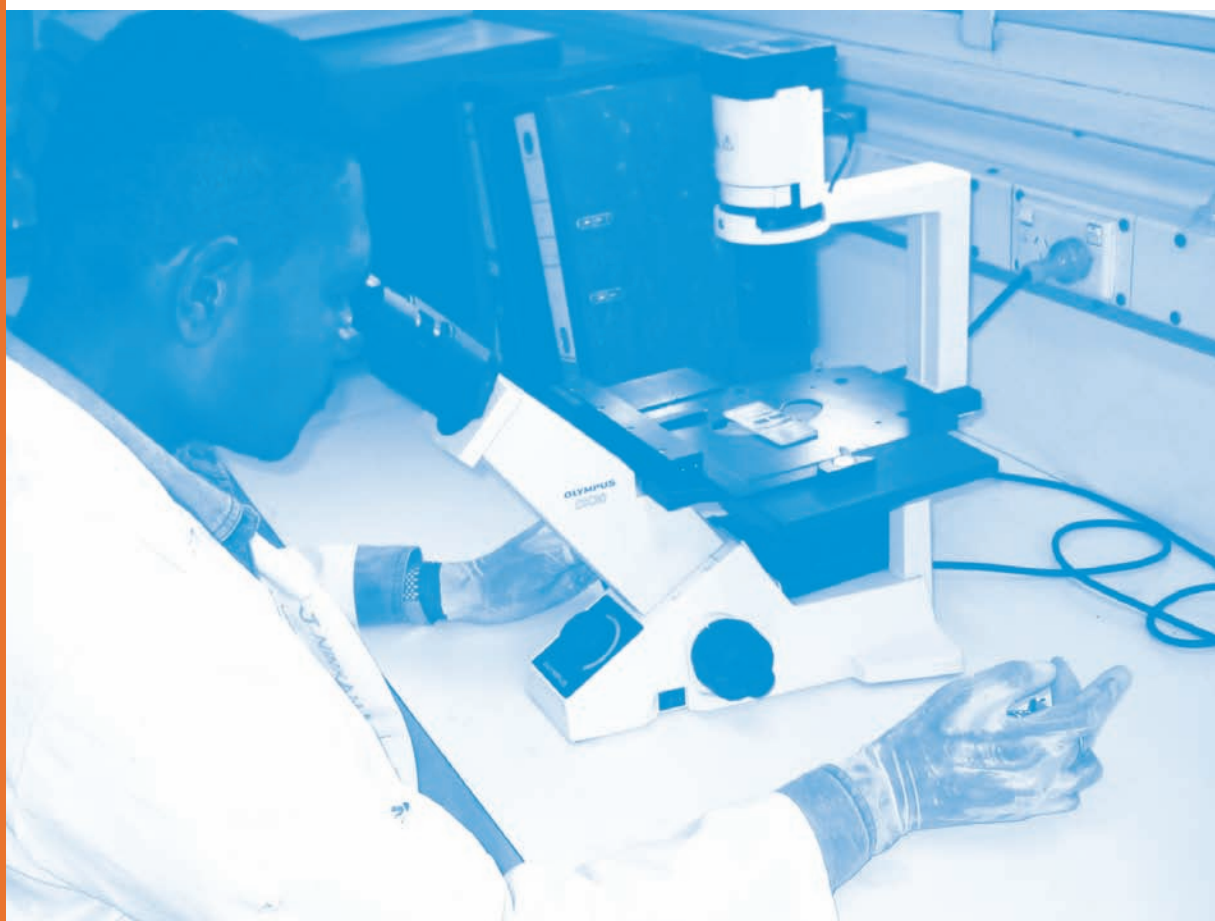


# Laboratory Quality Management System

## Handbook



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# Foreword

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 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.

This handbook is intended to provide a comprehensive reference on Laboratory Quality Management System for all stakeholders in health laboratory processes, from management, to administration, to bench-work laboratorians.

This handbook covers 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 is discussed in a separate chapter. The chapters follow the framework developed by CLSI and are organized as the “12 Quality System Essentials”. A diagram representing these 12 essentials is shown below.



### Note:

Health laboratories, in this handbook, is a term that is meant to be inclusive of clinical laboratories, diagnostic laboratories, medical laboratories, public health laboratories, animal and environmental health laboratories or any other laboratories performing testing for the purpose of disease diagnosis, screening, 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 handbook.

### Revision information:

The version 1.1 of the present handbook includes updated Glossary, Acronyms, and References and resources by chapter sections.

## Key words

Laboratory quality management system, laboratory quality, laboratory quality systems, 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.

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