Record-keeping for Central Sterile Supply Departments

CRCST SELF-STUDY LESSON PLAN

LESSON NO. CRCST 113
(Technical Continuing Education-TCE)

Lesson Author
Patti Koncur, CRCST, CHMMC, ACE
Corporate Director, CSP
Detroit Medial Center, Detroit Michigan

Lesson Reviewer
Susan Klacik, ACE, CHL, CRCST, FCS
CSS Manager
St. Elizabeth Health Center • Youngstown, OH

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LEARNING OBJECTIVES:

1. Discuss education documentation for Central Sterile Supply Department employees.
2. Review record-keeping requirements for high temperature sterilization.
3. Present record-keeping requirements for low temperature sterilization.
4. Explain record-keeping requirements for high-level disinfection.
5. Summarize record-keeping requirements for washer-decontaminators.
6. Describe record retention requirements.

Technicians are the most important link in the record-keeping system within their Central Sterile Supply Departments (CSSDs). While almost every task performed during every work shift is recorded, documentation still does not receive the priority attention that is necessary for an activity that is critical to the success of the department.

Analyzing documentation is, arguably, not very exciting; however, properly developed and maintained records provide verification of a process that was well done and another process that may have failed. Although record-keeping has always been important, today's healthcare environment requires increasingly careful attention to this very important responsibility. In this lesson, you'll learn about some of the most important CSSD records that must be maintained.

Objective 1: Discuss education documentation for Central Sterile Supply Department employees.

In the past, the facility's Human Resources (HR) department was responsible for most employee-related record-keeping. Although Human Resources personnel still maintain some records, many other records have now become the responsibility of CSSD staff.

Surveying organizations, including The Joint Commission, the Centers for Medicare and Medicaid Services (CMS), the International Standards Organization (ISO), and the Occupational Safety and Health Administration (OSHA), look for proof that all CSSD employees have been properly trained and are competent in their job. Therefore, new employee departmental orientation, ongoing training and annual competency records must be current and readily available for survey staff. These documents must be specific and detail the training and competency level for specific tasks listed in each employee's current job description, including those related to the decontamination, assembly, sterilization, and distribution processes. Documentation regarding safety training to handle hazardous chemicals used within the department, to use Material Safety Data Sheets (MSDSs), and to update employees about the facility's hazard communication program must also be available. All of these training records must contain the date and a description of the training and the results of any competency testing, as well as the signature of the person observing the competency process.

OSHA requires records of employee injuries, such as needle sticks, sharps incidents, ethylene oxide (EtO) exposure, and information about job-related illness, to be maintained. Documentation about the type and level of treatment, and the severity of the injury or illness, is required. These incidents must be maintained in a log and reported at least annually to OSHA. The information is used to evaluate work place safety and will become the basis for recommendations or requirements about improvements, if any, that should be made.

Objective 2: Review record-keeping requirements for high temperature sterilization.

High temperature (steam) sterilization is the most common type of sterilization performed in healthcare facilities. Steam sterilizers must be effectively maintained to ensure proper operation. Sterilizer manufacturers must provide information about the proper use and maintenance of their equipment. Sterilizer maintenance should be performed by a qualified service technician who may be employed by the healthcare facility, the equipment manufacturer or a third-party provider.

All sterilizer service should be documented and retained at least for the life of the equipment. Records of maintenance and repair should contain at least the following information:

- Identity of equipment, including serial number
- Date of repairs
- Type of repairs
- Parts utilized

- Verification testing
- Follow-up action, if necessary
- Name of the person performing the maintenance or repair

Service records should be reviewed periodically to determine if there are repairs or trends that require further analysis. Examples include tracking data, such as wet packs, positive biological indicators, and other sterilizer process failures. Note: records should also be kept of the sterilizer cleaning schedule.

In addition to the above records, the Association for the Advancement of Medical Instrumentation (AAMI) suggests several routine tests, the documentation of which is reviewed by surveying entities, such as The Joint Commission:

- Biological indicator (BI) process control devices (PCDs) should be utilized in all steam sterilizers. Their use is required after sterilizer installation or major repair. Standard operating procedures have historically required that a PCD be run at least weekly, although it was always recommended that one PCD be run daily. Today, there is a growing trend for the use of a biological PCD with every sterilizer load. Note: a BI is required with each sterilization cycle containing implantable items.
- Dynamic air removal sterilizers require the use of an air removal (Bowie-Dick) test for each sterilizer at least each day that it is used. This test should be run and documented at least daily before the first process load and after any steam sterilizer shut-down or major repair.
- A lot control number must be affixed to each package that is sterilized. This will allow facility personnel to trace a sterilized package to the exact date and processing time, sterilizer and load contents if there is the need for a recall. Lot control numbers should be documented and retained with all sterilizer load information.
- A load log should be maintained to document every item sterilized in each sterilizer load. The log should also contain the sterilizer cycle parameters specific to the cycle documented.

This information can be manually documented on the log or in a computer tracking system. A good practice is to attach the data log strip to the manual log sheet so all pertinent information will be in one location for easy retrieval. Parameters that should be documented include at least the sterilizer's temperature and cycle time, and the name of the CSSD technician running the cycle.

Documentation for a flash sterilizer is the same as for terminal sterilizers with the exception of the lot control numbers. However, flash sterilizer documentation should be traceable to the exact patient on whom a flashed item was used.

Objective 3: Present record-keeping requirements for low temperature sterilization.

There have been many advances in low temperature sterilization processes in recent years. These sterilization cycles are more complex than their steam sterilizer counterparts, and it is very important that these cycles be carefully monitored and documented. In addition to the requirements discussed for steam sterilization above, there are other documentation requirements for low temperature sterilization:

- Biological indicators must be run in every low temperature cycle, and BI results must be documented.
- EtO sterilizers require more documentation than other types of low temperature sterilizers because EtO has been classified as a mutagen (it may cause changes in human genes) and a carcinogen (it may cause cancer). Although there are no standards that regulate EtO sterilization in every state, OSHA requires that exposure levels in work area breathing zones be carefully monitored. This should be done to obtain a baseline followed by ongoing monitoring to ensure compliance within the regulated levels of 1.0 part per million (ppm) and the action level of 0.5 ppm. To date, there is no definite frequency of air sampling testing required although twice a year is widely used. Documentation should include:
  - Date of air sampling
  - Equipment used for air sampling
  - Duration of air sampling
  - Description of the sterilization process, including the area in which the sterilizer is installed and protective equipment, if any, utilized by employees
  - Name and social security numbers of the employees monitored
  - EtO concentration level
  - Proof that the results were shared with the monitored employees

If an actual EtO exposure has occurred, its documentation must contain the above information. As well, records should indicate the written opinions of any physicians, and a plan to return exposure concentrations to below the action level. These documents must be retained for at least 30 years after the affected employee's last day of employment.

Objective 4: Explain record-keeping requirements for high-level disinfection.

High-level disinfection has become more common in recent years to process semi-critical items (those which contact non-intact skin or mucous membranes) such as expensive flexible endoscopes. The most common chemicals used for high-level disinfection are glutaraldehyde and Ortho-Phthalaldelyde (OPA). While both of these chemicals are effective disinfectants, their concentration must be monitored to ensure that the products remain effective. Due to the complex processes needed to clean and high-level disinfect complex scopes, more record-keeping is required. Current documentation requirements are:

- High-level disinfectant solutions must be tested at least each day of use. The manufacturer of the high-level disinfectant provides recommendations for their product, and their recommendations must be followed. Most manufacturers recommend testing the solution prior to each use to assure the solution is effective.
- Expiration date of the disinfectant.
- Expiration date of the test strip.
- Testing results (pass or fail) for the disinfectant's concentration:
  - Glutaraldehyde must be 2% or greater.
  - OPA must be 3% or greater.
- Identification of the person conducting the test.
- Items disinfected; include serial number, if appropriate.
- Identification of the person disinfecting the instruments.

Objective 5: Summarize record-keeping requirements for washer-decontaminators.

As instrumentation becomes more complex and difficult to clean, cleaning processes must

be documented to ensure they are effective. As with sterilizers, washer- decontaminators require a routine maintenance plan with documentation of repairs and maintenance. ANSI/AAMI ST79 recommends the routine monitoring of the temperature of washer-disinfectors.[1] This documentation can be achieved using the data log strip, if one exists. If it does not, manual documentation will be required. It is also recommended that the cleaning ability of the washers be monitored and documented.

Several products are commercially available to monitor both the temperature and the cleaning ability of this equipment. Documentation should include the type of test utilized and its results, the date of the test, and the identity of the person performing the test.

Objective 6: Discuss record retention requirements.

With the exception of EtO exposure documentation, there are no set standards for records retained to document the above processes. Storage times should be set in conjunction with the facility's Risk Management and Legal departments. Many facilities retain records for three years while other organizations, especially those who treat newborn babies, retain them for 21 years. Since these are important documents, they should be properly stored to ensure they are safely and effectively protected throughout the storage period.

The volume of information that must be retained and stored is significant and, in this age of computerization, electronic rather than hard copy storage makes sense. Departments that use an electronic instrument tracking system can use computerized storage for many tray processing records and, in some cases, they have the ability to store sterilization and biological records, as well.

Facilities that do not use an electronic instrument tracking system or that can only track partial sterilizer or washer records can still computerize their information because most facilities can scan documents into their standard desktop computer system. If this cannot be done within the department, one can check with mailroom or copy center personnel to learn see if this task can be accomplished there. Sterilizer and washer records can be scanned into a PDF file so the information will remain secure while in computerized storage. If this method will be implemented, ensure that the files are organized in a manner, such as by date or equipment type, to allow for easy understanding for anyone who may access these files.

Maintenance and cleaning records can be entered into any word processing program available and can easily be sorted by each specific piece of equipment and/or repair type. Most hospital human resources and employee health records are already computerized, at least to some extent, and they can be retrieved by authorized personnel as needed.

In Conclusion

Documentation of CSSD processes is an important task with critical implications for the department, facility, physicians, and patients, among other constituents. Central Sterile Supply Department leaders who emphasize the need for ongoing education and accurate record-keeping, beginning at the time of orientation and continuing during initial training, influence the culture of their department. This, in turn, promotes the concept that documentation is integral to the "way things are done," rather than just being a time-consuming task that must be completed to comply with requirements.

Endnote

1 AAMI. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. ANSI/AAMI ST79 (7.6.2.3). 2006.

References

U.S Department of Labor (www.OSHA.gov). Process Safety Management of Highly Hazardous Chemicals (Regulation 1910.119).

ANSI/AAMI ST79: 2006. Comprehensive Guide to Steam Sterilization and Sterility Assurance.

Central Service Technical Manual. Seventh Edition. Chicago, IL. International Association of Health Care Central Service Materiel Management. 2007. (See Chapters 10,12,15,16, and 21).

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Quiz No. CRCST 113 (CIRCLE THE CORRECT ANSWER)

Lesson 113 •July 2010 • Lesson expires July 2013

Objective 1

1. A record of on-the-job employee injuries or illnesses is required by:
   a. The Centers for Medicare and Medicaid Services (CMS)
   b. The Joint Commission
   c. The Occupational Health and Safety Administration (OSHA)
   d. The International Standards Organization (ISO)
2. Annual competency documentation is required by:
   a. The Joint Commission
   b. The Centers for Medicare and Medicaid Services (CMS)
   c. The Food and Drug Administration (FDA)
   d. A and B above
3. Increasingly, the responsibility for employee record-keeping has moved from the _____ department to the _____ department:
   a. CSSD; HR
   b. HR; CSSD
   c. CSSD; Legal
   d. Legal; CSSD
4. Records concerning employee health _____ usually maintained within the CSSD.
   a. Are
   b. Are not
5. Documentation of training records must include all of the following except:
   a. Handwritten notes taken by the trainee
   b. Date of the training
   c. Description of training
   d. Results of competency testing, if any

Objective 2

6. Sterilizer repair records should be retained:
   a. For three years
   b. For five years
   c. For the life of the sterilizer
   d. None of the above
7. A BI PCD should be run in a steam sterilizer:
   a. With every load
   b. To verify the sterilizer's operation after installation
   c. With all loads containing implants
   d. B and C above
   e. All the above
8. Documentation for flash sterilizer cycles should include:
   a. All documentation required for terminal sterilizers
   b. A means to trace the item sterilized to the patient on whom it was used
   c. Results of the BI PCD, if run
   d. B and C above
9. A Bowie-Dick test should be run each day that a _____ sterilizer is used.
   a. Flash
   b. Ethylene Oxide
   c. Dynamic air removal
   d. All the above

Objective 3

10. Monitoring the low temperature sterilization process includes:
    a. Documentation of cycle time and temperature
    b. Documentation of load contents
    c. Documentation of biological indicator results
    d. All the above
11. Ethylene Oxide has more stringent monitoring requirements than other types of low temperature sterilization.
    a. True
    b. False
12. OSHA _____ established standards that regulate EtO sterilization in every state.
    a. Has
    b. Has not
13. Documentation of air sampling tests that show actual EtO exposure has occurred must be retained for at least _____ years after the employee's last day of employment.
    a. 15
    b. 20
    c. 25
    d. 30

Objective 4

14. High-level disinfectants should be tested:
    a. According to the recommendations provided by the disinfectant manufacturer
    b. Before disposal
    c. At least weekly
    d. Right after preparing the disinfectant for use
15. High-level disinfectants have become more common in recent years to process _____ items.
    a. Critical
    b. Semi-critical
    c. Non-critical
    d. Critical and semi-critical
16. Testing results for high-level disinfectant solutions _____ include the exact concentration of disinfectant in the solution.
    a. Must
    b. Need not

Objective 5

17. Testing of washer-decontaminators:
    a. Should be done daily
    b. Should be done after every cycle
    c. Should be done on a routine basis
    d. Cannot be effectively done at this time
18. Record-keeping documentation for washer-decontaminators should include all of the following except:
    a. Water hardness
    b. Date of test
    c. Identity of person performing test
    d. Type of test utilized
19. Standards for length of record retention have been established for almost all types of sterilization equipment.
    a. True
    b. False

Objective 6

20. CSSD records should be stored for:
    a. 3 years
    b. 10 years
    c. 21 years
    d. For the storage time determined by the facility

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