

INTERNAL AUDITS

What are internal audits good for?

The principal aim of conducting internal audits is to periodically verify that the internal operations continue to comply with the requirements of the management system, and the requirements of the standard.

Results of these audits – in particular deviations identified – offer valuable information for improving the organisation's management system as well as the laboratory activities and should be used for management reviews.

Note: The relevant competence standards for laboratories and inspection bodies require internal audits to be conducted regularly.

Audit programme and auditors

First an internal audit programme shall be established (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) which might be based on the fiscal year. The different internal audits could be distributed over the entire year and should cover all elements of the management system.

The quality manager is basically responsible for ensuring that the audits are carried out in accordance with the established programme. Depending on the size and complexity of an organisation, the various audits may be carried out either by the quality manager or any other qualified person as a lead auditor, either alone or with the assistance of an audit team.

The auditors should have sufficient technical knowledge but should, wherever resources permit, not audit their own activities. If this is not possible, the management should make sure that the activities of the auditors are also assessed and should nominate appropriate persons. Auditors performing such audits should be trained for this task.

External audits (e.g. audits carried out by accreditation bodies) cannot substitute internal audits.

Planning of internal audits

Based on the audit programme, the time schedule, the location, and the audit scope of an internal audit are defined.

In preparation of an audit, the auditor should access all relevant documents, manuals, previous audit reports, and records of the department to be audited to verify that they meet the requirements of the management system and establish a list of key issues.

In addition, the following documents are basic or helpful:

- Standards, such as ISO/IEC 17025 or ISO/IEC 17020 and ISO 19011
- Form for reporting audit observations, such as permitting to enter type of nonconformity or forms for requesting corrective actions.

Implementation of on-site audit activities

In the opening meeting the audit team should be introduced, the audit criteria be confirmed, the audit scope be reviewed, the audit procedure be explained, and the timetable be confirmed.

The on-site audit activities include asking questions, observing activities, examining facilities and records. The auditor checks the conformity of the records with the management system. For this purpose, he uses the quality management system documents (quality manual, system procedures, test equipment files, operating instructions etc.) and examines how they are actually implemented. Information should be collected as efficiently as possible, without prejudice and without making the auditees insecure.

After all activities have been audited, the auditor (together with the audit team, if applicable) thoroughly reviews which of their findings should be included as nonconformities in the report and which should be included as recommendations or be highlighted as particularly positive aspects.

In case serious nonconformities have been identified, the management of the audited department must be informed of who is responsible for implementing the agreed corrections and decides on the measures to be taken.

In a closing meeting with those responsible for the department audited, the lead auditor should present the audit findings and conclusions. Nonconformities must be recorded and a corrective action schedule to be completed should be agreed.

Whenever a nonconformity is detected that could jeopardise the result of any laboratory activity, the appropriate action should be discontinued until the appropriate corrective action has been taken and proved to be successful. If the validity of already issued certificates, calibration and/or test reports might be affected by this nonconformity, the findings shall be examined accordingly, and the customer should be informed, if necessary.

Follow-up corrective action and close-out

The lead auditor shall provide a clear and unambiguous report on the nonconformities based on objective audit findings. Recommendations for improvement are marked and documented as such. The quality manager makes sure that all staff members involved in the audited functions receive an audit report.

The head of the audited department is responsible for the definition, implementation and planning of corrective actions. If this is provided for in the quality management system, the auditor can check the implementation of the corrective measures after an agreed period of time.

All audit records shall be retained for a specified period of time. The trends identified in the internal audits are followed by the quality manager and the result of the internal audit is taken into consideration in the next management review.

References

- [1] EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
- [2] EN ISO/IEC 17020:2012 Requirements for the operation of various types of bodies performing inspection
- [3] EN ISO 19011:2018 Guidelines for auditing management systems
- [4] EN ISO 15189:2012 Medical laboratories -- Requirements for quality and competence

See also

- [1] Cook Book document no. 10: Internal audits, the auditor
- [2] Cook Book document no. 14: Internal audits, audit report