Procedure for Corrective Action and Non-conformities

1.0 Purpose - This procedure establishes the process to identify, track, investigate, and correct non-conformities within the State Crime Laboratory (Laboratory) Quality Management System.

2.0 Scope - This procedure is applicable to all organizational units and personnel in the Laboratory.

3.0 Definitions

- **Cause** – A deficiency that results in a non-conformity which must be corrected to prevent reoccurrence of the same or similar non-conformity.
- **Corrective action** – An action taken to eliminate the cause(s) of a detected non-conformity, defect, or other undesirable situation in order to prevent reoccurrence.
- **Non-conformity** – A non-fulfillment of a specified or implied requirement of the Quality Management System.

4.0 Procedure

4.1 Overview

4.1.1 Technical or administrative case-related non-conformities shall be grouped into four classes as determined by the impact on the Laboratory.

4.1.2 Class I non-conformities shall be documented and corrected on the spot, while Class II, Class III and Class IV non-conformities require management involvement.

4.1.3 The goals of this corrective action policy are to identify the root cause of a problem; correct non-conformities; implement a solution to avoid recurrence; and maintain the highest level of quality.

4.2 Class I Non-conformities

4.2.1 Class I non-conformities generally:

- Are discovered prior to case completion.
- Are foreseeable.
- Have a clear-cut, immediate cause.
- Have a defined remedial action, which shall be adequately documented by a simple entry on the examination documentation, or noted in the administrative or technical review.
- Shall be corrected on the spot by the individual who discovers them or by the original examiner when administrative or technical review is returned.
- Do not compromise the overall quality of work if properly addressed.
- Are not required to be documented on the Non-conformity Record.

4.2.1.1 Examples: administrative or transcription error, or failure in a quality control check such as carry-over in a blank, etc. (Some Class I non-conformities may be Section-specific and defined by the Technical Leader.)

4.2.2 Class I non-conformities occur as part of casework. Remediation for such Class I non-conformities shall be made on the spot by Forensic Scientists.

4.2.3 Staff shall take appropriate measures to correct or repair non-conforming data, reporting or equipment.

4.2.4 Remedial actions shall be documented in the Case Record.

4.3 Class II Non-conformities Raised by Laboratory Employee

4.3.1 Class II non-conformities generally:

- Are discovered prior to case completion.
- Are unexpected.
- Have a clear-cut, immediate cause.
- Do not compromise the overall quality of work if properly addressed.
- Are required to be documented on the Non-conformity Record and in the case file.

4.3.1.1 Examples: contamination issues, non-systemic identification of a Laboratory employee by DNA or Fingerprints.

4.3.2 The individual who identifies a Class II non-conformity shall inform the Forensic Scientist Manager and/or Technical Leader within two business days and initiate the Non-conformity Record (NCR) to document the issue. The Forensic Scientist Manager and/or Technical Leader shall conduct a basic fact finding and forward the NCR to the Deputy Assistant Director/Quality Manager (QM) within two business days.

4.3.3 The Deputy Assistant Director/QM, in collaboration with the Forensic Scientist Manager and/or Technical Leader, shall determine if the non-conformity rises to the level of a Corrective Action/ Preventive Action.

4.3.4 Remedial actions shall be documented in the case file.

4.3.5 The Quality Control Officer (QCO) shall keep a file of all Class II Non-conformities and place them on the Non-conformity Record Log.

4.3.6 The NCR shall use the following numbering scheme: YY-L-#, where the first two digits indicate the year, followed by a letter indicating the Laboratory (R=Raleigh, W=Western, T=Triad), and the next available sequential number.

4.4 Corrective Actions – Class III and Class IV Non-conformities

4.4.1 Class III non-conformities generally:

- Are unexpected.
- Require an inquiry to determine the root cause.
- Require comprehensive action with documentation.
- Require management involvement.
- May affect the quality of work, but are not serious enough to cause immediate concern for the overall quality of the Laboratory work product.

4.4.1.1 Examples: missed identifications (failing to identify something present) or false negatives, etc.

4.4.2 Class IV non-conformities:

- Are unexpected.
- Require an inquiry to determine their root cause.
- Require comprehensive action with documentation.
- Require management involvement.
- Raise immediate concern and may compromise the quality of the Laboratory work product.

4.4.2.1 Examples: erroneous identifications (identifying something not present), or systemic quality issues.

4.4.3 The employee who identifies a potential Class III or Class IV non-conformity shall inform the Forensic Scientist Manager and/or Technical Leader within two business days. The Forensic Scientist Manager and/or Technical Leader shall document the non-conformity and method of identification in a memo to the Deputy Assistant Director/QM within two business days of the identification of the non-conformity.

4.4.4 The Deputy Assistant Director/QM shall determine the appropriate class (Class III or Class IV) of the non-conformity. The Deputy Assistant Director/QM shall initiate the Corrective Action Record (CAR) and assign a team to evaluate the non-conformity. The inquiry team shall confer with the Deputy Assistant Director/QM and QCO to develop an approach to the inquiry and shall determine whether the employee shall be permitted to conduct casework. The team shall usually include the Section Forensic Scientist Manager and a designated Technical Leader.

4.4.5 Section I of the CAR shall be completed by the Deputy Assistant Director/QM and given to the Inquiry Team Leader.

4.4.6 The CAR shall use the following numbering scheme: YY-L-#, where the first two digits shall indicate the year, followed by a letter indicating the Laboratory (R=Raleigh, W=Western, T=Triad) and the next available sequential number.

4.4.7 Over the course of the investigation, the inquiry team shall determine and document the following:

- The non-conformity.
- Event(s) which identified the non-conformity.
- Extent of the non-conformity.
- Effect(s) of the non-conformity on the quality of work.
- Short term response.
- Root cause(s) of the non-conformity. Examples of findings or root causes may include, but are not limited to, equipment failure; incomplete or nonexistent procedures; non-compliance with procedures and regulations; improper collection, storage, handling, or preparation; calculation errors or transcription errors; and lack of training.

4.4.8 A tentative corrective action plan shall be developed by the inquiry team and provided via memo to the Deputy Assistant Director/QM within 30 days. If the inquiry and/or corrective action plan

extends over a period greater than 30 days, the team shall provide progress reports to the Deputy Assistant Director/QM every 15 days.

4.4.9 Once a corrective action plan is determined, Sections II and III of the CAR shall be completed and signed by the Inquiry Team Leader and the CAR returned to the Deputy Assistant Director/QM for review and approval.

4.4.10 The corrective action shall be implemented.

4.4.11 The Deputy Assistant Director/QM in collaboration with the inquiry team shall determine if the corrective plan has been completed or specify if further action is warranted. If deemed necessary, additional follow-up actions shall be identified by the Deputy Assistant Director/QM and a new date for completion set and approved.

4.4.12 If there is objective evidence that the actions are complete and effective, the Deputy Assistant Director/QM shall approve and close the corrective action, signing **Section IV** of the CAR.

4.4.13 The QCO shall maintain all original documentation on corrective actions.

4.5 Special Audits

4.5.1 If the findings of the corrective action indicate a systemic issue of non-compliance at Section or Laboratory-wide level, the Deputy Assistant Director/QM shall initiate an appropriate audit. The Deputy Assistant Director/QM, in consultation with the QCO, shall assign one or more experienced persons from outside of the Section or Laboratory to perform a special audit.

4.5.2 A report from the audit team shall be made to the Deputy Assistant Director/QM, who shall determine whether follow-up action is required.

4.6 Completed Cases Released To Clients

4.6.1 Data, reports, and actions shall not be released until the problem is resolved and verified by the Section Forensic Scientist Manager and/or QM. If the problem cannot be resolved, the submitting agency shall be notified in writing that the data cannot be reported or accepted, and disclaimers shall be made that the product did not meet quality standards.

4.6.2 In the event that a Class III or Class IV non-conformity has been identified and a Laboratory Report has been released through Forensic Advantage (FA - the laboratory information management system), the agency shall be notified. The Lab Director or designee may request resubmission of evidence for analysis. An amended report shall be issued to the submitting agency and the CAR shall be included in the FA case file.

5.0 Records

- Corrective Action Record (CAR)
- Non-conformity Record (NCR)
- CAR database

6.0 Attachments – N/A

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	Original Document