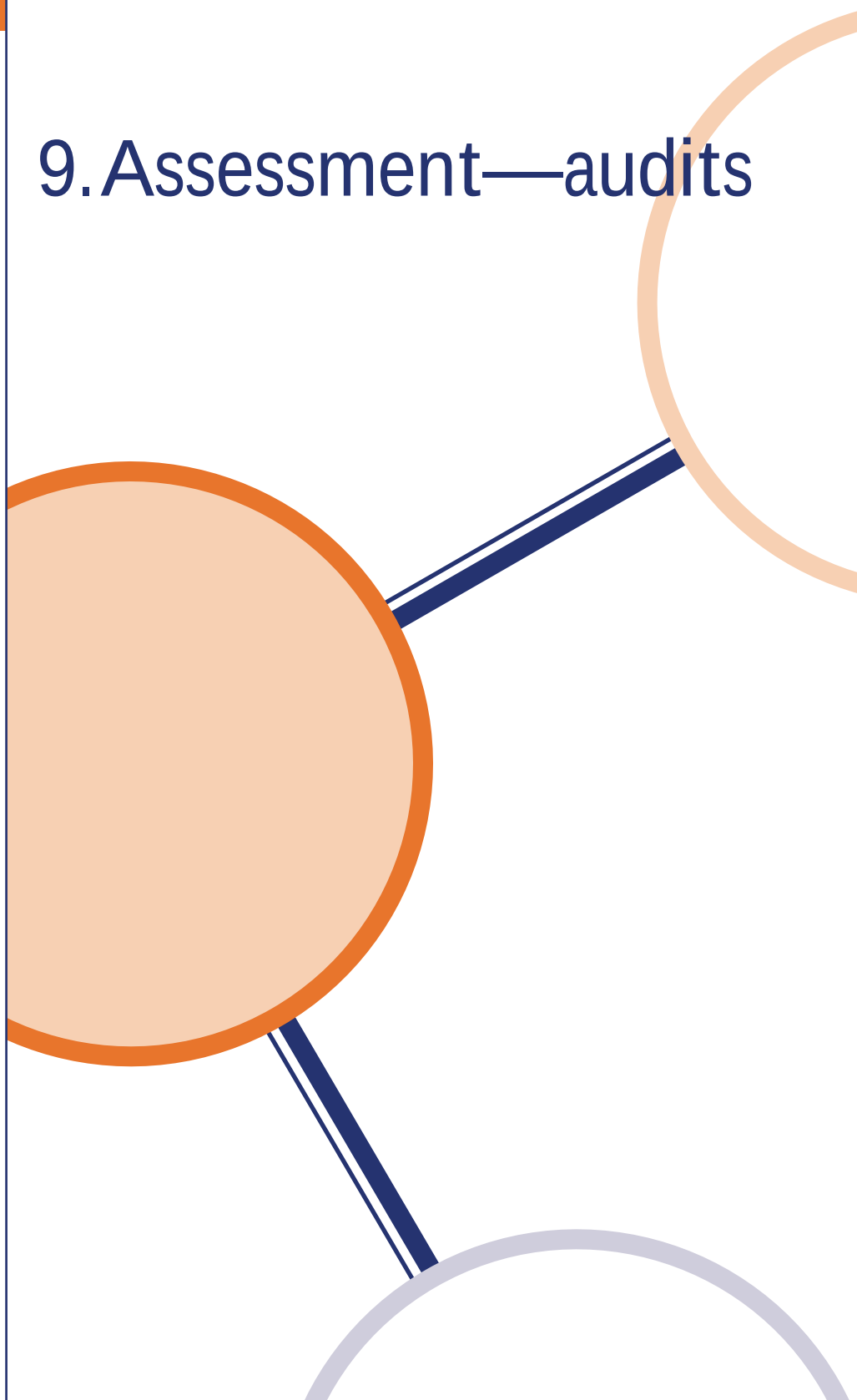
9. Assessment—audits



9-1: Overview

Role in quality management system

Assessment is an important element of the 12 quality system essentials. It is the means for determining the effectiveness of a laboratory's quality management system through internal and external audits, and evaluation of performance in an external quality assessment (EQA) programme. This chapter is focused on descriptions of internal and external audits; EQA will be described in Chapter 10.

What is assessment?

An assessment can be defined as the systematic examination of some part (or sometimes all) of the quality management system to demonstrate to all concerned that the laboratory is meeting regulatory, accreditation and customer requirements. Central-level laboratories are generally familiar with assessment processes, as most will have had some kind of assessment by an external group. However, intermediate or peripheral-level laboratories may not be assessed very often in resource-limited countries.

Accepted standards, whether international, national, local, or standards from accrediting organizations, form the basis for laboratory assessment. In that respect, assessment is interrelated with norms and accreditation (Chapter 11).

In an assessment, someone is asking the following questions:

- What procedures and processes are being followed in the laboratory; what is being done?
- Do the current procedures and processes comply with written policies and procedures? And in fact, are there written policies and procedures?
- Do written policies and procedures comply with standards, regulations, and requirements?

Why perform an assessment?

Assessments are performed in a variety of ways and under a number of different circumstances. The International Organization for Standardization (ISO) standards are very specific about assessment requirements, and the term "audit" is used instead of "assessment". The terms may be considered interchangeable, and local usage will determine the actual terminology required. The ISO definition for audit is a "systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which required criteria are fulfilled."

An assessment, or audit, allows the laboratory to understand how well it is performing when compared to a benchmark or standard. Any gaps or nonconformities in performance can show if the policies and procedures that the laboratory has set require revision or are not being followed.

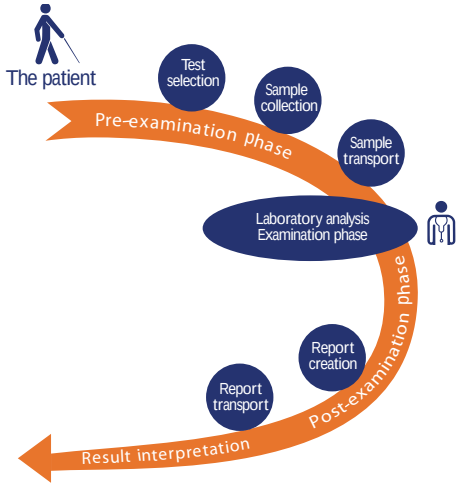
A laboratory needs this information about its performance for:

- planning and implementing the quality system
- monitoring effectiveness of the quality system
- correcting any deficiencies that are identified
- working toward continuous improvement.

External and internal audits

Assessments conducted by groups or agencies from outside the laboratories are called **external audits**. They can include assessments for the purpose of accreditation, certification or licensure.

Another type of assessment that laboratories can utilize is the **internal audit**, where staff working in one area of the laboratory conduct assessments on another area of the same laboratory. This provides information quickly and easily on how the laboratory is performing and whether it is in compliance with policy requirements.



Laboratory path of workflow

Audits should include the evaluation of steps in the whole laboratory path of workflow. They should be able to detect problems throughout the entire process.

Auditing

The value of a well-designed audit is that it will reveal weaknesses in the pre-examination, examination and post-examination phases. During audits, information is gathered about:

- processes and operating procedures
- staff competence and training
- equipment
- environment
- handling of samples
- quality control and verification of results
- recording and reporting practices.

The findings are compared with the laboratory's internal policies and to a standard or external benchmark. Any breakdown in the system or departure from procedures will be identified.

9-3: Internal audit

Purpose

Most technologists in central-level laboratories are relatively familiar with external audits; however, the idea of conducting internal audits might be new to some people.

An internal audit allows the laboratory to look at its own processes. In contrast to external audits, the advantages of internal audits are that laboratories can perform them as frequently as needed, and at very little or no cost. Internal audits should be a part of every laboratory quality system, and are a requirement of ISO standards.[1]

The audits should be conducted regularly and when problems that need to be studied have been identified. For example, internal audits should be performed after receiving a poor performance on a proficiency testing survey, after an increased number of unexpected abnormal results for a particular test, or after an increase in expected turnaround time.

Value of an internal audit

The internal audit is a valuable tool in a quality management system. An internal audit can help the laboratory to:

- prepare for an external audit;
- increase staff awareness of quality system requirements;
- identify the gaps or nonconformities that need to be corrected—the opportunities for improvement;
- understand where preventive or corrective action is needed;
- identify areas where education or training needs to occur;
- determine if the laboratory is meeting its own quality standards.

Internal audit and ISO

ISO standards put much emphasis on internal audits, and for those seeking accreditation under ISO, internal audits are required. ISO requirements state that:

- the laboratory must have an audit programme;
- the auditors should be independent of the activity;
- audits must be documented and reports retained;
- results must be reported to management for review;
- problems identified in the audits must be promptly addressed and appropriate actions taken.

1 ISO 19011:2002. *Guidelines for quality and/or environmental systems auditing*. Geneva, International Organization for Standardization, 2002.

9-4: Internal audit programme

Responsibilities

The laboratory director is responsible for setting overall policies for the internal audit programme. Responsibilities will include assigning authority for the programme (usually to the quality manager) and supporting the corrective action measures that are indicated. It is essential that the laboratory director be fully informed about the results of all internal audits. The quality manager is responsible for organizing and managing the laboratory internal audit programme. This includes setting a timeframe for the audits, choosing and training the auditors, and coordinating the process. The follow-up activities will also usually be the responsibility of the quality manager, and these include managing all corrective action efforts. The quality manager must be sure that laboratory management and the laboratory staff are fully informed about outcomes of the audit.

The commitment of laboratory management and the quality manager will be key to successfully establishing a process for internal audits.

Process

The quality manager or other designated qualified personnel should organize the internal audit following these steps:

- develop a formal plan
- prepare a checklist based on selected guidelines or standards
- meet with all staff and explain the audit process
- select staff to serve as auditors
- collect and analyze information
- share results with staff
- prepare a report
- present the report to management
- retain the report as a permanent laboratory record.

Select areas for audits

In order to facilitate the internal audit process, it is useful to keep it simple. Focus on defined areas of the laboratory activities, identified by issues such as customer complaints or quality control problems. Narrowing the audit to the specific corresponding process will save time and energy. Perform short and frequent audits rather than initiating an annual comprehensive and overwhelming effort.

Establish a schedule

ISO 15189:2007 [4.14.2] states: “The main elements of the quality management system should normally be subject to internal audit once every twelve months”. This requirement does not mean that a complete audit needs to be done annually. Rather, it means that over a period of a year, every part of the laboratory should have at least one inspection. Doing a number of small, bench-specific or section-specific audits is much easier than trying to do them all at the same time.

Establish a policy that, at specified intervals, some section of the laboratory or a specific process will have an internal audit. In general, audit regularly and consider three to six-month intervals between audits. If audits reveal specific problems, it may be necessary to include more frequent audits.

Checklists and forms used

When developing checklists for internal audits:

- Take into account any established national policies and standards. For example, most countries have standards for human immunodeficiency virus (HIV) and tuberculosis testing; laboratories conducting this testing need to ensure checklists reflect these standards.
- Ensure checklists are easy to use and include areas for recording information.
- Focus on specific tests or processes; whatever the area of focus, address all areas of the quality system. If auditing enzyme-linked immunosorbent assay (ELISA) tests, consider personnel competency or equipment maintenance, sample handling, and quality control associated with these tests.

Forms will be needed for recording corrective actions and for making reports.

Select auditors

When the laboratory initializes an internal audit programme, selection of auditors is one of the first steps to address. It is very important, and required by ISO standards, that the auditors are independent of the area audited. Some things to consider are:

- The availability of staffing and level of technical expertise—depending on the area for auditing, there might be many kinds of personnel who would be appropriate for conducting the audit; for example, if the laboratory is looking at safety issues, a hospital safety expert, or even a housekeeping expert might be appropriate.
- Whether to hire a consultant—this could still be conducted as an internal audit: the audit is planned by the laboratory itself, without any external constraints, but consultants or peers recruited by the laboratory for this specific audit will help the laboratory staff to conduct it.

Any knowledgeable person in the laboratory can perform internal audits, not just the manager or supervisor.

Important skills for auditors

When deciding the personnel to choose for the audit process, take into account the skills that will be needed for a good result. A good auditor will:

- pay attention to details—for example, check expiry dates, open and inspect refrigerators and storage areas;
- be able to communicate effectively, but also diplomatically—diplomacy is an important skill, since it is easy to imply criticism during an audit process.

The auditors chosen must have the technical skills needed to evaluate the area being audited, and must have a good understanding of the laboratory's quality management system. Some staff may have specialized expertise in a limited area, such as sample transport or housekeeping, but could serve as auditors in these areas. Some in-house training on how to conduct an audit should be provided to those who will serve as auditors.

If auditors are poorly chosen, the audits will be much less effective.

9-5: Actions as a result of audit

Audits should lead to actions

Audits should lead to actions—this is why laboratories conduct them, to further the process of continual improvement in the laboratory.

Audits identify opportunities for improvement (OFIs). Both preventive and corrective actions are steps taken to improve a process or to correct a problem.

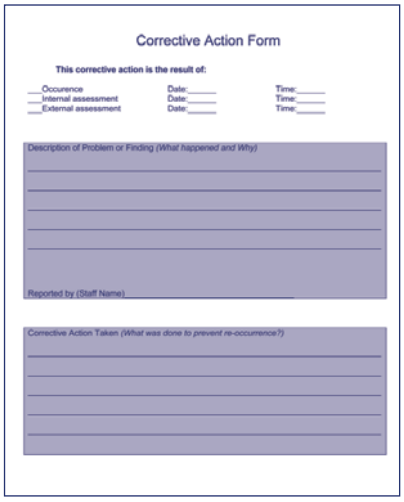
A record of OFIs should be kept, along with actions that are taken. Preventive and corrective actions should be carried out within an agreed-upon time. Normally the quality manager is responsible for initiating actions.

Problem solving

Sometimes the cause of the problem is not obvious or easily found; in such cases a problem-solving team may be necessary to:

- look for root causes;
- recommend the appropriate corrective action;
- implement the actions decided upon;
- check to see if the corrective actions are effective;
- monitor the procedures over time.

All actions and findings from the monitoring should be recorded so the laboratory can learn from its activities.


Corrective Action Form

This corrective action is the result of:

___Occurence Date:_____ Time:_____
___Internal assessment Date:_____ Time:_____
___External assessment Date:_____ Time:_____

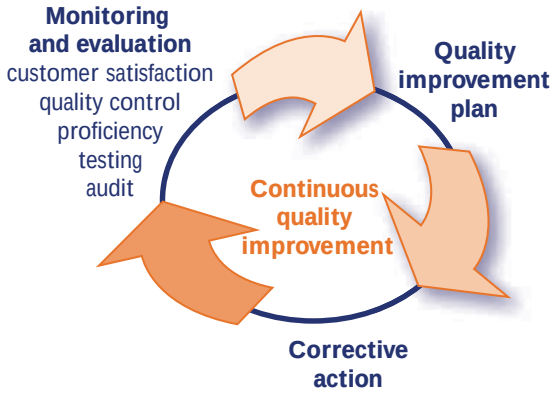
Description of Problem or Finding *(What happened and Why)*

Reported by (Staff Name)

Corrective Action Taken *(What was done to prevent re-occurrence?)*

Continuous monitoring

Continuous monitoring is the key element to success in the quality system. It is through this process that we are able to achieve the continual improvement that is our overall goal.



9-6: Summary

Summary

Assessment is important in monitoring the effectiveness of the laboratory quality management system. Both external and internal audits yield useful information. Audits are used to identify problems in the laboratory, in order to improve processes and procedures. An outcome of assessment is finding root causes of problems and taking corrective actions.

Key messages

- All laboratories should establish an internal audit programme. Conducted on a regular basis, it will provide information for continual improvement.
- Problems become opportunities for improvement.