# 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-wide Procedures.
- Laboratory Safety Manual.
- Laboratory-wide Forms.
- Section Administrative Policy and Procedures.
- Section Technical Procedures.
- Section Training Procedures.
- Section Forms and Work Instructions.

## 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-wide Procedures –Quality Manager.
  - Laboratory Safety Manual – Laboratory Safety Officer or Quality Manager.
  - Laboratory-wide Forms –Quality Manager
  - Section Technical Procedures and Section Training Procedures – Forensic Scientist Manager and/or Technical Leader, or ECU Supervisor.
  - Section Policy and Procedures – Forensic Scientist Manager, or ECU Supervisor.
  - Section Forms and Work Instructions– Forensic Scientist Manager, and/or Technical Leader or ECU Supervisor.
- **Author -** The employee who writes or revises the document.
- **Document Approval Attachment (DAA) -** A form to record and authorize the development, change and/or approval of all controlled, Laboratory generated documents (except forms). Each controlled, Laboratory generated document shall have a unique DAA. 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.
- **Form** – A document with a fixed arrangement of spaces designed for entering and extracting information.
- **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 blood borne 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.
- **Laboratory Quality Manual** - The controlled document that describes the QS.

- **Master List** - The list that identifies the current revision status and distribution of Laboratory generated 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.
- **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 Laboratory generated QS documents shall be the electronic copy that is published on the Laboratory intranet. Archived copies of these documents shall be stored by the Quality Manager (QM) on the Laboratory intranet. When a form is revised, the use of the previous version of the form shall be discontinued.

Employees may download and print copies of documents; however, copies shall be uncontrolled. If a controlled document other than a form 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 may be disposed of within the same work day or retained for future reference. If retained for future reference, the employee must verify that the uncontrolled printed version is still current prior to use. Forms may be printed for use and retained in printed format.

### 4.2 Format of Laboratory Generated Documents

**4.2.1** Each QS document (except forms and work instructions) 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 or Discipline identification.
- Issuing authority.

In addition, each page of the body of the document (except forms and work instructions) 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 (except forms and work instructions) 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 (except forms), 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. The revision history must detail the changes from the previous version. The revision history does not have to include all previous versions.

**4.2.4** Forms and work instructions shall have the following identifying information:

**4.2.4.1 Header**

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

**4.2.4.2 Footer**

- Signature of Approver.
- Pagination (Page _ of _) or a mark to signify the end of the document.

## 4.3 Document Development of Laboratory Generated Documents

**4.3.1** QS Documents (except forms and work instructions) 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 the required reviews.

## 4.4 Document Review of Laboratory Generated Documents

**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).

**4.4.1.1** For revisions to technical procedures or new technical procedures, the technical leader for the discipline/sub-discipline shall be the author, reviewer, or approver.

**4.4.2** Quality Assurance Review - The 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. The Laboratory Director and appropriate Assistant Director shall also review the document prior to final release.

**4.4.3** Legal Review – Upon a substantial change of a quality system document, the document shall be reviewed by Laboratory Legal Counsel. The determination of whether a document requires legal review shall be determined by the Quality Manager, Assistant Director, and/or Laboratory Director with consultation of 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.

**4.4.6** Laboratory and Section forms and work instructions do not require a Technical, Quality Assurance, or Legal Review.

## 4.5 Document Approval of Laboratory Generated Documents

**4.5.1** A Laboratory generated form or work instruction shall be approved before dissemination to staff. The approver shall review the form or work instruction. If approved, the form or work instruction shall be signed and dated by the approver and placed on the Laboratory intranet by the QM.

**4.5.2** All other Laboratory generated documents shall be approved before dissemination to staff. 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 placed in the Documents Approval Attachments folder on the Laboratory intranet by the Quality Manager or designee.

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

## 4.6 Issuance and Distribution of Laboratory Generated Documents

**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 QM. The QM shall update the Master List.

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

**4.6.3** Affected personnel shall be trained on management system documents (except forms). When lab-wide management system documents are issued, the QM 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. Forms do not require the completion of an Acknowledgement Sheet.

**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 of Laboratory-Generated Documents**

**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 QM shall be notified 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 QM 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 QM. 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.

**4.9 Document Revisions**

**4.9.1** 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.

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

**4.9.3** 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.

### 4.10 Instrumentation Manuals and other Externally Produced Documents

**4.10.1** Documents from external sources may be treated as references, QS documents, or case related information. If treated as a reference material, a copy shall be maintained in the Section. If treated as a QS document, a record shall be maintained on a Section distribution list to track the use of the document as part of the quality system. All manuals for critical equipment shall be treated as QS documents. If an external document is case related information, it shall be imported into the corresponding Laboratory file.

**4.10.2** The Forensic Scientist Manager shall review and approve the use of externally produced QS documents by approving the Section Distribution List. The Section distribution list shall be maintained by the Forensic Scientist Manager or Section Document Custodian. The document title, date, version number, distribution date, and the location of the copies shall be included on the list.

**4.10.3** After an externally produced QS 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.

### 4.11 Document Retention and Archival

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

**4.11.2** Archived copies of Laboratory generated documents shall be maintained by the QM.

**4.11.3** 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.

**4.11.4** 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).

**4.11.5** Externally produced documents containing case related information shall be maintained in the Laboratory file in Forensic Advantage. Once the document has been imported and approved in the FA System, it becomes the official copy and any other copy may be discarded.

**NOTE:** The imported file shall be an exact duplicate of the documents received (i.e., if document is in color, it shall be scanned in color before being added to the file).

## 5.0 Records

- SharePoint Master list
- Document Approval Attachment

- Section Distribution lists

**6.0 Attachments** – N/A

| **Revision History** | | |
|---|---|---|
| Effective Date | Version Number | Reason |
| 06/01/2021 | 14 | 4.3.5 - updated to required reviews<br>4.4.3 – updated legal review requirement. |