# Procedure for Conducting Audits and Management Reviews

**1.0 Purpose** – This procedure establishes the method by which Quality System audits and management reviews are performed within the State Crime Laboratory (Laboratory).

**2.0 Scope –** This procedure applies to all Laboratory personnel who conduct audits and management reviews.

**3.0 Definitions**

- **Audit** – A planned and documented investigative evaluation to compare various aspects of the Laboratory's performance against established requirements, standards, policies, and procedures.
- **Corrective Action Record (CAR)** – Documentation, by which non-conformities are identified, tracked, investigated, and corrected.
- **Finding** – An audit result stating non-compliance with accreditation criteria, Laboratory, and SBI policies or procedures.
- **Internal audit -** An evaluation by Laboratory personnel to determine compliance with requirements of the QA manual and other Quality System documentation.
- **Non-conformity** – A non-fulfillment of a requirement of the Quality Management System.
- **Objective evidence** – Information substantiated through examination, measurement, test, interview or other means.
- **Observation** – Objective evidence that may indicate a potential non-conformity.
- **On-the-spot corrective action -** Immediate step taken to correct or resolve the non-conformity.
- **Management Review** – An assessment by management of the Quality System to determine effectiveness, suitability, and future direction.

**4.0 Procedure**

**4.1 Overview** - The Laboratory shall conduct systematic internal audits 1) to monitor and determine compliance with the requirements of the Quality System and Standards and 2) to evaluate the technical activities and work product of employees.

**4.2 Internal Audits**

**4.2.1** The Quality Control Officer (QCO) is responsible for coordinating all internal audits. The QCO shall ensure that internal audits are performed by trained and qualified personnel independent of the Section being audited.

**4.2.2** Internal audits shall be conducted annually. The Forensic Biology Section, Trace Evidence Section, and Evidence Control Unit of the Raleigh Laboratory shall be audited in September. The Western Regional Laboratory and the Drug Chemistry Section and Firearm and Tool Mark Section of the Raleigh Laboratory shall be audited in October. The Triad Regional Laboratory and the Digital/Latent Evidence Section of the Raleigh Laboratory shall be audited in November.

**4.2.3** Each Section shall be notified in advance of audit dates to minimize disruption of operations and to ensure the presence of necessary personnel.

**4.2.4** Auditors shall use a modified version of the accrediting body checklist. These checklists are intended as a minimal list of audit items. Auditors shall not be restricted to items on the checklist and shall pursue any issue affecting quality.

**4.2.5** As part of the audit, the audit team shall conduct a 100 % evidence inspection for each analyst who has 100 cases or fewer in their custody. If the analyst has more than 100 cases in his/her custody, 100 cases will be selected at random by the auditor for inspection.

**4.2.6** The Lead Auditor shall collect feedback from the audit team regarding the quality standards evaluated.

**4.2.7** If a non-conformity is observed and can be corrected immediately, on-the-spot corrective action may be taken. If the non-conformity cannot be corrected immediately, the Forensic Scientist Manager or Section Supervisor shall conduct corrective and/or preventive action(s), if warranted, as provided in the Procedure for Corrective Action and/or Procedure for Preventive Action.

**4.2.8** Upon completion of the audit, the Lead Auditor shall brief the Forensic Scientist Manager or Section Supervisor who shall have an opportunity to respond.

**4.2.9** The Lead Auditor shall prepare a final written report of the audit findings, observations, and recommendations. The report shall state the objective evidence observed and shall express any finding in the words of the relevant standard, policy, procedure, or other Quality System document. The original report shall be given to the Lab Director and a copy shall be given to the Forensic Scientist Manager or Section Supervisor and the Deputy Assistant Director/Quality Manager (QM) within two weeks of completion of the audit. Upon receipt of the final Audit Report, the Forensic Scientist Manager or Section Supervisor shall initiate a Non-Conformity Record for each finding in accordance with the Procedure for Corrective Action and Non-Conformities.

**4.2.10** The Forensic Scientist Managers or Section Supervisor's response to the audit report shall address each finding and shall be incorporated into the Section's annual management review, as noted below.

### 4.3 External Audits

**4.3.1** External audits are under the control of, and performed by, an auditing body external to the Laboratory.

**4.3.2** Upon notice by the accrediting body, the Deputy Assistant Director/QM shall notify the Lab Director of all external audits.

**4.3.3** Corrective or preventive actions, if warranted, shall be conducted as provided in the Procedure for Corrective Action and Procedure for Preventive Action.

### 4.4 Management Review

**4.4.1** Management reviews shall be performed annually in conjunction with the internal audit program. An annual review of each Section quality system shall be performed by the Forensic Scientist Manager or Section Supervisor in December.

**4.4.2** The management review shall be documented via memo to the Lab Director, with a copy to the Deputy Assistant Director/QM.

**4.4.3** The management review shall examine the Quality System of each Section and determine if it meets the standards set by the Laboratory and ISO. The review shall also serve as a guide for future determinations regarding the effectiveness and direction of the Quality System due to changes in the organization, facilities, staffing, equipment, activities, or workload.

**4.4.4** As necessary, the QCO shall provide any needed information and/or records for the review and forward them to the Forensic Scientist Manager or Section Supervisor.

**4.4.5** The management review shall consider, but not be limited to, the following:

- Suitability of policies and procedures.
- Reports from managerial and supervisory personnel.
- Outcome of recent audits.
- Effectiveness of previous actions.
- Corrective and preventive actions.
- Assessments by external bodies.
- Results of inter-laboratory comparisons or proficiency tests.
- Changes in the volume and type of the work.
- Client feedback.
- Complaints.
- Recommendations for improvement.
- Non-conformity Records
- Other factors, such as quality control activities, resources, and staff training.

**4.4.6** Corrective or preventive actions identified during the management review shall be addressed as provided in the Procedure for Corrective Action and Procedure for Preventive Action.

**4.4.7** The Lab Director shall respond to Management Reviews via memo to the DAD/QM directing the QM and QCO to review the Management Reviews and follow up with a summary report.

**4.4.8** In January, a summary report of the Section Management Reviews outlining findings and observations shall be included in the Laboratory Quality System Review. This annual report is prepared by the QCO, in cooperation with the QM, and provided to the Lab Director and shall include a review of the overall effectiveness of the Quality System, the proficiency testing program, the court testimony monitoring system, etc.

**4.5 Documentation -** The QCO shall retain the management reviews and audit reports according to the Record Retention Schedule as set forth by the North Carolina Department of Cultural Resources or five years, whichever is longer.

**5.0 Records**

- Audit summary reports
- Management system review reports

**6.0 Attachments –** N/A

| **Revision History** | | |
|---|---|---|
| Effective Date | Version Number | Reason |
| 09/17/2012 | 1 | Original Document |
| 10/26/2012 | 2 | 4.2.2 - changed month of October to last quarter of year; 4.2.5 - changed 100 % evidence inspection to 100 % evidence inspection for analysts with 100 cases or fewer and a minimum of 100 cases selected at random for those with custody of more than 100 cases; 4.2.7 – replaced CAR shall be completed with the provision to use the Procedure for Corrective Action and/or the Procedure for Preventive Action |
| 02/01/2013 | 3 | 4.2.9 - added when to initiate Non-Conformity Record from an audit |
| 02/15/2013 | 4 | 4.2.7, 4.2.8, 4.2.9, 4.2.10,4.4.1, and 4.4.4 added Section Supervisor |
| 05/03/2013 | 5 | 4.4.7 - Changed QCM to QCO in cooperation with QM. |
| 05/14/2013 | 6 | 4.2.2 - Designated when each laboratory shall be audited. |
| 05/30/2013 | 7 | 4.4.1 - added December; 4.4.2 - deleted within two weeks of receipt; 4.4.5 - added recommendations for improvement and NCR's; added 4.4.7 Lab Directors response; 4.4.8 - added to be completed in January |
| | | |