

Quality Management System Personnel Requirements, Ethics and Continuous Improvement

APHL Quality Management System (QMS) Competency Guidelines

This course will increase awareness and understanding of personnel requirements, laboratory ethics, and continuous improvements to better meet the ISO/IEC standard in your laboratory.

Objectives:

At the end of this learning activity, the participant will be able to:

- Identify Personnel Requirements as stated in ISO/IEC 17025 standard
- Describe the expectations of employees to meet the requirements of the Laboratory Ethics policies
- Describe a Continuous Improvement method that could be used to better meet the ISO/IEC 17025 standard in the laboratory

The laboratory management shall ensure the competence of all who operate specific equipment, perform tests..., evaluate results, and sign test reports...

Public Health Laboratory Competency Guidelines

This learning activity provides content to support high-level competencies (desired skills or behaviors) for a laboratory professional in the listed domains. Also supports related content areas in the National Laboratory Curriculum Standard Framework.

Personnel

Quality Management System (QMS) domain

QMS 4.01. Staff qualification process: Describes education, training, and skills required for job performance

- Describes process required to verify staff qualification and competency



What is an ethics policy for the laboratory?

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The laboratory should have a policy in place addressing the laboratory's position on ethics, integrity, and code of conduct.

Procedures based on this policy should be put in place that define exactly how the policy will be implemented and ensured.

- Ensures each position has the required competencies, education, training, skills, experience, and where applicable, certification, and licensure
- Designs a process to determine required competencies, education, training, skills, experience and where applicable, certification and licensure for each job title

QMS 4.03. Training: Participates in required training

- Ensures that training and evaluation are carried out for assigned duties

QMS 4.04. Competence assessment plan: Describes competence assessment plans

- Participates in the development of an individualized competence assessment plan
- Evaluates individual competence assessment plans
- Oversees a competence assessment plan for the organization

Unethical or illegal actions are the deliberate falsification of analytical or quality control results...

Ethics

Quality Management System (QMS) domain

QMS 1.03 Quality culture: Describes the culture, programs, and communication processes regarding quality, safety, and ethical practices

- Adheres to the culture, programs, and communication processes regarding quality, safety, and ethical practices
- Advocates for a culture of quality, safety, and ethics
- Fosters a culture of quality, safety, and ethics

QMS 9.03. Information integrity: Describes the policies, processes, and procedures for ensuring integrity of information

- Complies with policies, processes, and procedures to ensure the integrity of information
- Develops processes and procedures to ensure the integrity of information
- Oversees the policies, processes, and procedures to ensure the integrity of information

Ethics (ETH) domain

ETH 1.00. Professional code of conduct: Adheres to policies and principles governing professional ethics and rules of conduct when working in a public health laboratory

ETH 1.01. Personal integrity: Aligns personal integrity with organizational culture

- Exemplifies integrity in interactions and activities
- Coaches staff in behaviors that exemplify integrity
- Creates a culture where integrity is the foundation for all interactions and activities



ETH 1.02. General ethical practices: Applies ethical principles and professional rules of conduct to the workplace

- Serves as a role model of ethical behavior by consistently conforming to the highest ethical standards and practices
- Ensures staff compliance with policies and procedures related to ethical principles and professional rules of conduct
- Oversees the policies, processes, and procedures related to ethical principles and professional rules of conduct

ETH 1.03. Stewardship of resources: Acts as a good steward of public funds and resources

- Identifies methods to improve stewardship of resources
- Ensures that the use of public funds and resources meet the policies for stewardship
- Oversees the policies, processes, and procedures to ensure the environment supports excellence in the stewardship of resources

ETH 2.01. Scientific integrity: Verifies scientific integrity of test results and findings

- Instructs others in policies, processes, and procedures regarding scientific integrity of test results and findings
- Ensures staff compliance with policies and procedures regarding scientific integrity of all results and findings
- Oversees the policies, processes and procedures to ensure practices are consistent with guidelines on scientific integrity

ETH 2.02. Scientific ethics: Applies scientific ethics and rules of conduct to the workplace

- Serves as a role model of scientific ethical behavior and rules of conduct by consistently conforming to the highest scientific standards and practices
- Ensures staff compliance with policies and procedures related to scientific ethics and rules of conduct
- Oversees the policies, processes, and procedures related to scientific ethics and rules of conduct

General Laboratory Practice (GEN) domain

GEN 1.09. Scientific ethics: Applies scientific ethics and rules of conduct to the workplace

- Serves as a role model, consistently conforming to the highest scientific standards and practices
- Ensures staff compliance with the policies and procedures related to scientific ethics and rules of conduct
- Oversees the policies, processes, and procedures related to scientific ethics and rules of conduct

Security (SEC) domain

SEC 5.01. Information security: Applies information security concepts, including principles of confidentiality, integrity, and availability



Research (RES) domain

RES 6.01. Data collection and quality: Monitors quality and integrity of recorded information and data

- Develops policies, processes, and procedures to ensure data quality and integrity

The laboratory shall continuously improve the effectiveness of its management system...

Continuous Improvement

Quality Management System (QMS) domain

QMS 5.03. Evaluation process: Describes the process to evaluate and provide feedback to suppliers

- Executes the process to evaluate and provide feedback to suppliers, consultants, and contractors
- Develops a process to evaluate the satisfaction with services and products from suppliers, consultants, and contractors
- Oversees a quality improvement plan for purchasing and inventory

QMS 12.01. Continuous Quality Improvement (CQI) program: Describes the policies, processes, and procedures related to the CQI program

- Implements changes identified through the CQI program
- Develops the processes and procedures of the CQI program
- Oversees the policies, processes, and procedures related to the quality improvement program

QMS 12.02. CQI activities: Participates in CQI activities

- Follows CQI processes and procedures for troubleshooting and documenting required CQI activities
- Documents staff compliance with CQI activities that support the CQI monitoring, evaluation, and review processes
- Oversees the policies, processes, and procedures related to CQI activities

QMS 12.03. Corrective action process: Develops corrective action processes and procedures to address quality improvement



QMS 12.04. Preventive action: Describes the policies, processes, and procedures related to preventive action

- Implements the processes and procedures related to preventive action
- Develops the processes and procedures related to preventive action
- Oversees the policies, processes, and procedures related to preventive action

Management and Leadership (MLD) domain

MLD 1.06. Analytical and operational services: Describes the processes for introducing improved analytical and operational services

- Participates in improvement of analytical and operational services
- Manages the improvement of analytical and operational services
- Oversees funding and stakeholder relationships needed to implement and improve analytical and operational laboratory services

MLD 1.07. Quality testing and services: Evaluates the quality of services for continued quality improvement

MLD 1.10. Program effectiveness: Oversees the policies, processes, and procedures regarding the measurement, analysis, and improvement of program effectiveness

MLD 4.07. Performance appraisal process: Evaluates effectiveness of the performance appraisal process in improving laboratory productivity and practice

- Oversees the continuous improvement of the performance management system

MLD 5.08. Critical thinking: Develops basic critical thinking skills

- Applies critical thinking to develop effective solutions to problems
- Leads critical thinking activities to achieve improvements in laboratory processes
- Fosters an environment that integrates critical thinking

Emergency Management and Response (EMR) domain

EMR 4.03. Long-term recovery: Lists improvements to laboratory plans based on the After Action Report (AAR)

- Identifies improvements to laboratory plans and operations based on the AAR
- Implements improvements to laboratory plans and operations based on the AAR
- Develops recommendations to improve laboratory plans and operations based on the AAR along with internal and external partners and stakeholders

Workforce Training (WFT) domain

WFT 5.04. Training activity effectiveness: Recommends improvements based on evaluation data from training assessment tools

- Implements improvements to the professional development activities of the laboratory



WFT 5.05. Continuous improvement of the training program: Participates in continuous improvement activities

- Identifies activities leading to the continuous improvement of a training plan
- Facilitates activities leading to the continuous improvement of a training plan
- Develops a training program improvement plan based on program evaluation

Informatics (INF) domain

INF 4.02. Management of test schedules: Uses specific data elements associated with process improvement to manage test schedules

- Evaluates the workflow for process improvement opportunities

INF 4.03. Prioritization of tests: Organizes specific data elements associated with process improvement indicators to prioritize test scheduling

INF 11.01. Document management systems: Evaluates document management systems to recommend improvements and efficiency and to meet contractual and grant obligations

INF 18.06. Software development life cycle (SDLC): Verifies needs for software process improvements

