

DOCUMENTATION – YOU HAVE GOT TO DO IT

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****This in-service has been Approved by the CBSPD, Inc. for 1 CEU.**

Someone once said, “do what you document and document what you do”. Truer words were never spoken. There are many processes we document in our daily lives however in healthcare, documentation becomes essential. Today, we live in a litigious society, meaning, people get sued for anything and everything. When it comes to healthcare, lawsuits are almost “assumed” if anything goes wrong, whether it was preventable or not!

Sterile Processing personnel should be following good manufacturing practices; these practices ensure a consistent product each and every time it is produced. Part of the process is documentation. In addition, to track and investigate problems, it is essential to know every individual who took part in the processing of the device, e.g. who cleaned it, who assembled it, who sterilized it and who distributed it. This is similar to the tracer methodology which the Joint Commission (JC) is requiring. With tracer methodology, the JC requires that the facility be able to fully trace a device to the patient.

For example, in the newspaper, you read about a recall on a food product. The company is able to tell the lot number, when the product was made, everyone who had a part in the process, when shipped, where shipped to, etc. This is all part of a quality system.

There are many types of documentation in sterile processing. Some do not relate to the process it self, for example, we must document the time we report to work and when we leave. This is required for payment of wages. Time records can be audited by the Department of Labor, so it is important that these records are maintained properly. Documentation can be required for other reasons such as return from a medial leave (clearance to return), etc.

However, in the processing area, there are many types of documentation needed. Let’s look at some of them.

Orientation – One of the most important pieces of documentation is the Orientation Guide form. This form documents the training the employee has received. It is proof that the employee received the training needed to be successful in the job. Usually, each step of the way a return demonstration is requested to make sure the employee has learned the specific task. These forms, once completed, should be retained in the employee’s file. The Orientation Guide should also document the facility orientation date, and all safety related training such as the date the employee reviewed the Material Safety Data sheets, safety manual, infection control manual, etc. In addition, a review of the dress code for the department (including personal protective equipment required in the Decontamination Area) should be documented.

Annual Competency - This documentation is required by the Joint Commission (JC). It requires that the facility verify specific competencies for each employee on an annual basis. Usually several key tasks or knowledge areas are selected and employees are questioned or asked to demonstrate the task without error. This annual testing is important because it verifies the competency of employees and may indicate areas of additional training needed.

Continuing Education - With the emphasis on mandatory certification, it is important for employees to keep careful records of their certification. All continuing education towards re-certification should be documented. Make sure you do not leave the Seminar without your certificate and make sure the certificate has been approved by the certifying board. The certificate should state the number of points approved for the program. These certificates usually cannot be replaced especially after a year so keep them in a safe place so you have them for re-certification when needed.

Environmental Documentation - This would include daily documentation of the AAMI recommended temperature and humidity levels in the Decontamination, Prep/Packaging/Sterilization and Sterile Storage areas. All environmental cleaning should be documented as well as sterilizer cleaning.

Maintenance records - All installation documentation, including installation testing, should be documented. All preventive maintenance on sterilization and processing equipment should be documented and records retained for the life of the equipment. Repairs should also be documented.

Decontamination - In the Decontamination area, in addition to the specific training received, all items processed should be documented. This can be accomplished with a surgical instrument tracking system or a manual system. The manual system can be a form that is made up with the date, shift, technician's name and then a list of devices processed. A listing of the number and types of patient care equipment should be documented. This documentation should include any testing performed on equipment.

Prep and Packaging - All sets assembled should be documented on a log by person. In addition, the initials of the preparer or an ID# should be prominently displayed on each package processed, even peel packs. If special testing performed (e.g. verification of the integrity of insulation on laparoscopic instruments) this should be documented. Lubrication of drills should be documented. If sharps are routinely sharpened, have the repair service document the date and keep a record.

Sterilization - the majority of the documentation is in the sterilization area. This area requires the following documentation:

- All items processed should be recorded on a log. Some facilities use a preprinted envelope. The contents of each load should be recorded; the records should include the number of items, a description of the items, and the using department. In addition, the inclusion of a BI test pack should be documented on the log form for all cycles containing BIs. This information should be specific rather than generic - six OR Mayo scissors, not six OR peel packs. Any PCDs included in the load should be documented as

well. All information should be written neatly and legibly. The use of whiteout to correct errors is prohibited, because it could suggest that the records were altered. Instead, the operator should draw a line through the incorrect information and initial it.

- All cycles run, including dynamic air-removal tests and aborted cycles, must be documented.
- All sheets from dynamic air removal tests should be saved.
- All BI test results should be carefully documented. This includes the lot control number of the BI vial, the lot control number of the control vial, the time the BI was placed in the incubator or autoreader, the time it was removed and read, the name of the person(s) incubating or final reading the BI, etc.
- The sterilizer printouts should be removed (either after each cycle or at the end of the day) and placed inside the preprinted envelope along with any CIs run in the load. To identify the sterilizer and load, a lot control sticker indicating the load number should be affixed to the CI or printout.
- The printout for each cycle run (regardless of the sterilization method) must be reviewed by the sterilizer operator and signed verifying all parameters were met,
- Verification of the results of the chemical indicators should be documented on the Sterilization Log.

LOT CONTROL - Lot control numbers are required so that each sterilized device can be tracked. This information is important in the event of a sterilizer malfunction necessitating a recall of the processed items. Each sterilizer should be labeled with a number (e.g., #1, #2) so that sterilizers can be differentiated in the event of a sterilizer malfunction. The lot control information, which should include the sterilizer number, the cycle or load number, and date of sterilization, is usually affixed to each item with a lot control label gun. It is important to verify that the lot control information is accurate before affixing the labels to the packages. Therefore, the CS/SPD technician should double-check the lot control information before each cycle.

Event Related Sterility Dating - Monitoring of compliance with Event Related Dating is recommended. Each month a different area of the facility should be visited and the storage areas reviewed for compliance. Look for trays that have damaged packaging or dust covers that have been removed, stained packages, storage under sinks, etc. Note the non-compliance issues and discuss with the manager for the area. The Sterile Processing sterile storage area should also be monitored for compliance with cleaning of shelves and bins, no cardboard in the area, etc. When performing monitoring, look for expiration dates for dated items from outside manufacturers and remove them if outdated.

Implants - All implants should be documented on the Sterilization Log form however it is helpful to keep a separate Implant Log form to help identify implants in the event of a recall. A sample Implant Log form is at the end of this Inservice. Implants should not be released until the result of the biological test is known. This is an AAMI, AORN and CDC

recommendation. However, if there is a documented emergency and an implant must be released before the BI test result is known, this should be documented on the Waiver form. A sample form is available in the AAMI ST-79 document.

CJD - Due to the difficulty inactivating prions, when known or suspect patients have eye, brain or spinal cord surgery, their instruments should receive special prion processing. This should be documented on a form similar to the implant log to be able to quickly identify instruments and how they were processed.

Rigid Container Testing - Rigid containers require pre-purchase biological testing as well as ongoing (annual) bi testing. The pre-purchase and annual testing should be documented and records kept where they can be retrieved. Some facilities copy the results from the BI record book and save them in a file folder labeled Rigid Container testing so facilitate location of the records.

Recalls - If there is a positive BI a recall of products processed in the affected sterilizer, back to the last known negative BI must be performed. The actions taken must be documented. Usually, as items from the affected loads are retrieved, a line is placed through the description on the Sterilization Log form. If the device cannot be located or was already used, the item should be circled and noted (not found, already used). Any similar process is acceptable as long as the records show who retrieved the items, what items were retrieved and when they were retrieved.

Outside Manufacturer Recalls - Sometimes manufacturers have recalls of their products. If the product is used within your department or dispensed from your department, it is your department's responsibility to retrieve the product from the various locations and return to the manufacturer per their instructions. The same documentation as an in-house recall is needed; when the recall notice was received, how it was received (e.g. FAX, email), when the products were retrieved, from what locations were they retrieved and when, where and how the recalled items were shipped back to the manufacturer.

References:

Association for the Advancement of Medical Instrumentation. *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities. ST-79. 2006.*

Basics of Sterile Processing, First Edition, Sterile Processing University, LLC, 2006.

POST TEST QUESTIONS: Documentation

This in-service is Approved by the CBSPD for 1 CEU. Complete this post test and follow the directions at the end of the test for payment and results.

1. The Joint Commission requires facilities to practice tracer methodology. This means the facility must
 - A) be able to trace the patient from admission to discharge.
 - B) be able to trace the patient to their physician.
 - C) be able to fully trace a device to a patient.
 - D) be able to fully trace a defective product.

2. Why should processed items from a known or suspect CJD patient be documented?
 - A) In order to document the number of CJD cases.
 - B) In order to document the extra workload in SPD.
 - C) To document how often trays are reused.
 - D) To document the special prion processing given to the items.

3. What environmental documentation should be performed daily in the Sterile Processing area?
 - A) Temperature and workload in Decontam.
 - B) Temperature and workload in Prep/Packaging.
 - C) Temperature and humidity levels in all work areas.
 - D) Temperature and humidity levels in the sterilizer access room.

4. Annual competency testing is important because
 - A) it verifies competencies of employees.
 - B) it verifies problem employees.
 - C) it helps new employees learn.
 - D) it helps identify productivity.

5. One of the most important tests to document in the Prep and Packaging area is:
 - A) strength of packaging materials.
 - B) ratchets hold on clamps.
 - C) tips of forceps approximate.
 - D) integrity of insulation on insulated instruments.

6. Lot control and documentation of all items processed in each load and each sterilizer is important because it
 - A) documents the workload in SPD.
 - B) identifies devices if they need to be recalled.
 - C) describes the items used in surgery each day.
 - D) identifies the workload for each sterilization technician.

7. Rigid container BI testing should be performed
 - A) before purchase and weekly thereafter.
 - B) before purchase and monthly thereafter.
 - C) before purchase and semi-annually.
 - D) before purchase and annually.

 8. Sterilization printouts must be signed
 - A) at the end of each cycle.
 - B) at the end of each shift.
 - C) at the end of each day.
 - D) at the end of each month.

 9. One of the most important pieces of documentation is the
 - A) CJD log.
 - B) Implant log.
 - C) Orientation Guide.
 - D) MSDS Manual.

 10. Continuing Education records are needed
 - A) to get reimbursed for Seminars.
 - B) to get a promotion.
 - C) to document the continuing education received.
 - D) to help obtain additional responsibility in the department.
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Directions for Payment and Results

This in-service = \$10

Re-do's = \$10 each

No refunds (all sales are FINAL), prices subject to change.

Payment is accepted in the form of a Credit Card, Facility Check, or Money Order only.
Sorry, no personal checks.

Please see the form on the following page.

Upon passing this in-service, your certificate will be mailed to you within 7-10 business days.

Please fill out the form below and submit it with your payment and the quiz to:

Sterile Processing University, 59 Allerton Road, Lebanon, NJ 08833.

Name: _____

Mail to: Home Work

Full Address: _____

Phone: _____

Email: _____

For Credit Card Orders Only: Visa MasterCard Discover

Credit Card Number: _____ Exp. Date: _____

Person's Name on Card: _____

Card Billing Address: _____

If you have any questions, please email heidi@spdceus.com

Thank you!