integrating indicator
  - Reacts to all critical variables
  - In a PCD to release non-implant loads
  - In a BI PCD to monitor implant loads
  - Correlates to the BI
- Class 6 – Emulating indicator
  - Reacts to all critical variables
  - Cycle specific

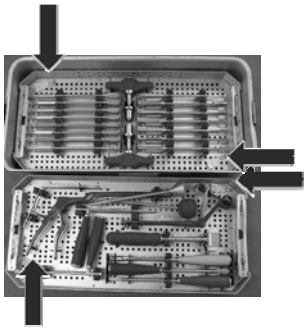
Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.4, 10.5.2.1, 10.5.2.2.2, Table 6 & 7

Chemical Indicator Placement



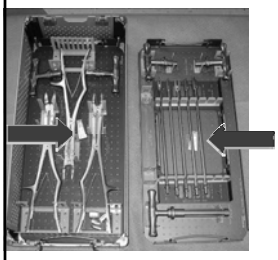
- Rigid container
  - ➢ Place two CIs inside rigid containers
  - ➢ Place one in each of two opposite corners

Chemical Indicator Placement



- Multi-layer container
  - Place two CIs in each level of multi-level rigid container
  - Place one in each of two opposite corners on each level

Chemical Indicator Placement



- Multi-level container

➢ Supplied by the manufacturer, holes in tray, has to be wrapped

➢ Place a CI in center on each level

Biological indicators provide the only direct measure of the lethality of the sterilization process.

BIOLOGICAL INDICATOR MONITORING

Biological Indicator Monitoring

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

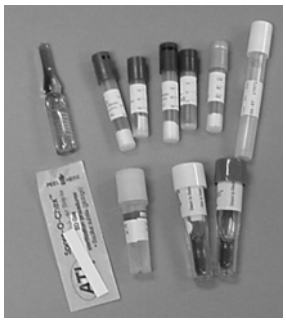
ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.3, Table 7

CDC Guidelines

- Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
  - "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 organisms (i.e., *Bacillus* spores) and not by merely testing the physical and chemical conditions necessary for sterilization."

Ref: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf , page 76

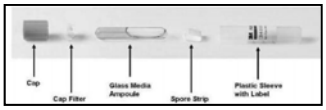
Biological Indicators/PCDs (Test Packs)



Biological Indicators

- How they work . . .
  - Spores are exposed to the sterilization process
  - After processing, exposed spores immersed in optimized recovery media and incubated at optimal temperature
    - Spore strips are transferred to medium using aseptic technique
    - Self-contained designs allow immersion without transfer

If spores viable – process failure



Biological Indicators (*Geobacillus stearothermophilus)*

- With enzyme-based early-readout capability (AAMI) or rapid-action readout (AORN)
  - Fluorescence in 1 to 3 hours
  - Visual color change in 24 to 48 hours for steam
- "Conventional"
  - Visual color change in 24-96 hours
- Manufacturer's incubation instructions should be followed
- AAMI ST79 – "*Periodic verification of the early-readout with spore growth should be performed in accordance with the manufacturer's written instructions for use and facility policy and procedures.*"
- Incubate a positive BI control each day a test vial is incubated in each incubator or auto-reader
- *From same lot number as the test BI*
- Purpose is to validate the test system is working and ensure
  - Correct incubation conditions
  - Viability of spores
  - Capability of medium to promote growth
  - Proper functioning of auto-reader and incubator
- Good Science

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.3.1

Sterilization Process Monitoring Devices

- Process challenge device (PCD)
  - designed to simulate the product to be sterilized
  - constitutes a defined resistance to a sterilization process and used to assess effective performance of the process
  - placed in the most challenging area in the sterilizer for sterilant penetration
- BI
- BI and a Class 5 integrating chemical indicator
- Class 5 integrating chemical indicator
- Class 6 Emulating Indicator

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.4

Routine Sterilizer Efficacy Monitoring

- Routine load release
  - non-implant
  - implant load
- Routine sterilizer efficacy monitoring
  - Establishing a regular pattern of testing the efficacy of the sterilization process for both gravity and dynamic air-removal testing.
  - BI PCD
    - Every load
    - Daily plus every implant load
    - Weekly plus every implant load
  - BD PCD
    - Daily
- Immediate Use Steam Sterilizer (IUSS)
  - BI PCD representative of tray routinely processed
  - Each type of tray configuration in routine use should be tested separately
    - Perforated, mesh bottom, open surgical tray
    - Rigid sterilization container system
    - Protective organizing case
    - Single-wrapped surgical tray
    - Empty load on bottom shelf over drain
  - BD PCD if dynamic-air-removal
    - Daily

Reprinted from ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.6.1, 10.6.2, Table 6 & 7

Routine Sterilizer Efficacy Monitoring

- Table-top sterilizers
  - BI PCD representative of package or tray routinely processed and most difficult to sterilize
  - BI PCD should contain items normally present during routine sterilization
  - Full load in cold point (check with sterilizer manufacturer)

Biological Indicator - Monitoring Frequency

- Weekly, preferably daily
- Every load with an implant
- Some sterilization systems (e.g., Ethylene Oxide) require every load monitoring

- Why monitor every load?
  - Universal standard of patient care
  - Cost and impact of a recall
  - To be certain all implants, including those in loaners, are appropriately monitored
  - Ensure every type of sterilization cycle used is monitored
  - Ensure every type of packaging used in flash sterilization is monitored
  - Reduce risk and cost of healthcare-associated infections (HAIs)

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.4

Routine Load Release - Nonimplant Loads

Routine Load Release-Non-Implant Loads

- Physical monitors
- External process indicator (Class 1) on every package
- Internal CI (Class 3, 4 or 5, or enzyme-only) inside every package
- If desired, a PCD containing a
  - BI
  - Class 5 integrating
  - Evaluation of all data by an experienced, knowledgeable person
- Do not distribute load if any data suggests a sterilization process failure
- If desired, a PCD containing a
  - BI
- If a BI PCD is not used in each load
  - Do not know spores were killed
  - Need to do a recall when a positive BI is obtained
  - More frequent monitoring → less to recall and reduce chance of patient receiving a non-sterile medical device
- **Immediate Use Steam Sterilization Cycles (IUSS)**
- Class 5 Integrating Indicator Challenge Pack for Releasing Flash Loads
  - Representative of load
  - Open surgical tray
  - Rigid sterilization container
  - Protective organization case
- Use as internal CI and to release non-implant loads

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Clause 10.5.4

Routine Load Release-Implant Loads

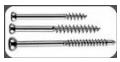
What is an Implant?

According to FDA, "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also 'implants.' " 21 CFR 812.3(d)

•Only BI results can be used to release implants

- **•"BIs within a PCD should be used to monitor every load containing implants (see 10.6.1)."**
- **•The PCD should include a Class 5 integrating CI**

•"The load should be quarantined until the results of the BI testing are available (CDC, 2008)."



ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 10.6.3

Implant Load Release - (Emergency Situations)

- Releasing implants before the BI results are known is unacceptable
- Immediate use steam sterilization (IUSS) should not be used for implantable devices except in cases of emergency when no other option is available.
- Exception, not the rule
- Define emergency situations in written guidance developed in consultation with infection prevention and control, the surgeon, and risk management

In an emergency, when flash sterilization of an implant is unavoidable, a rapid-action BI and a Class 5 chemical integrating indicator should be run with the load. The implant should be quarantined on the back table and should not be released until the rapid-action BI provides a negative result."

Sample - Implant Exception Form

- Name of
  - Implant prematurely released
  - Patient
  - Surgeon
- Reason for premature release
- What could have prevented premature release

Exception Form for Premature Release of Implantable Device/Tray

NOTE: with a biological monitor result. This form should accompany the tray/cart 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 device/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: _____

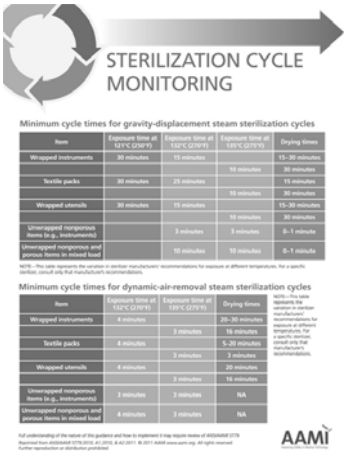
WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE? TRAY? _____

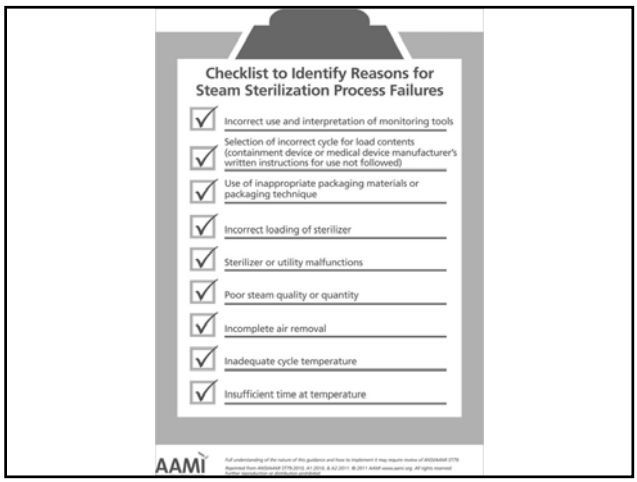
NAME OF OR PERSON COMPLETING THIS REPORT: _____

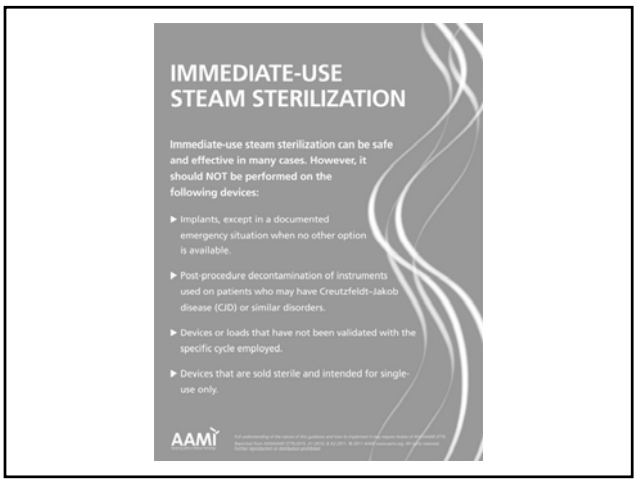
DATE REPORT COMPLETED: _____ FORM RETURNED TO CENTRAL SERVICE ON _____

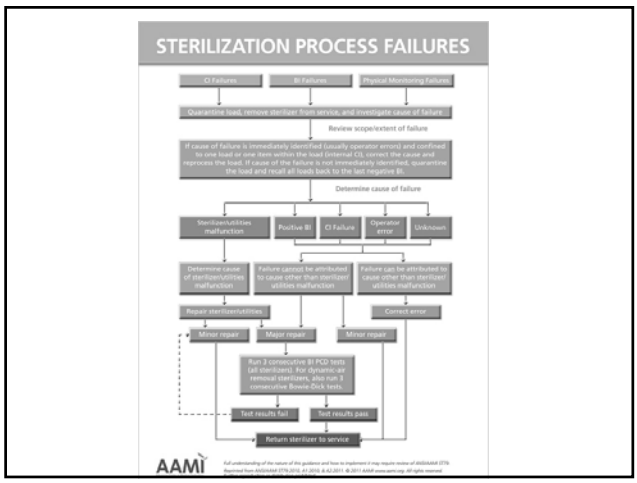
Figure L.2—Exception form for premature release of implantable device/tray

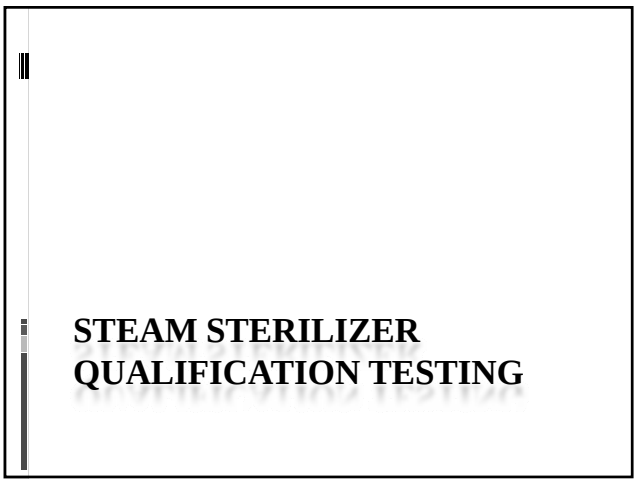
ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 Annex L




Checklist to Identify Reasons for Steam Sterilization Process Failures
Incorrect use and interpretation of monitoring tools
Selection of incorrect cycle for load contents (containment device or medical device manufacturer's written instructions for use not followed)
Use of inappropriate packaging materials or packaging technique
Incorrect loading of sterilizer
Sterilizer or utility malfunctions
Poor steam quality or quantity
Incomplete air removal
Inadequate cycle temperature
Insufficient time at temperature
AAMI


IMMEDIATE-USE STEAM STERILIZATION
Immediate-use steam sterilization can be safe and effective in many cases. However, it should NOT be performed on the following devices:
Implants, except in a documented emergency situation when no other option is available.
Post-procedure decontamination of instruments used on patients who may have Creutzfeldt–Jakob disease (CJD) or similar disorders.
Devices or loads that have not been validated with the specific cycle employed.
Devices that are sold sterile and intended for single-use only.
AAMI


STERILIZATION PROCESS FAILURES
CI Failures
BI Failures
Physical Monitoring Failures
Quarantine load, remove sterilizer from service, and investigate cause of failure
Review scope/extent of failure
Determine cause of failure
Sterilizer/utilities malfunction
Positive BI
CI Failure
Operator error
Unknown
Repair sterilizer/utilities
Correct error
Minor repair
Major repair
Minor repair
Run 3 consecutive BI PCD tests (all sterilizers). For dynamic-air removal sterilizers, also run 3 consecutive Bowie-Dick tests
Test results fail
Test results pass
Return sterilizer to service
AAMI


STEAM STERILIZER QUALIFICATION TESTING

Steam Sterilizer Qualification Testing

- This qualification testing should be conducted in the health care facility by health care personnel in cooperation with the manufacturer.
- Testing should be performed
  - at the time the steam sterilizer is installed, relocated, or repaired and the time it is released for use in the health care facility.
  - for both gravity-displacement and dynamic-air-removal sterilizers
  - three consecutive cycles should be run, one right after the other, with a PCD
- Negative results from all test BIs and appropriate readings from all physical monitors and CIs.
- Dynamic-air removal sterilizers
  - three consecutive cycles should be run, one right after the other, with the Bowie-Dick test pack
  - each test result demonstrating sufficient air removal
  - empty chamber should be used for the tests.
- Cool transfer cart between each cycle to ensure that superheating does not occur and to more closely duplicate normal processing procedures

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 10.8.1, 10.8.2

Sterilizer Qualification Testing

- Major repairs of steam sterilizer
  - Repairs outside the scope of normal maintenance
  - Examples:
    - Weld repairs of pressure vessel
    - Replacement of chamber door or piping assembly
    - Rebuilds or upgrades of controls
- Major repairs of utilities
- Changes to the utilities connected to the sterilizer
  - Examples:
    - Water-main break
    - Annual boiler maintenance
    - Additional equipment loads
    - Installation of new boilers

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3;2012 10.8

Steam Sterilizer Qualification Testing

- Table-top sterilizers
  - BI PCD representative of package or tray routinely processed and most difficult to sterilize
  - BI PCD should contain items normally present during routine sterilization
  - Full load in cold point (check with sterilizer manufacturer)
  - Three consecutive cycles
- IUSS
- BI PCD representative of tray routinely processed
  - Select a tray configuration to be tested
    - Perforated, mesh bottom tray, open surgical tray
    - Rigid sterilization container system
    - Protective organizing case
    - Single-wrapped surgical tray
  - Empty load on bottom shelf over drain
  - Three consecutive cycles

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 10.8.3 &10.8.4

Sterile items should be stored in a manner that reduces the potential for contamination.

STERILE STORAGE

Sterile Storage

- Separate area with restricted access
- Proper ventilation (at least 4 air changes/hour, positive pressure to corridor) to protect against dust, moisture and extremes of temperature (~24ºC /75ºF) and humidity (<70%)
- Free of insects and vermin
- Sterile items should be stored away from outside walls (at least 2 inches), off the floor (at least 8-10 inches) and away from the ceiling (18 inches)
- Stored to prevent physical damage (dragging, sliding, crushing, bending, compressing or puncturing)
- Sterile packages should be minimally handled to reduce the risk of contamination of the contents
- Should not be stored next to sinks or under exposed water or sewer pipes or in locations where they may become wet
- Should not be stored on floor or windowsills
- Shelf life is event related
- Sterile packages transported to the point of use should be protected to prevent contamination

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 8.9

RECORD KEEPING

Documentation
Manual or Electronic

- What?
  - Materials that have been processed
  - Results of the sterilization process monitoring
- How?
  - Load labels/package
  - Paper log systems
  - Electronic log systems
  - Filed as individual document

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 8.3.2

Documentation - Manual or Electronic

❖ Labeling on product
- *Lot or load control number*
  - Date of processing
  - Sterilizer number
  - Cycle number

❖ *Expiration date or statement:*

"Contents sterile unless package is open or damaged. Please check before using."

❖ Electronic system
- Reduction of human error
- Past records available with a touch of a finger
- Accessibility to all load records at any time
- All load information in one location

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 8.3.2

Documentation - Electronic or Manual

- Electronic system
  - Reduction of human error
  - Past records available with a touch of a finger
  - Accessibility to all load records at any time
  - All load information in one location

Documentation - Electronic or Manual

- Sterilizer and load records
  - Load contents
  - Date and time of cycle
  - Exposure time and temperature
  - Initials of operator
  - Biological results
  - Chemical indicator results
- Records of sterilizer repair, maintenance and calibration
- Maintain records for time determined by risk manager

Risk Communication

RECALL PROCEDURES

Recall Procedures

- Written policies and procedures for the recall of items from issued or stored loads should be developed in cooperation with the infection prevention and control committee and risk management of the individual health care facility.
- These policies and procedures should be documented, and records should be maintained.

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 10.11.1

Sterilization Process Failures

- A processed PCD with a positive BI (BI challenge test pack) or a failed Class 5 integrating CI or Class 6 emulating indicator (CI challenge test pack) is demonstrating a failure for the entire load and should be immediately reported by phone or messenger to the appropriate supervisor and to the infection prevention and control department.
- This notification should be followed by a written report.
- Quarantine load, remove sterilizer from service, investigate cause of failure
- Decision tree to assist with the recall

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 10.7.5.1 & Figure 12

When To Do a Recall

- If cause of failure immediately identified and confined to one load or item
  - e.g., using incorrect sterilization cycle
  - No recall, correct problem and reprocess load
- If cause of failure not identified
  - Quarantine load, recall all items processed since last negative BI
  - Determine cause of failure

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 10.7.5.1 & Figure 12

AREAS OF CONCERN

Cleaning Verification

How clean is visibly clean?

Cleaning Verification

- Test mechanical instrument washers:
  - *Before initial use*
  - *Weekly during service*
  - *After major maintenance*
- Evaluate manual cleaning
  - *When new instruments are reprocessed and periodically*

AORN Perioperative Standards and Recommended Practices. Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment, Recommendation XXII, 2013

Cleaning Verification

- Monitoring of mechanical cleaning equipment
- Frequency of testing
  - Upon installation
  - Weekly (preferably daily) during routine use
  - After major repairs
- Review and initial mechanical washer cycle printouts
- Document results
  Resource: Annex D User verification of cleaning processes

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 7.5.5, Annex D

Immediate Use Steam Sterilization (IUSS)

AREAS OF CONCERN

Immediate-Use Steam Sterilization

- Personnel involved in reprocessing should …
  - ✓Use critical thinking skills
  - ✓Staff have the appropriate training and education and are competent
  - ✓Be knowledgeable about evidence-based recommended practices and standards (AAMI, AORN, CDC)
  - ✓Cleaning and decontamination
  - ✓Aseptic transfer to the point of use
  - ✓Must follow device, sterilizer and container/wrapper manufacturers' written instructions
  - ✓Sterilization monitoring

http://www.aami.org/publications/standards/st79.html

Immediate-Use Steam Sterilization (IUSS)

- Used only when there is insufficient time to processed items by the preferred wrapped or container method intended for terminal sterilization
- Should not be used as a substitute for insufficient inventory
- Item for IUSS should go through the same cleaning and decontamination process
- IUSS should only be performed if the following conditions are met
  - Device and containment manufacturer's instructions (validated for use of IUSS)
  - Transfer to the sterile field without contamination
  - Monitoring the process to ensure parameters for sterilization has been met
  - Not used for implantable devices
  - Documentation to allow for tracking to the patient

Perioperative Standards and Recommended Practices for Inpatient and Ambulatory Settings. AORN 2013

Immediate-Use Steam Sterilization

- Not to be used on the following devices:
  - Implants except in a documented emergency situation when no other option available
  - Instruments used on patients who may have Creutzfeld-Jakob Disease (CJD)
  - Devices or loads that have not been validated with the specific cycle
  - Devices that are sold as sterile and intended for single-use only

http://www.aami.org/publications/standards/st79.html

Toxic Anterior Segment Syndrome (TASS)

AREAS OF CONCERN

Toxic Anterior Segment Syndrome (TASS)

- The Issue:
  Serious damage to a patient's intraocular tissue and vision loss as a result of contaminants introduced into the eye during ophthalmic surgery
- The Causes:
  Contaminated irrigating fluids; antiseptics; antibiotic ointments; powder from surgical gloves; "Most cases of TASS appear to result from inadequate instrument cleaning and sterilization"
- Inadequate or inappropriate instrument cleaning
- *"Detergents*
- *Heat stable endotoxin from overgrowth of Gram-negative bacilli in water baths or ultrasonic cleaners*
- *Degradation of brass containing surgical instruments from plasma gas sterilization*
- *Impurities of autoclave steam"*

Nick Mamalis, MD, *Toxic Anterior Segment Syndrome* Journal of Cataract and Refractive. Surgery 2006; 32:324-333.
ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3:2012 7.5.5, Annex N

Toxic Anterior Segment Syndrome (TASS)

- Follow manufacturing cleaning and sterilization instructions
- Adequate inventory-time for processing
- Designated cleaning area and dedicated equipment
  - Precleaned immediately
  - Transport in closed containers
  - PPE
  - Appropriate cleaning agent & water of appropriate quality as specified by the Mfr.
  - Sterilization according the Mfr's. instructions
  - Maintenance of cleaning and sterilization equipment, boilers and water filtration systems
  - Training
- AORN Recommendation XIV
  - Special precautions should be taken for reprocessing ophthalmic surgical instruments.
  - Provides a thorough list of recommended practices aimed at preventing TASS

ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3;2012 Annex N

AORN Perioperative Standards and Recommended Practices. Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment, Recommendation XIV. 2012

AREAS OF CONCERN

Loaner Instrumentation

Managing Loaner Instrumentation

- Use of loaners has become common practice across U.S.
  - Increasing need to borrow instruments, implants and other devices
  - Vendors
  - Neighboring facilities
- Why?
  - Ever-changing technology
  - Multiple cases in the same day: block scheduling
  - Procedures done infrequently
  - Specialty procedures (e.g., pediatrics)
  - Cannot afford to purchase everything
  - Space/storage issues

Loaner Instrumentation Issues

Loaner Instrumentation

- Last minute arrivals can result in:
  - Can lead to inadequate processing
  - Lack of processing time
  - Failure to obtain instructions for use.
  - Failure to ensure sufficient processing staff are available.
  - Failure to ensure processing capacity is available.
  - Failure to ensure processing implants can be properly monitored.
  - Failure to ensure staff are in-serviced or trained on how to process sets and to focus on complex medical devices.
  - Failed labeling and set identification.
  - Failure to ensure all loaned instruments and implants are accounted for.
  - Unnecessary stress!!
- Last minute arrivals can have a serious impact on patient outcome and cause major disruption in process flow.

Where have the trays been?

Loaned instruments are in no condition for use when they arrive. Move in "uncontrolled environments" (planes, trains, automobiles).

Mark Duro, New England Baptist Hospital

Where have the trays been?

Some vendor transport vehicles are less than ideal. Therefore, all items must be cleaned.

Loaner Instrumentation – Best Practices to Avoid Impact on Central Sterile and the OR

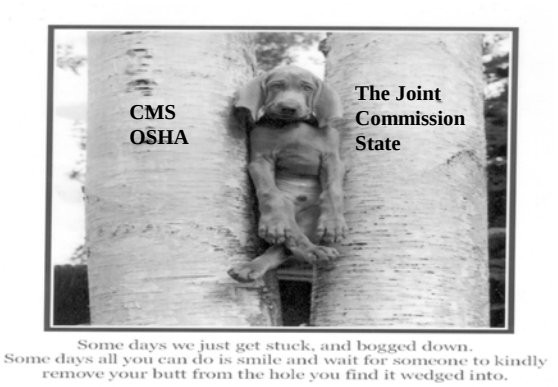
- ✓ Need to have Manufacturer's written Instructions for Use (IFU) including reprocessing instructions
- ✓ Staff need to be trained on the trays (disassembly, cleaning, inspection, packaging and sterilization)
- ✓ Some IFU provide excellent guidance, while others are poorly written and do not give clear guidance on cleaning issues for specific complex instrumentation and problem areas.
- ✓ Unfortunately, the CSD staff may know or have time to investigate problematic items if trays do not arrive for reprocessing in a timely manner.

Managing Loaner Instrumentation

- Develop and follow a policy and procedure to manage loaners
- Resources:
  - Joint position paper created and adopted by ASHCSP and IAHCSMM – now joined together
  - http://www.iahcsmm.org/current_issues_Joint_paper_loaner_instrumentation.htm
  - AORN Recommended Practice
  - Managing Infection Control Journal in-service "Loaner Instrumentation: Keeping Patient Safety First" by Rose Seavey, April, 2007
- Need adequate time to properly reprocess instrumentation: receive loaners at least by the evening before the procedure is scheduled

Summary – Breaking the Chain of Infection

- Collaboration with the CSD / SPD is key
- Include CSD / SPD in your Joint Commission tracer and rounding activities
- Include the function in your risk analysis and perform and FMEA and root cause analysis when issues arise that impact patient safety
- Develop policies and procedures for the management of loaner instrumentation
- Be knowledgeable of the contents of the AAMI standards and recommended practices and IFUs
- Monitoring of the sterilization process is necessity for maintaining patient safety
- Be aware of a few of the concerns in the CSD / SPD



THANK YOU!

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AAMI Standards and Technical Information Reports

- ANSI/AAMI ST79:2010, A2:2010 & A2:2011 &A3:2012 Comprehensive guide to steam sterilization and sterility assurance in health care facilities (Under ongoing review)
- ANSI/AAMI ST77:2013 Containment devices for reusable medical device sterilization
- ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities
- ANSI/AAMI ST81:2004/(R)2010 Sterilization of medical devices- Information to be provided by the supplier for the processing of resterilizable medical devices

AAMI Standards and Technical Information Reports

- ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.
- ANSI/AAMI ST41:2008 Ethylene oxide sterilization in health care facilities: Safety and effectiveness, 4ed (if you use EO sterilization; under review)
- Other
  - AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 3ed
  - AAMI TIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices, 2ed
  - AAMI TIR31:2008 Process challenge devices/test packs for use in healthcare facilities, 2ed
  - AAMI TIR34:2007 Water for reprocessing of medical devices, 1ed (under review)

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- Mail: AAMI Publications, P.O. Box 0211, Annapolis Junction, MD 20701-0211

References

- The Joint Commission: 2013 Accreditation Standards
- Association for the Advancement of Medical Instrumentation (AAMI). Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities. ANSI/AAMI ST79:2010 & A1:2010 &A2:2011 & A3;2012
- Association for the Advancement of Medical Instrumentation (AAMI). Containment devices for reusable medical device sterilization. ANSI/AAMI ST77:2013
- Recommended Practices for Sterilization in the Perioperative Practice Settings. In: Perioperative Standards and Recommended Practices. Denver, CO: AORN, Inc, 2013
- Rutala, William A, Weber, David J and HICPAC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
- Brachman, Philip S. Epidemiology of Nosocomial Infections. In Hospital Infections 3rd edition, edited by John V. Bennett and Philip s. Brachman. 1992 pp. 3-20.
- IAHCSMM Central Service Technical Manual, 7th Edition.
- http://www.iahcsmm.org/current_issues_Joint_paper_loaner_instrumentation.htm

References

- Recommended Practices for Cleaning and Sterilizing Intraocular Surgical Instruments. From the American Society of Cataract and Refractive Surgery and the American Society of Ophthalmic Registered Nurses. Special Report prepared February 16, 2007.
- Occupational Safety and Health Administration. 29 CFR 1910.1030 Occupational Exposure to Bloodborne Pathogens ; Final Rule. Federal Register December 6, 1991.
- Archibald, Lennox K. and Hierholzer, Walter J. Principles of Infectious Diseases Epidemiology. in Hospital Epidemiology and Infection Control 3rd edition. C. Glen Mayhall, Editor. 2004. Pp.1-17.
- Sehulster, Lynn and Schultz, Janet. Central Sterile Supply. In Hospital Epidemiology and Infection Control 3rd edition. C. Glen Mayhall, Editor. 2004. Pp.1301-1313.
- Steam Sterilization – Update on The Joint Commission's Position. June 16, 2009.
- The Joint Commission Perspectives. October 2009 Vol 29 (10)
- Reason, James Human error: models and management. BMJ 2000:768-70
- Nick Mamalis, MD, *Toxic Anterior Segment Syndrome* Journal of Cataract and Refractive. Surgery 2006; 32:324-333.