Lesson No. 79
December 2004

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For more information

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Learning objectives:

1. Define the concept of quality and explain why it is important.
2. Review the importance of quality audits.
3. Provide an overview of the quality auditing process.
4. List common types of errors noted in quality audits.
5. Explain how to plan revisions in sterile processing based upon quality audit findings.

Central Service personnel are very knowledgeable and skilled, and they work hard to assure that all of the sets and individual devices they process are sterilized and ready for use when needed. They are, however, never content with knowing just that all required protocols are followed. They also conduct follow-up quality audits to determine objectively the extent to which facility standards are attained. Their goal of “zero defects” (no deviations from standards) is of critical importance to them. Quality audits help them attain this goal as they strive for continuous quality improvement (CQI).

Objective 1:
Define the concept of quality and explain why it is important.

Quality can be defined as the consistent delivery of products and services according to expected standards. Central Service personnel must establish quality levels for the products and services they produce. They must also assure that these quality levels are attained consistently. Quality is determined by the customers, and the success of Central Service depends upon customer satisfaction. The quality of service—or a lack of it—can have a dramatic effect on the health and well-being of the personnel and patients who are Central Service’s customers.

Objective 2:
Review the importance of quality audits.

Quality audits are used to determine the extent to which medical devices processed by Central Service meet the quality standards established by the department and facility. Specific purposes of these audits are to:

- determine the extent to which existing policies, plans, and procedures are working consistently and effectively; that is, to assess whether expectations (standards) are being met
- chart the progress towards continuous quality improvement as noted by a reduction in errors and defects over time

- develop recommendations for revising output standards and expectations where appropriate
- quality audits should be an integral part of the CQI process because they help:
  - measure the quality of processed sets and other items which do or do not meet the facility’s standards
  - identify areas where additional staff training in instrument classification, appropriate processing methods, and other factors are needed (for example, frequent packaging errors will likely indicate that staff need additional training on “how to package”)
  - assess the most appropriate sterilization methods (for example, when instrument defects are corrected or alternative protocols are used)
  - promote communication between Central Service and user personnel in other departments

Objective 3:
Provide an overview of the quality auditing process.

Figure 1 shows where quality audits fit into the sterile processing activity. Note in Figure 1 that, after the decontamination and disinfection/sterilization process is completed, a quality audit becomes important. When planning the audit, consider:

- the aspect (standard, policy, or goal, for example) to be audited
- the scope/sample size of the audit
- the timeframe for the audit (week, month, or quarter, for example)
- the schedule for follow-up audits as necessary to evaluate the success of adjustments made as a result of the initial audit
- it is also important to develop:
  - data collection worksheet
  - an information summary form (charts or graphs, for example)
  - necessary reporting activities (how, when, and to whom you will present information summaries)

Record all the information you gain while following these steps. If you are auditing persons or shifts, be sure that personal information is

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Record all the information you gain while following these steps. If you are auditing persons or shifts, be sure that personal information is
protected! (This is a process to make improvements, not to “point fingers.”) Nothing will be gained if staff feel persecuted or ashamed by mistakes or flaws that are discovered by the audit. Publish results and summaries in a coded format to protect personal identities.

Figure 1 also suggests that there are two types of quality audits:

Proactive Audits — those done by Central Service personnel on a routine but random basis before products are distributed to user departments. Defects noted during a proactive audit are measured (counted), items are recycled for sterile reprocessing, and feedback is summarized.

Reactive Audits — those done by user department personnel (who receive defective items and return them) and, perhaps, by administrative personnel who may respond to quality audit summaries and reports. Defective sets and instruments noted during reactive audits are returned to Central Service for additional sterile processing, if applicable.

As a result of feedback from proactive and reactive audits, changes in procedures, policies, training activities, and other factors contributing to the observed defects are made, and the department’s continuous quality improvement (CQI) efforts evolve. In the process, the Central Service department improves, overall.

Objective 4:
List common types of errors noted in quality audits.
Numerous common types of defects can be noted in a quality audit. For instrument sets, these include:
- incorrect labeling
- incorrect set container
- absence of filter cartridge
- inappropriate-sized wrapper
- count sheet unavailable or filled out incorrectly
- improper or missing chemical indicator
- incorrect sterilization method
- incorrect instrument assembly
- missing instruments
- dirty instruments
- wrong-sized instruments
- wrong instruments
- extra instruments
- broken instruments
- hole in wrapper

Additional types of defects that can be noted in audits of single instruments include:
- inappropriate-sized peel pack/wrap
- improper chemical indicator
- incorrect instrument assembly
- incorrect sterilization method
- dirty instrument

Keep a summary of errors noted from the proactive and reactive audits. The information in this summary may identify problems that should be corrected.

See SELF-STUDY SERIES on page 38

Example:

Steam sterilizers are monitored with daily biological testing. All steam sterilizers in all units should be tested at 100% compliance. Data collection is performed daily and compiled monthly by Shift Leaders during the second and fourth quarters of 20XX. Follow-up audit to be completed during the second quarter of 20XX.

Tick Sheet for data collection (all sterilizers in all areas to be audited)

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Data summary is done with a bar graph to track the period of time that sterilizers in each unit meet 100% biological test standards.

Reports are made to Central Service staff, the Infection Control and Quality Committee members, Department Managers and others. If the goal of 100% is not met, provide ideas about contributing factors and an action plan for improvement.
Objective 5: Explain how to plan revisions in sterile processing based upon quality audit findings.

What process can be used to correct defects noted during quality audits? Figure 2 provides an example.

Assume that recent quality audits have identified a recurring defect: missing instruments from a specific type of set. As a first step (Step 1), alternatives are identified, including retraining, revision of orientation materials, supervision tactics, and related potential causes.

The alternatives are then evaluated. Determining the likelihood that each alternative contributes to the defect is Step 2. One or more alternatives are selected (Step 3) and implemented (Step 4). The extent to which the selected alternatives are helpful in reducing defects is assessed (Step 5) by noting the, hopefully, reduced number of defects (missing instruments from sets) in subsequent quality audits.

Central Service personnel cannot resolve problems until they first become aware of them. Results of quality audits provide measurements of the types and frequency of defects that occur during sterile processing. This knowledge can be used to take corrective actions as necessary. As seen in Figure 3, additional measurements can then be compared against earlier quality audit outcomes. The difference—the reduced numbers of defects—indicates how the Central Service department is progressing toward their ideal goal of zero processing-related defects.


Endnotes

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1. Which definition of quality is most correct?  
   a. Quality is the consistent delivery of products.  
   b. Quality is the consistent delivery of services.  
   c. Quality is the consistent delivery of products and services.  

2. Quality is determined by:  
   a. operating room personnel.  
   b. healthcare administrators.  
   c. customers.  
   d. Central Service personnel

3. Specific purposes of audits are to:  
   a. determine technicians who create significant defects.  
   b. determine the extent to which quality standards are met.  
   c. determine the cost of sterile processing.  
   d. meet JCAHO requirements.

4. Which is a purpose of quality audits?  
   a. to assess if standards are met.  
   b. to confirm that reactive audit information complaints are unjustified.  
   c. to evaluate one healthcare facility against another.  
   d. to help justify compensation increases for Central Service staff

5. Quality audits:  
   a. assess the most appropriate sterilization methods.  
   b. promote communication between Central Service and other departments.  
   c. are not necessary in departments with the philosophy of zero defects.  
   d. a and b above  
   e. all the above

Objective 1  

7. Defects noted from quality audits are:  
   a. discarded.  
   b. analyzed to assure that defects are present.  
   c. returned for reprocessing (if applicable).  
   d. all the above

8. Quality audit summaries involve information from:  
   a. proactive audits.  
   b. reactive audits.  
   c. sterilization records.  
   d. a and b above

9. Proactive audits are done by:  
   a. Central Service personnel.  
   b. user department personnel.  
   c. healthcare facility administrators.  
   d. all the above

10. Which can be implemented as a result of quality audit report summaries?  
    a. policy changes  
    b. training activities  
    c. procedure changes  
    d. all the above

11. Which statement is correct?  
    a. Quality audits help in a department's CQI efforts.  
    b. CQI is not possible without quality audits on a daily basis.  
    c. CQI information is used to develop quality audits.  
    d. All of the above are true.

Objective 2  

12. All of the following can be noted in instrument sets except:  
    a. use of incorrect sterilization equipment.  
    b. use of incorrect sterilization method.  
    c. incorrect instrument assembly.  
    d. missing instruments.

13. Which type(s) of defects can be noted in single instrument audits?  
    a. inappropriate-sized peel pack/wrap  
    b. incorrect instrument assembly  
    c. incorrect sterilization method  
    d. all the above

Objective 3  

14. Wrong-sized instruments _____ be detected in a quality audit of instrument sets.  
    a. can  
    b. cannot

Objective 5  

15. The first step in the process to reduce defects noted from quality audits is:  
    a. evaluate alternatives.  
    b. define alternatives.  
    c. select alternatives.  
    d. implement alternatives.

16. Possible alternatives to resolve defects involving missing instruments from a specific set include:  
    a. re-training.  
    b. revision of orientation materials.  
    c. use of a different sterilization method.  
    d. a and b above

17. Which statement(s) is/are correct?  
    a. Only one alternative to resolve a defect can be selected.  
    b. One or more alternatives to resolve a defect can be selected.  
    c. No alternative need be selected if there are only a few defects.  
    d. All of the above are correct.

18. Evaluation of alternatives for problem resolution ____ necessary when a quality audit process is in place.  
    a. is  
    b. is not

19. Which statement is correct?  
    a. Problems are always identified by Central Service personnel.  
    b. Problems are always identified by user department personnel.  
    c. Problems cannot be resolved until Central Service personnel are aware of them.  
    d. The least expensive resolution alternative should always be selected.

20. Which statement is true?  
    a. A goal of zero processing defects is attainable.  
    b. A goal of zero processing defects is ideal.  
    c. Neither a or b are true.

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