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8.5 Monitoring and auditing

A key aspect of quality assurance is the adoption of procedures to check whether the quality system is operating as intended. These procedures generally fall into two categories, described here as 'monitoring' and 'auditing', although other terms may be used. **Monitoring** entails experimental checks to determine whether the laboratory or other facility is actually producing data within specification. **Auditing** entails inspection and review of the quality system to see whether it is being operated as planned and whether modifications are needed. In either case the procedure may be undertaken internally or externally to the organisation. Ideally both approaches are required and internal auditing is an essential requirement of all external schemes. An essential element of both internal and external monitoring is provision to review the results and devise appropriate changes in procedures when problems are identified.

Internal monitoring is usually based on the inclusion of check samples of known value with sample batches. Often these will be QC samples prepared by the measurement staff, but 'blind' samples (i.e. samples where the property to be measured is already known and which are included with other work without prior warning) are also widely used in some areas. The use of 'blind' samples is sometimes controversial and may be difficult or expensive to achieve. When feasible, however, there can be little doubt that this approach provides a more realistic assessment of overall performance. **External monitoring** may simply involve the inclusion of check samples by the originator of a batch of samples. A widely used approach is known as **proficiency testing**. This is based on co-operative schemes which arrange for distribution of a test sample and subsequent collation and analysis of the data provided by participants. It is then possible to rank laboratories against the 'true value', which may be obtained either by the organisers or as a consensus value. Such schemes almost invariably show much wider variability of results than would be found within a single organisation, even when a standard measurement method is used. As such they often provide a more realistic estimate of actual measurement uncertainty than that quoted by individual measurement scientists.

Quality audits entail an on-site assessment of the quality system and its operation. Internal audits are an essential aspect of every formal quality system and must be carried out at regular intervals. Practice varies as to whether advance warning of an audit inspection should be given. In all cases, however, it is desirable for the auditor(s) to be independent of the day-to-day operations of the unit being audited. The audit may be conducted as a senior management function but many larger organisations have a designated quality manager or quality audit unit. Whatever the

approach, the auditor must have a good knowledge of quality assurance principles and adequate scientific knowledge to understand the work being undertaken. It is important to appreciate, however, that a conventional quality audit is assessing the system and not correcting any scientific failings in the measurements. In some organisations the audit is also used to assess technical performance, although the depth of this assessment varies widely. External auditing is also widely used in addition to the internal procedures. Its value lies in the provision of a completely independent assessment which can be made known or made available to interested parties such as senior management, customers or regulatory authorities. In order to provide maximum transparency for such assessments it is desirable that the audits take place within widely recognised **accreditation** or **certification** schemes. These generally entail the implementation of quality systems in accordance with an accepted national or international standard and auditing by officially approved organisations. The three most widely used international standards are the BS EN ISO 9000 series (certification), ISO Guide 25 (accreditation) and Good Laboratory Practice (GLP). Schemes in accordance with these standards are operated both by public agencies and on a commercial basis.

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