Content Sheet 3-1: Organizational Requirements for a Quality Management System

Definition

The term **organization** in the context of a quality management model is used to indicate the management and the supporting organizational structure of the laboratory.

Organization is one of the essential elements of the quality system, and is intimately related to all the other elements in the model.

Characteristics essential to success

The principal element for a successful quality management system is **managerial commitment**.

Management at all levels must fully support, and actively participate in the quality system activities.

Support should be visible to staff so that there is an understanding of the importance of the effort.

Without the engagement of management, including the decision-making level of the organization, it will not be possible to put in place the policies and the resources needed to support a laboratory quality management system.

A second vital element is that the **organizational structure** must be designed to assure that the quality goals of the organization are met.

The laboratory must be a legally structured entity according to local requirements.

All the organizational elements required to assure a properly functioning quality management system must be in place.

Key organizational components

The important organizational requirements for achieving a successful quality system include the following.

Leadership—Laboratory leaders must be fully committed to implementation of the system, and these leaders also will need vision, team-building and motivational skills, good communication techniques, and the ability to use resources responsibly.

Organizational structure—The structure of the organization should be clearly defined, and this should be reflected by a functional organizational chart with clear assignment of responsibility.

Planning process—Skills for planning are needed, and planning should address a time frame, responsibility for conducting the activities, the availability and use of human resources, management of workflow, and financial resources.

Implementation—Implementation requires that a number of issues must be addressed by the management staff. These include management of projects and activities, directing resources to accomplish plans, and assuring that timelines are met and goals achieved.

Monitoring—As components of the quality management system are put in place, processes for monitoring will be needed to assure that the system is working, that benchmarks and standards are being met. This element is essential to the primary goal of a quality system, which is **continuous improvement**.

Content Sheet 3-2: Management Role

Providing leadership

Leadership can be defined in many ways, but it is an important factor in the success of any organization's efforts for improvement.

A good leader will exercise responsible authority.

Important roles for a leader include:

- providing vision;
- giving a direction for goal-setting;
- motivating staff;
- providing encouragement.

A strong leader will help staff understand the importance of the task at hand.

Responsibilities of managers

"Laboratory management shall have responsibility for the design, implementation, maintenance, and improvement of the quality management system." ISO 15189 [4.1.5]

A quality management system outlines specific responsibilities of managers. Management must be responsible for:

- establishing the policies and processes of the quality system;
- assuring all policies, processes, procedures, and instructions are documented;
- making sure that all personnel understand documents, instructions, and their duties and responsibilities;
- providing personnel with the appropriate authority and resources to carry out their duties.

Management is charged with providing a quality manual which describes the quality management system. The quality manual is the means by which the policies are established and communicated to the staff and the users of the laboratory.

Laboratory Directors have the principal responsibility for setting up an organization that can support the quality system model. They are responsible for developing policies, assigning authority and responsibility to the appropriate persons, assuring resources, and reviewing the organizational aspects of the system for optimal functioning of quality processes. Laboratory directors must ensure that staff follows the quality policies established by the quality manual.

Quality Managers assist in developing policies, planning, and implementing the quality management system. They are usually responsible for many of the implementing and monitoring processes, and must communicate all aspects of the quality management system processes to the laboratory director or head of

the laboratory.

Laboratory Staff (Laboratorians) are responsible for understanding the organizational structure of the laboratory, including where authority and responsibility are assigned. The laboratory staff will follow all of the quality policies in their daily work routine.

Commitment of management

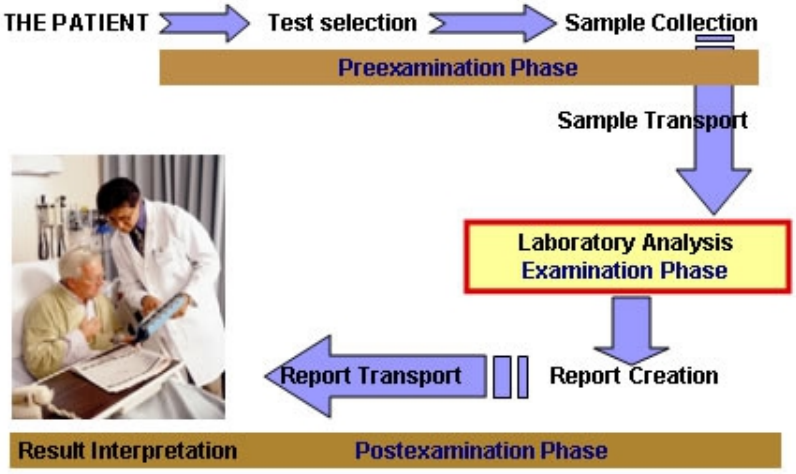
Most critical in beginning any new program is to seek approval from the top. Management needs to be involved at a sufficiently high level to assure success of the program. When implementing a quality system, determine what the "sufficiently high level" is; be sure to include those who make decisions as their approval and support is vital. Finally, it is important that laboratory managers communicate their commitment to the entire laboratory staff. Managers must show the way, and encourage and foster the "spirit" of the organization.

Content Sheet 3-3: Organizational Structure

Elements of structure

When considering organizational structure to support a quality management system, a number of elements should be considered:

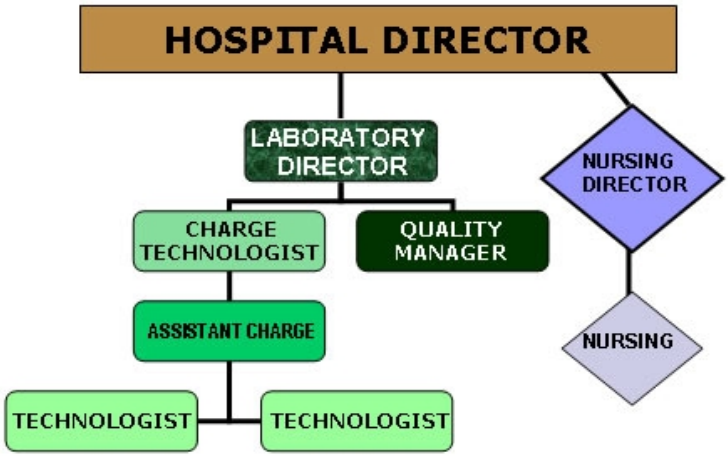
The **Path of Workflow** is the route of a sample through the laboratory, from collection to reporting of a result. The organizational structure of the laboratory must support an optimal Path of Workflow, by allowing processes that yield efficient sample handling while minimizing error. Considerable attention should be given to the design of this system.



An accurate and complete organizational chart is necessary. Many problems can be prevented if responsibilities are clearly defined and all members of the laboratory team understand what each is supposed to do.

A quality management system must have a quality manager.

Resource allocation must be sufficient to assure that personnel and infrastructure needs are met.



Quality Manager

ISO 15189 [4.1.5 i] states that a laboratory must have a quality manager. The quality manager is the person most directly responsible for assuring that the quality policies and procedures are carried out.

The quality manager should sit high in the organizational structure; he or she must be delegated the appropriate responsibility and authority to assure compliance to the quality system requirements. The quality manager should report directly to the decision maker(s) in the organization.

A very large laboratory may need several quality managers, perhaps one for each section. On the other hand, in a small laboratory this may be a part-time job for a senior technologist, or even a job that is carried out by the laboratory manager.

The quality manager may be assigned many tasks. Some typical responsibilities of the quality manager will include:

monitoring all aspects of the quality system;

assuring staff are following quality policies and procedures;

reviewing regularly all records, for example, QC and EQA that are part of the quality system;

organizing internal audits, and coordinating external audits;

investigating any deficiencies identified in the audit process;

informing management on all aspects of the quality system monitoring.

Content Sheet 3-4: Organizational Functions: Planning

Approaches to planning

Once management is committed to instituting a quality system in the laboratory, a planning process is needed. Approaches used will vary depending on many factors in the local situation.

What quality practices are already in use in the laboratory?

What is the level of knowledge of current staff?

What resources will be available?

All elements of the quality system should be included in the planning process. It is not necessary (usually not possible) to implement all parts of the plan at once; a stepwise approach will often be more practical.

In many laboratories, the implementation of a quality system may involve many changes. It is, therefore, important to keep all staff involved, and to not proceed too rapidly, as personnel may find it difficult to meet the goals and can get discouraged. Communicate with staff frequently, clearly, and positively; this will help to keep morale high.

During planning, priority areas will emerge as the bigger problems are identified. It will be important to keep objectives realistic and measurable. Inevitably, there will be some factors that are beyond the control of the laboratory. Recognize these and move on to other factors that can be addressed. If these factors are vital to the ultimate success of the quality program, then look for ways to influence those who can control them. Always advocate for quality.

Establish plan

In planning for implementation of a quality system, the first step is to analyze and understand the current practices. A useful way to accomplish this is the technique of **gap analysis**. To conduct a gap analysis:

use a good quality systems checklist, evaluate the practices in the individual laboratory;

identify gaps, or areas where the laboratory is not using the good laboratory practices required in the quality system.

Using the information provided by the gap analysis, develop a task list of everything needing to be addressed, and then set priorities. In determining priorities, consider first addressing problems that can be easily fixed; this will give some early successes and boost staff morale. Also evaluate what would have the most impact on laboratory quality and give these factors high priority.

Problems commonly identified in laboratories using a gap analysis include:

test ordering

sample management

incompetent technical staff

quality control

analytical process

recording and reporting results

reagent and equipment management.

The quality system plan

The implementation of a quality system in the laboratory requires a written plan. A written plan makes clear to all staff and all users of the laboratory how the process will proceed. The plan should contain the following components:

objectives and tasks—what should be done;

responsibilities—who will get the job done, who will be responsible;

timeline—when will each task be worked on, when will it be completed;

budget and resource needs—additional staff, training needs, facilities, equipment, reagents and supplies, quality control materials;

benchmarks—essential for monitoring progress in implementation.

The written plan should be made available to all laboratory staff, as everyone must understand the plan and the process of implementation.

Content Sheet 3-5: Organizational Functions: Implementation

Beginning implementation

Once a plan has been written and agreed upon, implementation will begin. These suggestions will help the laboratory in this process.

Commit from the beginning to complete the project and achieve the established objectives. Go in with a positive attitude—a "can do" approach.

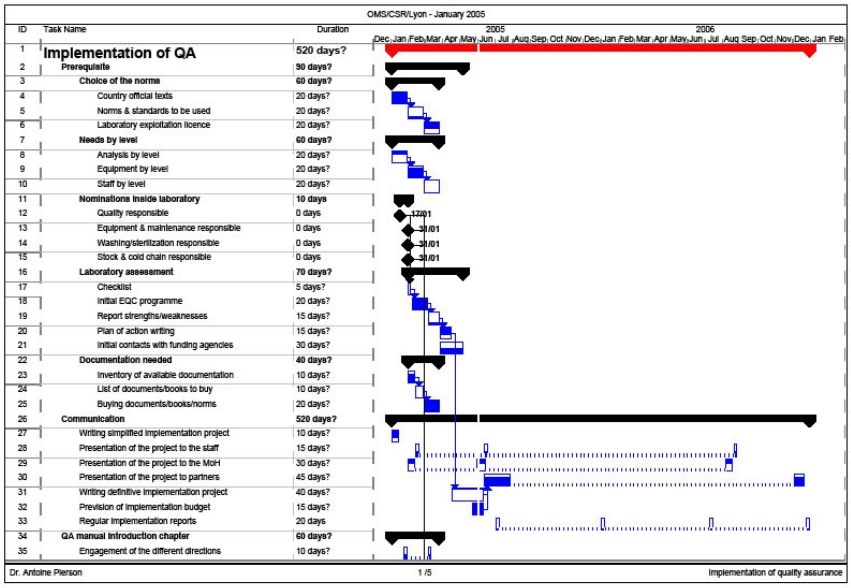
Prepare to implement in stages. It is important to prevent staff from getting discouraged, so choose manageable "bites" at the beginning. Staggering start dates will also be helpful; use established priorities to determine start dates.

Determine resource requirements early in the process, and secure the necessary resources before starting tasks. If working in a highly resource-limited environment, choose as initial activities those things that can be done with available funds and staff – there are many such activities, such as improving documents, records, or developing up-to-date and improved standard operating procedures or SOPs.

Engage all staff by communicating effectively. If training is needed to have personnel understand the quality system and its goals, this training should probably be done before starting other tasks.

Following the timeline

As a part of the planning process, the laboratory will have established a timeline for tasks to be performed, including a projected completion date. This timeline is a critical part of the process, as it allows everyone in the laboratory to observe progress. A **Gantt chart** (shown below and Annex 18-A [complete 5-page version]) is a very useful tool for visually representing the proposed time line; it shows tasks to be done, with times of beginning and completion.



The timeline should be very carefully prepared, so as to allow appropriate times for completion. Do not let the laboratory staff become overwhelmed with the tasks that need to be accomplished.

Providing resources

During the planning process, all additional resources that are needed will have been identified. As implementation begins, be sure that these resources are in place and available. Several kinds of resources need to be considered:

all financial requirements— establish a budget;

personnel needs—are additional laboratory staff required, will training be needed for any of the staff?

facilities, equipment, supplies, and computer needs.

Monitoring basics

Establishing a system for monitoring quality management is essential in implementing a quality system. It is the monitoring and maintenance part of the effort that will produce the continuous improvement that is the overall goal of a good quality system. Monitoring involves being able to check each part of the system to be sure that the system is working properly.

Establishing monitoring program

There are several steps in setting up a program to monitor compliance to the quality system.

Assign responsibility for the process. Usually the quality manager will be the person who is primarily responsible for the monitoring program.

Develop indicators or benchmarks using the laboratory quality policy. These indicators will be monitored over time.

Develop a system for the monitoring process; establish time or frequency of checks, decide how the monitoring will be managed.

Conduct audit, followed by management review; these constitute two important tools in monitoring compliance.

Internal audits should be conducted at regular intervals. They are valuable for evaluation, and they are required by ISO 15189.

Management reviews are a particularly valuable component of the monitoring process. It is the responsibility of management to review all appropriate quality systems information, and to look for opportunities for improvement.

Content Sheet 3-6: The Laboratory Quality Manual

Definition

The quality manual is a document which fully describes the quality management system of an organization. It is key to the process, serving as a guide for the entire system. The manual will clearly lay out the quality policies, and will describe the structure of the other laboratory documents.

In a laboratory that is implementing a quality management system, there must be a quality manual. However, there is considerable flexibility in how to prepare it, and a laboratory can construct the manual so that it is most useful and suited to the local need (see Module 16, Documents and Records, for additional information).

ISO 15189 [4.2.4] requires that laboratories have a quality manual, although style and structure are not specified.

Writing a quality manual

The purpose of a quality manual is to clearly communicate information, and to serve as a framework or roadmap for meeting quality system requirements. The manual is the responsibility of laboratory management, and thus conveys managerial commitment to quality and to the quality management system.

The manual should contain the following.

All quality policies of the laboratory—these should address all twelve elements of the quality system.

A reference to all processes and procedures— For example, SOPs are a part of the overall quality system. There are usually too many to include directly in the quality manual, but the manual should say that all procedures must have an SOP and that these can be found in the SOP manual.

A table of contents—ISO 15189 provides a suggested table of contents, and this includes a description of the laboratory, staff education and training policies, and all the other elements of a quality management system (e.g., documents and records).

Maintaining and using the quality manual

The quality manual is the framework for the entire quality management system, and, therefore it must always be correct and up-to-date. The laboratory will need to establish a process to assure this. The following steps offer suggestions for developing, maintaining, and using the quality manual.

When the quality manual is written and prepared, it must be approved by the head of the laboratory. In some laboratories, approval by another appropriate person, such as the quality manager, might also be required. This approval should be indicated by having official signatures and dates of signing recorded in the manual itself.

A process or system for updating needs to be established. This system should specify the frequency for reviewing the manual, assign responsibility for updating to someone (usually the quality manager), and define how changes in the manual will be incorporated and documented. Changes to the quality manual will need to be approved; approval should be indicated by having signatures of the person(s) with authority to make changes, and the date of the change, recorded in the manual.

Instruction on use of the manual should be provided to all laboratory staff; laboratory personnel must understand that the policies detailed in the quality manual are always to be followed.

Content Sheet 3-7: Summary

Steps for organization

As the laboratory moves from intent to action in the development of a quality management system, the major organizational steps will be to assign responsibility for implementation, allocate resources, develop and distribute a quality manual, begin implementation, and monitor compliance with the quality policy and the quality management system requirements.

Successful implementation of a quality management system requires planning, management commitment, an understanding of the benefits, engaging staff at all levels, setting realistic time frames, and looking for ways to continually improve.

Key messages

Remember:

Quality is not a science; it is a way of thinking.

Time invested today will help gain quality results, professional and personal satisfaction, and peer recognition.

Everyone in the laboratory is responsible for quality performance.

- Laboratory leaders and managers must commit to meeting quality needs.
- Laboratory personnel must follow all quality assurance procedures and adhere to requirements and standards.