FELLOWSHIP TRAINING ACTIVITY GUIDE

QUALITY MANAGEMENT SYSTEMS

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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ABOUT QUALITY MANAGEMENT SYSTEMS

The first responsibility of public health laboratories is to provide quality testing services to support the health of the public and meet the many needs of internal and external customers.

In this training activity guide, we will discuss how a quality management system (QMS) provides a systematic approach to all the business processes required to ensure the consistent quality of tests performed, products created, and the data reported.

LEARNING OBJECTIVES

Once you have completed all the activities in this guide and met with your mentor, you should be able to:

- Describe principles of a quality management system as they apply to research and laboratory operations.
- Illustrate the laboratory's relevant organizational structure and processes.
- Identify non-conforming events using given pre-analytical, analytical and post analytical indicators.
- Describes policies, processes and procedures related to the Continuous Quality Improvement (CQI) program.

REFLECTION

Describe how the objectives above can help you in your position as a fellow:

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FELLOW PROFILE: RAYMOND

Raymond is concluding his first week as a new fellow at a state public health laboratory.

He has just been tasked with testing several specimens for the presence of a particular pathogen.

As Raymond examines the protocols and procedures, he will need to follow to conduct the test, he is surprised to learn that the quality control procedures are extensive.

Coming from an academic background, Raymond is familiar with using control specimens in testing, but he has discovered that quality management impacts just about every aspect of laboratory operations.

WHAT IS A QUALITY MANAGEMENT SYSTEM?

A quality management system, or QMS, can be viewed as a set of policies, processes and procedures that provide a comprehensive structure for both the planning and execution of the many complex operations that take place in a public health laboratory. It can also be a guiding philosophy that ensures laboratory processes are managed for quality.

A QMS has broad impact. It ensures that staff are properly trained, that equipment is monitored for performance and accuracy, and it ensures that the complex processes surrounding the generating, interpreting and recording of data are executed consistently. When problems arise, a QMS ensures consistent mitigation of these issues.

Implementation of a QMS is an evolving state in many laboratories. Depending on the size and complexity of operations, a public health laboratory may have one or more managers dedicated to defining the processes and developing the documentation required to implement a quality framework.

The consequences of not developing a robust QMS are far-reaching. This can include:

- inefficiencies, such as cost overruns and invalidated tests
- negative impact on individual patient treatment
- regulatory sanctions, such as loss of accreditation or certification

There is currently no comprehensive quality management system that can be applied to all public health laboratories. Fortunately, APHL does provide a general framework and guidance on writing a laboratory quality manual. See the Additional Resources section of this document for more information about the laboratory quality manual.

QUALITY SYSTEM ESSENTIALS

The twelve quality system essentials, or QSEs are a general framework that will be applied according to the needs of the individual laboratory. However, it will provide a good understanding of the different and overlapping aspects of a laboratory's operations a QMS may impact.

These include:

Organization - describes the organizational structure of the laboratory, personnel roles and responsibilities, hiring and management policies, as well as policies for communication within the laboratory.

Personnel - addresses training processes, such as new employee orientation and continuing education, competency assessment, personnel qualification standards and policies on knowledge retention.

Equipment - specifies how equipment is installed and operated. This can include validation or verification, maintenance procedures, calibration procedures, as well as decontaminating and decommissioning protocols.

Facilities and Safety - addresses the laboratory's physical space. This can include building maintenance schedules and responsibilities, security policies and protocols, regulated hazardous waste disposal and building safety features.

Purchasing and Inventory - describes the laboratory's procurement processes such as contracts, vendor selection and ordering. Inventory processes include receiving, storing and managing reagents and supplies, as well as equipment.

Information Management - addresses information stored on both paper and electronic record keeping systems, information security issues such as computer access and use, records disposal, transmission of public health information and data integrity. This QSE can also address data backup procedures, laboratory information management system (or LIMS) operation and technical support.

Documents and Records - addresses document control and records management, record retention and disposal, archiving and management of standard operating procedures (SOPs). Document control is an important part of effective quality management, as many policies and procedures are constantly being updated and revised and versions must be tracked, and individual revisions must be identified so as to keep all personnel apprised of changes.

QUALITY SYSTEM ESSENTIALS (CONTINUED)

Assessments - addresses protocols for internal or external monitoring to verify that practices continue to meet regulatory requirements or to determine how well a process or procedure is functioning as part of the overall quality management system. This includes a variety of audits, tests and reviews.

Process Improvements - specifies a process for improving, assessing and monitoring the laboratory's operational protocols and procedures. This includes policies and procedures for determining and executing quality initiatives, management reviews and the setting of quality improvement goals.

Customer Service - ensures the laboratory's internal and external customers receive data that is of high quality, is exactly what they need, is in the format that they need and is reliable. They identify who the customers are, identify their needs and measure customer satisfaction including processes for complaint identification and resolution.

Process Management - specifies how the laboratory develops, disseminates, controls and changes workflow processes specifically for the three phases of samples testing: pre-analytic, analytic and post-analytic. We will discuss these three phases in greater detail in the training activity guide on general laboratory practice.

Non-conformance Management - A non-conformance or non-conforming event is defined as an unexpected outcome or result that is an indicator of a problem, such as a breakdown in quality, a process failure or a technical issue. The non-conformance management QSE describes the laboratory's policy around detecting, investigating, reporting and prevention of events that do not conform to existing processes and procedures. It includes root cause analysis and corrective action.

See the Additional Resources section of this document to read the Joint Commissions standards for QSE.

ACTIVITY: WHICH QSE WOULD APPLY?

Imagine you are Raymond and new to your laboratory.

Using APHL's "How to Write a Laboratory Quality Manual" as a reference (see the Additional Resources section of this document), determine which quality system essential (QSE) would apply.

1. The internal temperature of a refrigerator is too high.

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2. A message has appeared while using the laboratory information management system (LIMS) indicating a software update is available.

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3. The proper way to store reagents.

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ACTIVITY: QSE RESPONSES

1. That would be the equipment QSE. It covers maintenance and use of equipment.
2. We discussed laboratory information management systems (LIMS) in the information management QSE. In most cases, it will likely be best practice to consult your quality processes and procedures before automatically updating any software in the laboratory.
3. Reagents are a consumable and are typically kept in inventory. So, the purchasing and inventory QSE would apply. Documentation will likely address keeping inventory, correct storage and dealing with expiration dates.

ACTIVITY: WHICH QSE WOULD APPLY?

Using APHL's "How to Write a Laboratory Quality Manual" as a reference (see the Additional Resources section of this document), determine which QSE would apply.

1. You are about to receive several specimens for testing.

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2. The results of your quality checks did not indicate expected results.

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3. You believe you have found a more efficient way to complete a laboratory process.

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ACTIVITY: QSE RESPONSES

1. The answer is the process management QSE. This is the QSE that would address the pre-analytic phase of the samples testing process along with the analytic and post-analytic processes.
2. This result could be considered a non-conformance and call for a root cause analysis. The answer would be the non-conformance management QSE.
3. The process improvement QSE should specify a procedure for revising a process. The document and records QSE would likely apply as well, as this QSE specifies how SOPs and other similar documents are revised and updated.

QUALITY INDICATORS

Quality indicators are measures that make use of readily available data that can be indicative of a quality issue. They are indicators that can typically be measured numerically and make use of known correct parameters.

For example, let's consider quality indicators in the specimen testing process.

The process has three phases:

- Pre-analytical
- Analytical
- Post-analytical

A pre-analytical quality indicator could be metrics about the specimen itself, such as temperature or concentration. These indicators can be measured and there are known correct indicators.

An indicator during the analytical phase could be the operating parameters of an instrument. Any indication that testing has fallen outside known parameters could be a signal that something is wrong.

And finally, post-analytical indicators would involve analysis of the test results. This could include wildly erroneous results or failed control samples.

As you can see, these indicators are a signal that something needs the attention required to maintain quality.

CONTINUOUS QUALITY IMPROVEMENT (CQI)

Continuous quality improvement, or CQI, is a management philosophy that recognizes that most work processes can be incrementally improved. It is the exact opposite of the old saying "If it ain't broke, don't fix it."

A CQI approach does not wait for something to go wrong. Instead, it empowers teams to constantly look for ways to refine what they are doing and improve work processes.

CQI focuses on work processes instead of individuals. It also recognizes and considers the needs of both internal and external customers.

See the Additional Resources section to see an example of a CQI workbook dealing with newborn screening.

RAYMOND AND CQI

For example, our new fellowship participant Raymond has discovered a more efficient way to process specimens as they are delivered to his laboratory.

Instead of letting Raymond take shortcuts and follow his own new improved process, Raymond's supervisor would encourage him to follow procedures through experimentation and documentation of results.

If successful, Raymond's improved process could be adopted as an improved process by the entire team.

CASE STUDY: AN ACCIDENT AVOIDED

While destroying cultures in an autoclave, the gaskets on the door failed and released contaminated steam into the laboratory. The person operating the autoclave was not wearing respiratory protection and was therefore exposed to a dangerous pathogen.

Subsequent investigations found that laboratory workers were aware that the gaskets on the autoclave were worn for some time.

Imagine you are performing the same task. You are about to place cultures in an autoclave when you notice the door gaskets are worn and could potentially fail.

How would application of a quality management approach prevent an accident from occurring?

CASE STUDY RESOLVED

Two quality system essentials apply here.

1. **Equipment** – having procedures and protocols in place that address equipment use, and equipment maintenance could ensure that operators complete specific checks before using the autoclave. This approach could also ensure that a particular maintenance schedule was followed, thus preventing the use of the autoclave with worn gaskets.
2. **Facilities and Safety** – having procedures and protocols that address use of PPE would ensure that the autoclave operator was wearing respiratory protection. Safety protocols could also ensure that an unsafe condition was reported and addressed. In this case, that condition would be the worn gaskets on the autoclave.

NEXT STEPS: MENTOR MEETING

Meet with your mentor to:

- Illustrate your laboratory's organizational structure relevant to QMS
- Present an example of application of QMS at your laboratory

ADDITIONAL RESOURCES

Resource Name/Title	Institution	Website/Periodical Information
Knowledge Management for Public Health Laboratories	APHL	This white paper describes basic knowledge management concepts, tracking the evolution of data to knowledge and identifying key components of knowledge management.
How To Write a Laboratory Quality Manual	APHL	A manual developed by the APHL Laboratory Systems and Standards committee
Clinical and Laboratory Standards Institute	Clinical and Laboratory Standards Institute	This website describes the Clinical and Laboratory Standards Institute (CLSI), a not-for-profit organization that brings together the global laboratory community for a common cause: fostering excellence in laboratory medicine. CLSI does so by facilitating a unique process of developing clinical laboratory testing standards based on input from and consensus among industry, government, and health care professionals.
Gaining Ground	Prepare Iowa	This website provides information about Prepare Iowa, which provides support to coalitions within Iowa and six other states to develop a sustainable infrastructure to support accreditation readiness, performance, and quality improvement