L12 Internal Audit & Management Review Process

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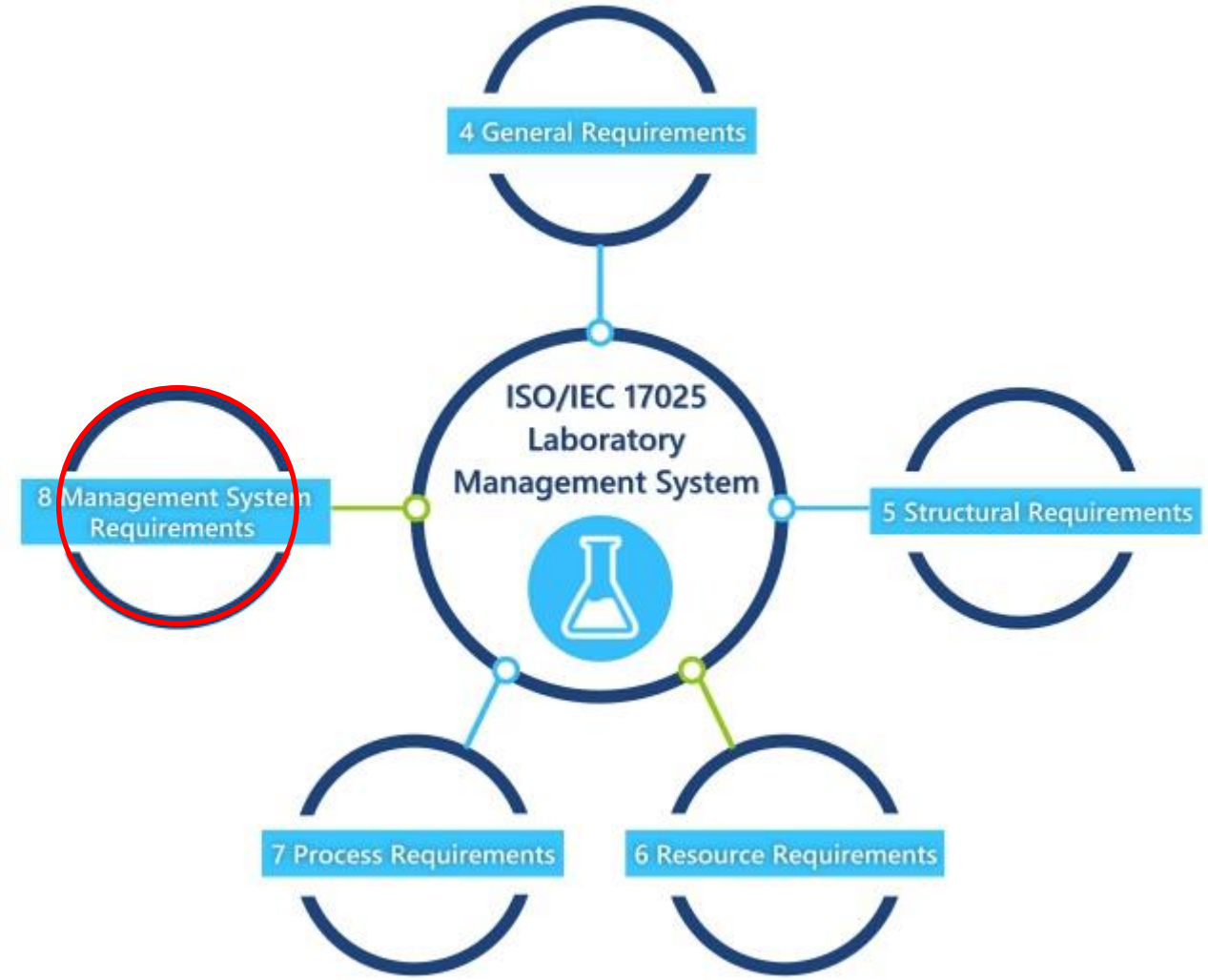
International Atomic Energy Agency

8 Management System Requirements



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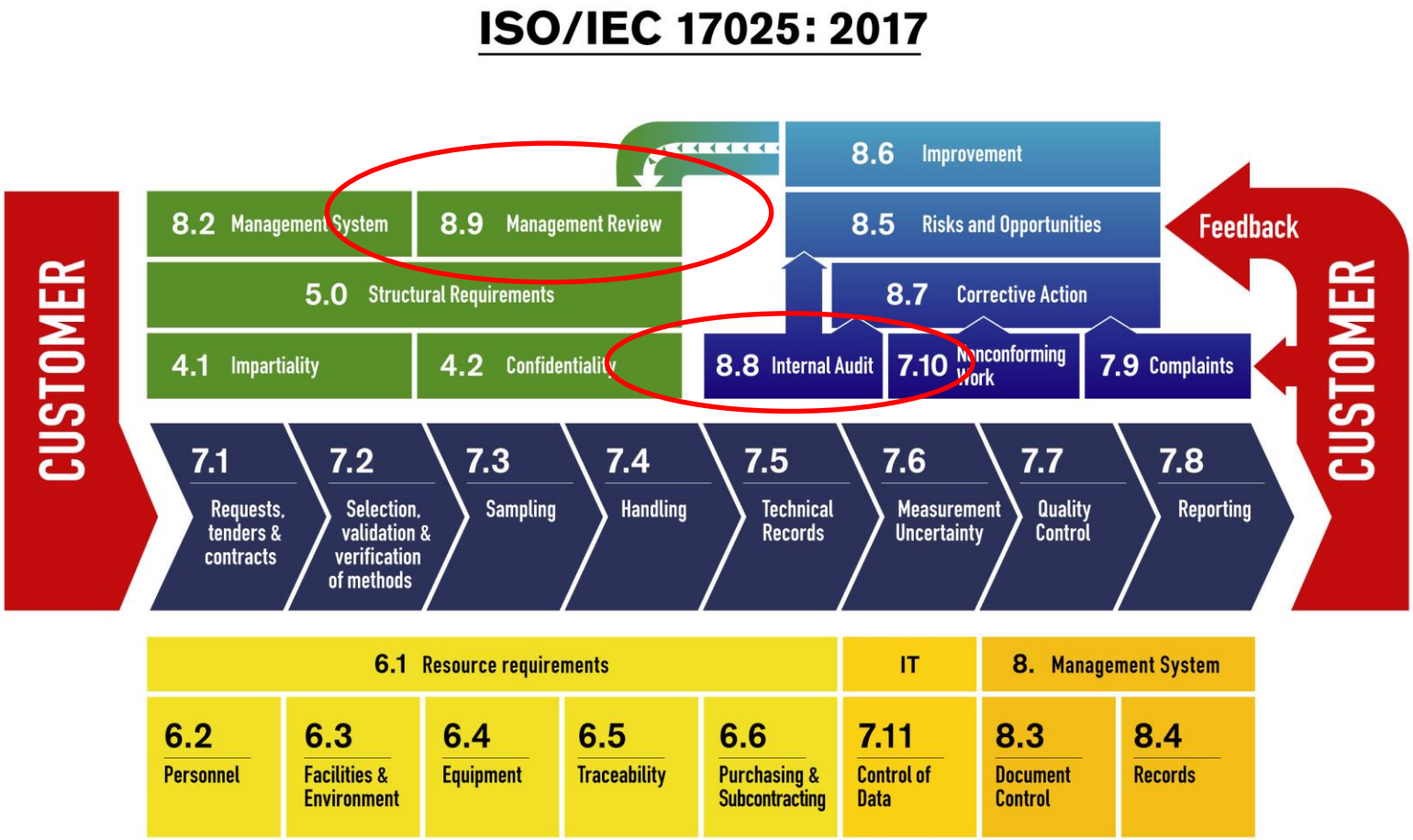
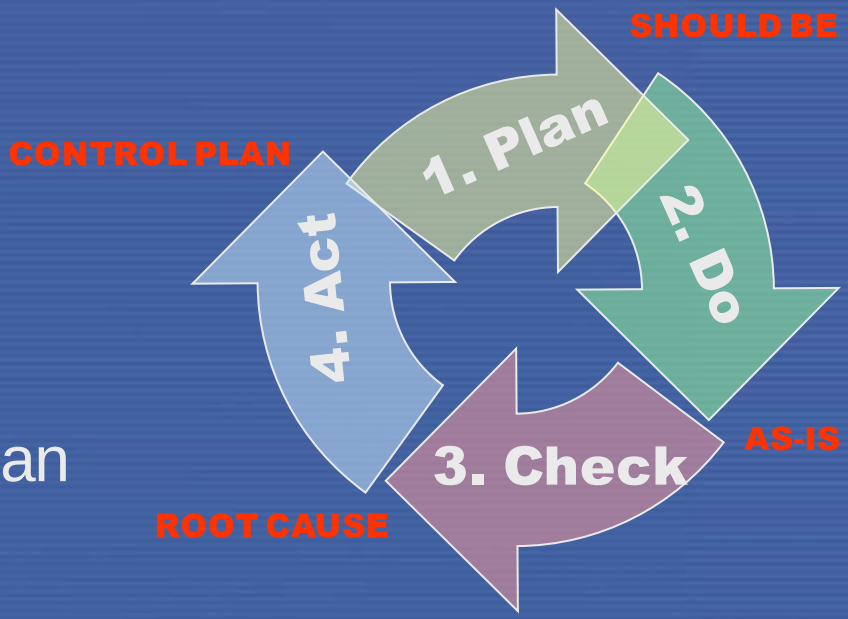
Structure


ISO/IEC 17025: 2017
8.6 Improvement
8.2 Management System
8.9 Management Review
8.5 Risks and Opportunities
Feedback
5.0 Structural Requirements
8.7 Corrective Action
CUSTOMER
4.1 Impartiality
4.2 Confidentiality
8.8 Internal Audit
7.10 Nonconforming Work
7.9 Complaints
CUSTOMER
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
IT
8. Management System
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

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. **D**o it all over again



Internal Audit and Management Review

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.

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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 Internal audit – ISO/IEC 17025 requirements

8.8.2 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

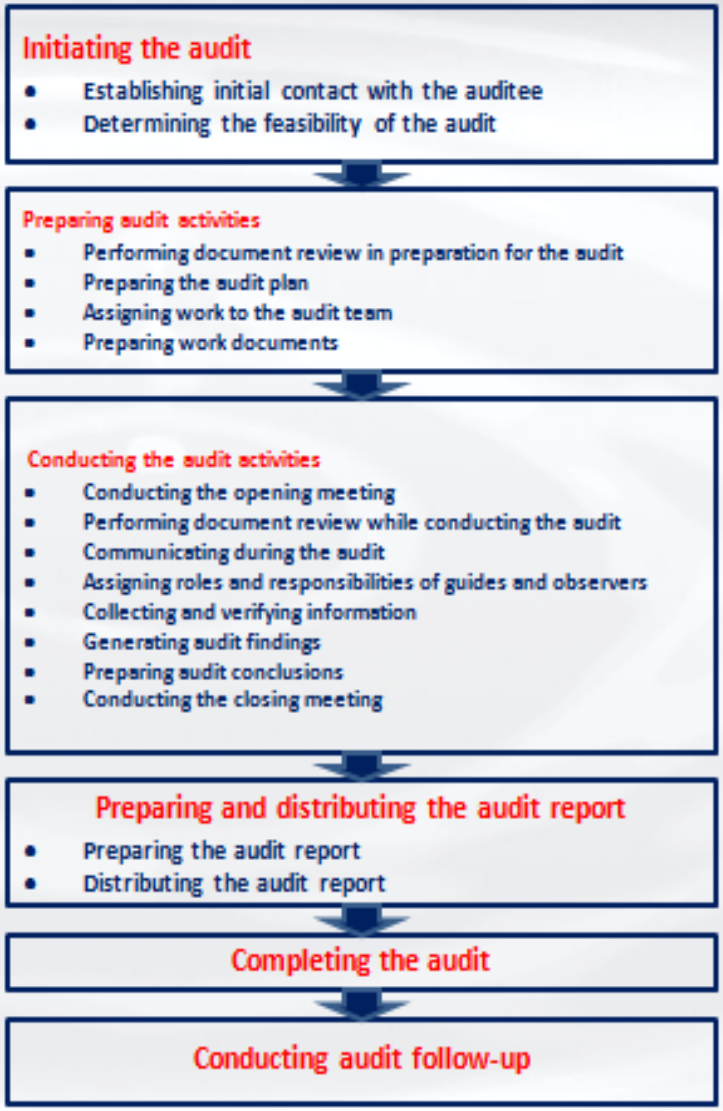
Personal attributes (ISO19011)

- 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

The internal audit process

Performing audit activities



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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

PROCESS		WEEK NUMBER									
		1	2	3	4	5	6	7	8	9	10*
Preanalytic	Test Ordering Specimen • Collection • Transport • Receipt/Accessioning	CD									Focused audits
Analytic	Hematology		RB								
	Chemistry			KM							
	Special Chemistry				JN						
	Microbiology					MG					
	Immunology						HT				
	Blood Bank							JB			
	Flow Cytometry								JR		
	Anatomic Pathology									LD	
Postanalytic**	Patient Reports Specimen Storage		RB	KM	JN	MG	HT	JB	JR	LD	
Support / Management Requirements	Client Services	CD							DM		
	Review of contracts		DM								
	Reference laboratories		DM								
	External services and supplies				CC						
	Advisory services				CC						
	Resolution of complaints						DM				
	Corrective action						DM				
	Preventive action						DM				
	Continual improvement						DM				
	Internal audits	CC									
	Management review	CC									
	LIS							CC			
	Safety							CC			
	Isensix					GM					

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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.

5th STEP: Recording results

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

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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

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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?
- What happened with the labeled weighted sample ? ….

In all cases : documentary evidence is needed

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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

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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

Internal Audit Notification

Format No.:

Pre-Audit Meeting			
Date	Start Time	End Time	Venue

Planned Audit Location & Dates			
Location	Audit Date & Time	Auditees	Auditors

Reference Standards list for Audit
1. 2. 3.

Audit Purpose: To Determine Compliance / non-compliance with above standard & Procedures

Audit Scope

Sr. No.	Audit Team Name	Signature

Distribution List:

✓	Auditees / Auditors				

Quality Control / Quality Assurance – Manager Signature	M.R. Signature

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Content of the audit report

Clause	Requirement	Document Reference	Statues of the Implementation	
				Comment
	from the tested or calibrated item and shall be clearly identified as such.			
7.8.7.3	When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.			
7.8.8	**Amendments to reports**			
7.8.8.1	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.			
7.8.8.2	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.			
	Such amendments shall meet all the requirements of this document.			
7.8.8.3	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.			
7.9	**Complaints**			
7.9.1	The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.			

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

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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