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INTERNAL AUDITING FOR LABORATORIES

What is an Internal Audit?

An 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 the objective of the organization. Therefore the term internal audit refers to an audit done by laboratory personnel to establish the extent of conformity of the laboratory to documented requirements or standards.

Who is responsible?

The Quality Manager is responsible for scheduling, recording and coordinating audits within the laboratory as well as ensuring that any corrective or preventive action required as a result of an audit is satisfactorily discharged. The Quality Manager may conduct the internal audit or delegate the task to another competent member of staff with training in conducting internal audits. Please note that auditors should not audit their own activities or activities for which they have direct responsibility! Therefore someone should be given the task of auditing the Quality Manager's activities to ensure that the quality function is carried out satisfactorily.

When is it done?

According to ISO/IEC 10725 and ISO 15189, audits must be carried out according to a predetermined schedule that ensures all aspects of the quality management system are audited at least once per year. If the entire quality management system cannot be audited in one session, then the laboratory must ensure that all areas, including all pre-examination, examination and post-examination processes are monitored over a 12 month period.

Additional unscheduled audits may be carried out when there is reason to doubt the effectiveness of the quality management system or the validity of test results. When a complaint is received about any aspect of the laboratory's activities, an audit should be carried out.

How is it done?

Internal audits are conducted by observing activities, asking questions, evaluating responses and examining items like records, equipment, manuals and reports. To ensure a strong audit program the laboratory should conduct both horizontal and vertical audits.

1. Horizontal Audit - This examines one element in a process on more than one item. It is a detailed check of a particular aspect of the documentation and implementation of the quality management system or examination processes. For example, horizontal audits can be conducted on aspects of equipment calibration - is the equipment calibrated at the appropriate time; is it coded to indicate calibration status; are calibration certificates and records of calibration up-to-date; are all documents readily available at designated location; etc.
2. Vertical Audit - This examines one sample looking at all of the inputs, operations and activities required to produce the output (result). It is a detailed check that all elements associated with the tests are implemented. In any single audit, one or a number of tests that have recently passed through the laboratory are randomly selected. Sample numbers can be randomly selected such that the start of the audit trail can be varied. It may begin with a specimen container, a computer record, a worksheet, or a printed test report. The principle is that all the activities that contributed to the final report are audited for conformance with the laboratory's processes and quality management system procedures.