Documentation for Instrument and Equipment Reprocessing
LEARNING OBJECTIVES
1. Identify education documentation for reprocessing employees
2. Review documentation requirements for high temperature sterilization
3. Define documentation requirements for low temperature sterilization
4. Explain documentation requirements for high-level disinfection
5. Summarize documentation requirements for washer-decontaminators
6. Describe record retention requirements

DOCUMENTATION IS THE MOST IMPORTANT LINK TO AN ADEQUATE record-keeping system relating to instrument reprocessing. 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 instrument reprocessing records that must be maintained.

OBJECTIVE 1: DISCUSS EDUCATION DOCUMENTATION FOR REPROCESSING 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 CS staff.

Surveying organizations, including The Joint Commission (TJC), 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 employees have been properly trained and are competent in their specific job duties. All training, orientation and competency documents may be reviewed by the surveyors, especially those pertaining to critical functions such as sterilization and sterilization documentation. Therefore, departmental orientation, ongoing training and annual competency records must be current and readily available for survey staff. 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 workplace safety and will become the basis for recommendations or requirements about improvements, if any, that should be made. When a pattern of employee injuries is discovered, documentation of education and training relating to the correction of the incidence must be maintained.

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 TJC, CMS, the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) and the Accreditation Association for Ambulatory Healthcare (AAAHC):

- Biological indicator (BI) process control devices (PCDs) should be utilized in all steam sterilizers. These monitoring devices are 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.1,2 Today, there is a growing trend for the use of a biological PCD with every sterilizer load as an improved patient safety initiative resulting in a consistent standard of care for each patient. Note: a BI and a class 5 chemical integrating indicator is required with each sterilization cycle containing implantable items.1,2

- 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.1,2

- 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.1,2

- 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.1,2

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 person running the cycle.

According to AORN, documentation for immediate-use steam sterilization (IUSS) load should include:

- Load contents
- Patient IUSS items were used on
- Type of cycle (e.g., gravity-displacement or dynamic air-removal)
- Cycle parameters used (e.g., temperature, duration of cycle)
- Load monitoring results
- Date and time the cycle was run
- Operator information (e.g., person who initiated the cycle, person who retrieved the items form the sterilizer), and
- The reason IUSS was necessary2

It is important that IUSS cycles are traceable to the exact patient on whom item(s) was used.1,2

If it is necessary to use IUSS on an implant due to an emergency, documentation describing what could have prevented the need for an IUSS cycle should be completed. As part of a quality monitoring system, this record can be helpful in determining problems, trends, or circumstances that can be addressed to prevent future IUSS of implants.2

**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:

- Written documentation for each specific device should be obtained from both the device manufacturer and the sterilizer manufacture of the acceptability of using a low temperature sterilization.2
- In every low temperature cycle, BIs should be used to monitor sterilizer efficacy and the BI results must be documented. Requirements for routine sterilizer BI efficacy monitoring for low temperature sterilization include:
  - EtO sterilization – in every load
• Hydrogen peroxide gas plasma sterilization - daily, preferable with every load
• Hydrogen peroxide vapor sterilization – in accordance with manufacturers’ instructions, and
• Ozone sterilization – in accordance with manufacturers’ instructions.2

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 employees4

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.8,9

OBJECTIVE 4: EXPLAIN RECORD-KEEPING REQUIREMENTS FOR HIGH-LEVEL
High-level disinfection (HLD) 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 HLD chemicals used are glutaraldehyde and Ortho-Phthalaldehyde (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. Documentation should be completed to demonstrate compliance with regulatory accrediting agency requirements and identify trends.7 Current HLD documentation requirements include:
• Identifying the patient (when applicable)
• The physician and the procedure
• Date and time HLD was performed
• Type and lot number of HLD used
• The Load contents (description, model and serial number, if applicable)
• Identification of person cleaning, disinfecting, rinsing, and transporting the device(s)
• The method of cleaning
• Identification of mechanical decontaminator (if used)
• Test results before each load showing the solution was at the proper concentration and not past the expiration date
• Temperature of the disinfection
• Length of time items were submerged
• Verification of rinsing of the disinfected item
• Use of correct BI and CI for automated processors
• Testing results of electrical instruments, and
• Disposition of defective equipment5,10

Employers must provide employees with hazardous communication training ensuring staff are knowledgeable of hazardous chemical exposure and exposure consequences. Records of that training must be maintained for each employee.3

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. Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs. ANSI/AAMI ST79 recommends the routine monitoring of the temperature of washer-disinfectors.1,3 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. A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically.1

OBJECTIVE 6: DISCUSS RECORD RETENTION
With the exception of EtO exposure documentation, there are no set standards for records retained to document the above
processes. Record storage times should be in the facilities records retention policy 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 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 reprocessing procedures is an important task with critical implications for the department, facility, physicians, and patients, among other constituents. Reprocessing 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.

**REFERENCES**


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