L12 Internal Audit & Management Review Process
8 Management System Requirements

ISO/IEC 17025 Laboratory Management System

- 4 General Requirements
- 5 Structural Requirements
- 7 Process Requirements
- 6 Resource Requirements
- 8 Management System Requirements
ISO/IEC 17025: 2017

8.2 Management System
8.9 Management Review

5.0 Structural Requirements

4.1 Impartiality
4.2 Confidentiality

7.1 Requests, tenders & contracts
7.2 Selection, validation & verification of methods
7.3 Sampling
7.4 Handling
7.5 Technical Records
7.6 Measurement Uncertainty
7.7 Quality Control
7.8 Reporting

6.1 Resource requirements

6.2 Personnel
6.3 Facilities & Environment
6.4 Equipment
6.5 Traceability
6.6 Purchasing & Subcontracting
7.11 Control of Data
8.3 Document Control
8.4 Records

8.5 Risks and Opportunities
8.6 Improvement
8.7 Corrective Action
8.8 Internal Audit
7.10 Nonconforming Work
7.9 Complaints

Feedback

CUSTOMER
Continual Improvement - The PDCA Cycle.

1. **Plan** what you will do
2. **Do** what you planned
3. **Check** what you actually accomplished
4. **Act** on the gap between the plan and the accomplishment
5. **Do** it all over again
**Internal Audit** is a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives. The term internal audit refers to an audit done by laboratory to establish the extent of conformity to the documented requirements or standards as per the laid down procedure.

The standard only gives you the general requirements; therefore, it is best to consult other standards e.g. ISO 19011 (Guidelines for auditing management systems) to fill in the details for internal audits for example.

**Management Review** is a formal, structured meeting which involves top management and takes place at once in year. The purpose is to review and evaluate the effectiveness of laboratories Management System, helping lab to determine its continued suitability and adequacy in relation to quality policy and objectives. possible need for changes to quality policy, objectives, targets and other elements of the QMS are also discussed in MR.
Internal audits

Procedure/Planning

➢ Qualified independent auditor
➢ Impartiality
➢ Report
➢ Corrective actions
➢ Follow-up
8.8 Internal audit – ISO/IEC 17025 requirements

8.8.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:

a) conforms to:
   • the laboratory’s own requirements for its management system, including the laboratory activities;
   • the requirements of ISO/IEC 17025;

b) is effectively implemented and maintained.
8.8 The laboratory shall:

a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;
b) define the audit criteria and scope for each audit;
c) ensure that the results of the audits are reported to relevant management;
d) implement appropriate correction and corrective actions without undue delay;
e) retain records as evidence of the implementation of the audit programme and the audit results.

NOTE ISO 19011 provides guidance for internal audits.
Internal audit

- Select and train auditors
- Plan audit for each process over a certain period of time e.g. 5 years which is an accreditation period
  - Critical processes or problems with problems: more frequent eg. annually
  - Less critical: every five years
- Conduct audit, find improvement possibilities
- Report results to management
- React on findings
Internal auditors

Personal attributes (ISO19011)

- **ethical** fair, truthful, sincere, honest and discrete;
- **open-minded** willing to consider alternative ideas or points of view;
- **diplomatic** tactful in dealing with people;
- **observant** actively aware of physical surroundings and activities;
- **perceptive** instinctively aware of and able to understand situations;
- **versatile** adjusts readily to different situations;
- **tenacious** persistent, focused on achieving objectives;
- **decisive** reaches timely conclusions based on logical reasoning and analysis; and
- **self-reliant** acts and functions independently while interacting effectively with others
The internal audit process

1. Audit Plan
2. Develop Checklists
3. Opening Meeting
4. Gather Evidence
5. Record Results
6. Closing Meeting
7. Audit report
The internal audit process

Performing audit activities

**Initiating the audit**
- Establishing initial contact with the auditee
- Determining the feasibility of the audit

**Preparing audit activities**
- Performing document review in preparation for the audit
- Preparing the audit plan
- Assigning work to the audit team
- Preparing work documents

**Conducting the audit activities**
- Conducting the opening meeting
- Performing document review while conducting the audit
- Communicating during the audit
- Assigning roles and responsibilities of guides and observers
- Collecting and verifying information
- Generating audit findings
- Preparing audit conclusions
- Conducting the closing meeting

**Preparing and distributing the audit report**
- Preparing the audit report
- Distributing the audit report

**Completing the audit**

**Conducting audit follow-up**
1st STEP: Audit plan

- Objectives & scope
- Collect documents
  - standard, documented information, forms
  - desk top review
- History - previous audit reports,
Audit Plan

is set up by the quality manager

➢ addresses processes in the lab
➢ lists auditors and tests to be audited
➢ sets up a time frame for audit and report
➢ is put into force by top management
2nd STEP: Developing checklists

- Review documents & guidelines
- Identify important aspects of the activity
- List in logical order
- Set of questions to ensure critical information is covered
Checklist is made to Establish Objective Evidence

Try to establish

➢ That Authorized documented information are in use and implemented as described
➢ That superseded documents have been removed
➢ That good housekeeping is practiced
➢ That facilities are adequate
➢ That supervision is adequate
➢ ....
Audit Check-list

➢ Planned audit of QMS management system requires check list which can serve as aid memoir for the auditor. The audit need not be limited to the questions given in the check-list.

➢ The questionnaire to be designed to assess whether the spirit of the standard has been captured

➢ The aim is that the QMS management system should add value to the organization and drive it towards achievement of organizational objectives and continual improvement.

➢ The questions help organization in deeper analysis of their processes for establishing robust QMS management system for better control over business processes.
Preparing the audit

The **auditor** shall:

- study the relevant quality documentation
- eventually adapt the audit questions
- ascertain the audit appointment (location, time, necessary personnel)
- conduct a preparatory discussion
Preparing the audit

The auditee shall:

- Check the quality documentation for completeness and actuality
- Make the documentation accessible to the auditor as soon as possible
- Ascertain that necessary personnel is available
- Prepare safety measures for site visiting if needed
Evaluating Responses to the Questionnaire / audit checklist

➢ While responding to questions the person responsible for the activity has to demonstrate that the requirement written in the question is being complied. Respondent need not always show a document or record as evidence.

➢ Where a procedure or instruction is not documented the auditor may seek response from two or three persons involved in the activity to assess that a standardized process has been established and is being operated satisfactorily.

➢ Effectiveness of a process can also be assessed during audit of next process which would receive the output of the process being audited.
3rd STEP: Opening meeting

• **Who ?**
  - auditor/audit team
  - Auditor must be trained
  - any staff from area to be audited that may be interviewed
  - Must be independent for area being audited

• **What ?**
  - Scope
  - expected duration
4th STEP: Conducting the audit

- Assign the auditors to their area
- Sample the system and witness few testing from technicians
- Collect objective evidence of system effectiveness
- Compare findings from checklist with requirements
- Decide compliance or non–compliance
- Audit team daily meeting
Conducting an audit

- Collect information as stated in the audit plan.
- Deviate only, when nonconformities are found.
- Verify this information by audit evidence (documents, recordings, samples).
- Document all audit questions, gathered information and collected audit evidence.
- Finalize the audit by explaining the audit findings.
Non-conformities

➢ Activities which do not adhere to Quality management system
➢ May be classified
  - major non-conformance
  - minor non-conformance
  - areas for improvement
Types of audits

**Horizontal audits:**
- Examine in detail single aspects of the quality system, for example, calibration or reporting

**Vertical audits:**
- Select a sample and follow its progress from receipt to disposal, examining all aspects of the quality system related to its testing

Check for: documentation & operationality
Check for: customer satisfaction
Example of horizontal audit - 1

Sample A, weighted on November 12, 2003

- Code of sample
- User list of balance on November 12 - Qualification of users
- Training of user-documented procedure for using the balance – Introduction date of procedure
- Adjustment of balance on or before November 12 – Documented procedure?
- By whom, qualification
- When, criteria/control chart-Calibration status of balance on November 12–When, by whom –Intermediate checks –By whom?
- Vials used for weighing: were they checked for fitness for purpose? Who did so and when? Was this marked on the bag? Where were they purchased and when? Has everyone access to them? Who else used them on the same day or one day before?
- **In all cases: documentary evidence is needed**
Example of horizontal audit-2

Measuring instrument, used on November 12, 2003

- Was the instrument fit-for-the-purpose? Who did the performance test? Was this person qualified to do so? When and by whom was he trained?
- What are the results of the most recent performance test?
- Which tools (control material, standards) were used on November 12? When were these purchased, and by whom? Were these materials still fit-for-the-purpose (not expired chemicals, recalibrated standards)? Who has been using these calibrants for other purposes?
- Who else used the instrument on November 12 and for what purpose? What were the results? How were these sample prepared?
- Was there a ‘blank’ measured? Where did this blank came from? Could it have been contaminated in another room/lab? What other activities went on in the lab of the measuring instruments and other labs that may have affected the blank?
- Are there spare parts? When and by whom were they purchased? Where are they? Are they still fit-for-the-purpose?....

In all cases: documentary evidence is needed
Example of vertical audit - 1

Sample A, weighted on 12 November 2003

- When did it came in ? Registration form
- Who received it ?
- Was there a receipt inspection ? By whom ?
- Who labeled it and when ? Who decided on the code ? Which procedure for the coding ?
- Where was it stored after receipt and when ? Who did so ? Was it listed in an inventory ?
- How was the sample further treated ?
- How was the sub-sampling done and when ? Is there a procedure for sub-sampling ?
- What happened with the remainders of the sample after a sub-portion was weighted in? Has this been stored ? Where, when and by whom ? Has it been discarded ? When and how ?

In all cases : documentary evidence is needed
Example of vertical audit - 2

Measuring instrument, used on November 12, 2003

- Who used the instrument in the previous days and for what purpose?
- When was the last performance test and how were the tests of the previous period?
- When was the last maintenance and by whom? Was there any repair? Who did the inspection after the maintenance and what were the conclusions?
- When was the instrument purchased?

In all cases: documentary evidence is needed
Audit report

The audit report should contain:

- date, location and names of audit partners
- scope of the audit (quality objectives)
- listing of audit findings (also positive, eventually nonconformities)
- an evaluation statement of the quality situation.
- signature of auditors and
- a distribution list
Categorizing Non-Compliances

Major

➢ A single major system, product or service non-compliance
➢ A lack of documented information needed to satisfy an agreed requirement.
➢ Non-implementation of documented information and arrangements.
➢ A series of minor non-compliances in a particular area or activity which collectively have an adverse effect on qualify of the product or service.
Categorizing Non-Compliances

Minor

➢ There is a defined system of documented procedures and arrangements which satisfy agreed requirements against which the organization being assed can demonstrate an acceptable level on implementation overall, but there are minor discrepancies or lapses in discipline or only 1 area such mistakes found
Non – Conformity Report

➢ Used to report non – conformity audit findings.
➢ Must be factual.
➢ Must be understandable and traceable.
➢ Rise formal notification of any issues at the time of finding.
➢ Allow the auditee to implement corrective action prior to the closing meeting.
➢ The auditee is required to sign signifying an understanding and acceptance of the non – compliance.
6th STEP: Closing meeting

Audit team meeting

➢ discuss audit results

Closing meeting

➢ discuss corrective actions
➢ determine resolution dates

Identify corrective actions

➢ use corrective action forms
Audit report

Format No.:

<table>
<thead>
<tr>
<th>Pre-Audit Meeting</th>
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<tbody>
<tr>
<td>Date</td>
<td>Start Time</td>
<td>End Time</td>
<td>Venue</td>
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<table>
<thead>
<tr>
<th>Planned Audit Location &amp; Dates</th>
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<tbody>
<tr>
<td>Location</td>
<td>Audit Date &amp; Time</td>
<td>Auditees</td>
<td>Auditors</td>
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<tr>
<th>Reference Standards list for Audit</th>
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<td>1.</td>
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<td>2.</td>
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<td>3.</td>
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Audit Purpose: To Determine Compliance / non-compliance with above standard & Procedures

<table>
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<tr>
<th>Audit Scope</th>
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<thead>
<tr>
<th>Sr. No.</th>
<th>Audit Team Name</th>
<th>Signature</th>
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<tr>
<th>Distribution List:</th>
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<tr>
<td>✓ Auditees / Auditors</td>
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<thead>
<tr>
<th>Quality Control / Quality Assurance – Manager Signature</th>
<th>M.R. Signature</th>
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Content of the audit report

<table>
<thead>
<tr>
<th>Clause</th>
<th>Requirement</th>
<th>Document Reference</th>
<th>Statues of the Implementation</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>from the tested or calibrated item and shall be clearly identified as such.</td>
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<tr>
<td>7.8.7.3</td>
<td>When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.</td>
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<tr>
<td>7.8.8</td>
<td><strong>Amendments to reports</strong></td>
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<tr>
<td>7.8.8.1</td>
<td>When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.</td>
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<td>7.8.8.2</td>
<td>Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number... [or as otherwise identified]”, or an equivalent form of wording.</td>
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<td></td>
<td>Such amendments shall meet all the requirements of this document.</td>
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<td>7.8.8.3</td>
<td>When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.</td>
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<tr>
<td>7.9</td>
<td><strong>Complaints</strong></td>
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<td>7.9.1</td>
<td>The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.</td>
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8.9 Management Review

The system and calibration and or test activities must be reviewed by top management at planned intervals

➢ To ensure continuing suitability, adequacy and effectiveness

➢ To re-establish the effectiveness of the management system and its processes;

➢ To initiate actions related to the improvement of the laboratory activities related to the fulfilment ISO/IEC 17025

➢ The define the provision of required resources (equipment, personnel, …)

➢ To define any need for change and new objectives

No recommendation of planned intervals, but an annual meeting is still well recommended
8.9 Management Review (2)

The input to management review is recorded and include information related to the following:

a) changes in internal and external issues that are relevant to the laboratory;

b) fulfilment of objectives;

c) suitability of policies and procedures;

d) status of actions from previous management reviews;

e) outcome of recent internal audits;

f) corrective actions

g) assessments by external bodies;

h) changes in the volume and type of the work or in the range of laboratory activities;
8.9 Management Review (3)

The input to management review is recorded and include information related to the following:

i) customer and personnel feedback;

j) complaints;

k) effectiveness of any implemented improvements;

l) adequacy of resources;

m) results of risk identification;

n) outcomes of the assurance of the validity of results; and

o) other relevant factors, such as monitoring activities and training.
The output of the management review: a report – minutes of the meeting

Management Review Outputs

- any implications for the strategic direction of the organization
- opportunities to improve integration of the management system with other business processes
- resources needed
- the continuing suitability, adequacy and effectiveness of the management system in achieving its intended outcomes
- continual improvement opportunities
- any need for changes to the management system
- actions, if needed
- Top management shall communicate the relevant outputs of management reviews to workers, and, where they exist, workers’ representatives
- The organization shall retain documented information as evidence of the results of management reviews