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 in general 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 different audits may be carried out by the quality manager or any other qualified person as lead auditor, alone or assisted by an audit team.

The auditors should have sufficient technical knowledge but should – wherever resources allow – not audit their own activities. If this is impossible, the management should take care that the activities of the auditors are also assessed and should nominate respective 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 fixed.

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 check whether they conform to the requirements of the management system and to establish a list of key issues.

In addition, the following documents are basic ones or are helpful:

- Standards, such as ISO/IEC 17025 or ISO/IEC17020 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 examining 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 (if necessary together with the audit team) reviews carefully which of their findings should be included in their report as nonconformities and which should be included as recommendations or be highlighted as particularly positive aspects.
In case serious nonconformities have been established, the management of the audited department must be informed who carries the responsibility for implementing the agreed corrections and decides on measures to be taken.

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

Whenever a nonconformity is discovered that may jeopardise the result of any laboratory activity, the corresponding 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 may be affected by this nonconformity, the findings must be examined accordingly and the customer be informed, if necessary

Follow-up corrective action and close-out
The lead auditor presents a clear and unambiguous report of the nonconformities based on objective audit findings. Recommendations for improvement are marked as such and are also documented. 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 defining, implementing and scheduling the corrective actions. If provided for in the quality management system the auditor may check the implementation of the corrective actions after an agreed period of time.

All audit records shall be kept for a certain period of time. The trends observed in the internal audits are followed by the quality manager and the result of the internal audit shall be considered 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 19011:2011 Guidelines for auditing management systems
[4] EN ISO 15189:2012 Medical laboratories -- Requirements for quality and competence

See also
Cook Book document no. 10: Internal audits, the auditor
Cook Book document no. 14: Internal audits, audit report