

A decorative graphic on the right side of the page. It features a vertical orange bar at the top left. Below it, a large orange circle is partially visible on the left edge. A dark blue line with a white double-line border connects this circle to another orange circle on the right edge. Below the first circle, another dark blue line with a white double-line border connects it to a light grey circle at the bottom edge.

1. Introduction to quality

1-1: The importance of laboratory quality

Definition of quality

Laboratory quality can be defined as accuracy, reliability and timeliness of reported test results. The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting.

Level of accuracy required

When making measurements, there is always some level of inaccuracy. The challenge is to reduce the level of inaccuracy as much as possible, given the limitations of our testing systems. An accuracy level of 99% may at first glance appear acceptable, but the resulting 1% error can become quite large in a system where many events occur, such as laboratory testing.

Negative consequences of laboratory error

Laboratories produce test results that are widely used in clinical and public health settings, and health outcomes depend on the accuracy of the testing and reporting. If inaccurate results are provided, the consequences can be very significant, including:

- unnecessary treatment
- treatment complications
- failure to provide the proper treatment
- delay in correct diagnosis
- additional and unnecessary diagnostic testing.

These consequences result in increased cost in time and personnel effort, and often in poor patient outcomes.

Minimizing laboratory error

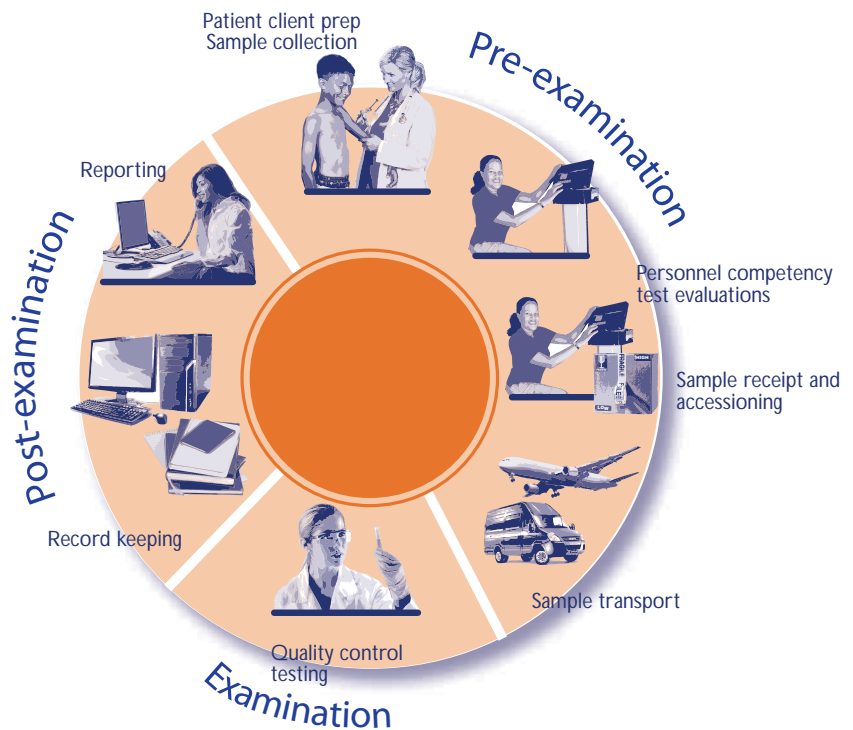
In order to achieve the highest level of accuracy and reliability, it is essential to perform all processes and procedures in the laboratory in the best possible way. The laboratory is a complex system, involving many steps of activity and many people. The complexity of the system requires that many processes and procedures be performed properly. Therefore, the quality management system model, which looks at the entire system, is very important for achieving good laboratory performance.

1-2: Overview of the quality management system

Definition of quality management system

A quality management system can be defined as “coordinated activities to direct and control an organization with regard to quality”. This definition is used by the International Organization for Standardization (ISO) and by the Clinical and Laboratory Standards Institute (CLSI). Both groups are internationally recognized laboratory standards organizations, and will be discussed later in this handbook.

In a quality management system, all aspects of the laboratory operation, including the organizational structure, processes and procedures, need to be addressed to assure quality.



Complexity of laboratory processes

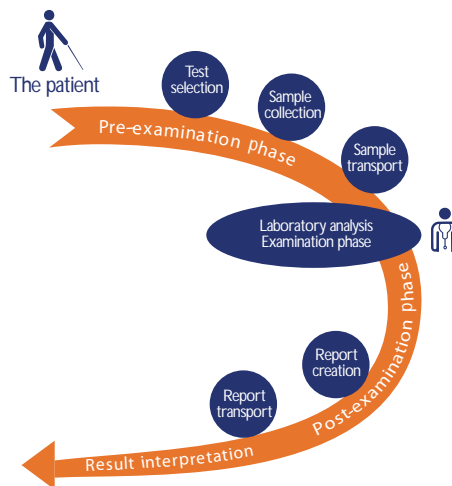
There are many procedures and processes that are performed in the laboratory, and each of these must be carried out correctly in order to assure accuracy and reliability of testing. An error in any part of the cycle can produce a poor laboratory result. A method of detecting errors at each phase of testing is needed if quality is to be assured.

Path of workflow

ISO standards group laboratory processes into pre-examination, examination and post-examination categories. Comparable terms in current laboratory use include: pre-analytic, analytic and post-analytic processes; or pre-test, test and post-test processes.

The entire set of operations that occur in testing is called the **path of workflow**. The path of workflow begins with the patient and ends in reporting and results interpretation, as shown in the figure below.

The concept of the path of workflow is a key to the quality model or the quality management system, and must be considered when developing quality practices. For example, a sample that is damaged or altered as a result of improper collection or transport cannot provide a reliable result. A medical report that is delayed or lost, or poorly written, can negate all the effort of performing the test well.



Quality management system addresses all processes

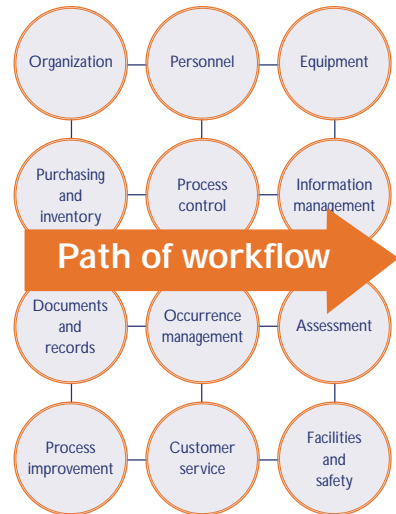
The complexity of the laboratory system requires that many factors must be addressed to assure quality in the laboratory. Some of these factors include:

- the laboratory environment
- quality control procedures
- communications
- record keeping
- competent and knowledgeable staff
- good-quality reagents and equipment.

Overview of the quality management system model

1-3: The quality management system model

When all of the laboratory procedures and processes are organized into an understandable and workable structure, the opportunity to ensure that all are appropriately managed is increased. The quality model used here organizes all of the laboratory activities into 12 quality system essentials. These quality system essentials are a set of coordinated activities that serve as building blocks for quality management. Each must be addressed if overall laboratory quality improvement is to be achieved. This quality management system model was developed by CLSI,¹ and is fully compatible with ISO standards.^{2,3}



Assuring accuracy and reliability throughout the path of workflow depends on good management of all of the quality essentials.

Organization

In order to have a functioning quality management system, the structure and management of the laboratory must be organized so that quality policies can be established and implemented. There must be a strong supporting organizational structure—management commitment is crucial—and there must be a mechanism for implementation and monitoring.

Personnel

The most important laboratory resource is competent, motivated staff. The quality management system addresses many elements of personnel management and oversight, and reminds us of the importance of encouragement and motivation.

Equipment

Many kinds of equipment are used in the laboratory, and each piece of equipment must be functioning properly. Choosing the right equipment, installing it correctly, ensuring that new equipment works properly, and having a system for maintenance are all part of the equipment management programme in a quality management system.

¹ CLSI/NCCLS. *A quality management system model for health care: approved guideline—second edition*, CLSI/NCCLS document HS1-A2. Wayne, PA, NCCLS, 2004.

² ISO 15189:2007. *Medical laboratories—particular requirements for quality and competence*. Geneva: International Organization for Standardization, 2007.

³ ISO 9001:2000. *Quality management systems—requirements*. Geneva: International Organization for Standardization, 2000.

Purchasing and inventory

The management of reagents and supplies in the laboratory is often a challenging task. However, proper management of purchasing and inventory can produce cost savings in addition to ensuring supplies and reagents are available when needed. The procedures that are a part of management of purchasing and inventory are designed to ensure that all reagents and supplies are of good quality, and that they are used and stored in a manner that preserves integrity and reliability.

Process control

Process control is comprised of several factors that are important in ensuring the quality of the laboratory testing processes. These factors include **quality control** for testing, appropriate **management of the sample**, including collection and handling, and **method verification and validation**.

The elements of process control are very familiar to laboratorians; quality control was one of the first quality practices to be used in the laboratory and continues to play a vital role in ensuring accuracy of testing.

Information management

The product of the laboratory is information, primarily in the form of test reporting. Information (data) needs to be carefully managed to ensure accuracy and confidentiality, as well as accessibility to the laboratory staff and to the health care providers. Information may be managed and conveyed with either paper systems or with computers; both will be discussed in the section on information management.

Documents and records

Many of the 12 quality system essentials overlap. A good example is the close relationship between "Documents and records" and "Information management". Documents are needed in the laboratory to inform how to do things, and laboratories always have many documents. Records must be meticulously maintained so as to be accurate and accessible.

Occurrence management

An "occurrence" is an error or an event that should not have happened. A system is needed to detect these problems or occurrences, to handle them properly, and to learn from mistakes and take action so that they do not happen again.

Assessment

The process of assessment is a tool for examining laboratory performance and comparing it to standards, benchmarks or the performance of other laboratories. Assessment may be internal (performed within the laboratory using its own staff) or it may be external (conducted by a group or agency outside the laboratory). Laboratory quality standards are an important part of the assessment process, serving as benchmarks for the laboratory.

Process improvement

The primary goal in a quality management system is continuous improvement of the laboratory processes, and this must be done in a systematic manner. There are a number of tools that are useful for process improvement.

Customer service

The concept of customer service has often been overlooked in laboratory practice. However, it is important to note that the laboratory is a service organization; therefore, it is essential that clients of the laboratory receive what they need. The laboratory should understand who the customers are, and should assess their needs and use customer feedback for making improvements.

Facilities and safety

Many factors must be a part of the quality management of facilities and safety. These include:

- **Security**—which is the process of preventing unwanted risks and hazards from entering the laboratory space.
- **Containment**—which seeks to minimize risks and prevent hazards from leaving the laboratory space and causing harm to the community.
- **Safety**—which includes policies and procedures to prevent harm to workers, visitors and the community.
- **Ergonomics**—which addresses facility and equipment adaptation to allow safe and healthy working conditions at the laboratory site.

Quality management system model

In the quality management system model, all 12 quality system essentials must be addressed to ensure accurate, reliable and timely laboratory results, and to have quality throughout the laboratory operations. It is important to note that the 12 quality system essentials may be implemented in the order that best suits the laboratory. Approaches to implementation will vary with the local situation.

Laboratories not implementing a good quality management system are guaranteed that there will be many errors and problems occurring that may go undetected. Implementing a quality management system may not guarantee an error-free laboratory, but it does yield a high-quality laboratory that detects errors and prevents them from recurring.

1-4: History of laboratory quality management

Definition of quality management

ISO 9000 defines quality management as “coordinated activities to direct and control an organization with regard to quality”. This is intimately related to the definition of a quality system—“organizational structure, resources, processes and procedures needed to implement quality management”. Quality management concepts in use today had their onset in the 20th century, and are primarily an outgrowth of manufacturing and shop processes.

Principal innovators and their contributions

One of the earliest concepts of the quality management movement was that of quality control of the product. Shewhart developed a method for statistical process control in the 1920s, forming the basis for quality control procedures in the laboratory. Quality control methods were not applied in the laboratory until the 1940s. Other critical thinkers and innovators, including Arman Feigenbaum, Kaoru Ishikawa and Genichi Taguchi, added to the concepts. The most recent method that is of importance to the laboratory is Galvin's work on micro-scale error reduction.

Quality management is not new.

1-5: International laboratory standards

Need for international laboratory standards

A part of quality management is assessment, measuring performance against a standard or benchmark. The concept of quality management requires that standards be set, and again industry has been in the lead.

Important laboratory standards organizations

Using a set of standards established by the United States of America military for the manufacture and production of equipment, the ISO established standards for industrial manufacturing; we know these standards as ISO standards.

ISO

The ISO 9000 documents provide guidance for quality in manufacturing and service industries, and can be broadly applied to many other kinds of organizations. ISO 9001:2000 addresses general quality management system requirements and applies to laboratories. There are two ISO standards that are specific to laboratories:

- ISO 15189:2007. *Medical laboratories—particular requirements for quality and competence*. Geneva: International Organization for Standardization, 2007.
- ISO/IEC 17025:2005. *General requirements for the competence of testing and calibration laboratories*. Geneva: International Organization for Standardization, 2005.

CLSI

Another important international standards organization for laboratories is the Clinical and Laboratory Standards Institute, or CLSI, formerly known as the National Committee for Clinical Laboratory Standards (NCCLS). CLSI uses a consensus process involving many stakeholders for developing standards. CLSI developed the quality management system model used in this handbook. This model is based on 12 quality system essentials, and is fully compatible with ISO laboratory standards.

CLSI has two documents that are very important in the clinical laboratory:

- *A quality management system model for health care; approved guideline—second edition*. CLSI/NCCLS document HS1-A2. Wayne, PA, NCCLS, 2004.
- *Application of a quality management system model for laboratory services; approved guideline—third edition*. CLSI/NCCLS document GP26-A3. Wayne, PA, NCCLS, 2004.



Other standards

The information in this handbook is based on the CLSI quality management system model and the ISO 15189 standard.

There are many other standards organizations, and many examples of laboratory standards. Some countries have established national laboratory quality standards that apply specifically to laboratories within the country. Some laboratory standards apply only to specific areas in the laboratory or only to specific tests. The World Health Organization has established standards for some specific programmes and areas.

Quality
management

Key messages



1-6: Summary

Quality management is not new; it grew from the work of innovators who defined quality over a span of 80 years. Quality management is as applicable for the medical laboratory as it is for manufacturing and industry.

- A laboratory is a complex system and all aspects must function properly to achieve quality.
- Approaches to implementation will vary with the local situation.
- Start with changes that can be easily accomplished and have the biggest impact.
- Implement in a stepwise process but ultimately, **all quality essentials must be addressed.**