Be on the Look-Out for These Top-10 risks in Sterile Processing

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Objectives

- Discuss the effect of not following the medical device manufacturer’s instructions for use for cleaning, packaging, and sterilization.
- Discuss biological indicator process challenge devices (BI PCD) for immediate-use steam sterilization (formally called flash).
- Discuss the recommendations for verifying the effectiveness of mechanical cleaning equipment.

Note: will see references on bottom of slide

Role of Infection Preventionist

- “Conduct infection control rounds periodically (e.g., annually) in high-risk reprocessing areas (e.g., the Gastroenterology Clinic, Central Processing); ensure reprocessing instructions are current and accurate and are correctly implemented. Document all deviations from policy. All stakeholders should identify what corrective actions will be implemented. Category 1B”

CDC Guideline for Sterilization and Disinfection: 2008, p. 92

Role of Infection Preventionist

- “Periodic infection control rounds to areas using sterilizers to standardize the sterilizer’s use may identify correctable variances in operator competency; documentation of sterilization records, including chemical and biological indicator test result; sterilizer maintenance and wrapping; and load numbering of packs. These rounds also may identify improvement activities to ensure operators are adhering to established standards.”

CDC Guideline for Sterilization and Disinfection: 2008, p. 79
Centers for Disease and Control (CDC) Guideline

Guideline for the Prevention of Surgical Site Infections, 1999

“Inadequate sterilization of surgical instruments has resulted in SSI outbreaks. The importance of routinely monitoring the quality of sterilization procedures has been established. Microbial monitoring of steam autoclave performance is necessary and can be accomplished by use of a biological indicator.”


The Joint Commission: National Patient Safety Goals

NPSG.07.05.01

“Implement evidence-based practices for preventing surgical site infections.”

Element of performance

- 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. 2011 Hospital Accreditation Standards (HAS)

The Joint Commission

- Joint Commission: Online July 2011
  - Focus on sterilization and high-level disinfection
  - “Beginning in 2010, surveys have spent additional time during survey evaluating the cleaning, disinfection and sterilization (CDS) processes”
  - Surveyors received in-depth training on sterilization processes through AAMI
    - 40% noncompliance for HLD/sterilization before training
    - 40% non compliance for HLD/sterilization after training
  - Survey to ANSI/AAMI ST79

http://www.jointcommission.org/assets/1/18/jointline_July_20_11.pdf
Incorrect loading technique in mechanical washing equipment - need to disassemble reusable rigid containers (remove disposable filter retentions plates) so all surfaces are exposed to the cleaning process.

What is wrong with this picture?

Top Ten Risks in Sterile Processing
10. Reusable rigid sterilization containers without instruments not broken down enough when placed in the mechanical washer (e.g., filter retention plates not removed from lids).

Cleaning of Reusable Rigid Sterilization Containers
- Remove lid
- Remove all disposable filters and discard
- Remove filter protector/holder or retention plate from both ends
- Valve-type closures (reusable filters) must be cleaned according to IFU
  - Usually remove and disassemble for cleaning
- Remove interior baskets
- Remove CIs, disposable labels, locks
- Remove posts/dividers if interfere with cleaning

Rigid Container Systems, (Part II), IAHCSMM Communique: September/October 2010
Cleaning of Reusable Rigid Sterilization Containers

- Follow manufacturer’s IFUs for cleaning agents, tools, methods, and rinsing
  - Cleaning agent
    - Some cannot be exposed to certain chemicals such as high alkaline solutions
- Follow instructions for loading containers into mechanical cleaning equipment
  - TJC wants these taken apart for cleaning*

Rigid Container Systems (Part II), IAHCSMM Communiqué: September/October 2010, *Joint Commission Perspectives®, July 2009, Vol. 29, Issue 7. Copyright 2009 Joint Commission on Accreditation of Healthcare Organizations, and personal communications with hospitals that have had surveys

What is wrong with this picture?

Incorrect loading technique—mats should not be placed in the bottom of the trays it prevent (hampers) proper spray coverage of instruments

What is wrong about this picture?

- Incorrect loading technique—mats should not be placed in the bottom of the trays
  - Prevent proper spray coverage of instruments
- Rigid containers are covered
- Poor loading technique—mats are piled on top of each other
Top Ten Risks in Sterile Processing

9. Containment device with instruments are run through the sterilizer with lid on.

8. Manufacturer’s IFUs for cleaning not followed (especially sonic cleaning step).

Loaner Instrumentation Issues

- Have you every received instruments the same morning as the case is scheduled?
- Do the instruments sometimes arrive without cleaning/sterilization instructions for use (IFUs)?
- Have you received sets you have never seen before so neither the OR or SPD/CSSD has been inserviced or provided with pre- or post-procedure processing information?

IAHCSMM

- Orthopedic Council of IAHCSMM published in June 2011
  - IAHCSMM Position Paper on the Management of Loaner Instrumentation
  - IAHCSMM Sample Policy and Procedure
- Available at
- “In recognition of the need to systematically manage loaner instrumentation and implants.”
Loaner Policy Should
- State responsibility of
  - Surgeons
  - Operating room (OR)
  - Sterile processing department (SPD/CSSD)
  - Sales representatives
- This is a partnership
- Responsibilities should be well defined and enforced to ensure patient safety

Zimmer Manual Orthopaedic Surgical Instruments-Cleaning Instructions

G. Manual Cleaning/Disinfection Instructions
1. Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e., pipe cleaner brush).
2. Remove the device from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.

Zimmer Manual Orthopaedic Surgical Instruments-Cleaning Instructions
3. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.
4. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
5. Repeat the sonication and rinse steps above (adds another 13 min)
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.
Total of 49 minutes
Zimmer Manual Orthopaedic Surgical Instruments-Cleaning Instructions

- Neutral pH enzymatic and cleaning agents
- Automated cleaning using a washer/disinfector alone may not be effective
- Disassemble for cleaning
- Remove instruments from container for manual or automated cleaning
- Use a soft-bristled, nylon brush
- Avoid use of hard water. Softened tap water should be used.
- Final rinse is purified water ultrafilter (UF), reverse-osmosis (RO), deionized (DI), or equivalent.


Its About Timing

- It can take 6 to 7 hours to reprocess one set of instruments and there may be 40 trays for one case
- IAHCSSM recommends:
  - “Healthcare facility requires receipt of loaner trays at least two (2) business days prior to the scheduled case.” (sales rep)
  - “All first-time vendor sets require three (3) business days for inservicing, inspecting and processing.” (sales rep)
- Need enough time to process without effecting the rest of the departments throughput

IAHCSSM Sample Policy & Procedure for Loaner Instrumentation, June 2011

Communications

- Need good communication between Surgeon, OR, CSSD, and vendor
- Surgeon or designee contact vendor to ensure
  - Instruments can arrive in time for scheduled case
  - IFUs arrive before instruments in CSSD unless already on file
  - What happens if the IFU shows up the same day as the case and the CSSD does not have the cleaning equipment, agents or sterilization cycles to process according to IFUs? Surgery postponed?
- Surgeons and material managers need to understand to order instruments after confirm can process in CSSD using IFUs

IAHCSSM Sample Policy & Procedure for Loaner Instrumentation, June 2011
Communications

- OR informs CSSD 1 business day before instruments arrive with information about case
  - Quantities
  - Estimated time of use and return
  - Restocking requirements to circumvent immediate use steam sterilization (IUSS)
    - IUSS is not an option because of risk to patient
- When case booked inform CSSD
  - Day of surgery
  - Doctor, procedure
  - Type of equipment needed

IAHCSMM Sample Policy & Procedure for Loaner Instrumentation, June 2011

Significance of Cleaning for Sterilization

- Potential sterilization process failures
  - If the medical device is not effectively cleaned, the sterilant cannot penetrate the material contaminating the item and sterilization will not occur
- Sterilization assurance monitors will not detect cleaning failures

ANSI/AAMI ST79:2010 Section 7.5.1

In-use tests available to assess efficacy of cleaning of medical devices (extracted from AAMI ST79 Table D.1)

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Soil Component Tested</th>
<th>Limitations</th>
<th>Length of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATP</td>
<td>Eukaryotic cells, dead ATP (protoplast, cells and live bacteria)</td>
<td>Need sterilization to react test</td>
<td>30 seconds</td>
</tr>
<tr>
<td>H2O2</td>
<td>Catalase-containing material</td>
<td>Instruments must be further cleaned to remove H2O2 residue</td>
<td>~1 to 5 min</td>
</tr>
</tbody>
</table>
Monitoring of Manual Cleaning

*Manual cleaning should be evaluated when new types of instruments are reprocessed and periodically, at intervals determined by the health care organization.*

- Evaluates performance of personnel

Can also use to monitor effectiveness of mechanical cleaning equipment

*AORN Care of Instruments Recommendation XXII
ANSI/AAMI ST79:2010 Annex D.1*

Steam Sterilization-Update on the Joint Commission’s Position User Concerns

Surveyor may, among other activities:
- Ask for manufacturers’ instructions
- Ask staff to describe and demonstrate how instruments are cleaned and decontaminated according to those instructions
- Be concerned about meticulous cleaning and rinsing


Steam Sterilization-Update on the Joint Commission’s Position User Concerns

Surveyor may, among other activities:
- Want instruments cleaned the same way no matter location (CSSD/SPD, OR, ASC, Clinic)
- Want loaner and other instruments cleaned the same way
- Want rigid container taken apart for cleaning

Steam Sterilization - Update on the Joint Commission's Position User Concerns

- Ensure you have the most up-to-date IFUs from the manufacturers of the:
  - Medical devices (standard or extended cycles)
  - Cleaning and disinfection products and equipment
  - Implements (brushes, cloths, etc)
- Have a method to keep your IFUs up-to-date
  - oneSource document site (www.onesourcedocs.com, 1-800-701-3560)

Joint Commission on Accreditation of Healthcare Organizations and personal communications with hospitals that have had surveys.

BI PCD IUSS (Flash) Sterilization
132°C Gravity Steam Sterilization
Process

BI PCD Used Daily
Packaging Used Routinely

Is this the correct BI PCD for the load contents? NO

Top Ten Risks in Sterile Processing

7. Wrong BI PCD is run for the day - not representative of trays run when using IUSS (formerly flash sterilization).
BI PCD IUSS (Flash) Sterilization
132°C Gravity Steam Sterilization Process

BI PCD Used Daily  Packaging Used Routinely

Correct BI PCD for Packaging Routinely Used

Top Ten Risks in Sterile Processing

6. Mechanical cleaning equipment is not monitored daily.

Mechanical Cleaning Equipment

- Mechanical cleaning equipment removes soil and microorganisms through an automated cleaning and rinsing process
- Some are designed to clean and/or disinfect specific kinds of medical devices, such as endoscopes
- Includes:
  - Utensil and cart washers
  - Washer-sanitizers, pasteurization equipment
  - Washer-disinfectors, washer-decontaminators, and washer-sterilizers
  - Ultrasonic

ANSI/AAMI ST79:2010 Section 7.5.3.3
Frequency of testing
- "Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs”
- Review and initial each cycle printout
- Document results
- "Ideally, cleaned medical devices should be traceable to the patients on whom they are used."

ANSI/AAMI ST79:2010 Sections 7.5.3.3 and 10.2

"A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affect the performance of the equipment"

Examples include replacement of:
- Water pump(s)
- Detergent delivery system
- Heating system
- Water delivery system
- Water treatment system
- Computer control
- Upgrade of software

ANSI/AAMI ST79:2010 Section 7.5.3.3

**In-use tests available to assess efficacy of washer-disinfector used for medical device reprocessing**
*(extracted from AAMI ST79 Table D.2)*

<table>
<thead>
<tr>
<th>Test Method</th>
<th>Soil Component Tested</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooperated blood test</td>
<td>Blood and protein</td>
<td>Valuable as a QA indicator for washer functionality</td>
</tr>
<tr>
<td>Blood test metal plate on the metal coupon</td>
<td>Water insoluble protein with properties similar to blood</td>
<td>Valuable as a QA indicator of washer functionality</td>
</tr>
</tbody>
</table>

TOSI® is a registered trademark of Pong GmbH
Annex D User verification of cleaning processes

- Cleaning efficacy tests
  - Monitor water temperature
    - Irreversible thermometer
    - Remote sensing equipment
  - No frequency recommended

Monitoring of Ultrasonic Cleaners

- Verify sonic activity or effective cavitation (sufficient energy and conditions are correct)
- Verify cleaning effectiveness
- Verify cleaning effectiveness of lumens
- Verify Temperature

Documentation of Entire Cleaning Process

- Documentation should include maintaining records of the cleaning of instruments including, but not limited to:
  - date
  - time
  - instruments
  - method of cleaning
  - number or identifier of mechanical decontaminator
  - name of person performing the cleaning
  - lot numbers of chemicals used
  - testing results on mechanical instrument washers
  - testing results on insulated electrical instruments
  - disposition of defective equipment

AORN Care of Instruments Recommendation XX.a.
What’s wrong with this picture?

- Spray arms were not cleaned. Result is inadequate water and detergent flow. Cleaning is not as effective.
- Clean daily or more often if needed.

Other Mechanical Cleaning Equipment Performance

- Daily and preventive maintenance is vital to the proper function of all mechanical cleaning equipment:
  - Descaling, cleaning strainer and spray arms and nozzles, checking pumps
  - Check to ensure correct chemical and lubricants are being used
  - Check the chemical feed rate and detergent feed lines (mark container to know use patterns)
- Understanding how to correctly operate equipment in the decontamination area is vital to efficiency and worker safety and to the successful outcome of the process

Ultrasonic Cleaners

- Check cleaning solution between cycles and change immediately if it becomes heavily contaminated or at least daily
  - If the solution is excessively contaminated, it will cause a loss of ultrasonic cleaning power and possibly damage to your machine
- Clean chamber when visibly soiled and at least daily (preferably after each use to prevent TASS)
  - Empty, clean, rinse with sterile water and wipe chamber with alcohol or other disinfectant recommended by the equipment manufacturer and a lint free cloth
Ultrasonic Cleaners

- If recommended, degas water to release dissolved air bubbles
- A lid should be in place to prevent aerosolization of contaminants
- Fully submerge instruments with lumens

Top Ten Risks in Sterile Processing

5. Not enough eye sets for surgery cases so not properly processed to prevent TASS.

To eliminate IUSS:
Beverly Kirchner, RN, BSN, CNOR, CASC
- “The ophthalmologists want trays of all 30 instruments when only seven are typically used”
- Created 2 sets of packs: one with seven instruments and the other with the additional instruments
- Has more seven instrument sets available
- No IUSS sterilization is used

Top Ten Risks in Sterile Processing

4. Loaner instrument arrive to late for adequate cleaning.

3. Loaner instruments with implants arrive too late to quarantine the implant until the BI result is available.
Sales Representative Duties before Surgery:
- Ensure all loaner items are delivered in sufficient time for CSSD to perform routine biological testing if implants are involved and allow adequate time for final results and quarantine.

Loaner Instrument Policy and Procedure
- Healthcare facility requires receipt of loaner trays at least two (2) business days prior to the scheduled case.
- All first-time vendor sets require three (3) business days for inservicing, inspecting and processing.

Routine Load Release of Implant Loads
- Physical monitors
- External process indicator (Class 1) on outside of every package unless internal CI is available
- Internal CI(s) (Class 3, 4, 5, 6) inside each package
- A PCD containing a BI and a Class 5 integrating indicator
- Evaluation of all data by an experienced, knowledgeable person
- Do not distribute load if any data suggests a sterilization process failure

Routine Load Release of Implant Loads

- “Each load should be monitored if it contains implantable objects. If feasible, implantable items should not be used until the results of spore tests are known to be negative.” (CDC)
- “Releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.” (AAMI)
- Class 5 integrating indicator used to release implant in emergency situations. (AAMI)
- “Emergency situations should be defined.” (AAMI)

Early Release of Implant Loads

Exception form for premature release of implantable device/tray in defined emergency situations

- Name of implant
- Name of patient
- Name of surgeon
- Reason for premature release
- What could have prevented the premature release
- Critical that this documentation be fully traceable to the patient

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Exception form (AAMI ST79 10.6.3 and Annex L)

- Early release of implant is unacceptable; an exception form must be completed
- Exceptions guided by policy: multidisciplinary input
- WHO can authorize early release of implants?
  - Signature not required
  - Should be a department of surgery policy
  - Suggest it be a surgeon

These slides were prepared based on what the author learned from a Joint Commission presentation at IAHCSMM in May 2011
The Joint Commission
New Emphasis for 2011

BI is correct for cycle, lot number of control and test vials should match and be documented

These slides were prepared based on what the author learned from a Joint Commission presentation at IAHCSMM in May 2011

Correct or Incorrect Packaging?

Incorrect: Unless the manufacturer(s) provides validated, written instructions for this packaging technique or any packaging technique

Top Ten Risks in Sterile Processing

2. Original loaner set container or instruments original packaging is changes (instruments removed and placed in a generic rigid sterilization container, entire original tray placed in a generic rigid sterilization container).
Risk Analysis

- Is there a risk of a patient acquiring an infection if the manufacturer’s instructions for use are not followed?
  - Cleaning, packaging, and sterilization
- Have you done a risk analysis for sterilization process failures?

Changes to Medical Devices You Should Not Make

- Changes should be validated by the medical device manufacturer
  - Doing one ultrasonic cycle to save time when 3 cycles are required
  - Using the basin cycle instead of the instrument cycle on the washer-disinfector/washer-decontaminator to save time
  - Breaking down a tray/container to 25 pounds by placing the instruments with or without their organizing trays in another type of packaging such as a generic rigid container or instrument tray with an overwrap (ask rep for more of the original validated trays to breakdown sets)

Changes to Medical Devices You Should Not Make

- Changes should be validated by the medical device manufacturer
  - Changing the original validated non-woven wrapper packaging to a generic rigid container because of surgeon preference
  - Placing peel pouches inside instrument trays or containers
Changes to Medical Devices You Should Not Make

- Changes should be validated by the medical device manufacturer
- Taking instruments from several vendor trays and adding them together in a vendor-provided tray or rigid container system to create a new set
- Not using the extended cycles provided in the manufacturer’s IFUs because they take too long, and effect department efficiency and output
- Placing instruments sets not validated for extended cycles in an extended cycle which could reduce the instruments functionality and use life

Red Flags from Manufacturer’s Reps

- Just clean it like you clean all your other instruments
- While it does not say it in the instructions for use, you can also do this…
- Use the same sterilization cycle you always use

Red Flags from Manufacturer’s Reps

- I don’t need to provide you with sterilization instructions because once you know how to sterilize one instrument you can sterilize all of them the same way
- I will help you use any packaging you want
- We do not have the information you requested so you will need to do the validation testing
Validation vs. Verification

They Are Not The Same

Validation

Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications."

- Covers three activities: installation qualification, operational qualification, and performance qualification
- Performed by device manufacturer
- Users cannot conduct validation testing

ANSI/AAMI ST79:2010 Section 2.129

Manufacturer Validation

- Sterilization efficacy testing is expensive and time-consuming
- Manufacturer selects most challenging product (master product) in product family to test
- Biological testing is done in half cycle, fractional cycles, or incremental critical process parameter cycles using BI spore strips, inoculated threads, or direct inoculation

ANSI/AAMI ST77:2006 Section 5.6
Internal temperature mapping is done inside containers or other packaging using multiple calibrated temperature sensors (Section 5.6)

- Sterilant residual removal testing (Section 5.8)
- Perform sterility maintenance testing, microbial challenge testing, and physical integrity tests to determine if sterility is maintained until the device is opened for use (Section 5.9)
- Repeat validation testing when design changes are made on device

ANSI/AAMI ST77:2006

User Verification

“Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met.”

AAMI product testing verifies the validated instructions provided by the device manufacturer

…”not a substitute for the more extensive validation testing conducted by manufacturers to quality their products”

ANSI/AAMI ST79:2010 Section 2.128, Section 10.9, Section 10.10.3.1

User Verification

Product testing does not allow a user to validate a change in the product instructions for use as received from the device manufacturer

– Packaging, sterilization time, etc.

ANSI/AAMI ST79:2010 Section 2.128, Section 10.9, Section 10.10.3.1
Manufacturer's IFUs

- Check corporate website
- oneSource document site (www.ondsourcedocs.com, 1-800-701-3560)
- Check with corporate Sterility Assurance or Quality Assurance Services to determine if they have validated the changes you want to make in the cleaning, packaging, or sterilization cycles or processes

Reduce Risk

The reusable medical device manufacturer is responsible for ensuring that the device can be effectively cleaned and sterilized."

"The written instructions of the device manufacturer should always be followed."

Top Ten Risks in Sterile Processing

1. Not sure which instruments require extended cycles
   A steam sterilization cycle that is extended beyond the sterilizer manufacturer's standard cycle time (i.e., 272°F, 10 minutes in a dynamic-air-removal system)
   Product testing does not allow a user to validate a change in the product instructions for use as received from the device manufacturer
   - Packaging, sterilization time, etc.
Has Anyone had a JC survey recently and want to share what they looked for?

Joint Commission New Emphasis for 2011
Will be using AAMI ST79 Steam Sterilization
Recommended Practices but a lot of the information is applicable across the spectrum of other sterilization processes used.

The Joint Commission New Emphasis for 2011
- NFPA 101: Engineer at every site for 2 days so will be in SPD, clinics, etc.
- Be proactive and read AAMI ST79
  - Section 3 Design Considerations
  - Section 9 Installation, care, and maintenance of sterilizers
- Environmental concerns
  - Temperature and humidity
  - Water quality
  - Eye wash stations (water temp 60-100°F)

These slides were prepared based on what the author learned from a Joint Commission presentation at IAHCSMM in May 2011.

The Joint Commission New Emphasis for 2011
- Environmental concerns
  - Air exchanges
  - Air flow (positive or negative (decontamination negative, clean area positive)
  - Separation of clean/dirty/assembly
  - Traffic patterns-related attire if appropriate

These slides were prepared based on what the author learned from a Joint Commission presentation at IAHCSMM in May 2011.
The Joint Commission
New Emphasis for 2011

- Equipment
  - Use/function of equipment-recalibration
  - Cleaning and maintenance: ongoing/periodic
  - Including contractor servicing
  - What did they do not just when

- Endoscope cleaning/processing
  - Physical setting and work processes [cleaning and processing (AER) cannot be in same room]
  - Air flow

These slides were prepared based on what the author learned from a Joint Commission presentation at IAHCSMM in May 2011

The Joint Commission
New Emphasis for 2011

- Housekeeping
  - Daily vs deep cleaning
  - Behind closed doors, under racks
  - Hidden corners, high level flat spaces
  - Is the "dirty" room clean

- Storage areas including security concerns
  - Cardboard boxes on floor, shipping containers

- Peg boards-absorbable surfaces (paint)

- 18" rule (minimum distance from sterile items to bottom of deflector plate of sprinklers)

These slides were prepared based on what the author learned from a Joint Commission presentation at IAHCSMM in May 2011

The Joint Commission
New Emphasis for 2011

- Supplies
  - Outdates and stock rotation
  - Also be aware that peel pouches have their own expiration dates because of Cs printed on packaging

- Symbols—teach your colleagues how to interpret

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- Do not use if package is open or damaged
- Evacuation procedures for EO
- Disaster planning
- QC test strips used to measure MRC/MEC of high-level disinfectants used according to the manufacturer’s IFU
- BI is correct for cycle, lot number of control and test vials should match and be documented

These slides were prepared based on what the author learned from a Joint Commission presentation at VAHCSMM in May 2011

The Joint Commission

- Inspected fire extinguisher and determined not blocked
- Asked staff where fire alarm pull stations were located
- Checked to see if workstations were adjustable (ergonomics) and clear of sprinkler heads
- Checked shelf life of high-level disinfectant
- Asked to see data on quality checks on solutions and test strips when opened bottle
- Asked if weigh trays and have a log

Personnel communications with facilities that have been surveyed by TJC

The Joint Commission

- Observe if washing loaner and other instruments the same way
- Observe if breaking down reusable rigid containers for cleaning
- Ask how often do you run a Bowie-Dick test
- Ask how often run a BI
- Checked steam and low temperature BI records in OR
- Checked to see BI and controls lots matched
- Asked to see documentation for last recall

Personnel communications with facilities that have been surveyed by TJC
The Joint Commission

- Are items processed by flash sterilization (IUSS) being tracked to the patient?
- Are loaner instruments received (at least 24 hours ahead of time), cleaned and processed and is there a backup if something happens?
- Check Steris System records in OR.
- Do storage shelves have solid bottom shelf?
- Which staff are certified and wanted them identified?

Personnel communications with facilities that have been surveyed by TJC

Any Questions?

Evidence-Based Guidelines

- Association for the Advancement of Medical Instrumentation (AAMI)
- Chemical sterilization and high-level disinfection in health care facilities. ANSI/AAMI ST58:2005
AAMI

Association for the Advancement of Medical Instrumentation (AAMI)
- Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers. AAMI TIR12:2010

Evidence-Based Guidelines

Also available to order through AORN and IAHcSMM at AAMI membership prices.
A free PDF of future amendment(s) may be downloaded by visiting http://www.aami.org/publications/standards/st79.html, which also includes information on how to update your copy of ST79.
Print and save to your hard drive.

Evidence-Based Guidelines

AORN Perioperative Standards and Recommended Practices (2011)
- Recommended Practices for Sterilization in Perioperative Practice Setting
- Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment
  - Recommended Practices for Surgical Attire
How to Purchase AORN Standards for Your Reference Library

AORN Standards can be purchased through AORN using the following options:
- Internet: www.aorn.org/bookstore/ordering.htm
- Call: 1-800-755-2676 x 1 or 303-755-6304 x 1 (Monday-Friday, 8AM to 4:30PM mountain standard time)
- Fax: 303-750-3212
- By mail: AORN, Inc., Customer Service/Book Orders, 2170 South Parker Road, Suite 300, Denver, CO 80231-5711, USA

Evidence-Based Guidelines

- Centers for Disease Control and Prevention (CDC)
  Available at: http://www.cdc.gov/hicpac/Disinfection_Sterilization/13_0_Sterilization.html

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- The Joint Commission, Hospital Accreditation Standards 2011
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AAMI News: August 2010, Vol. 45, No 8 (only accessible to AAMI members).
AAMI News: January 2011, Vol. 46, No. 1 (only accessible to AAMI members).

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