An approach to audit in the medical laboratory

1 Introduction

This document and the accompanying forms produced by CPA are intended to be indicative of a possible approach to audit in the medical laboratory. There are many ways to approach this topic and in the belief that ways of doing things can always be improved it is not intended to be prescriptive.

Audit is defined in ISO 9001:2000 as 'a systematic, independent and documented process for obtaining evidence and evaluating objectively the extent to which audit criteria are fulfilled'. A laboratory's activities can be audited for a number of purposes and audits can be categorised as external or internal. Visits by external inspection bodies such as CPA, The Audit Commission or the Health and Safety Executive (HSE) are examples of *external audits* and are known as assessments. Participation in external quality assessment schemes (Standard H5) is a form of external audit. Laboratory management can organise and carry out *internal audits* in areas such as Health & Safety (Standard C5), assessment of user satisfaction and complaints (Standard H2), the quality management system (Standard H3) and examination processes (Standard H4).

Both internal audits and external assessments have in common procedures whereby trained personnel attempt to establish the extent of conformity of a laboratory to documented requirements or standards.

The general principles outlined in this document can be applied to any type of audit whether it concerns safety, financial or quality matters. However, this publication has primarily been prepared to give laboratories some general guidance on how to establish an internal quality audit programme and how to conduct an audit. It acknowledges that the type of programme implemented will depend on the size, scope and organisational structure of laboratories.

2 Responsibilities

There is a requirement for an individual to be responsible for scheduling and co-ordinating audits within a laboratory and for ensuring that the audits have been conducted in accordance with agreed procedures. This will normally be the quality manager (Standard A7 Quality manager) but could be another nominated individual. The quality manager is responsible for ensuring that any corrective or preventive action required as the result an audit is satisfactorily discharged.

The task of performing audits can be delegated to personnel trained in internal audit procedures and where practicable they should be independent of the work being audited.

3 Organization and planning of audits

Internal audits should be carried out according to written procedures that are described or referred to in the Quality Manual. They should be planned and

scheduled such that each element of the quality management system and all pre examination, examination and post examination processes are checked regularly.

There are three types of audit that together provide this thorough approach:

3.1 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. The items for audit can be written as questions, for example, does the Quality Manual contain a quality policy?

Horizontal audits can be conducted on aspects of resources, for example, for staff training and education (Standard B9.3 a) the question might be, Is there access to library and information services for all staff? These questions are readily constructed from the CPA standards.

3.2 Vertical audit

This examines more than one element in a process, on one item.

It is a detailed check that all elements associated with a chosen examination (test) are implemented. In any single audit, one or a number of examinations that have recently passed through the laboratory are randomly selected.

Laboratory 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 pre examination, examination and post examination and quality system procedures

3.3 Examination (test) audit

This examines a person undertaking a task.

An examination (test) procedure is witnessed as it is performed. An examination currently being carried out in the laboratory is randomly selected for audit. There are two objectives in such an audit. Firstly, to ensure that what is being done reflects what is described in the procedure and secondly, that the person carrying out the examination has a good understanding of all aspects of the procedure.

3.4 The Audit Calendar

Laboratory management should plan a series of internal audits over a period of at least a year and this should be made known to all staff.

Over a period of time they should ensure that all their pre examination, examination and post examination procedures are checked for conformance.

Whenever there is reason to doubt the effectiveness of the quality system or the validity of test results, it may be necessary to carry out additional unscheduled audits. When a complaint is received about any aspect of the laboratory's activities, an audit should be initiated by the quality manager.

4 Documentation

There should be a designated person responsible for ensuring that results of audits are recorded correctly and that any corrective or preventive action is completed and signed off. This will normally be the quality manager. In order to standardise the way audits are performed and so that they relate to local working practices, it is recommended that laboratories design their own audit forms

A complete record of internal audits should be maintained and will include:

- Name(s) of the auditor(s)
- Date of audit
- Reference number
- The activities, areas or items audited
- Any non conformities or deficiencies found
- Any recommendations and timescales for corrective action
- Responsibilities for corrective action
- Any recommendations for preventive action
- Date and signature of confirmation of completion of corrective and preventive action

Sufficient detail must be included such that the audit can be reproduced in exactly the same way. Specific details such as staff observed, equipment used and records checked need to be listed. An example of a vertical audit form is available from CPA. The vertical audit form can be modified for use in horizontal audit.

It may be helpful to categorise any Non- conformities found according to their degree of seriousness. For instance, laboratory management could establish criteria for major and minor non-conformance.

Records of audits should be held for an agreed period of time. The results of internal audit will be communicated to all staff and regularly presented, in summary, in the laboratory's annual management review.

Further reading

Burnett D A Practical Guide to Accreditation in Laboratory Medicine, ACB Venture Publications (2002)

EAL-G3 Internal Audits and Management Reviews for Laboratories Edition 2 1996

Standards for the Medical Laboratory. CPA (UK) Ltd. Version 1 2000

Handbook for Medical Laboratory Assessments CPA(UK) Ltd. 2002