NCSBI Forensic Biology Section

Quality Assurance Manual

Approved by:

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NCSBI Quality Assurance Manual

Forensic Biology Section

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1 Goals and Objectives

1.1 Goals

1.1.1 Provide state and local law enforcement agencies laboratory services for identification and genetic typing of biological materials that pertain to a particular criminal investigation.

1.1.2 Ensure the quality, integrity, and scientific accuracy of testing results through the implementation of a detailed Quality Assurance/Quality Control (QA/QC) program.

1.2 Scope

1.2.1 To ensure that the identification and genetic typing procedures are operating within established performance criteria.

1.2.2 To ensure that the quality and integrity of the data are maintained and are scientifically sound.

1.3 Program Objectives

1.3.1 Ensure uniformity and accountability in records and analysis procedures.
1.3.2 Measure quality of performance with known standards and to be able to act on any differences encountered.
1.3.3 Ensure the accuracy of the data generated.
1.3.4 Document corrective actions taken.
1.3.5 Monitor personnel and equipment.
1.3.6 Eliminate non-conforming materials or work.
1.3.7 Prepare and/or verify all control materials used.
1.3.8 Ensure the use of documented and valid materials and procedures.
1.3.9 Provide guidelines to employees so they will know performance expectations.
1.3.10 Ensure that personnel performing these tests have the appropriate level of training and education.
1.3.11 Ensure that analysts are competent in performing the testing and interpreting the results through a series of proficiency tests.
1.3.12 Provide for external audits to ensure that operating procedures are followed and are adequate.

1.3.13 Provide for a safe workplace.

2 Organization and Management

2.1 Organization

2.1.1 The Forensic Biology Section is divided into three functional Units; the DNA Database, the DNA Unit, and the Body Fluid Identification Unit.

2.1.2 Each of the case working units will have at least one Team Leader which is an Assistant Supervisor. The DNA Database Unit has the DNA Database Manager as it=s Team Leader. The Special Agent In Charge oversees all three units.

2.1.3 Each Team Leader will have the following responsibilities:

2.1.3.1 To review and approve weekly report forms and overtime leave requests from the persons listed in their team. To review expense accounts when necessary and to work closely in conjunction with the Section Secretary in processing this information.

2.1.3.2 Administrative review of case reports and files will be conducted by the Team Leaders of the DNA and Body Fluid Identification Units, by the SAC or their designee/s.

2.1.3.3 Team Leaders will conduct work performance reviews and evaluations for members of their Teams after consultation with the SAC.

2.1.3.4 Other duties assigned by the SAC.

2.1.4 The DNA Database Manager has the additional responsibilities of running the day to day operation of the DNA Database Unit, evaluating the performance of DNA Database Unit Analysts, and to inform the SAC of significant events in the DNA Database Unit.

2.1.5 The SAC will handle the assignment of rush cases.

2.1.6 DNA Technical Leader (DNA TL)

2.1.6.1 The DNA TL=s role will be assigned by the SAC.

2.1.6.2 The DNA TL is responsible for the technical operations and Quality Assurance/Quality Control within the DNA Unit.

2.1.6.3 The DNA TL has the authority to suspend DNA operations in the Section if a Technical or Quality problem arises. It is the responsibility of the DNA TL to trouble shoot and solve problems and/or quality issues that arise within the DNA Unit.

2.1.6.4 The DNA TL is responsible for evaluating all methods and procedures used by the laboratory. The DNA TL must approve all SOPs, Protocols, and Quality Manuals within the DNA Unit.

2.1.6.5 The DNA TL is responsible for the implementation of new or modified SOPs and equipment within the DNA Unit. No changes, alterations, or deviations from validated procedures or protocols will be allowed without the approval of the DNA TL.

2.1.6.6 The DNA TL is responsible for the oversight of training, quality assurance, safety, and proficiency testing within the DNA laboratory.

2.1.6.7 The DNA TL will be kept fully informed of any anticipated problems, successes, changes, alterations, etc. within the DNA Unit.

2.1.7 CODIS Manager (State Administrator)

2.1.7.1 The CODIS Manager is responsible for all CODIS operations within the State of North Carolina including all upload of DNA data to the State/National Database.

2.1.7.2 The CODIS Manager has the authority to terminate an individual's or the laboratory=s participation in CODIS in the event of a problem until the reliability of

the computer data can be assured for this laboratory and any local CODIS site in the state of North Carolina.

2.1.8 Body Fluid Technical Leader (BF-TL):

2.1.8.1 The BFTL will be assigned by the SAC.

2.1.8.2 The BFTL is responsible for all technical operations and Quality Assurance/Quality Control within the Body Fluid Unit.

2.1.8.3 The BFTL has the authority to suspend DNA operations in the Section if a Technical or Quality problem arises. It is the responsibility of the BFTL to trouble shoot and solve problems and/or quality issues that arise within the Body Fluid Unit.

2.1.8.4 The BFTL is responsible for evaluating all methods and procedures used by the laboratory. The BFTL must approve all SOPs, Protocols, and Quality Manuals within the Body Fluid Unit.

2.1.8.5 The BFTL is responsible for the oversight of training, Quality Assurance, safety, and proficiency testing within the Body Fluid Unit.

2.1.8.6 The BFTL will be kept fully informed of any anticipated problems, successes, changes, alterations, etc. within the Body Fluid Unit.

2.2 Authority and Accountability

Analysts with delegated responsibilities are empowered by the Section SAC (Special Agent in Charge) to carry out these responsibilities and to act in his place. There will be one Quality Control Officer for the Body Fluid ID Unit and one for the DNA Unit.

Specific delegated responsibilities include:

2.2.1 The Technical Leader is responsible for the Quality Assurance

functions pertaining to proficiency tests and audits (DNA), as well as ensuring that all personnel within their disciplines adhere to QA guidelines.

2.2.2 The QC Officers have the responsibility to ensure that the QC functions are performed on a daily basis. These individuals are also responsible for maintaining the QC data from the manufacturers and the testing of critical reagents. The QC Officer may reject any chemical, solution, supply, reagent, or material that fails to meet specifications. The QC Officers should keep the Technical Leaders apprised of any problems or issues that arise within their respective area.

2.2.3 Designated section members are responsible for the preparation of buffers and solutions, verifying the calibration of scales and thermocyclers, and ensuring that the temperature charts are kept up to date. These individuals report to the respective QC Officer unless otherwise specified.

2.2.4 The Section Safety Officer is responsible for the following:

2.2.4.1 Monthly safety inspections (eye wash, fire extinguishers).
2.2.4.2 Representing the Section at lab wide safety meetings.
2.2.4.3 Ensuring safety training and maintaining these records.
2.2.4.4 Disposal of biohazardous and chemical waste.
2.2.4.5 Acting on reports of injury on the job.

2.2.5 The Documents Control Coordinator is responsible for procedures specified in the ADocument Control Procedure@ and AProcedure for Completion of Quality System Documents@. The Documents Control Coordinator is responsible for the following:

2.2.5.1 Archiving and Maintaining Outdated Section Quality Documents.
2.2.5.2 Logging and Filing New Section Quality Documents.
2.2.5.3 Maintaining Current Section Quality Documents.
2.2.5.4 Preparing Quality Documents for release pursuant to Discovery Orders.

2.3 Administrative Orders Manual

2.3.1 Issuance of the Forensic Biology Section Administrative Order 96-ADM-1 establishes a Section policy and procedures system which will be called the Forensic Biology Section Administrative Orders Manual. This system is designed and created as a communications tool to disseminate clear and understandable SECTION policy and procedures.

2.3.2 The creation of new Section policy or procedures and any modifications or changes to existing Section policy and procedures will be communicated to all staff by Administrative Orders. Any changes/modifications will bear the same number as the old Administrative Order but with a new effective date.

2.3.3 The Administrative Orders Manual will be subdivided into four (4) sections dealing with:

2.3.3.1 Administrative/Management issues (ADM)
2.3.3.2 Safety issues (SAF)
2.3.3.3 Technical Procedures issues (PRO)
2.3.3.4 Evidence issues (EVI)

2.3.4 Administrative orders issued will be numbered by the year, the three letter code above, and a sequential number (e.g. 96-ADM-1). Safety related Administrative Orders may be issued by the Section Safety Officer with the prior approval of the SAC.

2.3.5 The Section will review the manuals every year. This review must be documented and signed off by the respective Technical Leader.

3 Personnel Qualifications, Requirements, and Training

3.1 Overview

All persons involved in the actual recovery, evaluation, analysis, and interpretation of body fluid identification and DNA evidence shall have a background appropriate to their duties. All analysts will go through a training process which uses a four-prong test for competence:

3.1.1 Knowledge of the scientific literature and procedures with reference to body fluid identification procedures and/or DNA typing. This will be evaluated by college courses passed and/or by written tests given as part of an in-house training program.

3.1.2 Skills and mechanical abilities to perform the test which can be evaluated by the observation of qualified personnel and by determining if the proper test results are obtained.

3.1.3 The ability to correctly interpret test results being of paramount importance. All analysts will successfully complete qualifying competency tests prior to entering into a case internship or testing of DNA Database samples. Qualified DNA Analysts will undergo proficiency testing biannually; Body Fluid Analysts shall undergo annual proficiency testing.

3.1.4 The ability to present and defend results in a moot court.

3.2 Section Requirements

3.2.1 Business Hours

3.2.1.1 The normal working hours of the Forensic Biology Section are 8:00 am to 5:00 pm, Monday through Friday.

3.2.1.2 Employees will be allowed to work a flexible schedule as long as the section has full coverage between the normal working hours.

3.2.1.3 All employees are responsible for advising the section secretary or unit supervisor (at approximately 8:00 am) when they are sick, unable to come to work, or running significantly late if possible. This will allow the appropriate

messages to be relayed to that employee. If someone other than the section secretary takes this message, they are responsible for recording this information on the sign-out sheet in the Section office.

3.2.1.4 The Forensic Biology Section will maintain two SIGN OUT logs in the Section. One will be located outside the secretary=s office and the other one outside the main office in the DNA Database Unit. If the employee is not signed out on this board, they are expected to be at their duty station or in the Laboratory Building to receive phone messages and work assignments. Employees are required to sign out when leaving the section for an extended period of time, noting where they are going. The sign out log will identify if an employee is out on leave, if an analyst is in court, at a crime scene, or at a Bureau sanctioned training. Analysts will check out for lunch if they leave the section.

3.2.2 Overtime

If employees are on mandatory overtime, they must attempt to work the prescribed number of hours each pay cycle. Any employee that has a large single deviation from the requirement, or a habit of not making the set amount MUST have written documentation (e-mail is appropriate) to their Team Leader and/or SAC stating why they didn't work the prescribed number of hours.

3.2.3 Weekly Case Reports and Rush Reports

3.2.3.1 Need to be submitted via e-mail to the section secretary on the last day of the week by 3 pm.

3.2.3.2 Cases that are transferred within a unit are not to be counted as received, but are counted as total cases.

3.2.3.3 If an analyst is scheduled to be out of the office for a the following week - all reports for the scheduled time should be turned in IN ADVANCE of leaving.

3.2.4 Clothing

3.2.4.1 All agents must maintain, within the Section at all times, clothing that is appropriate for court and crime scenes, as well as for meetings and other functions where they will be representing the Bureau.

3.2.4.2 Bureau issued clothing (BDU=s) will be worn to crime scenes. Other appropriate clothing may be worn if the BDU=s are soiled and the employee has not had a reasonable period of time to launder the same. Under no circumstances, will jeans be worn while representing the Bureau in any capacity. Failure to comply with this policy (i.e. having to go home to obtain the proper dress) will be cited as failure to meet performance expectations.

3.2.5 On Call

3.2.5.1 The Forensic Biology Section will maintain an on-call program to ensure the availability of agents on a 24 hour, seven day a week basis. All agents who are qualified to perform crime scene analysis will participate. Agents will carry the designated pager at all times while on call. The section secretary will be responsible for seeing that the on-call duty roster is kept current in the DCI Mapper System.

3.2.5.2 All changes to the roster must be recorded in the Mapper System and the section secretary is responsible for making these changes and notifying the Special Agent In Charge and the Assistant Director=s office of these changes.

3.2.5.3 If an agent is out of the area during their on-call period, it is their responsibility to find a replacement to cover them until they return to their duty station.

3.2.5.4 Agents that are going off call are required to personally deliver the pager to the next Agent in rotation.

3.3 Job Description

A current copy of all job descriptions within the Forensic Biology Section will be maintained by the Section SAC in each employee=s personnel file.

3.4 Education, Training, and Qualifications of Personnel

3.4.1 Requirements for Individuals Performing Body Fluid Identification Analysis

All analysts will meet the following requirements prior to performing independent Body Fluid analysis on casework.

3.4.1.1 A minimum of a Bachelor=s Degree in a biological science (biology, zoology, medical technology, microbiology, biochemistry, etc.).

3.4.1.2 Completion of the Body Fluid Identification Training Program.

3.4.2 Requirements Qualified DNA Analyst

All DNA analysts will meet the following requirements prior to performing independent DNA analysis on casework.

3.4.2.1 A minimum of a Bachelor=s Degree in a biological science (biology, zoology, medical technology, microbiology, biochemistry, etc.) and undergraduate and/or graduate level course work in biochemistry, genetics and molecular biology, course work and/or training in statistics and population genetics as it applies to forensic DNA analysis, and 6 months of forensic DNA experience. An individual that does not possess a biological science degree must possess a degree accepted by Federal Standards. In addition, this individual must have the course requirements and have prior DNA laboratory experience.

3.4.2.2 Successful completion of the DNA Training Program.

3.4.3 Requirements for Individuals Performing independent DNA Database Testing

All DNA analysts will meet the following requirements prior to performing independent DNA analysis Database Samples.

3.4.3.1 A minimum of a Bachelor=s Degree in a biological science (biology, zoology, medical technology, microbiology, biochemistry, etc.) and undergraduate and/or graduate level course work in biochemistry,

genetics and molecular biology, course work and/or training in statistics and population genetics as it applies to DNA analysis, and 6 months of DNA experience.

3.4.3.2 Completion of the DNA Database Training Program.

3.4.4 Requirements for DNA Technical Leader

The DNA Technical Leader will meet the following "Quality Assurance Standards for Forensic DNA Testing Laboratories":

3.4.4.1 A Graduate Degree in a biological science or forensic-science related area.

3.4.4.2 A minimum of 12 semester hours in biochemistry, genetics, molecular biology, and statistics or population genetics. At least one of these courses will be at the graduate level.

3.4.4.3 A minimum of 3 years of forensic DNA experience.

3.4.4.4 A level II analyst or higher.

3.4.5 Requirements for Body Fluid Technical Leader

3.4.5.1 A Bachelors Degree in a biological science or forensic-science related area and 5 years of forensic Body Fluid experience or an advanced Degree in a biological science or forensic-science related area and 3 years of forensic Body Fluid experience.

3.4.5.2 A level II analyst or higher.

3.4.6 Requirements for CODIS Manager (State Administrator)

3.4.6.1 A Bachelor=s Degree in a biological science or computer science.

3.4.6.2 Have a working knowledge of computers, computer networks, computer database management, and DNA profile interpretation.

3.4.6.3 Is the system administrator of the laboratory=s CODIS network and is responsible for security of DNA profile data stored in CODIS.

3.4.6.4 Is responsible for oversight of CODIS computer training and quality assurance of the data in CODIS.

3.4.7 Technicians

3.4.7.1 Technicians will be required to assist Forensic Biology=s personnel with many functions essential to the daily operation of the Section.

3.4.7.2 Technicians may also assist Qualified Analysts in working forensic cases. The Technician will not be allowed to work independently from a Qualified Analyst until they become certified.

3.4.7.3 The following requirements must be completed in order for a technician to become certified.

3.4.7.3.1 BS degree in a biological science, such as biology, biochemistry, genetics, or microbiology.

3.4.7.3.2 Successful completion of a training program specific to the area in which they will be working.

3.4.7.3.3 Successful completion of a competency test specific to the tests/analysis that they will be performing.

3.4.7.4 The Certified Technician will participate in a Proficiency Testing Program in the specific area in which they were trained as soon as possible after training has been completed. The interval of these tests will be at the same interval for a case working analyst.

3.4.8 Intern Program

3.4.8.1 Goals and Objectives: To provide students interested in a career in forensics an opportunity to work in a

forensic DNA laboratory and to view the various kinds of off-site work environments in which the forensic scientist may work.

3.4.8.2 Interns may be assigned collateral duties to assist an analyst/agent with a specific research project or assignment in addition to their work in the Database Unit. These assignments are made by the Special Agent In Charge or designee. All interns shall go through a background check, are treated as employees (they have to fill out time sheets, do their assigned work correctly and timely, are held accountable for their utilization of time, and are given full access to necessary areas of the laboratory).

3.5 Continuing Education

Section analysts must stay current of developments within the field by reading current scientific literature and by attendance (minimum 8 hours per year) at seminars, college courses, or professional meetings. Management must provide analysts with an opportunity to comply with the above requirements as resources permit.

3.6 Training Records

3.6.1 Documentation of all training will be maintained in the Forensic Biology Section and submitted to the SBI Training Section. This official training log is downloaded from Mapper and is maintained by the SBI Training Division. A master training log is maintained by the SAC.

3.6.2 The Section SAC will maintain the proficiency tests results from each Analyst.

3.7 Personnel Records

The Section Special Agent In Charge maintains a personnel file on each analyst which may include but is not limited into the following categories:

1. Personnel history, assignments, promotions, etc.
2. Commendations
3. Complaints and disciplinary action
4. Training
5. Evaluations

6. Equipment issued
7. Job descriptions

4 Facilities

The laboratory is designed to provide adequate security and minimize contamination.

4.1 Access

Access to the laboratory is controlled and limited as described in the NC SBI Policy and Procedures Manual.

4.2 Facilities

4.2.1 Body fluid examinations should be performed in the lab rooms assigned to the Body Fluid Identification Unit.

4.2.2 DNA extractions will be conducted in the DNA laboratory space or the individual rooms assigned for the purpose of extracting DNA. All analysts will conduct the phenol/chloroform step under a certified chemical fume cabinet.

4.2.3 PCR setup is to take place in an AirClean 600 workstation (or equivalent).

4.2.4 Amplified DNA product is generated, processed and maintained only in the designated PCR amplification lab(s). The PCR amplification lab is a room that is separate and apart from the extraction, examination, and PCR set-up work areas.

4.2.5 Analysts will follow procedures for monitoring, cleaning, and decontaminating facilities and equipment. The documentation that work areas and equipment have been decontaminated will be noted on extraction and amplification worksheets for each case/database set. Efficacy of the cleanup will be monitored by the negative controls.

5 Evidence Handling Procedures

5.1 Sample Labeling and Documentation

Each sample will be labeled with a unique identifier as per the NC SBI Policy and Procedures Manual.

5.2 Storage

All evidence submitted for testing will be stored under the appropriate conditions to prevent contamination and minimize degradation of the sample.

5.3 Evidence Security

5.3.1 All evidence will remain in the possession of the individual who has signed for the evidence. Evidence will be maintained in a secure area except for when it is being analyzed. When being analyzed, it shall remain in the care and custody of the analyst.

5.3.2 Analysts will lock doors to lab rooms where evidence is examined, unless they are physically present in the room or leave for a brief period of time (i.e. to go to the stock room to get supplies). When they leave the room for a long period, the doors must be locked, or the evidence placed in a locked cabinet or drawer.

5.3.3 The Section Evidence Vault will be secured at all times, except when someone is in the vault.

5.4 General Procedures

Samples will be handled in a manner to prevent loss, alteration, contamination, or mixing. Analysts will wear gloves while handling samples both to protect the samples from contamination and for personal protection. Analysts will also discard disposable pipette tips after each use (when necessary), generally not have more than one sample open at a time, and use sterile solutions and reagents when necessary.

(Body Fluids) Benches and hoods should be cleaned with a disinfectant (i.e. ~10% bleach solution) prior to use, in between cases, and between processing items from the victim and suspect.

(DNA) Benches and hoods should be cleaned with a disinfectant (i.e. ~10% bleach solution) prior to use, in between cases (or batched cases), and between processing Known Standards and Forensic Unknowns.

5.4.1 Each analyst in the Body Fluid Identification Unit will process an

individual item of evidence over a piece of clean paper to capture any hair, fiber, or other trace evidence which may be dislodged during analysis. Upon completion of analysis, the evidence item will be placed back into its original container along with any debris found on the paper. Evidence items like Sexual Assault and Suspect Evidence Collection Kits, and their sub-items will be analyzed over a piece of paper, but it will not be necessary to place the examination paper into the kit upon completion of analysis because no loose trace evidence would be expected from these types of evidence.

5.4.2 Victim and suspect hair evidence found in the Victim and Suspect kits, the panties in the Sexual Assault Evidence Collection Kits and the hair standards will be transferred to the Trace Evidence Section, regardless of whether other bulky evidence exists in the case. In the event that DNA evidence is found, hair evidence will not be transferred.

5.4.3 All liquid blood samples will be removed from evidence packages within 2 days of receipt by an analyst and will either be refrigerated or a blood stain will be prepared on S&S 903 paper (or equivalent) unless the analyst determines that the sample is too old or degraded to be useful as a standard. All liquid blood samples will be processed in a Biological Safety Cabinet. After preparation of the blood stain, the blood tubes will be re-capped and the tube will placed in a heat sealed container. The blood stain will be packaged in a properly labeled and sealed coin envelope after it is dried.

5.4.4 Analysts will follow all approved safety precautions including wearing of nitrile gloves (or equivalent), lab coats, and safety glasses when processing evidence. Gloves will be changed when the analyst feels they have been contaminated or soiled (i.e. material spilled onto glove or a non-clean item is touched). Additionally, for Body Fluid Identification, gloves will be changed between cases and between handling evidence items from the victim, crime scene, and suspect.

5.4.5 Labeling

5.4.5.1 All tubes containing extracted DNA shall contain the SBI Case Number, the Item Number, the date of extraction and the analyst's initials.

5.4.5.2 Amplified product shall be stored in trays labeled the SBI Case Number, the date of amplification, and the analyst's initials.

5.4.5.3 The sides of 96 well trays used for capillary electrophoresis shall be labeled with the analysts initials. The columns used for a particular run shall be labeled by writing the date on the side of the tray and aligned with the specific columns (example, for December 14, 2006, the number 121406 or equivalent shall be used). If subsequent runs are loaded in the tray and run on the same date, then the date followed with ascending letters shall be used to designate the other runs (example of run on the same date: 121406, 121406a, 121406b, etc.).

5.4.6 Protective clothing (i.e. lab coats and gloves) will not be worn outside the laboratory or into office space in the laboratory.

5.4.7 If samples are lost through spillage, are inadvertently mixed, or accidentally contaminated, the analyst will immediately cease all work on that sample, document the incident in the case file, and notify the Section SAC. The final lab report will indicate the reason why no results were reported for samples lost, accidentally contaminated, etc.

5.4.8 To ensure that results are obtained from minimal sample amounts, it is permissible to consume the entire piece of evidence during analysis. However, DNA analysts should attempt to preserve half the raw evidence if possible. Any time evidence is consumed, it must be documented in the case notes. In addition, the consumption of the evidence must be noted on the envelope and in LIMS.

5.4.9 In the case of STR analysis, the known standards will be extracted separately from the questioned samples.

5.4.10 Amplified DNA from STR typing of case samples will be stored refrigerated until the case is finalized and the report has been issued.

5.4.11 DNA analysts will return all evidence and dried extracted DNA to the investigating agency. The extracted material (cuttings,

swabbings etc.) will be disposed of during analysis.

5.5 Disposition of human remains.

5.5.1 The Section occasionally receives human tissue or bone as standards in cases. The destruction of human remains can ONLY be done pursuant to a court order so it is imperative that we notify officers of this fact.

5.5.2 When this Section returns human remains to investigating agencies, the Disposition section of the lab report will contain the following statement (or equivalent):

NOTE: Evidence being returned in this case includes human remains which need to be kept frozen to avoid degradation and annoying odors. Human remains may ONLY be destroyed pursuant to a court order, so you should seek an ORDER FOR DESTRUCTION to dispose of these remains as soon after the judicial disposition of this case as possible.

5.6 Transfer of evidence to and from other laboratories.

5.6.1 All evidence transfers to outside agencies will be made through the Evidence Control Unit. In the unlikely event that an analyst should receive evidence from another laboratory directly, (either for analysis or after analysis) that evidence will be logged in and disposed of through the Evidence Control Unit.

5.6.2 The only exception to the above rule will be the direct transfer of evidence between an analyst and officer (such as when Evidence Control asks analysts to review and evaluate cases) or if an analyst examines the evidence in the officer=s custody. In this case, it will be with the knowledge of, and the paperwork cleared through, the Evidence Control Unit first.

5.7 Operational Guidelines for the Receipt, Identification, Storage, and Chain of Custody of Evidence

The operational guidelines set out in the SBI Policy and Procedures Manual will be followed to ensure that custody is maintained for each piece of evidence.

5.8 Unworked Evidence

Analysts will make every effort to assist investigators in preserving evidence for future testing by removing cuttings, absorbing stains if appropriate, or giving directions to officers on long term storage of unworked forensic evidence. Any exception to this policy must be approved by the SAC prior to retention of the samples by this laboratory.

5.9 Case Acceptance Policy

A copy of the SBI case acceptance policy for the DNA typing of biological materials can be found in the Appendix section of the Quality Assurance Manual. Internal guidelines for case submissions to the DNA unit are also found in the Appendix.

6 Validation

This laboratory shall use only validated methods and procedures for the analysis of forensic cases and/or convicted offender samples.

6.1 Developmental Validation of the DNA Analysis Procedures

Prior to the implementation of a new procedure and/or new equipment, validation studies must have been conducted by the scientific community or this laboratory to ensure the accuracy, precision, and reproducibility of the procedure. The developmental validation will include the following:

6.1.1 Documentation that defines and characterizes the locus.

6.1.2 Species specificity, sensitivity, stability, and mixture studies.

6.1.3 Population studies will be documented and available. This laboratory will utilize NC White, Black, Hispanic, and Lumbee Indian databases in reports. These databases will be tested for independence by a Population Geneticist.

6.2 Internal Validation of the DNA Analysis Procedures

Prior to initiation of DNA typing procedures that have been developmentally validated by other labs, the following studies will be conducted by this laboratory:

6.2.1 The procedure will be tested using known and non-probative evidence samples (if available). The lab will use a human DNA control(s) to monitor and document the reproducibility and precision of the procedure.

6.2.2 Before introduction of the method into forensic casework, the analyst(s) performing the validation will complete a qualifying/competency test.

6.2.3 Any significant modification made to the analytical procedure will be compared to the original procedure using identical samples.

6.2.4 Match criteria will be established and documented based on empirical data (if applicable).

6.3 Internal Validation of Body Fluid Identification Procedures

Prior to initiation of new Body Fluid typing procedures, studies will be conducted by this laboratory to ensure reproducibility and precision of the procedure as well as define and/or establish limitations to the procedure. The procedure will be tested using known samples and may include (but not be limited to) the following tests:

6.3.1 Reproducibility
6.3.2 Sensitivity
6.3.3 Species Study (if applicable)
6.3.4 Sample Stability

6.4 Non-specified Procedures

Where methods are not specified, this laboratory shall, whenever possible, select methods that have been published by reputable technical organizations or in relevant scientific texts or journals, or have been appropriately evaluated for a specific or unique application.

7 Analytical Procedures

7.1 Technical Procedures

7.1.1 All technical procedures used in the Forensic Biology Section will be found in the Section Standard Operating Procedures.

7.1.2 It is the responsibility of each analyst to ensure they are using the most recent revision of the SOP when performing the procedure.

7.1.3 Individual recipes and QC checks on commercially obtained critical reagents can be found in Appendices.

7.2 Body Fluid Identification - Controls

7.2.1 Known Standards for Tests

7.2.1.1 Preliminary: Phenolphthalein and luminol solutions will be tested daily in the section or prior to use (known bloodstains and clean filter paper for phenolphthalein and a penny or bloodstain for luminol).

7.2.1.2 Takayama reagent will be made fresh from stock solutions and will be tested against known blood stains each day in use.

7.2.1.3 Species antiserum: Each antiserum used will be tested against known sera as a positive control each day in use. New lots will be tested for species specificity before being released for casework.

7.2.1.4 Semen identification tests, i.e. acid phosphatase spot plate tests, will be tested simultaneously with a known semen standard and a blank reagent control for each run.

7.2.1.5 Amylase tests (i.e. Phadebas) will be simultaneously tested against known saliva and a blank reagent control during each run. New lots will be tested before being released for casework.

7.2.1.6 OneStep ABAcard7 p30 Test: Each lot of tests shall be evaluated before release for use in casework with a known standard and serial dilution for sensitivity.

7.2.1.7 OneStep ABAcard7 HemaTrace7 Test: Each lot of tests are evaluated before release for use in casework with known standards of various species.

7.3 DNA Unit - Controls

The following controls will be run at each step of the STR analysis in accordance with the Section=s STR SOPs.

7.3.1 Positive Extraction Control: For each case or batch of cases, a known human bloodstain (i.e. AMJB@) sample will be extracted and processed with the case samples. If known standards are not extracted with a case or a batch of cases, MJB may be extracted with the forensic unknown samples. The DNA Database Unit is not required to run a Positive extraction control.

7.3.2 Negative Extraction Control:

7.3.2.1 For each set of extractions (i.e. known standards and forensic unknown samples in a batch), a reagent blank will be prepared. This blank will consist of the reagents used in the extraction process and be treated the same as another sample throughout the entire process.

7.3.2.2 If a dilution is made of a sample prior to amplification, a dilution of the corresponding negative control does not have to be made if the same TE is used for the Negative Amplification Control.

7.3.2.3 It is acceptable to run more than one reagent blank in anticipation of having to re-run or dilute samples for amplification.

7.3.3 Quantitation: An appropriate yield calibration set consisting of DNA of known concentration will be run with each quantitation so that an estimate can be made as to the quantity of DNA present in the case samples. A Non-template Control (NTC) shall be included with each quantitation run. All forensic unknowns (and preferably all forensic knowns) will be quantitated. DNA Database samples need not be quantitated by a direct method, since a standard size cutting is used on all, which is an indirect method of quantitating these samples.

7.3.4 Negative Amplification Control: A reagent blank consisting of TE and the amplification reagents will be run at the time of amplification.

7.3.5 Positive Amplification Control: For each case or batch of cases being amplified, the known human cell line control (i.e. 9947A) will be amplified, electrophoresed, and analyzed with the samples. The 9947A allelic values must be confirmed correct before the samples can be used for comparison purposes. Note: If samples are re-injected and the corresponding 9947A has typed correctly, it is permissible to use a different 9947A for Genemapper ID analysis.

7.3.6 Genemapper ID Allele Call Verification: A Positive Amplification Control (9947A) will also serve to verify Genemapper ID's Allele Calls. A 9947A must be included with every Genemapper ID analysis. Note: On subsequent re-injections of samples, the original 9947A does not have to be re-injected.

7.3.7 Controls Run during Electrophoresis:

7.3.7.1 The following controls and markers will run during initial electrophoresis:

- 7.3.7.1.1 Known human cell line control (i.e. 9947A)
- 7.3.7.1.2 Negative Amplification Control
- 7.3.7.1.3 Extraction Control (MJB)
- 7.3.7.1.4 Reagent blanks for extraction chemicals
- 7.3.7.1.5 Allelic Ladder

7.3.7.2 The following controls and markers shall be run when samples are re-injected using the same plate as the first run and for the same injection time:

- 7.3.7.2.1 Allelic Ladder
- 7.3.7.2.2 Known human cell line control (i.e. 9947A) must be run or loaded imported in to project when Analyzed

7.3.7.3 The following controls and markers shall be run when samples are re-injected using a longer injection time:

- 7.3.7.3.1 Known human cell line control (i.e. 9947A) must be run or loaded imported in to project when Analyzed
- 7.3.7.3.2 Negative Amplification Control

7.3.7.3.3 Allelic Ladder
7.3.7.3.4 Reagent blanks

7.3.7.4 The following controls and markers shall be run when samples are re-run (amplified product loaded on another plate):

7.3.7.4.1 Known human cell line control (i.e. 9947A) must be run or loaded imported in to project when Analyzed
7.3.7.4.2 Negative Amplification Control
7.3.7.4.3 Allelic Ladder

Below is a table summarizing 7.3.7:

Controls Used During DNA Forensic Analysis		
Control	Purpose	Must be present when:
Positive Amplification (9947A)	Ensures amplification reagents are efficacious. Ensures thermocycler is working properly. Also serves as a positive control for GeneMapper ID.	X Initial Electrophoresis X Re-injection or Liz Failure X 22 second injections X Re-run on another plate
Negative Extraction	Ensures extraction solutions and disposables are not contaminated with foreign DNA.	X Initial Electrophoresis X 22 second injections
Positive Extraction (MJB)	Ensures extraction solutions and disposables are efficacious in lysis and DNA extraction.	X Initial Electrophoresis
Negative Amplification	Ensures Amplification Reagents and disposables are not contaminated with foreign DNA.	X Initial Electrophoresis X 22 second injections X Re-run on another plate

7.4 Reagents, Buffers, and Solutions

7.4.1 DNA Critical reagents
The following critical reagents used in the DNA Unit shall be QC tested prior to use:

Stain Extraction Buffer
STR TE
Taq Gold polymerase

STR kits (Includes Identifiler7 and Quantifiler7)

7.4.2 The following critical reagents are used in the Body Fluid Identification Unit and shall be QC tested prior to use:

ABA card Hemetrace kits
ABA card P-30 kits
Antiserum
Christmas Tree stains
Phenolphthalein
Phadebas Tablets
Takayama reagent

7.4.3 Sources of Materials, Reagents, Chemicals and Supplies

The Section will maintain records for commercial sources for all materials, reagents, chemicals and supplies used in the Section.

7.4.4 Procurement

7.4.4.1 All orders for materials, reagents, chemicals and supplies will be placed by individuals designated by the Section SAC.

7.4.4.2 Receipt of Chemicals, Supplies, Reagents and Materials by the Section:

7.4.4.2.1 All chemicals, reagents, supplies and materials will be received into the Section by the SAC or designee, so that they can be checked off against the orders placed. The date of receipt and initials will be placed on all chemicals and reagents upon receipt.

7.4.4.2.2 Analysts who open a new container of a common use reagent, solution, buffer, or chemical shall place the word AOpened@ or letter AO@ followed by their initials and the date the container was opened on the container. If the container is too small to be so labeled, the container will be placed in a larger container (i.e. a zip lock bag) and labeled with the above information.

7.4.4.2.3 Those items which need to be verified as part of a quality control process (e.g., STR Kits) will be turned over to the appropriate Quality Control Officer, who will ensure they are QC tested prior to placing them into the inventory for use. ACertificates of Analysis@ provided by the manufacturer of an item will be maintained in the QC files.

7.4.4.2.4 If a Quality Control Officer finds that a particular supply, chemical, reagent or material does not meet required quality control standards, he/she may retest the material or immediately notify the manufacturer and reject the entire lot. This material is not to go into inventory for use, but will be immediately returned to the supplier or discarded.

7.4.4.2.5 Inventory will be stored under the conditions specified by the manufacturer.

7.4.5 Laboratory Prepared Buffers and Solutions

7.4.5.1 Each solution prepared will have the following information recorded in a log book maintained by the Quality Control Officer. Manufacturer and lot number of the chemical(s) used, date prepared, pH check of the reagent or solution (if applicable), initials of the preparing analyst, the amount made (if applicable) and expiration date.

7.4.5.2 Extension of Expired Test Kits, Prepared Solutions and Reagents: Critical Reagents may be used after the expiration date if a second QC test is passed. If the QC test passes, then the expiration date may be extended for one month. If necessary, the expiration date may be extended monthly upon successful completion of QC retests and TL approval.

7.4.5.3 Buffers and solutions will be prepared using water from the lab's water purification system.

7.4.5.4 All lab prepared buffers and solutions will be clearly labeled to reflect contents, expiration date (if applicable), and initials of the preparer. All buffers will

be stored under the appropriate conditions. Lab prepared buffers and solutions required to be sterile will be autoclaved or filter sterilized into a sterile container.

7.4.5.5 BSA, Proteinase K, and DTT aliquots shall be placed different colored microcentrifuge tubes and stored in a container labeled with the Lot number, date prepared, expiration date, and preparer's initials.

7.4.5.6 Recipes for all lab prepared buffers and solutions will be listed in the Quality Control Inventory Log of Lab Prepared Reagents and Solutions and will not be deviated from. This procedure will give an ingredient list, safety notes if applicable, preparation instructions and storage instructions.

7.4.5.7 On the first working day of each month, each analyst in the Body Fluid Identification Unit will discard the Phenolphthalein and Sodium Acetate Buffer (for acid phosphatase testing) solutions, clean the containers with hot water. The analyst will retrieve new solutions at this time.

7.4.5.8 Analysts will observe the following rules for the correct storage and use of antiserum, Takayama working solutions, and other solutions and chemicals.

7.4.5.8.1 Antiserum

7.4.5.8.1.1 The Unit QC Officer will quarantine all antiserum and whole sera received until it passes all QC tests. Only then will it be placed into working stock.

7.4.5.8.1.2 The Unit QC Officer is responsible for seeing that all of the outdated and expired antiserum is discarded.

7.4.5.8.1.3 Anti-human sera and the corresponding normal animal sera will be reconstituted by each analyst as needed. At the time of reconstitution, the date and initials will

be recorded. Reconstituted antiserum and normal sera will be stored in the refrigerator and will expire one month from reconstitution. Reconstituted sera and antiserum that is frozen will expire in one year.

7.4.5.8.1.4 Animal antiserum, when reconstituted will be maintained in the stockroom freezer and must be tested each time with the appropriate known control serum. The date of reconstitution and analysts initials will be recorded on the bottle. Reconstituted sera will be stored in the refrigerator for one month or in the freezer for one year.

7.4.5.8.2 Takayama and other chemicals

7.4.5.8.2.1 Prepared working Takayama reagent will be prepared as needed. Prepared working Takayama reagent will expire at the end of the day.

7.4.5.8.2.2 Kernochtrot and Picroindigocarmine Stains for sperm slides will be stored at room temperature in a central location and will be prepared by the Unit QC Officer. Analysts may remove working stocks from this supply and store them at room temperature.

7.4.5.8.2.3 Fast Blue B Salt for acid phosphatase detection, to which water has been added for working solutions, will be used for no longer than a week. This compound may be carcinogenic so analysts must wear gloves when preparing and using this chemical. Care should be taken not to breathe the dust. Due to the potential toxicity, it is preferable to prepare small aliquots and discard them at the end of the working day. Fast Blue B Salt should be stored refrigerated.

7.4.6 QC Measures For The ABA p30 Card

7.4.6.1 Samples have been prepared from serial dilutions of liquid semen. Validation studies showed that positive results could be obtained from a 1:100 dilution, but not a 1:1000 dilution. Simply retrieve the stains prepared from neat, 1:10, 1:100, and 1:1000 dilutions of semen and test them.

7.4.6.2 Record each response as positive or negative. The lowest concentration that yields a positive result is considered the detection limit for that lot. If the kits pass the QC testing, the QC officer will write a statement such as AQC test passed (date)@ on the box and place it in the stockroom for use.

7.4.7 QC Measures for the ABA HemaTrace Card

7.4.7.1 Bloodstains from a variety of animal bloods have been prepared. Validation studies have shown that positive results can be obtained from ferret blood, higher primate blood and human blood. New lots of cards are to be tested with human, ferret, monkey, and other various animal blood samples.

7.4.7.2 Record each response as positive or negative. To pass the QC test, positive results must be obtained for the human blood sample and tests must be negative for the animal species other than ferret or higher primate. If the kits pass the QC testing, then the QC Officer will write a statement such as AQC test passed (date)@ on the box and place it in the stockroom for use.

7.4.8 Preparation of Glassware and Plasticware

7.4.8.1 All glassware and plasticware will be cleaned prior to use. If appropriate, glassware will be autoclaved.

7.4.8.2 Disposable plasticware which needs to be microbially decontaminated will be autoclaved prior to use and disposed of immediately after use.

7.4.9 Disposal of Materials, Reagents, Chemicals and Supplies

Disposal of hazardous wastes will be handled as described in the SBI Laboratory Safety Manual.

7.4.10 Verification of Performance of STR Kits

7.4.10.1 The performance of each STR Kit lot shall be verified. The reagents from each kit shall be used to amplify and separate, via electrophoresis, the 9947A DNA standard and a negative amplification control. Genemapper ID will then be used to determine the allelic values.

7.4.10.2 The lot number of each kit component, the data sheets, electropherograms, and calls shall be documented.

7.4.10.3 Acceptance Criteria

7.4.10.3.1 9947A alleles must match and correspond to the known 9947A alleles for each locus tested.

7.4.10.3.2 For each Locus, the allelic ladder must give correct values as per manufacturer's specifications.

7.4.10.3.3 The negative amplification control shall not demonstrate peaks above threshold or activity that would be indicative of contamination.

7.4.10.3.4 Failed lots may be retested to make sure the first test was done properly. If the kit passes the retest, then the kit may be accepted and used. If the kit fails the retest, then the kit must not be accepted for use and shipped back to the manufacturer as soon as possible.

7.4.10.4 Each lot of Quantifiler Kits shall be tested by running the standard curve in duplicate and an NTC. The acceptance criteria for each lot shall be as follows:

7.4.10.4.1 The slope shall be between -2.9 to -3.3. If the value falls outside of this range, then one point of the slope may be dropped to account for pipetting variations.

7.4.10.4.2 The R^2 value must be greater than or equal to 0.98.

7.4.10.4.3 The NTC shall have a Ct value of 36 or greater.

7.4.10.4.4 Failed lots may be retested to make sure the first test was done properly. If the kit passes the retest, then the kit may be accepted and used. If the kit fails the retest, then the kit must not be accepted for use and shipped back to the manufacturer as soon as possible

7.4.11 QC of Stain Extraction Buffer and STR TE

7.4.11.1 At least one MJB bloodstain and a negative extraction control shall be extracted, quantified, amplified, electrophoresed, and analyzed.

7.4.11.2 MJB shall give correct allele values at every locus.

7.4.11.3 The negative control sample shall not display allelic peaks or activity that is indicative of contamination.

7.4.11.4 In the event of a failure, the lot may be retested. If the lot fails the second test then it may not be used.

7.4.12 NIST Standard Reference Material (SRM)

7.4.12.1 The DNA Unit will test the current analytical procedure in use against the appropriate NIST SRM kit (or standard(s) traceable to the NIST SRM) on an annual basis. When substantial changes or new procedures are validated, they will be checked against the appropriate NIST SRM.

7.4.12.2 A known human blood standard may be tested simultaneously with the NIST SRM kit. If the NIST SRM standard is run successfully, then the Lot of material (bloodstain) shall be traceable to the NIST SRM standard. This blood can then be used instead of the

NIST SRM standard for yearly testing. However, once the lot of material is exhausted, then a new lot of material must be tested against a NIST SRM kit.

8 Calibration and Maintenance of Equipment and Instruments

8.1 Procurement: All equipment and instruments will be ordered by the Section SAC or designee.

8.2 Equipment Inventory Log: An inventory log will be maintained on each piece of equipment in the Forensic Biology Section.

8.3 Operating Manuals: Operating manuals and warranty information provided by the manufacturer will be maintained in a file in the Forensic Biology Section conference room or in close proximity to the instrument.

8.4 Training: Operators of scientific instruments will be knowledgeable in their use. Operator training will occur during the in-house training program and will cover the manufacturer's instructions, theory of application, procedures to be used, and any calibration requirements

8.5 Equipment Maintenance: Analysts will notify the Special Agent In Charge of equipment that is broken, needs to be repaired or serviced. Servicing or maintenance from the vendor or manufacturer will be documented and retained.

8.6 Temperature Records

8.6.1 Refrigerators/Freezers: Shall be recorded every business day unless the analyst is not in the laboratory. If the analyst is out of the lab, the analysts shall document this on the temperature chart.

8.6.2 Water Baths, Heat blocks, and Incubators: Shall be recorded on the day DNA extractions were performed.

8.7 Calibration Verification Logs

8.7.1 Each piece of equipment which needs to be monitored and/or verified will be checked on an appropriate schedule. Calibration Verification will be performed using appropriate certified standards and will be documented on a calibration log kept by the Quality Control Officer(s). A written procedure or set of instructions will be available for calibration verification of more complex instruments. The section will use the procedures for calibration verification of thermocyclers provided by the manufacturer.

8.7.2 Some instruments will be calibrated routinely by certified external agencies (e.g., bio-safety cabinets, pipettors, balances and

microscopes).

8.7.3 Other equipment will be maintained by external vendors (i.e. water systems).

8.7.4 Each calibration log will clearly show the calibration source used and the frequency of calibration.

8.8 Equipment Needing Calibration: The equipment listed below shall be calibrated prior to coming online for use in the Section.

8.8.1 Balances: The electronic top loading and analytical balances are cleaned, calibrated, and serviced biannually by a contract vendor.

Balances also undergo a weight check monthly by designated analysts in each unit.

8.8.2 Pipettors: Pipettors will be calibrated biannually by a contract vendor.

8.8.3 Biological Safety Cabinets: Biological safety cabinets will be inspected and certified annually by a contract vendor.

8.8.4 Digital Thermometer, Probe and Meter: The thermal probe and meter used to monitor the thermocyclers will be calibrated yearly by an outside calibration laboratory.

8.8.5 Thermometers: Thermometers will either be factory calibrated using a NIST standard, verified yearly against a NIST-certified thermometer or verified yearly against a 0E C ice bath.

8.8.6 Waterbaths, heat blocks, and glass bead sterilizers: These instruments will undergo a calibration check be calibrated yearly against a NIST traceable thermometer.

8.8.7 NIST Thermometer: Will be calibrated yearly against a 0E C ice bath.

8.9 Equipment Needing Service/Preventative Maintenance

8.9.1 Chemical Fume Hoods: Chemical fume hoods will be inspected and have their face velocity checked annually.

8.9.2 Water System: At approximate 6 month intervals, a contract vendor

will sanitize the units and change the cartridges and inspect the unit.

8.9.3 Microscopes: Microscopes are serviced annually by a contracted vendor.

8.9.4 Thermocyclers: Thermocyclers will be tested biannually by an external vendor and quarterly in-house for block temperature uniformity and for temperature verification quarterly or when concerns about performance occur.

8.9.5 3100 Genetic Analyzers (or equivalent): These instruments will be repaired or serviced as needed by the manufacturer.

8.9.6 7000 Sequence Detection Systems: The instruments will be repaired as needed by the manufacturer and serviced semiannually.

8.10 QC Requirements for Equipment Following Repairs or Preventative Maintenance

Before instruments can be used for analysis following repairs or preventative maintenance, the following instruments required Calibration checks.

8.10.1 Thermocyclers: Prepare, amplify, and separate positive control (9947A) and a negative reagent blank. The positive control must give the appropriate allelic values and the negative reagent blank must not show activity over the 75 RFU threshold.

8.10.2 3100/3130XL Genetic Analyzers (or equivalent): Prepare and run at least one amplified positive control (9947A) and a negative reagent blank. The positive control must give the appropriate allelic values and the negative reagent blank must not show activity over the 75 RFU threshold.

8.10.3 7000: Prepare and run duplicate standard dilutions. Standard Curve values should fall within the guidelines for use. The NTC should not show activity.

8.11 Instruments Out of Service: Any instrument that fails a calibration test, calibration verification, or is not working properly and cannot be repaired immediately, must be tagged with a label that states that it is out of service. This label must be readily apparent. If possible, the instrument should be moved to a location that it will not be used until repaired.

9 Proficiency Testing

9.1 Open External Proficiency Testing

9.1.1 Each Section analyst qualified to conduct DNA testing will complete open proficiency tests as outlined in the Federal QA standards for DNA analysis. Each Section analyst that is qualified to conduct Body Fluid Identification testing will be tested at least once a year with an open proficiency test.

9.1.2 If an analyst misses a scheduled proficiency test because of a long leave (i.e. pregnancy or long term illness), then that analyst must complete and pass a competency test prior to the re-initiation of casework. That analyst shall then re-enter the proficiency cycle at the next scheduled proficiency test.

9.1.3 The Due Date for DNA External Proficiency Tests will be the date used to monitor the semi-annual tests for DNA analysts.

9.2 Blind Proficiency Testing

Blind proficiency test specimens may be submitted to the Section and will be prepared in such a way as to appear to be routine case specimens. These specimens may be prepared internally and/or may be part of an external proficiency testing program.

9.3 Proficiency Test Files

The Unit Technical Leader or SAC will maintain all proficiency test records, any deficiencies noted, and corrective action taken. When deficiencies are noted, the file will identify the likely cause of the deficiency.

9.3.1 Records to be Maintained: The following materials will be present in a proficiency test file (DNA and Body Fluids):

- 9.3.1.1 The test set identifier.
- 9.3.1.2 Identity of the examiner.
- 9.3.1.3 Date of analysis and date the test is completed, the date the test was sent to the vendor, or the due date to the vendor.
- 9.3.1.4 Copies and/or originals of all data and notes supporting the conclusions.
- 9.3.1.5 The proficiency test results.
- 9.3.1.6 A grade sheet to be filled out after the final results have

been released by the test manufacturer.

9.3.1.7 Any corrective action (if necessary).

Proficiency test records will be stored and maintained for the time period specified in the SBI Policy and Lab Procedures Manual.

9.4 Evaluation of Proficiency Tests

9.4.1 Each DNA proficiency test will be evaluated to determine if:

9.4.1.1 All reported inclusions are correct or incorrect (not applicable for a DNA Database type test).

9.4.1.2 All reported exclusions are correct or incorrect (not applicable for a DNA Database type test).

9.4.1.3 All reported genotypes and/or phenotypes are correct or incorrect according to consensus genotypes/phenotypes or within established empirically determined ranges.

9.4.1.4 All results reported as inconclusive or un-interpretable are consistent with written laboratory guidelines. The basis for inconclusive interpretations in proficiency tests must be documented.

9.4.1.5 All discrepancies/errors and subsequent corrective actions must be documented.

9.4.1.6 All final reports are graded 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 corrective actions taken to minimize the error in the future (not applicable for a DNA Database type test).

9.4.1.7 All proficiency test participants will be given feedback and their feedback will be documented.

9.4.2 Each Body Fluid proficiency test will be evaluated to determine if:

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

9.4.2.2 All results reported are consistent with written laboratory guidelines.

9.4.2.3 All discrepancies/errors and subsequent corrective actions must be documented.

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

9.4.2.5 All proficiency test participants will be given feedback and their feedback will be documented.

9.4.3 Proficiency Test Evaluation Forms

The DNA proficiency test evaluation form that captures the points listed above in Section 9.4.1 will be used. A master evaluation form will also be filled out and sent to the Laboratory Quality Manager for review (DNA and Body Fluids).

9.5 Approved Vendors

Open proficiency tests will be purchased from an ASCLD-LAB approved vendor who prepares proficiency tests in a manner approved by ASCLD/LAB and which meet the Quality Assurance Standards For Forensic DNA Testing Laboratories issued by the FBI Director.

10 Corrective Action

10.1 Corrective Action Policy

10.1.1 Any time there is a discrepancy on a proficiency test or in casework reported out, this Section will follow the procedures outlined in the SBI Policy and Procedures Manual (Procedure 39).

10.1.2 Any time questions arise concerning discrepancies or the efficacy of a technical procedure used in casework analysis, the Special Agent In Charge and Technical Leader will be notified. The Technical Leader will immediately investigate the issue. In this instance, the analyst may be suspended from case work analysis until the problem has been successfully resolved. The guidelines offered in the SBI Policy and Procedures Manual dealing with discrepancies on proficiency tests will be used as a model for corrective action in case work analysis as well.

10.1.3 If the concern is with the efficacy of a technical procedure, this procedure will be suspended from use in case work until the problem has been resolved and the procedure can be shown to work as expected.

10.1.4 If the problem is administrative or clerical in nature, it will not require any more than an investigation of the reason for the error, and instructions to the analyst of how to avoid this problem in the future. The guidelines offered in the SBI Policy and Procedures Manual dealing with discrepancies on proficiency tests will be used as a model for corrective action in case work analysis as well.

10.2 Documentation

Documentation of all corrective actions taken, whether on proficiency tests, case work, or of technical procedures, will be maintained by the Special Agent In Charge in the analyst=s personnel file. A copy of the corrective action memo will be given to the analyst, a copy is also maintained in the analyst=s personnel file and copies will be forwarded to the Laboratory Director and the Laboratory Quality Assurance Manager.

11 Reports

11.1 Guidelines For The Proper Recording Of All Analytical Data From Casework

11.1.1 The following information will be recorded in the permanent file of every case submitted for analysis. The pre-printed forms used can be found in the Appendices.

- 11.1.1.1 A SBI Physical Evidence Examination Request Form (SBI-5)
- 11.1.1.2 A sample description, including packaging information.
- 11.1.1.3 Notes or documentation of all tests performed on each item and those test results.
- 11.1.1.4 A laboratory case notes cover sheet.
- 11.1.1.5 Technical review checklist.
- 11.1.1.6 The final lab report.

11.1.2 In the case of STR DNA analysis, the following additional documents will appear in the permanent case file. Copies of these documents can be found in the Appendices.

- 11.1.2.1 Type of DNA extraction performed.
- 11.1.2.2 A Quantitation Load sheet.
- 11.1.2.3 An amplification worksheet.
- 11.1.2.4 An electrophoresis worksheet and computer generated electropherograms scans.
- 11.1.2.5 PopStats sheets reflecting population frequencies .and a reference of the databases used (if applicable).
- 11.1.2.6 CODIS Search Sheet (if applicable).
- 11.1.2.7 Expected Results sheet.

11.1.3 The following documents will appear in the permanent files of the DNA Database Unit for STR analysis:

- 11.1.3.1 An extraction worksheet which will provide documentation of the sample bar code number. Comments concerning sample quality may also be included.
- 11.1.3.2 An amplification worksheet.
- 11.1.3.3 An electrophoresis worksheet and computer generated electropherograms.
- 11.1.3.4 A call sheet generated by the appropriate analysis

software or generated manually.

11.2 Data Handling, Storage, and Retrieval

All case files will be maintained by the laboratory Clerical Services Supervisor, the Records Section, or State Archives as described in the NC SBI Policy and Procedures Manual. If duplicate copies are needed for court, defense experts, etc., they will be made from the originals.

Copies of all quality control and calibration sheets will be maintained by the quality control officers or in the Forensic Biology Section files.

Validation studies, population studies, and research project results will be maintained in the Forensic Biology Section.

11.3 Report Writing

Lab reports will be issued on all cases that are analyzed and will be prepared in accordance with existing Bureau policy using the Laboratory Information Management System. All reports will include:

11.3.1 Unique case identifier
11.3.2 A description of the evidence examined (including date items were received and by whom)
11.3.3 Type of examination requested
11.3.4 A description of the methodology (DNA)
11.3.5 Loci tested (DNA)
11.3.6 Results and/or conclusions
11.3.7 An interpretative statement (DNA, either quantitative or qualitative)
11.3.8 Date of the report
11.3.9 Disposition of the evidence
11.3.10 The electronic signature and title of the analyst issuing the report

11.4 Interpretational Guidelines for Matches (STR Analysis)

These guidelines are specified in the Appendices and also describe how results are assessed in forensic casework.

11.5 Frequency Determination

Frequency determinations will be made using established databases that are compatible with the DNA loci used. A scientifically valid and accepted method for calculating these frequency determinations has been developed

by the FBI (PopStats) and will be used in this laboratory.

11.6 Frequency Release of Case Information

11.6.1 Analysts will follow the procedures described in the SBI Policy and Procedures Manual for release of case information.

11.6.2 As a general policy, Analysts will not disseminate results until all reviews have been completed. In exigent circumstances, case results may be released following an approved Technical Review and approval by the SAC or designee.

12 Review

12.1 Independent Analysis of Data

12.1.1 Technical Reviews: All data, test results, and reports will undergo a technical review by a second qualified analyst. The analyst conducting the technical review will sign and date the technical review sheet. Both analysts must agree on the interpretation of the data to be reported.

12.1.1.1 The Technical Reviewer for Body Fluid Cases should verify the following for the notes and/or report if applicable:

12.1.1.1.1 Cover Sheet Present
12.1.1.1.2 Notes Present and Accurate
12.1.1.1.3 Phone Log Present (if applicable)
12.1.1.1.4 DNA Evaluation Forms Present (if applicable)
12.1.1.1.5 All pages numbered and initialed
12.1.1.1.6 SBI-5 Evidence Submission Form Present and Correct
12.1.1.1.7 Report matches dates, numbers, and names on the SBI-5.
12.1.1.1.8 Proper tests were run
12.1.1.1.9 Proper controls were run
12.1.1.1.10 Appropriate conclusions were obtained
12.1.1.1.11 Administrative records properly identified
12.1.1.1.12 Chain of Custody reviewed in LIMS
12.1.1.1.13 Report is Accurate and Complete
12.1.1.1.14 Proper Report Format is Used

12.1.1.2 The Technical Reviewer for DNA Cases should verify the following for the notes and/or report if applicable:

12.1.1.2.1 Cover Sheet Present
12.1.1.2.2 Case Report Present
12.1.1.2.3 Phone Log Present (if applicable)
12.1.1.2.4 SBI-5 Evidence Submission Forms Present
12.1.1.2.5 Report Matches Dates, Numbers, and Names on the SBI-5 Form
12.1.1.2.6 Extraction Forms Completed and Reviewed

12.1.1.2.7 Quantitation Forms Present and Reviewed
12.1.1.2.8 Lumigraphs Present and Reviewed
12.1.1.2.9 Amplification Forms Completed and Reviewed
12.1.1.2.10 Capillary Forms Completed and Reviewed
12.1.1.2.11 Allelic Values Correct for 9947A.
12.1.1.2.12 PopStats Statistical Analysis Completed and Reviewed
12.1.1.2.13 Population Database Present
12.1.1.2.14 All pages numbered and initialed
12.1.1.2.15 Careful Visual Inspection of the Electropherograms
12.1.1.2.15.1 Negative Controls
12.1.1.2.15.2 Positive Controls
12.1.1.2.15.3 Ladders
12.1.1.2.16 Verify Alleles for Each Locus
12.1.1.2.17 Verification of Population Statistics
12.1.1.2.18 Report is Accurate and Complete
12.1.1.2.19 Report is in Proper Format
12.1.1.2.20 Chain of Custody checked in LIMS
12.1.1.2.21 Data marked for CODIS entry checked prior to upload

12.1.1.3 Technical Reviewer must not sign off on the case unless all changes that affect the interpretation or supportive data for interpretation have been completed.

12.1.2 An Administrative Review of the case file will be completed by the Section SAC or his designee and that review will be documented on the notes cover sheet. The Administrative Review shall be conducted by a different individual than who performed the Technical Review. The Administrative Reviewer may suggest technical changes in the notes and/or report. However, any technical changes must be approved by the technical reviewer prior to final approval. The Administrative Reviewer will ensure that:

12.1.2.1 The case worker=s Initials, the page number, the date, and the case number are present on every page of the case notes.
12.1.2.2 The header information on report is consistent with information on the SBI-5.
12.1.2.3 There are no typographical/clerical mistakes.

12.1.2.4 All changes in the report are completed prior to approving the case in LIMS.

12.1.2.5 The DNA profiles entered into CODIS are accurately entered.

12.1.3 Review of unanalyzed or Astop analysis@ cases: Cases that are being returned unanalyzed or that the work has been halted by a request from the submitting agency or DA will only be required to have an Administrative Review performed.

12.1.4 Resolution of Discrepant Conclusions

If an analyst and technical reviewer are unable to resolve a technical issue on which they disagree, then the administrative reviewer or the DNA Technical Leader will arbitrate the issue. For DNA, issues on how to report complicated mixtures which may fall outside section interpretation/reporting guidelines are often resolved at DNA Unit meetings where input from all analysts can be received. Such periodic meetings provide the basis for modifications and or changes in interpretation/reporting guidelines.

12.2 Review of Court Testimony

Each analyst who testifies will have their court testimony reviewed as described in the SBI Policy and Procedures Manual.

13 Safety

13.1 The Section will operate in strict concordance with the regulations of the pertinent federal, state, and local health and safety authorities.

13.2 Written general laboratory safety manuals will be made available to every member of the SBI Forensic Biology Section.

General Laboratory Safety guidelines are covered in the NC Department of Justice Safety and Health Manual, the Chemical Hygiene Plan, and the Blood Borne Pathogen Plan.

13.3 The Section Safety Officer (SSO) will be appointed by the SAC.

13.4 Material Safety Data Sheets

13.4.1 Material Safety Data Sheets will be maintained by the SSO on all chemicals used in the Forensic Biology Lab. The Section Safety Officer will file these sheets in a notebook found on the shelves in the Chemical Stock room.

13.4.2 It is the responsibility of each employee to become familiar with the MSDS of EACH chemical he/she is using.

13.4.3 If there are any questions with a MSDS or there is need for additional personal protective equipment, contact the SSO.

13.5 A First aid kit shall be maintained in the Section by the SSO.

13.6 Chemical Spills

13.6.1 Spill control kits shall be maintained by the SSO in the Forensic Biology Section. In the event of a chemical spill, the safety of the analyst(s) is most important. It is VERY IMPORTANT that each person read and understand the MSDS sheets and know the hazards of each chemical they are using.

13.6.2 If the analyst has proper knowledge and equipment, the analyst may clean up the spill.

13.6.3 If the analyst feels he/she does not possess the knowledge or proper equipment, then the SSO may be called to assist in the clean up.

13.6.4 If the spill is determined to be extremely dangerous, the evacuation of the rooms immediate to the spill, the section, or the entire floor, may be warranted. As a last resort, the entire building will be evacuated by pulling the Fire Alarm pull switch; when the building is evacuated, the building comes under control of Raleigh Haz*Mat and the chain of custody of evidence becomes an issue. However, this should not deter anyone from activating the alarm system. As always, employee safety comes first and one should err on the side of caution.

13.7 Injuries obtained while working should be reported to the Section Safety Officer and SAC.

13.8 Personal Protection Equipment (PPE)

13.8.1 PPE such as gloves, safety glasses, lab coats, respirators, and fume hoods is provided by the SBI for each analyst=s protection.

13.8.2 It is the responsibility of each analyst to read the MSDS of each chemical they are using and use the appropriate PPE. If there is a question about the level of PPE needed, contact the SSO before proceeding. If the SSO is not available, contact the Laboratory Safety Officer.

13.8.3 If an analyst feels additional PPE or additional training is needed for their safety, contact the SSO.

13.8.4 For individuals performing DNA analysis, eye protection (to guard against splashes, standard eyeglasses are acceptable), lab coats, and gloves will be worn during all procedures performed on the bench top.

13.9 Emergency and Fire Evacuation Plan

13.9.1 The Fire Alarm and Emergency Evacuation Plan is posted in the Forensic Biology Break Room (Room 2250D). Every employee must be familiar with the plan and how to safely leave the building in case of an emergency.

13.9.2 If the Fire Alarm sounds, even for a brief period (unless otherwise instructed), the building must be evacuated. Do not go back into the laboratory until the clear signal has been given.

13.9.3 If there is a visitor in the section and the alarm sounds, the section employee with the visitor is in charge of ensuring their

safe evacuation.

13.9.4 In the event of a fire alarm or an Emergency, the Forensic Biology Section will evacuate as follows:

No fire/smoke or dangerous situation in the section: Secure evidence if possible, but do not delay. On the 2nd floor, everyone will proceed to the front door of the section (people in the back of the section should knock on doors and go into labs to ensure everyone knows there is an alarm). On the basement level, everyone will proceed to the back door of the Section. Someone should carry the Section sign-out sheet out of the building. Once outside, the Forensic Biology Section will meet in the designated area and an accounting of all individuals will be made.

If there is fire/smoke or a dangerous situation in the section: Secure evidence ONLY if possible. Proceed to the nearest exit as quickly and safely as possible. If possible, someone should carry the Section sign-out sheet out of the building. Once outside, the Forensic Biology Section will meet in the designated area and an accounting of all individuals will be made.

13.9.5 If you are in another section of the laboratory, evacuate with that section using the nearest exit and then proceed to the Forensic Biology section=s designated meeting area.

13.10 Sole Occupancy/Hazardous Operations

The following procedure will govern sole occupancy and hazardous operations in the Section after normal working hours (Monday through Friday, 7:00 am - 5:00 pm):

13.10.1 Working late or Weekends

13.10.1.1 Any employee who enters the SBI Laboratory after 7 pm on business day or on weekends will enter through the main front entrance and notify the State Capital Police Officer on duty by signing the “SBI Crime Lab: After Hours Sign In Log” located in the Hallway of the Main Entrance. Upon completion of your work you will exit out the main front door and advise the State Capital Police Officer on duty that you are leaving the building by signing out of the “SBI Crime Lab: After Hours Sign In Log”.

13.10.1.2 Any employee who remains in the SBI Laboratory after 7 pm on a business day notify the State Capital Police Officer of their presence.

13.10.2 Hazardous operations should not be performed when analysts are alone in the laboratory. Hazardous operations are defined as follows:

13.10.2.1 Working with concentrated acids

13.10.2.2 Handling phenol/chloroform volumes in excess of 100 ml.

14 Audits

14.1 Audits are an important aspect of the quality assurance program. They are an independent review conducted to compare the Section=s performance with a standard for that performance. These audits are designed to provide management with an evaluation on the Section=s performance in meeting its quality policies and objectives.

14.2 External Audit of the DNA Section to "National DNA Quality Assurance Standards For Forensic and DNA Database Laboratories".

14.2.1 The SBI Forensic Biology Section will be inspected annually by qualified DNA examiners from another laboratory. The SBI is part of a regional auditing compact known as the Potomac Region Auditing Group. This group has agreed to utilize only MAAFS FBI certified auditors and/or ASCLD/LAB inspectors. Current members of this group include the Virginia Bureau Of Forensic Sciences, Pennsylvania State Police Crime Lab, Maryland State Police Crime Lab, Cellmark Diagnostics, South Carolina State Law Enforcement Division Crime Lab, AFDIL, Kentucky State Police Crime Lab, US Army Criminal Identification Lab, FBI Crime Lab, and the NCSBI Crime Lab. This audit will check the laboratory=s performance against the "Quality Assurance Standards For Forensic DNA Testing Laboratories".

14.2.2 The Section SAC will review all findings with the Section and will maintain the audit report along with documentation of steps taken to resolve any problems detected.

14.2.3 The audit will be conducted using the AQUALITY ASSURANCE AUDIT FOR FORENSIC DNA AND CONVICTED OFFENDER DNA DATABASING LABORATORIES IN ACCORDANCE WITH THE QUALITY ASSURANCE STANDARDS FOR FORENSIC DNA TESTING LABORATORIES AND CONVICTED OFFENDER DNA DATABASING LABORATORIES".

15 Subcontractor Laboratories

15.1 Use of a Subcontractor Laboratory for Forensic Cases and/or Convicted Offender Sample Testing is permitted.

15.2 SBI Forensic Biology Section employees may submit forensic case material and convicted offender samples to private laboratories, or any other laboratory for DNA testing. Most often this will take place as part of a coordinated outsourcing program to specific laboratories chosen for this work.

15.3 Criteria for Subcontractor Selection

15.3.1 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.

15.3.2 On Site Visits: In order to best evaluate these criteria, it will be important to perform laboratory site visits prior to their selection. These site visits will be performed by at least one trained DNA auditor from the NCSBI Forensic Biology Section and will certify that the laboratory meets or exceeds the AQuality Assurance Standards for Convicted Offender DNA Databasing Laboratories@. If an actual audit is not performed, the inspection team must obtain audit documentation from that Laboratory from another lab auditing against the same standards. The site visit will be documented by a report for future reference.

15.4 The Forensic Biology Section and the contracting laboratory will ensure that an appropriate chain of custody will be maintained at all times.

15.5 Review procedures of returned data:

15.5.1 The NCSBI shall conduct a thorough review of all of the Contractor=s Data prior to uploading the data in CODIS using parameters specified in the signed RFP.

15.5.2 Qualified Analyst(s) shall conduct the review of at least the following: electrophoresis sheet review, positive and negative controls, ladders, internal lane standards, allele drop out,

microvariants, triallelic samples, and quality assurance samples.

15.5.3 Each returned case file should be reviewed for at least the following: lot numbers of reagents, extraction, PCR setup/amplification, electrophoresis, electropherograms, result tables, allele calls, resulting population frequency data calculations, resulting CODIS match reports.

15.5.4 Each sheet should be dated and have the initials of the examiner/analyst performing the run.

15.5.5 Any electronic file provided by the vendor that contains data to be uploaded into CODIS must be compared to the hardcopy of the allele calls prior to upload. Each data file shall be opened and the sample names on the hard copies should be concordant with the electronic data to be uploaded.

15.6 NCSBI Forensic Biology personnel will establish and use appropriate review procedures to verify the integrity of the data received from the subcontractor to include:

15.6.1 Random re-analysis of samples.
15.6.2 Visual inspection and evaluation of the results/data
15.6.3 Inclusion of QC samples.
15.6.4 At least one on-site visit conducted by trained NCSBI DNA auditors.

Revision History		
Effective Date	Revision Number	Reason
Unknown	00	Original Document
April, 26, 1999	01	Manual Update
October 10, 2000	02	Manual Update
December 4, 2002	03	Procedure Update
March 1, 2003	04	Update to clarify Technicians training and responsibilities.
August 7, 2003	05	1) Update Evidence Handling Procedure to clarify when a) gloves should be changed during Body Fluid Identification and b) lab coats should or should not be worn; 2) Procedure change in the transfer of evidence to Trace Evidence; 3) Directions for Technical and Administrative Reviews added
November 17, 2003	06	1) Addition of Balance Limits and clarification of Placing Un-calibrated pipets out of service. 2) Replace AMolecular Genetics@ with AForensic Biology@ due to Section name change. 3) Remove requirements for advanced course work for DNA Caseworking Analyst.
May 6, 2004	07	Addendum to STR Interpretation Guidelines to include Capillary Electrophoresis data.
December 23, 2004	08	1) Creation of Technical Leader for Body Fluids Section; 2) Change Molecular Genetics to Forensic Biology; 3) Incorporation of capillary electrophoresis and RT-PCR; 4) Taking out some duplicated policies; 5) Take out commentary portions of the manual;6) Revising proficiency testing section so that it refers to the federal standards; 7) Procedure change in hair transfer to Trace evidence; 8) Take out prohibition statement on outsourcing of casework; 9) change educational requirements of database analysts 10) Added AProcedure for Completion of Quality System Documents@ and ADocument Control Procedure in Appendices; 11) Updated Section 15
December 09, 2005	09	1) Added statement about labeling equipment that is not in use Section 8.9 2) Added statement in Section 12 that the Technical Reviewer could not be signed off until substantial changes were made and that the Administrative Reviewer could not approve case in LIMS unless personally observed that all changes had been made and that the Administrative Reviewer

		could not be same individual that performed the Technical Review.
January 30, 2007	10	Section 2: Rearranged Sections pertaining to specific duties; Section 2: Updated Technical Leader duties for DNA and Body Fluid; Section 3.4.8: removed large section regarding Interns; Section 5.4.2: Added statement clarifying procedure with cases containing hair evidence; Section 7.3: Updated Section on DNA controls; Section 7.4.11: Addition of QC Requirements for TE and Stain Extraction Buffer; Section 12: Added requirement for Technical Reviewer and Administrative Reviewers;