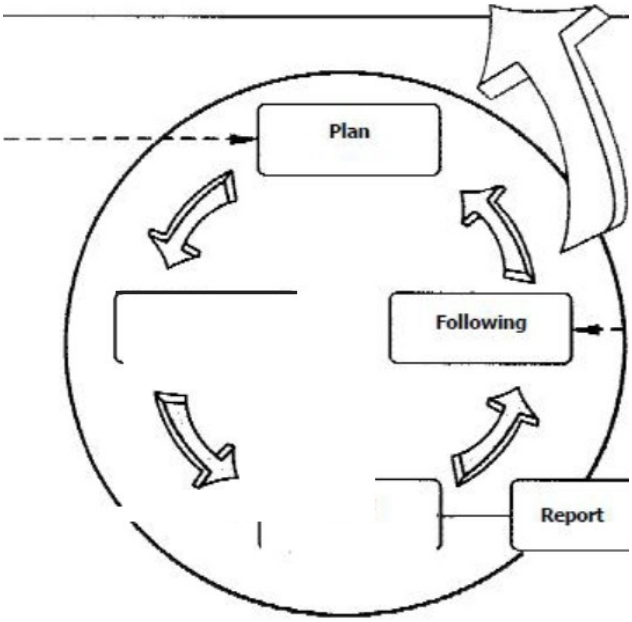
INTERNAL AUDITS, AUDIT REPORT

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 a part of its internal control system.



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

An audit report should not be just a "Faults report"; so, apart from deviations, it is important to include detected strong points and improvement actions, to balance the worst aspects with the best ones.

Oral statement at the closing meeting

In the closing meeting, generally the audit team leader makes a statement in the presence of the auditee, or their representative in which the following is set out:

- A global evaluation of the audit result. A general conclusion.
- All strong points and improvement actions detected during the audit process.
- The findings, pointing out if they are deviations against the audit criteria or not. It is important to inform about all deviations in a clear and non-ambiguous way.

Perhaps the audit team leader is not capable of classifying all deviations regarding their seriousness in that moment; this activity can be postponed until a later evaluation will be made by the audit team, but he/she shall describe all deviations and the findings supporting them.

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

Maybe the auditee will ask for advice about how to solve some of the detected problems. It is quite appropriate if the audit team suggests potential corrective actions. The audit team leader shall clearly indicate? has to make clear that their suggestions are not mandatory.

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

Audit Report

Report Inputs

Once the audit is finished, the auditor team leader has to write a draft report using the information given by the auditors or technical experts that were part of the audit team.

The audit team has to reach a consensus on the final report before it will be sent to the auditee.

Content

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

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, sometimes auditors can observe documents, records or behaviors that do not clearly constitute non-fulfillments.
This is why it is necessary for the auditor to tell the auditee immediately what could be a non-fulfillment, so the auditee has the chance to explain the matter.
Anyway, it is possible that the auditor observes an occasion for a punctual non-fulfillment, and this will not necessarily be translated into a nonconformity in the report. The auditor has to assess the frequency of its occurrence and seriousness to decide whether to include it or not in the report.

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 defined systematic, or its absence.

How should a nonconformity be described?
In the first place, deviations have to inform about the audit criteria that has not been fulfilled (a Standard ISO7IEC 17025 point, a clause in the Quality Manual –if any- an internal procedure, a test standard, etc.

The nonconformity should be described preferably in an objective and non-ambiguous way

Has to be supported by the findings. These findings could be written in detail, including the document, record or behavior observed

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

- Standard ISO/IEC 17025 point, a clause in the Quality Manual, an internal procedure, a test standard, etc.
- Shall be supported by the findings. These findings shall be written on detail, including the document, record or the behavior observed.

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 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, showing names and tasks,
7. Identification of those who were present at the closing meeting,
8. Audit objectives,
9. Audit criteria and all the laboratory quality system documentation assessed (it is important to include in this case 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. Strong points detected during the audit,
14. Weak points, preventive and improvement actions detected during the audit,
15. The audited points in which no deviations were detected can be included,
16. Deviations detected,
17. Tests/calibrations witnessed,
18. Any additional comment (non-covered areas, unsolved opposing views with the auditee, etc.),
19. Audit team leader signature,
20. It is advisable to get the auditee’s acknowledgement receipt.

In annex I an example of an audit report form is attached.

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	Review of requests, tenders and contacts			
4.2	Subcontacting of tests and calibrations			
4.3	Purchasing services and supplies			
4.4	Control of nonconforming			
4.5	Accomodation and enviromental conditions			
4.6	Test and calibration methods and method validation			
4.7	Handling of test and calibration items			
4.8	Assuring the quality of test and calibration results			

4.9	Reporting the results			
TOTAL NC				

(1) Fill with YES if the point has been audited or with N/A if the point doesn’t affect 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 detected in each section.

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*

References

[1] General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017)
[2] Quality Management Systems - Requirements (ISO 9001:2015)
[3] Requirements for the operation of various types of bodies performing inspection (ISO/IEC 17020:2012)
[4] Guidelines for quality and/or environmental management systems auditing (ISO 19011:2002)