Sterilization and High-Level Disinfection: Do you know the difference between the two?

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Clinical Improvement Advisor, Infection Prevention
Health Services Advisory Group (HSAG)

Wednesday, May 23, 2018
Before We Begin

Housekeeping
- Please do not put us on hold.
- Write any questions into the “chat” box.
  - Discussion portion is at the end of the presentation.
  - Participants will be muted until the discussion.
- We will email responses to questions to all participants.
- Recording and the presentation from today’s webinar will be posted on the HSAG website by next week.
Introductions

Angela Vassallo, MPH, MS, CIC, FAPIC
Nationally recognized expert in Infection Prevention

- Certified in Infection Control (CIC) and Fellow of APIC (FAPIC)
- Association for Professionals in Infection Control and Epidemiology (APIC)
  - Past-president, CA APIC and Greater LA APIC chapter
  - Vice-chair, national APIC Communications Committee
- Infectious Disease Association of California (IDAC)
  - First and only Infection Prevention board member
- LA County Department of Public Health Healthcare-Acquired Infection (HAI) Advisory Committee
  - Founding member who represents Infection Preventionists in LA County
- Faculty, MPH, MHA, and MS programs
  - West Coast University and Providence University
- Education
  - MPH, University of Texas Health Science Center, School of Public Health, Houston, TX
  - MS, Healthcare Management, West Coast University, Los Angeles, CA
  - BA, International Service, American University, Washington, DC
Webinar Objectives

• Learn the difference between sterilization and high-level disinfection (HLD).
• Describe when HLD should be used.
• Describe when sterilization should be used.
• Discover how to create an annual competency for staff members who perform each task.
Nearly 25% of the nation’s Medicare beneficiaries

HSAG is the Medicare QIN-QIO for Arizona, California, Florida, Ohio, and the U.S. Virgin Islands.
Ambulatory Surgery Center
Special Innovation Project (ASC SIP)
Step One

Spaulding Criteria
Spaulding Classification

- Dr. Earle H. Spaulding was a Microbiologist at Temple University in Philadelphia.
- He wrote a landmark paper in 1939 that proposed an approach to disinfection and sterilization of patient care items.
- This turned into the “Spaulding Criteria,” which was created in 1957 to determine when re-usable medical devices should be disinfected or sterilized based upon infection risk.


Spaulding Classification (cont.)

- Criteria used to establish Environmental Projection Agency (EPA) and Food and Drug Administration (FDA) guidelines.
  - Established germicidal activity for disinfection (low, intermediate, and HLD)
- He initially recommended that semi-critical devices (such as, scopes) should be sterilized, but noted that HLD could be used if sterilization was not practical/possible.


All items must be **cleaned** before disinfection or sterilization is performed.

- **Non-critical devices** come into contact with a patient’s **intact skin** (e.g., blood pressure cuff and stethoscope)
  - Low/intermediate level disinfection

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All items must be cleaned before disinfection or sterilization is performed.

- **Semi-critical devices** come into contact with mucous membranes or non-intact skin such as vaginal/rectal probes and colonoscopes.
  - High-level disinfection
All items must be **cleaned** before disinfection or sterilization is performed.

- **Critical devices** come into contact with **sterile areas of the body, including blood**. These include instruments used during surgery.
  - **Sterilization**

## Spaulding Classification (cont.)

<table>
<thead>
<tr>
<th>Requirement</th>
<th>FDA device class</th>
<th>Body Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low level disinfection</td>
<td>Non-critical</td>
<td>Intact skin</td>
</tr>
<tr>
<td>High level disinfection</td>
<td>Semi-critical</td>
<td>Mucous membranes</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Critical</td>
<td>Sterile body areas</td>
</tr>
</tbody>
</table>

Step Two

Understanding HLD
Semi-Critical Devices

• Endoscopes
• Endocavitary probes, vaginal probes, rectal probes
• Bronchoscopes
• Anesthesia equipment
• Respiratory therapy equipment
Monitoring HLD

- **Hand Washing:** Clean vs. Dirty Sink
- **Flow and storage:** dirty to clean
- **Manual reprocessing vs. automated endoscope reprocessors (AERs)**
- **Materials needed:** signage, splash guards, personal protective equipment (PPE)
Monitoring HLD (cont.)

- Pre-cleaning
- Post-procedure transport and storage
- Log books
- Quality controls for solution and test strips
- Solution disposal and expiration
- Leak-testing
- Spills
- Disinfection Failures—always plan ahead!
Policy

• Purpose

- To provide guidelines for staff members when using and testing a HLD.
- Five departments use X solution: Endoscopy, Cardiology, Labor and Delivery, Radiology, and the Cancer Center.
- To identify employee safety practices when working with X solution, ensure the appropriate testing with the test strips and verify the minimum effective concentration.
Policy (cont.)

Policy

• X solution a HLD for processing heat sensitive reusable medical devices. HLD is to be used only for semi-critical items when sterilization is not practical.

• Items that enter sterile tissue or the vascular system are considered critical and must be sterile (e.g., surgical instruments, cardiac, urinary catheters, implants, and needles).
• Items that come in contact with non-intact skin or mucous membranes are considered semi-critical and receive HLD (e.g., anesthesia equipment, bronchoscopes, and laryngoscopes).

• Items that come in contact only with intact skin are considered non-critical items and receive intermediate and low level disinfection.

• X solution should never be used with patients with bladder tumors as this may cause anaphylaxis.

• X solution must be used in a well ventilated room that has at least 10 air exchanges per hour.
Procedure

• X Test strips will be used to test the solution when opened and prior to every use to verify the minimum effective concentration of X solution. When X is found to be out of range for use, it will be discarded appropriately.

• Testing of positive and negative controls will be performed on a newly opened test strip bottle from each case of X solution test strips that is received (See section VIII) and once a week thereafter.

• Make sure to follow manufacturer’s guidelines regarding cleaning and disinfecting of the instrument prior to putting the device in the X.

• Always date opened containers of Test Strips and discard after 90 days as they expire.
CLEAN THE INSTRUMENTS OR DEVICE THAT WILL BE PUT IN THE X SOLUTION

• Put on personal protective equipment that should consist of:
  – Gloves
  – Gown
  – Safety goggles or mask with eye shield

• Clean the instrument that is going to be disinfected. Contaminated instruments must be thoroughly cleaned before disinfection. This can be achieved by using a mild protein dissolving enzymatic detergent. Manually pre-clean all devices immediately following the procedure at the bedside in order to remove all body fluids. The cleaning detergent must remain on the device during transport.

• ALWAYS follow the manufacturer’s guidelines.
Caution

The recommended disinfection time is twelve minutes (12).

Many manufacturers do not recommend greater than 12 minute disinfection cycle. Always consult the manufacturer for disinfection recommendations.

An example is the trans-esophageal endoscope (TEE) probes which are highly absorbent and can become damaged if soaked in solution for longer than 12 minutes.

Those areas using the AER machines require only 5 minutes soaking time. Soaking time is automatically monitored by the AER.

This is a great area to work with manufacturers/sales representatives and use their resources!
### CDPH Adherence Monitoring tool

#### Healthcare-Associated Infections Program Adherence Monitoring

**High-Level Disinfection of Reusable Devices**

Regular monitoring with feedback of results to staff can maintain or improve adherence to high-level disinfection practices. Use this tool to identify gaps and opportunities for improvement. Monitoring may be performed in any type of location where high-level disinfection of reusable devices is performed.

Instructions: Observe each practice in the high-level disinfection area and check a box if adherent, Yes or No. In the column on the right, record the total number of “Yes” for adherent practices observed and the total number of observations (“Yes” + “No”). Calculate adherence percentage in the last row.

<table>
<thead>
<tr>
<th>High-Level Disinfection Practices</th>
<th>Observation 1</th>
<th>Observation 2</th>
<th>Observation 3</th>
<th>Adherence by Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>HLL. Flexible endoscopes are inspected for damage and leak tested as part of each reprocessing cycle. Any device that fails the leak test is removed from clinical use and repaired.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>HL2. Devices are thoroughly cleaned according to manufacturer instructions and visually inspected for residual soil prior to high-level disinfection. Note: Cleaning may be manual (i.e., using friction) and/or mechanical (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizer). Ensure appropriately sized cleaning brushes are selected for cleaning device channels and lumens.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>HL3. Cleaning is performed as soon as practical after use (e.g., at the point of use) to prevent soiled materials from becoming dried onto instruments.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>HL4. Enzymatic cleaner or detergent is used and discarded according to manufacturer instructions (typically after each use).</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>HL5. Cleaning brushes are disposable or, if reusable, cleaned and high-level disinfected or sterilized (per manufacturer instructions) after use.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
| HL6. For chemicals used in high-level disinfection, manufacturer instructions are followed for:  
  - Preparation  
  - Testing for appropriate concentration  
  - Replacement (i.e., upon expiration or loss of efficacy) | Yes | No | Yes | No | Yes | No |
| HL7. If automated reprocessing equipment is used, proper connectors are used to assure that channels and lumens are appropriately disinfected. | Yes | No | Yes | No | Yes | No |
| HL8. Devices are disinfected for the appropriate length of time as specified by manufacturer instructions. | Yes | No | Yes | No | Yes | No |
Device Reprocessing

### Healthcare-Associated Infections Program Adherence Monitoring

**Device Reprocessing**

Regular monitoring with feedback of results to staff can maintain or improve adherence to device reprocessing practices. Use this tool to identify gaps and opportunities for improvement. Monitoring may be performed in any type of location where device reprocessing is performed.

### Instructions

Observe each practice in the reprocessing area and check a box if adherent, Yes or No. In the column on the right, record the total number of “Yes” for adherent practices observed and the total number of observations (“Yes” + “No”). Calculate adherence percentage in the last row.

<table>
<thead>
<tr>
<th>Device Reprocessing Practices</th>
<th>Procedure 1</th>
<th>Procedure 2</th>
<th>Procedure 3</th>
<th>Adherence by Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>DR1. Policies, procedures, and manufacturer reprocessing instructions for reusable medical devices used in the facility are available in the reprocessing area(s).</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DR2. Reusable medical devices are cleaned, reprocessed (disinfection or sterilization) and maintained according to the manufacturer instructions. Note: If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DR3. Single-use devices are discarded after use and not used for more than one patient. Note: If the facility elects to reuse single-use devices, these devices must be reprocessed prior to reuse by a third-party reprocessor that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. The facility should have documentation from the third-party reprocessor confirming this is the case.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DR4. Adequate space is allotted for reprocessing activities and a workflow pattern is followed such that devices clearly flow from high contamination areas to clean/sterile areas (i.e. there is clear separation between soiled and clean workspaces).</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DR5. Adequate time for reprocessing is allowed to ensure adherence to all steps recommended by the device manufacturer, including drying and proper storage. Note: Facilities should have an adequate supply of instruments for the volume of procedures performed and should schedule procedures to allow sufficient time for all reprocessing steps.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DR6. HCP engaged in device reprocessing wear appropriate PPE to prevent exposure to infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection). Note: The exact type of correct PPE depends on infectious or chemical agent and anticipated type of exposure.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DR7. Medical devices are stored in a manner to protect from damage and contamination.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Calculations

- # of Correct Practice Observed (“# Yes”):
- Total # Device Reprocessing Observations (“# Observed”):
  - Adherence (%) = \( \frac{\text{# of Correct Practice Observed ("# Yes")}}{\text{Total # Device Reprocessing Observations ("# Observed")}} \times 100 \)

*If practice could not be observed (i.e. cell is blank), do not count in total # Observed.*
Step Three

Understanding Sterilization
Sterilization

Critical devices

• Surgical instruments
  – Clamps and forceps, etc.

• Intravenous devices
  – Peripheral and central lines

• Urinary catheters
Monitoring Sterility

**Biological Indicators (BIs)**
- Test systems for sterilization that contain microorganisms with strong resistance usually usually spores.
- They monitor whether the autoclave is working properly and if sterilization is achieved.
- Demonstrate the ability of heated steam to kill organisms.
- Detect air removal after the use of heated steam to achieve sterilization.

**Chemical Indicators/Integrators (CIs)**
- Used to test certain parameters such as time, temperature, and steam quality.
- They are not meant to detect sterilization failures.
- They are not equivalent to BIs and should not be used alone.
- CIs should never be used in place of BIs.
- Must be used with BIs as a supplemental quality assurance measure.
CDPH Adherence Monitoring Tools

### Sterilization of Reusable Devices

Regular monitoring with feedback of results to staff can maintain or improve adherence to sterilization of reusable device practices. Use this tool to identify gaps and opportunities for improvement. Monitoring may be performed in any type of location where sterilization of reusable devices is performed.

**Instructions:** Observe each practice in the sterilization area and check a box if adherent, Yes or No. In the column on the right, record the total number of “Yes” for adherent practices observed and the total number of observations (“Yes” + “No”). Calculate adherence percentage in the last row.

<table>
<thead>
<tr>
<th>Sterilization Practices</th>
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<th>Adherence by Task</th>
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<tr>
<td><strong>RD1.</strong> Devices are thoroughly cleaned according to manufacturer instructions and visually inspected for residual soil prior to sterilization. Note: Cleaning may be manual (i.e., using friction) and/or mechanical (e.g., with ultrasonic cleaners, washer-disinfector, washer-stereizers). Ensure appropriately sized cleaning brushes are selected for cleaning device channels and lumens.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>RD2.</strong> Cleaning is performed as soon as practical after use (e.g., at the point of use) to prevent soiled materials from becoming dried onto devices.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>RD3.</strong> Enzymatic cleaner or detergent is used for cleaning and discarded according to manufacturer’s instructions (typically after each use).</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>RD4.</strong> Cleaning brushes are disposable or, if reusable, cleaned and high-level disinfected or sterilized (per manufacturer’s instructions) after use.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>RD5.</strong> After cleaning, instruments are appropriately wrapped/packaged for sterilization (e.g., package system selected is compatible with the sterilization process being performed, items are placed correctly into the basket, shelf or cart of the sterilizer so as not to impede the penetration of the sterilant, hinged instruments are open, instruments are disassembled if indicated by the manufacturer).</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>RD6.</strong> A chemical indicator (process indicator) is placed correctly in the instrument packs in every load.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>RD7.</strong> A biological indicator, intended specifically for the type and cycle parameters of the sterilizer, is used at least weekly for each sterilizer and with every load containing implantable items.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>RD8.</strong> For dynamic air removal-type sterilizers (e.g. prevacuum steam sterilizer), an air removal test (Bowie Dick test) is performed in an empty dynamic-air removal sterilizer each day the sterilizer is used to verify efficacy of air removal.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>RD9.</strong> Sterile packs are labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date.</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
### Device Reprocessing

#### Healthcare-Associated Infections Program Adherence Monitoring

Device Reprocessing

Regular monitoring with feedback of results to staff can maintain or improve adherence to device reprocessing practices. Use this tool to identify gaps and opportunities for improvement. Monitoring may be performed in any type of location where device reprocessing is performed.

**Instructions:** Observe each practice in the reprocessing area and check a box if adherent, Yes or No. In the column on the right, record the total number of “Yes” for adherent practices observed and the total number of observations (“Yes” + “No”). Calculate adherence percentage in the last row.

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<td>DR1. Policies, procedures, and manufacturer reprocessing instructions for reusable medical</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td># Yes</td>
</tr>
<tr>
<td>procedures, and manufacturer reprocessing instructions for reusable medical devices used</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td># Observed</td>
</tr>
<tr>
<td>in the facility are available in the reprocessing area(s).</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td># Yes</td>
</tr>
<tr>
<td>maintained according to the manufacturer instructions. Note: If the manufacturer does not</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
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<td>provide such instructions, the device may not be suitable for multi-patient use.</td>
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<td>Yes</td>
<td>Yes</td>
<td># Yes</td>
</tr>
<tr>
<td>Note: If the facility elects to reuse single-use devices, these devices must be reprocessed</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td># Observed</td>
</tr>
<tr>
<td>prior to reuse by a third party reprocessor that is registered with the FDA as a third party</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>reprocessor and cleaned by the FDA to reprocess the specific device in question. The facility</td>
<td></td>
<td></td>
<td></td>
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<td>should have documentation from the third party reprocessor confirming this is the case.</td>
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<td>Yes</td>
<td>Yes</td>
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<tr>
<td>followed such that devices flow from high contamination areas to clean/sterile areas (i.e.</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td># Observed</td>
</tr>
<tr>
<td>there is clear separation between soiled and clean workspaces.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DR5. Adequate time for reprocessing is allowed to ensure adherence to all steps</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td># Yes</td>
</tr>
<tr>
<td>recommended by the device manufacturer, including drying and proper storage. Note: Facilities</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td># Observed</td>
</tr>
<tr>
<td>should have an adequate supply of instruments for the volume of procedures performed and</td>
<td></td>
<td></td>
<td></td>
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<td>should schedule procedures to allow sufficient time for all reprocessing steps.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DR6. HCP engaged in device reprocessing wear appropriate PPE to prevent exposure to</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td># Yes</td>
</tr>
<tr>
<td>infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection).</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td># Observed</td>
</tr>
<tr>
<td>Note: The exact type of correct PPE depends on infectious or chemical agent and anticipated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>type of exposure.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DR7. Medical devices are stored in a manner to protect from damage and contamination.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td># Yes</td>
</tr>
</tbody>
</table>

**Adherence Calculation:**

\[
\text{Adherence} = \frac{\text{# Yes}}{\text{Total # Observed}} \times 100
\]

If practice could not be observed (i.e. cell is blank), do not count in total # Observed.

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CDPH. Device Reprocessing. Available at: [https://www.cdph.ca.gov/Programs/CHCQ/HAI/Pages/MonitoringAdherenceToHCPracticesThatPreventInfection.aspx](https://www.cdph.ca.gov/Programs/CHCQ/HAI/Pages/MonitoringAdherenceToHCPracticesThatPreventInfection.aspx).

Accessed on: May 14, 2018
Plan for Failures

Dr. Rutala’s 14 step method for managing disinfection or sterilization failures

1. Confirm failure
2. Embargo improperly disinfected/sterilized items
3. Do not use items
4. Inform key stakeholders
5. Investigate the cause of the disinfection/sterilization problem
6. Create a line list of potentially exposed patients
7. Does the failure increase the patient’s risk for infection?
8. Inform expanded list of stakeholders (prepare template press release)

9. Develop hypothesis for failure and initiate corrective action
10. Assess adverse patient events
11. “In conjunction with the legal department, notify state and federal authorities if required by regulation or law”
12. Consider patient notification (develop a script with talking points)
13. Develop long term follow up plan
14. Perform after-action report

Step Four

Creating Annual Competencies
Your Policy Must Match Your Staff’s Practice

1. Create your team: identify subject matter experts (SMEs) and those who should be involved
   – Who will sign off on competencies and conduct return demonstration?
2. Write the policy as a team with clear, step-by-step procedures
3. Write the annual competency based upon the policy
4. Write competency test questions based upon opportunities for improvement
5. Conduct annual return demonstration
6. Keep everyone’s records to prove completion and to use during evaluations
7. Provide feedback to staff members on their progress
Return Demonstration

• This is not (!) getting signed-off by the AER or scope manufacturer when they come out to conduct in-services

• Who assures that equipment is cleaned at point-of-use with an enzymatic cleaner prior to disinfection or sterilization?
  – One point person is needed to assure this is happening. Sometimes when everyone is involved NO one is really involved.
• Who follows up with staff members when they leave trays/scopes that haven’t been cleaned/are not left moistened in the clean up area for busy techs?
  – This is not the tech’s fault.
  – There are often only 1–2 techs who are busy cleaning, disinfecting, sterilizing, or assisting in procedures.
  – Techs cannot be in more places than one at the same time.
• All staff members who handle and transport scopes, probes, surgical instrumentation must be trained to understand the importance of point-of-care cleaning and their critical role in the disinfection/sterilization process.
# Example Return Demonstration

<table>
<thead>
<tr>
<th>Validator’s initials</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Put on personal protective equipment (PPE) - gloves, gown, mask with eye shield</td>
</tr>
<tr>
<td></td>
<td><strong>Quality Control of Solution</strong></td>
</tr>
<tr>
<td></td>
<td>1. Record the date opened and the date to discard on the bottle. Note: Opened container expires in 75 days (not to exceed manufacturer’s printed expiration date)</td>
</tr>
<tr>
<td></td>
<td>2. Document change of solution every 14 days in log book. (Important Note: Must be discarded after 14 days regardless of test strip results.)</td>
</tr>
<tr>
<td></td>
<td>3. Test the concentration of the solution before disinfection of each device and documents in log book.</td>
</tr>
<tr>
<td></td>
<td>4. Submerge test strip in solution and holds for 1 second and remove.</td>
</tr>
<tr>
<td></td>
<td>5. Read the results after 90 seconds. Note: Should turn purple.</td>
</tr>
<tr>
<td></td>
<td>6. Monitor the temperature of the solution before disinfection of each device and documents on the log sheet Note: Minimal temperature for manual processing = 20° C/68° F; for AER processing is 25° C/77° F.</td>
</tr>
<tr>
<td></td>
<td><strong>Quality Control of Test Strips</strong></td>
</tr>
<tr>
<td></td>
<td>1. Label newly opened test strip bottles with open date and date to discard. (Important Note: Once opened, shelf life = 90 days unless manufacturer’s expiration date is sooner).</td>
</tr>
<tr>
<td></td>
<td>2. Perform quality control test upon opening every new test strip bottle. This requires both positive and negative controls.</td>
</tr>
<tr>
<td></td>
<td>3. Negative Control - Dilute in a small container (1 part solution X and 1 part water).</td>
</tr>
<tr>
<td></td>
<td>4. Positive Control - Add full strength solution into another small container.</td>
</tr>
</tbody>
</table>
References

- California Department of Public Health (CDPH). High-Level Disinfection of Reusable Devices. Available at: https://www.cdph.ca.gov/Programs/CHCQ/HAI/Pages/MonitoringAdherenceToHCPracticesThatPreventInfection.aspx. Accessed on: May 14, 2018
- CDPH. Device Reprocessing. Available at: https://www.cdph.ca.gov/Programs/CHCQ/HAI/Pages/MonitoringAdherenceToHCPracticesThatPreventInfection.aspx. Accessed on: May 14, 2018
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