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.”

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?

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

Technical: How 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