QMS Quick Learning Activity

Internal Auditing and Control of Nonconforming Work

ISO/IEC 17025:2017

Clauses 8.8 and 7.10

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 work**: When any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer

Terms, Acronyms, and Definitions

- **Opportunities for Improvement:** Actions taken to enhance quality of a process; can be used to prevent potential future occurrences of a nonconformance
- **Quality Management System 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. Compliance is also called conformance.
  - Nonconformances can be identified by internal audits, and also found in other ways.

Internal Audit

ISO/IEC 17025 clause 8.8

8.8.1 The laboratory shall conduct internal audits at *planned intervals* to provide information on:

- whether the management system conforms to:
  - *the laboratory's own requirements* for its management system, including the laboratory activities;
  - *the requirements of ISO/IEC 17025*; and
- whether the management system is effectively implemented and maintained.

ISO/IEC 17025:2017 Auditing Requirements

- Audits shall be planned, established, implemented, and maintained in an audit program which shall take into account:
  - Frequency
  - Methods
  - Responsibilities
  - Planning requirements
  - Reporting
- Audit shall take into consideration the importance of the laboratory activities concerned.

ISO/IEC 17025:2017 Auditing Requirements

- Audits shall also take into consideration changes affecting the laboratory.
- Results of previous audits shall also be reviewed and considered.
- The laboratory shall:
  - Define the audit criteria and scope for each audit
  - Ensure that the results are reported to management
  - Implement appropriate correction and corrective actions without delay
  - Retain records as evidence of the implementation of the audit program and the results

ISO/IEC 17025:2017 Auditing Requirements

Audits should 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. Check with your accrediting body for specific requirements.

ISO/IEC 17025:2017 Auditing Requirements

- 8.7.1(d) Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.
- 8.9.2 Outcome of recent internal audits shall be included in the management review

ISO/IEC 17025:2017 Auditing Requirements-Periodic reviews

- 6.3.4 Implementation and monitoring of measures to control facilities including
  - Access to and use of areas affecting laboratory activities
  - Prevention of contamination, interference, or adverse influences on laboratory activities
  - Effective separation between areas with incompatible laboratory activities
- 6.3.5 Activities at sites or facilities outside its permanent control

ISO/IEC 17025:2017 Auditing Requirements-Periodic reviews

- 6.4.7 The calibration program shall be reviewed and adjusted as necessary
- 6.6.2 The laboratory's requirements for externally provided products and services shall be reviewed and records retained.
- 7.2.1.6 Periodic review of method development to confirm that the needs of the customer are still being fulfilled.

ISO/IEC 17025:2017 Auditing Requirements-Periodic reviews

7.7.2 The laboratory shall monitor its performance by comparison of results of other laboratories (i.e., participation in proficiency testing or interlaboratory comparisons), and this monitoring shall be planned and reviewed.

ISO/IEC 17025:2017 Auditing Requirements-Periodic reviews

8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions.

NOTE: Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

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, and 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 Manager
Do	The audit as scheduled Ask the questions Examine the records	Conducted by trained 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 non-compliances if found Implement Corrective Action	**Findings include compliance, noncompliance, and opportunities for improvement**

APHL

AAFCO Association of American Feed Control Officials

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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 17025:2017 clause 7.10

- 7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer

Control of Nonconforming Work

ISO/IEC 17025:2017 clause 7.10.1

- The procedure:
  - Defines responsibilities & authorities for managing nonconforming work
  - Ensures actions taken for managing when nonconforming work (i.e., halting work, withholding reports) are based on established risk levels
  - Ensures evaluation of the significance of nonconforming work is made; including an impact analysis on previous work
  - Ensures that a decision is made if the nonconforming work is acceptable
  - Ensures the customer is notified and work is recalled. if needed
  - Defines responsibility for authorizing resumption of work

Control of Nonconforming Work

ISO/IEC 17025:2017 clause 7.10.3

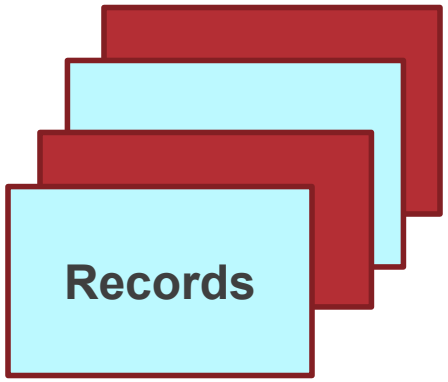
- 7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

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

Control of Nonconforming Work

ISO/IEC 17025:2017 clause 7.10.2

- The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1



What is nonconforming work?

Requires **evidence** that a specific requirement was not met

- Non-fulfillment of a requirement
- When any aspect of testing or other work does not comply to procedures (the laboratory's own procedures or those of the customer's)
- Out-of-control Quality Control
- Incorrect results reported
- Failing proficiency test

What is nonconforming work?

In 6.4.9 :

Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service.

- The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure.

How is a nonconformance is identified?

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

How to respond to nonconforming work

- Quality management system SOP (procedure) defines who can identify it and who is notified
- Based on risk level:
  - Should work be halted?
  - Must data be withheld/reports recalled?
- Evaluate the significance of the nonconformity
- Correct it
- Notify the customer and recall work, if needed
- Resume work as determined by authorized person

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: Reanalyze 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 17025:2017 *General requirements for the competence of testing and calibration laboratories*

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