



Introduction to Laboratory Quality Management System (LQMS)

The aim of the LQMS is to provide an accurate and consistently error free laboratory service that provides timely and dependable diagnostic pathology results to clinicians.

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). Diagnostic Laboratories worldwide seek to fulfil the requirements of ISO15189, ISO/IEC 17025:2017 or CLSI GP26-A3, as a quality marker of performance and status. Meaning that every aspect of the laboratory’s services are checked, monitored, documented and reported in accordance to these standard guidelines.

Laboratory quality can be defined as accuracy, reliability and timeliness of reported test results.

Laboratory testing involves many levels of activity and complexity associated with:

- people
- processes
- procedures

All are subject to many variables and hence errors.

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
- longer hospital stays
- additional and unnecessary diagnostic testing.

A Quality Management System model looks at the entire laboratory system processes which may impact on result reliability. Each process and procedure must be carried out correctly to assure accuracy and reliability of every component that contributes towards the final test result and its reporting.

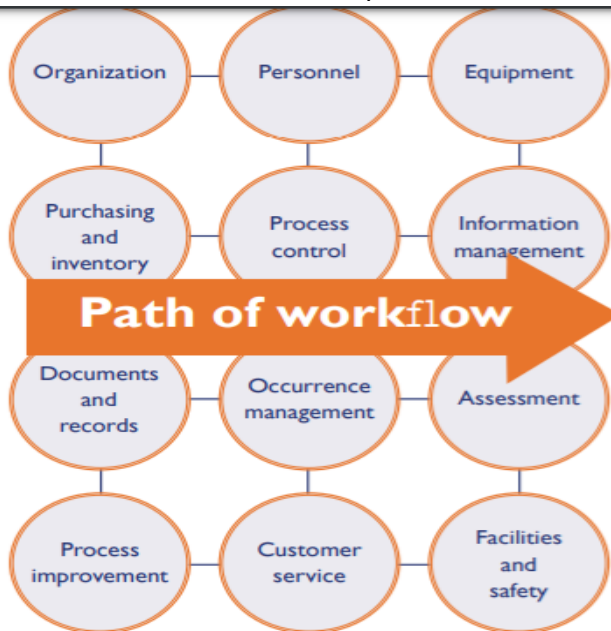
These processes include:

- the laboratory environment, facilities and workflow
- quality control procedures for equipment, tests kits, specimens, reagents
- communication chains across all levels of the organisation
- record keeping and recording
- competently trained and technically skilled staff
- high quality reagents and optimised equipment performing at its best level.

Laboratory Sample Path of workflow is divided into Pre exam, Exam and Post exam



The CLSI/ISO quality model organizes all the laboratory activities into 12 quality system essentials. It covers all the components influential in operating a laboratory service.



References

- WHO Laboratory Quality Stepwise Implementation Tool, WHO Laboratory Quality Standards and their Implementation.
<https://extranet.who.int/lqsi/content/quality-management-2>
<https://extranet.who.int/lqsi/content/create-commitment-go-accreditation-0>