

ISO/IEC 17025:2017 Internal Auditor Training



Trainer's Guide

Overview

These course materials are meant to train people to conduct internal quality audits within your organization, which are necessary to meet the internal audit requirements of the ISO/IEC 17025:2017 standard.

The course is divided into two sections:

1. The first section will familiarize the students with the ISO/IEC 17025:2017 requirements for laboratory quality management
 - Allow 4 hours for this section.
2. The second section is devoted to the auditing process. The students will go through all the steps required for an audit, with hands on involvement in performing each step by conducting a mock audit of a fictitious company.
 - Allow 8 hours for this section.

We recommend that you print this guide as you'll need the PowerPoint speaker notes to lead the class. This guide contains everything the instructor needs to lead the class.

Notes:

- It is assumed that the instructor has the education, credentials and/or equivalent experience. This is not meant as a self study course.
- It is recommended that the first audit the student is involved with be under the leadership of a lead auditor who has audit experience.

4.2 Confidentiality

CONFIDENTIAL

The laboratory and its personnel are responsible for the information obtained or created during the performance of laboratory activities.

All information is considered proprietary information and shall be regarded as confidential, except as required by law.

This means the Laboratory is not to disclose any of this information provided by the clients.

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8.3 Control of management system documents (Option A)

The Lab-MS includes the documented information required by the ISO/IEC 17025:2017 standard and the documented information determined to be necessary for an effective Lab-MS. Documented information must be controlled to ensure that it is available and suitable for use, where and when it is needed and it is adequately protected.

- Many companies will use a “Master List” to list the current revision and location of each document.
- Recording the distribution of documents is important; if a document is revised all previous revisions of the document must be replaced. This is only possible if you know where all those copies are.
- Documented information from external sources are controlled by the owner of the documents. The external documents must be regularly reviewed to ensure that the latest revision is being used.

The laboratory will need to ensure that:

- documents are approved for adequacy prior to issue by authorized laboratory personnel;
- documents are periodically reviewed, typically annually, and updated as necessary;
- changes and the current revision status of documents are identified. A revision history page works well to document this.
- relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
- documents have a unique identification;
- the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

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Closing Meeting

The agenda for the closing meeting includes:

- ❖ Thank the people involved
- ❖ Have the attendees sign-in
- ❖ Remind the auditees that the audit is a sampling and that you did not look at everything
- ❖ Each auditor presents their findings
- ❖ Lead presents overall status of the system
- ❖ Answer questions

Sample Audit Report — page 1

Example of Internal Audit Report

Audit Number: 1	Page 1	Closing Meeting Attendees:
Date: April 14, 2019		For Superior Calibration Lab:
Area(s) audited:		A Doer, R Ryan, D Delany,
Lab Quality Manual, including		D Thomas, M T Moore,
Laboratory Facilities,		J Sample, A Bolt,
Calibration Certificate,		+
Equipment and Records,		Auditors: R Richards,
Laboratory Management		A Anderson, R Roberts.
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:		
Quality Manual,		
CR-01 'Calibrated Equipment List',		
Calibration Certificate,		
Calibration Data		
List of persons interviewed:		
President, Albert S Doer		Manufacturing, R Ryan
Human resources, M T Moore		Laboratory Manager, J Sample
Technical support, A Bolt		Materials, D Delany

Have Students create a meeting agenda, page 1