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 policies or Laboratory 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 Manager (QM) or designee is responsible for coordinating all internal audits. The QM 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 Quality Management System shall be audited in July. The Triad Regional Laboratory, the Firearms Section and the Trace Evidence Section shall be audited in August. The Evidence Control Section of the Raleigh Laboratory, the Western Regional Laboratory, and the Drug Chemistry Section of the Raleigh Laboratory shall be audited in September. The Toxicology Section of the Raleigh Laboratory and the Forensic Biology Section shall be audited in October. The Digital Evidence Section, Latent Evidence Section, and DNA Database Section 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. The checklists have been separated to cover lab-wide criteria and section specific criteria. 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. In addition, auditors shall directly observe a sampling of testing within each discipline.

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 As part of the internal audit, all quality records associated with corrective actions and preventive actions completed since the previous audit will be reviewed. The audit team shall verify that the corrective or preventive action implemented is being followed and is effective.

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

4.2.8 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 improvements, if warranted, as provided in the Procedure for Corrective Action and/or Procedure for Risk Management.

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

4.2.10 The Lead Auditor shall prepare a final written report assessing each Section's operation and practices to the requirements of ISO 17025, lab-wide adherence to the standards set forth in ISO 17025, the Laboratory management system, and accrediting body supplemental requirements. 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 Assistant Director of Technical Operations and a copy shall be given to the Forensic Scientist Manager or Section Supervisor and the 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.

4.2.11 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 QM shall notify the Lab Director of all external audits.

4.3.3 Corrective actions or improvements, if warranted, shall be conducted as provided in the Procedure for Corrective Action and Procedure for Risk Management.

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 July.

4.4.2 The management review shall be documented via memo to the Assistant Director of Technical Operations, with a copy to the 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 QM 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:

- Changes in internal and external issues that are relevant to the Laboratory.
- Fulfilment of objectives.
- Suitability of policies and procedures.
- Status of actions from previous management reviews.
- Outcome of recent internal audits.
- Effectiveness of previous actions and implemented improvements.
- Corrective actions and nonconformity records.
- Assessments by external bodies.
- Technical Leader annual report.
- Outcomes of the assurance of the validating of results including results of inter-laboratory comparisons or proficiency tests.
- Changes in the volume and type of the work or in the range of laboratory activities.
- Customer and personnel feedback.
- Complaints.
- Recommendations for improvement.
- Work Authorizations.
- Adequacy of Resources.
- Results of risk identification, including risks to impartiality.
- Other factors, such as quality control activities and staff training.

4.4.6 Corrective actions or improvements identified during the management review shall be addressed as provided in the Procedure for Corrective Action and/or Procedure for Risk Management.

4.4.7 The QM shall review the Management Reviews and follow up with a summary report to the Laboratory Director. The summary report shall include a review of the overall objectives of the Laboratory, overall effectiveness of the Quality System, proficiency testing program, court testimony monitoring system, corrective and preventive action records, etc.

4.4.8 In September, the summary report of the Section Management Reviews outlining findings and observations shall be included in the Laboratory Quality System Review and assessed in a meeting

with Laboratory Top Management. This meeting shall be documented in a memorandum prepared by the Lab Director and provided to the QM. The memo shall include decisions and actions related to:

- The effectiveness of the management system;
- Improvements, and corrective or preventive actions that the Lab Director deems appropriate;
- Provisions of required resources;
- Any need for change.

4.5 Documentation - The QM 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
10/16/2013	8	4.4.8 - added corrective and preventive action records; added issuing authority to header
04/18/2014	9	4.2.9 - added assessing requirements, 4.4.8 - added requirement for meeting annually with top management
08/29/2014	10	4.2.2 - added Physical Evidence and DNA Database Sections; removed Firearms and Trace Evidence Sections to show the new Section name change; changed month in which Forensic Biology and Triad Laboratory are audited; 4.4.5 - added Technical Leader annual report
12/19/2014	11	Throughout document: Clarified roles of Lab Director, Assistant Director of Technical Operations, and QM; Removed QCO responsibilities; definition of finding – removed SBI
10/19/2015	12	4.2.9 – edited to reflect accrediting body instead of naming the specific accrediting body 4.4.5 - added work authorizations 4.4.7 and 4.4.8 – updated the management review process
07/01/2016	13	4.2.2 – edited to add lab-wide criteria audit and to redefine the annual audit schedule. 4.2.4 - edited to include the lab-wide and section specific checklists 4.2.9 – edited to include lab-wide criteria
04/28/2017	14	4.2.6 – added requirement to monitor and verify the effectiveness of completed corrective and preventive actions.
12/18/2017	15	4.2.2 – split Digital and Latent Sections
05/10/2019	16	4.2.2 – updated with Firearms and Trace Evidence sections 4.2.4 – Added direct observation of testing

		4.4.1 and 4.4.8 – changed timeframe of reports 4.2.8, 4.4.3 and 4.4.6 – updated for Procedure for Risk Management 4.4.5 – updated management review reporting requirements 4.4.8 - updated requirements for Quality System Review memorandum