NCSBI Forensic Biology Section	QA Manual Appendix K	Effective Date: December 23, 2004
Title: **DOCUMENT CONTROL PROCEDURE**		Revision 00

1 PURPOSE

This procedure defines a uniform method of controlling documentation that establishes and maintains Forensic Biology Section's Quality System.

2 SCOPE

This procedure applies to all Quality System documents (i.e. procedures and protocols) that originate in the Forensic Biology Section.

3 DEFINITIONS

Administrative Order: Written document that is used as a communications tool to disseminate clear and understandable policy and procedures. They may be incorporated into protocols or procedures at a later date.

Policy: The overall intention and direction of the Forensic Biology Section with respect to quality, as formally expressed by management with executive responsibility. The quality policy is outlined in the **Quality Manual**.

Standard Operating Procedure: Includes those documents that either 1) provide step-by-step information on how to perform a specific task or 2) that deal with the general flow and control of a process.

Protocol: A document that states how a validation, test, or study is to be performed.

Quality Manual: A document that states the quality policy and describes the Quality System.

Quality System: Organizational structure, responsibilities, procedures, processes, and resources needed to implement the quality policy as determined by the overall management function.

Quality System Documents: Documentation that establishes and maintains the NCSBI and the Forensic Biology Section's Quality System (i.e. policies, procedures, protocols, and records).

Records: Documents retained in order to provide evidence that specific activities were performed and/or results were achieved (e.g., validation documentation, maintenance/repair records, calibration records, worksheets for the preparation of solution and reagents, documentation of reagent quality checks, etc.).

4 REFERENCE DOCUMENTS

None

5 RESPONSIBILITY

5.1 All Forensic Biology personnel shall be responsible for following this procedure.

5.2 The Technical Leader shall be responsible for maintaining the contents of this procedure.

5.3 Anyone within a function/organization and with sufficient knowledge of the process of interest may take on the responsibility of initiating, reviewing, or approving a Quality System document.

6 PROCEDURE

6.1 Preparation

6.1.1 The document initiator is responsible for creating/revising the document and for seeing the document through implementation.

6.1.2 Original documents are revision 00 and subsequent revisions are 01, 02, 03, etc.

6.1.3 If a document is already in existence and only needs to be revised, a copy from the original document can be made or a copy from the electronic files can be printed and used for revision purposes.

6.2 Review

6.2.1 At least one person, not including the initiator, should review all draft documents. The document initiator may solicit as many reviewers as he/she feels necessary to ensure the effectiveness of the document. Reviewers can be at any position in the Section. A Team Leader from each affected Unit must review the document prior to approval.

6.2.2 Reviewers should complete their review within 3 days of receiving the document. If the reviewer does not respond in the indicated time frame, their review may be considered complete without comment.

6.2.3 Comments from the review process should be resolved by the initiator prior to the approval process

6.2.4 The format of the review process is at the discretion of the initiator. The document may be routed with a cover sheet to each reviewer or there may be a group review meeting. A "Document Review Record" may be completed by the initiator prior to starting the review process.

6.3 Approval

6.3.1 There shall be at least 2 approvers for all new/revised documents.

6.3.2 Procedures, instructions, and protocols, shall be approved by the Technical Leader.

6.3.3 All Quality System documents shall be approved by the SAC.

6.3.4 Document revisions shall be approved by the same Unit that performed the original approval unless designated otherwise in a specific document.

6.3.5 Any changes due to administrative content (e.g., correction of inadvertent errors, grammar, spelling) require only the approval signature of the SAC and/or Technical Leader and will not effect the revision status of the document.

6.3.6 Approvers are responsible for verifying the technical merit, appropriateness and accuracy of new/revised documents.

6.3.7 Approval with comments is not permitted. Comments must be resolved with the initiator in the review process, prior to obtaining approval signatures. If the individual does not have the knowledge needed to properly approve a document, background information should be provided by the appropriate functions/organizations.

6.4 Document Processing

6.4.1 The Technical Leader shall receive an electronic copy (disk copy or electronic mail copy) of the document from the document initiator.

6.4.2 The Technical Leader shall process a new/revised document by doing the following:

6.4.2.1 Verify completeness of the document including the revision history.

6.4.2.2 Update the appropriate file/manuals to include the new/revised document (e.g., Quality Control Manual).

6.5 Document Implementation and Obsoletion

6.5.1 Notification: The Technical Leader is responsible for notifying all impacted Units of the new/revised document.

6.5.2 Training: The Technical Leader is responsible for coordinating training and training documentation. The type of training needed should be determined by the Technical Leader, SAC, and Team Leaders.

6.5.3 Training on documents can be by routing the new/revised document if it is felt by the Technical Leader or SAC that affected personnel can interpret all aspects of the document without a training meeting. However, **training meetings shall be conducted if a document or the changes to a document are considered to be critical to the effectiveness of a process**.

6.5.4 Obsoletion: If a document is combined with another document or is no longer needed, the document may be removed from the Quality System.

6.6 Distribution and Maintenance

6.6.1 A copy of the Quality System Documents will be available to all Section Employees.

6.6.2 An electronic copy of the Quality System Documents will be available to all Section Employees. Paper copies may be produced and used by the Section Employees. Section Employees are responsible for making sure they are using the most current revision when performing a procedure of protocol.

6.6.3 The Technical Leader is responsible for updating the electronic when necessary.

6.7 Document Periodic Review and Retention

6.7.1 Periodic Review

6.7.1.1 All policies, procedures, and protocols shall be reviewed annually.

6.7.1.2 The SAC, Technical Leader, and Team Leaders are responsible for reviewing all documents pertinent to their function/organization. Designees may be assigned the task of document review.

6.7.2 Document Retention

Original copies of all Quality System documents shall be retained indefinitely.

6.0 APPENDICES

Appendix I - Training Record
Appendix II - Document Periodic Review Record

REVISION HISTORY

Revision History		
Effective Date	Revision Number	Reason
12/23/04	00	Original Document

APPROVAL SIGNATURES	Date
Author/Title (Print)	
(Signature)	
Name/Title (Print)	
(Signature)	
Name/Title (Print)	
(Signature)	

APPENDIX I **Record Number:**

TRAINING RECORD

I. TRAINING INFORMATION	
TRAINING TITLE:	
TYPE OF TRAINING: ☐ Routing ☐ Meeting	
DOCUMENT TITLE:	
DOCUMENT #/REVISION LEVEL:	
OTHER REFERENCE MATERIALS:	
DATE TRAINING COMPLETED:	
II. TRAINER'S INFORMATION	
TRAINER'S NAME	
III. PERSONNEL TRAINED	
EMPLOYEE NAME (Print Name)	EMPLOYEE SIGNATURE

APPENDIX II

DOCUMENT PERIODIC REVIEW RECORD

NOTE: Use as many forms necessary to complete review of documents.

Document Review Form	
Document Reviewed (Include Revision #):	
Unit Affected Body Fluid ID ☐ Database ☐ DNA ☐	
Reviewer (Print Name and Initial)	Date of Review
To Be Completed by Technical Leader	
Revision Required? ☐ NO ☐ YES	
New Revision Number:	
Training Required? ☐ NO ☐ YES	
Type of Training: ☐ Routing ☐ Meeting ☐ Training Program	
If "Yes", Who is Responsible for Training:	