Sterilizer/High Level Disinfection (HLD) Document Review

Friday, April 12th, 2019
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Billings Clinic
Disclaimer

• Nothing to disclose
• Presentation content is for purpose of providing education for Infection Prevention audit purposes.
• Product brand names or pictures do not constitute an endorsement of any kind.
Learning Objectives

The learner will be able to:

– Identify references for both sterilization and high-level disinfection
– Define key points for sterilization and high level disinfection (HLD)
– Explain how to use the audit form(s) demonstrated during the exercises
Why Audit Documentation

- Patient Safety
- Risk Management
- Survey Prep
- Practice with Sterile processing, operating room or department staff so they can explain reprocessing and their documentation

How do you tell your story of instrument reprocessing?
Surveyors Commonly ask for

- List of the location of sterilizers and semi-critical devices such as:
  - flexible scopes,
  - laryngoscope blades
  - ultrasound endocavity probes (Transvag, prostate, TEE)
  - RT/Sleep Lab (humidifier chambers, face masks, electrodes)

- Documentation of sterility assurance and high level disinfection product minimum effect concentration (MEC)

- Staff training and competencies

- Instructions for Use (IFU) for surgical and medical equipment or devices
Make Appointment for Document Review

• Choose three day audit period

• Take
  – Audit tool, blue pen
  – Clipboard

• Introduce self

• Ask employee name

• Explain your purpose

What is your knowledge base?
Knowledge Check

If any of the following presentation is new to you or unclear, refer to current AAMI standards

ANSI/AAMI ST79:2017
Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Available for purchase at www.aami.org
Sterilization
(Fill in the blanks)

• Validated process used to render a product free from viable ________.

• The first and most important step in reprocessing is thorough _____ and rinsing.
Sterilizer Documentation for all Healthcare Settings

- Load number
- Specific contents of lot or load
- Exposure time and temperature if not on printout
- Result of biological testing
- Result of Bowie-Dick testing, if applicable
- Response of the chemical indicator, including those in process challenge devices (PCD)
- Any reports of inconclusive or nonresponsive chemical indicators

Reference: ANSI/AAMI ST79:2017 pages 73-74
Cycle printouts are to be checked and signed by the operator.

Note: Sterilizers that do not have recording devices should not be used.

Reference: ANSI/AAMI ST79:2017 pg 77
**Sterilization Match Game**

- Bowie Dick test
- Low temperature sterilizer/H$_2$O$_2$
- Julian Sticker
- Implantable device released from quarantine without BI result
- Immediate Use
- 270 - 275 degree F
- Date of sterilization
- Pressure
- Flash sterilization
- Common steam autoclave temp range
- Sterrad or VPRO
- Emergency Release
Biological Indicator (BI) Match Game

• Control BI
• Organism in BI vial
• BI placed inside sterilizer/part of load
• Positive BI
• Cause of failure resulting in positive BI not immediately identified

• Recall sterilized packages to last negative BI
• BI kept outside sterilizer, not exposed to sterilant
• *Geobacillus stearothermophilus*
• Test BI
• Possible failure to sterilize, quarantine load & investigate
**Chemical Indicator (CI) Match Game**

- Internal CI
- Area or areas least accessible to steam penetration
- Type 5 or 6 CI
- Temperature only
- Autoclave Tape
- Should visually denote package exposed to sterilization agent

- Type 1 and 3
- One or more within each package, tray or rigid container
- Place internal CIs in
- Type 1
- External CI
- Time, Temp, Pressure and all variables
Cycle printouts should be reviewed for washers, automated reprocessors (AR) and all sterilizers.
Audit Sterilization Records

- 4 sets of records are located on each table
- Separate into groups of 2 or 3 at your table
- Share one set (either A, B, C or D)
  - A/from a clinic (Audit dates Nov 8-10, 2016)
  - B/from a main OR Center Core (Audit dates Dec 23-25, 2015)
  - C/from Sterile Processing depart (Audit dates Dec 23-25, 2015)
  - D/from a Sterile Processing depart (Audit dates Sept 10-12, 2016)
- Use audit form, circle response or write it in
- These are incomplete records! (1 of 3 days)
  - Identify what is documented
  - Not all questions on the audit form will be answered by the documents being reviewed
Time to Think
Review Sterilization Record A
Clinic Load & Cleaning Logs (Audit dates 11/8/16 thru 11/10/16)

• What is documented
  Focus on audit dates
  – Used Billings Clinic standardized forms
  – Department & Date (focus on dates)
  – Only one tabletop sterilizer onsite, brand of steam autoclave on third page
  – Gravity cycle (no Bowie Dick needed)
  – Initials & Signature match
  – Load number (should use load stamper)
  – Exposure time/temp written (no printer)
  – Good description of load contents
  – Chemical indicator results – “Pass”
  – Autoclave cleaning on separate page

• More questions to ask
  – Three pages sent/look at next PPT
  – Ability to trace load to patient
  – Repair and sharpening contact
  – Note the column, change the form?
Review Sterilization Record A
Clinic BI Log  (Audit dates 11/8/16 thru 11/10/16)

• What is documented
  – Used Billings Clinic standardized form
  – Brand of sterilizer “Ritter” written
  – Department “____ Clinic” written
  – Date for each BI placed
  – Load number (should use load stamper)
  – Lot number matches control BI
  – At least weekly BI (count days between)
  – Only one load in time period chosen so need to look at other dates too
  – BI in each load preferred
  – Time BI in incubator and taken out with employee initials (missing two)
Review Sterilization Record B
OR Center Core Load Log
(Audit dates 12/23-12/25/15)

- What is documented
  - Used Billings Clinic standardized form
  - Date and Department
  - Sterilizer identifier ("C" in upper left)
  - Load numbers in first column
  - Full signature
  - Control and Test BI lot # match on this page but no BI form sent
  - Autoclave cleaning written
  - Immediate use item so identified the item and reason/Patient ID sticker

- More questions to ask
  - BI Incubator well numbers and Bowie Dick results
  - See printouts sent on next PPT
Review Sterilization Record B
OR Center Core Cycle Printouts
(Audit dates 12/23-12/25/15)

- Put in order of load number for review
- Verify adequate ink so legible - Remember these are legal documents!
- Match printer load number to one on documentation form (Load # circled in red)
- Sterilizer printout signed by operator verifying exposure time and temperature met
Review Sterilization Record C
Hospital Sterile Processing (Audit dates 12/23/15 thru 12/25/15)

• What is documented
  – Sterilizer #1
  – Bowie dick results
  – Control and Test BI Lot #s match
  – Chemical indicator pass
  – Sterilizer printout is checked
  – Julian sticker with date
  – Load #
  – Operator

• More questions to ask
  – Department or location not documented
  – Content List that is more descriptive
  – Is master signature page available
  – Ability to trace load to patient
  – Cleaning of sterilizer documentation
Review Sterilization Record D
Hospital Sterile Processing
Sterrad, BI and Cleaning Logs
(Audit dates Sept 10-12, 2016)

• What is documented
  – Department
  – Sterilizer type (Sterrad)
  – Bowie Dick not applicable
  – Control & Test BI # match
  – Control BI for q/cycle type
  – No incubator wells documented
  – Load #s, Julian sticker/date
  – Sterilizer cleaning

• More questions to ask
  – Printout not sent
  – Content List on different page
  – Traceability to patient
Review Sterilization Record D
Hospital Sterile Processing
Sterrad, BI and Cleaning Logs
(Audit dates Sept 10-12, 2016)

| Date | Load Date | BI Lot # | BI Code | BI Code | Incubation | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result | Result |
|------|-----------|----------|---------|---------|------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|

- What is documented
  - Depart
  - Sterilizer Brand
  - Control & Test BI match
  - Control for q cycle type
  - Incubator well #s written
  - Load # and Julian/date

- More questions to ask
  - Bowie Dick cards in box
Review Sterilization Record D
Hospital Sterile Processing
Sterrad, BI and Cleaning Logs
(Audit dates Sept 10-12, 2016)

- What is documented
  - Used Billings Clinic standardized form
  - Sterilizer ID
  - Page per autoclave
  - Date
  - Documented monthly
  - Initials and signature

- More questions to ask
  - Recent repairs
Just touched on basics of sterilization documentation review

Didn’t cover:

• Water Quality
• Positive BI response
• Qualification testing to be done after a major repair or moving of sterilizer
• Composition of Process Challenge Devices (PCD)
• Process verification

Refer to ANSI/AAMI ST79:2017 pages 83-107
High Level Disinfection (HLD)
Fill in the blank

- Process that kills all microbial organisms but not necessarily large numbers of bacterial ______.
High Level Disinfection (HLD)

- Lid closed at all times
- Labeled – Contents & expiration
- Documentation
  - Check Strips
    - Quality check when opening bottle
    - Expiration date on bottle/not expired
    - Results of check strip MEC prior to use
  - Date of reprocessing
  - Temperature of HLD
  - Patient identifier
  - Time item placed in HLD
  - Time item removed from HLD
  - Initial/name of employee reprocessing the item
  - If department closed, write “closed” or “not used”

Air quality testing?
High Level Disinfection (HLD)

Documentation to include:

- Patient Identifier
- Probe ID (serial #, color coding with instrument tape)
- Date of reprocessing
- Cycle number
- Chemical Indicator Results (Check strips or impregnated disc)
- Operator - initials to match signature on master signature page
- Data capture in unit?
HLD Match Game

- Measure temperature
- IFU
- Store in manner
- Accountability
- Check expiration date on bottle
- Document time item placed in and removed from ___.
- Traceability
- Document employee who reprocessed item
- Check Strips
- Track item to patient
- High Level Disinfectant
- Instructions for Use
- Prevent contamination
- Water/enzymatic detergent & HLD
“Fitting” Face Masks for CPAP/BIPAP

• Follow facemask, electrodes & humidifier chamber IFU
  – High Level Disinfection (HLD)
  – Track number of times used
• Or discard facemask after use
• Chest straps, EKG pads, nasal cannula & oximetry probe wraps are disposable
• Consider disposable hoses or reprocess hoses with HLD.
• Package headgear and facemask as unique set.
# HLD Audit Form

## Sterilization - High Level Disinfection (HLD) Audit Form

### Date:  
### Location:  
### Surveyor:  
### Employees interviewed:  
### Three-day time period chosen for document review:

<table>
<thead>
<tr>
<th>Department</th>
<th>Name of device being disinfected</th>
<th>HLD brand name</th>
<th>Patient ID</th>
<th>Pre-cleaning done</th>
<th>Transports in container with biohazard label or processed in process</th>
<th>Frequency of check strip use for potency</th>
<th>Check Strips not expired/ Quality check done on bottle</th>
<th>Time of disinfection documented on cycle printout or written time in/time out with employee initials</th>
<th>Storage of disinfected item</th>
<th>How stored:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depart:</td>
<td>Device name:</td>
<td>Brand:</td>
<td></td>
<td></td>
<td>AR w/cycle printout</td>
<td>AR per IFU</td>
<td>Not expired</td>
<td>Disinfection time</td>
<td>How stored:</td>
<td></td>
</tr>
<tr>
<td>IFU on site</td>
<td>Yes</td>
<td>AR or soaking bin w/lid</td>
<td>Yes</td>
<td>No</td>
<td>How:</td>
<td>AR per IFU</td>
<td>Not expired</td>
<td>Disinfection time</td>
<td>How stored:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>Soaking bin w/lid</td>
<td>Yes</td>
<td>No</td>
<td>How:</td>
<td>AR per IFU</td>
<td>Not expired</td>
<td>Disinfection time</td>
<td>How stored:</td>
<td></td>
</tr>
<tr>
<td>Depart:</td>
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<td>Disinfection time</td>
<td>How stored:</td>
<td></td>
</tr>
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<td>Yes</td>
<td>AR or soaking bin w/lid</td>
<td>Yes</td>
<td>No</td>
<td>How:</td>
<td>AR per IFU</td>
<td>Not expired</td>
<td>Disinfection time</td>
<td>How stored:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>Soaking bin w/lid</td>
<td>Yes</td>
<td>No</td>
<td>How:</td>
<td>AR per IFU</td>
<td>Not expired</td>
<td>Disinfection time</td>
<td>How stored:</td>
<td></td>
</tr>
</tbody>
</table>

*Use flexible endoscope audit form for departments with flexible scopes  
**AR = Automated Reprocesser**
Audit HLD Records

• 3 sets of records are located on each table
• Separate into groups of 2 or 3 at your table
• Share one set (either A, B or C)
  – A is for a Trophon unit
  – B is for a soaking basin with lid (Sleep Lab)
  – C is for an endoscopy unit w/automated reprocessors
• Use audit form provided, circle or write
• These are incomplete records! (1 of 3 days)
  – Identify what is being documented
  – Not all questions on audit form will be answered by the documents being reviewed
Time to Think
Review of HLD Record A
Trophon Unit

- **What is documented?**
  - Brand of reprocessor
  - Date
  - Patient Identifier
  - Cycle number
  - Probe identifier (*is EV sufficient?*)
  - Operator
  - Time cycle initiated
  - Results of cycle

- **More questions to ask**
  - No check strips to audit
  - Pre-cleaning and transport
  - Storage of item

What items is being reprocessed?
Review of HLD Record B

Soaking basin with lid in Sleep Lab

• What is documented?
  – Name of department
  – Name of product
  – Date
  – Patient Identifier
  – Date solution expires
  – Temp of HLD solution
  – Employee Name
  – Time in, Time out
  – #7 is a humidifier chamber (7/7)
  – Writing “closed” when appropriate

• More questions to ask
  – Missed circling result on 10/9/18
  – Expiration date on check strips
  – Pre-cleaning and Transport
### Review of HLD Record C - Endoscopy Unit

**What is documented?**
- Department & Date
- HLD brand is under thermometer
- Temp of water used to mix with enzymatic detergent
- Result of MEC prior to use
- Temp of HLD
- Time in and Time out
- Date HLD solution expires
- Employee reprocessing item

**More questions to ask**
- What item(s) since AR on site
- What about AR cycle printouts
- Quality Check on opening bottle of check strips

<table>
<thead>
<tr>
<th>Date</th>
<th>Temp of water in °F</th>
<th>Time of Use</th>
<th>Temp of HLD in °F</th>
<th>Time placed in HLD</th>
<th>Time removed from HLD</th>
<th>Date Solution Expires</th>
<th>Employee First Initial &amp; Last Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/22/19</td>
<td>110.4</td>
<td>Pass</td>
<td>107.6</td>
<td>1431</td>
<td>1451</td>
<td>3/11/19</td>
<td>Change</td>
</tr>
<tr>
<td>3/22/19</td>
<td>110.4</td>
<td>Pass</td>
<td>114.6</td>
<td>192.8</td>
<td>144.3</td>
<td>3/11/19</td>
<td>C</td>
</tr>
<tr>
<td>3/24/19</td>
<td>108.3</td>
<td>Pass</td>
<td>114.6</td>
<td>192.8</td>
<td>144.3</td>
<td>3/11/19</td>
<td>CL</td>
</tr>
<tr>
<td>3/24/19</td>
<td>108.1</td>
<td>Pass</td>
<td>114.6</td>
<td>192.8</td>
<td>144.3</td>
<td>3/11/19</td>
<td>CL</td>
</tr>
<tr>
<td>3-27-19</td>
<td>108.3</td>
<td>Pass</td>
<td>114.6</td>
<td>192.8</td>
<td>144.3</td>
<td>3/11/19</td>
<td>A</td>
</tr>
</tbody>
</table>

**Ability to track item to patient?**
“We’ve always done it this way”

- 3 Rs
  - Recognize
  - Reassess
  - Refocus

When you let go – you open up new possibilities
Close the Loop

• Provide written report back to manager within time frame

• Clear documentation of changes needed

• Circle back within the month to visually confirm that the changes were made

• Provide references

• May be okay to scan in handwritten report
Now that performing Sterilizer/HLD Audits seems easy

More on 2017 AAMI standards regarding common topics
Pre-cleaning

- Pre-clean at point of use (OR, clinics, hospital room)
- Remove gross soil
- Follow IFU for scopes or items with lumens
- Prevent organic soils from drying during transport:
  - Placing towel moistened with water (NO saline) over instrument
  - Apply a product designed for pretreatment
  - Place in package designed to maintain humid conditions
- Transport to designated area which allows for cleaning process to be performed in a controlled environment by personnel who are protected by PPE

Instrument Transport

- Label container as biohazard or color coded
- Type of container depends on items being transported
  - Bins with lids
  - Enclosed or covered carts
  - Sterilization container systems
  - Impermeable bags
- OSHA standard for sharps
  - Closable and puncture-resistant
  - Leak proof on the sides/bottom

Decontam Side

- Clear separation of dirty from clean
- Controlled Access
- Facility laundered scrubs
- Personal Protective Equip worn
  - Utility gloves fitted at wrist
  - Fluid-resistant face mask
  - Liquid-resistant covering w/sleeves
  - Liquid-resistant shoe covers
  - Eye protection includes goggles, full-length face shields when cleaning contaminated items or risk of splash

- Decontaminate reusable PPE per IFU, at least daily and between employees

Decontam Match Game

- Enzymatic detergent
- Biofilm
- Prevents coagulation of protein substances
- Digital thermometer
- Instrument brush diameter
- Disassemble

- Match size of lumen
- Not a disinfectant
- Instrument or device prior to cleaning
- Measure temp of water mixed with enzymatic detergent
- Forms within minutes
- Water temp 80-110°F (don’t exceed 140°F)
Instrument Brushes (Fill in the blanks)

• Clean ________ instrument brushes after each use & disinfect/sterilize _____.

• Reusable brushes with ____ or _____ bristles should be discarded.

• Discard disposable brushes after ________.

Reference: ANSI/SMMI ST79:2017 page 40
## Manual vs Automated Cleaning

<table>
<thead>
<tr>
<th>Mechanical Cleaning/Disinfection Equip</th>
<th>Manual Cleaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Open hinged instruments</td>
<td>• Follow detergent IFU for water hardness, pH, temp and type of soil</td>
</tr>
<tr>
<td>• Position to prevent damage</td>
<td>• Clean lumen with recommended brush of type, size and bristle type</td>
</tr>
<tr>
<td>• Verify dosing of detergent</td>
<td>• Flush lumen with cleaning solution, rinse with treated water unless otherwise specified in IFU</td>
</tr>
<tr>
<td>• Ensure all surfaces have contact w/cleaning solutions</td>
<td>• Clean immersible devices under water to minimize aerosolization</td>
</tr>
<tr>
<td>• Remove debris from washer floor and clean filter at least daily, if debris present</td>
<td>• Clean items that cannot be immersed in a manner that does not produce aerosols</td>
</tr>
<tr>
<td>• Verify correct cycle and dry time per IFUs</td>
<td>• Avoid abrasive cleaning compounds and tools (i.e. metal scouring pads)</td>
</tr>
<tr>
<td>• Validation testing daily and documented</td>
<td>• Monitor water temperature</td>
</tr>
<tr>
<td></td>
<td>• Change cleaning solution after every use</td>
</tr>
</tbody>
</table>

Ultrasonic Cleaning Equipment

- Only if allowed by device IFU
- After gross soil and detergents removed
- Keep lid closed during the cycle
- Followed with clean water rinse or detergent wash
- Inspect device carefully after cycle
- Change tank solution after each use
- Clean and disinfect tank at least daily

Reference: ANSI/SMMI ST79:2017 page 172
Are these being tracked?

• Laryngeal Mask Airway (LMA)
  – Follow manufacturer’s guidelines
  – Sterilization preferred
  – Document number of uses as defined by IFU and discard appropriately

• Other medical devices such as fiberoptic catheter cables can only be reprocessed a certain number of times prior to discard as defined by the device IFU
Clean Side

- Controlled Access
- PPE removed & Hand Hygiene when going from Decontam to Clean
- Inspection
  - Good lighting
  - Magnifying glasses or lens available
  - Ability to pull damaged instruments for repair or sharpening

Prevent wet packs by drying instruments before packaging

Label Packages before Sterilization

- Julian sticker
  - Sterilizer identification
  - Date of sterilization
  - Cycle or load #
- List of contents
- Person who assembled the package
- Ability to track item to patient
- Internal and external chemical indicators
- “Contents sterile unless package is opened or damaged. Please check before using”.
- Clearly identifiable expiration date if product contains material that degrades over time (e.g. latex). Follow IFU.

Chemical Indicators (CI)

- Indicates instrument or device was exposed to the sterilization process  
  - Temperature, Time, Pressure
- Distinguishes between processed and unprocessed items
- Use CI labeled for use in cycle per IFU
- External (e.g. autoclave tape, manufacturer mark on peel pouch)
- Internal – preferably Type 5 or 6 indicator
- “Pass” response is not proof of sterility

Reference: ANSI/AAMI ST79:2017 pages 77-80
Biological Indicators (BI)

- Intended to demonstrate that conditions in sterilizer adequate to kill large number of highly resistant bacterial spores, a negative BI does not prove sterility
- Ensure the control BI lot # matches test BI lot #
- Control BI done for each type of cycle for each sterilizer

- BI at least weekly, preferably every day sterilizer in use (however many facilities do BI with each load)
- Date/time documented when BI placed into incubator and when removed with staff initials (master signature page)

Whew! Take a Moment

Write down one thing that you’ve learned during this session that will become part of your daily work.
Summary

• Use current AAMI Standards
• Audit documentation regularly
• Ensure traceability to the patient

Be able to Tell your Story of Instrument Reprocessing
References


• Association for Advancement of Medical Instrumentation. ANSI/AAMI ST58:2013. Chemical sterilization and high-level disinfection in healthcare facilities.


