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Learning Objectives

1. ***Discuss guidance related to Immediate-Use Steam Sterilization provided in AAMI and AORN recommended practices.***
2. ***Describe elements of a policy for the handling of loaner instrumentation.***
3. ***Discuss the handling of contaminated reusable items at the point of use.***

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Sterilization recommended practices

Checking in on 2012 updates

by Susan Flynn, BESc, CSPDT

Healthcare facilities performing sterilization rely on recommended practice documents from AAMI and AORN to guide their practice. This self-study article highlights some recent changes to the guidance documents from both associations. In June, AORN released a revised version of their Recommended Practices (RP) for Sterilization. The new document is available now to those with an e-Subscription and will be included in the print edition of AORN's *Perioperative Standards and Recommended Practices* that will publish 2013. Revised using a new evidence-based process, the evidence supporting individual recommendations for implementation is now rated. AORN's Sterilization RP grounds the reader on the importance of the contents by stating, "A major responsibility of the perioperative registered nurse (RN) is to minimize patient risk for surgical site infections (SSIs). One of the measures for preventing SSIs is to provide reusable surgical items that are free of contamination at the time of use."[1]

The other 'go-to' document, ANSI/AAMI ST79 *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities,* is subject to a continuous maintenance process. Sterile processing professionals have now become accustomed to the regular release of amendments. This fall AAMI is releasing Amendment 3:2012 to the ST79:2010 document. The amendment is available for free download at www.AAMI.org.

One significant change common to both documents is the replacement of the term 'flash sterilization' with the new term 'Immediate-Use Steam Sterilization' (IUSS) introduced last year in the multi-society position paper.[2] Both the new term and the updated guidance, which stresses that items sterilized using this method should be used immediately, have been incorporated into the documents.

IUSS

Good news: the multi-society consensus on IUSS summarized in the position paper is now reflected in the recommended practices. Recommendation VII in AORN's revised Sterilization RP is devoted to immediate use steam sterilization. The preamble states, "Immediate use is considered the shortest time possible between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field."[1] Some important points in Recommendation VII are:

- If there is time to conduct terminal sterilization, do so. (VII.a.);
- Ensure items to be sterilized for immediate use receive proper decontamination (VII.a.1.);
- Perform IUSS only if the device manufacturer's written instructions include instructions for IUSS. These instructions should be followed. (VII.a.2.);
- Include either a Class 5 or Class 6 chemical indicator in each container used for IUSS. Use Class 6 indicators only in the specific cycles for which they are labeled. (VII.c.3);
- To protect sterilized items during transport, use rigid sterilization containers designed for IUSS. (VII.e.);
- Implantable devices should only be sterilized using IUSS in defined emergencies. (VII.f.);
- Run a biological indicator and a Class 5 chemical integrating indicator with any IUSS load containing an implant. (VII.f.1);
- Detailed documentation should be kept on IUSS cycles. (VII.g)[1]

The section on 'flash sterilization' in the introduction to AAMI ST79 was similarly updated to use the term IUSS. This section is sometimes missed because of its position in the document, but it contains valuable guidance. For example, this section reminds the reader that cleaning processes used prior to IUSS should be consistent with the cleaning processes used in other parts of the facility. A new sentence reads, "Sterilizing unwrapped items is not recommended."[3]

Cycle selection is another important consideration in IUSS and the selected cycle should be consistent with the written instructions provided by the sterilizer manufacturer, the container manufacturer, and the device manufacturer. This section continues to state that IUSS should not be used for implantable items. The recommendation to ensure traceability to the patient in the event an implant does need to be sterilized for immediate use remains in place (Section 10.3.1).

Revised guidance on IUSS is also provided in section 8.6.2.1. For example, it is recommended that dynamic-air removal cycles be used unless the device manufacturer specifies the use of a gravity-displacement cycle. Other than updating the term 'flash sterilization' to IUSS, the monitoring recommendations for IUSS cycles remain unchanged. AAMI continues to recommend that implant loads, whether processed using IUSS or terminal sterilization, be monitored with a Process Challenge Device (PCD) containing a biological indicator and a Class 5 integrating indicator. The implant should be held until the biological indicator test result is available.

Contaminated reusable items

New guidance on the care and handling of contaminated reusable items at the point of use is provided in Section 6.3 of AAMI ST79:2010/A3:2012. As instruments can be damaged during transport, it's recommended that instruments be placed into containers or transport pans in an orderly fashion. For example, sharps should be segregated and delicate instruments should be placed on top of heavier devices. It is also recommended that instruments requiring repair be identified at the point of use. The segregation of these damaged instruments should be maintained throughout the decontamination process. Specific suggestions to prevent organic material from drying on contaminated reusable items are provided. Measures which can be practiced at the point of use include covering instruments with a moist towel; using an instrument spray; or using a package intended to maintain a moist environment.

Loaners

Facilities across the country struggle with the development of and adherence to a policy around the use of loaner instrumentation. Fortunately, there are several resources available to reference!

A detailed recommendation (Recommendation XIV) on loaners remains an element of AORN's revised Sterilization RP. As a starting point, AORN recommends that: "A formalized program between the healthcare organization and healthcare industry representatives should be established for the receipt and use of loaned instrumentation."[1] The AORN Recommended Practice suggests hospitals obtain the medical device reprocessing instructions before receiving the loaned item (XIV.c.); that "All loaned instruments, regardless of whether they were processed in another healthcare facility, should be considered contaminated and delivered directly to the sterile processing department for decontamination." (XIV.e.1.); and that loaner instrumentation arriving late is not a justification to perform immediate-use steam sterilization (XIV.d.2). Putting this last point into practice, AORN recently reported that a large hospital found that enforcing their 24 hour prior to surgery loaner drop-off policy with vendors made a huge difference in their efforts to reduce the incidence of IUSS.[4]

Loaner instrumentation was also considered by the AAMI committee that is responsible for continuous maintenance of AAMI ST79. The section addressing design considerations of the decontamination area now reminds the reader to consider how the receipt of loaners will be conducted and documented, and to ensure space is allocated for the storage of these received loaners.[3]

While this article focuses on information in AAMI and AORN sterilization recommended practices, IAHCSMM's Orthopedic Council has also developed very practical resources designed to help facilities manage loaner instrumentation that warrant mention. These resources, a position paper and a sample Policy & Procedure, can be downloaded for free at IAHCSMM's website (www.iahcsmm.org).[5]

Design of the sterile processing area

Although medical device reprocessing may be performed in a designated area in office-based practices and at ambulatory surgery centers, this area is not typically a separate department. In an effort to be more inclusive, AAMI ST79:2010/A3:2012 therefore revises the term 'Sterile processing department' to 'Sterile processing area'. This area is defined as: "Area within a healthcare facility that processes and controls medical supplies, devices, and equipment, sterile and not sterile, for some or all patient care areas of the facility." (Section 3.2.1 a)[3]

If you're dreaming about a renovation or relocation of the sterile processing area in your facility, AAMI ST79:2010/A3:2012 adds a new factor to the list of general considerations: provisions for communication, both internal and external. Examples of electronic equipment were also added to the electronic needs factor along with a reminder to consider data drops needed for connectivity.

The decontamination area has unique requirements. In a nod to the continuing focus on following device manufacturers' Instructions for Use (IFU), AAMI ST79:2010/A3:2012 states that staff working in decontam need a way to access IFUs. It also reminds the reader that only surgical instrumentation, and not dietary service items, should be processed in the area. Does your decontam area feature anti-fatigue mats at the sinks? If not, you can now reference Section 3.3.7.1 to lobby for the mats. When selecting anti-fatigue mats for decontam, remember they must be able to withstand frequent cleaning. A new paragraph addresses water quality. To avoid instrument staining, it is recommended that treated water be used for the **final** rinse, whether in an automated washer or during manual cleaning.

Moving to the preparation area, another new worker-friendly suggestion will be welcomed by those working at fixed height tables: "processing tables made of nonporous materials (e.g., stainless steel) should be ergonomic and preferably height adjustable" (Section 3.3.7.3 h). Revisions to the section discussing the sterile storage area include the reminder that items stored in this area should have been removed from external shipping containers. Does your sterile processing area have a place to remove items from their shipping containers? ST79 now recommends that a break out area be located nearby (Section 3.3.7.6). A new recommendation states that hand hygiene facilities should be available in the sterile storage area. Installing a wall-mounted alcohol-based instant hand antiseptic dispenser would be a quick way to comply with this recommendation.

Chemical indicators

Sterilization cycles are monitored using physical, chemical, and biological indicators. A variety of chemical indicators are available to healthcare facilities. AAMI ST79:2010/A3:2012 clarifies that the use and application guidance for chemical indicators provided in ST79 is based on the chemical indicator classifications found in ANSI/AAMI/ISO 11140-1 (Section 10.5.2.1). These classifications are different than those in the FDA's "Guidance for Industry and FDA Staff:

*See **SELF-STUDY SERIES** on page 40*

Self-Study Test Answers: 1. A, 2. A, 3. B, 4. A, 5. A, 6. A, 7. B, 8. A, 9. B, 10. B

Premarket Notification [510(k)] Submissions for Chemical Indicators". While there are six numerical class designations in the international consensus standard, the FDA has only three categories: process indicators; chemical integrators; and air removal indicators. A new annex, Annex O, was added to AAMI ST79 to explain the differences between the chemical indicator classifications and performance requirements in the two documents.

Chemical indicators are considered medical devices in the US and manufacturers must therefore secure FDA clearance to market a new product. As many chemical indicator manufacturers sell their products globally, it is common that they also have data to support a product's compliance to the international performance requirements found in ANSI/AAMI/ISO 11140-1:2005(R)2010. For example, a product cleared by the FDA as a 'chemical integrator' may also be able to meet the performance requirements of a Class 5 integrating indicator specified in the international document. Bottom line to the end-user: use and application guidance for chemical indicators does not change with the publication of AAMI ST79:2010/A3:2012.

Low temperature sterilization

AORN's RP for Sterilization includes recommendations applicable to low temperature sterilization. Recommendation VIII discusses ethylene oxide sterilization. One update in this section reflects the EPA regulation that items be sterilized and aerated in a single chamber (VIII.f.1.). There are two different hydrogen peroxide based sterilization technologies available in the US and AORN now has a recommendation for each. Recommendation IX discusses hydrogen peroxide gas plasma sterilization, including recommendations for a quality monitoring program. A new section, Recommendation X, discusses sterilizers using vaporized hydrogen peroxide as the sterilant. The user is advised to follow the sterilizer manufacturer's instructions for using, monitoring, and maintaining this type of sterilizer. For both types of hydrogen peroxide sterilizers, more specific monitoring guidance is provided in Recommendation XX. For example, it is recommended that "Routine sterilizer efficacy monitoring should be at least daily on each cycle type, preferably with each load…" (XX.h.4. and XX.h.5.). Similarly, when conducting sterilizer qualification testing, a biological indicator PCD should be run in three consecutive empty cycles for each cycle type enabled on the sterilizer.

The recommendation on using liquid chemical sterilant systems that use peracetic acid has been revised to state that this method should only be used for items that cannot be sterilized using terminal sterilization methods (Recommendation XIII).

Conclusion

Feel like tackling an editing task? If your facility hasn't already revised your 'flash' sterilization policy to use the new term, Immediate-Use Steam Sterilization, now would be a good time to do so. Both AAMI and AORN have incorporated this term, and the associated updated guidance, into their steam sterilization recommended practices. As you budget for 2013, consider adding some ergonomic features like anti-fatigue mats in decontam and height-adjustable work stations in the preparation area to the plan. As a final suggestion, tour through your sterile processing area, from decontam to sterile storage, and scan for the accessibility of hand hygiene stations. HPN

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We're issuing an open call to nominate noteworthy hospital presidents/CEOs for HPN's 2013 "S.U.R.E. Award for Supply Chain-Focused CEOs." We're looking to recognize chief executives who *support, understand, recognize* and *empower* the supply chain department to achieve bottom-line savings and top-line revenue.

We ask you, our dedicated and loyal readers, to recommend worthy candidates for recognition in our January 2013 edition by e-mailing us reasons how and why your CEO deserves the spotlight – no more than a couple of paragraphs are needed for each of the four S.U.R.E. categories listed above that comprise the "SURE" acronym. Please describe how and why he or she supports, how and why he or she understands, how and why he or she recognizes and how and why he or she empowers the materials management department and its top executive.

For your nomination to qualify, please be sure to comply with the following rules:

1. Any nomination must be original and exclusive to ***HPN*** and not have been submitted – either original or edited – to any other publication or online media outlet currently or within the previous year.
2. GPO and distributor support is commendable, but we're looking for internally driven details beyond GPO- and distributor-driven contributions, including outsourcing operations to a GPO or distributor.
3. Any nominated executive (or nominator) must be willing to share relevant basic financial details with our readers – specifically annual revenues, annual expenses and annual purchasing volume.
4. Only administrators/CEOs are eligible for consideration – not COOs or executive/senior vice presidents.

Help us share the stories of these remarkable CEOs in our January 2013 edition so that the industry may learn from them and be inspired. Thanks in advance.

E-mail us your nominations by Monday, November 5, to editor@hpnonline.com

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Susan Flynn is a Technical Service Specialist with 3M Infection Prevention Division. She is routinely involved in troubleshooting and addressing questions about sterilization processes. Flynn's role at 3M includes providing education for customers and sales personnel on improving the performance of the sterilization process and implementing best practices. Flynn is a certified Central Sterile Processing and Distribution Technician. In addition, she is a member of several AAMI working groups.

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1. Association of periOperative Registered Nurses. *Perioperative Standards and Recommended Practices*. Recommended Practices for Sterilization (June 2012).

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Sterilization Recommended Practices: Checking in on 2012

Circle the one correct answer:

1. **AAMI ST79 recommends identifying contaminated, reusable instruments requiring repair at the point of use.**
   A. True B. False
2. **If IUSS is used for an implantable item, the load should be monitored with a biological indicator and a Class 5 integrating indicator.**
   A. True B. False
3. **Staff working in decontam does not need access to device manufacturers' IFUs.**
   A. True B. False
4. **During instrument decontamination, it is recommended that treated water be used for the final rinse.**
   A. True B. False
5. **AAMI ST79 states that dynamic-air removal cycles should be used for IUSS unless a gravity-displacement cycle is specified by the device manufacturer.**
   A. True B. False
6. **For hydrogen peroxide based sterilizers, AORN recommends that routine efficacy testing be performed at least daily on each cycle type, and preferably with each load.**
   A. True B. False
7. **FDA and ANSI/AAMI/ISO chemical indicator classifications and performance requirements are perfectly aligned.**
   A. True B. False
8. **Measures should be taken at the point of use to prevent organic material from drying on contaminated reusable items.**
   A. True B. False
9. **Ethylene oxide sterilized items should be transferred to a separate cabinet for aeration.**
   A. True B. False
10. **AORN considers the late arrival of loaner instrumentation to be a valid reason to perform IUSS.**
    A. True B. False

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