The right documentation!

An examination of sterilization record keeping

by Dorothy Larson, CSPDT

A question that often comes up in discussions about record keeping is “What type of documentation do we need to keep for our steam sterilization process, and how should information be recorded?” It is important to know not only what to document, but also the purpose for retaining pertinent information. Record keeping is an essential component of an effective sterile processing department’s quality assurance program. You may be aware that surveyors are paying close attention to this area, and have an expectation that everyone working in sterile processing has a clear understanding of their procedures. How does your knowledge of documentation stack up? A review of key information from the Association for the Advancement of Medical Instrumentation (AAMI) and Association of periOperative Registered Nurses (AORN) will equip you with needed information so that you can be assured you are documenting correctly!

Documenting with purpose

Whether the sterilization process is being done in a hospital’s CSSD or Operating Room, Ambulatory Surgery Center or Clinic, some essential information needs to be documented every time a medical device is reprocessed! Documentation, also commonly referred to as record keeping, documents materials that have been processed and the results of the sterilization process monitoring. While this might sound easy, proper documentation requires diligence by everyone involved as this data provides critical information for tracking processed instruments to the patient and assessing the reliability of the sterilization process. Sterilization documentation is used when:

- Products need to be recalled in the healthcare facility, and
- Determining the reason for a sterilization process failure.

Documentation provides a permanent record that you’ve done everything you said you did, from cleaning to product distribution. Simply put, documentation establishes accountability.

Product identification and traceability

An important aspect of quality control, this part of record keeping documents each item or product that is processed, assists in proper stock rotation, establishes accountability, and assists with recalls. “Accountability to the patient and surgeon for the sterility of a reprocessed device requires documentation that can be directly traced to the patient. Traceability of implants is especially important because the consequences of implant-related infections are particularly severe and result in increased morbidity and mortality.”

- AAMI: “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.”
- AORN: “Documentation of cycle information and monitoring results should be maintained in a log (electronic or manual) to provide tracking of the flashed item(s) to the individual patient.” “Documentation allows every load of sterilized items used on patients to be traced.”

Lot identification enables the retrieval of items in the event of a recall and the ability to trace quality concerns (e.g. failed internal chemical indicator). Each item or pack should be labeled with a lot or load control number, to include:

- date of processing,
- cycle number, and
- sterilizer identification number or code.

The types of labels commonly used are:

- bar-code labels printed as the sterilizer cart is being loaded, and
- sterilizer labels applied using a label applicator.

For Immediate-Use Steam Sterilization (I USS), or flash, labels are not used. Instead, information should be generated for each sterilization cycle using a load record.

To assist with proper rotation, each individual product should be labeled with an expiration date or statement that reads “Contents sterile unless package is opened or damaged. Please check before using.”

Product recall

Written 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. Healthcare facilities should establish a recall process 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.”
With certain sterilization process failures, e.g., 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) and the source of failure is not immediately identifiable, a recall must be initiated. A written report should be prepared following the recall, to document the recall. The report should include:

- Circumstances that prompted the recall order;
- 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 reprocessed;
- Corrective action taken to prevent this situation from occurring again.

**Immediate-Use Steam Sterilization (IUSS) cycles**

There has been an increased focus on IUSS, or flash, from the Joint Commission and the Centers for Medicare and Medicaid Services. This is a result of recent infection control issues regarding patient exposures to improperly reprocessed medical devices. All aspects of sterilization are being looked at, including documentation!

IUSS is the process designed for the steam sterilization of patient care items for immediate use. IUSS involves a high temperature ranging from 270-275°F / 132°C to 135°C with little or no dry time. The sterilization process used may be either gravity or dynamic-air-removal cycles. Items sterilized by IUSS are to be used immediately and not stored for later use or cycles. Items sterilized by IUSS are to be used immediately and not stored for later use or cycles.

There is sometimes confusion about what an IUSS cycle is. For example, if you switched from running a gravity cycle that has little or no dry time to a prevacuum cycle that has little or no dry time, or from using mesh-bottomed open trays to using reusable rigid containers, you might think that you are no longer “flashing.” Note however, if your flash sterilizer has either a prevacuum or gravity sterilization cycle with little or no dry time programmed, or if you are running reusable rigid sterilization containers in a cycle with little or no dry time, these are IUSS cycles and need to be documented as such.

AORN suggests that for each IUSS sterilization cycle, the information at right be recorded.

IUSS should be kept to a minimum. If you run IUSS cycles, all critical reprocessing steps must be done, the same as when processing a wrapped goods cycle. “Documentation of the flash sterilization process is necessary and should be consistent with the requirements applicable to and the practices used in documenting the routine processing of wrapped loads.”

**Sterilization monitoring tools**

Sterilization monitoring tools are used to help ensure the probability of sterility of a processed load. These include physical monitors, internal and external chemical indicators (CIs), biological indicators (BIs), and process challenge devices (PCDs), also called test packs or challenge packs. Each monitoring tool plays a distinct and specific role in monitoring the sterilization process, and results are used to determine the effectiveness of the sterilization process.

Sterility assurance requires continuous attention to sterilizer performance. Documentation requirements are associated with each of the four essential elements of an effective sterility assurance program:

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

<table>
<thead>
<tr>
<th>Non-implant</th>
<th>Implant</th>
<th>Checklist - Sterilizer Records: Nonimplant / Implant loads</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>X</td>
<td>Lot number (sterilizer identification number or code, cycle number, and date of sterilization);</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>Specific contents of the lot or load (including quantity, department, specific description of items);</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>Exposure time &amp; temperature (if not provided on sterilizer recording chart);</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>Name or initials of operator;</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>Results of Bowie-Dick testing, if applicable;</td>
</tr>
<tr>
<td>Optional testing</td>
<td>X</td>
<td>Results of biological testing (test and control);</td>
</tr>
<tr>
<td>Optional testing</td>
<td>X</td>
<td>Response of CI from inside the PCD (BI challenge test pack or test tray, or CI challenge test pack);</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>Reports of inconclusive or nonresponsive CIs found later in the load;</td>
</tr>
<tr>
<td>X</td>
<td>X</td>
<td>Time &amp; temperature recording chart, printer, or tape should be dated, reviewed and signed by the operator.</td>
</tr>
</tbody>
</table>

**Routine sterilizer efficacy monitoring**

This testing of all steam sterilizers should be conducted weekly, preferably daily, using appropriate BI PCDs, to ensure their effectiveness in sterilizing medical devices. If a sterilizer is designed to run multiple types of cycles, each sterilization mode should be tested. In addition to the test Bls, incubate a nonprocessed BI from the same lot as a positive control each day a test BI is incubated. If the sterilizer is dynamic-air-removal, Bowie-Dick tests are conducted daily to evaluate the efficacy of the air removal and steam penetration. Document results of all routine efficacy monitoring.

**Routine load release**

The following sterilization monitoring tools are used to release nonimplant and implant loads:

- **Nonimplant loads** - Sterilizer’s physical monitors, and external and internal chemical indicators. Optional monitoring can be done with a PCD containing a BI or BI and a Class 5 integrating indicator, or a PCD containing a Class 5 integrating indicator or Class 6 emulating indicator.

**Implant loads** - In addition to physical monitors and chemical indicators, each implant load should be monitored with a PCD containing a BI and Class 5 integrating indicator. (If an implant must be released on an emergency basis, the Class 5 CI provides additional information about the critical parameters of the sterilization process.) “The load should be quarantined until the results of the BI testing are available (CDC, 2008).” If an implant is prematurely released before the BI result is available, the event should be documented using an implant exception form. (See AAMI ST79, Annex L example.)


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Documentation of this verification provides evidence that the sterilizer is functioning properly.

- **Checklist – Sterilizer Qualification Testing**
  - Physical monitor results (e.g., cycle printouts);
  - Chemical indicator results (internal/external);
  - Bowie-Dick test results, if applicable;
  - Biological indicator results (negative test BIs and positive control BIs).

### Periodic Product Quality Assurance Testing

Biological indicator process challenge devices used for routine and qualification testing present a known challenge to the sterilization process but do not always reflect the same challenge as items routinely processed. Therefore, routinely processed products should be tested periodically, and when there are major changes made in packaging, wraps, or load configurations.

### Sterilizer maintenance and repairs (AAMI ST79, section 9.7)

For sterilizer repairs and preventive maintenance, records should be kept for each sterilizer.

#### Checklist – Sterilizer Maintenance/Repairs

- Date service was requested;
- Model and serial number of sterilizer;
- Location of the equipment (hospital identification, if applicable);
- Name of individual who requested and authorized the service;
- Types and quantities of parts replaced;
- Name of person who performed the service;
- Date work was completed;
- Signature and title of person who acknowledged completion of the work;
- Results of any post-maintenance testing performed, if needed, before sterilizer was returned to service.

### Document retention

How record keeping documentation is maintained varies from facility to facility. Would you be able to produce the proper records if, for example, there were an infection associated with an implant a year following surgery requiring investigation of the sterilization processing records? It is important to have an orderly filing system when events such as this occur. Documentation can be accomplished with the use of a paper or electronic record keeping system, or a combination of both. With a paper system, envelopes can be used to store sterilizer items, such as cycle printout tapes and Bowie-Dick test sheets. Load record cards and log books are other examples of paper record keeping tools. It is not so important the method used to collect the information as having complete and accurate records, and a system that will allow for easy retrieval of data. To this point, electronic documentation offers certain advantages, such as the ability to access past records instantaneously, as all load information is in one location.

### Mechanical cleaning equipment

- **Monitoring and verifying cleaning processes are important elements of quality assurance and all results should be documented.** Mechanical washers having digital readouts and cycle printouts should be reviewed for each cycle and initialed. This confirms that the washer completed all phases of the cycle. Ideally, cleaned medical devices should be traceable to the patients on whom they are used.1
  - AORN: mechanical instrument washers should be tested for proper functioning before initial use, weekly during service, and after major maintenance.3
  - AAMI: test mechanical cleaning equipment upon installation, weekly (preferably daily) during routine use, and after major repairs.1

#### Checklist – Mechanical Washers

- Verification testing results;
- Digital readouts are reviewed for each cycle;
- Cycle printouts are reviewed and initialed;
- Results of post-maintenance testing, following major sterilizer repair.

### Temperature and Relative Humidity controls

It is the responsibility of personnel in each work area to monitor and record both temperature and relative humidity (RH), daily (see Table 1). Some types of record keeping log books have a place to record the sterile processing department’s RH. An independent humidity monitor should be located in each area that requires controlled RH. Controlling the temperature and RH in the work area helps minimize microbial growth, improve employee comfort, and prevent excessively dry materials from adversely affecting sterilization cycles.

#### Table 1 - Recommended Temperature and Relative Humidity Values1

<table>
<thead>
<tr>
<th>Work Area</th>
<th>Recommended Temperature</th>
<th>Recommended Relative Humidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decontamination</td>
<td>16°C to 18°C (60°F to 65°F)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Prep and Pack</td>
<td>20°C to 23°C (68°F to 73°F)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Sterile Storage</td>
<td>20°C to 24°C (68°F to 75°F)</td>
<td>&lt;70%</td>
</tr>
</tbody>
</table>

With an electronic record keeping system, instrument tray labels are generated at Prep & Pack where they are placed onto packages, and are then scanned as the sterilizer cart is being loaded. This creates an individual load record that is stored electronically. Some instrument tracking systems provide cycle documentation by tying a detailed list of scanned load items to sterilization parameters and biological indicator results. Electronic record keeping systems can help reduce human errors.

The length of time sterilization records must be retained varies throughout the country, taking into account various state and local regulations, and any legal considerations. Each healthcare facility, with direction from the Risk Manager will need to determine the time that records need to be maintained.

### Documentation tools

Is your record keeping documentation system complete? It is critical to have manufacturer’s written instructions for all the medical devices you are reprocessing. You should have the proper tools to document recommended information as per AAMI and AORN, and from manufacturers of the products you’re using. Everyone involved in sterilization processing, in both the OR and CS, should be knowledgeable about what and how to record. If you find yourself questioning any document related procedures, take the time to ask for help from someone knowledgeable within your department, or consult the manufacturer, if applicable.

### Process improvements (CQI)

Documentation can be powerful when used with the intent of improving practices and patient outcomes. Continuous quality improvement (CQI) programs are recognized as an effective means of improving the performance of any process.1 Ask yourself the following:

- Are we running too many immediate-use steam sterilization (flash) cycles?
- Are we routinely releasing implants prior to having biological indicator results?

For routine sterilizer efficacy testing, both AAMI and AORN guidelines recommend running a BI PCD weekly, preferably daily and with implants. Some facilities choose to run a BI PCD with every load.

- Are you able to quarantine all loads until BI results are available, not only implant loads?

A review of record keeping documents could facilitate sterilization process improvements. “Trending data for the number of BI tests, number of BI failures for each sterilizer, education compliance (percent attending or percent passing tests or competency measures), time and completeness of sterilizer preventive maintenance, ability to locate all items during recalls, and completeness of test records are examples of measures to be considered when assessing the process.”1

Website links:
- www.hpnonline.com

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1. The patients on whom they are used.1
2. A review of record keeping documents could facilitate sterilization process improvements. “Trending data for the number of BI tests, number of BI failures for each sterilizer, education compliance (percent attending or percent passing tests or competency measures), time and completeness of sterilizer preventive maintenance, ability to locate all items during recalls, and completeness of test records are examples of measures to be considered when assessing the process.”1

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Sterilization is a process in which you cannot determine its effectiveness by inspection and testing of each product. Part of a quality process is risk analysis, which includes risk assessment, risk management, and risk communication. A risk analysis should be performed at least annually and whenever significant changes occur, and documented.

Summary
After a review of this information, take a look at your facility’s policies and procedures to find out if there are any gaps in your documentation system. Is there enough detail provided so that everyone understands what and how to document? Is everyone in CSSD and OR complying with established policies? Performing random audits of sterile processing personnel can be useful to ascertain a level of understanding and help develop proficiency. An educated and well-informed department plays a significant role in protecting the healthcare facility and the patient. Record keeping requires diligence. It is everyone’s responsibility to help ensure that proper documentation is being done for the safety of every patient!

References:
1. Association for the Advancement of Medical Instrumentation.

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Circle the one correct answer:

1. Product identification and traceability documents each item or product that is processed, assists in proper stock rotation, establishes accountability, and assists with recalls.
   A. True  B. False

2. A prevacuum sterilization cycle that has little or no dry time is not considered to be an IUSS (flash) cycle, and does not need to be documented as such.
   A. True  B. False

3. Documentation, or record keeping, documents materials that have been processed and the results of the sterilization process monitoring.
   A. True  B. False

4. A load containing implants may be routinely released before results of the BI testing are available.
   A. True  B. False

5. When reviewing a cycle printout tape you only need to verify that the parameters of time and temperature were met.
   A. True  B. False

6. Documentation of the IUSS (flash) cycle is necessary and should be consistent with requirements for routinely processed wrapped loads.
   A. True  B. False

7. Personnel in sterile processing are responsible for monitoring and recording both temperature and relative humidity in their work areas.
   A. True  B. False

8. Maintaining documentation of cycle information and monitoring results is not necessary to provide tracking of the flashed item(s) to the individual patient.
   A. True  B. False

9. A recall procedure should be established to expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions are taken.
   A. True  B. False

10. The length of time sterilization records are retained varies throughout the country.
    A. True  B. False

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References:
1. Association for the Advancement of Medical Instrumentation.

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