

ISO/IEC 17025 2017 Internal Auditor Training



Student Manual

Internal Auditor Training

AGENDA

I. The Standard

- 0:15 Introduction to Auditing
- 0:15 Presentation: Guide to Internal Auditing ISO/IEC 17025:2017 Review Document: ISO/IEC 17025:2017
- 0:30 Exercise: Is it a Requirement?
- 2:00 Presentation: Requirements of ISO/IEC 17025:2017
- 0:45 Exercise: Find the Requirement
- 0:15 Questions

II. The Audit

- 0:30 Scheduling the Audit
- 0:30 Planning the Audit
- 0:45 Opening Meeting
- 0:20 4.1 Impartiality
- 0:20 6.3 Facilities and Environmental Conditions
- 0:30 6.4 Equipment
- 0:30 7.5 Technical Records
- 0:30 7.7 Ensuring the Validity of Results
- 0:30 7.8 Reporting of Results
- 0:30 8.6 Improvement
- 0:20 8.9 Management Review
- 0:30 Auditors Document Findings
- 0:30 Final Audit Report
- 0:30 Closing Meeting
- 0:30 Creating the Audit File

Why Audit?

Internal auditing is one of the most challenging requirements of ISO/IEC 17025.

Audits are necessary and need to be done to take advantage of the possible benefits.

.. Audits are the Key to Improvement ..

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Who Can Audit?

❖ Auditors typically represent the people employed by the organization and must be objective, impartial, and dedicated to this important task.

❖ ISO/IEC 17025 Par. 4.1.3 requires that your "*Laboratory be responsible for the impartiality of its activities and does not allow pressures to compromise impartiality*".

❖ The implication is that **Auditors cannot audit their own work.**

❖ There are important techniques that they must be aware of when they prepare for and perform the audits.

❖ Internal auditors must become familiar with the auditing process.

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Performing an Internal Audit »Overview

Internal Auditor training covers:

❖ The purpose and scope for auditing the LMS to the ISO Standard

❖ The requirements for planning and scheduling internal audits

❖ The practices followed during the internal audit, including opening and closing meetings

❖ How to develop check lists and questions for the audits

❖ How to interview and what to look for when asking questions

❖ Reporting on the internal audit and follow-up activities.

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Is it a Requirement

<i>The standard requires that:</i> If the requirement is true, circle True and list the clause. If it is false, circle False and list the clause used.	True	False
1. The laboratory shall establish a management system that is capable of assuring the quality of the laboratory results	T <i>Clause:</i>	F <i>Clause:</i>
2. Reports do not need to include the contact information of the customer.	T <i>Clause:</i>	F <i>Clause:</i>
3. Records shall be retained for equipment which can influence laboratory activities.	T <i>Clause:</i>	F <i>Clause:</i>
4. The laboratory does not need to be a legal entity or be legally responsible for its laboratory activities.	T <i>Clause:</i>	F <i>Clause:</i>
5. The laboratory does not need to retain records for the supervision of personnel.	T <i>Clause:</i>	F <i>Clause:</i>
6. Management must review the management system at least every quarter of the year.	T <i>Clause:</i>	F <i>Clause:</i>
7. The laboratory shall document the competence requirements for each function influencing the results of laboratory activities.	T <i>Clause:</i>	F <i>Clause:</i>
8. Upon receipt of the test or calibration item, deviations from specified conditions need to be recorded.	T <i>Clause:</i>	F <i>Clause:</i>
9. Any differences between the request or tender and the contract shall be resolved at the end of the calibration or testing.	T <i>Clause:</i>	F <i>Clause:</i>
10. The laboratory shall identify and select opportunities for improvement.	T <i>Clause:</i>	F <i>Clause:</i>
11. Information about the customer obtained from sources other than the customer need to be confidential between the customer and the laboratory.	T <i>Clause:</i>	F <i>Clause:</i>
12. The laboratory needs to retain records for at least two years.	T <i>Clause:</i>	F <i>Clause:</i>
13. Actions to address risks and opportunities need to be determined for the laboratory's activities.	T <i>Clause:</i>	F <i>Clause:</i>
14. The laboratory shall provide the complainant with progress reports and the outcome of the complaint.	T <i>Clause:</i>	F <i>Clause:</i>

Sample Opening Agenda

Opening Meeting Agenda

- **Introductions**
The lead auditor will conduct the opening meeting and introduce the auditors and other attendees as needed.
- **Attendee Sign In**
Pass around the copy of the Internal Audit Plan to have each person sign in. This will go into the audit file and be a record of who attended.
- **Review Scope of the Audit**
Explain what is going to be audited, and why the audit is being performed.
- **Establish Communications**
Determine who the contact person or persons in each area will be. Who should the auditors talk to?
- **Confirm Times**
If there are schedule conflicts with the audit times on the audit plan, now is the time to adjust the times to audit when people are available.
- **Schedule the Closing Meeting**
Confirm the time and place for the closing meeting.
- **Ask for any Questions**

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Ask Question of Employees

- Open ended questions will give you more information
 - What, Why, When, How, Where, Who ??
- The most useful question of all...
“Can you show me?”

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Prepare your checklists: 4.1 Impartiality

- Read the Section 4.1 of the Quality Manual.
- Review the checklist in the student manual for Section 4.1, 'Impartiality'.
- Write any additional questions you would like to ask to verify that SCL is following their procedure.

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Example of Internal Audit Report

Audit Number 1	Page 1	Closing Meeting Attendees For Superior Calibration Lab A Doer, R Ryan, D Delany, D Thomas, M T Moore, J Sample, A olt, Auditors R Richards, A Anderson, R Roberts.
Date April 14, 2019		
Area(s) audited Quality Manual, including Laboratory Facilities, Calibration Certificate, Equipment and Records, Laboratory Management	Lab	
Changes to Scope of Audit No changes, areas audited as planned.		
Lead auditor Richard Richards		Auditors Ander Anderson, Robbie Roberts
Audit Record (Describe what you did, who you spoke to, what records you examined below)		
General Comments All involved were very helpful and open when audited. The documents and records requested were promptly provided.		
List of documents reviewed		
Documented information Manual, CR 01 Calibrated Equipment List , Calibration Certificate, Calibration Data	Quality	
List of persons interviewed		
President, Albert S Doer		Manufacturing, R Ryan
Human resources, M T Moore		Laboratory Manager, J Sample
Technical support, A olt		Materials, D Delany