

Management Review

APHL Quality Management System (QMS) Competency Guidelines

The participant will understand

- * The definition of management review
- * What is covered by a management review
- * What a management review procedure should define

Why do a management review? The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Management Review...

Is a formal evaluation by top management of the status and adequacy of the quality system in relation to the quality policy and objectives.

Public health laboratory competency guidelines:
Quality Management System (QMS) domain

QMS 1.00. Organization: ensures that the laboratory's organizational structure is committed to achieving and maintaining quality

QMS 1.01. Commitment to quality

QMS 1.03. Quality culture

QMS 1.04. Resources

QMS 2.00. Customer focus: ensures that customer needs, expectations, and requirements are consistently met

QMS 2.01. Customer satisfaction

QMS 2.02. Customer services

QMS 3.00. Facilities and safety: ensures that the laboratory's physical environment, maintenance, and safety programs meet applicable requirements

QMS 4.00. Personnel: ensures recruitment and retention of a qualified, well-trained, and competent workforce

QMS 4.03. Training

QMS 4.05. Professional development plan

QMS 4.07. Recruitment, retention, and succession plans

QMS 5.00. Purchasing and inventory:

ensures that requirements for supplies



and services are consistently met

QMS 5.01. Procurement process

QMS 5.02. Inventory processes

QMS 5.03. Evaluation process

QMS 6.00. Laboratory equipment: ensures that laboratory equipment selection, installation, use, maintenance, and troubleshooting meet performance standards

QMS 6.03. Maintenance process

QMS 7.00. Process management: ensures that operational processes meet organizational requirements

QMS 7.01. Workflow† processes

QMS 7.02. Process control

QMS 7.03. Method validation and performance verification processes

QMS 8.00. Documents and records: ensures that there is an effective system to control and manage documents and records

QMS 9.00. Information management: ensures the confidentiality, security, and integrity of generated and disseminated information

QMS 10.00. Nonconforming event management: ensures that processes are in place for detecting and managing nonconforming events

QMS 11.00. Assessments: ensures that processes are in place to perform internal audits* and external assessments

QMS 11.04. Quality indicators

QMS 11.05. Quality indicator data collection and analysis

QMS 12.00. Continual improvement: ensures mechanisms for continuous quality improvement

QMS 12.01. Continuous Quality Improvement (CQI) program

QMS 12.02. CQI activities

QMS 12.03. Corrective action process

QMS 12.04. Preventive action

QMS 12.05. Change management

MLD 1.00. General management: ensures sound management of laboratory operations

MLD 1.01. Mission, vision, and values

MLD 1.03. Laws and regulations for laboratory operation

MLD 1.07. Quality testing and services

MLD 1.08. Customer service

MLD 1.09. Project management

MLD 1.10. Program effectiveness

