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Learning Objectives

1. Describe the objectives and primary elements of a Quality Assurance program.
2. Discuss the benefits of information systems and the reference tools they provide.
3. Determine the applicability of electronic documentation and record keeping for your facility.

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SELF-STUDY SERIES

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Quality assurance using sterile processing information systems

by Peggy Pittenger, RN, BSN, CRCST

As consumers, we are constantly bombarded by claims from companies about quality: "Quality is Job 1" (Ford), "Quality Runs Deep" (Rust-Oleum) and "Quality Trucks Always Cost Less" (Chevrolet) are but a few examples. We tend to make product quality a central consideration in our purchase decisions as well as in our sense of product satisfaction. As consumers, our sense of quality, and its importance, is almost a sub-conscious exercise. On the other hand, Quality Assurance, from a manufacturing standpoint in general and in Sterile Processing in particular, requires much more. Awareness, understanding, tools and intentional behavior are but a few of the essential components for establishing and maintaining an effective system for quality assurance.

In today's Sterile Processing Department (SPD) the complexities have multiplied significantly in the past decade. Instrumentation, cleaning and sterilization processes, end-user demands, growing impacts from Hospital Acquired Infections (HAI's), and the demands of training, equipping and maintaining qualified staff have all contributed to the growing challenge. While automation and other software products continue to provide tremendous benefits, much is left to the management team to design processes in a way that allows trained staff to deliver the quality outcomes today's healthcare facilities require.

In the broadest of terms, Quality Assurance is a function of people and processes. The people, in this case department staff, depend on logical and comprehensive policies and procedures for all aspects of the job. They require training in order to understand and execute these policies and procedures, and tools for guiding and documenting the work. The processes include both human (cleaning instruments, assembling trays) and machine (washers, sterilizers, incubators) elements. When properly designed these processes are efficient, consistent and deliver the outcomes that the SPD requires. When departments are sufficiently automated, software products guide,

support and document all aspects of departmental activity needed for predictable quality outcomes.

The detailed playbook for the SPD is found in the facility and departmental policies and procedures. Not only do these serve as the general reference tools for all departmental functions, but they also provide specific guidance for specific tasks under specific circumstances. If all SPD did was generate towel packs it would be one thing, but that is obviously not the case. An information system can recognize the circumstances and provide the information to the technician so correct processes can be understood, appropriate actions can be taken, and proper decisions can be made.

The benefits of an information system to guide and document quality processes and outcomes can be tremendous, just as not having such a tool can be prohibitively expensive. A few of the more direct examples would include the cost of incomplete, inaccurate or unfit (whether functional or sterility-related) instrumentation resulting in end-user dissatisfaction, case delay and disruption of routine work priorities as staff respond to nonconforming situations. Some of the extended implications include the issues associated with flash sterilization, the expense arising from increases in HAI's and the economic exposure tied to the many aspects of patient liability.

Database build and asset barcoding

The cornerstone of most SPD information systems is the permanent barcode labeling of instrument sets. There is a wide range of information that can be included on the label but a unique index number (Major Lap Tray -01, -02, -03...), department, service/specialty, sterilization method, and storage location tend to be common components. This barcode is scanned at each step of the processing chain for data capture or for accessing information the information system can provide. In SPD, this barcode is scanned from receipt in the decontamination area through the time the item is packaged.

After packaging, a corresponding external barcode is printed which may be in three parts: the first attached to the packaged tray, the second available for documenting flash sterilization (if applicable) and the third for the patient record.

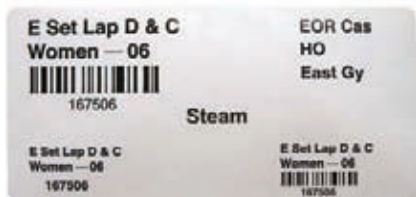


Figure 1: The permanent barcode label affixed to the tray, and the matching external label affixed to the packaging, can provide extensive information at a glance including Index Number, Specialty, Sterilization Method, Storage Location and other Information that is beneficial to both Technicians and Users

While each instrument tray has a unique identifier, so does each staff person using the system. Each task performed is preceded by a scan to record employee ID so credit can be given for work performed (productivity measurement) and the work performed by the individual is captured for QA traceability. This information can be beneficial for targeting educational needs, identifying cross-training opportunities and tracking overall staff proficiency. Additionally, this information can be useful in making determinations about process flow, process design and other workflow factors that depend on objective and quantifiable data as the basis for change and improvement.

Work flow

SPD users scan trays at each stage in their journey through the department, allowing the information system to track tray location at all times. The first instrument tray scan is typically referred to as Decontam Receipt. This is a critical scan for a variety of reasons: the chain of custody is transferred to SPD through an employee ID and time/date stamp scan; the timing for set turnaround begins; and if there is an Expedite Message (*This tray is needed for a case at 11:45 a.m. in OR #6, for example*) it can be executed by staff. Any special instructions on disassembly and cleaning of devices can also be accessed so the sets are delivered to the clean side of the department ready for assembly and sterilization. The Decontam scan, like many of the scans that will follow, also documents the work being done and the people doing the work.

In addition to the human processes, the machine processes in Decontam can be supported by information systems in a variety of ways. As outlined in AAMI ST79, section 10.2, "to ensure that mechanical cleaning equipment is working properly, and according to the manufacturer's specifications, healthcare personnel may perform verification tests as part of the overall quality assurance program."¹ Providing prompts on the use of products to measure or challenge the efficacy of the mechanical cleaning equipment, recording the results and taking any additional necessary steps required, and documenting the actual process parameters of the mechanical cleaning equipment are key components of quality documentation. This can be done either by collecting washer printouts and scanning these printouts to create an electronic file (.PDF) or through a direct input of information from the washer to the software application.



Figure 2: Loaner instrumentation (and associated policies, procedures, custom count sheets and IFUs) can be included in the overall system database with uniquely identifiable barcodes

Loaner instruments

While the vast majority of the assets catalogued in a typical information system database is comprised of instrumentation and sets owned by the facility, the impact of loaner instrumentation continues to increase. The complexity of these items, the lack of familiarity of staff given their irregular exposure to them, and the unique requirements many of these sets may have in the Decontam, Assembly and Sterilization areas can put a tremendous burden on the department. One of the keys for quality outcomes is to have similar processes and support/reference information available regardless of the instrument set being processed. The ability to handle loaners in essentially the same way as hospital-owned sets is beneficial and having an information system that can compile, organize and make available such information can be the most effective option for an otherwise almost unmanageable situation. The Association of

periOperative Registered Nurses (AORN) addresses loaner instrumentation in their 2009 *Recommended Practices for Sterilization in the Perioperative Practice Setting* which states, "The systematic management of loaner instrumentation reduces loss and ensures proper decontamination and sterilization through increased communication and accountability"² and provides detailed guidance on the recommended components of a loaner instrumentation process. AAMI recommendations are also clear about managing loaner instruments within the hospital by specifying that the "user should document how the device was decontaminated, the date of processing, and a means of identifying the person who decontaminated the device"¹ prior to returning the set to the vendor. (ST79, Annex G, section 4.2) An information system can facilitate the implementation and compliance to a process for managing loaner instrumentation as well as the documentation from receipt to return. Additionally, information systems can facilitate the set ordering process from various vendors, can measure response time and overall performance of multiple vendors, and can streamline the communication process related to Loaner Instrumentation whether internally or with the vendor.

Training: Count sheets, images, repetition, checks ...

Once the clean set is scanned to Prep/Pack, information systems have even more to offer. With the primary department goal of accurate and complete sets made up of fit (clean, functional, etc.) instrumentation, the systems can provide up-to-date count sheets, prompt reminders for inspection of instrumentation and display images and video clips of individual items, sub-assemblies and final set configurations. Additionally, with unique identifiers on each set, utilization rates are easily measured and utilization-based preventive maintenance (PM) schedules can be established, managed and documented. This approach to PM ensures that funds are spent when and where needed. This is especially important since unfit instrumentation in the hands of end-users is unacceptable, but premature or excessive sharpening of instruments shortens device lifespan and may unnecessarily accelerate instrument repurchase expense when PM is based strictly on time intervals.

Information systems support adherence to manufacturer's Instructions for Use

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(IFU's), where care instructions and sterilization exposure times are defined, by ensuring that these requirements are readily available, understood and met. Sets that call for extended exposure times are identified, grouped and processed accordingly. The building of sterilizer loads that factor end-user needs while balancing the processing times of sets available for sterilization requires a software tool that makes the information readily available, supports the decisions such situations require and documents these activities for compliant record-keeping.

Additionally, information systems can support the building of proper sterilizer loads by ensuring the appropriate load configuration based on weight, metal mass and density of the items in the load. If a load is built outside of the range re-

Once the load contents and sterilization cycle have been determined, information systems can also prompt use of a Biological Indicator Process Challenge Device (BI PCD) as required by items in the load (implants) or by department policy (Every Load Monitoring). This sets in motion one of the most critical aspects of SPD Quality Assurance and also represents an area where system connectivity, automation and software decision-support tools can provide significant benefit.

When the sterilization cycle is completed and the BI PCD removed from the load, the

process of documenting the monitoring results begins. Sterile processing information systems can support this process through connectivity with the BI incubator by ensuring that all documentation is complete, that it is available in real-time, and that all of this information resides in a single location to simplify access and reporting features.

AAMI ST79, Section 10.3.2 states: "Documentation helps personnel determine whether a recall is necessary, should evidence subsequent to lot release, such as a positive BI or nonresponsive CI suggest sterility problems. Knowing the contents of the lot or load enables personnel to identify the medical devices to be recalled. Digitization of this process will allow quick access to load information, facilitating a quick response."¹ An interface between the BI incubator and Information Software assures that should a recall be necessary, the process can be expedited with a system wide alert and load content information that is readily available.

In addition to the interface for BI monitoring, SPD Information Systems can also record sterilizer data in a manner similar to those for washers: through a direct interface, through creating an

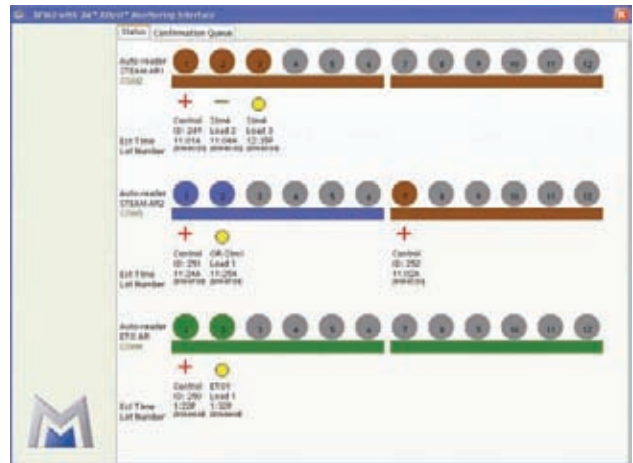


Figure 5: Example of information system providing real-time tracking of BI incubator results

electronic record from the paper machine output, or by simply collecting and preserving the paper output and confirming that these records have been preserved. Generally speaking, any comprehensive method will meet the AAMI guidelines for compliant record-keeping, however, the greater the percentage of data that can be captured electronically and stored centrally the more straightforward the storage, retrieval and use.

Summary

A responsible approach to quality assurance, including the policies, procedures, products, tools and training required, entails substantial investment and a long-term commitment. When properly implemented and maintained, a sterile processing information system should document all aspects of quality functions resulting in end-user satisfaction, patient safety and improved financial performance within the department and throughout the facility. **HPN**

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References

1. Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ANSI/AAMI ST79: 2006 and A1:2008 (Consolidated text).
2. Association of periOperative Registered Nurses. *Recommended Practices for Sterilization in the Perioperative Practice Setting*. *Perioperative Standards and Recommended Practices*. 2009 Edition.

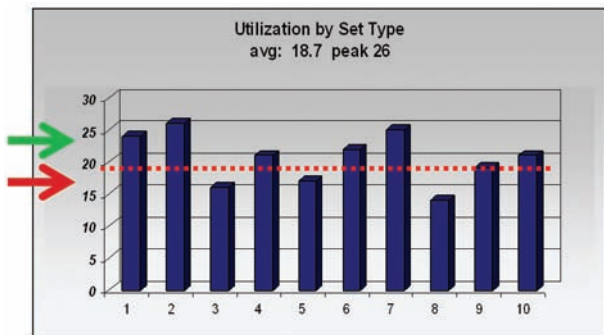


Figure 3: Utilization rates by Set Index # shows average and peak demand and is useful for inventory-related decisions.

quired for sterility assurance, all of the prior good efforts in Decontam and Assembly will be lost. Establishing values for each instrument set, accumulating those values as the load is built, and checking the cumulative totals for weight, mass and density against the known performance parameters of the equipment can be one of the most effective means for avoiding unacceptable or unsafe situations.



Figure 4: As items are scanned into a sterilizer load, information can be provided about weight, mass and density aspects of load configuration, compatibility of items to sterilant, and the necessity of extended cycle alerts, if required.

CONTINUING EDUCATION TEST • APRIL 2009**Quality assurance using sterile processing information systems**

Circle the one correct answer

- Today's Sterile Processing Departments have become increasingly complex areas to manage due to:
 - Complexity of instrumentation
 - End User Demands
 - Impact of Hospital Acquired Infections (HAIs)
 - Demand for qualified and well trained staff
 - All the Above
- Automated information systems rely on barcodes or ID numbers for:
 - Sets
 - Staff
 - Tasks
 - A and B
 - A, B, and C
- When the task performed is scanned and the employee ID scan linked to the task, information software can provide:
 - Staff accountability
 - Staff Productivity
 - Reports to assess the need for additional training
 - All of the above
- Machine processes, such as washer-decontaminators, can be supported either by a direct interface or by scanning the machine's print-out that records the cycle parameters. Documenting these parameters is part of a QA program.
 - True
 - False
- Quality Assurance for Vendor/Loaner Sets should include:
 - Documentation of the ordering process
 - Documentation of the receipt of the instruments
 - Instructions for care of the instruments
 - Documentation of the processes carried out in SPD
 - Documentation of return of the instruments
 - All the Above
- Instrument set utilization rates are a better basis for establishing a Preventive Maintenance (PM) interval rather than establishing PM solely on a time interval.
 - True
 - False
- Information systems assure quality in the sterilization of sets by recognizing and confirming the appropriate sterilant and parameters for each set as they are scanned into the sterilizer, including reminders for QA such as a BI or PCD, then documenting the entire process.
 - True
 - False
- Information Systems can support proper building of sterilizer loads when the weight and density of the sets are established, the values calculated during the building of the load, and the values compared to known performance parameters.
 - True
 - False
- Sterile Processing Information systems that interface with the BI incubator can guide the process and assure:
 - Documentation is complete
 - Information is available in real time
 - Data is in an electronic form
 - System wide alerts should a recall be necessary
 - All the above
- When departments are sufficiently automated, software products guide, support and document all aspects of departmental activity needed for predictable quality outcomes.
 - True
 - False

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