

## 9-2: External audit

### External audits

Assessments conducted by groups or agencies from outside the laboratory are called external audits. Some examples of external auditors are described below.

- Health authorities may assess laboratories to evaluate the quality of performance, or compliance with licensing requirements and national regulations. They may also assess as part of a capacity strengthening plan of action, or for public health programme needs.
- Accreditation bodies are organizations that provide accreditation or certification. When a laboratory seeks accreditation, an initial audit will be required to evaluate compliance with standards. In order to maintain accredited status, the accreditation bodies will require periodic audits (see Chapter 11).
- An audit may be requested by major public health programmes, or by agencies that provide funding for programmes. These groups want to ensure that quality standards are being met and that quality practices are in place. International programmes such as the World Health Organization (WHO) Polio Initiative regularly assess disease-specific laboratories according to their own standards with their own checklists; for example, WHO polio laboratory accreditation standard and WHO measles accreditation standard.

### Standards

In conducting external audits, the assessors will verify that laboratory policies, processes and procedures are documented and comply with designated standards. Different standards can be used for the assessment processes, ranging from international standards to a locally developed checklist.

Laboratory management must demonstrate to the assessment team that all requirements as laid down in the standard are being followed.

### Preparation

When a laboratory undergoes an external audit, the laboratory needs to be fully prepared so that the assessment experience is as easy as possible for both the assessors and the laboratory staff, and so the assessment yields the maximum amount of information.

To be ready for the external audit, it is necessary to:

- plan thoroughly and carefully;
- organize everything ahead of time, including documents and records, to save valuable time during the audit;
- make all staff aware of the audit, and arrange schedules so that all staff needed for the audit will be available.

On occasion, some external audits might occur without prior notification. In this case, the laboratory would not be able to make special preparation, so the laboratory should always be sure its system is operating properly.

## Audit report and plan of action

After the audit, the recommendations of the assessors are often presented as a verbal summary to the laboratory management and staff, which are then followed by a thorough written report. After the external audit has been completed the laboratory should:

- review the recommendations of the assessors;
- identify gaps or nonconformities, learning where benchmarks or standards were not fully met;
- plan to correct the nonconformities—this will result in a plan for all needed corrective actions to be taken by the laboratory, which should include a timeline, as well as indicate who is responsible for doing the work;
- record all results and actions taken so that the laboratory has a permanent record of the event—often a written report is useful for preserving all information.