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INTRODUCTION

Quality assurance systems have been applied to many services within health care facilities, often leading to great confusion and misunderstanding. The intent of this document is to apply the widely accepted "International Standards Organization" (ISO) quality system model to Central Services. We believe that this system, which was developed in 1987, is applicable to Central Services as manufacturers of sterile reusable instruments and devices. The production of a sterile product encompasses many complex manual and mechanical processes. In today's health care system, the customer base has expanded to include ambulatory care facilities, physicians and even neighboring hospitals. The suppliers of medical devices are manufacturing complex instruments that require specialized cleaning methodologies including specific detergents and equipment. All these factors make the task of documenting a quality system based upon ISO an important mandate.

In order to establish a starting point for Central Service in their quest for a quality system, it was necessary to identify the primary functions within the department. Thirteen functions common to Central Service were identified. With these functions in mind, you are ready to move on to the first step in creating a quality system, which is to document your process. Since each hospital provides different services based upon its customer base and its mechanical and physical layout, it is important to develop policies and procedures that are specific to your process. State Regulations and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) require hospital policies to be reviewed and updated every three years. It is important to follow government regulations as well as national guidelines when developing hospital policy as it provides the means to defend proposed policies and enhances the professionalism and credibility of the manager and department.

Policies are broad based documents that provide direction to personnel in all aspects of Central Service such as, but not limited to: receiving; decontamination; preparation; sterilization; storage and distribution. Government regulations are minimum standards that must be met and may differ from national standards or guidelines. In cases where they differ, the more stringent of the two should be selected. Each chapter of this document references the state and federal regulations as well as the national guidelines that should be utilized when creating or revising hospital policy. In order to develop meaningful policies, it is necessary to obtain the most current versions of these regulations and standards. Once you have the current regulations and standards, you need to compare existing hospital policy to these guidelines to determine discrepancies and correct them. Once policies have been reviewed and/or revised, they must be submitted through your organizational chain of command for final adoption. In most cases, revisions will be submitted to the infection control committee and or safety committees for review and approval.

The next step in establishing a quality system is to develop specific work practices or procedures. Staff involvement is critical to developing procedures for each step of the manufacturing process as you will be asking them to document how they perform their duties on a daily basis. There are many different approaches to accomplish this task. However, the following method may prove to be the easiest.

First, choose a procedure and have your employees develop a handwritten flow chart of each step in the process. It is best to begin with a basic process and avoid unusual, or special situations such as an OR emergency, loaner instrumentation, or portable patient care equipment. These situations require deviation from the normal process and should be avoided until the basic process is developed. Specific flow charts will need to be established for each situation. Once a flow chart has been established for each step of the manufacturing process, employees should provide a written description of exactly what they do at each step of the flow chart. In essence you are looking for: "what to do, when to do it, and who and what are needed to do it?"

Once the current work practices have been developed, and flow charts developed, a review process should be performed by management and staff. The department's work practices should be compared to the ISO outline in this document to ensure that all issues are covered. At the same time, work practices can be compared to hospital policy, state and federal regulations, and national guidelines. By including staff in the process of comparing their work practices to outside sources you are empowering them to identify problems and improve practices.

Management and staff should review existing work practices looking for the following:

1. Poor work practices.
2. Short cuts.
3. Duplication of effort.
4. Staffing shortfalls.
5. Special requirements for specific products.
6. Additional training/in-servicing needs for staff.
7. Compliance with State and Federal regulations as well as national standards.

As part of this process, each should prepare recommendations for change.

Consideration of customer needs is also a major component of the quality system process. The department's ability to satisfy its customers' needs on a consistent basis is the first step towards being considered "reliable" and "professional" by your organization. In each section of this ISO guidance document, key players are identified. Although it is the manager's responsibility to work with the department's customers to identify their needs, at least one staff member should be included in the process. Time should be taken to work with departments to:

1. Review and revise forms.
2. Determine documentation issues.
3. Determine appropriate scheduling.
4. Develop communication systems.

Once management and staff have had an opportunity to review the work practices and prepare their recommendations, it's time to meet and collaborate to improve these practices. You should have before you, the actual practices, changes based on government regulations and/or national guidelines, input from customers, revised documents and forms, and management assessment of work practices. Before the process begins, a recorder should be appointed to keep the minutes and prepare drafts of the final document for review prior to the next meeting. Each step of the process should be reviewed and input solicited from each person present. There should be rules set for the process to assure that everyone is heard in an orderly and fair manner.

It is important that the group set attainable goals for each session and not attempt to do more than is reasonable at one session. Once the work practices have been revised and all parties are in agreement, a draft will be prepared. This draft will be distributed to all members of the group for final review before the next session. At the next meeting the changes should be minimal and, once everyone has had the opportunity to comment, the practice should be unanimously approved. Once done, the practice will be initiated. It is imperative that the practice not be changed or adapted to individual circumstances. Any recommendations for change or improvement must be made to, and approved by, the group. This will assure standardized practice and improve the performance of all employees and on all shifts.

The last step is to determine how you are going to monitor and measure the efficacy of the process. Determine the critical steps in the process and develop a method to continuously monitor and measure the efficiency of the process. Prepare documentation that will allow you to collect the data necessary to monitor the process. Internal audits should be conducted. You may use peer review, management audits or outside audits as a means of detecting problems. It's important to determine how the audit function will be performed, the frequency of the audit process, verification of corrective action, and report on the effectiveness of corrective action. It's important to focus on the process and not the outcome. Important tools to use are the responses from customers such as customer surveys, informal customer comments and complaints. The group must decide how you collect this data and how to analyze the data?

The final issue is process improvement. Think of process improvement as a race without a finish line. At each stage of the system, identify goals or objectives that the staff can use to improve the system. Start small and work off your successes. You may include both corrective action and preventive action as process improvement. In the case of corrective action, you are fixing problems in an effort to make the system meet your known needs. In this instance, the process isn't working as planned or wasn't right from the beginning and is in need of repair. Preventive action, on the other hand, is intended to avoid potential problems.

Regardless of the role that you play, you must follow the documented procedure for corrective action. It's important to have good closure, which means that the problem has been completely analyzed, permanently remedied, recorded, implemented, and reviewed.

Now you may begin your journey down the quality systems path. Please use this guidance document as a guiding light. As time goes on and we receive feedback from those brave souls that embark on this most difficult journey, we will revise and update this document. This is truly an endless journey, which will lead to a more efficient system, safe medical/surgical devices for patients, increased productivity, reduced costs, and employee satisfaction.

This is a guidance document that should be used as a tool in developing a quality control system in Central Services. References will change over time as well as Central Supply issues.