Scotland and Northern Ireland EQA Scheme in General Histopathology

EQAQ03

AUDITS OF THE EQA SCHEME

ISO 17043:2010 ref	5.9 and 5.14
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1 PURPOSE

Continued internal audit of the QMS including the pre, intra and post examination phase forms a vital part of verifying the quality management system within the EQA Scheme. The quality management system has been produced in accordance with the requirements of the International Standard, ISO 17043:2010.

Audits review whether the management's statements of intent, as defined in the Quality Manual **EQAQ01**, are being fulfilled. Where there is an outcome which deviates from the stated intent, internal audit is a powerful tool for identifying opportunities to improve the service, with the results from audit reports being used as evidence for the annual management review.

This document describes the process of audit within the EQA Scheme.

2 DEFINITIONS

BS EN ISO 19011:2002; Guidelines for quality and/or environmental management systems, defines the following:

Audit: A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Evidence: Records statements or fact or other information, which are relevant to the audit criteria and verifiable

Criteria: Policies, procedures or requirements

Horizontal Audit: A detailed check of all the aspects (documentation, training and procedures) of the quality management system, detailed in the quality manual

Vertical Audit: A detailed check that all aspects of an examination are implemented. Within the EQA Scheme a vertical audit is where a circulation that has recently passed through the scheme and has been completed, is selected for audit. The start of the audit trail can be varied: from a slide received at the management team meeting, from one of the ten final slides for the circulation, or from slides and diagnoses coming back in. The principle is that all the activities that contributed to the final results will be audited for conformance with the scheme's procedures.

Examination Audit: A witness of an examination procedure to ensure that the activity being carried out reflects the description in the procedure and the person carrying out the procedure has a good understanding of all the aspects associated with it.

Non-conformity: The non fulfilment of a specified requirement.

Immediate or Remedial Action: The action taken at the time of a non-conformity to mitigate its immediate effects.

Corrective action: The action taken to remove the root cause of the problem that is causing the non-conformity.

Preventive action: The pro-active process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints.

3 DEVELOPING & MANAGING AN AUDIT PROGRAMME

The Quality Manager (or designated deputy) will develop and manage the audit programme.

They will:

- Establish, implement, monitor, review and improve the audit programme
- Identify staffing and training resources to ensure that the audit programme is suitable for purpose.

4 ACTIONS AND METHODS

The Quality Manager must keep records of all audits. This is now done within Q-Pulse. All records of audits must include: -

- The activities, areas or items audited.
- A unique, sequential, identifying reference number designated by the Quality Manager.
- Any non-conformities or deficiencies found must be recorded against the audit, within Q-Pulse, with an identifying non-conformance (NC) reference number, along with the source and time scale for corrective and preventive actions. Details of this process can be found in **EQAQ02**.
- Any Quality Improvement suggestions must also be recorded against the audit, within Q-Pulse, along with any actions or changes to procedure, brought about by the Quality Improvement suggestion.
- Name of Auditor and Auditee.
- Date of audit.

4.1 Vertical Audit Programme

At least one vertical audit will be carried out for each run of the scheme, i.e. two per year. The Vertical Audits are recorded completely within Q-Pulse, with the question sheet being composed within the "check list" facility.

4.2 Examination Audit Programme

Examination audits can and must examine all areas of the scheme, e.g. secretarial, technical, data handling, results, etc.

All examination audits are recorded completely within Q-Pulse, with the question sheet being composed within the "check list" facility.

4.3 Quality (Horizontal) Audit Programme

As a minimum requirement, the department will carry out at least one horizontal audit per scope heading within the standard per year. Within one calendar year, the department will audit the entire scope of the quality management system, which is in line with ISO 17043:2010.

4.4 Non-Conformance

If a non-conformance is raised during audit, the auditor must record the non-conformance against the audit, within Q-Pulse. It will be given a sequential non-conformance (NC) reference number within the system.

Corrective and preventive actions must be recorded, along with an expected completion date. Details of any further process investigations and actions must be recorded by the auditor/auditee. An audit of all corrective action must be carried out. The results recorded and dated, then the audit can be closed off.

All non-conformances are minuted and discussed at Executive and Management meetings.

4.5 Corrective Actions

The Quality Manager shall be responsible for implementing corrective actions when nonconforming work or departures from policies have been identified and these shall be recorded within Q-Pulse. If a non-conformance is raised during audit, the auditor records the incident against the audit, within Q-Pulse. Corrective actions and completion dates are also recorded.

The auditor/auditee records immediate and corrective actions carried out against the non-conformance. A completion date is recorded. All corrective actions are minuted and discussed at Executive and Management meetings. Details of any further process investigations and actions, as well as a completion dates are also recorded.

EQAO04 and **EQAO07** also contain measures to prevent non-conformities, for example double checking of input of scores into the computer record system.

4.6 Quality Improvement

During audit, an auditor may find issues which do not result in a non-compliance, but where scheme practice or governance could be improved. In these circumstances observations can be recorded. These are recorded against the audit within Q-Pulse and it is important that any individuals affected or involved are made aware and encouraged to make any changes to procedures they perceive as necessary.