

Quality Management System Introduction

APHL Quality Management System (QMS) Competency Guidelines

“QMS is a systematic approach for ensuring the consistent quality of the tests performed, the products created, the data generated, and the results reported. Operating within a quality system meets the needs and requirements of public health laboratories as well as the expectations of partners, stakeholders, and users (internal and external customers).”

A QMS is more than quality assurance and quality control — it also includes all the business processes of a laboratory that are required to ensure quality. Adhering to quality standards for laboratory operations helps laboratories generate consistent, reliable, and reproducible data and results.”

What you do is relevant and important! You contribute to the overall effectiveness of the Quality System

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

What is a Quality Management System?

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The term ‘Quality Management System’ (QMS) covers the quality, technical and administrative system that governs the operations of the laboratory.

Technical: How you do something (in the laboratory area as well as in the support services area)?

Quality: How well you do something?

What are your Responsibilities?

Staff should:

- Be free of conflict of interest
- Have appropriate decision making authority and resources
- Initiate corrective actions when necessary
- Follow procedures and policies
- Monitor Quality Control (QC)
- Take required training to document competency and be authorized to perform function
- Complete a job description
- Be adequately supervised
- Communicate with management
- Complete their job function to ensure data integrity
- Identify opportunities for improvement (preventive actions)

Management should:

- Assign responsibilities (job descriptions)
- Ensure documented procedures are in place to maintain quality
- Review and monitor the QMS
- Perform corrective actions
- Identify opportunities for improvement (preventive actions)
- Enable staff to perform their jobs to ensure data integrity
- Monitor Quality Control (QC)
- Write and maintain a Quality Management Plan (QMP) and Quality Policy
- Appoint a Quality Manager with associated responsibilities
- Appoint a Technical Manager with associated responsibilities

