# Laboratory Quality Management System

# Training toolkit

# Participant's Guide – Table of contents and overview


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Contacts

WHO Lyon Office
58 avenue Debourg – 69007 Lyon – France
ihrinfo@who.int

Clinical and Laboratory Standards Institute
940 West Valley Road, Suite 1400
Wayne, PA 19087 – USA
customerservice@clsi.org

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# Section 1: Overview

## Introduction

This section provides an overview of the content and the structure of the Laboratory Quality Management System training toolkit:

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# About this training toolkit

## *Background*

Achieving, maintaining and improving accuracy, timeliness, and reliability are major challenges for health laboratories. Countries worldwide committed themselves to build national capacities for the detection of, and response to, public health events of international concern when they decided to engage in the International Health Regulations implementation process.

Only a sound management of quality in health laboratories will enable countries to produce test results that the international community will trust in cases of international emergency.

Training laboratory managers, senior biologists, and technologists in quality management systems is a step towards obtaining international recognition; it is a step that all countries should take.

Note: Health laboratories, in this training package, is a term that is meant to be inclusive of clinical laboratories, diagnostic laboratories, medical laboratories, public health laboratories, or any other laboratories including animal and environmental health laboratories performing testing for the purpose of disease diagnosis, screening or prevention, medical treatment decisions, surveillance or public health. Because all these terms for laboratories are frequently used interchangeably, the terms may likewise be used interchangeably in this training package.

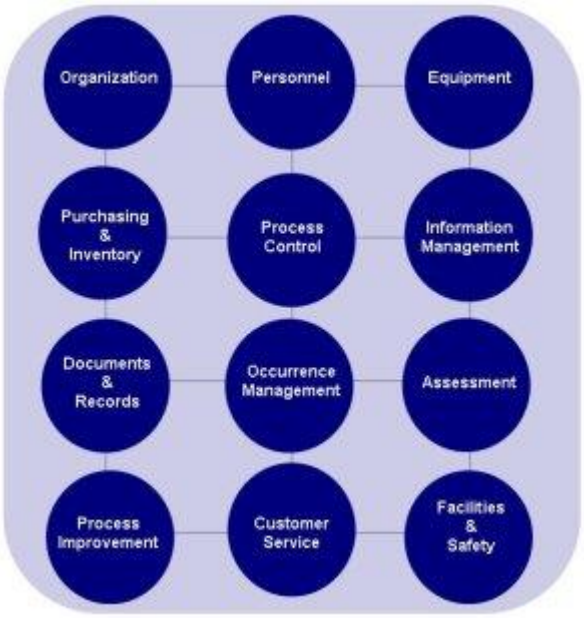
## *Key Words*

laboratory quality management system, laboratory quality, laboratory information management, laboratory information system, laboratory documents and records, laboratory quality manual, quality control, laboratory facilities and safety, laboratory equipment, laboratory sample management, laboratory sample transport, laboratory purchasing and inventory, laboratory assessment, laboratory customer service, occurrence management, process improvement, quality essentials, laboratory process control, clinical laboratory, ISO 15189.

# Contents of the training toolkit

Materials in this toolkit consist of topics that are essential for quality management of a public health or clinical laboratory. They are based on both **ISO 15189** and **CLSI GP26-A3** documents.

Each topic consists of a separate module. The modules are organized following the framework developed by CLSI and organized as the "12 Quality System Essentials". A diagram representing these 12 essentials is shown on the right.




The following table lists the available modules grouped according to the 12 Quality System Essentials, together with their respective learning objectives.

| Quality System Essentials | Module | Learning objectives |
|---|---|---|
| | Introduction | • explain the importance of a quality management system<br>• list the quality management system essential elements<br>• describe the history of development of quality principles<br>• discuss relationship of this quality management system model to ISO and CLSI standards |
| Facilities and safety | Facilities and Safety | • relate how facility design impacts the efficiency and safety of laboratory workers<br>• describe practices to prevent or reduce risks<br>• list personal protective equipment (PPE) that should be used routinely by laboratory workers<br>• explain general safety requirements for the laboratory<br>• describe steps to take in response to emergencies such as biological or chemical spills, or laboratory fires |
| Equipment | Equipment | • list items to consider prior to purchasing equipment for the laboratory<br>• manage the selection and acquisition of new equipment<br>• describe the requirements for a preventive maintenance program for equipment<br>• provide a rationale for developing a preventive maintenance program in your laboratory<br>• explain how to retire old or outdated equipment |
| Purchase and inventory | Purchasing and Inventory | • describe the steps required to implement an inventory control program<br>• name factors to consider in procurement of supplies<br>• develop a monitoring plan for the inventory system |

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| | | • discuss the importance of documentation related to purchasing and inventory |
| Process control | Sample Management | • name some sample collection errors that could lead to incorrect laboratory examination results<br>• list contents that should be included in a handbook designed for people who collect samples off-site<br>• provide a rationale for rejecting unsatisfactory samples<br>• describe a system for sample handling, including collection, transport, storage, and disposal<br>• explain the importance of maintaining sample integrity and assuring that all regulations and requirements are met when transporting samples |
| Process control | Introduction to Quality Control | • define quality control and describe its relationship to the overall quality management system<br>• describe differences in quantitative, semi-quantitative, and qualitative examinations |
| Process control | Quality Control for Quantitative Tests | • differentiate accuracy and precision<br>• select control material for a specified examination method<br>• establish acceptable control limits for a method when only one level of control material is available<br>• explain the use of a Levey-Jennings chart<br>• give two examples of rule violations using Westgard Multirule System<br>• describe how to correct “out of control” problems |
| Process control | Quality Control for Qualitative Tests | • differentiate between built-in and traditional controls<br>• describe how to use stock cultures for microbiology QC<br>• discuss the use of quality control procedures for stains used in microscopic examination<br>• describe methods for verifying performance of microbiological media |
| Assessment | Audits | • develop a process to prepare your laboratory staff for an external audit<br>• plan and manage an internal audit<br>• discuss how to use results from a laboratory audit<br>• advocate for the importance of taking corrective actions |
| Assessment | External Quality Assessment (EQA) | • discuss the importance of an EQA program in improving the quality of laboratory test results<br>• describe at least three EQA methods and the advantages and disadvantages of each<br>• outline a method to investigate an unacceptable test result from an EQA sample |
| Assessment | Norms and Accreditation | • compare and contrast accreditation, certification and licensure<br>• describe the process involved in development of standards<br>• discuss the need for laboratory norms and standards |
| Personnel | Personnel | • describe the role of personnel in the quality management system<br>• develop a plan to verify employee competency |

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| | | • describe the steps involved in assessing and maintaining employee competency<br>• explain a process to maintain personnel records |
| Customer Service | Customer Service | • recognize the variety of laboratory customer groups<br>• develop methods to measure customer satisfaction<br>• discuss problems that may develop with customers<br>• suggest solutions for customer service problems<br>• discuss how quality management processes help the laboratory meet customer group needs and requirements |
| Occurrence management | Occurrence Management | • define the term “occurrence”<br>• describe the essential quality monitoring tools<br>• differentiate among preventive action, remedial action, and corrective action<br>• describe the relationships between preventive action and risk management practices<br>• define and describe root cause analysis |
| Process improvement | Process Improvement | • relate the historical perspective of process improvement<br>• describe the importance of process improvement in maintaining quality<br>• explain the need for tools to monitor laboratory processes so problems can be identified and improved |
| Documents and records | Documents and Records | • explain the difference between documents and records<br>• describe the hierarchy of documents and the role of each level<br>• outline the content that should be included in a standard operating procedure<br>• explain the important steps, or elements, of a laboratory document management system<br>• outline the contents of a quality manual<br>• describe methods and tools to properly store documents and records |
| Information management | Information Management | • describe important elements of an information management system<br>• explain things to consider when developing a manual, paper-based information system<br>• describe the advantages and disadvantages of a computerized information management system |
| Organization | Organization | • describe organizational elements needed for a quality management system<br>• discuss management roles and responsibilities in a quality system<br>• explain the process for designing, implementing, maintaining, and improving the laboratory quality system<br>• explain the purpose of a quality manual |