QMS Quick Learning Activity

Internal Auditing and Control of Nonconforming Work

ISO/IEC 17025, clauses 4.14 and 4.9

What will be covered in this training?

- Internal Auditing
  - What is it?
  - Who performs it?
  - What are the possible outcomes?
- Control of Nonconforming Work
  - What is it?
  - How do I identify it?
  - What do I do if it happens?

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

Terms, Acronyms, and Definitions

- **Preventive Action:** Action taken to remove or improve a process to prevent potential future occurrences of a nonconformance
- **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

Connections

- How are internal audits and nonconforming work related to each other?
  - Internal audits look for compliance with the ISO/IEC 17025 standard and quality management system. Noncompliance is also called nonconformance.
  - Nonconformances can also be identified by ways other than internal audits.

Internal Audit

ISO/IEC 17025 clause 4.14

- 4.14.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard. The internal audit program shall address all elements of the management system, including the testing and/or calibration activities.

ISO/IEC 17025:2005 Auditing Requirements

- It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

- Note: The cycle for internal auditing should normally be completed in one year.

ISO/IEC 17025:2005 Auditing Requirements

- 4.14.2 When audit findings cast doubt on the effectiveness of the operations or the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.

ISO/IEC 17025:2005 Auditing Requirements

- 4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

- 4.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

Internal Auditors look for:

- Does the laboratory “say” what they do?
  - Do we have written documents (policies, procedures, arrangements) that meet the requirements of ISO/IEC 17025?
- Does the laboratory “do” what we say?
  - Are we in compliance with our own management system, the ISO/IEC 17025 standard, and our technical SOPs?
- Can the laboratory “prove” it with records?
  - Training records, standard preparation records, work books, customer reports, audit reports, are all examples of records (proof) that the laboratory is “doing what we say”.

Purpose of Internal Audits:

- Provide assurance to management that the quality management system is implemented as intended.
- Identify opportunities for improving the management system itself and its effectiveness.
- Find problems before they affect quality of data.
- Prepare for external audits.
- Can be used as training tool.
- Internal auditing is a requirement of ISO/IEC 17025 Standard

Basic Internal Audit Process

Plan	The audit schedule The audit checklist The auditors	Usually planned by QA or QA Manager
Do	The audit as scheduled Ask the questions Examine the records	Conducted by auditor, independent of area being audited
Check	Degree of conformity	Does the laboratory meet requirements of ISO/IEC 17025 and its own SOPs
Act	Cite nonconformities if non-compliances are found Corrective Action/Closure	**Findings include compliance, non-compliance, and opportunities for improvement**

APHL™

AAFCO Association of American Feed Control Officials

AFDO Association of Food & Drug Officials Founded 1896

Audit the System, NOT the People

- Gather objective evidence
  - Policies, SOPs, records, auditor observation
- Interview the people
  - Understand the system and its effectiveness
  - How do they:
    - Receive and interpret information
    - Carry out instructions
    - Produce the data
- If nonconformances arise, fix that system
  - Very few problems are due to the people
  - The better the system, the fewer times people will be the problem

Control of Nonconforming Work

ISO/IEC 17025 clause 4.9

- 4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customers.

Control of Nonconforming Work

ISO/IEC 17025 clause 4.9

- The policy and procedures:
  - Establish responsibilities & authorities for managing nonconforming work
  - Define actions taken when nonconforming work is identified (i.e. halting work, withholding reports)
  - Ensure evaluation of significance of nonconforming work is made
  - Ensure correction is taken immediately
  - Determine if the nonconforming work is acceptable
  - Ensure customer is notified if needed
  - Define responsibility for authorizing resumption of work

Control of Nonconforming Work

ISO/IEC 17025 clause 4.9

- 4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedure shall be promptly followed.

  - 4.9.1 (previous slide) required *correction* to always be taken when nonconforming work identified
  - 4.9.2 (this slide) only requires *corrective action* in certain circumstances

What is nonconforming work?

- Non-fulfillment of a requirement
- When any aspect of testing or other work does not comply to procedures (our own or the customers')
- Out-of-control Quality Control
- Incorrect results reported
- Failing proficiency test
- Requires evidence that a specific requirement was not met

How a nonconformance is identified

- Audit
- Customer complaint/feedback
- Quality control data
- Proficiency test results
- Observation/self-reporting

How to respond to nonconforming work

- Quality SOP (procedure) defines who can identify it and who is notified
- Should work be halted?
- Must data be withheld/reports recalled?
- Evaluate the significance of the nonconformity
- Correct it
- Notify the customer, if needed
- Resume work when appropriate

Correction vs. Corrective Action

- Correction
  - An action to eliminate one instance of a nonconformity
  - Does not identify causes
  - Immediate fix
- Corrective Action
  - An action to identify and eliminate the cause of a nonconformity so that it will not happen again
  - Prevent recurrence
  - Problem solving process

Correction Examples

- Quality control (QC) samples fail:
  - Correction: Re analyze the QC sample and all samples since the last QC was in control
- Failure to complete all scheduled audits during the time period specified in quality management system
  - Correction: Conduct the audits that were missed

After the correction

- Resume work and release data when appropriate and with proper authorization.

- If deemed necessary, begin root cause analysis and corrective action process.
  - *Note: this is covered in a separate QMS Quick Learning Module*

Summing it up

- Internal audits are planned activities, with the goal of assuring compliance to ISO/IEC 17025 and the laboratory's policies and procedures.
- A nonconformance requires immediate correction, along with additional decisions about significance of the nonconformity and acceptability of the work.

Reference

ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*

–https://www.iso.org/standard/39883.html