North Carolina
State Crime Laboratory
Quality Manual

TABLE OF CONTENTS

	Topic	Page
1.0	**Introduction**	3
2.0	**Controlled Distribution of the Quality Manual**	3
3.0	**Quality Policy Statement**	4
4.0	**Management Requirements**	
4.1	Organization	5
4.2	Management System	8
4.3	Document Control	12
4.4	Review of Requests, Tenders, and Contracts	13
4.5	Subcontracting of Tests	14
4.6	Purchasing Services and Supplies	15
4.7	Service to the Customer	15
4.8	Complaints	16
4.9	Control of Non-conforming Work	16
4.10	Improvement	16
4.11	Corrective Action	17
4.12	Preventive Action	17
4.13	Control of Records	18
4.14	Internal Audits	21
4.15	Management Reviews	22
5.0	**Technical Requirements**	
5.1	General	23
5.2	Personnel	23
5.3	Facilities and Environmental Conditions	26
5.4	Technical Procedures and Procedure Validation	27
5.5	Equipment	31
5.6	Measurement Traceability	32
5.7	Sampling	34
5.8	Handling Items of Evidence	35
5.9	Ensuring the Quality of Test Results	37
5.10	Reporting Results	40
Revision History		43
APPENDIX A – Strategic Vision		44
APPENDIX B – Definitions		45
APPENDIX C - ASCLD/LAB GUIDING PRINCIPLES OF PROFESSIONAL RESPONSIBILITY FOR CRIME LABORATORIES AND FORENSIC SCIENTISTS		52

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1.0 Introduction

This State Crime Laboratory (Laboratory) Quality Manual has been prepared to meet the requirements for accreditation of the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025. The manual has been formatted using clause numbers from ISO/IEC 17025. Terms and definitions have been included in Appendix B.

2.0 Controlled Distribution of the Quality Manual

The Laboratory is responsible for maintaining the official master copy of the Quality Manual. General distribution of the Quality Manual and all associated procedures is controlled by using a computer network. An annual review of the Quality Manual shall be conducted by Laboratory management.

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3.0 Quality Policy Statement

The Laboratory was established by the North Carolina General Assembly to be of service to the public and the criminal justice system according to the provisions of Chapter 114 of the General Statutes. The Laboratory is committed to performing unbiased forensic analyses which are accurate, precise, reliable, timely, and honest.

The Laboratory is dedicated to the highest level of service as defined by ISO/IEC 17025 and any additional supplemental requirements. The Laboratory has adopted a Quality System established upon a Quality Manual based on internationally accepted standards and that:

- Produces a quality analytical product in a timely manner.
- Utilizes procedures for Laboratory operations based upon validated testing methods.
- Maintains the integrity of both the samples tested and the documentation to support the analytical data.
- Employs qualified and trained personnel to perform the forensic analyses.
- Ensures the quality of its analyses through a program of proficiency testing, testimony monitoring of employees, routine maintenance of quality control data, and 100 % peer review of Laboratory Reports.
- Focuses on continual improvement through the use of corrective and preventive action.
- Evaluates effectiveness through the use of an internal audit process.
- Allows for periodic revisions as part of an annual management review.

The primary objective of the Quality System established by the Laboratory is to ensure the accuracy and precision of analyses so that they shall be reliable, interpretable, and repeatable. The second objective is to meet or exceed the customer's needs and expectations for precision, accuracy, sensitivity, and specificity. The third objective is to maintain the Laboratory's commitment to quality by fostering continual process improvement and problem prevention.

Quality System documents and procedures are included as elements in the training program. Laboratory personnel shall follow the policies in this Quality Manual and corresponding procedures. In addition, Laboratory personnel shall follow Section technical procedures and administrative documents.

The policies for operation of the Quality System are established to address the requirements of ISO/IEC 17025 and the Laboratory is committed to maintaining accreditation according to these International requirements.

John A. Byrd
Laboratory Director

Chuck McClelland
Assistant Director of Technical Operations

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Assistant Director of Administrative Operations

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4.0 Management Requirements

4.1 Organization

Principal Responsibilities

The Laboratory Director (Lab Director) is responsible for establishing the organization's commitment to the management system and the implementation thereof. The Lab Director is also responsible for issuing policy and procedures and for ensuring analytical activities meet the requirements of the Laboratory.

Overview of Organization and Management

The Laboratory is part of the North Carolina Department of Justice (NCDOJ). The Laboratory is composed of the Raleigh Crime Laboratory, the Triad Regional Laboratory, and the Western Regional Laboratory.

Laboratory management consists of the Lab Director, Assistant Directors, Quality Manager, and Forensic Scientist Managers. Management defines policies; manages fiscal and human resources; establishes legislative and budgetary initiatives; and coordinates programs to ensure uniformity and compliance with applicable policies and procedures.

The duties of the Lab Director include oversight of the day-to-day functions and operations of the Laboratory and other duties as assigned by the Attorney General.

The Assistant Directors report to the Lab Director. The duties of the Assistant Directors include quality assurance and control; continued compliance with accreditation requirements; acquisition and implementation of grants; oversight of budgets; and administration of Forensic Advantage and the Evidence Control Unit. The Assistant Directors also assist the Lab Director with the day-to-day management of the Laboratory.

The Raleigh Crime Laboratory is a full service laboratory which has the following Sections: Drug Chemistry, Evidence Control, Forensic Biology, Digital/Latent Evidence, and Physical Evidence, which is composed of a Firearms Unit and Trace Unit. Each forensic Section is led by a Forensic Scientist Manager.

The Western Regional Laboratory provides analysis in arson, drug chemistry, latent evidence, and firearm/tool mark. The Triad Regional Laboratory provides analysis in drug chemistry, toxicology, and latent evidence. Each Laboratory is supervised by a Forensic Scientist Manager.

The Forensic Scientist Manager ensures compliance with Laboratory policies and procedures and with accreditation standards; reviews Section operations; recommends changes in staffing, equipment and facilities; and maintains liaison with criminal justice partners.

Each Forensic Scientist Manager shall designate the Technical Leader(s) who has/have ultimate responsibility for technical aspects of each discipline, including analytical procedures and protocols, interpretation and reporting of analytical results, quality assurance, and resource and training needs. Each Technical Leader shall possess technical training and experience in the discipline(s).

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Policies

4.1.1 North Carolina General Statute § 114-60 states the following:

"In the Department of Justice there shall be provided laboratory facilities for the analysis of evidences of crime, including the determination of presence, quantity and character of poisons, the character of bloodstains, microscopic and other examination material associated with the commission of crime, examination and analysis of projectiles of ballistic imprints and records which might lead to the determination or identification of criminals, the examination and identification of fingerprints, and other evidence leading to the identification, apprehension, or conviction of criminals. A sufficient number of persons skilled in such matters shall be employed to render a reasonable service to the public and the criminal justice system in the discharge of their duties. In the personnel of the Bureau shall be included a sufficient number of persons of training and skill in the investigation of crime and in the preparation of evidence as to be of service to local enforcement officers, under the direction of the Governor, in criminal matters of major importance."

"The laboratory and clinical facilities of the institutions of the State, both educational and departmental, shall be made available to the Bureau, and scientists and doctors now working for the State through its institutions and departments may be called upon by the Governor to aid the Bureau in the evaluation, preparation, and preservation of evidence in which scientific methods are employed, and a reasonable fee may be allowed by the Governor for such service."

4.1.2 The intent of Laboratory management is to operate according to the following:

- ISO/IEC 17025.
- DNA Advisory Board requirements.
- Laboratory and Section technical policies and procedures.
- Federal and State laws and regulations.
- Supplemental Standards of the accrediting bodies.

4.1.3 The Laboratory operates permanent facilities in Raleigh, Greensboro, and Asheville. Forensic examinations may be conducted in other locations where Laboratory personnel perform forensic services (i.e., crime scenes, clandestine laboratories). Reviews and other administrative work performed outside these facilities shall follow Laboratory policies and procedures.

4.1.4 The State Crime Laboratory is part of the North Carolina Department of Justice. The Laboratory maintains organizational charts which identify key personnel. The organizational charts are found on the Laboratory internal network. Analysis results generated by the Laboratory shall be free from bias and outside influence. Laboratory personnel encountering situations or conditions which may cause undue pressure and/or adversely affect the quality of work shall inform the Forensic Scientist Manager or the Quality Manager.

4.1.4.1 The responsibilities and authority of the Lab Director are defined in the job description for that position.

4.1.4.1.1 The Lab Director has the authority to make and enforce decisions affecting the Laboratory.

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4.1.5 The Laboratory shall:

- Have managerial staff with the authority to discharge duties as reflected in the job description for each position. This authority includes implementation, maintenance, and improvement of the management system. The authority to identify and resolve analytical problems lies with the Lab Director or designee. Departures from the Quality System shall be documented according to the Procedure for Corrective Action and Non-Conformities.

- Create an atmosphere in which all personnel are free from undue internal or external pressures and influences which may negatively impact the quality of work performed. Laboratory personnel shall be responsible for ensuring the integrity of the analytical process.

- Transmit and file reports of information and data in accordance with official policies, procedures, notices of the Laboratory and State and Federal laws and regulations. Reports of Examination shall not be released until verified through a technical and administrative review and shall not be released to the customer except as permitted by law. The Procedure for Reporting Results provides guidance for reporting analytical results. Additionally, Laboratory facilities shall be controlled-access buildings to ensure protection of data. All data in the network shall be controlled with limited access (see **4.13.1.3**).

- Avoid conflicts of interest, pressures, and influences, and personnel shall comply with the Laboratory Policy on Ethics and Conduct. No employee shall use, or attempt to use, his official public position for personal gain, obtaining privileges, or avoiding the consequences of illegal acts. Training shall be provided on ethics rules, regulations, and integrity in order to help personnel avoid any conflict of interest. Any employee who fails to uphold the Code of Conduct is subject to disciplinary procedures including warning, suspension, demotion, or dismissal.

- Define organizational relationships. The State Crime Laboratory is a division of the North Carolina Department of Justice.

- Document job responsibilities for personnel in the management system procedures and operating instructions. Position descriptions, technical qualifications, and work plans shall be maintained by each Section. Each employee shall be accountable to one and only one immediate supervisor per function.

- Designate Laboratory management to provide suitable supervision to staff. Demonstration of competence for technical personnel shall be documented as evidence of desired familiarity with Laboratory methods. Trainees shall not issue reports until competent as Forensic Scientists in accordance with Section training programs.

- Hold the Forensic Scientist Manager and/or Technical Leader responsible for technical operations and provision of resources. The DNA Technical Leader shall be selected in accordance with Federal DNA Standards and the state personnel policy and procedure. The Forensic Scientist Manager in each of the other Sections in the Raleigh Laboratory shall designate a Technical Leader for each discipline. The Technical Leader for each discipline shall serve as the Technical Leader for the Raleigh, Western and Triad Laboratories.

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- Employ two Assistant Directors to assist the Lab Director. The Assistant Directors shall have direct access to the Lab Director, who shall be responsible for decisions concerning policy and resources. The Assistant Director of Administrative Operations shall have responsibility for personnel, budget, grants, IT and logistics. The Assistant Director of Technical Operations shall directly supervise all of the Forensic Scientist Managers who manage forensic Sections and the Quality Manager.

- Employ one Deputy Assistant Director to assist the Lab Director. This Deputy Assistant Director (FA Manager) shall be responsible for the administration of the Forensic Advantage (FA) System and the Evidence Control Unit.

- Employ one Quality Manager to assist the Lab Director in administering and implementing the Quality Management System.

- Assign qualified Laboratory personnel to serve in the absence of key managerial personnel.

- Ensure personnel are aware of the relevance and importance of each job function and the contributions of the job function to the objectives of the management system. Each employee shall be instructed according to the Procedure for Personnel Training and shall be authorized by the Forensic Scientist Manager to perform duties.

4.1.6 Laboratory management shall ensure appropriate communication processes are established (through the use of memos, electronic presentations, emails, verbal statements, etc.) and shall ensure that communication takes place regarding the effectiveness of the management system.

4.1.7 The Safety Manager shall be responsible for ensuring that the provisions of the Health and Safety Program described in the Safety Manual are implemented and followed at all times.

4.1.8 Key management shall be identified on the organizational charts available on the internal network drive. Top management shall include the Laboratory Director, the Assistant Director of Technical Operations, and the Assistant Director of Administrative Operations. Key Management will appoint a designee in their absence.

4.2 Management System

4.2.1 The management system shall be established to address all facets of activities, the requirements in ISO/IEC 17025, and any supplemental accreditation requirements. The Laboratory management system is outlined in the following documents:

- Quality Manual – sets forth the quality policy. Policy statements and subsequent revisions to the Quality Manual shall be approved by the Lab Director and the Quality Manager.

- Procedures – written documents used to implement policies regarding the Quality Program. Procedures and subsequent revisions to the procedures shall be approved by the Lab Director and the Quality Manager.

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- Section policies, technical procedures, guidelines, references, forms, and records supplement lab-wide policies and procedures. The Quality Manager shall establish and maintain a Master List of procedures according to the Procedure for Document Control and Management. Section policies and procedures and any revisions thereto shall be approved by the Forensic Scientist Manager, Lab Director and Quality Manager. Technical procedures and subsequent revisions shall also be approved by the Section Technical Leader.

- Safety Manual - sets forth occupational health and safety policy and supplements the North Carolina Department of Justice Safety and Health Manual (DOJ Safety Manual) to meet the special conditions unique to the Laboratory. Any revisions to the manual shall be approved by the Safety Manager, Lab Director and Quality Manager.

Management documents shall be accessible on the internal network file server. When lab-wide management system documents are issued, the Quality Manager shall ensure that each affected Laboratory employee signs an Acknowledgement Sheet to indicate review of the document. When Section specific management system documents are issued, the Section Manager/Supervisor shall ensure that each affected Laboratory employee signs an Acknowledgement Sheet to indicate review of the document. The Acknowledgement Sheets shall be scanned and stored on the internal network file server.

4.2.2 Management System Policy

The Quality Policy Statement is addressed in Section 3.0.

4.2.2.1 The document ***ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists*** has been incorporated into this Quality Manual as Appendix C.

4.2.2.2 These principles shall be reviewed annually with employees and the records of this review shall be maintained in each Section.

4.2.3 Commitment to Quality

Laboratory management shall be committed to the development, implementation, and continual improvement of the management system; therefore, managers shall participate in management reviews, internal audits, and the distribution and/or analysis of proficiency tests and quality control samples.

4.2.4 Communication

State Crime Laboratory management shall communicate to personnel the importance of meeting customer, statutory, and regulatory requirements. Management shall communicate effectively with all personnel regarding the development, implementation, and continual improvement of the Quality System.

4.2.5 Procedures and Outline of the Management System

The Quality Manual shall include or make reference to all supporting administrative and technical procedures. The outline of the documentation used in the management system is

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included in subsection 4.2.1 of this manual. Each Section shall have procedures to implement the quality policies and refer to the corresponding requirements in this Quality Manual.

4.2.6 Roles and Responsibilities

4.2.6.1 Lab Director

- Ensure that the management system is established, implemented, and maintained in conformance with the requirements of ISO/IEC 17025.
- Support and promote the Quality System.
- Ensure that personnel understand and apply current policies and practices.
- Ensure that the policies and practices within the Quality System are documented.
- Advocate and coordinate quality improvements to the management system.
- Serve as a member of the North Carolina Forensic Science Advisory Board.

4.2.6.2 Section Forensic Scientist Managers and Technical Leaders

- Support and promote the Quality System.
- Participate in the selection and use of technical procedures within the Section, establish criteria for technical procedure validation, and review and update technical procedures.
- Ensure that the Section-specific Quality System is reviewed annually.
- Communicate the Quality System and related policies, practices, and procedures to all Section employees.
- Ensure that current policies and procedures are followed in conformance with the requirements of the accrediting body.
- Ensure compliance with the requirements of ISO/IEC 17025.
- Ensure that corrective action is taken and documented to resolve deficiencies.
- Ensure that Section personnel receive training and resources and are qualified for assigned work.
- Ensure that products and services satisfy customer requirements.
- Conduct quarterly meetings with senior level scientist(s) and make annual report to the Forensic Scientist Manager by December 1st of each year. Include Technical Leaders report in annual management review.

4.2.6.3 DNA Technical Leader (DNA TL)

- Oversee the technical operations and quality assurance/quality control to include functions pertaining to proficiency tests and audits within the DNA Unit.
- Suspend DNA operations in the Section if a technical or quality problem arises. Troubleshoot and solve problems and/or quality issues that arise within the DNA Unit.
- Evaluate all methods and procedures used within the DNA Unit, and approve all quality system documents within the DNA Unit.
- Implement new or modified procedures and equipment within the DNA Unit.
- Oversee training, quality assurance, and proficiency testing within the DNA Unit.

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- Review the academic transcripts and training records for newly qualified Forensic Scientists or DNA Databasing Analysts and approve his/her qualifications prior to independent casework analysis and document such review.
- Approve the technical specifications for outsourcing agreements.
- Review requests by contract employees for employment by multiple NDIS participating and/or vendor laboratories and, if no potential conflict exists, approve such requests.
- Review internal and external DNA audit documents, Lab procedures, and approve corrective action(s) and document the review.
- Stay abreast of any problems, successes, changes, alterations, etc. within the DNA Unit.
- The contingency plan for a vacated DNA Technical Leader position is for the Deputy Assistant Director (Quality Manager), in consultation with the Forensic Biology Manager and DNA Database Manager, to assign as Technical Leader a qualified DNA Forensic Scientist who meets the Federal DNA Standards.

4.2.6.4 Quality Manager

- Ensure conformance with accrediting bodies.
- Ensure Quality System functions in accordance with goals and objectives.
- Ensure documentation of policies, practices and procedures within the Quality System.
- Advise management regarding the development, implementation, and maintenance of the Quality System.
- Provide reports to the Lab Director on the progress of Quality System activities.
- Coordinate development and revision of the Quality System.
- Assist Sections in development of Quality System policies, practices, and procedures.
- Conduct annual audits to verify established quality policies, procedures, and objectives are being met.
- Provide guidance and direction regarding accreditation standards.

4.2.6.5 Forensic Scientists and Technicians

- Ensure compliance with current policies and procedures.
- Ensure the quality of work by performing technical procedures in accordance with current policies and practices.
- Make recommendations and suggestions for improving the Quality System.

4.2.6.6 Administrative Personnel

- Perform administrative/clerical duties accurately.
- Comply with current policies and procedures.

4.2.6.7 Quality Assurance Working Groups

- Formed as determined by the Quality Manager.
- Composed of representatives from Laboratory Sections.

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- Participate in revising lab-wide policies and procedures.
- Provide assistance in performing quality audits.

4.2.7 Effect of Changes

The management system policies and procedures in this manual are designed to maintain the integrity of the management system. The Quality Manager shall ensure changes do not affect the quality management system adversely.

4.3 Document Control

4.3.1 General

The process for controlling all documents that form part of the management system shall be conducted as provided in the Procedure for Document Control and Management. These management system documents (internally generated or from external sources) include but are not limited to regulations, standards, test methods, instructions and manuals.

Documents posted on the internal network shall be the official version of the document. Hard copies printed from the internal network shall be uncontrolled.

4.3.2 Document Approval and Issue

4.3.2.1 The Master List

Documents issued as part of the management system shall be thoroughly reviewed and approved prior to issuance in accordance with the Procedure for Document Control and Management. The Master List shall identify the current revision status and distribution of documents thereby precluding the use of invalid or obsolete documents.

4.3.2.2 Procedure Content

The Master List and Procedure for Document Control and Management shall provide the following:

- Authorized management system documents shall be located where operations essential to the effective functioning of the Laboratory are performed.
- Documents shall be reviewed according to a schedule and revised to ensure continuing suitability and conformance with management system and accreditation requirements.
- Invalid or obsolete documents shall be removed from all points of issue to ensure no unintended use occurs.
- Obsolete documents shall be retained indefinitely and marked as *Archived*.

4.3.2.3 Document Identification

A document generated by the Laboratory shall be identified uniquely as described in the Procedure for Document Control and Management. Identification includes the document title, effective date of issue, revision number, and the Section identification. Pagination shall be included and shall state the page number and

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total number of pages in the document. Each document shall indicate the issuing authority.

4.3.3 Document Changes

4.3.3.1 Authority

Changes to documents that are part of the management system shall be reviewed and approved by the same personnel that performed the original review unless specifically designated otherwise. Designated personnel shall have access to pertinent background information upon which to base review and approval. Changes to policies, procedures, and training program manuals shall be described in the revision history of each document.

4.3.3.2 Identification of Changes

As provided in the Procedure for Document Control and Management, altered or new text shall be identified in the revision history.

4.3.3.3 Amendment by Hand

Amendment of documents by hand (handwritten notes) shall not be authorized.

4.3.3.4 Computerized Systems

The control of electronic management system documents shall be conducted in accordance with the Procedure for Document Control and Management.

4.4 Review of Requests, Tenders, and Contracts

4.4.1 Review

The review of examination requests shall be conducted as provided in the Procedure for Evidence Management. This procedure shall ensure that:

- The requirements, including the methods to be used, are defined, documented, and understood.
- The Laboratory has the capability and resources to meet the requirements.
- The selected test method is capable of meeting the customers' requirement.

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable to both the Laboratory and the customer.

The Laboratory shall enhance services to the public and the criminal justice system through the following:

- Developing and maintaining good working relationships with participants in the criminal justice system.
- Clarifying requested examinations when the request is ambiguous.
- Maintaining contact with criminal justice system partners.

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- Providing explanations, clarifications, elaborations, and interpretations of the results presented in the report of analysis and the examinations performed to support those results.
- Seeking feedback from clients to improve the Quality System and technical operations.
- Testifying in court.
- Presenting seminars and training sessions.

4.4.2 Records of Review

Receipt of evidence shall take place according to the Procedure for Evidence Management. Discrepancies between the Request for Examination and the actual evidence submitted shall be addressed according to the Procedure for Evidence Management.

Records of reviews, including change requests, shall be maintained. All discussions with the customer shall be documented in the laboratory information management system, Forensic Advantage (FA).

4.4.3 Subcontracting Laboratories

The policies regarding the use of subcontracting laboratories are found below in section 4.5 Subcontracting of Tests. The Forensic Scientist Manager or designee shall review the request on any work that is subcontracted.

4.4.4 Contract Deviations

Laboratory personnel shall interact with customers to determine whether deviations from the original contract are acceptable. If the Laboratory is unable to meet the service agreement or contract, a new agreement shall be reached. This communication shall be documented in FA.

4.4.5 Amendments to Contracts

If a contract is amended, the same contract review process shall be repeated. Amendments shall be communicated to all affected personnel and documented in FA.

4.5 Subcontracting of Tests

4.5.1 Subcontracting Laboratories

The Laboratory may subcontract forensic analyses to competent laboratories. Subcontracting for Forensic Biology and the DNA Database Sections shall meet FBI and QAS standards.

Prior to the contract award, the Forensic Scientist Manager or designee shall ensure that the selected contractor is competent to perform the testing and to meet the needs of the contract. The bidders shall permit the State Crime Laboratory to inspect facilities and to perform an audit to verify the bidders' capabilities to meet the scope of work as stated in the contract. The subcontractor shall be accredited for the work in question by a recognized International Standard, by an ILAC recognized accrediting body or accredited by another nationally recognized body such as College of American Pathology (CAP) or American Board of Forensic Toxicology. The State Crime Laboratory shall maintain a copy of the accreditation certificate of the subcontracting lab. The subcontractor shall permit site visits, review of

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documents, and an annual audit by the State Crime Laboratory. Audits and site visits shall be documented and the records shall be maintained by the State Crime Laboratory.

Each analyst employed by the subcontractor shall participate in a proficiency-testing program using an approved proficiency test provider if available. The State Crime Laboratory may re-analyze samples tested by the subcontractor and may submit quality assurance samples for analysis.

4.5.2 Notification of Customer

The requesting agency shall be notified in writing when work may be transferred to a subcontracting laboratory.

4.5.3 Responsibility

The State Crime Laboratory shall be responsible to the customer for work performed by the subcontractor.

4.5.4 Registration of Subcontractors

Forensic Scientist Managers shall maintain a record of subcontractors approved to conduct forensic examinations and shall include documentation to demonstrate the subcontractor's compliance with International standards.

4.6 Purchasing Services and Supplies

4.6.1 Procedure

The selection, purchase, receipt and storage of equipment, supplies, services, reagents, and consumable materials which critically affect the quality of tests shall be conducted according to the Procedure for Procurement and Receipt.

4.6.2 Inspection and Verification

Equipment, supplies, services, reagents, and consumable materials that affect the quality of tests shall not be used until inspected or otherwise verified to comply with the specifications or requirements defined in methods for tests. Section Procedures shall contain protocols describing verification procedures and record maintenance.

4.6.3 Purchasing Documents

Purchasing documents for items affecting the quality of Laboratory output shall describe the services or supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to submission to the Assistant Director of Administrative Operations or designee.

4.6.4 Evaluation of Supplies Vendors - Records and Registry

The Laboratory shall evaluate suppliers of critical consumables, supplies, and services which affect the quality of testing. The Assistant Director of Administrative Operations shall maintain a list of approved suppliers and records of all evaluations.

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4.7 Service to the Customer

4.7.1 Customer Service

The Laboratory shall cooperate with customers to clarify the customer's request and to monitor performance of work. Employees shall observe statutory requirements regarding confidentiality of customer communications and submissions.

4.7.2 Customer Feedback

The Laboratory shall seek customer feedback on services and general performance in accordance with the Procedure for Evaluating Customer Satisfaction. Records of all comments shall be maintained and shall be used to identify management system improvements.

4.8 Complaints

The receipt and documentation of complaints from any party shall be conducted in accordance with the Procedure for Complaints.

4.8.1 Employee Complaints Regarding the Quality System

Laboratory employee complaints concerning the Quality System shall be processed in accordance with the Procedure for Corrective Action and Non-Conformities and the Procedure for Preventative Action.

4.9 Control of Non-conforming Work

4.9.1 Procedure

The Procedure for Corrective Action and Non-Conformities shall be implemented when any aspect of the analysis does not conform to requirements of the management system, testing methods, or the requests of the customer.

This procedure shall address the following elements:

- Identification of non-conforming work and actions such as the halting work or withholding test reports.
- Application of criteria to evaluate the significance of non-conforming work.
- Actions and decisions regarding acceptability of nonconforming work.
- Notification of the customer and, if necessary, recall of work.
- Authorization of the resumption of work.

4.9.2 Follow-Up

If the non-conforming work recurs, or other problems are identified, the Procedure for Corrective Action and Non-Conformities shall be followed.

4.10 Improvement

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The Laboratory shall be committed to improvement of the management system through the use of quality policies and objectives, procedures, audit results, customer feedback and criticisms, corrective and preventive actions, management reviews, and analysis of data.

4.11 Corrective Action

4.11.1 General

The Procedure for Corrective Action and Non-Conformities shall designate the policies for implementing corrective action upon the identification of the following: non-conforming work, departures from the policies and procedures in the management system, and non-approved departures from required technical operations.

A corrective action is intended to prevent the recurrence of a non-conformity that affects the quality of work performed by the Laboratory. Corrective actions shall be initiated in a timely manner to minimize the impact of the non-conformity.

4.11.2 Cause Analysis

The investigation and determination of the root cause of the non-conformity is fundamental to the Procedure for Corrective Action and Non-Conformities.

4.11.3 Selection and Implementation of Corrective Actions

The Laboratory shall identify potential corrective actions and select the action most likely to eliminate the problem and prevent recurrence. The corrective action shall be based on the magnitude and the risk attributed to the non-conformity. The Laboratory shall implement and document any change resulting from a corrective action.

4.11.4 Monitoring of Corrective Actions

The Forensic Scientist Manager or designee and the Quality Manager shall monitor results to ensure corrective actions are effective.

4.11.5 Additional Audits

If the Quality Manager determines that a non-conformity may affect the Laboratory's compliance with management system policies and procedures or accreditation requirements, the areas of activity affected by the non-conformity shall be audited as soon as possible in accordance with the Procedure for Conducting Audits and Management Reviews.

4.12 Preventive Action

4.12.1 General

The Laboratory shall be proactive in identifying opportunities for improvement by taking actions including the following:

- Encouragement of employees to identify improvement opportunities.
- Review of the results of proficiency tests.

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- Review of the results of testimony monitoring.
- Review of audit reports.
- Management reviews.

If preventive action is required, the Procedure for Preventive Action shall be followed and plans shall be developed, implemented, and monitored to reduce the likelihood of the occurrence of a non-conformity or to address the identified opportunities for improvement.

4.12.2 Procedure

The Procedure for Preventive Action shall include the initiation of preventive action and the application of controls to ensure the effectiveness of such actions.

4.13 Control of Records

4.13.1 General

4.13.1.1 Procedure

The Procedure for Record and Data Management shall include the process for identifying, collecting, indexing, accessing, filing, storing, maintaining, and disposing of quality and technical records. Quality records shall include reports from internal audits, management reviews, corrective actions, and preventive actions. Technical records include, but are not limited to, the following: forms, worksheets, control graphs, external and internal test reports and calibration certificates, customer notes, papers and feedback.

4.13.1.2 Legibility, Storage, and Retention

Records shall be legible. Records shall be stored and retained according to the Procedure for Record and Data Management.

4.13.1.3 Security and Confidentially

Access to the Laboratory shall be controlled and records shall be stored in secured areas. Records shall be confidential and shall be released in accordance with the Procedure for Record and Data Management.

4.13.1.4 Electronic Records

Electronic technical records shall be maintained in FA, a restricted-access database. The Procedure for Record and Data Management shall describe the protection and back-up of all electronic records and the safeguards to prevent unauthorized access to or amendment of electronic records.

4.13.2 Technical Records

4.13.2.1 Retained Records, Audit Trail, and Identification

The Laboratory Case Record found in FA includes Laboratory Reports, original observations, derived data, calculations, standard preparation,

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instrument printouts, and results. The Case Record identifies the personnel responsible for sampling, performing each test, and reviewing the results.

Staff records, equipment calibration, and verification reports shall be retained in accordance with the Procedure for Record and Data Management. Records shall: contain information to establish an audit trail; identify factors that affect uncertainty of the test; and enable the test to be repeated under conditions as close as possible to the original.

4.13.2.2 Recording and Identification

Observations, data, and calculations shall be recorded at the time they are made and shall be identifiable to the activity performed.

4.13.2.2.1 Analysis Date

Analysis documentation shall reflect the date(s) of analysis.

4.13.2.3 Corrections

Corrections to records shall not be made by erasure, deletion, or obliteration. Corrections shall be made using strikethrough followed by the correct value and the initials of the employee who makes the correction. Equivalent measures shall be taken to avoid loss or change of original data in FA.

4.13.2.3.1 Initials

Any changes or additions to hard copy documentation shall be initialed by the employee making the change or addition.

4.13.2.3.2 Changes to Electronic Records

Changes made to electronic records shall be tracked in FA.

4.13.2.4 Case Records

Documents shall be maintained in the Laboratory Case Record as provided in the Procedure for Evidence Management and Section procedures.

4.13.2.5 Supporting Documentation

Examination documentation shall be such that, in the absence of the analyst, another qualified Forensic Scientist could evaluate the examinations performed and interpret the data.

4.13.2.5.1 Latent Print Documentation

Examination documentation in the latent print discipline shall meet the criteria as described in the ASCLD/LAB-*International* Appendix C – Latent Prints Examination Records and FQS FRA 4 Forensic Requirements for Agencies that Perform Latent

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Print Testing and are accredited to ISO/IEC 17025 (see Latent Evidence Section procedures).

4.13.2.5.2 Operating Parameters

When instrumental analyses are conducted, the operating parameters shall be recorded.

4.13.2.6 Identification of Documentation

The Laboratory Case number and the handwritten initials (or secure electronic equivalent of case number, initials or signature in FA) of the Forensic Scientist shall be associated with the examination documentation.

4.13.2.7 Employee Identification

When examination documentation is prepared by an employee other than the reporting Forensic Scientist (e.g., a technician), the work performed shall be documented in FA and reviewed by the reporting Forensic Scientist as provided in the Procedure for Record and Data Management.

4.13.2.8 Administrative Documentation

Administrative documentation may include scanned copies of Request for Examination forms; internal chain of custody documents; Forensic Scientist statement of qualifications (CV); notes and logs of case-related communications; subpoenas; discovery records; and other pertinent non-technical information related to the Case Record.

The Laboratory Case number shall be on the first page of scanned administrative documents. For bound multi-page documents, the first page of the document shall be identified and an inclusive page numbering system shall be used.

4.13.2.9 Multi-case Printout Identification

When data from multiple cases is recorded on a single printout, the Laboratory Case number for each case for which data was generated shall be recorded on the printout.

4.13.2.10 Treatment of Two-sided Documents

When information is recorded on the front and back of an examination document, each side shall be treated as a separate page (initialed and identified with the Laboratory Case number).

4.13.2.11 Permanence

Examination documents shall be of a permanent nature. Handwritten case documentation shall be made in ink.

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4.13.2.12 Confirmation of Identification

When an independent check of a critical finding is necessary, it shall be conducted by a qualified Forensic Scientist. The review shall be documented to indicate the critical finding has been checked and agreed to by the reviewer and the date of the review shall be included. If there is not a qualified employee within the Laboratory to confirm a critical finding, a deviation shall be requested in accordance with the Procedure for Authorizing Deviations.

4.13.2.13 Abbreviations

Abbreviations and symbols used in examination records shall be clearly defined. Laboratory Sections shall maintain a list of common abbreviations and/or symbols that are used by their personnel.

4.14 Internal Audits

4.14.1 General

Internal audits are conducted to verify that operations continue to comply with management system and accreditation requirements. Internal audits shall be conducted according to a schedule included in the Procedure for Conducting Audits and Management Reviews. The internal audit program shall address all elements of the management system, including testing activities.

4.14.1.1 Audit Frequency

All Sections of the laboratories shall be audited at least once per calendar year.

4.14.1.2 Records Retention

Internal audit records shall be retained according to the record retention schedule as set forth by the North Carolina Department of Cultural Resources.

4.14.2 Corrective Action

Audit findings that question the effectiveness of operations or validity of test results shall be reviewed according to the Procedure for Corrective Action and Non-Conformities**.**

4.14.3 Audit Records

The area of activity audited, the audit findings, and resulting corrective action shall be recorded according the Procedure for Conducting Audits and Management Reviews.

4.14.4 Follow-up Audit Activities

As part of the management review process, follow-up audit activities shall be conducted to verify and record the implementation and effectiveness of the corrective action.

4.14.5 Notification

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The Laboratory shall submit reports of each annual audit to the accrediting body within the time period required by the accrediting body.

4.15 Management Reviews

4.15.1 General

Laboratory management shall conduct an annual review according to the Procedure for Conducting Audits and Management Reviews to determine if the Laboratory's Quality System and operational activities remain suitable and effective and to introduce any necessary changes and improvements

4.15.1.1 Review Frequency

Management reviews shall be conducted at least once per calendar year. This planned review does not preclude management from reviewing operational activities throughout the year.

4.15.1.2 Records Retention

Management reviews shall be documented through memo to the Lab Director and the documentation shall be retained by the Quality Manager according to the record retention schedule as set forth by the North Carolina Department of Cultural Resources.

4.15.2 Documentation

The review, findings from the review, and any corrective and preventive actions that arise from those findings shall be documented as provided in the Procedure for Conducting Audits and Management Reviews. An agreed upon schedule to complete the actions shall be established. Non-conformities identified through the management review process shall be documented and remediated through the Procedure for Corrective Action and Non-Conformities.

5.0 Technical Requirements

5.1 General

5.1.1 Factors affecting the correctness and reliability of the analyses performed by the Laboratory include contributions from trained personnel; accommodation and environmental conditions; validated test methods and method selection; properly maintained and calibrated equipment and instruments; and measurement uncertainty and traceability.

5.1.2 Contribution to Total Uncertainty of Measurement

The factors noted above in Section 5.1.1 shall be considered in determining total measurement uncertainty; developing technical procedures; training and qualification of personnel; and selecting equipment and instrumentation utilized.

5.1.3 Reliability of Reagents

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Laboratory Sections shall have procedures for routinely checking the reliability of reagents.

5.1.3.1 Reagent Preparation

Reagents prepared in the Laboratory shall be labeled according to the Safety Manual. Labeling, at a minimum, shall identify contents, date of acquisition or preparation, and date of expiration. Records maintained by the Sections shall identify lot numbers, preparer of the reagent, and the results of reliability testing. Section procedures may establish additional requirements regarding the preparation of reagents. Reliability testing of all reagents shall occur prior to use.

5.2 Personnel

5.2.1 Personnel Competence

Management shall ensure that personnel have the knowledge, skills, abilities, experience and training to perform assigned duties and shall document competence and qualification in employee records. These records shall be detailed to demonstrate that an employee has been properly trained and that his/her ability to perform tests has been formally evaluated.

5.2.1.1 Training Program

Each case working Section shall have a documented training program that is used to develop the knowledge, skills, and abilities required to perform forensic examinations. The requirements for the training program shall be found in the Procedure for Personnel Training.

5.2.1.2 Moot Court

Prior to qualification, Forensic Scientist trainees shall undergo moot court/oral review board training in their respective discipline(s) or sub-discipline(s) according to the Procedure for Personnel Training.

5.2.1.3 Core Forensic Training

Training shall include the application of ethical practices in forensic sciences, a general knowledge of forensic science, and all applicable civil and criminal laws and procedures.

5.2.1.4 Certification

Forensic science professionals at the Laboratory shall be required to obtain individual certification consistent with international and ISO standards within eighteen months of the date the analyst becomes eligible to seek certification according to the standards of the certifying entity unless no certification is available. All forensic science professionals shall have access to the certification process.

5.2.2 Goals for Education, Training and Skills

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Management shall establish goals for the continuing education and training of all personnel to meet the present and anticipated needs of the Laboratory. Case working Sections shall identify training needs; provide this training to personnel; and evaluate the effectiveness of this training. Management and employees are jointly responsible for the establishment, pursuit, and achievement of educational goals for professional advancement.

Personnel shall be trained and knowledgeable in their tasks. New personnel shall participate in formalized training and demonstrate competency before beginning independent casework. Experienced Laboratory personnel shall participate in a program of continuing education. Each Section shall maintain the training record for assigned employees.

An annual performance evaluation is required for each full-time employee. The evaluation of full-time employees shall be documented according to the North Carolina Department of Justice Human Resources policy.

5.2.3 Employees and Contracted Personnel

The Laboratory utilizes the skills and talent of full-time employees and those qualified personnel who are under contract. Supervision, training, and competence shall be documented for all contracted and additional technical and key support personnel.

5.2.4 Job Descriptions

The Laboratory shall maintain active job descriptions for managerial, technical, and key support personnel. Job descriptions shall include the following:

- Knowledge, skills and abilities (KSAs).
- Minimum educational requirements.
- Level and type of experience.
- Required certifications.
- Core job responsibilities.

A copy of the current job description for each position shall be maintained in the personnel file of each employee. The original of each job description shall be maintained by the Department of Justice Human Resources Department.

Each Forensic Scientist Manager shall maintain on the Section shared drive a current Statement of Qualifications (CV) for Section Forensic Scientists and technical support staff and shall update the CV at least annually.

5.2.5 Management Authorization

Upon successful completion of approved training programs, management shall authorize personnel to perform forensic analysis, issue reports of analyses, give opinions and interpretations, and operate particular types of equipment.

Each Section shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

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5.2.6 Forensic Scientist/Technical Personnel Qualifications

5.2.6.1 Education

5.2.6.1.1 Forensic Scientists working in the Controlled Substances (Drug Chemistry) and Trace disciplines of forensic science in the Laboratory shall possess a baccalaureate or an advanced degree in a natural science or closely related field.

5.2.6.1.2 Forensic Scientists working in the Toxicology discipline of forensic science in the Laboratory shall possess a baccalaureate or an advanced degree in a natural science or closely related field.

5.2.6.1.3 Forensic Scientists working in the Biology discipline of forensic science in the Laboratory shall possess a baccalaureate or an advanced degree in a natural science or a closely related field and, if performing DNA analysis and where applicable, shall meet the education requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories.

5.2.6.1.4 Forensic Scientists working in the Latent Evidence, Digital Evidence and Firearm & Tool Mark disciplines in the Laboratory shall meet the educational requirement(s) specified in the job description (i.e., a baccalaureate or an advanced degree with science courses).

5.2.6.1.5 Technicians working in the Laboratory shall meet the educational requirement(s) specified in the job description.

5.2.6.2 Competency Testing

5.2.6.2.1 Forensic Scientists, regardless of education or past work experience, shall satisfactorily complete a competency test in each category of analysis prior to assuming casework responsibilities.

5.2.6.2.2 Competency testing of employees shall include at a minimum:

- Examination of unknown samples to cover the anticipated spectrum of duties and to evaluate the ability to perform proper analyses.
- Preparation of a written report to demonstrate the ability to convey results and/or conclusions and the significance of those results and conclusions accurately.
- Completion of a written or oral examination to assess knowledge of the discipline, analysis or task being performed.

5.2.7 Library Resources and Reference Material

The Laboratory and each Section shall maintain a library and internet service to provide access to forensic science resources such as books, journals, articles, and other information.

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5.3 Facilities and Environmental Conditions

5.3.1 Facilities and Environmental Conditions

The Laboratory shall provide safe and secure facilities for employees, equipment, supplies and evidence. The facilities shall be designed to provide space, engineering controls, and proper environmental conditions for optimal sample storage, handling, and analysis, in accordance with general laboratory practices and applicable federal, state and local regulations.

The Laboratory shall monitor critical environmental conditions to ensure that results of tests and the quality of measurement are not adversely affected or invalidated. Test methods shall include instructions addressing applicable environmental conditions, including energy sources, lighting, biological sterility, dust, humidity, and temperature.

Employees shall be aware of environmental conditions that may affect the results of tests conducted at a site other than a permanent facility and extreme care shall be taken when tests or examinations are conducted at such locations. Section technical procedures shall document the environmental conditions that may affect the results of tests performed outside the Laboratory and any precautions that shall be utilized.

5.3.2 Monitoring

If environmental conditions affect the quality of an examination, Sections shall monitor, control, and record those conditions as required by Section technical procedures. Analysis shall be stopped when environmental conditions jeopardize test results or adversely affect quality control.

5.3.3 Cross-contamination

Separate areas shall be maintained for incompatible activities. Measures to prevent cross-contamination shall be documented in Section procedures.

5.3.4 Access

Facilities shall be limited access areas. Access shall be controlled by issuing employee identification badges/keys/keycards for entrance; escorting visitors; using a visitor sign-in log; and/or using security guards or police services.

5.3.4.1 Laboratory Security

Laboratory policies and/or procedures for security shall be provided in the Procedure for Laboratory Security. The Safety Manager shall be responsible for ensuring that security guards or police services are familiar with security policies and practices. These policies and practices shall ensure that:

- Access to operational areas is controlled and limited and visitors do not have unrestricted access to these areas of the Laboratory.
- All exterior entrance/exit points have badge readers and/or closed circuit television is used to monitor and enforce security.
- Internal areas requiring limited/controlled access have a lock system.

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- Accountability of all access keys is documented and access is limited to those individuals designated by the Lab Director or designee.
- Facilities are monitored during vacant hours by an intrusion alarm or by security personnel.
- Main evidence storage areas shall be limited, controlled access areas and shall be secured by intrusion detection and lock systems. The storage conditions shall be such as to prevent loss, deterioration, and contamination to maintain the integrity of evidence. Security measures apply both before and after examinations/analyses have been performed.

5.3.5 Housekeeping

Housekeeping measures to prevent the contamination of evidence and to facilitate Laboratory operations shall be conducted as specified in the Procedure for Facilities and Environmental Conditions and the Chemical Hygiene Plan and Hazardous Waste Management Plan. When necessary, Sections shall create special housekeeping procedures to ensure the quality of examinations.

5.3.6 Health and Safety Program

The Laboratory Safety Manual documents the health and safety program. The Laboratory shall maintain safety training records, safety inspection records, and documentation of preventive actions.

5.4 Technical Procedures and Procedure Validation

5.4.1 General

Each Section's technical procedures for the examination of forensic evidence shall be generally accepted and utilized by the scientific community. Each technical procedure, in combination with validation and other applicable records, shall contain detail to demonstrate scientific validity as provided in the Procedure for Validation of Technical Procedures.

Case working Sections shall have and use written technical procedures for all examinations within their scope. Procedures shall include sample selection, handling, transfer, storage, and preparation of evidence to be examined. Where required, procedures shall include an estimation of the measurement uncertainty; statistical techniques for the analysis of examination data; and limitations of the procedure to include any quality-affecting environmental conditions. All technical procedures shall be reviewed and authorized prior to implementation. Sections shall ensure that technical procedures, standards, manuals, and reference data are current and readily available to personnel.

Case working Sections shall have procedures for the use and operation of all relevant equipment and for the handling and preparation of evidence for examination. Any deviations from a technical procedure shall be documented, justified, and authorized according to the Procedure for Authorizing Deviations.

5.4.2 Selection of Technical Procedures

Forensic Scientists shall select technical procedures which meet the needs of the submitter and which are appropriate for the tests to be performed. The Laboratory shall inform the

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submitting agency of the method chosen and shall select the method if not selected by the submitter.

The Laboratory shall select procedures that have been published in regional, national or international standards; by reputable technical organizations; in relevant scientific texts or journals; or as specified by the manufacturer of the equipment. The Laboratory shall ensure use of the latest valid edition of a standard technical procedure unless it is not possible to do so. The standard procedure shall be validated and supplemented with additional details to ensure consistent application. The Laboratory shall confirm that it can properly use a standard procedure prior to introducing it for forensic examinations. Confirmation shall be repeated if the standard procedure changes.

Procedures developed in the Laboratory or adopted by the Laboratory may also be used. Prior to use, all technical procedures shall be fully validated and documented as provided in the Procedure for Validation of Technical Procedures.

Infrequently performed tests or analyses are those that are performed less than once in a twelve month period. Infrequently performed tests or analyses shall have verification of positive and negative controls completed prior to examination. The verification shall be documented in the case file.

5.4.3 Laboratory-Developed Procedures

If a Section develops a technical procedure for its own use, the procedure shall be validated according to the Procedure for Validation of Technical Procedures.

5.4.4 Non-standard Procedures and Deviations from Technical Procedures

Non-standard procedures may be selected for use when a customer request cannot be addressed by the use of a standard procedure. Prior to use, non-standard procedures shall be validated according to the Procedure for Validation of Technical Procedures. Changes to, or deviations from, a technical procedure shall be approved according to the Procedure for Authorizing Deviations.

5.4.5 Validation of Procedures

5.4.5.1 Definition

Validation is the confirmation by examination and the provision of objective evidence that the particular specifications for an intended use are fulfilled. Validation studies shall be conducted on all new technical procedures used for the analysis of evidence. Validation includes specification of the requirements; a determination of the characteristics of the procedures; a check that the requirements can be fulfilled by using the procedure; and a statement on the validity.

5.4.5.2 Procedures Requiring Validation

The Laboratory shall validate to the extent necessary any non-standard procedures, Laboratory developed procedures, standard procedures used outside their intended scope and amplifications and modifications of standard procedures to confirm the procedure is suitable for the intended use. Sections shall maintain records of the

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validation including, but not limited to, the procedure used, the results, and a statement as to whether the procedure is suitable for its intended use.

5.4.5.3 Scope and Accuracy

The scope and accuracy of the values obtainable from validated procedures shall be relevant to the submitting agency's needs.

5.4.5.4 Method Verification

Prior to applying a new technical procedure to the examination of evidence, the reliability of the procedure shall be demonstrated against any documented performance characteristics. Records of this performance verification shall be maintained according to the Procedure for Validation of Technical Procedures.

5.4.6 Estimation of Uncertainty of Measurement

5.4.6.1 Procedure for Calibrations

The Laboratory does not perform calibrations.

5.4.6.2 Procedure for Testing

Technical procedures shall include considerations for estimating the uncertainty of measurement for barrel length, overall firearm length, drug weight (net only), alcohol/acetone quantitation, and reported drug quantitation (Drug Chemistry and Toxicology). If the nature of the examination procedure precludes a metrologically and statistically valid calculation of uncertainty of measurement, the case working Sections shall attempt to identify all the components of uncertainty and produce a reasonable estimate. The degree of rigor in an estimation of uncertainty of measurement depends on factors such as:

- The requirements of the test procedure.
- The existence of limits on which decisions on conformity to a specification are based.

Estimation of uncertainty of measurement shall be based on knowledge of the performance of the method, previous experience and validation data as well as any significant parameters that affect the measurement result. Records shall be maintained by the case working Sections to describe the process used to develop the estimation of uncertainty.

The Firearm and Tool Mark, Drug Chemistry, and Toxicology disciplines shall identify each technical procedure in which uncertainty of measurement may be required. A quantitative numerical measurement result for a measurement that matters shall be included in a Laboratory Report and the uncertainty of measurement (when established) shall be reported clearly.

5.4.6.3 Uncertainty Components

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When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account. Contributors to uncertainty include, but are not limited to, reference standards and reference materials used; methods and equipment used; environmental conditions; properties and condition of the item being tested; and the employee performing the test and estimate.

5.4.7 Control of Data

5.4.7.1 Calculations and Data Transfers

Case working Sections shall ensure that manual calculations and data transcriptions are checked for accuracy before a report is issued. All forensic case examinations shall be reviewed technically and administratively according to the Procedure for Reviewing Laboratory Reports.

5.4.7.2 Electronic Data Transfer and Integrity

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, case working Sections shall ensure that:

- Computer software developed in-house is documented, evaluated and validated prior to use.
- Procedures shall be established and implemented for the protection of data. Procedures include, but are not limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing.
- Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions to maintain the integrity of testing and data.
- Commercial off-the-shelf software in general use within the designed application range may be considered to be validated.

5.4.7.2.1 Digital Evidence

Unauthorized access of computer systems used for examining digital evidence shall be prevented.

5.5 Equipment

5.5.1 Laboratory Equipment

The Laboratory shall maintain sample preparation, measurement and analysis equipment for the correct performance of forensic analyses. In those cases where the Laboratory needs to use equipment outside of its permanent control, it shall ensure that International standards are met. The Laboratory shall maintain ancillary equipment for processing samples and for processing data. Equipment purchases shall conform to the Procedure for Procurement and Receipt. Maintenance contracts shall be established as needed by the Assistant Director or designee. The Laboratory shall maintain an inventory of all equipment used to perform testing.

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5.5.2 Equipment Capability

Equipment and its software used for testing, calibrating and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the testing and/or calibrations concerned. Laboratory equipment shall have a maintenance and calibration schedule and performance checks shall be performed to verify that the equipment meets the Section's specifications according to the Procedure for Procurement and Receipt. All equipment shall be calibrated or checked prior to being placed into service and supporting documentation shall be maintained.

5.5.3 Authorized Operation

Equipment shall be operated by authorized personnel. Authorization shall be determined according to the Procedure for Personnel Training based upon work assignment, training, experience, and demonstrated competency. Up-to-date manuals on the operation and maintenance of equipment shall be maintained and shall be readily available to personnel as provided in the Procedure for Equipment Calibration and Maintenance.

5.5.4 Equipment Identification

Each item of equipment and related software used for testing and significant for analysis shall be uniquely identified. This may be accomplished through a property number, an identification number that is unique to each instrument, or through some other naming method.

5.5.5 Equipment Records

As provided in the Procedure for Equipment Calibration and Maintenance, each Section shall maintain records of all equipment and related software significant for analysis.

5.5.6 Management of Equipment

Each Section shall have procedures for the safe handling, transport, storage, use, and planned maintenance of equipment to ensure proper functioning and to prevent contamination or deterioration.

5.5.7 Equipment Out of Service

Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits shall be taken out of service, isolated and/or clearly labeled as provided in the Procedure for Equipment Calibration and Maintenance. The equipment shall be returned to service only when shown by calibration or performance check to operate correctly. Laboratory personnel shall examine the effect, if any, of the malfunction on analysis results and implement the Procedure for Corrective Action and Non-Conformities as required.

5.5.8 Calibration Status

Equipment requiring calibration shall be labeled or coded to indicate the calibration status as provided in the Procedure for Equipment Calibration and Maintenance.

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5.5.9 Equipment Leaving the Laboratory

If equipment leaves the direct control of the Laboratory, the function and calibration status of the equipment shall be checked and shown to be satisfactory before being returned to service as provided in the Procedure for Equipment Calibration and Maintenance.

5.5.10 Calibration Confirmation

Intermediate calibration confirmation checks (quality control checks) performed to maintain confidence in the calibration status of the equipment shall be conducted according to the Procedure for Equipment Calibration and Maintenance.

5.5.11 Correction Factors

Where calibrations give rise to a set of correction factors, the Section shall ensure copies (e.g. in computer software) are correctly updated and are made available to personnel.

5.5.12 Safeguards

Test equipment, including hardware and software, shall be safeguarded from adjustments which would invalidate test results.

5.6 Measurement Traceability

5.6.1 General

Equipment shall be calibrated or its performance verified (1) before being placed into service for forensic analysis, (2) as scheduled, and (3) following repairs. Procedures for equipment calibration are provided in the Procedure for Equipment Calibration and Maintenance and in each Section's procedures**.**

5.6.1.1 Calibration Intervals

Calibration or performance check intervals for each instrument requiring calibration shall be established. Intervals shall generally not be longer than the manufacturer's recommendations; however, instruments that are not calibrated or performance checked according to the manufacturer's recommended interval shall be calibrated or performance checked prior to use. Section personnel shall check the calibration and/or performance after a power shut down, whether deliberate or otherwise. Instrument calibration shall be checked following service or other substantial maintenance.

5.6.2 Specific Requirements

5.6.2.1 Calibration – Requirements for Contracting Metrologists

The Laboratory is not a calibration laboratory.

5.6.2.2 Testing

5.6.2.2.1 Testing and Calibration

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If calibration is a significant component of measurement uncertainty, case working Sections shall establish traceability to the International System of Units (SI units) for the calibration. If it has been established that the associated contribution from the calibration contributes little to the total uncertainty, Sections shall ensure that the instrument used can provide the necessary uncertainty of measurement.

Sections that perform internal calibrations of instrumentation shall establish traceability by a means of an unbroken chain of calibrations or comparisons linking the calibration standards to the relevant primary standards of the SI units of measurement.

When necessary, Sections shall utilize competent external calibration services that can demonstrate measurement capability and traceability. The calibration certificates issued by these entities shall contain the calibration results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

5.6.2.2.2 Non-traceability to SI Units

Where traceability of measurements to SI units is not possible and/or not relevant, Sections shall establish traceability to other measurement standards such as certified reference materials or reference standards.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards

The Laboratory shall ensure that reference standards are calibrated by an organization that provides traceability to SI Units as provided in the Procedure for Equipment Calibration and Maintenance. The reference standards shall be used for calibration only and calibrated before and after any adjustment.

5.6.3.2 Reference Materials

Where possible, reference materials shall be traceable to SI units of measurement or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

5.6.3.2.1 Reference Collections

Reference collections of data or items/materials encountered in casework which are maintained for identification, comparison or interpretation purposes shall be fully documented, uniquely identified and properly controlled.

5.6.3.3 Intermediate Confirmation of Calibration Status

In order to maintain confidence in the calibration status, intermediate checks shall be performed on reference standards and reference materials as provided in the

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Procedure for Equipment Calibration and Maintenance and Section technical procedures.

5.6.3.4 Transport and Storage

In order to prevent contamination or deterioration, and to protect the integrity of reference standards and reference materials, the safe handling, transport, storage and use of reference standards and reference materials shall be conducted as provided in the Procedure for Equipment Calibration and Maintenance and Section technical procedures.

5.7 Sampling

Sampling is the testing of a representative sample of a substance, material or item and reporting on the whole substance, material or item.

5.7.1 Sampling Plans

Each Section utilizing sampling shall include in the technical procedures a plan for the sampling of evidence. Sampling plans shall be based on statistical methods whenever reasonable. The sampling plans shall address the factors to be controlled to ensure the validity of the test results and shall be available where sampling is undertaken.

5.7.2 Sampling Deviations

If the submitter or the nature of the evidence requires deviation or exclusion from the sampling plan described in the technical procedures, the deviation shall be documented as provided in the Procedure for Authorizing Deviations.

5.7.3 Sampling Procedures

Sections shall document the sampling data in the Case Record and shall include the sampling procedure, the identification of the sampler, relevant environmental conditions, diagrams of the sampling location as necessary and, if relevant, the statistical basis for the sampling procedures.

5.8 Handling of Items of Evidence

5.8.1 Items of Evidence

In order to ensure the integrity of evidence and to protect the interests of the Laboratory and the customer, the transportation, receipt, handling, protection, storage, retention, and/or disposal of samples shall be conducted as provided in the Procedure for Evidence Management.

5.8.1.1 Chain of Custody

The electronic Chain of Custody Log in FA shall document receipt of evidence and all internal transfers of evidence. The chain of custody shall be documented initially on the Request for Examination or by electronic receipt. The chain of

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custody shall include the date of receipt or transfer and a description or unique identifier of the evidence.

5.8.1.1.1 Subdivision of Evidence

When evidence is sub-divided in the Laboratory, sub-items shall be identified and tracked as provided in the Procedure for Evidence Management.

5.8.1.1.2 Proper Seals

All evidence accepted and stored shall be properly sealed according to the Procedure for Evidence Management.

5.8.2 Identification of Items of Evidence

The Laboratory shall maintain a system for uniquely identifying and tracking items of evidence as provided in the Procedure for Evidence Management. The unique identifier shall be retained throughout the life of the item in the Laboratory.

5.8.3 Departures, Additions or Exclusions

Upon receipt of the item, abnormalities or significant departures from normal or specified conditions (i.e., analysis requested and chain of custody) are recorded according the Procedure for Evidence Management. When items do not meet the established acceptance criteria, personnel shall consult with the submitter for further instructions before proceeding with analysis.

5.8.4 Protection of Items during Processing and Storage

Evidence shall be protected from deterioration, loss, cross-transfer or damage during storage, handling and processing as provided in the Procedure for Evidence Management. Handling instructions provided with the evidence shall be followed. When items must be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where evidence is to be held secure, the Laboratory shall provide for storage and security that protects the condition and integrity of the evidence.

5.8.4.1 Maintenance

All evidence not in the process of examination/analysis shall be maintained under proper seal in a secured, limited-access storage area.

5.8.4.2 Security of Unattended Evidence

All evidence which is being processed but is unattended shall be secured as provided in the Procedure for Evidence Management.

5.8.4.2.1 Definition of Examination

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As defined in the Procedure for Evidence Management, the time period for active examination shall not be open-ended and shall be based upon a justifiable expectation of frequent examination/analysis.

5.8.4.3 Unique Identification of Evidence

Each item of evidence shall be marked, either by hand or with a FA-generated barcode, to ensure that it is uniquely identifiable and traceable to the Laboratory case number. If the evidence does not lend itself to marking, its proximal container or identifying tag shall be marked.

5.8.4.4 Photography and Digital Evidence

When evidence, such as latent prints and impressions, can only be recorded or collected by photography or digital capture and the print or impression itself is not recoverable, the photograph, negative or digital image of the print or impression shall be treated as evidence.

5.8.4.5 Crime Scene Evidence

Evidence collected by Laboratory personnel from a crime scene shall be protected from loss, cross-transfer, contamination and/or deleterious change whether in a sealed or unsealed container during transportation to the Laboratory or other evidence facility as provided in the Procedure for Evidence Management. Further processing to preserve, evaluate, document, or render evidence safe shall be accomplished prior to final packaging. Additionally, crime scene evidence shall be properly identified, packaged, and entered into the Laboratory evidence control system as soon as possible as provided in the Procedure for Evidence Management.

5.8.4.6 Individual Characteristic Database Procedures

Sections shall have procedures for the operation of individual characteristic databases.

5.8.4.6.1 Declaration of Individual Characteristic Database

Individual characteristic databases are collections of items which can be uniquely associated with an object or person or associated to a high degree of probability (e.g., fingerprints of known individuals, reference bloodstains, test-fired ammunition).

Section technical procedures shall establish whether individual characteristic database items are treated as evidence, reference materials, or examination documentation. Individual characteristic database samples treated as evidence shall meet chain of custody, evidence sealing and protection, evidence storage, and evidence marking requirements. Individual characteristic database samples not treated as evidence shall meet the criteria set out in sub-sections 5.8.4.6.2 through 5.8.4.6.4.

5.8.4.6.2 Identification

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Individual characteristic database samples shall be uniquely identified.

5.8.4.6.3 Sample Protection

Individual characteristic database samples shall be protected from loss, cross transfer, contamination and/or deleterious change. Individual characteristic database samples shall be treated in a manner that reasonably ensures their utility as comparison samples.

5.8.4.6.4 Access

Access to individual characteristic database samples shall be restricted to those persons authorized by the Lab Director.

5.9 Ensuring the Quality of Test Results

5.9.1 Quality Control Procedures

Quality control procedures for monitoring the validity of tests shall be provided in the Procedure for Ensuring the Quality of Test Results. Resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.

5.9.1.1 Use of Controls and Standards

Technical procedures shall specify standards and controls and the use of standards and controls shall be recorded in the Case Record.

5.9.2 Quality Control Data

Sections shall define the criteria for evaluating quality control data. When data is found to be outside the established criteria, action shall be taken in accordance with Section technical procedures.

5.9.3 Proficiency Testing

The Laboratory proficiency testing program shall be documented in the Procedure for Ensuring the Quality of Test Results. Proficiency testing applies to Forensic Scientists and technicians in each discipline and sub-discipline in which casework is performed.

5.9.3.1 Proficiency Test Technical Procedures

When working proficiency tests, Forensic Scientists shall follow the approved technical procedures.

5.9.3.2 Proficiency Testing Program Compliance

The Laboratory proficiency testing program shall comply with the requirements of the accrediting body.

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5.9.3.3 Proficiency Timetable

All Forensic Scientists and technicians engaged in testing activities shall successfully complete at least one internal or external proficiency test per calendar year in his/her forensic science discipline(s).

5.9.3.3.1 DNA Proficiency Tests

Forensic Scientists and technicians performing DNA analysis shall comply with the proficiency test requirements of the *Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories*.

5.9.3.3.2 Proficiency Testing in Sub-disciplines

Forensic Scientists and technicians shall successfully complete at least one proficiency test during each four year accreditation cycle in each category of testing appearing on the Laboratory's Scope of Accreditation in which the Forensic Scientist or technician performs testing.

5.9.3.4 Use of Approved Proficiency Test Providers

The Laboratory shall participate annually in at least one external proficiency test for each forensic science discipline in which it conducts testing. Proficiency test providers approved by the accrediting body shall be used whenever available. If an approved test provider is not available for a particular discipline or sub-discipline, the Laboratory shall administer a proficiency test as provided in the Procedure for Ensuring the Quality of Test Results.

5.9.3.5 Proficiency Test Maintenance

The Laboratory shall maintain proficiency testing records as provided in the Procedure for Ensuring the Quality of Test Results.

5.9.3.6 Retention of Proficiency Tests

Proficiency testing records shall be retained by the Laboratory as provided in the Procedure for Ensuring the Quality of Test Results.

5.9.4 Technical Reviews

Technical reviews of examination records and Reports of Examination shall be conducted as provided in the Procedure for Reviewing Laboratory Reports. Section technical procedures may contain additional requirements for conducting and documenting technical reviews.

5.9.4.1 Technical Review Specifications

Each technical review shall be conducted to ensure at least the following:

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- Conformance with technical procedures and Laboratory policies and procedures.
- Accuracy of the Laboratory Report and that the data support the results and/or conclusions in the report.
- Proper qualifications in the Laboratory Report.
- Provision of all required information in the Laboratory Report.

5.9.4.2 Technical Reviewer Qualifications

Technical reviews shall be conducted by personnel authorized by Laboratory management based on expertise gained through training and experience in the forensic discipline or sub-discipline being reviewed. The reviewer shall have knowledge of the Laboratory's technical procedures.

5.9.4.3 Identity of Reviewer

A technical review of a Laboratory Report shall not be conducted by the author or co-author.

5.9.5 Administrative Reviews

Administrative reviews of examination documentation and Laboratory Reports shall be conducted as provided in the Procedure for Reviewing Laboratory Reports. Section procedures may contain additional requirements for conducting and documenting administrative reviews. Administrative reviews shall not be conducted by the author or co-author of the report.

5.9.5.1 Administrative Review Specifications

Each administrative review shall include at least the following:

- A review of the Laboratory Report for spelling and grammatical accuracy.
- A review of all administrative and analysis records to ensure unique identification according to policies and procedures.
- A review of the Laboratory Report to ensure that all key information is included.

5.9.6 Monitoring of Court Testimony

The testimony of Laboratory personnel shall be monitored and evaluated as provided in the Procedure for Ensuring the Quality of Test Results. Feedback shall be provided to each employee by the Forensic Scientist Manager, Supervisor or designee who shall initiate remedial action(s) as necessary.

5.9.7 Retention of Court Testimony Monitoring

Records of testimony monitoring shall be retained by the Laboratory according to the record retention schedule as set forth by the North Carolina Department of Cultural Resources.

5.10 Reporting Results

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5.10.1 General

Laboratory personnel shall accurately, clearly, unambiguously, and objectively report the results of each examination as provided in the Procedure for Reporting Results.

5.10.1.1 Stop Work Cases

All submitted evidence shall be returned to the submitter as provided in the Procedure for Stop Work Orders. The policy for reporting adjudicated or terminated cases shall be provided in the Procedure for Reporting Results.

5.10.2 Reporting Results

Each Laboratory Report shall include the following information, as applicable:

- Title.
- Identification of the State Crime Laboratory performing the casework.
- Unique identification of the report, identification on each page and a clear indication of the end of the report.
- Name and address of the submitting agency.
- Type of analysis requested.
- Description of the items analyzed.
- Date of receipt of the items analyzed as well as the date of analysis.
- Test results, including the unit of measurement, if applicable.
- Name and signature of the individual authorized to report the results.
- Statement that the results relate only to the items analyzed, when relevant.

Any reference to the sampling plan or the identification of the method used shall be included in the Case Record.

5.10.3 Additional Requirements for Reports

5.10.3.1 Specific Requirements

The following additional information shall be included in reports when necessary for the interpretation of the analysis results:

- Deviations from, additions to, or exclusions from the test method, and information on test conditions, such as environmental conditions.
- A statement of conformance or non-conformance with requirements and/or specifications.
- A statement of the estimated uncertainty of measurement when applicable.
- Opinions and interpretations.
- Additional information that may be required by submitters.

5.10.3.2 Sampling Results

Laboratory Reports containing the results of sampling shall include additional information when it is necessary for the interpretation of the examination results as provided in the Procedure for Reporting Results.

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5.10.3.3 Issuance of Reports

Laboratory Reports shall be issued as provided in the Procedure for Reporting Results.

5.10.3.4 Review of Documentation

Forensic Scientists who issue findings, including writing reports and providing testimony, based on examination documentation generated by another person shall document the review of such examination documentation, as provided in the Procedure for Reviewing Laboratory Reports.

5.10.3.5 Significance of Associations

The significance of an association shall be communicated clearly and qualified properly in the Laboratory Report.

5.10.3.6 Negative Results or Eliminations

All eliminations shall be communicated clearly in the Laboratory Report.

5.10.3.7 Inconclusive Results

When a definitive conclusion cannot be reached, the reason shall be stated clearly in the Laboratory Report.

5.10.4 Calibration Certificates

The Laboratory does not conduct calibration activities and does not issue calibration certificates.

5.10.5 Opinions and Interpretations

All opinions and interpretations shall be clearly marked as such in the Laboratory Report. The basis for any opinions and/or interpretations shall be documented in the analysis Case Record.

5.10.6 Testing Results Obtained from Subcontractors

Subcontractors shall report their results to the Laboratory either in writing or electronically. Data or test results from subcontractors shall be clearly identified as such in a Laboratory Report.

5.10.7 Electronic Transmission of Results

The transmission of test results by telephone, facsimile or other electronic means shall be conducted as provided in the Procedure for Reporting Results.

5.10.8 Format of Report

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As provided in the Procedure for Reporting Results, the format of the Laboratory Report shall be designed to accommodate the type of test conducted and to minimize the possibility of misunderstanding or misuse.

5.10.9 Amendments to Report

Any amendments to analytical findings after issuance of the Laboratory Report shall be made in the form of an additional document. Amendments shall meet all reporting criteria and be flagged as an Amended Report as provided in the Procedure for Reporting Results.

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	Original Document
10/26/2012	2	Added 4.13.2.7.1, 4.13.2.7.2 and 4.13.2.7.3; Changed 4.13.2.8 to read scanned administrative documents; 5.8.1.1 - electronic equivalent changed to electronic receipt
12/07/2012	3	4.13.2.6 - changed sentence to read shall be associated with the examination documentation; 5.9.3.3.2 - changed to correspond with ISO/ASCLD critera
02/01/2013	4	4.7.2 - changed Assessing to Evaluating to correspond with name of procedure; 5.10.2 – updated wording; 5.3.4 - added key
03/08/2013	5	Added 4.13.2.5.2 - requirement for instrumental operating parameters
05/03/2013	6	4.2.1 - changed responsibility for duty from Section to Quality Control Officer; 5.4.2 - added documentation of infrequently performed test
05/10/2013	7	5.4.6.2 - added Drug Chemistry and Toxicology after reported drug quantitation; 5.9.3.3.2 - changed five year accreditation period to four; 5.10.2 - removed extra space
05/14/2013	8	4.3.2.3 – made consistent with Procedure for Document Control and Management
08/16/2013	9	5.10.1.1- revised to reflect consulting procedure for stop work orders; 5.10.9 – corrected typo
10/16/2013	10	Page 4 added operations manager; 4.1, 4.1.1, 4.1.2, 4.1.4, 4.1.5, 4.13.2.8, 5.8.1.1 removed SBI reference; 4.1.5 -

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		clarified technical leader appointment; 4.1.8 - defined top management; added issuing authority to header; added key management will appoint a designee in their absence
12/18/2013	11	4.1.5 - added DNA Technical Leader to bullet; 4.2.6.3 - added DNA Technical Leader responsibilities
01/24/2014	12	4.5.1 - clarified subcontractor required accreditation; 4.1.4 - changed SBI to Laboratory
2/27/2014	13	5.10.2 – deleted the requirement that address of laboratory and the title of the reporting analyst be included on the Laboratory Report
04/18/2014	14	4.5.1- removed defined within the scope of accreditation and added meet FBI, QAS standards
08/29/2014	15	3.0 – updated Lab Director; 4.1 – removed digital evidence; 4.1.5 – removed Administrative Services and SBI and categorized Deputy duties as administrative; 4.2.6.2 - Added bullet to include technical leader meetings and reports; 4.1, 5.2.6.1.1, 5.2.6.1.4,5.4.6.2 - corrected to reflect organizational change; 4.11.4 - added or designee.
12/19/2014	16	Throughout document: clarified roles of Lab Director, Assistant Director of Technical Operations, Assistant Director of Administrative Operations, and QM. Removed QCO responsibilities; 5.2.2 - removed performance reviews stored in personnel file; 5.3.4.1- removed SBI logistics requirement
02/27/2015	17	4.13.2.7 – added wording to clarify; 4.13.2.7.1, 4.13.2.7.2 and 4.13.2.7.3 – removed and incorporated into Procedure for Record and Data Management

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APPENDIX A

The Strategic Vision of the State Crime Laboratory is as follows:

The North Carolina State Crime Laboratory endeavors to be the most highly respected forensic laboratory in the United States. To this end, the Crime Laboratory employees shall produce work that meets and/or exceeds accreditation and certification standards with the highest level of competence. The Crime Laboratory shall maintain the highest accreditations achievable in the disciplines of Controlled Substances, Toxicology, Forensic Biology, Trace Evidence, Latent Evidence, Digital Evidence and Firearms & Tool Marks. All Forensic Scientists shall be of the highest possible ethical and educational standards and be certified in their respective forensic discipline by an external certifying agency.

The Laboratory is committed to integrity, honesty, thoroughness, openness, timeliness, and professionalism for the Criminal Justice System and the citizens of the State of North Carolina.

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APPENDIX B – Definitions

Accreditation – A process by which an authoritative body gives formal recognition that an entity meets or exceeds established standards or requirements.

Administrative documentation – Case Record materials which do not include technical records but may include scanned copies of additional Request for Examination Forms, internal chain of custody documents, Forensic Scientist statement of qualifications (CV), notes and communication logs of case-related conversations, subpoenas, records of discovery, and other pertinent information that is related to the Case Record but does not necessarily support the conclusions drawn.

Administrative review – A procedure that checks Case Record documentation and reports for consistency with Laboratory policy and for editorial correctness.

Amended report – A Laboratory Report which has been revised, corrected, or remediated after the original Laboratory Report has been issued.

Analysis – An examination of an item or comparison of items. Analysis is equivalent to the test and examination as used in this manual.

ASCLD/LAB-*International* – An accreditation program of ASCLD/LAB through which any crime laboratory may demonstrate that its management, technical operations and overall quality management system meet ISO 17025 requirements and ASCLD/LAB-*International* Supplemental Requirements.

Approved test provider – A proficiency test provider that has complied with the test manufacturing guidelines established by the ASCLD/LAB Proficiency Review Committees.

Audit – A planned and documented investigative evaluation to compare various aspects of the Laboratory's performance against established requirements, standards, policies, and procedures.

Calibrate – To adjust or standardize the accuracy of a measuring instrument, usually by comparison with a certified reference or standard.

Case file – The complete administrative and examination record of a forensic case generated prior to the implementation of Forensic Advantage (FA).

Case Record – The body of work completed for one examination in a case.

Cause – A deficiency that results in a non-conformity which must be corrected to prevent reoccurrence of the same or similar non-conformity.

Certified reference material (CRM) – A reference material, whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or documentation issued by a certifying organization.

Clean area – An area of the Laboratory which is kept free of open evidence and chemicals.

Complaint – An expression of dissatisfaction regarding quality of service.

Commercial reagent – A chemical purchased to conduct a specific forensic test.

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Competency test – The evaluation of an individual=s ability to conduct examinations in a forensic discipline or sub-discipline prior to the performance of independent casework.

Competent – Possessing the requisite knowledge, skills and abilities to perform a job.

Contract – A written agreement between a supplier and customer.

Control – A test performed to demonstrate that a procedure worked correctly and to ensure the validity of data.

Controlled document – A document issued and distributed in a manner that may be tracked.

Contributor – Agencies authorized by law to submit evidence to the Laboratory.

Convenience package – A container which is used to facilitate storage and/or transfer of sealed containers or items, but is not part of the chain of custody.

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.

Corrective Action Record (CAR) – Documentation by which non-conformities are identified, tracked, investigated, and corrected.

Crime Laboratory – A laboratory which examines physical evidence in criminal matters, issues test reports, and provides opinion testimony with respect to such physical evidence in a court of law.

Crime Laboratory Procedure – A controlled document describing the execution of policies in the Quality Manual.

Crime Laboratory Safety Manual – The controlled document describing the safety program at the State Crime Laboratory (i.e., protection of employees from hazardous chemicals, wastes, and bloodborne pathogens; evacuation in cases of fire, explosion, or natural disaster, etc.). It supplements the North Carolina Department of Justice Safety and Health Manual (DOJ Safety Manual) to meet the special conditions that are unique to the Laboratory.

Critical laboratory equipment – Analytical instrumentation and equipment affecting the accuracy or precision of a test method.

Critical reagents – Chemicals which affect the quality of tests and which have been determined by empirical studies or routine practice to require reliability testing on established samples before use on evidentiary samples.

Custody – The care and control of an item for its protection and preservation.

Data file – Related numeric, graphic or textual information that is organized in a strictly prescribed form and format.

Deviation – A departure from the standard method or technical procedure generally used in the analysis of evidence.

Discipline – A major area of casework for which a laboratory may seek accreditation.

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Document – Information in any medium including, but not limited to, paper copy, computer disk or tape, audio or video tape, electronic file, compact or digital video disc, photograph, overhead, photographic slide, etc.

Document Approval Attachment (DAA) – A form used to detail the development, change and/or approval of each controlled document.

Document control – Ensuring that documents and document revisions are reviewed for adequacy, approved for release by authorized personnel, and distributed for use.

Electronic record – Information recorded in a form that only a computer can process.

eProcurement system – The online method by which supplies, equipment, and services may be purchased and contracted by North Carolina government entities.

Evidence - An item submitted for analysis. An item of evidence is equivalent to a "test item" as described in ISO 17025.

Examination documentation – Records of tests conducted, standards and controls used, diagrams, printouts, photographs, spectra, chromatograms, hand-written notes and other material used by the Forensic Scientist to reach a conclusion.

External proficiency test – A test prepared by, provided by, and reported to a source outside the Laboratory.

Fact-finding – The preliminary process of gathering information on a complaint to determine whether a formal investigation is warranted.

Finding – An audit result stating non-compliance with accreditation criteria, and Laboratory policies or procedures.

Forensic Advantage (FA) – The current information management system used in the Laboratory.

Form – A document with a fixed arrangement of spaces designed for entering and extracting information.

FQS – Forensic Quality Services is an accrediting organization through which a crime laboratory may demonstrate that its management, technical operations and overall quality management system meet ISO 17025 standards.

Good practice – Operating practices and procedures for promoting quality and ensuring the integrity of the work product.

Incompatible – Activities or analyses which interfere or adversely affect other activities or analyses in the same area.

Intact seal – Closure of a package containing evidence by a taped, heat or other tamper-proof means in order to prevent loss, contamination or deleterious change while ensuring that attempted entry into the container is detectable.

Internal audit – An evaluation by Laboratory personnel to determine compliance with requirements of the QA manual and other Quality System documentation.

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Internal proficiency test – A test produced by the Laboratory in which the expected results are unknown to the Forensic Scientist.

Investigation – The process of determining the nature of a complaint in order to make an informed decision on the method of resolution.

Laboratory Director – The highest ranking manager within the Laboratory.

Laboratory Quality Manual – The controlled document which details management system policies related to quality.

Management review – An assessment by management of the Quality System to determine effectiveness, suitability, and future direction.

Management system – The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly.

Master list – The list identifying the current revision status and distribution of documents in the management system.

Material – The hardware, software media, raw materials or components used in the development or testing of samples.

Method – The course of action, procedure or technique followed in conducting a specific analysis or comparison leading to an analytical result.

Non-conformity – A non-fulfillment of a requirement of the Quality Management System.

Non-standard method – A scientifically-sound method that is not frequently used or well-documented; a method not included in Section technical procedures.

Notes – The documentation of procedures, standards, controls, instruments, observations, test results of tests performed, charts, graphs, photos, and/or other documents generated which are used to support the Forensic Scientist's conclusions.

Objective evidence – Information substantiated through examination, measurement, test, interview or other means.

Original report – The report resulting from the initial forensic analysis conducted on evidence.

Performance verification – The confirmation of the reliability of a previously validated method(s) or equipment.

Policy – A guiding principle, operating practice or plan of action governing decisions made on behalf of an organization.

Prepared reagent – A chemical generated within the Laboratory.

Preventive action – An endeavor to eliminate the cause of a potential nonconformity.

Proficiency test – A test to evaluate the continuing capability of Forensic Scientists and technicians and the performance of the Laboratory. The expected results of the test are unknown to those individuals taking the test.

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Proficiency test file – All documentation related to a proficiency test, either in paper or electronic format.

Proper seal – An intact seal with initials.

Quality Assurance – Those planned and systematic actions necessary to provide confidence that a Laboratory's product or service satisfies given requirements for quality.

Quality control – Internal activities, or activities conducted according to externally established standards, used to monitor the quality of analytical data and to ensure that it satisfies specified criteria.

Quality control checks – Periodic confirmation of the reliability of equipment, instrumentation, and/or reagents.

Quality Manager – The Deputy Assistant Director of the Laboratory who has the defined authority and obligation to ensure that the quality requirements of the management system are implemented and maintained.

Quality records – Documentation of the activities of the quality program including, but not limited to, records of corrective and preventive actions, reports from internal audits and management reviews, requests for deviation, and evaluation of testimony.

Quality System – The organizational structure, responsibilities, procedures, and resources for implementing quality control. This term is equivalent to Amanagement system@ as used in ISO 17025.

Reagent – A substance used because of its chemical or biological activity.

Records – Documentation of the activities of the Laboratory.

Re-examination of evidence – Retesting of evidence by a Forensic Scientist who has no knowledge of the original test results.

Reference material – A material or substance having known properties.

Reference standard – An object or substance which is used as a control or measurement base for similar objects or substances.

Request – The act of a submitter seeking analysis of evidence by the Laboratory.

Retraining – The process required when personnel assessments indicate less than satisfactory performance or when procedures are modified significantly.

Root cause – The fundamental reason for a quality issue that, if corrected, would prevent that issue from occurring.

Sampling – The testing of a representative portion of a substance, material or item and reporting on the whole substance, material or item.

Section Policy and Procedures – A controlled document which provides written guidance for the performance of administrative functions within the Section.

Section Technical Procedures – Controlled documents that provide detailed directions for the performance of technical duties.

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Section Training Procedures – Controlled documents which include specific components for the development of the skill set necessary to perform job functions.

Secured area – A locked space with access restricted to personnel authorized by the Lab Director or designee.

SI Units – The International System of Units; a system of units of measurement devised around seven base quantities assumed to be independent.

Standard method – A method that is traceable to a recognized and validated method within the scientific community.

Subcontractor – A competent outside forensic laboratory that conducts analyses for the Laboratory that are within the scope of the Laboratory=s accreditation.

Sub-discipline – A specific type of analysis within an accredited discipline of forensic science.

Supplies – The inventory necessary to perform the work processes of an organization.

Technical records – Accumulations of data and information which result from performing tests as specified in technical procedures. Technical records include, but are not limited to, forms, worksheets, photographs, and test reports.

Technical review – An in-depth review of examination records and test reports to ensure the validity of results and conclusions.

Technical support staff – Evidence technicians, forensic technicians, and database personnel who perform casework related duties within the Laboratory at the direction of a Forensic Scientist but who do not issue reports related to the conclusions reached.

Training checklist – The documentation prepared by the training coordinator that reflects the steps necessary for completion of an employee's training, dates of completion and the signatures/initials of the trainee and training coordinator.

Training coordinator –The experienced and qualified employee who oversees the training of others.

Training verification – The testing used to confirm an employee's training has been successful and that the employee is competent to perform procedures encompassed by the training.

Traceability – The linking of measurement standards and/or measuring instruments to relevant national or international standards through an unbroken chain of comparisons.

Uncertainty of measurement – A parameter associated with the result of a measurement that characterizes the distribution of values that could reasonably be attributed to that being measured. Sources contributing to the uncertainty include, but are not limited to, the operator, reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated.

Uncontrolled document – A document that is not issued and distributed in a manner that may be tracked.

Validation – The process of performing a set of experiments which establish the efficacy and reliability of a technique or procedure or modification thereof.

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Work area – Any area of the Laboratory in which chemicals are present or evidence is examined.

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APPENDIX C

ASCLD/LAB GUIDING PRINCIPLES OF PROFESSIONAL RESPONSIBILITY FOR CRIME LABORATORIES AND FORENSIC SCIENTISTS

"If the law has made you a witness,
Remain a man of science.
You have no victim to avenge,
No guilty or innocent person to convict or save --
You must bear testimony within the limits of science."

Dr. P.C.H. Brouardel
19th Century French Medico-legalist

Preamble

These Guiding Principles are written specifically for forensic scientists[i] and laboratory management. The concepts presented here have been drawn from other professional codes and suggestions made by leaders in the forensic community.[ii] The Guiding Principles have been vetted[iii] and adopted by the ASCLD/LAB Board of Directors and staff with the hope that laboratory management will use them in training sessions, performance evaluations, disciplinary decisions, and as guides in other management decisions. It is also important that all laboratory personnel, including forensic scientists and other laboratory employees who assist forensic scientists in their work, are equally aware of these Guiding Principles and support forensic scientists and managers by incorporating the principles into their daily work.

These Guiding Principles provide a framework for describing ethical and professional responsibilities in the forensic laboratory community. While not all inclusive, they describe key areas and provide some specific rules to supplement existing codes of ethics adopted by professional organizations and individual laboratories. The Guiding Principles are designed to promote integrity among practitioners, and to increase public confidence in the quality of laboratory services, whether or not the laboratory is accredited by any accrediting body.

ASCLD/LAB has adopted the ASCLD Guidelines for Forensic Laboratory Management Practices, many of which have been incorporated into the ASCLD/LAB accreditation standards. Those practices provide for management support of the guiding principles set forth below and are intended to create a culture of ethical behavior and professional responsibility within the laboratory. The ASCLD practices should be implemented and followed to give practical meaning to the Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists.

Professionalism

The ethical and professionally responsible forensic scientist and laboratory manager . . .

1. Are independent, impartial, detached, and objective, approaching all examinations with due diligence and an open mind.
2. Conduct full and fair examinations. Conclusions are based on the evidence and reference material relevant to the evidence, not on extraneous information, political pressure, or other outside influences.
3. Are aware of their limitations and only render conclusions that are within their area of expertise and about matters which they have given formal consideration.
4. Honestly communicate with all parties (the investigator, prosecutor, defense, and other expert witnesses) about all information relating to their analyses, when communications are permitted by law and agency practice.
5. Report to the appropriate legal or administrative authorities unethical, illegal, or scientifically questionable conduct of other laboratory employees or managers. Laboratory management will take appropriate action if there

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is potential for, or there has been, a miscarriage of justice due to circumstances that have come to light, incompetent practice or malpractice.

6. Report conflicts between their ethical/professional responsibilities and applicable agency policy, law, regulation, or other legal authority, and attempt to resolve them.
7. Do not accept or participate in any case on a contingency fee basis or in which they have any other personal or financial conflict of interest or an appearance of such a conflict.

Competency and Proficiency

The ethical and professionally responsible forensic scientist and laboratory manager . . .

8. Are committed to career-long learning in the forensic disciplines which they practice and stay abreast of new equipment and techniques while guarding against the misuse of methods that have not been validated. Conclusions and opinions are based on generally accepted tests and procedures.
9. Are properly trained and determined to be competent through testing prior to undertaking the examination of the evidence.
10. Honestly, fairly and objectively administer and complete regularly scheduled:
    - relevant proficiency tests;
    - comprehensive technical reviews of examiners' work;
    - verifications of conclusions.
11. Give utmost care to the treatment of any samples or items of potential evidentiary value to avoid tampering, adulteration, loss or unnecessary consumption.
12. Use appropriate controls and standards when conducting examinations and analyses.

Clear Communications

The ethical and professionally responsible forensic scientist and laboratory manager . . .

13. Accurately represent their education, training, experience, and area of expertise.
14. Present accurate and complete data in reports, testimony, publications and oral presentations.
15. Make and retain full, contemporaneous, clear and accurate records of all examinations and tests conducted, and conclusions drawn, in sufficient detail to allow meaningful review and assessment of the conclusions by an independent person competent in the field. Reports are prepared in which facts, opinions and interpretations are clearly distinguishable, and which clearly describe limitations on the methods, interpretations and opinions presented.
16. Do not alter reports or other records, or withhold information from reports for strategic or tactical litigation advantage.
17. Support sound scientific techniques and practices and do not use their positions to pressure an examiner or technician to arrive at conclusions or results that are not supported by data.
18. Testify to results obtained and conclusions reached only when they have confidence that the opinions are based on good scientific principles and methods. Opinions are to be stated so as to be clear in their meaning. Wording should not be such that inferences may be drawn which are not valid, or that slant the opinion to a particular direction.
19. Attempt to qualify their responses while testifying when asked a question with the requirement that a simple "yes" or "no" answer be given, if answering "yes" or "no" would be misleading to the judge or the jury.

[i]The term "forensic scientist" is used throughout this document. These Guiding Principles are meant to apply to all laboratory personnel, including technical support personnel and others who assist forensic scientists in their work.

[ii]The materials from which the concepts embodied in these Guiding Principles have been drawn include:

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a. ASCLD Guidelines for Forensic Laboratory Management Practices. http://ascld.org/files/library/labmgtguide.pdf.
b. ASCLD Code of Ethics. http://ascld.org/files/library/Code%20of%20Ethics.pdf
c. American Academy of Forensic Sciences Code of Ethics and Conduct. www.aafs.org.
d. The Code of Ethics of the California Association of Criminalistics. www.cacnews.org.
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[iii]The draft of this document was distributed to thirty (30) forensic science organizations and several legal commentators for comment. The comments received were considered and many suggestions incorporated into the final version.

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