ISO/IEC 17025:2017 Laboratory Management System Internal Auditor Training Programme Outline

Course Overview

ISO 17025 Laboratory Management System Internal Auditor Training is a specialized program designed to equip individuals with the knowledge and skills necessary to conduct effective internal audits within laboratories that adhere to ISO/IEC 17025 standards. The purpose of this program aims to ensure that internal auditors understand the requirements of ISO/IEC 17025 and can effectively assess the laboratory's compliance with these requirements.

In summary, ISO 17025 Laboratory Management System Internal Auditor Training provides participants with the knowledge, skills, and confidence to effectively assess laboratory compliance with ISO/IEC 17025 standards, driving quality, compliance, and continual improvement within the laboratory setting.

Who should attend?

The training program is suitable for laboratory personnel involved in QMS Auditors, Quality assurance, Quality control, or management roles, as well as individuals seeking to become internal auditors within ISO/IEC 17025 accredited laboratories.

Course Duration – 04 Days

Organizational Objective or benefits

1. To have a competent team with complete understanding & knowledge of laboratory management system auditing.
2. To have a competent auditor who can perform Internal Audits as per ISO/IEC 17025:2017 requirement and guideline.
3. Confidence in facing and successful compliance satisfaction during ISO/IEC 17025:2017 CB Audits.

Learning / Program objective

1. To acquire complete knowledge of ISO/IEC 17025:2017 Standard Requirements
2. Improve Compliance to ISO/IEC 17025:2017
3. Plan and initiate the Internal Audit on decided frequencies.
4. Conduct audit activities using the process approach Prepare and distribute the audit report to management.
5. Complete the audit follow-up, closing the NC and keeping the ISO/IEC 17025:2017 system alive within the organization.

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Training methodology & Benefits

1. Class room activity based / Interactive online (Inhouse & Public Course)
2. Group discussion

Body of Knowledge / Contents

Day 1 - Session I (Quick Review of ISO/IEC 17025 Requirements)

- Development of ISO/IEC 17025:2017 standard
- Scope of ISO/IEC 17025:2017 standard
- Definition of Laboratory as per ISO/IEC 17025:2017 standard
- Management System Standard V/s Competency based Standard
- CASCO Guidelines for Competency based standard
- Structure of ISO/IEC 17025:2017 standard
- Requirements of ISO/IEC 17025 :2017

✓ General Requirements (# 4)
✓ Structural Requirements (# 5)
✓ Resource Requirements (# 6)
✓ Process Requirements (# 7)
✓ Management Requirements (# 8)

Test 1 - General Appreciation Test

Day 1 - Session II (General, Structural & Resource Requirements)

General Requirements (# 4)
- Impartiality & Confidentiality

Structural Requirements (# 5)
Resource Requirement (# 6)

Personnel (# 6.2)
- Training, Authorization & Methods suggested for supervision & Monitoring

Equipment (# 6.4)
- New definition of Equipment as per ISO/IEC 17025:2017 standard
- RMs/CRMs & QC Materials

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Metrological Traceability (# 6.5)

- Definition as per ISO/IEC 17025:2017 standard
- BIPM History, Objective & Spectrum
- International System of Units (SI)
- Identified changes in ISO/IEC 17025:2017 standard

Externally provided products & processes (# 6.6)

- Requirements at ISO/IEC 17025:2017 standard

Day 2 - Session I -Process & Management System Requirements

Review of test / Calibration request (# 7.1)

- Review Mechanisms- Service Request, Service level agreement
- Agreement on Methods, statement of conformity & Decision Rules

Selection, Verification & Validation of Methods (# 7.2)

- Standard, Non-Standard & Laboratory developed Methods
- Verification & Validation -Overview

Sampling (# 7.3)

- Applicability of sampling – Testing of Lot or sample
- Sampling Plan, Sampling Procedure & Sampling Record

Handling of Test/ Calibration Items (# 7.4)

- Unique identification of samples / artifacts
- Preservation & Retention of samples

Technical Records (# 7.5)

- Records of Original Observations, data & Calculations
- Amendment of Technical Records

Evaluation of Measurement Uncertainty (# 7.6)

- Concept of Measurement Uncertainty
- Contributions for UoM

- Ensuring Validity of Results (# 7.7)
- Internal Quality Assurance – Re-testing / Re-Calibration, Replicate Testing/ Calibration , Blind samples , Correlation of results etc

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- External Quality Assurance – Proficiency testing / Inter Laboratory Comparison
- Classical Z score & Robust Z score, ISO IEC 17043

Reporting of Results (# 7.8)
- Results, Statement of Conformity, Opinions & Interpretation
- Documenting Decision Rules

Complaints (# 7.9)
NC Work (# 7.10)
Control of data (# 7.11)

Day 2 – Session II -Process & Management System Requirements

Options A & B (# 8.1.2)
Management System Documentation (# 8.2)
Control of Documentation (# 8.3)
Control of Records (# 8.4)

Actions to address Risks & Opportunities (# 8.5)
- Possible risks exist at Typical Laboratory
- Risks to Impartiality, False accept & False Reject
- Risk Mitigation

Improvement (# 8.6)
Corrective Action (# 8.7)
Internal Audit (# 8.8)
Management Review Meeting (# 8.9)

Test 2 – Test On Requirements (#4, 5, 6, 7 and 8)

Day 3 - Session I –Introduction to Audit & Audit Planning

- Objectives
- Definitions
- Introduction to Auditing
- Types of Audits
- Principles of Auditing
- Do's & Don'ts for Audit

Group Exercise 1 - Adequacy Audit

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Day 3 - Session II – On-Site Audit Implementation

- Audit Strategies
- Audit Process
- Types of Checklists –High level & Low level

Group Exercise 2 – Checklist Preparation

Day 4 - Session I – On-Site Audit Implementation (Contd…)

- On-Site Audit
- Interviewing & Questioning Techniques
- Recording the Results -Notes

Group Exercise 3 – Identification of Nonconformities

Day 4 - Session II –Nonconformity Writing

- Writing Nonconformities
- Classification of Nonconformities
- Examples of well written NCs

Final Examination

Identifying NCs from given situations, Assigning Clause Number, Writing NCs if any , Classification justification in case of No NC

Recommended Training and / or Experience (Pre-requisite)

A basic understanding & Awareness of ISO 17025:2017 and/or work experience in laboratory management system

Take away for participants

- To get the knowledge of ISO/IEC 17025:2017 Standard requirement for laboratory management system along with internal auditing knowledge

Certificate

Certificate of successful completion shall be issued to all the delegates who attend entire duration of the course & qualify the assessment on the last day of the training.