

September 2018

The self-study lesson on this central service topic was developed by STERIS. The lessons are administered by Endeavor Healthcare Media.

Earn CEUs

After careful study of the lesson, complete the examination at the end of this section. Mail the completed test and scoring fee to *Healthcare Purchasing News* for grading. We will notify you if you have a passing score of 70 percent or higher, and you will receive a certificate of completion within 30 days. Previous lessons are available at www.hponline.com.

Certification

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this in-service for one (1) contact hour for a period of five (5) years from the date of original publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individual until re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD. For additional information regarding certification contact CBSPD: 148 Main Street, Suite C-1, Lebanon, NJ 08833 or www.sterileprocessing.org.

IAHCSMM (International Association of Healthcare Central Service Materiel Management) has pre-approved this in-service for 1.0 Continuing Education Credits for a period of three years, until August 8, 2021. The approval number for this lesson is **STERIS-HPN 180808**.

For more information, direct any questions to *Healthcare Purchasing News* (941) 927-9345, ext. 202.

LEARNING OBJECTIVES

1. Describe the overall types of electronic documentation systems for SPDs.
2. Discuss the benefits and capabilities of electronic documentation and workflow management systems for the SPD.
3. Explain the critical factors to consider before investing in any electronic documentation system.

Sponsored by:



SELF-STUDY SERIES

Beyond digitized documents

Options, benefits and considerations for electronic documentation in the SPD

by Heide Ames

It's eleven o'clock in the morning. Case carts have been returning to the decontamination side for processing. The phone rings. It's OR seven. They've discovered two trays with failing chemical indicators. They need immediate replacement trays. A technician finds replacement trays, but are they okay to send up to the OR?

Twenty minutes have passed. The replacement sets were sent to the OR. The paper sterilization cycle record for the failed sterilizer load has not yet arrived from storage. Risk management personnel are in the department and they are asking a thousand questions. The stress is growing by the minute.

Sterile processing departments around the world fear this scenario. Sterility assurance failures trigger investigations that can lead to product recalls, patient notifications and public relations nightmares. The longer it takes to determine the number of loads to recall, the more strain on everyone involved.

Relying on a manual paper documentation system means losing precious time. It takes time to find and retrieve the necessary critical information. And time is not on your side when a possible recall is involved. Had your records been created and stored in an electronic format, finding and retrieving them would have been fast and easy.

If electronic documentation is implemented and used well, speed of retrieval is not the only benefit sterile processing departments can gain from it. Management can reduce documentation errors, perform trend analyses, achieve continuous improvement and gain peace of mind.

What is electronic documentation?

Electronic documentation is a term used to describe activities in which electronic documents are created and saved. Electronic documents include text, graphics, data, audio, pictures or other information created in a digital format.

When applied to healthcare, electronic documentation is divided into segments

based upon the area in which it is used and whether sensitive patient information is included. *Electronic Health Records* is the most recognized electronic record keeping system, and it pertains to patient information. Additional examples include drug dispensary records, pharmacist interventions and instrument tracking.

What needs to be documented?

The sterile processing department must maintain records from a variety of activities performed within the department. These records become critically important when investigating sterilization failures. They also provide proof that the department is doing its job properly. Some records are created automatically by equipment, while others are manually created by the individual performing the task.

The types of records maintained by a hospital for sterile processing departments fall into four buckets: equipment records, facility records, sterilization records and administrative records.

Equipment records include the documentation of all activities that may have a significant impact on the performance of the instrument reprocessing equipment. Documentation includes preventative maintenance, repair history, routine biological indicator testing, routine cleaning indicator tests, and Bowie-Dick tests, to name a few. Table 1 provides a list of necessary equipment records.

Facility records include documentation of activities and room conditions necessary for safely processing medical equipment. These records include documentation of steam quality tests, and HVAC performance and air exchange tests. Facility personnel must also document the testing of safety equipment such as eyewash stations. Table 2 lists records required to be maintained by facilities.

Sterilization load records are the most important records reviewed during a sterilization failure investigation. These records document the sterilization process for a giv-

en set of instruments and make it possible to track them from a patient procedure back to their most recent sterilization process.

Sterilization load records are organized around a batch or lot number. This number is encoded with the sterilization date, sterilizer ID and sterilization cycle number. All documentation and test results associated with a specific sterilization cycle are identified and stored under this unique number. Records include biological indicator results, load contents, emergency release documents and many others. Table 3 lists documentation maintained for sterilization loads.

The last type of documentation is *administrative records*. These include documentation of training that has been received, audits of other documentation records, communications with suppliers or device manufacturers and many other documents that support the decisions made to ensure proper processing of items by the department.

It also includes the data and information that documents continuous quality initiatives and any investigations of sterilization failures and recalls. Table 4 lists the type of administrative documents maintained.

Though some or all of these records may be needed during a sterilization failure investigation, sterilization load records are important for every sterilization-related investigation. They provide the evidence of a facility's compliance with legal, regulatory and accrediting requirements, so auditors from credentialing agencies, lawyers and government officials may all need to review these records. It is critical that they be correct, complete and accessible.

Maintaining these records electronically makes these requirements easier to achieve. Electronic records provide a means to standardize the collected information, and to establish a library of easily and quickly accessible documents and data.

Healthcare providers have already begun to use electronic documentation for many of the critical processes used to service patients. In addition, the Association for the Advancement of Medical Instrumentation (AAMI) states that "Electronic records of sterilization process monitoring results, including specific load identification, are recommended," and sterilization-related guidance documents such as ANSI/AAMI S179 are recommending the use of electronic documentation.¹

Types of electronic documentation

Electronic records are generated and stored using several methods. The simplest method is the *document management*

system (DMS), which electronically stores documents, images and other files that are created manually or by semi-automated processes. A DMS allows easy retrieval of this information. Scanned documents, word documents and Excel spreadsheets are examples of items that would be stored in these systems.

Documents are scanned or saved as files in a computer software program that groups this information together. Information is typically grouped by equipment identification or sterilization batch number. Files are time stamped to allow retrieval of documents from a specific date range.

A *semi-automated system (SAS)* automates the collection of some information but still relies on manual inputs from users. The SAS electronically captures data exported from other devices and centralizes the data to one location with one electronic record. This type of system also allows users to record important information in an electronic form that is maintained by the SAS.

The SAS differs from a DMS in that the data that is entered or retrieved from exporting devices can be organized and mined. Data mining allows users to look at trends, evaluate compliance rates and perform other data-driven analysis within the program.

Advanced SASs are capable of setting alerts and reminders to complete tasks, notify users of incomplete data forms, and give real-time information about important processes occurring in the sterile processing department.

Instrument tracking systems are an example of a SAS. The system utilizes unique device set or instrument identifiers to track each item's usage and location throughout the facility. The SAS also maintains additional information such as sterilizer cycle printout, load contents, biological or chemical indicator test results, set preparation instructions and other important documents regarding sterilization of the set or instrument. Some information is automatically collected by the system, such as cycle printout, while other pieces, such as biological indicator test results, may be manually entered into the system using a data form.

Another type of SAS is a *remote access equipment monitoring system*. Remote access equipment monitoring allows critical performance data from equipment to be securely accessed from any computer by staff or by original equipment manufacturer service providers. Analysis and trending of the data generates a predictive maintenance plan and reduces downtime of equipment. It also provides access to the equipment's alarm history.

Table 1: List of equipment records maintained in sterile processing

Service & Maintenance
• Changes to equipment parameters settings
• Preventative maintenance records
• Repair records
• Calibration records
• Installation records
• Relocation records
• Daily maintenance activities
Tests
• Daily cleaning indicator test results
• Leak test results
• Daily Bowie-Dick test results with cycle printout
• Daily biological indicator test results
• Qualification test results
• Cleaning verification test results
• Product testing test results

Table 2: List of facility records maintained

Maintenance
• Corrective actions for steam delivery system
• HVAC parameters by room for the department
Tests
• Assessment of steam quality
• Assessment of water quality (tap and treated)
• Routine testing of safety equipment such as eye-wash stations

Table 3: List of sterilization load records maintained

Records
• Detailed load content list
• Load/lot number identification
• Sterilizer cycle printout
• Sterilization cycle parameters
• Operator identification
• Reports of inconclusive or non-responsive chemical indicators found later
• Emergency release documentation
Tests
• Biological indicator test, when applicable
• Chemical indicator test, when applicable

Table 4: List of administrative records maintained

Records
• Completed training competencies
• Departmental audit findings and corrective actions
• Additional instructions for processing devices received from the manufacturer but not included in the IFU
• Product failure tracking and corrective actions
• Recall records
• Critical supplier communications for defective vendor supplied products
• Receipt of supplies and loaned equipment transactions
• Continuous quality improvement records including trending and analysis

Electronic documentation can also be found within a *workflow management system (WMS)*, which provides an infrastructure for the set-up, performance and monitoring of a defined sequence of tasks that are arranged as a workflow application.³ A WMS not only collects and stores information; it also integrates with reprocessing equipment, operating room schedules and test equipment. A WMS allows proactive scheduling of events, including maintenance. It alerts users to necessary tasks that are overdue. It provides the most comprehensive support of all the electronic systems presented here.

Considerations when choosing a system

Electronic documentation systems can do as little or as much as a facility requires. They can be simple, such as biological incubator and OEM software packages that record and track biological indicator test results. Or, they can be comprehensive documentation systems with software packages that interface with facility equipment, identify set and instrument usage, schedule tasks, provide reminders and alerts, and much more. Regardless of the scope of the system, there are several key factors to consider when selecting an electronic documentation system.

First and foremost is *security of the documents and data*. Security features must be able to limit access to the material and protect against hacking. This is especially true if third parties may interface with facility electronic documentation programs.

Accessibility and ease of use are critical for system efficiency. The system must be able to store, generate and retrieve records quickly and easily. To do this, the system must have the bandwidth to accommodate the volume of facility users, the electronic storage capacity to maintain high volumes of records, and a means to remove old records from the system.

The system must also work seamlessly. It should be simple to navigate, provide system warnings before removing or correcting records, and must interface with department scanners.

Scalability is also an important factor to consider. Initial needs may be small, but as the facility grows or standards change, the electronic documentation system needs to adapt to meet the facility's most current needs. Consider what functionality will be desired in the future, which could include:

- Instrument tracking
- Workflow management
- Operating room schedule interfacing
- New sterile processing equipment

The system will need to adapt and accommodate these new requirements, or it will need to be replaced.

The last determination is *where to host the records and system*. Hosting the package requires digital space, IT capabilities and accessibility through security measures. *Self-hosted packages* allow the facility to maintain all records on the facility servers. This allows facilities the security of their servers and the flexibility of personalizing the system. However, it also means that the facility IT department has responsibility for maintaining the network, program and servers. Self-hosted systems usually require a fee for the software package and costs associated with installation and start-up of the system, after which the facility assumes responsibility. Licensing fees may also be required depending on the system. Often, service packages are available to support the program and users.

Cloud-hosted systems store documentation remotely and are serviced by a third-party provider. This option requires little to no support from facility IT. A use fee is charged monthly or annually. Packages also include user and technical support. Cloud-hosted systems are more expensive than self-hosted systems. Cloud-hosted systems are a good choice for facilities that lack the necessary IT support. Table 5 compares the features of a self-hosted and cloud-hosted system.

Table 5: Comparison between Self-Hosted and Cloud-hosted Document Retention Locations

Self-hosted Record Location	Cloud-based Record Location
Interfaces with scanners/equipment	Interfaces with scanners/equipment
Utilizes digital forms	Utilizes digital forms
Facility-owned electronic storage	External storage maintained by third party
Utilizes facility security protocols	Utilizes facility and third-party security protocols
Flexible programing/customization	Limited programming and customization
Software purchase fee	Software purchase fee
Licensing fees	Annual contract fee
Little or no developer IT support	Third party IT and technical support
Facility responsible for updates	Automated updates

Faster reporting and a better result

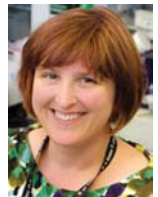
Electronic documentation provides a fast and easy way to find information, respond to auditors and support sterile processing documentation needs. Now when that 11:00 a.m. call comes, you are ready.

If electronic documentation was in place in our sterilization failure scenario, a quick search of the load records would identify that 23 other items were sterilized in that load. Two clicks of the mouse would generate a report identifying the location of all the

items, which could be printed out. By 11:15 a.m. you would have reviewed the biological indicator tests before and after the sterilization cycle in question. Everything looks normal and all biological indicators were passing, so no other loads are implicated. At 11:20 a.m., when the infection prevention team enters the department demanding answers, you have them. When the IP asks you how soon the remaining items from the load will be pulled off the shelves and out of procedures, you can say, "Give me 10 minutes."

Electronic documentation gives you the information you need when you need it. By eliminating the stressful delays of waiting for documents from storage, and the risk of potentially missing or incorrect records that result in reprimands from administration, electronic documentation offers you greater confidence and peace of mind. **HPN**

Heide Ames is a product manager for the Infection Prevention Technologies unit of STERIS Corporation, responsible for managing the company's sterilization packaging products. Prior to this role she managed the entire offering of biological indicators, sterilization containers and pouches. Ames also has many years of experience as a senior scientist and microbiology laboratory manager for STERIS. She holds a Bachelor of Science degree in Biology from Niagara University, and is a member of the Association for the Advancement of Medical Instrumentation (AAMI) and the



International Association of Healthcare Central Service Materiel Management (IAHCSMM).

References

1. Association for the Advancement of Medical Instrumentation. (2017). ANSI/AAMI S179: 2017. Arlington, VA: Author.
2. en.wikipedia.org/wiki/Document_management_system. Wikipedia The Free Encyclopedia. Accessed June 7/2018.
3. en.wikipedia.org/wiki/Workflow_management_system. Wikipedia The Free Encyclopedia. Accessed June 7/2018.
4. Andreas Rivera. Document Management Systems A buyer's Guide A business News Daily Buyer's Guide., 2/8/2018, www.businessnewsdaily.com/8026-choosing-a-document-management-system.html. Accessed June 7, 2018
5. Six elements to a Secure Document Management Solution Ingram Micro Advisor www.ingrammicroadvisor.com/document-imaging/the-six-elements-to-a-secure-document-management-system. Accessed June 7, 2018
6. Craig Borowski. Buyer's Guide. Software Advice, 6 June 2018, www.softwareadvice.com/cms/document-management-comparison/#buyers-guide. Accessed June 7, 2018.
7. Content Central. The Document Management System Buyer's Guide 5 Lessons for purchasing the right document management system the first time. Ademero Inc. V6.5.x 2016, learn.ademero.com/document-management-buyers-guide/. Accessed June 7, 2018

CONTINUING EDUCATION TEST · SEPTEMBER 2018

Beyond digitized documents

Circle the one correct answer:

1. Which item would not be considered a record?
 - A. Calibration form
 - B. An Excel spread sheet of biological indicator results
 - C. An online consumable catalog
 - D. A and B
2. Which is an administrative record that must be maintained by healthcare facilities?
 - A. Preventative maintenance record
 - B. Training competencies
 - C. Sterilizer cycle printout
 - D. Leak test results
3. Which is a benefit of electronic documentation?
 - A. Records can be retrieved quickly
 - B. Data can be analyzed for trends
 - C. Documentation errors can be reduced
 - D. All the above
4. What can an electronic documentation management system do?
 - A. Check records for documentation errors and correct them
 - B. Store scanned documents
 - C. Track the location of an instrument within the facility
 - D. None of the above
5. Instrument tracking and remote access monitoring systems are examples of which type of system?
 - A. Semi-automated system
 - B. Workflow management system
 - C. Document management system
 - D. None of the above
6. What is a benefit of semi-automated systems?
 - A. The system can retrieve old records directly from equipment
 - B. The system can directly receive and compile records from equipment, scanners and technicians
 - C. The systems can direct tasks, manage workflow and alert users to failed sterilization cycles
 - D. None of the above
7. The SAS differs from a DMS in which of the following ways?
 - A. Data that is entered or retrieved from other devices can be organized
 - B. SAS allows users to look at trends, evaluate compliance rates and perform analysis within the program.
 - C. Stored data can be mined
 - D. All of the above
8. All systems that manage sterile processing records must be protected from unwanted intrusion.
 - A. True
 - B. False
9. Which of these items are considered when evaluating a system for electronic documentation?
 - A. System security, the number of users and the number of sterilization cycles processed in steam
 - B. System security, system compatibility with smart phones and the types of instruments sterilized
 - C. System security, system compatibility with department scanners, and the number of users
10. A cloud-hosted system requires a strong internal IT department.
 - A. True
 - B. False

CONTINUING EDUCATION TEST SCORING



The approval number for this lesson is **STERIS-HPN 180808.**

HPN is thrilled to now offer all CEU quizzes online by scanning the QR code on the right or visiting:

<https://educationhub.hpnonline.com>.

The cost to take the quiz online remains at \$10.

Due to rising costs if you would like to mail in your completed quiz using the method below the price is now \$50 for each test taken.

Request for Scoring

I have enclosed the scoring fee of **\$50 for EACH test taken** — payable to **Endeavor Business Media**. We regret that no refunds can be given. (It is not necessary to submit multiple tests separately.)

Detach exam and return to:

Continuing Education Division
Healthcare Purchasing News
2477 Stickney Point Road, Suite 221B
Sarasota, FL 34231

