NCSBI Forensic Biology Section	QA Manual Appendix J	Effective Date: December 23, 2004
Title: **PROCEDURE FOR COMPLETION OF QUALITY SYSTEM DOCUMENTS**		Revision 00

1 PURPOSE

This procedure details the content and format requirements for Standard Operating Procedures and Protocols that are generated in the NCSBI Crime Laboratory Forensic Biology Section.

2 SCOPE

This procedure applies to all Standard Operating Procedures and Protocols that are generated in the NCSBI Crime Laboratory 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

Administrative Order 96-ADM-1: Administrative Orders Manual

Document Control Procedure

5 PROCEDURE

5.1 Document Preparation

Create the document in WordPerfect™ or MS Word™ using Outline Format using Arial font.

5.2 Format

5.2.1 Headers: The header contains standard information at the top of each page and must include the document title, revision number, and effective date.

5.2.2 Title: The title of the document should be included at the top of the first page, centered and below the logo. The title should include the type of document (i.e.- SOP or Protocol).

5.2.3 Numbered Sections

5.2.3.1 All SOPs written or modified after this document shall include at least the following sequentially numbered sections:

1.0 Purpose
2.0 Scope
3.0 Safety
4.0 Definitions (list alphabetically)
5.0 Reference Documents (list alphabetically)
6.0 Procedure
7.0 Appendices

5.2.3.2 All Protocols shall include at least the following sequentially numbered sections:

1. Purpose
2. Scope
3. Definitions (list alphabetically)
4. Criteria for Success
5. Reference Documents (list alphabetically)
6. Equipment and Materials Required
7. Responsibility
8. Strategies
9. Procedure
10. Prerequisites
11. Appendices

NOTE: See Appendix I and Appendix II for the content guidelines for each section. If a section is not applicable, enter "NA".

5.2.3.3 Adminstrative Orders: Administrative Orders do not have any specific numbering system.

5.2.3.4 Footers: There are no designated footers. An author may use footers in a document, if desired.

5.2.3.5 Pagination: The main body of the document and each appendix should be numbered separately. Page numbers should be in the format "Page X of Y".

5.2.4 Appendix

5.2.4.1 Create appendices using WordPerfect™ or MS Word™ whenever possible.

5.2.4.2 The main body of a document and the appendices should be created as one WordPerfect™ or MS Word™ document whenever possible.

5.2.5 Revision Summary:

5.2.5.1 A revision summary page must be included and be the last page of the document. The document initiator is responsible for updating the revision history.

5.2.5.2 List the revision history with the most recent revision at the bottom in the Revision Information Block.

5.2.5.3 The reason for document creation or change should be included.

5.3 Section Numbering and Aligning: Use WordPerfect™ or MS Word™ Outline Format.

NOTE: Numbering and aligning within a document serves two purposes: 1) to add clarity for the user to understand the logical flow within the document AND 2) to provide users a location reference for identifying specific requirements.

5.3.1 Examples of logical numbering and alignment:

EXAMPLE 1

1.0 Section title

Text starts immediately below the title.

1.1 Subsection title

Text starts immediately below the title

1.1.1 (and so on)

EXAMPLE 2

1.0 Section title

Text starts immediately below the title.

(NO TITLE)
1.1 Text starts one indent to the right of the number.

1.1.1 (and so on)

5.3.2 Numbering is not required in the DEFINITION and REFERENCE DOCUMENTS sections. Definitions and references should be listed in

alphabetical order.

5.4 Document Control

All Quality System documents shall be controlled in accordance with the Forensic Biology "Document Control Procedure".

NOTE: The primary elements of document control are review/approval, processing, maintenance, distribution, implementation, obsoletion, revision/change, periodic review, and retention.

6 APPENDICES

Appendix I - Policy/Procedure/Instruction Content Guidelines

Appendix II - Protocol Content Guidelines

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)	

Standard Operating Procedure Content Guideline

DOCUMENT TITLE

1. PURPOSE

Define what this document accomplishes.

2. SCOPE

Identify the applicability of the document, it may include, but is not limited to following:

2.1 Which Unit (DNA, Database, Body Fluid) does this effect?

2.2 What is to be tested.

3. SAFETY

Describe all issues with Saftey and necessary PPE to carry out the procedure safely

4. DEFINITIONS

4.1 Define terms, within this document, that require a specific interpretation.

4.2 Any abbreviations used within a document should be defined prior to use.

NOTE: Numbering is not required for definitions.

5. REFERENCE DOCUMENTS

5.1 Reference testing standards in procedures or instructions may be appropriate.

5.2 Reference internal documents that are necessary for performing this document's requirements. **Do not include revision designation.**

5.3 List reference documents alphabetically in the following manner:

Reference Name - Document #

NOTE: As a guideline, reference a document that, if revised, would require a revision or an associated change in the document you are creating or revising.

Standard Operating Procedure Content Guideline

6. PROCEDURE

6.1 Use a step-by-step approach. Make each step a separate numbered item. Order the steps in a logical and sequential manner. Write to the knowledge level of anticipated users. Be sure to answer the following questions:

- What to do?
- Where to do it?
- When to do it?
- Who should do it?
- How it should be done?

6.2 Do not specify an individual's name in a document. Specify the job function or title instead.

6.3 Do not quote sections from other documents. Other documents shall be referenced instead.

7. APPENDICES

Appendix I - Title

Appendix II - Title

Protocol Format and Section Guidelines

DOCUMENT TITLE

1.0 PURPOSE

Define what this document accomplishes. Describe what you are trying to demonstrate and what type of equipment or process is being tested .

2.0 SCOPE

Define the applicability of the protocol, it may include, but is not limited to the following:

2.1 Specific items being tested or validated

2.2 Specific equipment work station and/or equipment (by title designation).

2.3 Specific Section and Unit.

3.0 DEFINITIONS

3.1 Define terms, within this document, that require a specific interpretation.

3.2 Any abbreviations used within a document should be defined prior to use.

NOTE: Numbering is not required for definitions.

4.0 CRITERIA FOR SUCCESS

Make a decision statement that clearly describes those criteria required to consider the test or study successful. State levels of significance (e.g., confidence levels, reliability levels), if applicable.

NOTE: The investigation of the root cause of a failed criteria for success and the corrective action must be included as a completion activity.

5.0 REFERENCE DOCUMENTS

NOTE: As a guideline, reference a document that, if revised, would require a revision or an associated change in the document you are creating or revising.

5.1 Reference testing standards in procedures or instructions may be appropriate.

5.2 Reference internal documents that are necessary for performing this document's requirements. **Do not include revision designation.**

Protocol Format and Section Guidelines

5.3 List reference documents alphabetically in the following manner:

Reference Name - Document #

5.4 Reference testing standards in procedures or instructions may be appropriate.

5.5 Reference internal documents (by title and number) that are necessary for performing this document's requirements. **Do not include revision designation.**

5.6 List reference documents alphabetically in the following manner:

Reference Name - Document #

6.0 EQUIPMENT AND MATERIALS

List specific equipment, tooling, materials, and chemicals that must be used when conducting the protocol.

7.0 RESPONSIBILITIES

7.1 Identify person responsible for the overall protocol coordination and completion (Normally the Technical Leader).

7.2 Identify persons responsible for specific sections of the protocol.

7.3 Identify the specific function titles responsible for investigation of root causes and corrective action in the case of a failed criteria.

8.0 STRATEGIES

Include any information in this section needed to support the protocol strategies. (e.g., Identify sampling/testing strategies and rationale).

9.0 PREREQUISITES

Identify any steps that are required in preparation for the protocol (e.g., calibrations).

Protocol Format and Section Guidelines

10.0 PROCEDURE

10.1 Use a step-by-step approach. Make each step a separate numbered item. Order the steps in a logical and sequential manner. Write to the knowledge level of anticipated users. Be sure to answer the following questions:

- What to do?
- Where to do it?
- When to do it?
- Who should do it?
- How it should be done?

10.2 Do not quote sections from other documents. Other documents shall be referenced instead.

NOTE: Never specify an individual's name in a protocol. Specify the job function or title instead.

11.0 APPENDICES

Appendix I - Title

Appendix II - Title