Best sterile processing managers anticipate, collaborate, stay up to date

With more than 36 years of experience in sterile processing, I have seen many changes occur, and I know what it takes to be an effective sterile processing (SP) manager. The goal of an effective SP manager is to determine where the department is now, where you want it to be, and how to get there. It is all about being prepared for change and keeping up to date. An effective SP manager does not go it alone but utilizes the expertise of staff from SP, infection control and prevention, and the operating room to collect data and ask for more resources to improve quality and patient outcomes.

Trends over time
The number of loaner instruments has increased, and so has their complexity. For example, the longer and narrower lumens makes them more challenging to clean, and without a good loaner policy it is more difficult to have in house implants cleaned, sterilized, and quarantined until the biological indicator (BI) result is available.

Steam sterilization cycles have been expanded to include extended cycles, which lead to logistical nightmares when it comes to preparing for the next day’s surgical schedule—and the schedule, of course, is also affected by loaner instruments not arriving on time. More low-temperature sterilization options are available, but with more lumen and material limitations to be aware of, it has been a challenge to ensure items are effectively sterilized.

I have seen advances in cleaning and disinfection equipment and chemicals, faster BI results, commercially available process challenge devices and Bowie-Dick test packs, more chemical indicator options, more options for containment devices, and a disposable wrap that is stronger and reduces the chances of tears. Another addition has been monitors for verifying the effectiveness of mechanical cleaning equipment, the instruments processed by mechanical and manual cleaning, and scopes.

Ensure easy access to current manufacturers’ IFU
The first step to ensuring that instruments are effectively processed is to have access to and read the current manufacturer’s instructions for use (IFU). Each staff member should be provided with education and training as well as the tools needed to execute the IFU and recognize that the objectives of the IFU have been met (eg, cleaning verification tools, BIs, etc).

Competency verification is done after education and training to verify the staffs’ ability to perform the critical steps in the processing and to evaluate the effectiveness of those steps.

An effective SP manager establishes a system that provides for easy access to the current manufacturer’s IFU. Requiring an IFU to accompany loaner instruments before they arrive, and reviewing to see if any IFUs have changed, will assist in ensuring you have the most up-to-date IFU for those instruments. Corporate websites may also provide IFUs.

Another option is using a service that provides (for a reasonable fee) up-to-date IFUs. Best Practice Professionals, Inc. (www.onesourcedocs.com, 1-800-701-3560)
can assist you in obtaining IFUs. The website describes the oneSOURCE Document Site as “an online, electronic binder of Manufacturers’ Instruction for Use documents for equipment and surgical instruments, with a search engine that provides multiple paths to needed documents.”

Searching is done by instrument catalogue number, manufacturer, or description. This system can be used as a facility-wide electronic binder by all departments in the healthcare facility.

An effective SP manager identifies and prepares a trainer, schedules sufficient time for training, and has the tools and the IFUs available. A competency testing schedule is established to include periodic and regular competency verification.

An effective SP manager never alters the IFU for any reason without contacting the corporate Sterility Assurance or Quality Assurance Services of the manufacturer to see if the changes (e.g., changes in the cleaning, packaging, or sterilization cycles or processes) have been validated. Request that information in writing.

If the change you want to make has not been validated by the medical device manufacturer, it is risky to make that change. Doing so could result in improperly processed medical devices and poor patient outcomes.

**Keep up to date and follow recommended practices**

The Joint Commission states that all policies and procedures should be aligned with evidence-based guidelines and/or professional organization guidelines. This information, along with the most up-to-date manufacturer’s IFU, is needed to keep the SP department’s policies and procedures current. The recommended practices to follow are published by the Association for the Advancement of Medical Instrumentation (AAMI), AORN, and the Centers for Disease and Control and Prevention.

The Joint Commission uses the most up-to-date Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013 (Consolidated Text) for surveys. An effective SP manager ensures that the SP department has the most up-to-date copy of AAMI ST79 and the most current edition of the AORN Perioperative Standards and Recommended Practices or access to the AORN documents through the OR.

The International Association of Healthcare Central Service Materiel Management (IAHCSMM) and AORN sell the AAMI ST79 recommended practice at membership prices. Another option is to ask the hospital library to purchase the documents for you to store and use in your department. Electronic versions of AAMI and AORN recommended practices are available to share between departments.

An effective SP manager ensures policies and procedures are updated to reflect both the up-to-date manufacturer’s IFU and the most recent changes to recommended practices. Choose a person on your staff to become the expert in standards and recommended practices and to be in charge of the updating. An effective SP manager needs to stay on the cutting edge of standards and recommended practices to assist with periodic review of policies and procedures.

**Require certification of all SP personnel**

AAMI ST79 states that all supervisory personnel should successfully complete a sterile processing management certification examination from either the Certification Board of Sterile Processing and Distribution (CBSPD, www.sterileprocessing.org) or IAHCSMM (www.iahcsmm.org) (Section 4.2). In addition, all personnel performing sterile processing activities should be certified as a condition of employment within 2 years of employment. New Jersey and New York currently have mandatory certification.

An effective SP manager is certified as a SP technician and manager and works with administration to develop a career path for employees that involves certifica-
tion. In addition, the manager is a member of the national and local IAHCSMM chapter, which provides education and an opportunity for interaction with peers about common problems and solutions. Other departmental staff should be encouraged to join IAHCSMM.

**Make informed purchasing decisions**

Sometimes new products enter the market before they are addressed in AAMI and AORN standards and recommended practices. Section 12 of AAMI ST79 on new product evaluation suggests what to consider when choosing a product for which there are no guidelines from AAMI or similar organizations.

An effective SP manager, along with the rest of the members of the multidisciplinary committee who are conducting a product evaluation, will review this list and AORN Recommended Practices for Product Selection in Perioperative Practice Settings. FDA clearance documents are the place to start. Read the labeling cleared by the FDA and compare with all the literature supplied by the company. Any discrepancies between the FDA and the literature, or totally different claims among different pieces of the literature, are red flags.

If you have questions about product claims, contact the FDA using MedWatch (www.fda.gov/Safety/MedWatch/HowToReport/defaults.htm). Also seek out experts’ opinions and relevant research articles published in peer-reviewed journals, along with reports from peers who are using or have trialed the product. Effective SP managers do their homework before making new product decisions.

**Identify quality process improvement programs**

The Joint Commission is interested in quality improvement processes that reduce the risk of transmitting infections associated with medical equipment, devices, and supplies (Standard IC.01.04.01) that are processed in the SP area. The first step in this process is to perform a risk analysis in SP to determine what risks are being taken that could lead to a sterilization process failure and healthcare-associated infections.

Here is a list of my top quality process improvement programs that are related to sterilization process failures. Every effective SP manager should be working on these process improvements.

- Loaner instruments not arriving on time for the cleaning and sterilization IFUs to be followed and the implants to be quarantined until the BI results are known.
  
  Time is the critical word here. Develop a loaner policy based on IAHCSMM’s documents that require loaner instrumentation to be received in the facility’s decontamination area at least 2 working days (48 hours) before a scheduled case for existing sets or 3 working days (72 hours) for new sets. This will ensure enough time to follow the IFUs (which should arrive before the sets) and comply with AAMI and AORN recommended practices.

- Reduce the number of implants released before the BI result is available. This can happen with a loaner policy with teeth and better planning and inventory.

  The Joint Commission wants SP departments to use the Exception Form for Premature Release of Implantable Device/Tray from Annex L in AAMI ST79 and to have in place a department of surgery policy with multidisciplinary input that addresses who can authorize early release of implants. The Commission suggests it be a surgeon, but a signature is not required on the exception form. Many hospitals do require the surgeon’s signature to stress the importance of making this decision to release implants before the BI results are available.

- Allow immediate-use steam sterilization (IUSS) only for instruments that are intraoperatively contaminated to reduce the risk of surgical site infections.

  The Commission will check to make sure you are collecting data on instances
when IUSS is used. (See Annex L in AAMI ST79 for an implantable device load record for data collection along with the Premature Release of Implantable form.) The Commission will then check to see if action is being taken based on the data. If surveyors don’t find that to be the case, they may cite the organization under the performance improvement standards.

- Monitor or verify the cleaning process to determine if instruments are clean. You cannot see microorganisms, bioburden, or inside lumens or crevices. Don’t become another news headline. Cleaning process monitoring tools are available and addressed in recommended practices.

Martha Young, MS, CSPDT, is president, Martha L. Young LLC, providing SAVVY Sterilization Solutions for Healthcare in Woodbury, Minnesota. She is an independent consultant with long experience in medical device sterilization and disinfection.

References


