AAMI ST79 Updates: New Sterilizer Wrap Drawings and Wet Pack Assessment Tools

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Objectives

After completion of this self-study activity, the learner will be able to:

1. Discuss updated guidance (provided by AAMI) related to wrapping packages to be sterilized.
2. Describe the sources of internal and external moisture on sterilized devices.
3. Describe available tools to help guide an investigational process for wet packs and wet loads.

Test Questions

1. There has only been one edition of the Association for the Advancement of Medical Instrumentation Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79.
   A. True B. False

2. If you purchased the second edition of ST79 in 2010 you can download the amendments on the AAMI website for free.
   A. True B. False

3. In addition to upgraded diagrams, amendment 4 of ST79 includes detailed instructions on how to wrap a package for sterilization.
   A. True B. False

4. Simultaneous double wrapping means two layers of wrap material are used, wrapping one layer at a time.
   A. True B. False

5. Wrapping procedures should comply with the device, wrap and sterilizer manufacturers’ instructions for use.
   A. True B. False

6. Wet packs are a concern because the moisture on or within a package can create a pathway for microorganisms to migrate from the outside to the inside of a package.
   A. True B. False

7. Moisture is defined as any visible dampness, droplets, or puddles of water on or inside a pack.
   A. True B. False

8. Instruments do not need to be dry when assembling sets.
   A. True B. False

9. Some wet pack issues can be due to sterilizer equipment or utility malfunctions.
   A. True B. False

10. Amendment 4 includes two tools that will be very helpful for performing a moisture assessment investigation.
    A. True B. False
Introduction

This article will discuss the updated recommended practices described in the fourth and final amendment to the second edition of the Association for the Advancement of Medical Instrumentation Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79 2010. Among other things, this latest amendment updates the four figures on sterilization wrapping and includes written step-by-step instructions on the four different ways to wrap a package for sterilization. The amendment adds an entire annex that provides additional information on moisture assessment to help users investigate the causes of and therefore prevention of the occurrence of wet packs.loads.

Staying current with standards

When ST79 was first published in 2006, AAMI incorporated five recommended practices relating to steam sterilization into this one comprehensive standard. The art and science of reprocessing reusable medical devices changes very rapidly due to technological advancements and evidence gathered from research studies. Therefore, AAMI decided that this publication should be on a continuous maintenance process so that it can evolve and be updated on a regular basis. All other AAMI standards are on a 5-year schedule update. This makes ST79 a very unique and ever evolving document. In order to keep these standards updated, AAMI published amendments to the first edition (including some editorial changes) in 2008 and 2009. The second edition of the book was published in 2010 and has had numerous amendments. A4:2013 will be the last amendment to the 2010 edition of ST79. If you have previously purchased the second edition of ST79, these amendments can be downloaded free from the AAMI website. Any further updates will be included in a future third edition of the document.

Update questions:

• Does your facility have the 2010 edition of ST79?
• Have you incorporated all four amendments into your ST79 book?
• Is ST79 available to all reprocessing staff?

New sterilization wrap drawings and instructions

Amendment 4 of ST79 includes a complete revision of the sterilization wrap instructional drawings labeled as figures 4, 5, 6 and 7 found in section 8 Packaging, preparation, and sterilization. The figures are labeled as:

• Figure 4 – Simultaneous double-wrapping: envelope fold
• Figure 5 – Simultaneous double wrapping: square fold
• Figure 6 – Sequential wrapping: envelope fold
• Figure 7 – Sequential wrapping: envelope fold

The previous wrap drawings were basic squares with no real sense of directions. These did not contain any written instructions on how to wrap. The old figures were confusing and not very helpful, especially if you were new to wrapping sterilization packages.

The new and improved wrap drawings are much more thorough and user friendly. The figures are easier to understand and it is clear which way the pack is facing and which way the folds should go. Written step-by-step instructions are now included with each figure.

For example, Figure 4 – Simultaneous double-wrapping: envelope fold instructs users to “Use only wrappers validated for use in double simultaneous wrapping. Two single-layer wrappers or one bonded double-layer wrapper can be used. Simultaneous double wrapping refers to when two layers of wrap material are wrapped together simultaneously using the fold technique described below.

1. Place the wrap sheets on the table to form a diamond shape. Place the device(s) to be wrapped in the center of the wrap, parallel with the edge of the table.

2. Bring the lower corner up to completely cover the contents and fold the tip back on itself to form a tab or flap (which is used later to assist in opening the pack aseptically).

3. Fold the left corner over the contents and fold the tip back to form a tab.

4. Fold the right corner over the left fold and fold the tip back on itself to form a tab.
5. Bring the top corner down over the contents and tuck the corner under the right and left folds. A small tab should be left out for easy opening. Secure with two pieces of chemical indicator tape as shown in Figure 4 (one piece of tape may be sufficient for smaller packages).” (1, page 69)

Healthcare facilities should develop policies and procedures for packaging techniques described in ST79 and ensure their procedures comply with the wrap, device and sterilizer manufacturers’ written recommendations.

Update questions:
- Are processing personnel wrapping packages according to ST79 recommendations?
- Are the new wrap drawings and descriptions available to your staff?
- Do you have a copy of the wrap manufacturers’ instructions for use readily available?

Annex P – Wet packs and wet loads

The second exciting addition to ST79 in this fourth amendment is the entirely new annex on moisture assessment. Previously there was very little direction on what may cause a wet pack or how to prevent them, and there was no information on wet loads. Before, users were directed to a couple of older references for further information on wet packs. ST79 is considered the comprehensive guide to steam sterilization, so it only made sense to include wet pack/load information in this document.

Processing staff knows that items with torn or wet packaging are considered contaminated but we never really defined why; therefore, Annex P includes an explanation stating, "Wet packs are a concern because the moisture on or within a package can create a pathway for microorganisms to migrate from the outside to the inside of a package." (1, Annex P, page 237)

Update questions:
- Does your facility have a policy and procedure that addresses wet packs and wet loads?
- Do staff understand why moisture on or within a package is considered a contaminated pack?

Figure 4 – Simultaneous double-wrapping: envelope fold
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Wet Pack vs. wet loads

Visible moisture found inside or outside of a package after sterilization and the proper cooling period is considered a wet pack. Moisture is defined as any visible dampness, droplets, or puddles of water on or inside a pack. A load is considered a wet load if visible moisture is present on or in several packages of that load.

Wet packs discovered in the processing area should not be released. These packs should be reprocessed and an investigation should be conducted. In section 8.8 Handling and Inspection, a statement was added to remind users that if they find a wet pack in a load they should open other packs in the questionable load to check for moisture and/or recall all items from the load. Wet packs found in the user area, such as the OR should not be used.

Update questions:

- If a wet pack is discovered, do you check the rest of the load for additional wet packs?
- Do your customers know that they should not use a wet pack and that it should be returned for reprocessing?

Exterior vs. interior moisture

One of the most frustrating things about wet packs is trying to discover what happened and what caused the moisture retention. AAMI states moisture found on the outside of a processed package can be caused by:

- improperly trapped, sloped, or insulated steam lines,
- dripping from the sterilizer cart, railings or shelves, or
- dripping from metal items above other items.

Moisture on the inside of a processed package may be caused by positioning items in the load that may trap moisture. How packs are assembled or wrapped may also cause wet packs. Package preparation techniques that may contribute to moisture retention include:

- heavy or dense instruments packed too tightly,
- no absorbent material to wick moisture away from heavy loads,
- putting wet instruments into trays,
- textile packs wrapped too densely, and
- improperly prepared items (e.g., items or trays wrapped while moist).

Update questions:

- Do staff understand the causes of internal and external moisture retention?
- Are packages assembled according to the device manufacturers’ recommendations?

Moisture assessment investigation process

Wet packs and wet loads are a complex issue with many factors that may be involved. The investigation can be a complicated process involving many steps. Annex P lists a series of questions to begin the exploration process. A good place to start is by asking did the wet packs happen:

- at a certain time of day,
- at a certain time of the year,
- only with certain trays,
- in a specific sterilizer,
- on a certain level or location of the sterilizer cart, and
- on the inside and outside at the same time?

It is important that the investigational team document all moisture assessment issues to observe for common occurrences in the future.

Update questions:

- Do you begin a wet pack investigation by asking the above type of questions?
- Are all moisture assessment issues recorded?
Two helpful investigational tools

There are two very helpful tools included in Annex P to help streamline your investigational process. Table P.1 is a Moisture Assessment Check List, which is an extensive list of possible causes of internal and external moisture retention. This check list has two major sections. The first section lists the possible processing steps that may retain moisture. The processing issues are broken down into:

- Clinical Practice,
- Set and Load Content Configuration, and
- Sterilization Process.

The second major section in the check list is Sterilizer or Utility Malfunctions. This part lists various causes relating to:

- Boiler System,
- Steam Delivery System (Piping),
- Sterilizer Performance, and
- Environmental Issues.

The second tool in Annex P is Figure P.1 – Moisture assessment flow chart. This flow chart or decision tree walks the investigators through the steps to take depending on where the moisture was found.

“Combining information from the initial questions, the check list, and the flow chart will help identify the issue and solutions to the wet pack issues. Some solutions may be equipment or utility oriented. Others may be from changes in clinical practice. Or, it may be a combination of all three to resolve the wet pack issues.” (1. Annex P, page 240)

Update questions:

- If you have a wet pack/load does your facility investigate how your packs and loads were assembled?
- Is your facility or maintenance department aware of moisture assessment issues?
- Is the Moisture Assessment Check List readily available to the staff?

Figure P.1 – Moisture assessment flow chart

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Summary

The Association for the Advancement of Medical Instrumentation Comprehensive guide to steam sterilization and sterility assurance in health care facilities, ANSI/AAMI ST79 is considered to be the bible for reprocessing of reusable medical devices. Following these written professional guidelines can help ensure safer patient care. Accrediting agencies such as The Joint Commission and the Centers for Medicare and Medicaid Services (CMS) are conducting their onsite surveys according to recommendations listed in ST79. Therefore, it is important for healthcare facilities to stay current with all updates to standards and recommend practices.

ANSI/AAMI ST79 Ordering Information

The PDF version of ANSI/AAMI ST79:2010/A4:2013 Comprehensive guide to steam sterilization and sterility assurance in health care facilities is available FREE on the AAMI website. The modifications to this amendment are in redline/stikeout. Amendments A2:2011 and A3:2012 should be incorporated into the ANSI/AAMI ST79:2010 prior to incorporating Amendment 4. If you have the first edition of ST79 (purchased prior to 2010) you will need to purchase a new copy of the standard.

Reference

Answers

1. B
2. A
3. A
4. B
5. A
6. A
7. A
8. B
9. A
10. A

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Rose Seavey MBA, BS, RN, CNOR, CRCST, CSPDT is the President/CEO of Seavey Healthcare Consulting, LLC, and formerly the Director of the Sterile Processing Department at The Children’s Hospital of Denver. Ms. Seavey served on the Association of periOperative Registered Nurses (AORN) Board of Directors from 2008-2010. She received AORN’s award for Outstanding Achievement in Mentorship in 2012 and the Outstanding Achievement in Clinical Nurse Education in 2001.

In 2003 Rose served as President of the American Society of Healthcare Central Service Professionals (ASHCSP) and was awarded the National Educator of the Year award in 2002. Rose was selected as one of the Who’s Who in Infection Prevention in 2006 by Infection Control Today.

Ms. Seavey also received the 2013 national IAHCSMM Award of Honor, the Industry Leadership Award from the Massachusetts chapter and the Educator of the Year Award from the Golden West chapter.

Ms. Seavey is the author of the book titled Sterile Processing In Healthcare Facilities: Preparing for Accreditations Surveys, published by AAMI. She sits on the AAMI National Nominating Committee for 2011-2014 and co-chaired the AAMI Working Group for Hospital Steam Sterilizers from 2006-2013. She is a member of several AAMI working group committees and is on the ST79 Advisory Council (2013-2015). In addition, she has lectured nationally and internationally and authored numerous articles.

Ms. Seavey is an Educational Consultant to 3M Health Care.
Sterile Process and Distribution CE Information

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The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 1 contact hour for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding Certification contact: CBSPD, Inc. 148 Main St., Lebanon, NJ, 08833 or call 908-236-0530 or 1-800-555-9765 or visit the website at www.sterileprocessing.org.

IAHCSMM has awarded 1 approved contact point for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CE Application Form

This inservice is approved by the California Board of Registered Nurses, CEP 5770 for 1 contact hour. This form is valid up to five (5) years from the date of publication.

1. Make a photocopy of this form.

2. Print your name, address and daytime phone number and position/title.

3. Add the last 4 digits of your social security number or your nursing license number.

4. Date the application and sign.

5. Answer the true/false CE questions. Keep a copy for your records.

6. Submit this form and the answer sheet to:
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   Attn: HC4160
   RR Donnelly Fulfillment Services
   585 Hale Avenue North
   Oakdale, MN 55128-9935

7. For questions please call the 3M Healthcare helpline: 1-800-228-3957.

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Offer expires February 2019

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