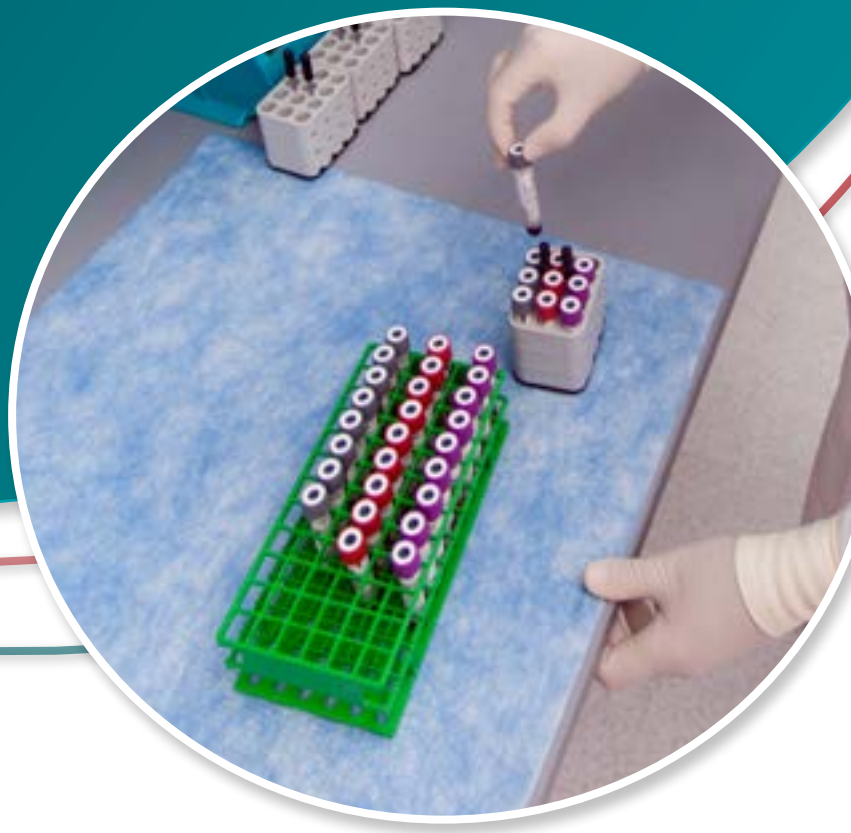
APHL Guide

How to Write a Laboratory Quality Manual



APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

December 2024

Contents

Find digital versions of this and other APHL publications at APHL.org/pubs-search

Purpose of this Guide

Testing laboratories perform work that is complex and requires high levels of accuracy, precision, reliability and confidentiality provided in a timely and cost-efficient manner. To achieve this level of quality, laboratories must adopt a systematic approach to address regulatory and accreditation requirements regarding the organization, planning and review of their testing services.

This document brings a comprehensive, structured approach to creating a laboratory quality manual for use in all types of testing laboratories. The approach used is based on twelve elements that are building blocks for developing an effective laboratory quality management system (QMS). These elements are called Quality System Essentials (QSE) as described by the Clinical and Laboratory Standards Institute (CLSI). QSEs provide a framework to ensure that all laboratory policies and procedures are performed correctly within established guidelines.

The 12 QSEs are:

- **Organization:** establish the overall quality management structure and leadership commitment
- **Personnel:** define the roles, responsibilities, and required qualifications for staff
- **Facilities and Safety:** ensure the laboratory environment is safe and suitable for operations
- **Equipment:** manage equipment procurement, calibration, maintenance, and performance monitoring
- **Purchasing and Inventory:** identify purchasing and inventory management for quality materials
- **Process Management:** define and monitor critical process parameters to ensure quality consistency
- **Documents and Records:** establish a system for document control and recordkeeping
- **Information Management:** manage data collection, analysis, and reporting
- **Nonconforming Event Management:** investigate and address nonconformities from procedures
- **Assessments:** regularly evaluate the effectiveness of the QMS through audits and reviews
- **Continual Improvement:** identify opportunities for quality improvement
- **Customer Focus:** understand customer needs and use feedback to improve quality of services

Components of a Laboratory Quality Manual

The structure of a quality manual should allow for flexibility, and the content should include a description of the laboratory's goals, policies, procedures, roles, responsibilities and monitoring process for each QSE. Each organization should first identify all regulatory requirements to determine if it is more efficient to have multiple quality manuals, a single overarching quality manual, or one quality manual with multiple process management appendices to address each accredited area of the laboratory.

Cover or Title Page

The cover or title page should contain the following, at a minimum:

- **Title of the manual**
- **Name and address of the organization**
- **Document control information** (i.e., ID number, version, etc.)
- **Name and contact information of laboratory director**

Table of Contents

List the titles and sections of the manual in the order they appear.

Introduction

Provide a brief overview/history of the laboratory. Include physical location, relation to any parent organization, hours of service and a short summary of each laboratory unit/discipline. Items to consider:

- **Mission/vision statement**
- **Goals and objectives of laboratory**
- **Purpose for the quality manual** (describe the structure and contents of the laboratory's QMS)
- **Scope of the quality manual** (identify laboratory areas to which the manual applies)
- **Quality policy statement** (i.e., quality is everyone's responsibility)
- **Statement on how the manual will be maintained, reviewed and updated**

Acronyms/Abbreviations

Include a list of acronyms and abbreviations used throughout the document.

Definitions

Include a list of definitions of terms which may need clarification for the document.

QSE: Organization

Describe the organizational structure of the laboratory, assignment of roles and responsibilities, hiring and management of personnel, and communication within the laboratory. Items to consider:

- **Organizational chart(s)**
- **Ethics statement**
- **Test menu or scope of testing services**
- **Communication policies, procedures and templates** (agendas, meeting minutes, frequency, etc.)
- **Administration policies and procedures** (management of meetings, conflict of interest, confidentiality, HIPAA, etc.)
- **Regulatory licenses and certifications maintained by the laboratory**

QSE: Personnel

Describe the human resources of the laboratory, including the hiring of qualified individuals, training policies and procedures, assessing competency to perform and manage laboratory activities, and retaining knowledge. Items to consider:

- **Roles and responsibilities for positions** (i.e., laboratory director, quality manager, safety officer, managers/supervisors, testing staff, etc.); include a statement that the quality manager has delegated authority and direct responsibility to oversee compliance with the laboratory's QMS).
- **Minimum qualifications or personnel documents required by regulatory authorities** (i.e., diplomas, transcripts, resumes, etc.)
- **HIPAA and other confidentiality policies**
- **Ethics and scientific data integrity**
- **Computer use policy**
- **Recruitment and retention** (specific criteria developed)
- **New employee orientation/required trainings**
- **Laboratory-specific personnel policies and procedures:**
  - Method training
  - Competency assessments and training logs
  - Safety orientation
- **Continuing education and professional development**
- **Performance evaluations**
- **Certification requirements** (i.e., hazardous materials packaging and shipping, radiation safety officer, etc.)
- **End of employment policies and procedures**
- **Knowledge retention tool**

QSE: Facilities and Safety

Describe the laboratory's physical space and necessary maintenance and safety programs. Items to consider:

- **Facility environment** (i.e., requirements for air flow, electrical, comfort, testing, etc.)
- **Facility use and maintenance** (i.e., routine service and scheduling, workspace allocations, housekeeping, pest control, etc.)
- **Safety concerns** (i.e., biosafety, chemical hygiene, radiation safety, occupational health, hazardous waste management, fire prevention, emergency management, etc.)
- **Security issues** (i.e., building visitor's logs, housekeeping access log, lab access logs and tiers, etc.)
- **Communication avenues** (i.e., routine and emergency communication with lab personnel, etc.)

QSE: Equipment

Describe the selection, purchase and installation of general laboratory equipment (i.e., autoclave, balance, centrifuge, incubator, etc.), function checks, maintenance, calibration and decommissioning protocols. Items to consider:

- **Selection and installation considerations**
- **Safety considerations and environmental sustainability practices**
- **Installation qualification**
- **Operational qualification**
- **Performance qualification**
- **Function checks**
- **Calibration verification**
- **General maintenance requirements** (i.e., schedules, agreements, logs)
- **Manufacturer preventive maintenance**
- **Review of equipment documentation**
- **Equipment downtime**
- **Service and return to use**
- **Decommissioning equipment**

QSE: Purchasing and Inventory

Describe the laboratory's purchasing and inventory procedures, including qualification and selection of vendors, contracts, receipt of supplies and inventory management. These procedures are defined to ensure that specified requirements are consistently met and appropriate inventory is maintained. Items to consider:

- **Selection, qualification and evaluation of suppliers/vendors of equipment, materials and services**
- **List of approved vendors/suppliers**
- **Contracts or Memorandums of Agreement / Understanding** (MOA/MOU)
- **Selection, ordering, receipt, inspection and storage conditions of:**
  - Reagents and supplies (e.g., environmental storage requirements and qualification of reagents)
  - Certificates of Analysis or Certificates of Sterility
  - Ordering required certification certificates (e.g., required traceability and uncertainty, etc.)
- **Inventory management** (i.e., minimum/maximum of inventory stock, responding to manufacturer's recalls and escalating to nonconforming events if necessary, etc.)
- **Identification and tracking of critical materials and services critical to laboratory operations**

QSE: Process Management

Describe how the laboratory develops, disseminates, controls and changes pre-analysis, during analysis and post-analysis workflow procedures. Workflow quality procedures should optimize effectiveness in meeting all requirements and efficiency in use of resources to minimize variation and ensure correct performance. Items to consider:

- **Pre-analysis workflow policies and procedures:**
  - Instructions to submitters for sample collection, processing and shipment to the laboratory
  - Laboratory sample criteria (i.e., acceptability, identification, chain of custody, etc.)
  - Sample accessioning, handling, processing and storage
- **Analysis workflow policies and procedures:**
  - Testing and examinations
  - Results review, approval and follow-up
  - Method validation or verification
  - Quality control requirements, frequency, and corrective actions for out-of-range QC
  - Calibration and function verification
  - Method/instrument comparison studies
  - Method limitations and interferences
  - New reagent/control verification
  - Calculation validation and review
- **Post-analysis workflow policies and procedures:**
  - Result release
  - Report preparation (i.e., reference values, critical values, etc.)
  - Report delivery
  - Amending reports
  - Sample archiving and management
- **Quality assurance:**
  - Quality control plans, logs and review
  - Sample storage and disposal requirements
  - Test requisitions
- **Change management:** Define process to review and evaluate established work practices (i.e., QC results, nonconforming events, internal/external audits, etc.) and make any necessary changes or improvements

QSE: Documents and Records

Describe the laboratory's policies and procedures for document control and records management from creation through destruction, including retention requirements and document destruction policies. Generally, documents are used to convey information, while records are used to provide evidence of actions and events. Items to consider:

- **Document management system** (i.e., creation, editing, review, approval, change control, archiving, etc.)
- **Document types and templates**
- **Master document list**
- **Records management for creation, retention and disposal**

QSE: Information Management

Describe the laboratory's information management system (LIMS) controls around confidentiality, privacy, security and accessibility of information, whether using paper-based or electronic record keeping systems. This includes storage, retrieval or dissemination of information to users or to computer systems. Items to consider:

- **Confidentiality of information**
- **Confidentiality agreements**
- **Planning overall information needs**
- **Computer security, access and use**
- **Integrity and monitoring of data transfer or transmission**
- **Retrieval and back-up of data**
- **Availability of information during Information Technology downtime**
- **LIMS/software support, validation, maintenance, user manual, updates**
- **Electronic records disposal**
- **Spreadsheet validation**
- **Requests for information or records**

QSE: Nonconforming Event Management

Describe the laboratory's policies and procedures for detecting, investigating, documenting, performing corrective action, and monitoring and prevention of events that do not conform to existing laboratory policies and procedures. Items to consider:

- **Identification and documentation of nonconformances**
- **Initial notification to management**
- **Investigation and classification**
- **Root cause analysis**
- **Corrective action(s)**, both short-term and long-term
- **Designation of responsible individuals and timeline for corrective action(s)**
- **Follow up and monitoring of corrective action effectiveness**
- **Monitoring event trends**
- **Reporting to staff and management**

QSE: Assessments

Describe the laboratory's internal and external assessment protocols to verify that they meet regulatory requirements and to determine how well they function as part of the overall QMS. This includes audits, proficiency tests and quality assurance reviews. Include a general statement or policy describing what assessments (internal and external) are conducted in the laboratory and how the laboratory monitors these policies and procedures. Items to consider:

- **Quality indicators to be assessed**
- **Assessment checklists to use**
- **Scheduling and conducting internal assessments**
- **Participating in external assessments and responding to assessment findings**
- **Frequency of monitoring assessments**
- **Proficiency testing program management, including process of assessing any failures**

QSE: Continual Improvement

Describe the laboratory's policies and procedures for monitoring the effectiveness of the QMS and to identify areas for improvement. Items to consider:

- **General statement of the laboratory's commitment to quality improvement**
- **Identifying quality improvement goals**
- **Preventative measures**
- **Regular management review of the QMS and QSEs**
- **Trending and control charting**

QSE: Customer Focus

Describe policies and procedures that identify expectations of customers (internal and external), collect customer feedback, and take appropriate follow-up actions. This should include a process for complaint identification and resolution. Items to consider:

- **Identifying customers**
- **Assessing customer satisfaction**
- **Handling of customer complaints**
- **Improving services based on customer feedback**
- **Communicating customer feedback to staff**
- **Process for handling records requests**

Resources

APHL

The Association of Public Health Laboratories' (APHL) member representatives and associates can sign in to the APHL website to access the APHL Member Resource Center, a document repository of member-created presentations, templates, shared practices, communications tools, protocols, and checklists in areas such as environmental health, infectious disease, emergency preparedness and workforce.

CLSI Standards

- QMS01-ED5:2019: A Quality Management System Model for Laboratory Services
- QMS02-ED7:2024: Developing and Managing Laboratory Documents
- QMS03-ED4:2016: Training and Competence Assessment
- QMS06-ED3:2011: Quality Management System: Continual Improvement
- QMS11-ED2:2015: Nonconforming Event Management
- QMS12-ED2:2019: Developing and Using Quality Indicators for Laboratory Improvement
- QMS13-ED1:2011: Quality Management System: Equipment
- QMS14-ED2:2024: Quality Management System: Leadership and Management Roles and Responsibilities
- QMS15-ED2:2022: Laboratory Internal Audit Program
- QMS16-ED1:2015: Laboratory Personnel Management
- QMS17-ED2:2023: External Assessments, Audits, and Inspections of the Laboratory
- QMS18-ED2:2023: Process Management
- QMS19-ED1:2017: Customer Focus in a Quality Management System
- QMS21-ED1:2016: Purchasing and Inventory Management
- QMS22-ED1:2018: Management of Paper-based and Electronic Laboratory Information
- QMS23-ED2:2019: General Laboratory Equipment Performance Qualification, Use, and Maintenance
- QMS24-ED3:2016: Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality
- QMS25-ED1:2017: Handbook for Developing a Laboratory Quality Manual
- QMS26-ED1:2021: Managing Laboratory Records
- QMS29-ED1:2024: Management Reviews

World Health Organization

- Laboratory Quality Management System: Handbook
  This handbook provides a comprehensive reference on laboratory quality management systems, for those involved at all levels of health laboratory processes.
- Quality Manual Template
  The 2014 quality manual template is a supplement to the laboratory quality management system training toolkit, Module 16 - Documents and records.

Acknowledgments

APHL would like to thank the Laboratory Systems and Standards committee for reviewing and making improvements to the 2017 version of this document.

This publication was supported by Cooperative Agreement number #NU60OE000104, funded by the US Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Department of Health and Human Services.

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

7700 Wisconsin Avenue, Suite 1000 Bethesda, MD 20814 | 240.485.2745 | www.aphl.org