## Purpose

This procedure outlines the method by which internal quality audits are conducted within the laboratory.

The laboratory should conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system.

These audits should check that the quality system fulfils the requirements of ISO 17025, the Pitt County Forensic Services Unit Quality Management System or other relevant supplemental criteria.

These audits should also check whether or not the requirements stated in the laboratory's quality manual and related documents are applied at all levels of work.

Internal audits give valuable information for the improvement of the laboratory‘s quality system and should thus be used as input to the management reviews.

## Scope / Field of Application

This procedure applies to all areas of the laboratory whose processes directly affect the quality of products and services delivered to clients.

## Definitions and Acronyms

**Audit Results** – Summary of audit scope and findings.

**Auditee** - Work area being audited.

**Nonconformity** – Nonfulfillment of a specific requirement.

**Corrective Action Request** - Action taken to eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.

**Quality system** – Organizational structure, procedures, processes and resources needed to implement quality management.

**Quality management** - The management team that determines and implements the quality policy.

**Quality assurance** - All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

**Audit**−Systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

**Management review**-A formal evaluation by top management of the status and adequacy of the quality system in relation to quality policy and objectives.

**Quality manager**-The staff member who has responsibility for the laboratory's quality system and its implementation and who, in this capacity, reports directly to top management.

**Quality auditor-**Person to perform quality audits.

**Objective evidence**-Qualitative or quantitative information, records or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on observation, measurement or test and which can be verified.

## Responsibilities

**Quality Manager shall:**

- Appoint appropriate personnel
- ensure that all auditors have received training
- ensure that the annual audit schedule is developed, updated, and approved
- ensure that internal quality audits are performed in accordance with this procedure and the approved audit schedule
- reconcile any disagreements between Lead Auditor and audited work area
- ensure that patterns of observations across audits are looked for
- review audit results and distribute to audited work areas
- plan audit

**Lead Auditor shall:**

- perform audit in accordance with approved audit schedule
- conduct audit meetings
- prepare audit results

**Auditor (Technical Assessor) shall:**

- review documentation
- participate in the audit, including the verification of effectiveness of corrective actions taken
- collect objective evidence to support findings, Corrective Action Request (CAR) verifications, and follow-up of observations from prior audits

- record findings

**Auditee shall:**

- inform area personnel of the time and scope of the audit
- ensure that timely access to processes, products, and documentation needed by the auditor(s), including objective evidence is provided
- attend audit meetings if applicable
- sign or otherwise acknowledge audit results

## Procedure

### Initiating the audit

The internal audits should be carried out according to a documented Internal Audit Plan.

Internal audits shall be programmed such that each element of the quality system is checked each calendar year.

The quality manager is normally the audit program manager and may lead the audit.

The quality manager should be responsible for ensuring that the audits are carried out in accordance with the established plan.

Such audits shall be carried out by qualified personnel who have sufficient technical knowledge of the operations they are auditing, and who are trained specifically in auditing techniques and processes.

The quality manager may delegate the task of performing audits provided that the person used is familiar with the laboratory's quality system and accreditation requirements and meets the requirements given.

Wherever resources permit, the auditor shall be independent of the activity to be audited. Personnel shall not audit their own activities or activities under their own direct responsibility except where there is no alternative and it can be demonstrated that an effective audit has been carried out.

Laboratories should pay particular attention to checking the effectiveness of an internal audit where it has been carried out by staff that is not independent of the audited activities.

**Planning of internal audits**

An audit plan including the audit scope, the audit criteria, the audit schedule, reference documents (such as the lab's quality manual and audit procedure) and audit members, shall be established by the quality manager.

Each auditor shall be assigned specific quality system elements or functional departments to audit. These assignments should be made by the lead auditor.

Assigned auditors shall have some technical knowledge of the disciplines they are to audit.

Working documents required to facilitate the auditor's investigations and to document and report results, may include:

- Criteria document such as ISO 17025 and any supplementary criteria.
- Laboratory manuals and documents.
- Checklists used for evaluating quality system elements (normally prepared by the auditor assigned to audit that specific element).
- Forms for reporting audit observations, such as 'non-conformance' record or 'correction action request' form. These permit the recording of the nature of the 'nonconformity', the agreed corrective action, and the eventual confirmation that the action has been effectively taken.

An audit timetable should be developed by each auditor in conjunction with the auditee to ensure the smooth and systematic progress of the audit.

Prior to the actual audit, a review of documents, manuals, previous audit reports and records should be carried out to check for conformity with the system criteria.

**Implementation of internal audits**

The key steps of an audit are Planning, Investigation, Analysis, Reporting, Follow-up corrective action and Close-out:

The audit personnel shall confirm with auditee the audit criteria, review the audit scope, explain the audit procedure, clarify any relevant details, and confirm the timetable including the time or date and attendees for the closing meeting.

The investigation process for gathering objective evidence will involve asking questions, observing activities, examining facilities, and examining records. The auditor will be examining the conformity of the activities with the quality system.

The auditor will use the quality system documents as reference (quality manual, system procedures, test methods, work instructions, and so on), and compare what is actually happening with what these quality system documents state should happen.

At all times during the audit, the auditor will be seeking objective evidence that the quality system requirements are being fulfilled. Evidence should be collected as efficiently and effectively as possible and without prejudice.

Internal audits shall include direct observation of a sampling of testing within each discipline.

Nonconformities should be noted and should be investigated further by the auditor to identify underlying problems.

All audit observations should be recorded.

After all activities have been audited, the audit team should carefully review and analyse all of their observations to determine which are to be reported as nonconformities and which can be included as recommendations for improvement.

The audit personnel should prepare a clear, concise report supported by objective evidence of nonconformities and recommendations for improvement.

Nonconformities should be identified in terms of the specific requirements of the lab's quality manual and related documents against which the audit has been conducted.

The audit team should meet with the senior management of the laboratory and those responsible for the functions concerned. The main purpose of this meeting is to present audit findings and report to senior management in such a manner so as to ensure that they clearly understand the results of the audit.

The lead auditor should present observations, taking into account their perceived significance. Both positive and negative aspects of the operations should be presented.

The lead auditor should present the audit personnel's conclusions regarding the quality system's conformity with audit criteria and the conformance of the operations to the quality system.

Nonconformities identified during an audit should be noted and the appropriate corrective action and the time limit for correction agreed with the auditee and recorded.

Records of the meeting should be kept.

**Follow-up corrective action and close-out**

The implementation of the agreed corrective action is the responsibility of the auditee.

Whenever a non-conformity that may jeopardise the result of a test is discovered, the corresponding activity should be halted until the appropriate corrective action has been taken and shown to lead to satisfactory results. In addition, results that may have been affected by the non-conformity should be investigated.

The formal corrective action procedure may need to be followed to reveal the root causes of some problems and to implement effective corrective and preventive actions.

The quality manager should have the ultimate responsibility for confirming the clearance of nonconformity by the auditee and then closing them out.

**Records and reports of internal audits**

A complete record of the audit should be maintained even where no nonconformities have been found.

Each of the nonconformities that have been identified should be recorded, detailing their nature, their possible cause(s), corrective action(s) required and appropriate time limits for their clearance. Following the audit closeout, a final report should be prepared which should summarise the outcome of the audit and include the following information:

- the name(s) of the auditor(s);
- date of audit;
- the areas audited;
- the details of all areas examined;
- the positive or good aspects of the operations.
- any nonconformity identified along with their document references.
- any recommendations for improvement.
- corrective action agreed, the time period allowed for completion, and the person responsible for carrying out the action;
- Corrective actions taken.

All records of audits should be stored for ten years.

The quality manager should ensure that the report of the audit and, where appropriate, individual nonconformity, are seen by the laboratory's senior management.

The trends in results of internal audits and the corrective actions should be analysed by the quality manager and a report prepared for review by senior management at the management review meeting.

The purpose of such reviews is to ensure that the audits and the corrective actions are contributing to the continuing effectiveness of the quality system as a whole.

The Quality Manager is responsible for developing the plan and schedule for internal quality audits.

The audit plan and schedule shall:

- address all applicable elements of the quality management system during each 12 month period
- identify the depth and frequency of each audit based on prior audit history and operational status of the area to be audited

The internal audit results including (CARs) from the previous audit are available for the management review meeting.

## Documentation

Internal audits, implementation of resulting corrective actions, and the follow-up audits are documented using the CARs form.

The following records are generated and managed:

| Required Record | Custodian |
|---|---|
| Internal Audit Results | Quality Manager |
| Corrective Action Request | Quality Manager |
| Nonconformity Record | Quality Manager |

## Reference Procedures

QSP 4-9-1 – Control of Nonconforming Work
QSP 4-11-1 – Corrective Action

| REVISION HISTORY | | |
|---|---|---|
| **CURRENT VERSION** | **EFFECTIVE DATE** | **SUMMARY OF CHANGES** |
| 1 | 2016/07/01 | Original version |
| 2 | 2018/04/01 | Change references to planning schedule form 4 year to all each calendar year. Change Rev. # to Ver. #, change issue date to effective date. |
| 3 | 2018/10/17 | Add new requirement for direct observation of testing during audit. |