Procedure for Document Control and Management

1.0 Purpose - This procedure provides requirements for the creation, revision, and control of quality documents used by State Crime Laboratory (Laboratory) employees.

2.0 Scope - This procedure applies to the creation, revision, and control of all documents pertaining to the Laboratory Quality Management System (QS). QS documents include, but are not limited to, the following:

- Laboratory Quality Manual.
- Laboratory Procedures.
- Laboratory Safety Manual.
- Section Administrative Policy and Procedures.
- Section Technical Procedures.
- Section Training Procedures.

3.0 Definitions

- **Approver** – The employee responsible for the content of the document. Approvers shall be considered the Issuing Authority. **Approvers** for the following documents shall be:

  Laboratory Quality Manual and Laboratory Procedures – Lab Director and Deputy Assistant Director/Quality Manager.
  Laboratory Safety Manual – Laboratory Safety Manager, Lab Director and Deputy Assistant Director/Quality Manager.
  Section Technical Procedures and Section Training Procedures – Forensic Scientist Manager and/or Technical Leader, Lab Director and Deputy Assistant Director/Quality Manager.
  Section Policy and Procedures – Forensic Scientist Manager, Lab Director and Deputy Assistant Director/Quality Manager.

- **Author** - The employee who writes or revises the document.
- **Laboratory Procedures** - The controlled documents that describe the execution of policies in the Quality Manual. Procedures describe the means by which activities (tasks, examinations, analyses, etc.) shall be performed.
- **Laboratory Safety Manual** - The controlled document that describes the safety program at the Laboratory (i.e., protection of employees from hazardous chemicals, wastes, and bloodborne pathogens; evacuation in cases of fire, explosion, or natural disaster; etc.). The Safety Manual supplements the North Carolina Department of Justice Safety and Health Manual (DOJ Safety Manual) to meet the special conditions that are unique to the State Crime Laboratory.
- **Document Approval Attachment (DAA) -** A form to record and authorize the development, change and/or approval of each controlled document. Each controlled document shall have a unique DAA. A DAA is attached after the revision history and accompanies the document through the review and approval process. The blank copy of the DAA is located on the Laboratory internal network server.
- **Document Custodian** – The employee at either the Laboratory-wide or Section level who is responsible for ensuring the proper formatting, publishing, distribution, and archiving of controlled documents.
- **Laboratory Quality Manual** - The controlled document that describes the QS.
- **Master List** - The list that identifies the current revision status and distribution of documents in the management system. For each document, the Master List shall include the title, version number, issue date, and date for next scheduled review. The Master List of QS documents shall be maintained by the Laboratory Document Custodian for all controlled documents.

- **Reviewer** – The employee responsible for reviewing documents using reference sources and other pertinent information to ensure inclusion of all necessary elements and compliance with any associated policies and procedures. The review may be conducted for technical, legal, or quality assurance purposes.
- **Section Technical Procedures** – The controlled documents that provide detailed directions for the performance of technical duties.
- **Section Policy and Procedures** – The controlled documents that provide written guidance for administrative functions within the Section.
- **Section Training Procedures** – The controlled documents that provide instructions for training in specific skills required for analyses or examinations.

4.0 Procedure

4.1 The official copy of a QS document shall be the electronic copy that is published on the Laboratory intranet. Archived copies shall also be stored by the Quality Control Officer on the Laboratory intranet. Employees may download and print copies of documents; however, copies shall be uncontrolled. If a controlled document is printed, the effective date shall be clearly indicated and it shall be identified as an uncontrolled copy. Printed copies of electronically controlled documents used for casework activities shall be disposed of within the same work day.

4.2 Format

4.2.1 Each QS document shall have a unique title and each page of the body of the document shall have a header that includes the following:

- Title.
- Version Number.
- Effective date.
- Section identification.

In addition, each page of the body of the document shall have a footer that includes the following:

- Pagination (Page _ of _).
- All copies of this document are uncontrolled when printed.

4.2.2 Each QS document shall be written using the following:

- Microsoft Word.
- Times New Roman.
- Font 11.
- Full margin justification.

4.2.3 At the end of the body of each QS document, a Revision History shall be included to detail the changes made. The Revision History shall contain the revision number, the effective date, and the reason(s) for revision. Any typographical and grammatical changes may be summarized in one statement.

4.3 Document Development

4.3.1 QS Documents shall be created or modified according to the basic process described below.

4.3.2 The author of a document shall have expertise in the subject matter. The technical details of the document shall correspond to the complexity of the activity being performed as well as the background of the intended user. The document shall include enough detail to ensure that the activity conforms to quality requirements. Documents in draft form shall be labeled as such.

4.3.3 Once the document has been drafted or revised, it may be informally reviewed by other Laboratory employees with subject matter expertise. When a final draft has been prepared, the document changes shall be detailed in the Revision History. An original document shall be indicated as such in the Revision History.

4.3.4 The author shall complete the Requestor sections of the DAA. Any safety, training, or resource requirements shall be summarized on the DAA. The document and DAA shall be submitted to the Reviewer(s).

4.3.5 An author shall not review a manual or document that he/she has written. The author shall ensure that all manuals and documents undergo technical, quality assurance, and legal reviews.

4.4 Document Review

4.4.1 Technical review - The technical reviewer shall have knowledge of the procedure to evaluate the document. The technical reviewer shall evaluate the document for technical accuracy, technical sufficiency, and clarity of presentation using reference documents and other pertinent information. (Note: the approver may also conduct this technical review).

4.4.2 Quality Assurance Review - The Deputy Assistant Director/Quality Manager (QM) shall perform a quality assurance review of the process and of the document. The quality assurance review shall evaluate the document for the inclusion of quality requirements, quality sufficiency, and adherence to Laboratory policies and procedures.

4.4.3 Legal Review – The document shall be reviewed by Laboratory Legal Counsel.

4.4.4 If the review of the document is approved, the DAA shall be signed and dated by the reviewer.

4.4.5 If the review of the document is not approved, the author shall be notified of the reasons. Conflicts shall be resolved between the author and reviewer and any agreed upon modifications shall be incorporated into the document. The review cycle shall be repeated until such time as each reviewer has indicated approval on the DAA.

4.5 Document Approval

4.5.1 A document shall be approved before dissemination to staff.

4.5.2 The approver shall review the document. Changes and concerns shall be noted and discussed with the reviewer(s) and author. If there is disagreement, the approver shall determine the final action. After any changes and identification of additional training and resources or impact to customers or other Sections, if any, the approver shall perform one of the following:

4.5.2.1 If the document is approved, the DAA shall be signed, dated, and returned to the appropriate Document Custodian.

4.5.2.2 If the document is not approved, the author shall be notified of the reason(s).

4.6 Issuance and Distribution

4.6.1 After approval, the effective date of the document shall be included in the file name. The document shall be submitted to the Quality Control Officer (QCO). The QCO shall update the Master List.

4.6.2 Documents shall be converted to Portable Document Format (PDF) before issuance, publication on the Laboratory intranet, or distribution. For Laboratory and Section documents, the QCO shall post the approved document on the Laboratory intranet site and the Laboratory shared drive. The QCO shall notify the Section Document Custodian when process has been completed.

4.6.3 Affected personnel shall be trained on management system documents. When lab-wide management system documents are issued, the Quality Control Officer 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 Sheet(s) shall be scanned and stored on the internal network file server.

4.6.4 The use of new or revised documents shall begin on the effective date.

4.7 Document Removal - The Section Forensic Scientist Manager and/or Technical Leader shall have the authority for removal of Section documents. The Lab Director shall have the authority for removal of Laboratory documents. If the decision is made to remove a document, the appropriate authority shall notify the Document Custodian to remove and archive the document and to update the Master List.

4.8 Monitoring

4.8.1 The Forensic Scientist Manager or designee shall ensure that all controlled Section documents are reviewed annually (and revised as necessary) to ensure that the documents reflect current policies, practices, procedures, and technology. This review shall be documented in a memorandum and posted on the Laboratory intranet. The Lab Director, Deputy Assistant Director/QM and the QCO shall be notified electronically of the posting. Documentation shall include the name of the reviewer(s), the title(s) of the document(s) reviewed, and the date(s) the documents were reviewed. Internal or external audits and/or quality reviews do not satisfy this requirement.

4.8.2 The QCO shall ensure that all controlled Laboratory policies and practices are reviewed annually and revised when necessary. This review shall be documented and retained by the QCO. Documentation shall include the name of the reviewer(s), the title(s) of the document(s) reviewed, and the date(s) the documents were reviewed.

4.8.3 If changes are required to any document or manual (including administrative/typographical), a DAA shall be initiated and the procedure followed for document revisions.

4.8.4 Documents may be updated and reissued as necessary. A new version number (the next whole number) shall be assigned when a new document version is approved. Amendments or changes to final documents by hand shall not be permitted.

4.9 Instrumentation Manuals and other Externally Produced Documents

4.9.1 Documents from external sources (such as instrumentation manuals and other externally-produced documents) may be treated as references or as QS documents. If treated as a reference material, a copy shall be maintained in the Section. If treated as a QS document, the manual or document shall be maintained by numbering the manual/document and creating a Section distribution list to track the use of versions as part of the quality system.

4.9.2 A list shall be maintained for the manufacturer operator manuals and other reference documents by the Forensic Scientist Manager or Section Document Custodian. The manual/document title, date, version number, distribution date, and the location of the copies shall be included on the list.

4.9.3 After an instrumentation manual or an externally produced quality document has been issued, the Forensic Scientist Manager or Section Document Custodian shall distribute the manual/document or a copy to the appropriate party or location.

4.10 Document Retention and Archival

4.10.1 Superseded documents shall be removed from use; however, one electronic copy of the document shall be retained as an archived copy.

4.10.2 Archived copies of Laboratory Quality Manual, Laboratory Procedures, and the Safety Manual shall be maintained by Laboratory Document Custodian.

4.10.3 After the implementation of ISO, archived copies of Section Policy and Procedures, Section Technical Procedures, and Training Procedures shall be maintained by the Quality Control Officer. Prior to the implementation of ISO, archived copies of Section Policy and Procedures, Section Technical Procedures, and Training Procedures shall be maintained by the Section Document Custodian.

4.10.4 Instrumentation manuals or externally produced quality documents shall become superseded when the entity that produced the manual/document issues a new version or the manual/document becomes obsolete. Archived instrumentation manuals/external documents shall be retained by the Section Document Custodian.

4.10.5 The superseded manual or document shall be labeled (Ex. “Archived on…” or “Superseded on…”). If the archived copy is maintained in electronic format, the effective range shall be added to the filename (e.g., TRACE XRF 2008.8.11 – 2010.10.15).

5.0 Records

- Master list
- Document Approval Attachment
- List of external documents

6.0 Attachments

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	Original Document
10/26/2012	2	Modified 4.6.2 to show the QCO posting lab-wide and Section documents to the intranet and shared drive. Modified Definition for DAA - removed sentence referring to Appendix A. 4.10.3 - archived copies of ISO of procedures maintained by QCO, previous policy and procedures shall be maintained by the Section Document Custodian.
12/7/2012	3	Modified 4.1 to agree with 4.10.3