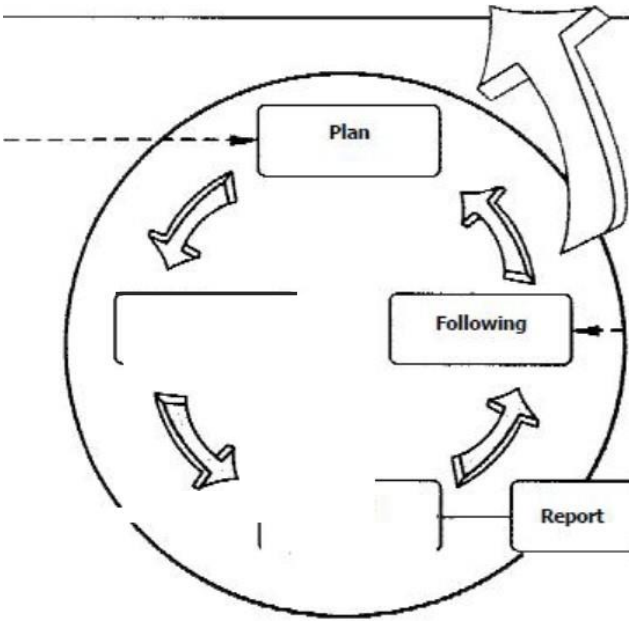
INTERNAL AUDITS, AUDIT REPORT

Introduction

The audit report is the document resulting from the audit activity.
Any laboratory in compliance with Standard ISO/IEC 17025:2017 requirements should describe and implement an internal audit process as part of its internal control system.



The main objective of internal audits is to improve laboratory management, emphasizing weak points detected in all different systems described, and to protect the good performance of the laboratory in terms of achieving the goal.

An audit report should not be just a "Faults report"; therefore, apart from deviations, it is important to include identified strengths and improvement measures in order to reconcile the worst aspects with the best ones.

Oral statement at the closing meeting

At the closing meeting, the audit team leader will usually make a statement in the presence of the auditee or their representative, which includes:

- A global evaluation of the audit result.
- A general conclusion.
- All strengths and improvement measures identified during the audit process.
- The findings indicating if they are deviations from the audit criteria or not. It is important to inform about all deviations clearly and unambiguously.

Perhaps the audit team leader is not capable of classifying any deviations in their seriousness at that moment; this activity may be postponed until later assessed by the audit team, but he/she shall describe any deviations and the findings supporting them.

At this point it is important for the auditee to state any doubt about informed deviations and discuss them with the audit team until all issues have been resolved.

Maybe the auditee will ask for advice on how to solve some of the problems identified. It is quite appropriate for the audit team to suggest potential corrective actions. The audit team leader shall clearly indicate that their suggestions are not binding.

If possible, it is advisable to write down all identified deviations in a preliminary audit report.

Audit Report

Report Inputs

Upon completion of the audit, the auditor team leader shall write a draft report using the information provided by the auditors or technical experts who were part of the audit team.

The audit team shall reach consensus on the final report before it is sent to the auditee.

Content

The main part of an audit report, but not the only one, is the part “identified deviations”.

What constitutes a deviation?
By definition, a deviation is a non-fulfillment of a requirement of the audit criteria.
Even though the definition seems to be clear, auditors can sometimes observe documents, records or behaviors that do not clearly constitute non-fulfillments.
For this reason it is necessary for the auditor to notify the auditee immediately, what could be a non-fulfillment, so the auditee has the chance to explain the matter.
However, it is possible that the auditor may perceive a reason for a timely non-fulfillment, which will not necessarily lead to a nonconformity in the report. The auditor shall assess the frequency of occurrence and severity in deciding whether to include it in the report or not.

What are the different types of deviations?
Considering their seriousness, there are usually two different types of deviations:

- Minor nonconformities, observations, or any other name they receive: Non-fulfillments that do not put at risk the technical competence of the laboratory.
- Major/critical nonconformities or any other name they receive: Non-fulfillments that put at risk the technical competence of the laboratory, repetitive non-fulfillments of a requirement on a defined process or a system, or their absence.

How should a nonconformity be described?
First and foremost, deviations shall inform about the audit criteria that have not been fulfilled (a Standard ISO/IEC 17025 point, a clause in the Quality Manual, if available, an internal procedure, a test standard, etc.

The nonconformity should preferably be described objectively and unambiguously.

The nonconformity shall be supported by the findings. These findings could be written in detail, including the document, record or behavior observed.

Sometimes, a reference to the assessed audit criteria, in which no deviations have been found, as well as the information before is included. This allows to show the completeness of the audit to a third party.

Record, content and form

The content of the report should include the following:

1. Report reference (unique ID),
2. Title: e.g. “Audit report, according to the standard ISO XXXX criteria, to XXXX laboratory”,
3. Audit data location,
4. Audit team identification, showing clearly who performed the audit team leader role,
5. Report date,
6. Auditee identification, identifying names and tasks,
7. Identification of those who attended the closing meeting,
8. Audit objectives,
9. Audit criteria and all laboratory management system documentation assessed (in which case it is important to consider the documents’ current edition),
10. Audit scope (activities audited),
11. Followed audit plan (detailed or include the reference to the document containing the audit plan),
12. It is important to keep a consistent pagination, including the total number of pages,
13. Strengths identified during the audit,
14. Weak points, preventive and improvement actions identified during the audit,
15. The audited points where no deviations have been identified may be included,
16. Deviations detected,
17. Tests/calibrations witnessed,
18. Any additional comments (non-covered areas, unresolved opposing views with the auditee, etc.),
19. Audit team leader signature,
20. It is advisable to get the auditee’s acknowledgement receipt.

Annex I gives an example of an audit report form.

INTERNAL AUDIT REPORT ACCORDING TO STANDARD ISO/IEC 17025:2017 CRITERIA, TO THE XXXXX LABORATORY

Audit execution date:	*Xx/xx/xxxx*
Report date:	*Xx/xx/xxxx*
Facilities audited: *Address*	
Audit team:	
Audit team leader: *Name and surname*	
o	*Technical field*
o	*Technical field*
...	...

Auditee:

Name and surname	*Job*
Name and surname	*Job*
...	...
Attendees of the closing meeting:	
Name and surname	*Job*
Name and surname	*Job*
...	...

Audit objectives:	
Description	
Audit criteria:	
Document xxxxx	*Edition/date*
Document xxxxx	*Edition/date*
...	...
Audit scope:	*Description*
Audit plan followed:	*Reference*
Strong points:	*Description*
Weak points:	*Description*
Improvement actions:	
o	*Description*
...	...

Audited points				
o	STANDARD ITEMS	AUDITED ITEMS *(1)*	INTERLOCUTOR *(2)*	TOTAL N.C. *(3)*
4.1	Impartiality			
4.2	Confidentiality			
5	Structural Requirements			
6.1	Resource Requirements / General			
6.2	Personnel			
6.3	Facilities and Environmental Conditions			

6.4	Equipment			
6.5	Metrological Traceability			
6.6	Externally provided Products and Services			
7.1	Review of Request, Tenders and Contracts			
7.2	Selection, Verification and Validation of Methods			
7.3	Sampling			
7.4	Handling of Test or Calibration Items			
7.5	Technical Records			
7.6	Evaluation of Measurement Uncertainty			
7.7	Ensuring the Validity of Results			
7.8	Reporting of Results			
7.9	Complaints			
7.10	Nonconforming Work			
7.11	Control of Data and Information Management			
8.1	Options (A/B)			
8.2	Management System Documentation			
8.3	Control of Management System Documentation			
8.4	Control of Records			
8.5	Actions to address Risks and Opportunities			
8.6	Improvement			
8.7	Corrective Actions			
8.8	Internal Audits			
8.9	Management Reviews			
TOTAL NC				

DEVIATION 1	
Audit criteria not fulfilled	*Refer to a document*
Description	*Description*
Classification	*NC/OBS*
Findings	*Refer to evidences*
DEVIATION N	
Audit criteria not fulfilled	*Refer to a document*
Description	*Description*
Classification	*NC/OBS*
Findings	*Refer to evidences*
Comments:	
Witnessed tests/calibrations	
Test/calibration 1	*method*
...	...
Audit team leader signature:	*Name and signature*
Receipt acknowledged:	*Name and signature*

(1) Fill with YES if the point has been audited or with N/A if the point has no effect or is not applicable.
(2) Fill with the abbreviation of the area responsible for the audited item.
(3) Fill with the total number of nonconformities identified in each section.

References

[1] EN ISO/IEC 17025:2017General requirements for the competence of testing and calibration laboratories
[2] EN ISO 9001:2015 Quality Management Systems - Requirements
[3] EN ISO/IEC 17020:2012 Requirements for the operation of various types of bodies performing inspection
[4] ISO 19011:2018 Guidelines for quality and/or environmental management systems auditing