NCSBI Molecular Genetics Section

Quality Assurance Manual

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Approved by:

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NCSBI Quality Assurance Manual
Molecular Genetics Section

Table of Contents

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

The QA/QC program described in the following manual has two purposes:

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 feedback to management on performance standards.
1.3.10 Ensure that identification and genetic typing results are technically sound and/or legally.
1.3.11 Provide guidelines to employees so they will know performance

expectations.

1.3.12 Ensure that personnel performing these tests have the appropriate level of training and education.

1.3.13 Ensure that analysts are competent in performing the testing and interpreting the results through a series of proficiency tests.

1.3.14 Provide for external audits to ensure that operating procedures are followed and are adequate.

1.3.15 Provide for a safe workplace.

2 Organization and Management

2.1 Organization

2.1.1 The Molecular Genetics 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 a 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 approve and sign weekly report forms, and overtime requests from the persons listed in their team. Team Leaders will also review and initial expense accounts and the monthly overtime report, but these forms will be signed by the SAC. Team Leaders are to work closely in conjunction with the Section Secretary in processing this information. The overtime report will be generated by the Section Secretary and distributed through the appropriate Team Leaders.

2.1.3.2 Supply orders will be generated by each Team Leader for their Unit and they will also be responsible for seeing that proper inventory is on hand. Team Leaders may delegate portions of this responsibility to others on their Teams if they do not personally work in all areas of expertise requiring supplies. Orders will be passed to the SAC for approval.

2.1.3.3 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 his designee.

2.1.3.4 Other duties assigned by the SAC.

2.1.3.5 Team Leaders will conduct work performance reviews evaluations for members of their Teams after consultation with the

SAC.

2.1.4 The DNA Database Manager and 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. The DNA Database Manager reports directly to the SAC, and the other two Team Leaders will not be responsible for handling the DNA Database Manager=s duties.

2.1.5 The SAC or the sworn Team Leaders will handle the assignment of DNA cases. All cases which fall outside our established DNA Case Acceptance Policy signed by the Director are to be deferred to the SAC, except for police shootings, and when ordered to make an exception by the Assistant Director or designee.

2.1.6 Technical Leader: A Technical Leader role will be assigned by the SAC. The Technical Leader will be responsible for all technical operations of the laboratory.

2.1.7 CODIS Manager: The CODIS Manager is responsible for all CODIS operations within the State of North Carolina including all uploads of DNA Data to the State Database.

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 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, as well as ensuring that all personnel within the Section adhere to QA guidelines. 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.

2.2.2 Designated analysts 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.

2.2.3 The Section Safety Officer is responsible for the following:

2.2.3.1 Monthly inspections of safety.
2.2.3.2 Representing the Section at safety meetings.
2.2.3.3 Ensuring safety training and maintaining these records.
2.2.3.4 Disposal of biohazardous and chemical waste.
2.2.3.5 Acting on reports of injury on the job.

2.3 Administrative Orders Manual

2.3.1 Issuance of the Molecular Genetics Section Administrative Order 96-ADM-1 establishes a Section policy and procedures system which will be called the Molecular Genetics 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 Effective August 26, 1996, 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. Upon receipt of changed or modified Administrative Orders, Molecular Genetics Section members are update their Administrative Orders Manual.

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 (eg. 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 the manuals every year, and at this time, some of the administrative orders may be incorporated within other manuals. At this time, they may be rescinded and removed from the Administrative Orders Manual. Periodically, the rescinded orders will be removed totally from the Administrative Orders Manual and the whole Manual renumbered.

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:

3.1.1 All examiners will go through a training process which uses a three-prong test for competence:

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

3.1.3 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.

3.1.4 The ability to correctly interpret test results being of paramount importance. All examiners will successfully complete a qualifying competency test prior to starting case work or testing of DNA Database samples, and then undergo proficiency testing periodically to test this skill.

3.2 Section Requirements

3.2.1 Business Hours

3.2.1.1 The normal working hours of this Section are 8:00 am - 5:00 pm, Monday through Friday. The section secretary will work the normal working hours that the section is open for business.

3.2.1.2 Employees who desire to work an alternate work schedule will request the same by memo and state the reasons why they desire to work an alternate work schedule. Alternate work schedules will be approved on a case-by-case basis.

3.2.1.3 All employees are reminded that they 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 Molecular Genetics Section will maintain a SIGN OUT log in the Section office. 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 their duty station noting where they are going. The sign out log will have a notation on it if an employee is out on leave, if an analyst is in court, at a crime scene, or at a Bureau sanctioned training mission. Analysts will check out for lunch if they leave the floor of their duty station.

3.2.2 Overtime

If agents are on mandatory overtime and don't work the proscribed number of hours each pay cycle - they MUST have written documentation (e-mail is appropriate) to their Team Leader and/or SAC via the section secretary, stating why they didn't work the proscribed number of hours. Until the SAC has this material, the overtime report doesn't get signed, and if we miss the time reporting deadline, the payroll may be delayed for the Section.

3.2.3 Weekly Case Reports

3.2.3.1 Need to be submitted on every Friday afternoon - not Monday. The Section=s report is due to the Lab Director every Monday morning by 10:00 am.

3.2.3.2 Need to be accurate. Look at the printout on the bulletin board from the previous report. Take the total number of cases you reported on the last printout, add in those received during the reporting period and subtract those worked. Your total number

should equal the number you have on the reporting form. If it doesn't, YOU have to get the figures correct.

(How to count re-submissions - if you get a re-submission and already have issued a report in the case - it's a new case. If you get a re-submission and you haven't issued a report - it isn't a new case).

3.2.3.3 If you are scheduled for leave - turn this report in for the time you're off 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 (Bureau issued coveralls or scrubs) may be worn if the BDU=s are soiled and the employee has not had a reasonable period of time to launder the same. Since we deal with infectious agents at crime scenes, it is strongly suggested that coveralls be worn over the BDU=s, while working with blood an other body fluids. Under no circumstances, will jeans be worn while representing the Bureau in any capacity. Failure to comply with this policy (ie. 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 Molecular Genetics 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.

3.3 Job Description

A current copy of all job descriptions within the Molecular Genetics 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

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.

3.4.1.3 Completion of a series of competency test samples.

3.4.2 Requirements for Individuals Performing Forensic DNA Analysis

All 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.

3.4.2.2 Graduate Level Molecular biology courses at NC State University (or comparable courses at another university) to include:

a. Advanced Genetics (or equivalent): 3 semester hours
b. Biochemical and Microbial Genetics (or equivalent): 3 semester hours

3.4.2.3 Successful completion of the DNA Training Program.

3.4.2.4 Successful completion of a series of competency test samples.

3.4.2.5 At least six months of forensic DNA experience.

3.4.3 Requirements for Individuals Performing DNA Database Testing

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

3.4.3.2 Completion of the DNA Database Training Program.

3.4.3.3 Completion of a series of competency test samples.

3.4.3.4 Database analysts are encouraged to meet the same course requirements set for forensic DNA analysts.

3.4.3.5 Six months of DNA Database experience.

3.4.4 Requirements for DNA Technical Manager/Leader

The DNA Technical Manager/Leader will meet the following Quality Assurance Standards For Forensic DNA Testing Laboratories

3.4.4.1 A Master=s 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.

3.4.5 Duties of the DNA Technical Manager/Leader

The DNA Technical Manager/Leader will manage the technical operations of the laboratory and specifically is responsible for:

3.4.5.1 Managing the technical operations of the Section.

3.4.5.2 Evaluating all methods used in the Section including proposing new of modified analytical procedures to be used by the examiners.

3.4.5.3 Solving technical problems with analytical methodologies used in the Section.

3.4.5.4 Training, quality assurance, safety and proficiency testing in the laboratory.

The Technical Manager/Leader will be kept fully informed of any anticipated problems, successes, changes, alterations, etc. by members of the Section. No changes, alterations, or deviations from validated procedures or protocols will be allowed without the approval of the Technical Leader.

3.4.6 CODIS Manager

The DNA Database Unit Manager serves as the CODIS Manager. The CODIS Manager will meet the following requirements and be assigned the following duties:

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.

3.4.6.5 Has the authority to terminate 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.

3.4.7 Technicians

3.4.7.1 Technicians will be required to assist Molecular Genetic=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. All test results obtained by a non certified technician must be confirmed by the case working Analyst.

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.

3.4.8 Intern Program

3.4.8.1 Goals and Objectives

3.4.8.1.1 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.

3.4.8.1.2 To provide interns with meaningful work experiences, not just routine office work. Some 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 go through a background check, are treated as employees (they have to fill out time sheets, do their assigned work correctly and timely, they are held accountable for their utilization of time, and they are given full access to necessary areas of the laboratory).

3.4.8.1.3 To allow the interns conduct DNA testing on some non-forensic / non-Database samples if possible. This can be either family reference samples they bring in, or samples donated by members of the lab. Interns are expressly prohibited from analysis of forensic or Database samples. They will be allowed to run confirmation and quality assurance samples. To be able to state on a resume that they have actually done identity testing will be a big selling point for the intern when they seek work after graduation.

3.4.8.1.4 To have the responsibility to run the stain room operation in the DNA Database Unit. They are trained and given responsibility to receive the blood samples for the DNA Database Unit, to make stains from these samples, prepare the samples for storage, and to enter the samples into the Specimen Manager Program. The work that the interns do in this regard free up our analysts in the DNA Database to actually analyze samples. Other routine

responsibilities include pouring gels for the DNA and DNA Database Units, making solutions, keeping temperature logs, organizing files and data generated by the Database Unit, etc. as time permits.

3.4.8.1.5 To provide the interns with relevant forensic literature as part of their training regiment.

3.4.8.1.6 Each intern may have the opportunity to witness Section Agents testify in court. The purpose of the intern witnessing court testimony is to learn what it would be like to be sitting in the witness stand in an important case. Agents are to notify the Special Agent In Charge when they have a case which meets the following criteria:

3.4.8.1.6.1 Both the Body Fluid Identification and DNA analyst will testify.

3.4.8.1.6.2 The case involves a DNA match that is of evidential significance (i.e. the victim=s blood on the suspect=s clothing in a homicide case, or the suspect=s semen on the victim=s vaginal swabs or panties in a rape case).

3.4.8.1.7 To provide a safe work environment for the intern.

3.4.8.2 Rules and Regulations: The following are important for everyone to follow so that the goals and objectives of the Intern Program are met.

3.4.8.2.1 The interns are assigned to the DNA Database Unit. The individual directly responsible for the intern program is the DNA Database Manager or designee (or the Special Agent In Charge in his absence).

3.4.8.2.2 Anyone outside the DNA Database Unit who requests assistance or to spend time in the laboratory from an intern, must seek the approval of the DNA Database Manager (or the Special Agent In Charge in his absence).

The actual assignment, if approved, will be made by the DNA Database Manager (or the Special Agent In Charge in his absence). This is important, since the interns have assigned duties, and we must see that these assigned duties are completed first before other duties are allowed.

3.4.8.2.3 Any off-site travel by interns will be first screened by the Special Agent In Charge (or in his absence the DNA Database Manager). This includes observing court, attendance at crime scenes, or assisting the training division as role players, etc. The Special Agent In Charge (or in his absence the DNA Database Manager) must consider if the off-site travel is warranted, that the assigned duties of the intern have been completed or will not suffer, but most importantly that the intern can complete the travel assignment safely. For these reasons, interns will only be allowed to travel on assignments if they travel in Bureau vehicles (so they are covered by our collision and liability insurance). If they are going to court or a crime scene it will be the responsibility of the agent accompanying the intern to provide for their safety and to return them safely to the laboratory. For this reason, the agent will be armed and a primary function will be to protect the intern from harm.

3.4.8.2.4 Interns will not drive State vehicles.

3.4.8.3 The interns have the following responsibilities to the SBI:

3.4.8.3.1 To complete their assignments to the best of their ability and to do so in a timely fashion.

3.4.8.3.2 To keep the DNA Database Manager (or his designee) aware of the progress of their work assignments.

3.4.8.3.3 To let the DNA Database Manager (or his designee) know when they have completed their assignments

and are available to spend some time in another unit to learn something about Body Fluid Identification or DNA casework. The DNA Database Manager (or his designee) will then seek out someone to spend some time with the intern. It is important that when these assignments are made that the intern work with a wide variety of individuals so that they can see a broad spectrum of the work we do and the different styles each agent uses to meet these work requirements. Interns are not to seek out these opportunities for enrichment on their own volition. While observing other unit agents at work, interns are reminded that they shouldn=t distract the agent and cause the agent to make a serious mistake or omission. Such distractions, if serious enough, could jeopardize not only the case being worked, but the career of the agent as well.

3.4.8.3.4 To learn as much as possible about the section and our work.

3.4.8.3.5 To come to work at, and to leave work at the appointed time.

3.4.8.3.6 To maintain confidentiality of Bureau records and what they see and hear here subject to criminal and civil penalties. In particular North Carolina General Statute ' 15A-266 provides criminal penalties (up to two years imprisonment for misuse of genetic information).

3.4.8.4 Either the intern or Bureau management may terminate the interns participation in the intern program should irreconcilable problems with the internship occur.

3.5 Continuing Education

Section analysts must stay current of developments within the field by reading current scientific literature and by attendance (at least once 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

Documentation of all training will be maintained in the Section office. An official training log is maintained in each employee=s personnel file by the SAC. This official training log is downloaded from Mapper and is maintained by the SBI Training Division.

3.7 Personnel Records

The Section Special Agent In Charge maintains a personnel file on each analyst which is subdivided 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

The Section Special Agent In Charge also maintains a separate file of competency tests results from each trainee, and proficiency tests results from trained analysts.

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 Crime Laboratory Procedures Manual.

4.2 Facilities

4.2.1 Evidence examinations will 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 in one of the two chemical fume cabinets assigned to the section for that purpose (in the DNA extraction lab or the stockroom).

4.2.3 PCR setup is to take place in a AirClean 600 workstation (or equivalent) unless using the robotic workstation.

4.2.4 The DNA Database Unit may utilize the Qiagen robotic extraction workstations which performs DNA extractions and PCR setup.

4.2.5 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.

4.2.6 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 SBI Crime Lab Procedures Manual.

5.2 Storage

All evidence submitted for testing will be stored under the appropriate conditions to minimize degradation of the sample. 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, generally not have more than one sample open at a time, and use sterile solutions and reagents when necessary. Samples will be stored under conditions to prevent contamination and degradation.

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 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

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

5.4.2 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.

5.4.3 Victim and suspect hair evidence found in the Victim and Suspect kits (which includes the panties in the Sexual Assault Evidence Collection Kits) will be transferred to the Trace Evidence Section, regardless of whether other bulky evidence exists in the case.

5.4.4 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 unless the analyst determines that the sample is too old or degraded to be useful as a standard. Liquid blood samples will be stored in the refrigerator for not longer than one week prior to preparation of the stain. All liquid blood samples will be processed in a Biological Safety Cabinet. After preparation of the blood stain, the blood tubes will be re-stoppered 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.

5.4.5 Analysts will follow all approved safety precautions including wearing of nitrile gloves (or equivalent) and lab coats when processing evidence. Gloves will be changed when the analyst feels they have been contaminated or soiled (e.g. material spilled onto glove, a non-clean item is touched). Protective clothing will not be worn outside the laboratory or into office space in the laboratory.

5.4.6 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.

5.4.7 In the case of STR analysis, the known standards will be extracted separately from the questioned samples. STR pre-amplification and post-amplification areas will have dedicated equipment and supplies.

5.4.8 The SBI Sexual Assault Evidence Collection Kit contains a control swab. This control was placed in these kits to be used only in PCR analysis procedures as a DNA contamination control if necessary.

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

5.4.10 DNA analysts will return all evidence and dried extracted DNA to the investigating agency.

5.4.11 Analysts in the Body Fluid Identification Unit will use the DNA SAMPLE SUBMISSION FORM (see attachment) when submitting evidence to the DNA Unit. This will effectively document the transfer of evidence within the Section.

5.5 Return of Liquid Blood Samples

To minimize the potential for liquid blood tubes leaking onto other evidence within the package and the health hazard to evidence technicians and mail clerks, all liquid blood samples will be sealed in heat sealed plastic bags to contain spills. The vacutainer tubes (or ME vial) will be heat sealed in plastic and then returned to the ziplock or bubble pack container it was in which it was delivered.

5.6 Disposition of human remains.

5.6.1 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.

5.6.2 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 in this case being returned 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.

5.7 Transfer of evidence to and from other laboratories.

5.7.1 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.

5.7.2 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.

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

The operational guidelines set out in the SBI Crime Laboratory Procedures Manual will be followed to ensure that custody is maintained on the evidence.

5.9 Unworked Evidence

There is a legal issue with the destruction of ***unworked*** evidence; its destruction can only be authorized by the District Attorney=s Office in writing pursuant to NCGS ' 15A-11. Based on the above information,

the decision of the Section and the recommendation of Legal Counsel was that we will no longer retain unworked evidence, pending future submissions. 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.

5.10 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

6.1 Use of Validated Procedures

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

6.2 Developmental Validation of the DNA Analysis Procedures

Prior to the implementation of a new procedure, 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:

6.2.1 Documentation that defines and characterizes the locus.

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

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

6.3 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:

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

6.3.2 Before introduction of the method into forensic casework, the examiner will complete a qualifying/competency test.

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

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

6.4 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:

6.4.1 Reproducibility
6.4.2 Sensitivity
6.4.3 Species Study (if applicable)
6.4.4 Sample Stability

6.5 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 Molecular Genetics Section will be found in the Section Technical Procedures Manual. The procedures in this manual provide step-by-step instructions how to conduct the test and to use the equipment (if applicable).

7.1.2 Information on the controls to be used follows in Section 7.2 and 7.3 of the Quality Assurance Manual.

7.1.3 Information on reagent, buffer, and solution preparation and the quality checks of critical reagents is found in section 7.4 of the Section Quality Assurance Manual. 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 antisera: Each antisera used will be tested against know 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 and a blank reagent control.

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 are evaluated before release for use in casework with a known standards and serial dilutions for sensitivity.

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

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 technical procedures.

7.3.1 Use of Human DNA Controls

For each case, the known human cell line control (i.e. K562, 9947A) will be amplified and run along with the samples. A known human bloodstain (i.e. AMJB@) sample will be extracted and also run with the case samples. Operational monitoring of these controls will verify the procedural method in use. The DNA Database Unit will only use the known human cell line control.

7.3.2 Extraction Controls

For each set of extractions, a reagent blank will be prepared. This blank will consist of the reagents used in the extraction process and be treated as another sample.

7.3.3 Procedure for Estimating DNA Recovery

An appropriate yield calibration set consisting of DNA of known concentration will be run on each membrane so that an estimate can be made as to the quantity of DNA present in the case samples. 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 Lumigraphs: Exposure intensity will be monitored by the use of multiplefilms or by successive exposures, if necessary, in order to obtain films of the proper intensity so that quantitation can occur.

7.3.5 Amplification Control: A reagent blank consisting of sterile water and the amplification reagents will be run at the time of amplification. This amplified sample will be run on each analytical gel as a negative amplification control.

7.3.6 Analytical gel: The analytical acrylamide gel will contain the following controls and markers:

7.3.6.1 Known human cell line control and MJB Positive Controls (Database uses only Known human cell line control).
7.3.6.2 Negative Amplification Control.
7.3.6.3 Allelic Ladder for fragment allele designation (run with maximum of 2 sample lanes between ladders). All samples will be bracketed by allelic ladders.
7.3.6.4 Reagent blanks for extraction chemicals
7.3.6.5 Visual marker to allow for the determination of the end of electrophoresis.

7.3.7 Image and Data Processing: The functioning of image and data processing is monitored by the human DNA control allelic values.

7.4 Reagents, Buffers, and Solutions

7.4.1 Critical reagents

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

Taq Gold polymerase
STR kits

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

ABA Hemetrace cards
ABA P-30 cards
Antisera
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. Copies of all orders will be maintained for a period of three years.

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 chemical 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@ 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 (eg., STR Kits) will be turned over to the appropriate Quality Control Officer, who will certify them for use 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 shall 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 All inventory will be stored under the conditions specified by the manufacturer.

7.4.5 Laboratory Prepared Buffers and Solutions

7.4.5.1 All lab prepared reagents and solutions will be made with great care following appropriate lab practices. Each solution prepared will have the following information recorded in a log book maintained by the designated 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 Buffers and solutions will be prepared using water from the Lab's Millipore Milli-Q water purification system.

7.4.5.3 All lab prepared buffers and solutions will be clearly labeled to reflect contents, expiration date, 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.

7.4.5.4 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.

7.4.5.5 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 from the stockroom refrigerator at this time.

7.4.5.6 Analysts will observe the following rules for the correct storage and use of antisera, Takayama working solutions, and other solutions

and chemicals.

7.4.5.6.1 Antisera

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

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

7.4.5.6.1.3 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. Antisera and normal sera will be stored in the refrigerator.

7.4.5.6.1.4 Animal antisera, 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.

7.4.5.6.2 Takayama and other chemicals

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

7.4.5.6.2.2 Phadebas tablets for the detection of amylase are dated items and will be stored in a central location. Analysts are not to store these tablets in their work areas, but will remove them from stock as needed. The Unit QC Officer is responsible for discarding outdated Phadebas tablets.

7.4.5.6.2.3 Kernochtrot and Picroindigocarmine Stains for sperm slides will be stored 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.

7.4.5.6.2.4 Fast Blue Salt B 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 Salt B should be stored refrigerated.

7.4.5.6.2.5 Alpha-napthyl acid phosphate (calcium salt) used for acid phosphatase detection may also be carcinogenic. It must be stored frozen when not in use. Gloves must be worn when using this compound and only a minimum amount should be used. Spot plates must be washed immediately after use.

7.4.6 QC Measures For The ABA p30 Card

7.4.6.1 The p30 standard is received from Scripps Laboratories, San Diego, CA. The quantity provided is 50 Φg/vial. Reconstitute by adding 1 ml of dH_20 and allow time for the freeze dried standard to dissolve. Store at 4^o C.

7.4.6.2 Place 10 Φl reconstituted p30 standard into a 15 ml conical, screw-capped plastic tube. Add HEPES Buffered Saline (HBS) to a final volume of 9 ml. Mix by inversion. This yields a solution of 56 ng/ml. If the standard has not been reconstituted, do so by adding 1 ml of dH_20 to a 50 Φg vial and allow to dissolve. Store at 4^o C.

7.4.6.3 Set up the following dilutions:

Vol. Of p30	Vol. Of HBS	Conc. Of Final Solution
1 ml of 56 ng/ml stock	0	56 ng/ml
1 ml of 56 ng/ml stock	1 ml	28 ng/ml

Vol. Of p30	Vol. Of HBS	Conc. Of Final Solution
1 ml of 28 ng/ml sample	1 ml	14 ng/ml
1 ml of 14 ng/ml sample	1 ml	7 ng/ml
1 ml of 7 ng/ml sample	1 ml	3.5 ng/ml

7.4.6.4 Test duplicate 200 Φl portions of each p30 dilution and a blank as designated by ABAcard p30 test procedures

7.4.6.5 Record each response as positive or negative. The lowest concentration that yields a positive result is considered the detection limit for that lot. Each lot will be tested prior to release for casework analysis. 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 Alternate QC Measures For The ABA p30 Card

Should the Scripps p30 standard not be available, or if it has degraded after re-constitution, the following method can be used to QC new test kits:

7.4.7.1 Stains have been prepared from serial dilutions of liquid semen (the fact that stains have been prepared offers a further dilution factor). Validation studies showed that positive results could be obtained from a 1:100 dilution, but not a 1:1000 dilution. Simply cut the stains prepared from neat, 1:10, 1:100, and 1:1000 dilutions of semen and test them.

7.4.7.2 Record each response as positive or negative. The lowest concentration that yields a positive result is considered the detection limit for that lot. Each lot will be tested prior to release for casework analysis. 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.

7.4.8 Preparation of Glassware and Plasticware

7.4.8.1 All glassware and plasticware will be clean 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.

7.4.10.2 To test the performance, the reagents from each kit shall be used to amplify, separate via electrophoresis, scan and make calls for the kits K562 DNA standard using current NCSBI Molecular Genetics Laboratory Protocols. The D16S539 add-in primers will be tested along with PowerPlex 1.1 kits. The D16S539 add-in will be additionally tested with known profiles that have exhibited drop-out at that locus in the past.

7.4.10.3 The lot number of each kit component, the data sheets, gel scans, and calls shall be documented.

7.4.10.4 Each lot of STR kits shall pass and be accepted for use if all of the amplified K562 alleles match and correspond to the known K562 alleles for each locus tested. If the K562 does not amplify or if a wrong allele per a given loci is obtained, then the lot fails. 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.

7.5 NIST Standard Reference Material (SRM)

7.5.1 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.

7.5.2 A known human blood standard may be tested simultaneously with the NIST SRM kit. If the NIST SRM standard is run successfully, then the Alot@ 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.

8.2 Equipment Inventory Log: An inventory log will be maintained on each piece of equipment in the Molecular Genetics Section. This log will include the following categories (not all are required fields):

Description/Model/Model #
Asset Number
Serial Number
Location (Room Number)
Mapper (do we have a receipt on file)
Year Purchased
Life Expectancy
Purchase Price (if known)
Condition
Annual Maintenance
Replacement Year

See Appendix A for a copy of this form

8.3 Operating Manuals

Operating manuals and warranty information provided by the manufacturer will be maintained in a file in the Molecular Genetics 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 needs to be repaired or serviced. Servicing or maintenance from the vendor or manufacturer will be documented.

8.6 Calibration Logs

8.6.1 Each piece of equipment which needs to be monitored and/or calibrated will be checked on an appropriate schedule. Calibration 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 of more complex instruments. The section will use the procedures for calibration of thermocyclers provided by the manufacturer.

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

8.6.3 Other equipment will be maintained by external vendors (e.g. water systems and the film processor).

8.6.4 Each calibration log will clearly show the calibration source to be used and the frequency of calibration.

8.7 Equipment Needing Calibration

8.7.1 Balances: The electronic top loading and analytical balances are cleaned, calibrated, and serviced yearly by a commercial firm.

Balances also undergo a weight check monthly by designated analysts in each unit. This weight check is not calibration, and is designed solely to make sure that the balances are not grossly off expectations.

8.7.2 Pipettors: Pipettors will be calibrated annually by a contract vendor. If an analyst suspects that a pipettor may be out of calibration, they should draw a new pipette from stock and notify the Special Agent In Charge that one of our pipettors needs re-calibration or service.

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

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

8.7.5 Thermometers: Thermometers will either be factory calibrated using a NIST standard or each thermometer will be verified yearly against a NIST-

certified thermometer.

8.8 Equipment Needing Service/Maintenance

8.8.1 Film Processor: The Konica film processor is cleaned, serviced, and inspected under a service contract with a commercial firm.

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

8.8.3 Millipore Milli-Q Water System: Every six months, a contract vendor will sanitize the units and change the cartridges and inspect the unit. In addition these units have several monitoring devices which may be checked during use. If one of these devices indicates a problem, then the vendor is called to correct it.

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

8.8.5 Thermocyclers: Thermocyclers will be tested for block temperature uniformity and for temperature verification at the end of January, April, July, and October of each year (quarterly), or if concerns about performance occur.

8.8.6 FMBIO DNA Scanners: The scanners will be repaired or serviced as needed by the manufacturer.

9 Proficiency Testing

9.1 Open External Proficiency Testing

Each Section analyst conducting DNA testing will complete an open proficiency test every 180 days. The 180 day rule means that an analyst will receive a proficiency test within 180 days of completing the prior test, and that two tests will be completed each year. Each Section analyst conducting only Body Fluid Identification testing will be tested at least once a year with an open proficiency test.

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 Section Technical Leader 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:

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 of all data and notes supporting the conclusions
9.3.1.5 The proficiency test results - for DNA Database type tests this could simply be a table of the genotypes
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 necessary

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

9.4 Evaluation of Proficiency Tests

9.4.1 Each 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 uninterpretable 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 minimiz 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 Proficiency Test Evaluation Form

The proficiency test evaluation form that captures the points listed above in Section 9.4.1 will be used.

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

Any time there is a discrepancy on a proficiency test or in casework reported out, this Section will follow the procedures outlined in the Crime Laboratory Procedures Manual (Section 14).

Any time questions arise concerning discrepancies or the efficacy of a technical procedure used in casework analysis, the Special Agent In Charge will immediately investigate the issue.

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.

Any time questions arise from case work of analyst competency or performance, the Special Agent In Charge 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 Crime Laboratory Procedures Manual dealing with discrepancies on proficiency tests will be used as a model for corrective action in case work analysis as well.

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 Crime Laboratory 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 proficiency test files. 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 A sample description, including packaging information and type of DNA extraction performed.
11.1.2.2 A lumigraph and quantitation sheet.
11.1.2.3 An amplification worksheet.
11.1.2.4 An electrophoresis worksheet and computer generated scans.
11.1.2.5 Allelic call sheets for examiner and second reader.
11.1.2.6 PopStats sheets reflecting population frequencies and a reference of the databases used (if applicable).
11.1.2.7 Inventory Sheet of retained evidence (if applicable)

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, sex and race. 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 gel scans.
11.1.3.4 A call sheet generated by the appropriate analysis software or generated manually
11.1.3.5 A second read sheet.

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 Crime Lab 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 Molecular Genetics Section files.

Validation studies, population studies, and research project results will be maintained in the Molecular Genetics Section.

11.3 Report Writing

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

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

11.4 Interpretational Guidelines for Matches (STR Analysis)

11.4.1 For proper data interpretation, the allelic values of the human DNA control (K562) must agree with documented allelic values.

11.4.2 The unknown or questioned samples will first be compared to the known samples visually for match/non-match status. All visual observations must be confirmed by a second reader for match status.

11.4.3 These guidelines are specified in the Appendix and also describe how results are assessed in forensic casework. The human DNA control will be monitored on each case against established guidelines.

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 Release of Case Information

Analysts will follow the procedures described in the Crime Laboratory Procedures Manual for release of case information.

12 Review

12.1 Independent Analysis of Data

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

12.1.2 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 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 Section 6 of the Crime Laboratory 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 Molecular Genetics Section.

General Laboratory Safety guidelines are covered in the NC Department of Justice Safety and Health Manual, the NCSBI Safety Procedures Manual (found at the back of the Crime Lab Procedures Manual), the Chemical Hygiene Plan, and the Blood Borne Pathogen Plan.

13.3 Material Safety Data Sheets

13.3.1 Material Safety Data Sheets will be maintained on all hazardous chemicals used in the Molecular Genetics Lab. The Section Safety Officer will file these sheets in a notebook found on the shelves in the Chemical Stock room.

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

13.3.3 If there are any questions with a MSDS or there is need for additional personal protective equipment, contact the Section Safety Officer.

13.4 All First Aid Kits are located in the fire-hose receptacles in the walls across from room 2250J (PCR Lab) and beside of room 2250GG.

13.5 Chemical Spills

13.5.1 Spill control kits are located in the Chemical Stock room. 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.

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

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

13.5.4 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.

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

13.7 Personal Protection Equipment (PPE) such as gloves, safety glasses, lab coats, respirators, and fume hoods is provided by the SBI for your protection. 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 Section Safety Officer before proceeding. If the Section Safety Officer is not available, contact the Laboratory Safety Officer. If you feel additional PPE or additional training is needed for your safety, contact the Section Safety Officer.

13.8 Emergency and Fire Evacuation Plan

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

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

13.8.3 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.

13.8.4 In the event of a Fire Alarm or an Emergency, the Molecular Genetics Section will evacuate as follows:

<u>No fire/smoke or dangerous situation in the section:</u> Secure evidence if possible, but do not delay. 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). At the front door, there will be a brief head count to ensure everyone is accounted for and then everyone will proceed down the stairs. Someone should carry the Section sign-out sheet out of the building.

Once outside, the Molecular Genetics Section will meet in the designated area.

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 safety as possible. If possible, someone should carry the Section sign-out sheet out of the building. Once outside, the Molecular Genetics Section will meet in the designated area.

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

13.9 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):

13.9.1 Working late as a sole occupant- Anyone who stays after normal working hours and he/she is the sole occupant of the section will notify the State Capital Police Officer on duty of your work situation, location by section and approximately how long you will be working. 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.

13.9.2 Outside normal working hours as a sole occupant- Anyone who comes into work after normal working hours will enter through the main front entrance and notify the State Capital Police Officer on duty of your work situation, location by section and approximately how long you will be working. 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.

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

13.9.3.1 Working with concentrated acids
13.9.3.2 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 CALEA Mandated Audit

The SBI Molecular Genetics Section is audited once every two or three years by a SBI Inspection Team pursuant to our CALEA Accreditation. This unit is composed of several agents and individuals from various SBI divisions. A typical inspection will last one week. During this time, all phases of the operation of the section are scrutinized including: evidence handling and accountability, case turn around time, report writing, note taking, management practices, leave and time management policies, security, records security, inventory of equipment and supplies, and personnel records.

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

14.3.1 The SBI Molecular Genetics Section will be inspected annually by a qualified DNA examiner 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 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, Kentucky State Police Crime Lab, US Army Criminal Identification Lab, FBI Crime Lab, and the SBI Crime Lab. This audit will check the laboratory=s performance against the Quality Assurance Standards For Forensic DNA Testing Laboratories.

14.3.2 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.

14.3.3 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 ISSUED BY THE FBI DIRECTOR@. Use of this audit document will satisfy National DNA Quality Standards and all components of this standard.

15 Subcontractor Laboratories

15.1 Use of a Subcontractor Laboratory for Forensic Cases is Prohibited

SBI Molecular Genetics Section employees will not submit forensic case material to a private laboratory, or any other laboratory for DNA testing. Even if the laboratory receives a court order to send material to another lab, laboratory personnel will not send or transfer evidence to another laboratory. Rather they will contact the submitting agency to make arrangements for them to pick up or submit the evidence.

15.2 Use of a Subcontractor Laboratory for Convicted Offender Sample Testing

15.2.1 The subcontractor will certify that they meet or exceed the AQuality Assurance Standards for Convicted Offender DNA Databasing Laboratories@. This can be accomplished by trained auditors from the NCSBI Molecular Genetics Section conducting an audit against these standards, or receipt of an audit document from another lab against the same standards.

15.2.2 NCSBI Molecular Genetics personnel will establish and use appropriate review procedures to verify the integrity of the data received from the subcontractor to include:

15.2.2.1 Random re-analysis of samples
15.2.2.2 Visual inspection and evaluation of the results/data
15.2.2.3 Inclusion of QC samples
15.2.2.4 On-site visits

Revision History		
Effective Date	Revision Number	Reason
	00	Original Document
April, 26, 1999	01	Manual Update
October 10, 2000	02	Manual Update
December 4, 2002	03	Procedure Update