How to Write a Laboratory Quality Manual

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APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES ®

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PURPOSE OF THIS MANUAL

Public health laboratories' work is highly complex and requires high levels of accuracy, precision, reliability and confidentiality provided in a timely and cost-efficient manner. To achieve this high level of quality, laboratories must adopt a systematic approach to the organization, planning and review of their testing services.

This document provides guidance to public health laboratories on preparing a Laboratory Quality Manual. It is designed to be customizable to any laboratory's organizational structure, with the content, format and structure left to the discretion of the individual facility based on the size and complexity of its testing services.

This document brings a comprehensive, structured approach to creating a Laboratory Quality Manual, for use in all types of analytical laboratories, based on the twelve Quality System Essentials (QSE) within a Quality Management System (QMS). These QSEs provide a framework to ensure that all laboratory processes are performed correctly and within established guidelines.

12 Quality System Essentials (QSE):

1. Organization
2. Customer Service
3. Facilities and Safety
4. Personnel
5. Purchasing and Inventory
6. Equipment
7. Documents and Records
8. Information Management
9. Non-conformance Management
10. Assessments
11. Process Improvements
12. Process Management

COMPONENTS OF A LABORATORY QUALITY MANUAL

While the structure of a Quality Manual allows for flexibility, the content should include a description of the laboratory's goals, policies, procedures, roles, responsibilities and monitoring process for each of the QSEs. Each organization should first identify all of its accreditors and 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. This template follows the latter option to allow each appendix to be updated independently during annual updates.

TITLE PAGE: The title page should contain the following:

Minimum:
- Title of the manual
- Name and address of the organization
- Document control information (version, number, etc.)

Optional:
- Name and contact information of laboratory director

INTRODUCTION: Provide a brief overview/history of the laboratory. Include physical location, certifications, licenses, relation to parent organization, hours of service, short summary of each laboratory unit/discipline.

Items to consider including:
- Goals and objectives of laboratory
- Mission/vision statement
- Scope of the quality manual–areas to which this QM applies; include a statement that quality is everyone's responsibility
- Description of how the manual will be maintained, reviewed and updated
- Quality policy
- State the purpose for the quality manual, i.e., it is a set of documents that describe the structure and contents of the laboratory's QMS.

TABLE OF CONTENTS: List the titles and parts of the manual organized in the order in which they appear.

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 throughout the document.

QSE: Organization

This QSE describes the organizational structure of your laboratory, including how the lab is structured, assignment of roles and responsibilities, hiring and management of personnel and communication within the laboratory. Include a statement that the quality manager has delegated authority and direct responsibility to oversee compliance with the laboratory's QMS.

Items to consider including:

- Organizational chart(s)
- Authority and responsibilities of all management and QA roles
- Ethics statement
- Laboratory Quality Policy statement – if not stated in introduction
- Scope of services
- Communication policies and templates (Agendas, meeting minutes, frequency, etc.)
- Administration policies (meeting management, conflict of interest, confidentiality, HIPAA, etc.)
- Statement on commitment to quality and good laboratory practices
- Regulatory licenses maintained by the laboratory

Management review includes at a minimum: Customer feedback, findings from internal and external audits, PT performance, and quality indicator performance.

QSE: Personnel

This QSE describes the human resources of your laboratory: hiring qualified individuals, training processes, assessing competency to perform and manage laboratory activities, and retaining knowledge in positions when employees leave.

Items to consider including:

- Policies and procedures for:
  - Recruitment and retention – specific criteria are developed
  - New employee orientation/required trainings
  - Employee training
  - Competency assessment
  - Continuing education and professional development
  - Performance evaluations
  - HIPAA
  - Computer use
- Minimum qualifications
- Position descriptions (spells out roles and responsibilities)
- Class specifications
- Personnel documents required by regulatory authorities (diplomas, transcripts, resumes, etc.)
- Personnel list with contact/emergency information
- Training logs
- Performance evaluation forms
- Interview forms and questions
- Reference checks
- End of employment process and checklist
- Knowledge retention tools
- Packaging and shipping training and shipper certification

QSE: Equipment

This QSE describes selection, purchase and installation of equipment: validation/verification, maintenance, calibration, decontamination and decommissioning protocols.

Items to consider including:

- Policies and procedures for:
  - Selection of equipment
  - Installation, validation, and acceptance criteria
  - Maintenance requirements (schedules, documentation, logs)
  - Equipment use
  - Quality control
  - Procedures for replacement, decontamination and disposal
  - Disposal or retirement of equipment
  - Operational qualification
  - Calibration program

QSE: Facilities and Safety

This QSE describes your laboratory's physical space and the maintenance programs necessary to maintain it. Include floorplans, building maintenance schedules and responsibilities, building safety features, etc.

Items to consider including:

- Policies and procedures for:
  - Space allocation process
  - Working environment
  - Facility use and maintenance
  - Safety, ergonomic and efficiency policies
  - Required safety programs
  - Routine building maintenance procedures
  - Regulated medical waste/hazardous waste disposal
  - Storage of dangerous materials
  - Unsafe condition reporting and response
- Floor plans
- Requirements for security (visitor's logs, housekeeping log, maintenance log, access logs, access levels, etc.)
- Requirements for signage (hazards, PPE, etc.)
- Laboratory environmental requirements, including pest control
- Facility design and renovation requirements

QSE: Purchasing and Inventory

This QSE describes your laboratory's purchasing and procurement processes, such as selection of vendors, contracts, receiving of supplies, inventory management, etc.

Items to consider including:

- Policies and procedures for:
  - Contracts/MOA/MOU (vendors, reference labs, etc.)
  - Selection, ordering, receiving and storing of reagents and supplies
    - Receipt and storage of Certificates of Analysis or Certificates of Sterility
    - Ordering of certificates displaying required traceability and uncertainty
  - Managing reagents and supplies (environmental storage requirements, lot to lot comparisons)
  - Purchase orders
  - Procurement cards

- Selection/purchasing of equipment
- Selection of vendors
- Inventory management—including responding to manufacturer's recalls and escalating
- Minimum/maximum stock
- List of approved vendors/suppliers
- List of reference laboratories
- New equipment checklist, etc.

QSE: Information Management

This QSE describes your laboratory's information management controls around confidentiality, privacy, security and accessibility of information stored on both paper and electronic record keeping systems, including storage and retrieval of information.

Items to consider including:

- Confidentiality agreements
- Policies and procedures for:
  - Computer access and use
  - Computer security
  - Electronic records disposal
  - IT downtime documentation
  - Electronic transmission of public health information (PHI) including results
  - LIMS maintenance and update
  - LIMS validation
  - LIMS help desk coverage
  - Software and spreadsheet validation
  - Monitoring of electronic data integrity
  - Requests for information
  - Requests for changes to patient records in LIMS (demographic changes)
  - Retrieval and back-up of data

- LIMS user manual

QSE: Documents and Records

This QSE describes your laboratory's policies, process and procedures for document control and records management, from creation through destruction, including retention requirements, document destruction policies.

Items to consider including:

- Policies and procedures for:
  - Document creation, editing, review and approval
  - Record retention and disposal (record management)
  - Document management
  - Document control (manual or electronic)
  - Archiving
  - SOP management
- SOP template(s)

QSE: Non-Conformance Management

This QSE describes your laboratory's policy around detecting, investigating, reporting, tracking, monitoring and prevention of events that do not conform to existing laboratory policies, procedures and processes. Include root cause analysis and corrective actions taken.

Items to consider including:

- Policies and procedures for:
  - Designation of responsible individuals
  - Identification and documentation of non-conformances
  - Initial notification to management
  - Investigation and classification
  - Root cause analysis
  - Corrective action(s)—both short-term and long-term
  - Follow up and monitoring of corrective action effectiveness
  - Monitoring event trends
  - Reporting to staff and management

QSE: Assessments

This QSE describes your laboratory's assessment protocols, for both internal and external monitoring, to verify that they meet regulatory requirements and determine how well those processes are functioning 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 processes.

Items to consider including:

- Policies and procedures for:
  - Scheduling internal assessments
  - Conducting internal assessments
  - Hosting external assessments
  - Responding to external assessment findings
  - Monitoring schedules
  - Assessment checklists
  - Corrective action review and follow-up

- Quality indicators
- Procedure/process review
- Ordering, receiving, handling, testing and reporting proficiency tests
- Client/staff suggestion form
- Accreditation and/or certification (if not included in introduction)
- Proficiency testing program and schedule
- Policy for when no PT is available

QSE: Process Improvements

This QSE describes your laboratory's processes for identifying areas for improvement, assessment and monitoring to optimize the effectiveness of the QMS and to increase and sustain quality.

Items to consider including:

- Policies and procedures for:
  - Determination of quality improvement initiatives
  - Preventative measures
  - Process mapping
  - Identification of quality initiatives
  - Conducting management reviews, including action items and follow up
  - Trending
  - Control charting
  - Scheduling and recording minutes from quality and process meetings (management review, quality improvement, staff meetings, etc.)
- List of laboratory's quality initiatives
- General statement of the laboratory's commitment to quality improvement, including goals

QSE: Customer Service

This QSE describes processes and procedures that identify your laboratory's customers, identify customer expectations, collect customer feedback and take appropriate follow-up actions. This should include general expectations of your laboratory's external and internal customers, methods for determining customer satisfaction, methods to gather customer feedback, and the process for complaint identification and resolution.

Items to consider including:

- Policies and procedures for:
  - Identifying customers
  - Assessing customer satisfaction
  - Collecting customer feedback
  - Improving services based on customer feedback
  - Handling of customer complaints
  - Communicating customer satisfaction, expectations, feedback to lab staff
- Customer satisfaction survey
- Complaint logs
- Incident reports
- Faxing reports policy
- Laboratory service agreements
- Policy for giving out results to patients
- Policy for handling legal and FOIA requests

QSE: Process Management

This QSE describes how your laboratory develops, disseminates, controls and changes pre-analytic (pre-examination), analytic (examination) and post-analytic (post-examination) workflow processes and the management processes that support them.

Items to consider including:

- Policies and procedures for:
  - Pre-analytic workflow processes:
    - Verification of patient/specimen identification
    - Specimen collection and transport
    - Specimen receipt
    - Specimen rejection criteria
    - Specimen handling, preparation, and storage
    - Specimen acceptance and rejection
    - Sample custody (Chain of custody forms, etc.)
    - Data entry and review

  - Analytic Workflow Processes:
    - Testing and examinations
    - Results review and follow-up
    - Method verification
    - Method validation
    - Quality control requirements, frequency, and corrective actions for out of range QC
    - Calibration and calibration verification
    - Method/instrument comparison studies
    - Method limitations and interferences
    - Calculation validation and review

  - Post-analytic workflow processes:
    - Result release
    - Report preparation
    - Report delivery
    - Sample archiving and management
    - Demographic and results corrections
    - Critical values
- Quality control logs
- Test menu
- Sample storage and disposal requirements
- Test requisitions
- Patient identification verification form

RESOURCES AND APPENDIX

Resources:

CLSI guidelines GP26-A4: Quality Management System: A Model for Laboratory Services

CLSI guidelines GP38: Quality Management System: Leadership and Management Roles and Responsibilities

CLSI guidelines GP32: Management of Nonconforming Laboratory Events

CLSI document QMS25: Handbook for Developing a Laboratory Quality Manual

Ontario Laboratory Accreditation Program; Quality Management Program – Laboratory Services (QMP-LS), Version 3, August 2006. *Guidance for Laboratory Quality Manuals*

World Health Organization (WHO)/CLSI; *Supplement to the Laboratory Quality Management System Training Toolkit,* Quality Manual, Version 2013

Appendix: Examples of Laboratory Resources by Quality Systems Essentials

These documents are located in the APHL Member Resource Center. Click on the hyperlink or type the document name into the search field to access the document.

Organization
Quality Policy

Customer Service
Patient Results Access Policy

Facilities and Safety
Emergency Action Plan
HVAC Equipment Shutdown Checklist
Infection Control Checklist
Select Agent Training for One Time Visitors

Personnel
Clinical Staff Competency Assessment Policy
Competency Assessment Template
General Supervisor Competency Form
Personal Electronics Policy
Problem Solving Skills Competency Assessment Form
Technical Supervisor Competency Form

Purchasing and Inventory
Daily Audit Form
New Equipment Checklist
Revenue Log

Equipment
Disposing of Supplies and Equipment
Smart-Vue Policy
Smart-Vue Monthly Review Form
Smart-Vue Temperature Check Log
Standard Operating Procedure Template

Document and Records
Records and Storage and Disposal

Information Management
Computer Use Policy and Procedures

Non-conformance Management
Corrective Action Log
Using the Incident Management Program

Assessments
Clinical Laboratory Audit Tool
Clinical Laboratory Tracer Audit Checklist
Internal Audit Policy
Internal Audit Plan Template
Missed Proficiency Testing Analyte Investigation Report
Proficiency Tracking Form
Proficiency Testing Policy

Process Improvements
Example Graphs of Performance Indicators
Quality Metrics

Process Management
Quality Control Policy
Method Verification Template

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