SPD Employee Continuing Education

Training Guides

Quality Control

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March 2001

QUALITY CONTROL

Upon completion of this session, participants will be able to:

- Define Quality and its importance in Central Service
- Differentiate between Quality Control, Quality Assurance and Continuous Quality Improvement
- Describe three Categories of Quality Control Indicators used in Central Service
- Explain three types of Quality Control Records

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Introduction to Quality Control

What is Quality Control? A check system designed and implemented to provide quality processes (hence quality products). A technical, statistical sampling method that measure the quality of production.

What is Quality? Quality means producing a product or service that consistently meets or exceeds customer's expectations and standards of practices. It is critical that Central service personnel establish quality levels for the products and services they produce to assure that these levels are consistently attained. The customers determine quality; therefore, Central Service's success depends upon customer satisfaction. Customers can include patients, physicians, nurses, and staff in other departments, visitors, administration, and staff within the Central Service Department.

A common definition for Quality relates to the "degree or grade of excellence of a product or service". Many rules and regulations govern the activities and responsibilities of the Central Service Department. Some are established by federal, state, or local government agencies and accrediting bodies, some by the hospital administration, and some by the Central Service Department Management. All the Central Service Department employees must know the rules and regulations that affect them. Written rules, regulations, policies, and procedures should be available for reference. In this training session we will be discussing some basic terms, Quality Control Indicators, and Records.

Identifying Some Basic Terms

The Central Service Departmental staff must understand some basic terms as they consider the Philosophy and procedures necessary to plan implement and move along in their journey toward Quality:

Quality Assurance – A program to monitor, document, control, and/or improve the quality of service provided.

Total Quality Management (TQM) – The process (or journey) that defines, measures and continuously improves the manner in which needs of the customers and facility are met.

Continuous Quality Improvement (CQI) – A scientific approach, which applies statistical methods to improve work, processes *(A process is a series of work activities that produce a product or service).*

Quality Control Indicators

A complete definition of quality must also include features and deficiencies. The right features satisfy the patients and make it easier to provide required/desired products and services. Freedom from deficiencies means fewer errors, less re-work, fewer complaints,

and higher productivity levels. Quality control indicators are grouped into the following three categories:

Administrative control monitors – Are activities regulated by policies, procedures and other administrative actions to assure safe and efficient departmental performance. The most important control of quality in central Service begins with the *management of the department*. All directors, managers, supervisors and lead technicians must be thoroughly trained in modern Central service principles. They must realize that human resources are the most important resource.

Customer Satisfaction Quality Control Indicators – Anyone who has an expectation concerning the products or services of the department is a customer whether they are medical personnel, diagnostic imaging technicians, physicians, surgical service personnel or motor pool drivers. Remember, it is in the eyes of the customer that quality is measured. Customer surveys indicate problematic areas that may not be apparent in the SPD/Central Service/PAD department itself. Surveys provide opportunities for developing excellent customer relations because they facilitate open communication. The Medical Center staffs are the people who communicate with individual Central Service department technicians; their input is of most importance to help provide quality care to patients.

Technical Quality control Indicators – are utilized in the more intricate and precise areas of Central service such as the sterile processing area. These are process control measures and are utilized to make certain that the planned technical conditions within sterilizers and aerators are performing to expectations. Sterility is considered to be the absence of all microorganisms on an inanimate item. This part of Central Service is considered the manufacturing area because medical items are reprocessed and made ready for use. There are many processes that can be measured to assure quality, starting in the decontamination area, traveling through preparation, assembly and packaging areas and finally through the terminal sterilization process.

Quality Control Records and Controls

Sterilization Records – quality control measures must be documented. All sterilizer-recording charts, digital printouts, registers, biological and Bowie-Dick test results, reports, and all other associated quality control documentation will be maintained for at least **36 months**. The SPD Manager will ensure that all equipment used in the SPD section functions and all patient care equipment assigned to SPD is scheduled for routine preventive maintenance (by Bio-Med).

Lot Control and Traceability:

- A six-digit control number will be assigned for each sterilizing cycle.
- An external indicator will be applied to each item prepared for sterilization, indicator tape or tamper resistant tags with specific sterilization indicators.
- Each package or item terminally sterilized will be labeled prior to sterilization with the common name of the package contents or item and initialed by the employee who prepared the package or item for sterilization. Identification will be placed on the indicator tape for packaged items or load control cards for containers. **Do not write directly on packages**.
- The control number and expiration date will be affixed to each package or item intended for use as a sterile product **after** the mechanical and chemical indicators have been verified after sterilization.
- A register will be established for all sterilizing equipment without an automatic recording device.

For all sterilizer equipped with a recording device, the appropriate chart or digital printout will be examined and **signed** by the sterilizer operator after each cycle, before any items are removed from the sterilizer to verify adequate temperature and duration of exposure.

Sterilization Process Controls – All reusable medical/surgical devices used for patient care (direct or indirect) should be sterilized in the SPD section. Reusable devices are items, which are manufactured for, reuse or which the manufacturer has provided specific written resterilization instructions. If, for some reason, sterilizers are located in other sections of the medical facility, they will be monitored mechanically and with biological indicators. The results of these tests must be reported to the Chief (Manager) of SPD (or CS, or PAD, etc.). The Chief is responsible for all sterilizers within the facility per VHA Handbook 7176.

- Mechanical Monitoring – Effective sterilization processes depend on the exposure of items to an adequate amount of sterilant for a specified period under certain environmental conditions. Sterilizers are equipped with recorders and gauges that enable the operator to verify that all-important "cycle parameters" have been met. These parameters, which vary with the type of sterilization process, must be monitored and documented either manually or by means of an automated recording device.

- Chemical Monitoring – Chemical indicators (CI) are physical or chemical devices employed to monitor one or more sterilization process parameters for the purpose of detecting failures in packaging, loading or sterilizer function. CIs are used internally or externally, or both, to verify that items have been *exposed* to one or more sterilizing conditions. *External* chemical indicators are place on the outside of packaged items to be sterilized and are often used as package closures (for example,

sterilization indicator or autoclave tape). *Internal* chemical indicators or process integrators are placed inside packages to indicate whether the contents have been exposed to conditions necessary for sterilization.

- Biological Monitoring – A biological indicator (BI) is a device that has been impregnated with a known number and type of microorganisms and is used to verify that all the conditions necessary for sterilization have been met. The spores are known to be very resistant to specific sterilization processes. *Bacillus stearothermophilus* for steam sterilization, and liquid peracetic acid; *Bacillus subtilis* for EtO and Hydrogen Peroxide Plasma sterilization sterilization processes. BI must be run a minimum of daily on steam and peracetic acid. Each load for the EtO and all loads containing implants. The BI must be run with a normal load and be placed at the point of greatest challenge, "cold point", usually in the middle of the load, near the front of the sterilizer. Commercially prepared, self-contained, biological indicators are recommended for steam, EtO and Plasma.

Bowie Dick (BD) is used to determine the efficacy of the vacuum system of pre-vacuum sterilizers. The BD must be conducted each day the sterilizer is used, before the first processed load. The BD is run in an empty sterilizer and it should be run at the same time every day. The BD test pack must be placed horizontally in the front, bottom section of the sterilizer rack, near the door and over the drain. Sterilizer operators must be trained in test preparation and interpretation. The test results will be recorded on the sterilizer-recording chart. The results must be documented and maintained with the records of that sterilizer.

- A standard procedure will be instituted by the Chief, SPD
- Implantable devices/intravascular material will be monitored with the appropriate biological indicators and quarantined for 48 hours until the incubation is complete and the results are known.
- When positive BI's occur, it is important to immediately determine whether the cause was sterilizer malfunctioned, operator error, or a BI incubation problem.

Summary

There are several quality control monitors in Central Service Departments. Some provide for the employee safety while others provide for safe patient care. The most important part in obtaining quality is the human element. This quality is ensured by various means from customer satisfaction indicator to administrative control monitors. Some precise indicators of quality are the technical quality control indicators. These indicators usually measure equipment and machinery performance rather than performance by Central Service personnel. Some industrial quality control standards can be applied to some aspects of Central Service quality control. A complete quality assurance program encompasses all areas of quality, not only the production segment. Continuous quality improvement programs provide ongoing betterment of Central Service products and services.

Timeframe and Teaching Method

Lecture and Discussion – 40 minutes
Post Test (Quiz) – 20 minutes

Quality Control
Post Test Quiz

1. What is Quality Control?

2. The customers determine quality; therefore, Central Service success depends upon customer _____.

3. Quality _____ is a program to monitor, document, control and/or improve the quality of service provided.

4. A complete definition of quality must also include features and _____.

5. The most important control of quality in Central Service Begins with the *management of the department*. TRUE ( ) FALSE ( )

6. Customer surveys provide opportunities for developing excellent customer relations because they facilitate open communication. TRUE ( ) FALSE ( )

7. The Central Service department provides very few processes that can be measured to assure quality. TRUE ( ) FALSE ( )

8. All sterilizer recording chart, digital printouts, registers, biological and Bowie-Dick test results will be maintained for seven (7) years. TRUE ( ) FALSE ( )

9. The six-digit control number and expiration date will be affixed to each package or item prior to sterilization. TRUE ( ) FALSE ( )

10. Which of the following should be examined and signed by the sterilizer operator after each cycle.

    a. Recording Device
    b. Appropriate Chart
    c. Digital printout
    d. All of the above

11. Sterilizers located outside the Central Service department, in other section of the medical center should be monitored.

    a. Mechanical

b. Biological Indicators
c. a & b
d. none of the above

12. Sterilizers are equipped with recorders and gauges provide the following type of monitoring.

    a. Mechanical Monitoring
    b. Chemical Monitoring
    c. Biological Monitoring
    d. All of the above

13. Select the chemical indicator test, utilized in an empty chamber, to test the air removal characteristics of prevacuum steam sterilizer.

    a. Internal chemical indicator
    b. External chemical indicator
    c. Bowie-Dick test pack
    d. None of the above

14. Match column 1 with column 2. Write the letter that corresponds with the word in column 1.

COLUMN 1	COLUMN **2**	**ANSWER**
1. External chemical indicator	a. EtO Biological	1._____
2. Bacillus Stearothermophilus	b. Test chamber air removal	2._____
3. Bowie-Dick test pack	c. Autoclave tape	3._____
4. Standard Procedures	d. Steam Biological	4._____
5. Internal chemical indicator	e. instituted by SPD Chief	5._____
6. Bacillus Subtilis	f. determine the cause	6._____
7. Positive BI's	g. placed inside packages	7._____

Quality Control
Post Test Quiz Answers

1. A check system designed and implemented to provide quality processes. (or)
   A technical, statistical sampling method that measure the quality of production.

2. SATISFACTION

3. ASSURANCE

4. DEFICIENCIES

5. TRUE

6. TRUE

7. FALSE

8. FALSE

9. FALSE

10. d. all of the above

11. c. a &b

12. a. Mechanical Monitoring

13. c. Bowie-Dick test pack

14. Matching
    1. c. autoclave tape
    2. d. Steam Biological
    3. b. test chamber air removal
    4. e. instituted by SPD Chief
    5. g. placed inside packages
    6. a. EtO Biological
    7. f. determine the cause