

MOTIVA

Laboratory Internal Auditor Course

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Course Logistics

1. Introductions
2. Course Objectives
3. Our Contract
4. Health and Safety (fire exits and washrooms)
5. Breaks
6. Facilitator Evaluation

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Course Objectives

- Know how to perform an audit and what to ask ✓✓✓
- How to summarize the report ✓✓
- Good line to follow during the audit ✓
- How to treat people with respect while auditing them ✓✓
- How to enhance buy-in for the QMS ✓
- Get prepared for audits and assessments. ✓✓✓
- Familiarity with ISO/IEC 17025.
- Have a record of training and evidence of qualification.
- Curiosity about a different perspective about auditing.
- What kind of questions to ask as an auditor.
- Understanding what an auditor is required to do.
- Build an internal audit team (multi-disciplinary).
- Better implementation of the QMS.

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Course Outline – 4 Modules

1. QMS and the need for internal audits
2. Planning internal audits
3. Meetings and interviews
4. Writing findings

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Course Outline – Module 1

1. QMS and the need for internal audits
2. Planning internal audits
3. Meetings and interviews
4. Writing findings

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QMS in Lab Operations

QUALITY MANAGEMENT SYSTEMS (QMS)

Includes all functions with emphasis on those that influence the safety of persons and/or the (quality) validity of technical decisions or results

- All business operations functions
- All management and administrative functions
- All finance functions
- All HR functions
- All purchasing and contract review functions
- All marketing and communications functions
- All maintenance functions

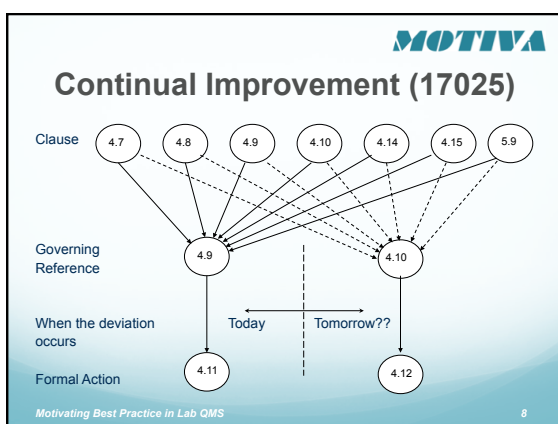
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Why do Internal Audits?

- Internal audits are the most comprehensive method of determining if the management system is working for us:
 - Is it supporting the work of the people in the laboratory?
 - Does it help provide a safe environment?
 - Does it help us produce only technically valid results?
- Internal audits tell us of our management system is:
 - Implemented;
 - Effective, and
 - Allows for continual improvement.

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Continual Improvement Pieces

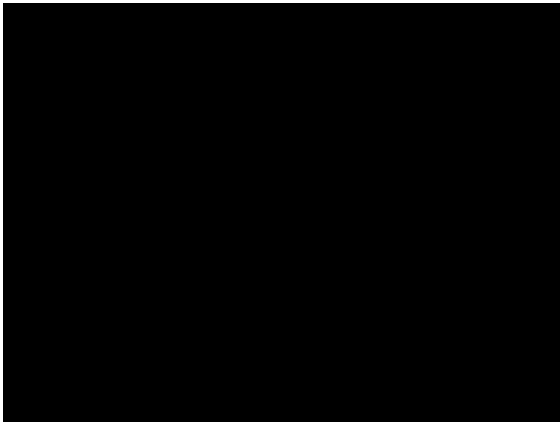
Do we need Corrective- or Preventive-Action?


- Yes, if the risk to the lab and its people is unacceptable
- Yes, if the deviating condition prevents us from producing technically valid results
- Yes, if either of these is easier than many remediations.

What are the steps to Corrective- or Preventive-Action?

- Root cause analysis
- Determine a range of suitable solutions
- Pick one
- Implement it
- Document it
- Monitor it for effectiveness.

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Course Outline – Module 2

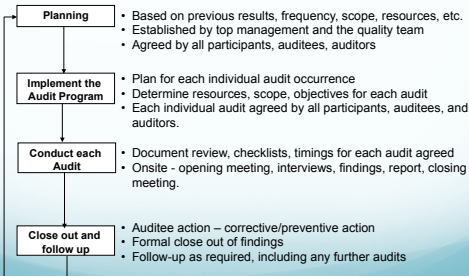
1. QMS and the need for internal audits
2. **Planning internal audits**
3. Meetings and interviews
4. Writing findings

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Internal Audit Cycle



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graph TD; A[Planning] --> B[Implement the Audit Program]; B --> C[Conduct each Audit]; C --> D[Close out and follow up]; D --> A;
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System Readiness for Audit

1. Documented system
2. Structured system
3. Implemented system

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Documented System

- Quality policy document
- Processes / procedures
- SOPs / instructions
- Specifications
- Standards
- Codes of practice
- Regulations
- Records

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Structured System

Policy

Procedures

Work Instructions

Proof

Level 1

Level 2

Level 3

Level 4

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Implemented System

Do people have access to the policies and procedures that govern their work?

Do people maintain records that demonstrate their use of the policies and procedures that govern their work?

- Records indicate the level of implementation of Documents, Processes and Procedures
- Records provide evidence that a system is being used
- 17025 has comprehensive recording requirements throughout

"If you did not write it down - it did not happen!"

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Internal Audit Programme

Approved by top management and contains:

- Resource allocations
- Scope and objectives of audit activities
- Timelines

Audit Area / Period	Q1-2007	Q2-2007	Q3-2007	Q4-2007
Admin		Sally	George	
Engines	Karen			
Polymers				Bruce
Sample Reception / dispatch			Jill	

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Developing the Audit Plan

1. See the example on page 14 of Chapter 2.
2. Note the list of requirements on page 15 of Chapter 2 when formally presenting the plan during an opening meeting.

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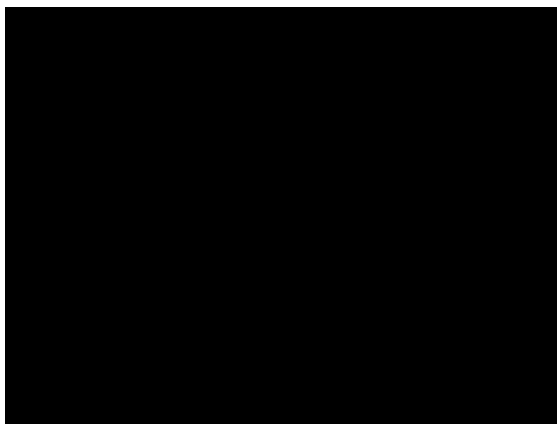
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Exercise 1 – Audit Planning

Let's review this together

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Course Outline – Module 3

1. QMS and the need for internal audits
2. Planning internal audits
3. Meetings and interviews
4. Writing findings

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Opening Meeting

1. Introductions and thanks
2. Audit scope and objectives
3. Audit plan
4. Audit methods and procedures
5. Confidentiality
6. Respond to questions
7. Depart for the tour of the facility

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Audit Schedule / Plan

1. Agreement on the planned approach
2. Respond to necessary adjustments to the plan
3. Confirm arrangements for logistics and resources
4. Confirm arrangements and timings for subsequent meetings
5. Confirm arrangements for the end of the audit

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Audit Methods

1. Clearly explain investigation activities
2. Be open about the process and emphasise its transparency

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Confidentiality

1. Confirm audit team's responsibilities
2. Confirm auditing authority's responsibilities

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Respond to Questions

Be prepared to handle questions from the auditees – focus on the benefits of the approach and the transparency of the activities.

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Responsibilities for Conduct

1. The auditor is solely responsible for the success of the audit. If a team, it is the team leader.
2. Chair meetings (all of them)
3. Declare findings
4. Sign the report
5. Official link between team and auditees.

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Sampling

1. Discuss the process and pick some records along the way. Best when the process is simple and records are few.
2. Start with random selection of records and discuss the process based on the records. Best when process is complex and records are many.

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Facing Conflict

1. Remain calm - create distance and space
2. Tell someone (lead auditor) or senior auditee
3. Tell someone else (quality manager)
4. Pause the audit until the situation is resolved


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Recording Observations

1. From the document review (system audit)
2. During onsite visit (conformance audit)
 - Auditor's aim is to sell the idea of the observation to the auditee
 - Use the Colombo approach
 - Get agreement (prevents surprises later)

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Wash up Meetings

- 1. Daily to prevent surprises later
- 2. List of observations - not findings
- 3. Keep auditee current with progress of audit

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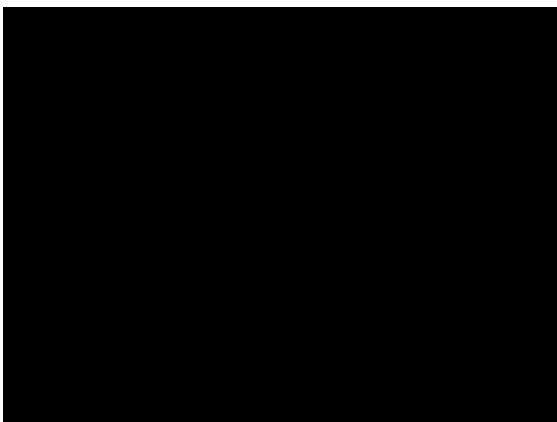


Exercise 2 – Interviews

Let's review this together

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Course Outline – Module 4

1. QMS and the need for internal audits
2. Planning internal audits
3. Meetings and interviews
4. **Writing findings**

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Audit Findings

Three required elements of every finding:

- A statement of the condition observed,
- A statement of the requirement, and
- A reference to the evidence that supports the comparison of these two.

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Evidence Supports Findings

Three sources of audit evidence:

- Review of reference documents and audit documents and records,
- Interview of auditees, and
- Observation of processes.

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Scope of Evidence

Try and select evidence from:

- Some recent records
- Some not-so-recent records, and
- Some records from shortly after the last audit.

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Sense of Conformance

In gathering evidence, try and obtain a sense of the overall conformance of the process to requirements. One or two records may not be enough to indicate a problem. Acquire more to confirm the level of conformance (or non-conformance) of the process.

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Writing the Report

- Solely the responsibility of the auditor (or lead auditor).
- Only the auditor (or the lead auditor) MUST sign the report.
- Only the auditor (or the lead auditor) declares the non-conformances.
- Good lead auditors get consensus.

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Contents of the Report

The report must:

- Be a factual description of the audit activities it covers, and
- Provide a fair and accurate picture of the quality system audited.

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Structure of the Report

The report contains:

- Cover page
- Audit Summary
- Activity Summary
- Findings

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Cover Page

The cover page contains:

- Report number
- Dates
- Scope and objectives
- Reference documents
- Audited documents
- Team names
- Auditee names
- Signature of lead auditor (and....)
- Page numbers...

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Audit Summary Page

The summary page contains:

- Report number
- Auditor overall comments
- Auditor conclusions
- Auditor recommendations
- Date of next planned activity
- Page numbers

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Activity Summary Page

The activity summary page contains:

- Report number
- List of observations (areas/activities)
- List of associated references
- List of deviations and other finding notation numbers
- Auditor activity comments
- Page numbers

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Findings Page(s)

Each finding page contains:

- Finding (NCR) log number
- Indication of type of finding
- Identification of process owner, date and reference
- Description of the finding
- Space for root cause analysis, corrective action, and follow up

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Closing Meeting

Agenda is similar to opening meeting:

- Introductions and thanks
- Audit scope and objectives (Audit Report Cover Page)
- Audit methods and procedures
- Confidentiality (Audit Report Cover Page)
- Present the Audit Report (Audit Report Summary and Findings Pages)
- Respond to questions
- Discuss Recommendations and Follow Up (Audit Report Summary)
- Obtain Signatures (Audit Report Cover Page)
- Ensure one copy remains with the auditee and one copy is forwarded to the quality manager / coordinator.

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Team Debriefing

After the conclusion of the audit activity, gather the team together to discuss how it went and look for areas to improve.

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Exercise 3 – Audit Reports

Let's review this together

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Quiz

32 questions

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Facilitator Evaluation

Please complete it so that we know what needs to be considered for the next course.

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