Management Controls Subsystem

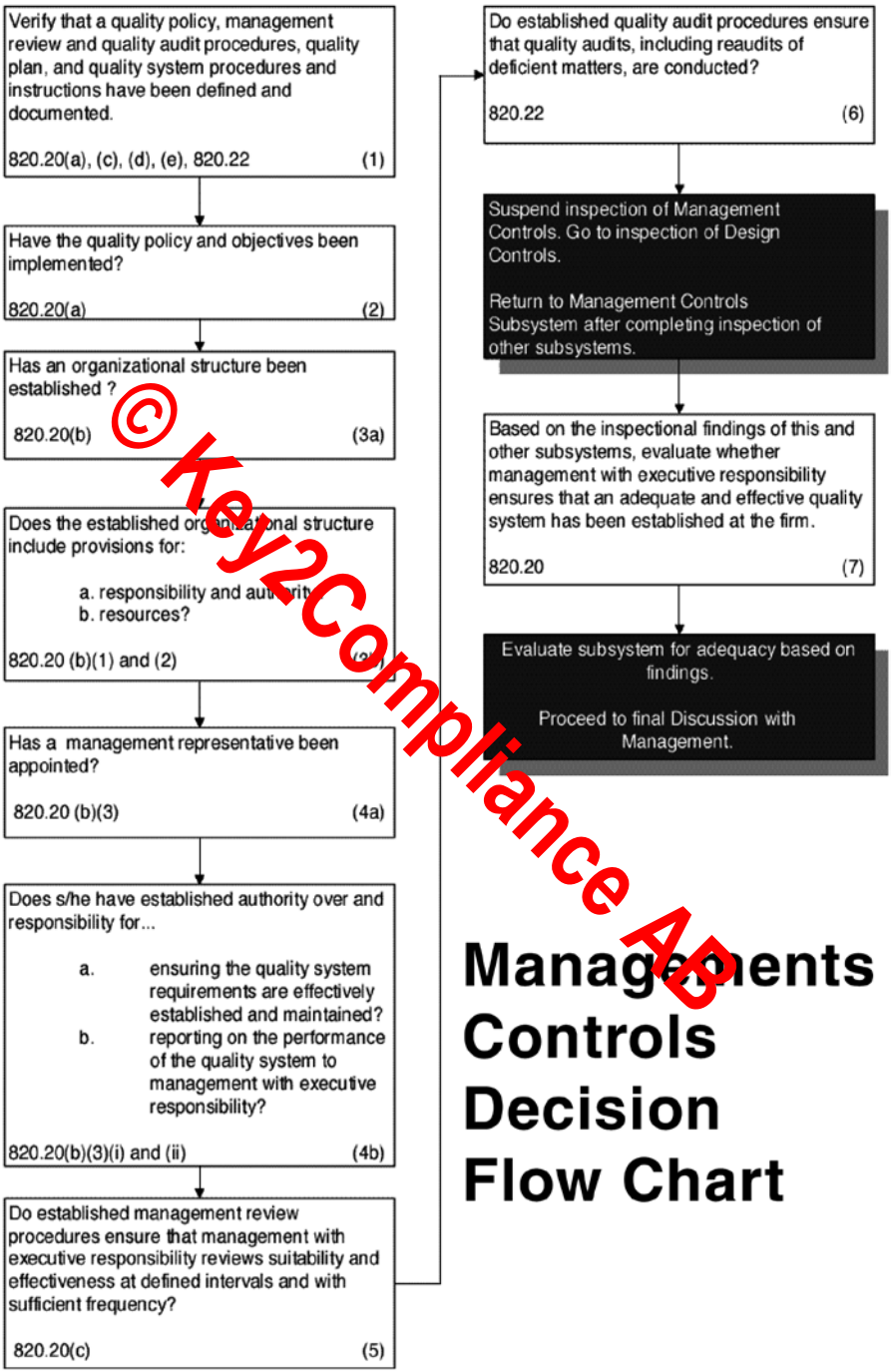
Management Controls

Inspectional Objectives

1. Verify that a quality policy, management review and quality audit procedures, quality plan, and quality system procedures and instructions have been defined and documented.
2. Verify that a quality policy and objectives have been implemented.
3. Review the firm's established organizational structure to confirm that it includes provisions for responsibilities, authorities and necessary resources.
4. Confirm that a management representative has been appointed. Evaluate the purview of the management representative.
5. Verify that management reviews, including a review of the suitability and effectiveness of the quality system, are being conducted.
6. Verify that quality audits, including re-audits of deficient matters, of the quality system are being conducted.

   At the conclusion of the inspection....

7. Evaluate whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained.



Management Controls Decision Flow Chart

Management Controls

Narrative

Purpose/Importance

The purpose of the management control subsystem is to provide adequate resources for device design, manufacturing, quality assurance, distribution, installation, and servicing activities; assure the quality system is functioning properly; monitor the quality system; and make necessary adjustments. A quality system that has been implemented effectively and is monitored to identify and address problems is more likely to produce devices that function as intended.

A primary purpose of the inspection is to determine whether management with executive responsibility ensures that an adequate and effective quality system has been established (defined, documented and implemented) at the firm. Because of this, each inspection should begin and end with an evaluation of this subsystem.

1. **Verify that a quality policy, management review and quality audit procedures, quality plan, and quality system procedures and instructions have been defined and documented.**

Prior to the start of the inspection, preferably at the time you make the preannouncement of the inspection (if preannounced), you should ask the firm to send you their overall (or top level) quality system policies, objectives, and procedures. This should include their management review procedures, quality policy, and quality plan. If not received prior to the start of the inspection, you will need to review these documents at the start of your inspection.

Quality Policy and Objectives

The firm must have a written quality policy. The definition of quality policy is provided in the Quality System Regulation. It means the overall intentions and directions of an organization with respect to quality. The firm is responsible for establishing a clear quality policy with achievable objectives then translating the objectives into actual methods and procedures. Management with executive responsibility (i.e. has the authority to establish and make changes to the company quality policy) must assure the policy and objectives are understood and implemented at all levels of their organization. The policy does not need to be extensive. Personnel are not required to be able to recite the policy but they should be familiar with it and know where to obtain it.

Management Review and Quality Audit Procedures

Management reviews and quality audits are a foundation of a good quality system. Assure that the manufacturer has written procedures for conducting management reviews and quality audits and there are defined intervals for when they should occur. The firm's quality audits should examine the quality system activities to demonstrate that the procedures are appropriate to achieve quality system objectives, and the procedures have been implemented. A successful implementation of the firm's procedures should result in the firm achieving its quality policy and associated objectives. Whether the quality policy and objectives are "good" may become evident as the other subsystems are reviewed during the inspection.

Quality Plans

The firm must have a written quality plan that defines the quality practices, resources and activities relevant to the devices that are being designed and manufactured at that facility. The manufacturer needs to have written procedures that describe how they intend to meet their quality requirements.

For firms that manufacture devices as well as other products, there must be a quality plan that is specifically relevant to devices. Much of what is required to be part of the plan may be found in the firm's quality system documentation, such as, the Quality Manual, Device Master Record(s), production procedures, etc. Therefore, the plan itself may be a roadmap of the firm's quality system. The plan in this case would need to include reference to applicable quality system documents and how those documents apply to the device(s) that is the subject of the plan.

Quality plans may be specific to one device or be generic to all devices manufactured at the firm. Quality plans can also be specific to processes or overall systems.

Quality System Procedures and Instructions

All manufacturers of medical devices are required to establish and implement a quality system tailored to the device manufactured. Each manufacturer must prepare and implement all activities, including, but not necessarily limited to the applicable requirements of the Quality System Regulation, that are necessary to assure the finished device, the design process, the manufacturing process, and all related activities conform to approved specifications.

The term "quality system" as specified in the Quality System Regulation encompasses all activities previously referred to as "quality assurance" which were necessary to assure the finished device meets its predetermined design specifications. This includes assuring manufacturing processes are controlled and adequate for their intended use, documentation is controlled and maintained, equipment is calibrated, inspected, tested, etc. Some manufacturers may use the terms "quality control" or "GMP Control" or "quality assurance" instead of quality system.