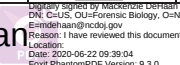


Deviation Request Form (DRF)

Directions: The Initiator will complete Sections A through C. Additional continuation pages can be included if necessary.

Initiator	MJ DeHaan			Date	06/19/2020			
A. Requested deviation applies to (Technical Procedure – include specific section):								
Forensic Biology Section Administrative Policy and Procedure - multiple sections, see attached.								
B. Requested deviation:								
See attached								
C. Necessity for the deviation:								
To incorporate changes from the 2020 QAS Audit document.								
D. Technical review and Authorization (to be completed by the Quality Manager and/or Technical Leader)								
Comments(to include merits and impacts):								
Approved	☒	Yes	☐	No	Duration	until next version		
Signature	 Mackenzie DeHaan Digitally signed by Mackenzie DeHaan DN: cn=US, ou=Forensic Biology, o=NCSCSL, cn=Mackenzie DeHaan, E=mdehaan@ncdoj.gov Reason: I have reviewed this document Location: Date: 2020-06-22 09:39:04 Posti PhantomPDF Version: 9.3.0				Date	06/22/2020		
E. Quality Assurance Authorization (to be completed by the Quality Manager, Forensic Scientist Manager or designee)								
Acceptable within general QA guidelines and good laboratory practice?					☒	Yes	☐ No	
Significant negative impact to Crime Laboratory Quality System?					☐	Yes	☒ No	
Restrictions/limitations:								
Effective 07/01/2020								
☒	Authorized	☐	Rejected	Signature	 Jody H. West Digitally signed by Jody H. West DN: cn=Jody H. West, o=DOJ, ou=State Crime Laboratory, email=jwest@ncdoj.gov, c=US Date: 2020.06.25 09:06:57 -0400		Date	6/25/20

DRF_Forensic Biology Section Administrative Policy and Procedure Continuation

Wording for the following sections will be updated:

3.1.1 The Forensic Biology Section performs testing in the following areas DNA Casework (STR, YSTR) and Body Fluid Casework.

3.1.2 The organizational chart for the Section reflects the management structure, responsibilities (e.g., technical leader, CODIS state administrator, safety officer, etc.). Areas in which the Forensic Scientist has shown competency is documented on the work authorization record. The date of qualification (documented on the work authorization) will be used to define the applicable version of QAS used to assess education, experience, and training.

3.1.2.1 If the Technical Leader position is vacated the laboratory procedure for selection will be followed. If there is no qualified personnel within the laboratory, then a request to the Charlotte Mecklenburg PD Laboratory will be made to establish a temporary MOU until a technical leader can be employed. A contingency plan will be submitted to the FBI.

3.1.2.2 If the number of qualified analysts falls below two, the laboratory COOP will be followed.

3.1.2.3 Notification of the TL vacancy or the number of qualified analysts falling below 2 as assigned to each laboratory facility (e.g., Raleigh or Western sites) will be made as required in the QAS audit document and the NDIS Operational Procedures Manual.

3.1.2.4 The laboratory shall not upload DNA profiles to NDIS in the event that the casework CODIS administrator position is unoccupied.

4.1.1.2.1 “Hard copies” will now read “Documentation”

4.4.3 The casework CODIS Administrator will be notified in the event of non-administrative discrepancies that affect the typing results and/or conclusions.

4.5 Change name of procedure to Lab-wide Procedure for Corrective Actions and Non-Conformities. The plan must be approved by the Technical Leader prior to implementation and when the non-conformity impacts DNA records entered into CODIS, the casework CODIS administrator must also be notified.

4.6 As a part of the annual internal audit, a representative sample of cases worked will be reviewed. The scope of this review will be defined by the Technical Leader as a part of the internal review process.

4.7.1 Update wording to applicable Laboratory Procedures

4.7.2.2.2 Initial and annual on-site visits will follow the requirements from the most current version of QAS Section 17.

4.8 Additional discussion of uncertainty will be discussed within the individual section procedures if applicable.

Forensic Biology Section Administrative Policy and Procedure

1.0 Purpose - The purpose of the document is to ensure the following:

- 1.1** The Forensic Biology Section meets the standards set forth in the State Crime Laboratory Quality Manual and the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.
- 1.2** The Forensic Biology Section provides the North Carolina Criminal Justice System services for identification of Body Fluids and DNA typing and ensures that these procedures are operating within established performance criteria.
- 1.3** The quality and integrity of the data are maintained and are sound scientifically.
- 1.4** The Forensic Biology Section provides the North Carolina Criminal Justice System with laboratory services for identification and genetic typing of biological materials that pertain to a particular criminal investigation.
- 1.5** Corrective actions are documented.
- 1.6** The Forensic Biology Section provides guidelines to employees so they are aware of performance expectations.
- 1.7** Personnel performing these tests have the appropriate level of training and education.
- 1.8** The Forensic Biology Section adheres to FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, ISO 17025 and supplemental requirements.
- 1.9** Forensic Scientists are competent in performing the testing and interpreting the results through a series of proficiency tests.

2.0 Scope - This procedure applies to all personnel assigned to the State Crime Laboratory Forensic Biology Section.

3.0 Responsibilities

3.1 Organization Overview

- 3.1.1** The Forensic Biology Section performs testing in the following areas: DNA Casework and Body Fluid Casework.
- 3.1.2** The organizational chart for the Section reflects chain of command, responsibilities (e.g., technical leader, CODIS state administrator, safety officer etc.) and areas in which the Forensic Scientist has shown competency.

4.0 Procedure

4.1 Section Obligations

4.1.1 Continuing Education

- 4.1.1.1** Qualified Section Forensic Scientists shall complete a minimum of 8 hours of continuing

education each calendar year. This requirement does not apply to Forensic Scientists in training status and may be prorated for the year. This requirement shall be met one of the following ways: by attending seminars, college courses, professional meetings or by taking on-line courses. DNA on-line courses shall be submitted to the DNA-TL for review and approval prior to participation. Section Forensic Scientists shall stay current of developments within the field by reading current scientific literature and signing the appropriate acknowledgement sheet as documentation. Forensic Scientists shall have access to the internet and local university libraries for reading scientific literature. The TL or designee shall circulate literature when pertinent scientific literature is published.

4.1.1.2 Records

4.1.1.2.1 Hard copies of continuing education training records (e.g., certificates, BDAs, etc.) shall be stored in the Forensic Biology Section according to the record retention schedule as set forth by the North Carolina Department of Cultural Resources or for five years, whichever is longer.

4.1.1.2.2 Documentation shall be incorporated into a master training log for each Forensic Scientist.

4.2 Facilities

4.2.1 Section secure areas:

- Areas designated by the DNA QC procedure as being limited access.
- Areas where evidence is actively being stored/analyzed to include evidence vault, personal evidence lockers, refrigerators and freezers.

4.3 Validation

4.3.1 This Laboratory shall use only validated methods and procedures for the analysis of forensic cases.

4.3.2 Developmental and Internal Validation of the DNA Analysis Procedures

All developmental and internal validation studies will be performed according to the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories (Standard 8).

4.3.3 Internal Validation of Body Fluid Identification Procedures

Prior to initiation of new Body Fluid typing procedures, studies shall be conducted by this Laboratory to ensure reproducibility and precision of the procedure as well as define and/or establish limitations to the procedure. These studies shall be performed by the Body Fluid Technical Leader or designee. The procedure shall be tested using known samples and may include (but not be limited to) the following tests: reproducibility, sensitivity, species study (if applicable) and sample stability.

4.3.4 Validation studies, population studies, and research project results shall be maintained in hard copy and on the Forensic Biology Section shared drive by the Forensic Scientist Manager or designee.

4.3.5 Documentation for historical procedures

The following procedures are used as a part of the Forensic Biology Section and have undergone the audit process numerous times. These procedures have been utilized in-house and verified by multiple analysts over time. This verification is documented in the training files, which are available upon request. These procedures were in place before increased validation requirements were made under ISO 17025 standards. References are available for each of these procedures.

- Kastle-Meyer Test
- Acid Phosphatase Test
- Christmas Tree Stain

4.4 Proficiency Tests

4.4.1 All Forensic Scientists shall follow the procedure for proficiency testing as outlined in the Laboratory Procedure for Ensuring the Quality of Test Results. In addition, all proficiency vendors shall meet FBI Quality Assurance Standards for Forensic DNA Testing Laboratories. DNA Forensic Scientists shall complete an external proficiency test twice a year (every 180 days, based upon the due date set by the vendor). If a Forensic Scientist is on extended leave during the period of time when the proficiency test is to be analyzed, they shall complete an internal competency test prior to returning to the bench for analysis.

4.4.2 DNA Proficiency tests shall be reviewed and recorded on a Proficiency Test Evaluation Form which contains the elements required by the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories (Standard 13).

4.4.3 All final reports shall be graded as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data. Administrative errors shall be documented and actions taken to minimize the error in the future.

4.4.4 All proficiency test participants shall be given feedback which shall be documented.

4.4.5 The vendor due date for DNA External Proficiency Tests shall be the date used to monitor the semi-annual tests for DNA Forensic Scientists.

4.4.6 Each Body Fluid proficiency test shall be evaluated to determine if:

4.4.6.1 The correct body fluid(s) have been identified.

4.4.6.2 All results reported are consistent with written Laboratory guidelines.

4.4.6.3 All final reports shall be graded satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors made. Administrative errors shall be documented and corrective actions taken to minimize the error in the future.

4.4.6.4 All proficiency test participants shall be given feedback which shall be documented.

4.4.7 Storage of Proficiency tests - For storage and retention schedule, see the State Crime Laboratory Procedure for Ensuring the Quality of Test Results.

4.5 Corrective Action – See State Crime Laboratory Procedure for Corrective Action.

4.6 Audits -The Laboratory Procedure for Conducting Audits and Management Reviews shall be referred to

for Section wide internal audits. For the purpose of DNA audits, the Forensic Biology section shall adhere to the FBI Quality Assurance Standards for Forensic DNA testing laboratories standard 15.

4.7 Subcontracting

4.7.1 Body Fluid – refer to the Laboratory Quality Manual.

4.7.2 DNA

4.7.2.1 Use of a Subcontractor Laboratory for Forensic Cases is permitted. Most often this will take place as part of a coordinated outsourcing program to specific laboratories chosen for this work.

4.7.2.2 Criteria for Subcontractor Selection

4.7.2.2.1 The DNA Technical Leader shall approve the technical specifications of the outsourcing agreement and/or document the approval of acceptance of the ownership of the DNA data prior to uploading or accepting data to upload or search in CODIS from any vendor laboratory or agency.

4.7.2.2.2 The criteria for evaluating prospective subcontractor labs may include, but not be limited to, the following: compliance with the proposal, adherence to quality standards (audit report and responses), personnel, equipment/materials/facilities, security, evidence handling procedures, proficiency testing, documentation, validation, safety, analytical procedures, data interpretation and reporting, etc.

On-site visits: When samples are outsourced to a vendor laboratory for DNA analysis, an on-site visit of the vendor laboratory shall be performed or the laboratory may elect to accept information/documentation generated from an on-site visit conducted of the vendor laboratory by an NDIS laboratory using the same technology, platform, and typing amplification test kit as long as it was conducted within the past twelve months. Alternatively, the technical leader of the NDIS participating laboratory may accept an on-site visit conducted by a designated FBI employee. The site visit will be performed by the technical leader or designee from the Forensic Biology Section and will verify that the laboratory meets or exceeds the FBI Quality Assurance Standards. A memorandum should be generated by the employee(s) conducting the site visit and that documentation shall be retained by the Forensic Biology Section. The memorandum shall include the date the on-site visit was performed, a summary of the visit, and documentation of the employee who performed the on-site.

4.7.2.2.3 The Forensic Biology Section and the contracting laboratory shall ensure that an appropriate chain of custody is maintained at all times.

4.8 Uncertainty of Measurement – The Forensic Biology Section acknowledges that its measurements have a level of uncertainty. Since there are no quantitative results reported from the Section, it has no measurements that need an uncertainty measurement formula applied to them.

5.0 Safety – Refer to the State Crime Laboratory Safety Manual.

6.0 References

State Crime Laboratory Quality Manual

ISO 17025

State Crime Laboratory Procedure for Ensuring the Quality of Test Results

State Crime Laboratory Procedure for Conducting Audits and Management Reviews

State Crime Laboratory Safety Manual

State Crime Laboratory Document Control and Management Procedure

Federal Bureau of Investigation “QUALITY ASSURANCE STANDARDS FOR FORENSIC DNA TESTING LABORATORIES.” *September 1, 2011.*

7.0 Records

- Forensic Biology Proficiency Test Evaluation Form
- Key inventory
- Duty list
- Reviewer list
- Work Authorization
- Vendor list
- Forensic Biology section equipment inventory

8.0 Attachments – N/A

Revision History		
Effective Date	Version Number	Reason
09/17/2012	1	Original Document
12/7/2012	2	4.1.1.1 - added wording to show documentation of reading literature; 4.7 - subcontracting added wording from QAS document for criteria for selection and on-site visit of labs (4.7.2)
12/18/2013	3	Header – add issuing authority; 1.1, 1.8, 1.9, 3.1, 4.1, 4.3, 4.4, 4.6, 4.7 – removed DNA Database reference; 3.1.3 – removed (language in Quality Manual); 3.1.3.1, 3.1.3.2, 3.2 through 3.10 – removed section (language in job descriptions); 6.0 – removed QAS Standards for Databasing; 7.0 – updated naming
02/27/2015	4	4.1.1.1 - clarified wording for required training; 4.1.1.2 - removed SBI-88; 4.3.1 – removed reference to database samples; 4.3.5 – removed procedures no longer in use by Section; 4.4.1, 4.4.5 - clarified 180 day date range; 4.7.2.2.2 - clarified wording