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Learning Objectives

1. Develop a policy and procedure for documentation of sterilizer maintenance, product identification and traceability, and the results of routine sterilizer efficacy monitoring, sterilizer qualification testing and product testing.

2. Develop a policy and procedure for documentation of implant loads.

3. Describe how to use documented results to do a recall and solve sterilization process failures.

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Documenting the steam sterilization process

by Susan Flynn, BESC, CSPDT

Documentation, while not glamorous, is an essential element of the Sterile Processing department's Quality Control program. Commonly referred to as recordkeeping, documentation makes an inventory of the materials that have been processed and the results of the sterilization process monitoring. All data is incorporated into a paper or electronic log system or filed as individual documentation records. This documentation is essential in determining the reasons for sterilization process failures which can include human error, equipment failures, and/or poor sterilant quantity and quality. Documentation is also used when products need to be recalled in the healthcare facility. This self-study highlights the information required to document the steam sterilization process and to facilitate product recall of healthcare manufactured products. The main references used in the preparation of this self-study were:

- Association for the Advancement of Medical Instrumentation's (AAMI's) *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006).¹
- Association of periOperative Registered Nurses (AORN), *Recommended Practices for Sterilization in Perioperative Practice Settings*. AORN Standards, Recommended Practices, and Guidelines:2007.²

Work area and equipment

Work area

Controlling the temperature and relative humidity in the work area at recommended values helps minimize microbial growth, improve employee comfort, and prevent excessively dry materials from adversely affecting sterilization cycles. Recommended

values are provided in Table 1. It is the responsibility of personnel in each work area to record the temperature and relative humidity daily.

Mechanical cleaning equipment

Documenting the monitoring and verification of mechanical cleaning equipment is recommended as part of a complete quality assurance program because decontamination is such a critical step in device reprocessing. If available, the cycle printout should be reviewed and initialed. Verification methods include visual inspection of cleaned instruments, the use of test devices (e.g. metal coupons with test soil that simulates coagulated blood), or the use of artificial soil on medical devices.¹

Sterilizers - Maintenance record and calibration

A major part of recordkeeping is documentation of the maintenance of each sterilizer in a healthcare facility. This documentation "should include information to identify the equipment and to establish a continuous history of all scheduled and unscheduled service."¹ This information is important because it can be used to verify that the sterilizers are working, have appropriate preventive maintenance, were repaired when a problem was identified, and assist in troubleshooting when a sterilizer malfunctions or a sterilization process failure occurs.

According to ANSI/AAMI ST79:2006, a **maintenance record should be kept for each sterilizer**. This maintenance record should include:

1. date on which service was requested;
2. model and serial number of the sterilizer;
3. location of the equipment (healthcare fa-

Table 1: Recommended Temperature and Relative Humidity Values¹

| Work Area | Recommended Temperature ¹ | Recommended Relative Humidity ¹ |
|-----------------|--------------------------------------|---|
| Decontamination | 16°C to 18°C (60°F to 65°F) | 30% to 60% |
| Prep and Pack | 20°C to 23°C (68°F to 73°F) | 30% to 60% (ideally 50%, and not less than 35% for best results) |
| Sterile Storage | 20°C to 24°C (68°F to 75°F) | <70% |

- cility identification, if applicable);
4. name of individual from healthcare facility who requested and authorized service;
 5. reason for service request;
 6. description of service performed (e.g., calibration, repair);
 7. types and quantities of parts replaced;
 8. name of the person who performed the service;
 9. date the work was completed;
 10. handwritten or electronic signature and title of person who acknowledged completion of the work; and
 11. results of any post-maintenance testing performed, if needed, before the sterilizer was returned to service.¹

"These records must be maintained by the healthcare facility" for the time determined by state and local regulations, legal considerations, individual situation, and according to the facility's policies and procedures.¹ These records should be kept by all of the following:

- supervisor responsible for the equipment (e.g. sterile processing, OR, etc.);
- hospital engineering staff;
- service person;
- whomever deemed appropriate by the healthcare facility.¹

In addition to keeping a maintenance record for each sterilizer, **periodic calibration**, as specified in the manufacturer's operating manual, should be performed and documented. Recalibration should also be done after repair or replacement of any component that may affect sterilizer performance.¹

Product identification and traceability

This part of recordkeeping documents each item or product processed, assists in proper stock rotation, establishes accountability and assists with recalls. Both AAMI and AORN stress the goal of traceability. AAMI ST79:2006 states: "Ideally, every reprocessed medical device, especially an implant, should be fully traceable to the patient on whom it is used or in whom it is implanted; such traceability can be accomplished by recording the sterilizer load identifier on the patient chart or the patient name on the load record."¹ While AORN's practice guidelines reads: "Documentation should be maintained to allow for traceability of every load to the patient for whom the instruments are used."²



Figure 1:
Options for lot control identifier labels

Lot control numbers

Each item or pack should be labeled with a lot control identifier (sterilizer identification number or code, date of sterilization and cycle number). These lot control labels are typically bar-code labels printed as the sterilizer cart is being loaded or sterilization labels applied using a label applicator (see Figure 1).

Expiration dating

For proper stock rotation, each item should also be labeled with an expiration date or statement such as: "Contents sterile unless package is open or damaged. Please check before using."¹

For flash sterilization, labels are not used, but the following information should be generated for each sterilization cycle using a load record:

- sterilizer identification and cycle number;
- contents of load;
- time and temperature of exposure phase of cycle;
- signature or identification of operator;
- date and time of cycle.

Sterilization process outcomes

Chapter 10 of ANSI/AAMI ST79:2006 discusses the four essential elements of an effective sterility assurance program:

- Routine load release for both implant and nonimplant loads;
- Routine sterilizer efficacy monitoring;
- Sterilizer qualification testing;
- Periodic product quality assurance testing.

Details about performing each of these elements were provided in previous self-study articles.^{3, 4, 5, 6} This article focuses on the documentation requirements associated with each element.

Routine load release for nonimplant loads

The sterilization monitoring tools used to release a **nonimplant load** include the sterilizer's physical monitors, external and internal chemical monitoring of packages,

and the optional use of a Process Challenge Device (PCD or test pack) containing one of the following: a biological indicator (BI), a BI and a Class 5 integrating indicator, a BI and an enzyme-only indicator, a Class 5 integrating indicator, or an enzyme-only indicator.

Sterilization records for each cycle must be maintained either in a paper or electronic system, with electronic records recommended because they facilitate access to information for a quicker response when sterilization process failures occur. The information for each sterilization cycle includes:

- lot number;
- contents of load;
- exposure time and temperature if not on a recording chart;
- operator identification;
- results of BI testing, if applicable;
- results of the Bowie-Dick testing, if applicable;
- results of chemical indicator (CI) in the PCD (BI challenge test pack, BI challenge test tray, CI challenge test pack), if applicable;
- any reports of inconclusive or nonresponsive CIs in the load.¹

For flash sterilization, AORN recommendations state:

- Record the physical parameters for each cycle, and verify the results before the item is transferred to the point of use;
- Use a sterilization process monitoring device with each load to be flash sterilized;
- Documentation should be traceable to each patient;
- Document information on each load:
 1. Device(s) processed;
 2. Patient receiving item(s);
 3. Reason for flash sterilization.

Routine load release for implant loads

Monitoring tools recommended to release implant loads are the sterilizer's physical monitors, external and internal chemical monitoring of packages, and a PCD containing either a BI and a Class 5 integrating indicator or a BI and an enzyme-only indicator. Except in defined emergency situations, the implant should not be released until the results of the BI are available. AAMI ST79:2006 references the CDC to stress this point: "**The load should be quarantined until the results of the BI testing are available** (CDC, 2003a)."¹ If an implant is prematurely released before the BI result is available, the event should be documented using an implant exception

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form. This form requires providing the following information each time an implant is prematurely released:

- Name of implant prematurely released, patient and surgeon;
- Reason for premature release;
- What could have prevented premature release of the implant?

Documentation described in ST79 related to processing implants that may be new to your facility includes:

- Recording the results for the Class 5 integrating indicator or enzyme-only indicator now included in the BI PCD for implant loads;
- Implant Devices Load Record (sample provided in Annex L of AAMI ST79:2006);
- Written guidance defining emergency situations developed in consultation with infection control, surgeons, and risk management;
- Exception Form for Premature Release of Implantable Device/Tray (sample provided in Annex L of AAMI ST79:2006).

Implants and flash sterilization

Neither AAMI nor AORN recommend flash sterilization of implantable devices. If flash sterilization of an implant is done, the sterilization process monitoring results should be documented and fully traceable to the patient on whom it is used or in whom it is implanted.^{1,2} AORN's recommended practice states: "If an emergency situation makes flash sterilization unavoidable, a rapid-action biological monitoring device should be used along with a class V chemical integrator. The implant should not be released until the rapid-action indicator provides a negative result. After the rapid-action negative result is obtained, the implant can be released for use in the immediate situation."²

Routine sterilizer efficacy monitoring

Routine sterilizer efficacy monitoring of all steam sterilizers should be conducted weekly, preferably daily, using appropriate BI PCDs, to ensure their effectiveness in sterilizing medical devices. Remember that if a sterilizer is designed to run multiple types of cycles, each sterilization mode should be tested. In addition to the test BIs, incubate a nonprocessed BI from the same lot as a positive control each day a test BI is incubated.

Additionally, for dynamic-air-removal sterilizers, Bowie-Dick tests are conducted daily to evaluate the efficacy of the air removal and steam penetration. Document the results of all routine efficacy monitoring (CIs, physical monitors, Bowie-Dick

test, test and control BIs) using either a paper or electronic record keeping system.

Sterilizer qualification testing

Sterilizer qualification testing should be conducted in cooperation with the sterilizer manufacturer. Sterilizer qualification testing using a biological indicator process challenge device (BI PCD) is performed after sterilizer installation; sterilizer relocation; sterilizer malfunctions; sterilizer major repairs; and sterilization process failures.¹ Qualification testing is also performed when major repairs or changes are made to the utilities connected to the sterilizer that may affect its performance. These include: changes necessitated by water-main breaks, annual boiler maintenance, additional equipment loads that place a strain on the utilities, and installation of new boilers.¹

Three consecutive empty cycles (except in tabletop sterilizers where this testing is done in a full load) should be run with a BI PCD. In dynamic-air-removal sterilizers, this testing is followed by Bowie-Dick test packs (BD PCDs) run in three consecutive empty cycles.

Documentation of this verification that the sterilizer is functioning properly would include recording appropriate CI results (including the Bowie-Dick test result sheets for dynamic-air-removal sterilizers), physical monitor results (e.g. cycle printouts), and all biological indicator results (negative test BIs and positive control BIs).

Periodic product quality assurance testing of routinely processed items

Product testing is recommended because the BI PCDs used for routine and qualification testing present a known challenge to the sterilization process but do not necessarily reflect the same challenge as items routinely processed. Routinely sterilized products should be tested periodically, and testing should also occur when "major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type or material of packaging or wrapper."¹ The testing is conducted both to verify the effectiveness of the sterilization process and to avoid wet packs. Obtaining current recommended reprocessing instructions from the medical device manufacturer is a critical first step in conducting product testing.

As with any sterilization monitoring, documentation is important. In the case of product testing, document the test protocol, the test results (physical monitors, BI and CI results, and evidence of moisture) and any corrective action taken.

Recall of products processed within a healthcare facility

The objective of a recall is to "expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions such as quarantine of the sterilizer, notification of physicians and affected clinical departments, and surveillance of patients."¹

Each healthcare facility should have written policies and procedures for the recall of items from issued or stored sterilization process loads. These policies and procedures should be developed for compliance with the Safe Medical Devices Act of 1990 as it pertains to failures of reusable medical devices.¹ Documentation, from the lot control numbers and sterilization records to the recall report, is the major ingredient for an effective and timely recall. A computerized or electronic recordkeeping system can simplify the recall and the investigation of a sterilization process failure. With such a system, it is easier to review the various types of monitoring data and to identify items in the failure load, other loads from the specific sterilizer, and all loads recently processed by a particular operator. An electronic system may also permit access to sterilizer maintenance records, which may provide links to previous sterilization process failures, reasons for the failure, the resolution required, and the results of qualification testing of the sterilizer.

When to recall

In a healthcare facility, when a load of processed medical devices is released prior to obtaining the results of a BI and the BI subsequently indicates a sterilization process failure (i.e., is positive), a recall must be initiated. At that time, all medical devices processed since the last load showing a negative BI should be considered nonsterile, retrieved and reprocessed.¹ The only exception would be if it was determined that the sterilization process failure was a result of operator error such as running the incorrect cycle for the load.

A recall can also occur if, after the medical devices are released, a review of the monitoring data shows that the physical parameters were not met or internal chemical indicators from several packages from a load did not reach the desired endpoint.

How to do a recall

The key to an effective recall is immediate communication to appropriate personnel and departments responsible for retrieving the medical devices before they reach the patient. As soon as the BI is positive, recall all loads processed since the last negative BI.¹ Monitoring more frequently with a BI and

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obtaining results within a minimal incubation time (e.g., one or three hours) allows sterilization process failures to be identified much sooner, instruments to be turned around faster, costs associated with inventory and recall to be reduced, and patient outcomes to be improved.⁷

Recall report

A written report should be prepared following the recall. The report serves to document the recall and should include the following:

- The circumstances that prompted the recall order;
- The total number of products intended to be recalled and the percentage actually recalled;
- Surveillance measures taken if affected devices could not be retrieved and have been in contact with patients;
- Verification that recalled items were re-processed;
- Corrective action taken to prevent this situation from occurring again.

Summary

Documentation provides supporting historical records of the items processed and the outcome of the steam sterilization process, both of which are important parts of a Quality Control program. A healthcare facility needs clear policies and procedures in place that describe the documentation required for the sterilizers, sterilization processes, and recalls of processed medical devices. It is the responsibility of the leadership of the healthcare facility to ensure that these policies and procedures are in place and followed so that patient safety is maintained. Review your department's record keeping policies and procedures, especially those applicable to the sterilization of implants, to be sure they reflect current recommended practices. **HPN**

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Documenting the steam sterilization process

Circle the one correct answer:

- Daily recording of temperature and relative humidity in each work area is recommended.
A. True
B. False
- It is recommended that both a maintenance record and calibration record be maintained for each sterilizer.
A. True
B. False
- Product identification and traceability is needed for stock rotation, establishing accountability and assisting with recalls.
A. True
B. False
- The sterilization record for each cycle does not need to include the contents of the load.
A. True
B. False
- Perform product quality assurance testing to verify that medical devices are being properly sterilized and that packs/trays are dry when the medical device manufacturers' instructions for use are followed.
A. True
B. False
- A load containing implants should be quarantined until the results of the BI testing are negative.
A. True
B. False
- The sterilization process monitoring results of an implant should be documented and fully traceable to the patient on whom it is used or in whom it is implanted.
A. True
B. False
- Written documentation defining emergency situations in which an implant may be released before the BI is available should be developed in consultation with infection prevention and control, the surgeon and risk management.
A. True
B. False
- Documentation is the major ingredient for an effective and timely recall, beginning with lot control numbers and sterilization records to the recall report.
A. True
B. False
- A computerized or electronic record keeping system can facilitate a recall and the investigation of a sterilization process failure.
A. True
B. False

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