Maine State Police Crime Laboratory

Document Control

1. Scope

The laboratory will maintain control of the documents created and held by the laboratory for use by the management system in addition to the critical documents generated by external sources. Each issuing authority will ensure consistency within the section(s) so that all staff members are utilizing the documents in the same manner.

2. Internal Document Control

2.1 Documents that will be controlled by the laboratory are those which could have an impact on evidence examination or the quality assurance system.

2.2 Controlled documents will be categorized according to the following scheme:

2.2.1 Form: A form is any document used to record information that has a direct impact on casework or the quality system. Examples of forms are case notes pages, temperature recording charts, cleaning logs, etc.

2.2.2 Policy: A policy is a guide for decision-making and outlines the general principles and practices of the laboratory.

2.2.3 Method: A method is a guideline for how to perform a particular task or analysis.

2.2.4 Software: Software developed in-house that is used for instrumental analysis or comparisons

2.2.5 Training Manuals: A training manual should contain references to any required readings, practical exercises, or any other information that a trainee is required to complete prior to performing independent casework.

2.3 All controlled internal laboratory documents are found by accessing Paradigm document management software. The only controlled versions of these documents are the ones located electronically in Paradigm.

2.4 Each section is responsible for implementing the appropriate forms, policies, methods, software, and / or training manuals.

2.5 All documents issued to laboratory staff will be reviewed and approved for use by the Quality Manager prior to distribution.

2.6 Any printed version of a document will be marked in a way to denote that it is an uncontrolled version.

2.7 Any electronic version disseminated via e-mail, disk, or other means will be marked as uncontrolled.

2.8 If an employee uses a printed copy of a document, it is that employee's responsibility to ensure that they are using the current version.

2.9 Each section supervisor is responsible for ensuring obsolete printed versions of documents in laboratory spaces are promptly removed from service.

2.10 Obsolete documents are removed electronically through Paradigm. These documents are clearly marked as obsolete and are available only to supervisory staff.

2.11 Laboratory documents are also available through the Paradigm website which can be accessed from any computer in the laboratory.

2.12 During any transition period, the documentation and practices in effect while a case is in progress may be carried through to a case completion. If additional requests are received after a report has been issued, the new practices and procedures will be employed.

3. Electronic Storage of Internal Documents

3.1 All controlled internal documents will be stored electronically in Paradigm.

3.2 Only "Normal" users and "Administrators" will have access to edit documents. This includes the Quality Manager, Section Supervisors, and Laboratory Sergeant.

3.3 Changes made to a document will be noted in the document history in Paradigm.

3.3.1 The "Compare Two Versions" feature in Paradigm may be used for a side-by-side comparison of document versions.

4. Creation and Approval of Internal Documents

4.1 If laboratory staff needs to create, amend, or rescind a document, the proposed document and revisions will be presented to the appropriate supervisor or document owner.

4.2 All documents that are in draft form will be clearly identified as draft.

4.3 Once a document has been created or revised, and is ready for approval, the document owner will convert the document to "Ready." The document owner should make a notation in the comments field to indicate the changes made in the document.

4.3.1 Section-specific documents will be submitted to the Quality Manager for approval upon conversion to "Ready".

4.3.2 Major changes to laboratory wide documents will be submitted to the Laboratory Director for approval upon conversion to "Ready".

4.3.2.1 Minor changes or medium changes that do not significantly impact the content of a laboratory wide policy do not need the Laboratory Director's approval.

4.4 The Quality Manager will review the document and make suggested changes if necessary. Once the document has been determined to be complete, the Quality Manager will convert the document to "Current."

4.5 The Quality Manager will notate the changes in the document for the change history and will determine a revision number. The revision numbering scheme is as follows:

Major Revisions = significant text or content revisions

Medium Revisions = minor text revisions or minor changes in content

Minor Revisions = grammatical or punctuation changes

4.6 Upon converting to Current, notifications will be sent to relevant laboratory staff for review. Additionally, the Director will be notified that a new document has been created.

4.6.1 Notices will be sent for Major and Medium revisions.

4.6.2 Minor revisions do not require staff review.

5. Internal Document Identification

5.1 Each document will be uniquely identified with a document number and revision number. The document number follows the format XX-YZZZ where:

XX = Issuing section: QA, FC, FB, FA, LP, ER
Y = Type of document: F=form, P=policy, M=method, S=software. T=training
ZZZ = numerical order

5.2 The revision number will be identified on the document.

5.3 All documents will have a footer which will include:

- Document number
- Revision number
- Date of issue
- Page number and total number of pages
- Who approved the document

6. Annual Review and Revision of Internal Documents

6.1 All documents will be reviewed on an annual basis by the document owner who is the issuing authority. The annual review date is determined by the date the document is converted to Current in Paradigm.

6.1.1 If the issuing authority determines that the document requires changes, the document will be converted to Draft and the changes made. The document will then follow the normal document review and approval process.

6.1.2 If the issuing authority determines that the document does not require changes, upon completion of the annual review action item, notice will be sent to the distribution list for review.

6.2 Hand amendments of documents are not acceptable. Hand amendments include memos or e-mail addendums to documents. If amendments are needed, the document must be revised.

7. Externally Generated Documents

7.1 If there are any analytical methods generated by an external governing body, that the laboratory is required to follow, these documents will be controlled. The laboratory will maintain a master list of these documents in Paradigm.

7.2 All externally generated documents will be labeled with a master list number. This number will follow a similar format as the internally generated documents, with X denoting external. Documents will be denoted with the letter D before the number; software will be denoted with the letter S before the number. For example:

QA-XD001, QA-XS001, etc.

7.3 It is the responsibility of the appropriate supervisor to:

- Ensure that the master list of externally generated controlled document list remains up-to-date.
- Ensure that the externally generated controlled documents in use are current and applicable.
- Maintain a master or official copy of the current version of any externally generated controlled documents. The master or official copy may be the copy in use.

7.4 Only the current version identified on the master list is to be used by laboratory staff.