Internal Auditing and Control of Nonconforming Work

APHL Quality Management System (QMS) Competency Guidelines

The participant will understand

* What ISO/IEC 17025 requirements are for internal auditing

* How a non-conformance is identified

* What needs to be done when a nonconformance is detected

There needs to be a mechanism to check the day-to-day operations of the Quality Management System . When nonconformances are identified, staff must know what steps need to be taken.

Laboratories must take active steps to ensure a quality system is operating at all levels. Internal auditing ensures compliance to the ISO/IEC 17025 standard and the laboratory's own QMS. When nonconformances are detected, the laboratory is required to take steps to correct the problem and, in some cases, identify what caused the nonconformance, among other things. Ongoing monitoring of all aspects of operations to determine compliance can detect and prevent problems before data quality is affected.

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

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 11.01 Quality assessment plan
QMS 11.02 External assessments
QMS 11.03 Internal audits
QMS 11.04 Quality indicators

Why perform internal audits? What happens when a nonconformance if detected?

- Does your laboratory have a system to check day-to-day operations of the laboratory?
- Does your laboratory have policies and procedures in place that are implemented when any aspect of the work done does not conform to your laboratory's quality management system?

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QMS 11.05 Quality indicator data collection and analysis

QMS 12.00 Continual improvement: ensures mechanisms for continuous quality improvement

Terms, Acronyms, and Definitions

Audit (assessment): The on-site verification activity, such as inspection or examination, of a process or quality system, to ensure compliance to requirements. An audit can apply to an entire organization or might be specific to a function, process or production step

Correction: The immediate fix to the problem

Corrective Action (CA): Need to dig deeper to find out "WHY"

Documents: "Say" what you are going to do

Nonconforming record (NCR): A permanent record—made in writing—for accounting and preserving the knowledge of a nonconforming condition for the purposes of documenting facts or events

Nonconformance: The nonfulfillment of a specified requirement or a failure to meet a professional standard

Quality Audit: A systematic, independent examination and review to determine whether quality activities and related results comply with plans and whether these plans are implemented effectively and are suitable to achieve the objectives

Quality Management System (QMS): The quality, administrative and technical systems that govern the operations of the laboratory

Records: "Proof" of what you are doing

Root Cause: A factor that caused a nonconformance and should be permanently eliminated through process improvement

Tools

Examples of open-ended questions:

- How, what, where, why, when…?
- What is your process…
- Where can we find…?
- Could we have a look at…?
- Can we review…?
- Show me…?

- What happens when…?
- How have you met…?
- So, can you tell me of your…?
- What is your role in…?
- Walk me through…?
- You seem busy. How do you deal with…?
- Can you tell me more of how … occurs?

How to determine a Nonconformance:

- Procedures and/or protocols do not address requirement
- Procedures are not followed
- It is a repeat nonconformance