

# Forensic Biology Unit Quality Assurance Manual FBQA01

## Table of Contents

1. Goals and Objectives
2. Organization, Management Structure and Position Responsibilities
  - 2.1. Forensic Biology Unit Manager
  - 2.2. Forensic Biology Technical Leader
  - 2.3. Forensic Biology Lead Scientist
  - 2.4. Casework CODIS Administrator
  - 2.5. Analyst
  - 2.6. Technician
  - 2.7. Laboratory Support Staff
3. Personnel Qualifications and Training
  - 3.1. Job Descriptions and Qualifications
    - 3.1.1. Unit Manager and Lead Scientist Qualifications
    - 3.1.2. Technical Leader Qualifications
    - 3.1.3. Casework CODIS Administrator Qualifications
    - 3.1.4. Analyst (i.e., Forensic Scientist) Qualifications
    - 3.1.5. Technician Qualifications
    - 3.1.6. Laboratory Support Staff Qualifications
    - 3.1.7. Contract Employee Qualifications
  - 3.2. Training
    - 3.2.1. Training and Qualification File(s)
    - 3.2.2. Training Program
      - 3.2.2.1. Re-training guidelines
    - 3.2.3. Continuing Education
4. Facilities and Security
  - 4.1. Facilities
  - 4.2. Contamination
    - 4.2.1. Contamination Prevention and Clean-up Procedures
    - 4.2.2. Spills
    - 4.2.3. Biohazard Waste Disposal
    - 4.2.4. Chemical Waste Disposal
  - 4.3. Security
5. Evidence and Sample Control
  - 5.1. Receipt
  - 5.2. Chain of Custody
  - 5.3. Sample Handling and Storage
    - 5.3.1. FSL\_FBU\_QA Database Samples
  - 5.4. Examination and Analysis
  - 5.5. Disposition
  - 5.6. Case Acceptance and Priority Criteria

- 6. Validation
  - 6.1. Developmental Validation
  - 6.2. Internal Validation
- 7. Analytical Procedures
  - 7.1. Analytical Procedures
  - 7.2. Standards and Controls
  - 7.3. Interpretation
  - 7.4. Reagent Quality Control
  - 7.5. Quality Control of DNA Procedures
- 8. Equipment Calibration and Maintenance
  - 8.1. Equipment Inventory and Operation Manuals
  - 8.2. Calibration/Maintenance Procedures and Logs
- 9. Reports and Documentation
  - 9.1. Analytical Notes
  - 9.2. Report Writing
  - 9.3. Case Files
  - 9.4. Issuance of Case Reports
- 10. Review
  - 10.1. Case Review
    - 10.1.1. Elements of Technical Review
    - 10.1.2. Testimony review
- 11. Proficiency Testing
  - 11.1. Purpose
  - 11.2. Assignment, Frequency and Documentation
  - 11.3. Verification of Performance
- 12. Corrective Action
  - 12.1. Procedure
  - 12.2. Clean Run
- 13. Audits
  - 13.1. Annual DNA Audit
  - 13.2. Quality Audit
  - 13.3. Quality Review
- 14. Safety
- 15. Outsourcing Casework for DNA Analysis
  - 15.1. Vendor Laboratory Requirements
  - 15.2. On-Site Visits
    - 15.2.1. On-Site Visit Process and Elements

## 1. Goals and Objectives

The Forensic Biology Unit quality assurance system operates in accordance with the quality policies and practices established in the laboratory's *Quality Assurance Manual (QAM)*, the *Departmental Operations Manuals (DOMs)*, the *Laboratory Operations Manuals (LOMs)* and the stated requirements in the *FBI Quality Assurance Standards for Forensic DNA Testing Laboratories (QAS)*.

It is the goal of the Forensic Biology Unit (FBU) to:

- Provide user agencies access to testing services of selected biological materials.
- Ensure the quality, integrity and reliability of the DNA typing data and its presentation through the implementation of a detailed quality assurance (QA) program.
- Provide expert testimony regarding laboratory findings resulting from forensic biological analysis of evidentiary materials.

It is the objective of the FBU quality assurance program to ensure that:

- All forensic biology screening and DNA typing procedures are operating within established performance criteria, that the results and conclusions are technically correct, and the presentation of information is clear, accurate and of high quality.
- The analytical testing and reporting procedures are monitored by means of quality control procedures, proficiency testing and audits.

## 2. Organization, Management Structure and Position Responsibilities

### 2.1. Forensic Biology Unit Manager

The manager functions as the head of the Forensic Biology Unit. The manager duties and responsibilities include, but are not limited to:

- Managing and coordinating all programs within the unit.
- Approving and documenting policies and procedures, standard operating procedures, quality assurance/quality control procedures, and other unit specific documents as necessary.
- Serving as the supervisor for the Forensic Biology Unit.
- Ensuring that the Technical Leader is provided with opportunities for training and continuing education.
- Ensuring that the necessary resources are made available to adequately address deficiencies and potential deficiencies; directing, reviewing and approving implemented quality corrective actions and preventative actions; ensuring the quality corrective and preventative actions have been completed in a timely manner; ensuring appropriate follow-up activities are carried out; and that the associated documentation is maintained.
- Reviewing and approving training in the laboratory.

- Ensuring that unit personnel comply with the applicable health and safety policies and practices.

## 2.2. Forensic Biology Technical Leader

The technical leader oversees the technical operations in the Forensic Biology Unit. As such, the technical leader has the authority to suspend/terminate operations in the Forensic Biology Unit if a determination is made that the current casework operations have been compromised. The technical leader duties and responsibilities include, but are not limited to:

- Authority to initiate, suspend, and resume DNA analytical operations for the laboratory and individuals.
- Managing and coordinating all technical programs within the unit.
- Ensuring that a qualified individual is designated to serve as the unit's Technical Leader in the Technical Leader's absence.
- Approving and documenting technical standard operating procedures, quality assurance/quality control procedures, validation studies and other unit specific documents as necessary.
- Upon appointment, in the capacity as Technical Leader, this individual will be responsible for a documented review of all FBU quality documents within one year.
- Assessing and documenting the annual review of the procedures of the unit.
- Assessing and documenting the review of academic transcripts and training records for newly qualified analysts and approving their qualifications before allowing them to perform independent casework analysis.
- Ensuring that the lead forensic scientist and forensic scientists (analysts and technicians) are provided with opportunities for training and continuing education and are qualified for their assigned work responsibilities.
- Ensuring that the Forensic Biology Unit's quality assurance program complies with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.
- Directing, reviewing and approving implemented quality corrective actions and preventative actions; ensuring the quality corrective and preventative actions have been completed in a timely manner; ensuring appropriate follow-up activities are carried out; and that the associated documentation is maintained.
- Assessing and documenting the review of internal and external DNA audit documentation. If any corrective actions have resulted from these audits, review and approve the corrective actions to ensure that the findings were appropriately and adequately addressed.
- Determining the course of action appropriate for resolving a discrepancy between analysts/reviewers and adopting steps to minimize or eliminate a discrepancy from reoccurring.

- Reviewing and approving training, quality assurance and proficiency testing programs in the laboratory.
- Reviewing and approving the technical specifications for outsourcing agreements.

### 2.3. Forensic Biology Lead Scientist

The Lead Scientist is responsible for case management to include discussion with submitting agencies regarding processing decisions, laboratory workflow and efficiency of casework. The lead scientist's duties and responsibilities include, but are not limited to:

- Assigning cases to laboratory analysts.
- Ensuring all submitted paperwork is correct and up to date.
- Ensuring cases are completed within expected timelines.
- Communication with submitting agencies regarding case processing questions.
- Management of laboratory practices for efficient and accurate processing.
- Recommending updated lab procedures and practices to ensure quality casework and efficient processing.
- With technical leader coordination, implementation of procedures within the casework team.
- Raising concerns with the technical leader and manager about quality of casework, should it arise.

### 2.4. Casework CODIS Administrator is responsible for:

- Administration of the laboratory's local CODIS network.
- Scheduling and documentation of the CODIS computer training of casework analysts.
- Ensuring that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.
- Ensuring that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.
- Ensuring that matches are dispositioned in accordance with NDIS operational procedures.
- Ensuring that a qualified individual is designated to serve as the unit's casework CODIS Administrator in the casework CODIS Administrator's absence.
- The casework CODIS Administrator will be authorized to terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified.
- Reviewing and/or approving, as appropriate, protocols or procedures for entry, searching and match resolution of DNA records in the state DNA database.

2.5. Analysts (i.e., forensic scientists) are responsibilities to include:

- Performing analyses on evidentiary materials: including evaluation and preparation of the evidence; performing analytical techniques and/or interpretation of analytical results; preparation of case reports and/or casework documentation; and expert testimony.
- Serving as a second reader (verifier) of DNA testing results and/or as technical reviewer and/or administrative reviewer of serology and/or DNA testing results, if approved by the Technical Leader.
- Understanding and following established procedures and interpretation in casework, including the use of proper controls.
- Bringing possible analytical or interpretation problems to the Technical Leader immediately, including suggestions for corrective action.
- Actively seeking new knowledge and remaining current with appropriate literature and training opportunities.
- Participating in proficiency testing and remedial training as assigned.
- Conducting and documenting selected quality control checks such as calibration checks, maintenance of equipment and quality control testing of reagents and materials used for analysis.
- Perform other duties specified by the Technical Leader, Lead Scientist and/or Unit Manager.

2.6. Technician responsibilities to include:

- Performing analytical techniques (e.g., extraction, quantitation, amplification, capillary electrophoresis loading) on evidentiary materials under the supervision of a qualified analyst, including preparation of casework documentation and expert testimony (as needed).
- Conducting and documenting selected quality control checks such as calibration checks, maintenance of equipment and quality control testing of reagents and materials used for analysis.
- Understanding and following established procedures in casework, including the use of proper controls.
- Bringing possible analytical problems to the Technical Leader immediately, including suggestions for corrective action.
- Participating in proficiency testing and remedial training as assigned.
- Perform other duties specified by the Technical Leader, Lead Scientist, Unit Manager or designee.

2.7. Laboratory Support Staff (i.e., interns) responsibilities to include:

- Performing duties (e.g., administrative tasks such as scanning case files, laboratory cleanup) designated by the Technical Leader, Lead Scientist, Unit Manager or designee.

Note: It is the responsibility of all FBU personnel to immediately report to the Technical Leader any data which appears to have a quality control problem.

### 3. Personnel Qualifications and Training

#### 3.1. Job Descriptions and Qualifications

The general knowledge, skills and abilities required for each technical classification within the Forensic Biology Unit are set forth in the job specification statements prepared by the Department of Forensic Sciences and the D.C. Department of Human Resources and maintained by the D.C. Department of Human Resources. In addition, technical staff must meet the educational requirements of the FBI *Quality Assurance Standards for Forensic DNA Testing Laboratories*. These requirements are designed to ensure that technical staff have the training, education and proficiency commensurate with their duties. An individual's training file, as well as documentation of qualifications, is maintained for all technical staff.

##### 3.1.1. Unit Manager and Lead Scientist Qualifications

- Documented previous experience within an accredited DNA laboratory.

**Note:** If additional technical duties are assigned, such as technical review or case reporting, see analyst qualifications.

##### 3.1.2. Technical Leader Qualifications

- Minimum of a Master's degree in a biology, chemistry or forensic science related area. (NOTE: A Bachelor's degree in a biology, chemistry or forensic science related area is permissible only with an ASCLD waiver.)
- Successful completion of a combination of undergraduate and graduate coursework (12 semester or equivalent credit hours) covering the subject areas of biochemistry, genetics, molecular biology (molecular genetics, recombinant DNA technology), and statistics or population genetics. The 12 semester or equivalent credit hours will include at least one graduate level course registering three (3) or more semester or equivalent credit hours.
- A minimum of three years of human-DNA laboratory experience as a qualified analyst on forensic samples.
- Demonstration of competence in review and interpretation of DNA typing results in a variety of samples typical of evidentiary material.
- Must successfully complete the FBI sponsored auditor training within one year of assuming their technical leader duties if the individual had not previously attended such training.

##### 3.1.3. Casework CODIS Administrator Qualifications

- Minimum of a Bachelor's degree in a biology, chemistry or forensic science related area.
- Successfully completed undergraduate and/or or graduate course work covering the subject areas of biochemistry, genetics and



molecular biology (molecular genetics, recombinant DNA technology); and coursework and/or training in statistics and/or population genetics as it applies to forensic DNA analysis.

- Must be a current or previously qualified DNA analyst with documented mixture interpretation training.
- Must participate in the FBI sponsored training in CODIS software within six months of assuming CODIS administrator duties if the Administrator had not previously attended such training.
- Must successfully complete the FBI sponsored auditor training within one year of assuming their Administrator duties if the Administrator had not previously attended such training.

#### 3.1.4. Analyst (i.e., Forensic Scientist) Qualifications

- Minimum of a Bachelor's degree in a biology, chemistry or forensic science related area.
- Successfully completed undergraduate and/or graduate course work covering the subject areas of biochemistry, genetics and molecular biology (molecular genetics, recombinant DNA technology); and coursework and/or training in statistics and/or population genetics as it applies to forensic DNA analysis.
- A minimum of six months of forensic DNA laboratory experience, including the successful analysis of a range of samples typically encountered in forensic case work prior to independent case work analysis using DNA technology.
- Demonstration of competence in review and interpretation of DNA typing results in a variety of samples typical of evidentiary material.
- Successful completion of a competency test prior to performing independent DNA casework.

#### 3.1.5. Technician Qualifications

- Documented training specific to their job function(s).
- Successful completion of a competency test before participating in analytical techniques in DNA analysis (e.g., extraction, quantitation, amplification, capillary electrophoresis loading).

#### 3.1.6. Laboratory Support Staff Qualifications

- Documented training specific to their job function(s).

#### 3.1.7. Contract Employee

- Responsibilities: Provide DNA typing and/or analytical support services to the laboratory.
- Qualifications: The person performing these services must meet the relevant qualifications for the equivalent position in the laboratory. A contract employee cannot serve as the casework CODIS Administrator or Technical Leader and will not be counted

as a full-time qualified analyst for the purposes of satisfying the definition of a laboratory. Employment of a contract employee by multiple NDIS participating and/or vendor laboratories will be disclosed and will only be permitted subject to approval by the Technical Leader of the NDIS participating laboratory for which the contract employee is performing DNA typing and/or analytical services.

### 3.2. Training

An assessment of the education, training and experience of each new employee is conducted at the time of hire by review of transcripts and certificates, interview of former employers and, where appropriate, review of prior work or proficiency test results by the Technical Leader. The Technical Leader will document this review and forward such information to the Deputy Director, Quality Specialist and/or designee to maintain in the individual personnel files.

#### 3.2.1. Training and Qualifications File(s)

A training file is established for each technical staff member and is maintained by the Deputy Director and/or designee. The Deputy Director and/or designee will periodically review this file(s) to ensure it/they is/are updated. The training and qualifications file(s) will include:

- A current CV and/or statement of qualifications listing relevant education, in-service training and other qualifications.
- In-service training courses, seminars and other continuing education.
- Documentation of completed competency and proficiency tests.
- College transcripts (copies are sufficient).
- Other information related to training and qualifications (e.g., copies of certificates, papers or presentations authored) at the discretion of the employee.

#### 3.2.2. Training Program

The purpose of the training program is to provide a consistent approach to the training of new staff assigned to the Forensic Biology Unit. Trainees are expected to undergo training and competency/proficiency testing sufficient to acquire and demonstrate an understanding of the principles, usage and limitations of the equipment and procedures they use. Because of their role as expert witnesses, analyst trainees must also be familiar with relevant procedures and practices followed in the broader scientific community.

The specific content and length of the initial training period will be a function of the individual's prior education, background and experience. The trainer will evaluate the progress of training by

assessing the trainee's knowledge, understanding and skill in conducting and describing the procedures, as well as the analytical and interpretive competence as demonstrated through practice analysis, competency/proficiency testing and report writing exercises.

A complete description and outline of the training program is listed in the *Forensic Biology Unit Training Manual* (Document Control Number: 831). In general, the training program is designed to provide the trainee with the background knowledge and experience needed to perform quality casework. The following topics are covered in detail:

- Safety - An introduction to the laboratory environment and the potential biological and chemical hazards will be provided in order to familiarize the trainee with proper safety and emergency procedures.
- Forensic Biology Screening - The screening training will provide the trainee with the knowledge and practical experience necessary to examine biological evidence. Upon completion, the trainee will be able to locate and identify (as applicable) various biological fluids and have the ability to assess and collect them according to their suitability for further DNA testing.
- Foundational Scientific Knowledge - The trainee will be provided with the information necessary to gain a working knowledge of the principles and fundamental scientific basis of forensic DNA analysis.
- Forensic DNA Analysis - Practical instruction on analytical procedures relating to the analysis of DNA (e.g., extraction, quantitation, PCR amplification, capillary electrophoresis, interpretation, statistics) will be provided. The trainee must be able to perform the various techniques and understand all aspects of the procedure.
- Casework Training - Samples representative of casework will be analyzed by the trainee. These samples will provide them with the experience necessary to examine evidence and interpret the analytical results. The trainee will also become familiar with report writing procedures, appropriate statistical calculations, evidence storage and disposition, if applicable to the duties/responsibilities the trainee will perform.
- Competency Tests - Competency in a given procedure will be demonstrated by the trainee prior to beginning independent casework. Successful completion of the competency test will be documented prior to the individual performing such procedures on casework. Documentation will be in the form of a memorandum.
- Court Presentation - Information regarding legal issues, courtroom etiquette, and the presentation of scientific evidence will be provided.

Note: The Technical Leader will have his/her previous training, experience, education, published articles, and other credentials reviewed by the FBU Manager and/or Deputy Director and a specialized training plan for the technical leader will be documented in an individual training plan memorandum.

#### 3.2.2.1. Re-training guidelines

The re-training of an analyst/technician may occur when findings from a corrective action or preventative action indicate that it is necessary. Re-training will be done in the same manner as the initial training, followed with the necessary competency test in serology, DNA analysis, report writing, etc., which will need to be successfully completed prior to the analyst/technician being re-approved to perform the re-trained casework duty. If re-training is necessary for court testimony, the analyst/technician will be required to undergo and successfully complete a moot court in the presence of the FBU Technical Leader and/or designee(s). For all documented instances of re-training, there will be a 60-day evaluation of the re-trained analyst/technician following the return to casework duties.

#### 3.2.3. Continuing Education

The purpose of continuing education is to keep the Technical Leader, casework CODIS Administrator and analyst(s) abreast of the current state of DNA research and technology in the forensic community. The Technical Leader, casework CODIS Administrator and all analysts will complete, at a minimum, eight cumulative hours of continuing DNA education per year. Sessions may include scientific meetings (e.g., AAFS, Promega), college courses, or documented in-house training relating to relevant subject areas (e.g., DNA analysis, CODIS). In addition, each analyst must review current scientific literature regarding DNA throughout the year. Each analyst will document their relevant literature reviews electronically.

### 4. Facilities and Security

#### 4.1. Facilities

FBU laboratory casework spaces are located separately from office space. FBU laboratory areas are arranged in a manner that ensures the physical separation of laboratory areas used for examination and extraction (pre-amplification laboratory) from those areas used for the DNA amplification and typing (post-amplification laboratory).

- **Screening Lab** – Analysts are provided with a work area to screen and document evidence submitted to the FBU. This area is to be used to

examine evidence for the presence of biological fluids, perform presumptive and confirmatory screening tests, and collect and preserve samples for further testing. **A separation in time and space must be maintained between questioned and known samples during inventory, examinations, cutting, and re-packaging.** Only one item of evidence is to be examined at a time.

- **Extraction Lab** – This room is used for the extraction of DNA from questioned and known samples. To maintain a separation in time and space, questioned and known samples cannot be incubating in the same heat block/thermomixer at the same time, nor may they be extracted in the same fume hood and/or EZ1 instrument at the same time.
- **Pre-Amplification Lab** – This room is used for PCR setup (real-time and STR). Equipment and supplies located in this area are specific for these tasks.
- **Post-Amplification Lab** - This room is used only for those activities that involve the handling of amplified DNA. This includes DNA typing, real-time PCR, waste disposal of amplified DNA products and storage of amplified DNA. Dedicated equipment and supplies located in this room (e.g., thermal cyclers, pipettes, glassware, electrophoresis instruments) are specific for use only with amplified DNA procedures and are not to be removed from the room without decontamination.
- **Reagent Prep Lab** – This room is used for the preparation of reagents used in serological and DNA testing procedures.

#### 4.2. Contamination

Because of the sensitivity of PCR based procedures, special precautions must be taken to avoid contamination of samples. Potential sources of contamination and basic preventive measures are listed below:

- **Sample contamination from the environment.** To minimize the potential of chance contamination, all who enter designated laboratory areas will wear laboratory coats, gloves, safety goggles, hairnets (pre-amp only) and masks (pre-amp only) at all times. Sample tubes will be closed when not in use. Dispersal of aerosols will be kept to a minimum.
- **Cross-contamination between samples.** Precautions will be taken to prevent transfer of DNA from one sample to another. A fresh pipette tip will be used for each sample, tubes will be opened carefully, and sample containers will be kept closed when not in use. Only barrier filtered tips are to be used when pipetting biological samples. Samples expected to have low concentration of DNA should be processed at a different time and/or space from those of higher concentration. **A separation in time and space must be maintained between questioned and known samples during inventory, examinations, cutting, re-packaging, extraction, and microcon.** Questioned and known samples may be processed together for all post extraction steps of the DNA analysis process (e.g., quantitation, amplification, and detection) as long as they are separated by space (i.e., empty column) and questioned samples are processed on the plate before

known samples. For CE detection, questioned and known samples must be separated by an empty column and must also be injected in separate injections, i.e. for the 24-capillary 3500xL, questioned samples may not be in column "1" and known samples in column "3".

- **Contamination of sample with amplified DNA from a previous PCR reaction (PCR product "carry-over")**. Product carry-over occurs when amplified DNA contaminates a sample that has not yet been amplified. It is important to contain amplified PCR product to prevent it from coming into contact with samples before they are amplified. Directly after exiting the Post-Amplification Lab wash hands thoroughly. Any item removed from the Post-Amplification Lab must be thoroughly decontaminated.

#### 4.2.1. Contamination Prevention and Clean-up Procedures

The object of developing careful analytical techniques is to recognize and minimize contamination of samples with exogenous sources of DNA. Forensic samples need to be protected from conditions and agents that might serve to destroy, deteriorate, or otherwise change the DNA to be evaluated. The list below will be used as a basic guideline for cleaning equipment and work areas.

- **Benchtops** - All working bench top surfaces will be thoroughly cleaned with a 10% bleach solution before and after use. 70% ethanol will be used to remove bleach residue to protect surfaces. Clean paper or other similar material will be placed on the bench top work area prior to use.
- **Rooms** - All work surfaces are to be wiped down with a 10% bleach solution or appropriate cleaning solution (commercial preparation) before and after analysis. 70% ethanol will be used to remove bleach residue to protect surfaces. After wiping, fresh clean paper or similar material will be placed on the bench top. At the conclusion of an analysis, all equipment used (e.g., pipettes, centrifuges) will be wiped down with a 10% bleach solution or appropriate cleaning solution (commercial preparation) followed by 70% ethanol to protect surfaces.
- **Small Tools** - Clean all small tools (e.g., forceps, scissors, pens) with a 10% bleach solution or other appropriate instrument cleaner prior to use and after handling each specimen. If bleach is used, clean small tools with 70% ethanol to remove any bleach residue that may be on the tools.
- **Autoclaving Materials** - Glassware and plastic supplies are autoclaved (refer to applicable Quality Standard Operating Procedure for information on when to use). Only autoclave appropriate types of plastics (e.g., polypropylene, polymethylpentene, polypropylene copolymer). Polycarbonate is autoclaveable but the cycle will be limited to 20 minutes at 121°C. All items will be carefully cleaned before autoclaving. Set cap or closure on top of the container without engaging the threads. Attach

autoclave indicator (e.g., dot or strip) to container. Small items (e.g., forceps, scissors) may be autoclaved inside a beaker covered with foil. Do not autoclave detergents or wetting solutions (i.e., those containing SDS). Do not autoclave solutions containing DTT. Do not fill containers more than 75% of capacity with a liquid solution.

- **Glassware Cleaning** - Wash glassware with 10% bleach or appropriate cleaning solution (commercial preparation) and thoroughly rinse with distilled, deionized or tap water. Heavily soiled items may be washed with tap water, then thoroughly rinsed with distilled or deionized water and allowed to dry. For many applications, washing with a mild detergent will remove greases and oils. When more rigorous cleaning is needed, organic solvents (e.g., alcohols, acetone) may be used. This will then be followed by the regular cleaning procedure as specified above.
- **Gloves/Masks/Laboratory Coats/Eye Protection/Hair Nets** – Gloves, laboratory coats, eye protection (e.g., goggles, safety glasses, face shields), hair nets and masks are to be worn by all persons in the screening and pre-amplification rooms. Gloves, laboratory coats and eye protection only are to be worn in the post-amplification room. At a minimum, lab coats and gloves will be worn when in the evidence storage area. Lab coats are specific to laboratory space: white lab coats are worn in the screening and pre-amplification rooms and blue lab coats are worn in the post-amplification room. At a minimum, lab coats will be disposed of once a week and face masks and hair nets will be disposed of at the end of the work day.

**Note:** If facial hair cannot be properly covered by a mask additional protective covering must be worn.

- **Pipette Tips** - Only barrier (filtered) tips are to be used when pipetting biological samples. Tips are to be changed between each sample. Pipette tips used to handle biohazard materials are disposed of into biohazardous waste containers. Pipette tips may be disposed of in regular trash if they did not come in contact with biohazardous materials or other potentially infectious materials (OPIMs).
- **Microcentrifuge Tubes** - Microcentrifuge tubes may be opened with a decapping tool. Autoclaved tubes will be used exclusively. After use, the tubes exposed to biohazards or OPIMs will be discarded in the biohazard trash. All tubes not exposed may be discarded in regular trash.
- **Pipettes** - Pipettes are to be cleaned with a 10% bleach solution followed by 70% ethanol on a regular basis.

- **Thermal Cyclers** - Each thermal cycler heating block and outer surfaces are to be wiped down at minimum quarterly with a 10% bleach solution or appropriate cleaning solution (commercial preparation) followed by 70% ethanol (or isopropanol for the 9700 thermal cyclers). Individual wells are cleaned as needed.
- **Centrifuges** - The centrifuges used in the FBU are to be cleaned at minimum quarterly with a 10% bleach solution or appropriate cleaning solution (commercial preparation) followed by 70% ethanol. If a spill occurs, the surfaces are to be wiped with a 10 % bleach solution or appropriate cleaning solution (commercial preparation) followed by 70% ethanol, prior to further use.
- **EZ1 Instruments** - The EZ1 instruments used in the FBU are to be cleaned prior to use using ethanol followed by deionized water, followed by UV light to assist in further decontamination. **Bleach should never be used** on these instruments, as toxic fumes can be produced when bleach comes into contact with salts from the buffers of the Qiagen EZ1 DNA Investigator kit. If a spill occurs, the surfaces are to be thoroughly washed with soap and water.
- **Fume Hoods** - As with the bench top work area, the hood used for phenol/chloroform extractions will be cleaned with a 10% bleach solution or appropriate cleaning solution (commercial preparation) followed by 70% ethanol before and after use. Optional: A clean sheet of paper, similar material, or Kimwipe may be placed over the cleaned area prior to use.
- **Biosafety Hoods** - Before and after each use, the Biosafety Hood is to be cleaned with a 10% bleach solution or appropriate cleaning solution (commercial preparation) followed by 70% ethanol.
- **Benchtop Hoods** - Before and after each use, the bench top hoods are to be cleaned with a 10% bleach solution or appropriate cleaning solution (commercial preparation) followed by 70% ethanol. The hood UV light will be used to assist in further decontamination. Optional: A clean sheet of paper, or similar material, is placed over the cleaned area prior to use.

In addition to the list above, a quarterly cleaning of instruments, hoods, equipment and work surfaces will be performed in the evidence room, screening room, extraction labs, and pre- and post-amplification laboratories.

4.2.2. Spills - Refer to *DOM13 - DFS Health and Safety Manual* (Document Control Number: 1617) for further information.

4.2.3. Biohazard Waste Disposal – Refer to *DOM13 - DFS Health and Safety Manual* for information regarding Biohazard Waste Disposal.



4.2.4. Chemical Waste Disposal – Refer to *DOM13 - DFS Health and Safety Manual* for information regarding Chemical Waste Disposal.

#### 4.3. Security

- The FBU follows the security practices set forth in the *Forensic Science Laboratory (FSL) Quality Assurance Manual* (Document Control Number: 1300) and *DOM01 – Security Procedures* (Document Control Number: 1421).
- FBU personnel have unrestricted access to laboratory areas by means of an electronic access badge, biometric scan and/or assigned unit specific access keys.
- Unit personnel will ensure that any visitor under his/her care is escorted at all times while in the office and laboratory areas.
- Unit personnel will ensure that any non-DFS visitors to FBU operational laboratory areas will document their visit on the Visitor Log.
- Access to unit evidence storage areas is limited to FBU personnel (e.g., forensic scientists) and individuals authorized by the FBU Manager, FBU Technical Leader, FSL Laboratory Director, and/or DFS directorate.
- When the laboratory space is unoccupied, all evidence must be secured and the laboratory work areas locked when evidence is not actively being examined.

#### 5. Evidence and Sample Control

Specific procedures regarding case acceptance, evidence handling and security are detailed in the *DOM01 – Security Procedures* (Document Control Number: 1421), *DOM10 – Procedures for Handling Evidence and Clinical Specimens* (Document Control Number: 1281), and *LOM01 – Procedures for Examination of Evidence* (Document Control Number: 1315). The purpose of these procedures is to ensure that the chain of custody is maintained and evidence is protected from loss, cross-transfer, deterioration or deleterious change. The following general quality assurance guidelines apply:

##### 5.1. Receipt

Case acceptance will be done in accordance with the *DOM10 – Procedures for Handling Evidence and Clinical Specimens*. The designated person receiving the evidence will:

- Ensure the chain of custody is properly documented.
- Ensure the number of packages received is correctly recorded.
- Mark the outer container(s) with case/item number(s).
- Ensure container(s) are properly packaged, sealed and are placed in a designated location.
- Submit case information (chain of custody and case submission information) to the Forensic Biology Unit Manager or designee (e.g., lead forensic scientist).

## 5.2. Chain of Custody

A clear, well-documented chain of custody must be maintained in chronological order from the time the evidence is first received in the Forensic Biology Unit until it is released from the Forensic Biology Unit.

## 5.3. Sample Handling and Storage

In general, biological evidence should be thoroughly dried and stored in a temperature controlled environment (e.g., freezer, refrigerator) as soon as possible upon receipt. It may be appropriate to store items (e.g., knives, baseball bats) suspected of having biological material at room temperature. Liquid samples will be refrigerated upon arrival and processed as soon as possible. Evidence from which all usable biological material has been removed may be stored at room temperature.

### 5.3.1. FSL\_FBU\_QA Database Samples

For the purposes of the Forensic Biology Unit, FSL\_FBU\_QA Database Samples are samples on which DNA typing has been performed. Such samples may include, but are not limited to, buccal swabs from visitors or vendors to the laboratory, post-mortem tissue or blood samples, and electronic data transmitted under contractual obligation from an externally accredited laboratory for the purposes of quality assurance. Such samples, when physically stored in the laboratory, will be properly identified and kept isolated and separate from all casework samples by standard packaging and storage procedures. Access to such samples will be limited to authorized laboratory staff.

- DNA profiles developed from samples mentioned above will be electronically stored in the FSL\_FBU\_QA Database for the purposes of quality control. The entries in this database will be anonymized with chronological numbers to protect the identity of the individual or source of the DNA profile. The relationship between the sample ID number in the FSL\_FBU\_QA Database and the contributing individual or source will be accessible only by the laboratory management or designated FBU employees. See *FBQ30 – Maintenance of the DNA QA Database* (Document Control Number: 1473) for information regarding entry and maintenance of samples/profiles.
- Single source or deconvoluted unknown evidence profiles will be searched against profiles generated by the laboratory prior to issuing a report. This is to ensure that the unknown profile is not contamination from another case, from staff members, or from other samples processed by the laboratory. This search will be documented in the examination documentation. See *FBQ30 -*

*Maintenance of the DNA QA Database* (Document Control Number: 1473).

5.4. Examination and Analysis

The FBU Manager, Lead Scientist or designee may complete a Schedule of Analysis, prior to the case being assigned per *LOM02 – Practices for Case Documentation and Report Writing* (Document Control Number: 1319). This will detail which items of evidence are to be examined, which examinations are to be performed for each item (e.g., serology, DNA) and which items will not be examined at that time. All examinations performed by the FBU and/or directed by the Schedule of Analysis will result in a Forensic Biology *Report of Examination* and will be written in accordance with *LOM02 – Practices for Case Documentation and Report Writing* (Document Control Number: 1319).

Once assigned to a case, the analyst/technician will review and inventory the submitted evidence documentation. The FBU Manager, Lead Scientist, designee, or assigned analyst will coordinate with the submitting agency and/or attorney(s) as needed.

An analyst will examine only one item of evidence at a time, marking the evidence with a unique identifier and returning it to its container before opening another item. Analysts will confine examination of their evidence as much as possible to their own work areas. Evidence will be left out on the lab bench or exam table only long enough to be examined and have appropriate samples removed for further analysis.

Before altering the evidence by sampling, an analyst will record its condition (e.g., written description, diagram and/or photography).

Where possible, the analyst will ensure that sufficient sample is left for possible reanalysis. If the entire sample must be consumed in order to obtain an interpretable result, the substrate remains will be saved during the extraction procedure and may be utilized for possible additional testing. The analyst will ensure that the legal implications of sample destruction have been considered, addressed and documented by the submitter and/or attorney.

5.5. Disposition

The item of evidence and original packaging containing identifying markings will be returned in tape-sealed condition to the DFS Central Evidence Unit (CEU) upon completion of the case. The evidence will be returned in person.

The analyst/technician is responsible for repackaging and resealing the evidence for return.

Work product is defined by FBU as all forms of cuttings of evidence, swabbings of evidence, DNA extracts, substrate remains, sperm search

slides, PCR amplification product, and capillary electrophoresis product. DNA extracts, substrate remains, and sperm search slides will be retained by the FBU indefinitely, unless outsourcing is requested. Disposition of these items to an outside agency or laboratory (outsourcing) requires prior approval by the Lead Scientist, Technical Leader, and/or Unit Manager.

#### 5.6. Case Acceptance and Priority Criteria

The following factors will affect the level of priority given to an evidence examination request:

- **Judicial Deadlines**
  - Judicial deadlines include filing deadlines, preliminary hearings and trials. Highest priority will usually be given to a request when the case is faced with a short judicial deadline and when the results of the examination are necessary for the judicial event.
- **Investigative Demands**
  - Examples of investigative information developed through evidence examinations include determining the identity of a suspect, tying together otherwise unrelated cases, and producing the information necessary to obtain a search warrant. Higher priority will usually be given to a case when the rapid development of such investigative information is critical to the identification of a suspect or in order to seize evidence that might be lost.
- **Perishable Nature of Evidence**
  - When an item of evidence cannot be protected or preserved for examination at a later time, priority will be given to the examination to avoid loss of the evidence.
- **Date of the Laboratory Request**
  - Barring any special circumstances such as those mentioned above, cases within a unit will be prioritized based on the date of receipt of the request in the laboratory. Cases with earlier request dates will be examined first.
- **Seriousness of the Offense**
  - Cases may be prioritized on the basis of the seriousness of the offense. However, when resources are limited such that all critical deadlines cannot be met, priority will be given to felony offenses over misdemeanor offenses. Priority will not usually be given to infractions and minor property crimes.
- **Merit of the Examination**
  - Except in rare circumstances, cases will usually not be prioritized on the basis of the merit of the examination. Examinations that cannot reasonably be expected to yield meaningful results are not examined regardless of the seriousness of the offense, availability of resources, or other factors in the case.

## 6. Validation

Validation is the process used by the scientific community to assess the ability of a procedure to reliably obtain a desired result, to determine the conditions under which such results can be obtained, and to determine the limitations of the procedure. The validation process identifies the critical aspects of the procedure, which must be carefully controlled and monitored.

Testing procedures used by the FBU will be validated according to the current version of the Quality Assurance Standards (QAS) and the SWGDAM Validation Guidelines and the validation will be reviewed and approved by the Technical Leader prior to being implemented in casework.

### 6.1. Developmental Validation

Developmental validation work may be done externally by an outside laboratory developing the procedure or internally if the procedure was developed in-house. Where applicable, loci used will have been characterized as to inheritance, chromosomal location, nature of the polymorphism and molecular basis for its detection. Validation studies will address various subjects including, but not limited to, reproducibility, accuracy, precision, mixed specimens, specificity, sensitivity, and known samples.

### 6.2. Internal Validation

Prior to implementing a new analysis procedure that was developed and validated in another laboratory, the FBU will conduct internal validation tests. These tests will be performed using, at minimum, known samples, human DNA control(s), and non-probative evidentiary samples to establish the reliability of the system. If non-probative samples are not available, then simulated case samples will be used. Prior to incorporating the new procedure into casework, analysts/technicians using the new procedure must successfully complete a competency test that is reviewed and approved by the Technical Leader.

If a modification (e.g., material, procedural, software-based) to a current method is made that could affect the analysis results, the modified procedure will be compared with the original procedure on similar samples. Analysts/technicians using the modified procedure(s) will complete a competency test that is reviewed and approved by the Technical Leader.

Validation studies addressing each point set forth by the QAS and the SWGDAM Validation guidelines have been performed by the FBU. The work performed as part of these experiments has been compiled in validation binders (located in FBU office space) and scanned versions (located on internal network).

## 7. Analytical Procedures

Protocols for each analytical method routinely used in casework are maintained as standard operating procedures (SOP) and are approved through the procedures outlined in the *DOM03 – Procedures for Writing Standard Operating Procedures* (Document Control Number: 1271). These SOPs describe reagent and sample preparation, extraction, quantitation, amplification, interpretation guidelines, equipment, standards, controls and necessary documentation (e.g., forms, logs) for forensic biological analysis. Where appropriate, references on which the procedures are based have been included.

New protocols or changes in existing protocols must be approved through the procedures outlined in the *DOM02 – Procedures for Document Control* (Document Control Number: 1270) and/or *DOM03 – Procedures for Writing Standard Operating Procedures* (Document Control Number: 1271) prior to casework implementation. Protocol changes will not be approved without prior verification of the method through appropriate validation studies.

### 7.1. Analytical Procedures

Refer to the Forensic Biology Unit SOPs for detailed protocols covering body fluid identification, evaluation and preparation of samples, DNA isolation, estimation of DNA recovery, PCR-based techniques, interpretation of results, documentation, standards and controls, and equipment. Some of these topics are discussed in this manual as well.

### 7.2. Standards and Controls

Incorporated in the Forensic Biology Unit SOPs are standards and controls that assess critical parameters during normal operations.

**Substrate Controls** - If applicable, controls will be collected from the evidence and will be processed in the same manner as evidence samples. The analyst might use the adjacent area as a control to confirm that the results of the tests performed were brought about by the stain and not by something on the substrate on which it was deposited. However, this practice is normally not necessary when DNA determinations are carried out in the laboratory.

**Reagent Blank (extraction control)** - The reagent blank is a check for the possible contamination by human DNA or by amplified STR product during the extraction process. See *FBS30 – GlobalFiler™ Data Analysis using GeneMapper® ID-X* (Document Control Number: 5575).

**Negative Amplification Control** – The negative amplification control is a check for contamination during set up of the PCR amplification reaction. It essentially monitors the “environment” during the process for possible sources of contamination. See

FBS30 – *GlobalFiler™ Data Analysis using GeneMapper® ID-X* (Document Control Number: 5575).

**Positive Amplification Control(s)** - This is a human male DNA sample with a predetermined autosomal STR genotype. The positive amplification control ensures that the amplification and typing processes are working properly and is included in the AmpF $\mathcal{L}$ STR® amplification kits. See FBS30 – *GlobalFiler™ Data Analysis using GeneMapper® ID-X* (Document Control Number: 5575).

**Other Controls** - To characterize amplified fragment length polymorphisms and STRs, appropriate allelic ladders and internal size standards must be used. See FBS30 – *GlobalFiler™ Data Analysis using GeneMapper® ID-X* (Document Control Number: 5575). The non-template control (NTC) is a check for possible contamination during the quantitation process. See *Quantitation by Real-Time PCR Using Plexor® HY* (FBS24) (Document Control Number: 3867).

### 7.3. Interpretation

The purpose is to establish a general framework outlining minimum standards to ensure that:

- Conclusions in casework reports are scientifically supported by the analytical data, including those from appropriate standards and controls.
- Interpretations are made as objectively as possible and consistently from analyst to analyst.

See Forensic Biology Unit Standard Operating Procedures for procedure specific interpretations. See *Identifiler® Plus Interpretation* (FBS21) and *GlobalFiler™ Interpretation Guidelines* (FBS31) which outlines procedure specific DNA interpretations.

### 7.4. Reagent Quality Control

The purpose of the *General Quality Control Guidelines* (Document Control Number: 1436) (FBQ01) is to identify the laboratory's critical reagents and to ensure the reliability and success of the testing process. It is possible to verify that reagents used in an analysis have not significantly affected the reliability of the results. However, when the samples are limited in amount, it is desirable to minimize the need for repeat analysis due to failure of reagents. The quality control SOPs focus on the prevention of possible issues. See *General QC Guidelines* (FBQ01) and other reagent/kit specific FBQs.

### 7.5. Quality Control of DNA Procedures

The laboratory will check its DNA procedures and typing results for each genetic system used in the laboratory annually, or whenever substantial changes are made to the protocol(s), against an appropriate and available NIST Standard Reference Material (SRM) or standard traceable to a NIST

SRM. This check will be conducted by analyzing a NIST SRM or NIST traceable standard using the appropriate laboratory procedures currently in effect at the time of testing. NIST SRM standard reference material or standards traceable to NIST will be handled and stored according to manufacturer's instructions. See *FBQ34 – Quality Control of Standard Reference Material (SRM)* (Document Control Number: 1479).

## 8. Equipment Calibration and Maintenance

The purpose of the *FBQ01 – General QC Guidelines* (Document Control Number: 1436) and the quality control SOPs is to ensure that the parameters critical to the testing process are routinely monitored in the manner necessary to maintain the success and reliability of the testing procedures.

It is possible to verify that the equipment used in an analysis has not significantly affected the reliability of the results. However, when the samples are irreplaceable and/or limited in amount, it is desirable to minimize the need for repeat analysis due to failure of equipment. Quality control procedures adopted by the laboratory focus on the prevention of possible issues.

Only suitable and properly operating equipment will be employed in casework analyses. Critical parameters of equipment operation are generally identified in validation studies, and will be monitored and documented periodically to maintain successful operation.

### 8.1. Equipment Inventory and Operation Manuals

A list of DNA equipment requiring calibration and monitoring is maintained. Documented information includes:

- The identity of the item of equipment and its software
- The manufacturer's name, type identification, and serial number or other unique identification checks that equipment complies with the specification
- Current location, where appropriate
- The manufacturer's instructions, if available, or reference to their location
- Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration
- The maintenance plan, where appropriate, and maintenance carried out to date
- Any damage, malfunction, modification or repair to the equipment.

A complete inventory of DNA equipment is maintained by the designated staff member. Some manufacturer's operation manuals are in the laboratory, while others are maintained in designated equipment binders and/or stored electronically. All equipment acquired for the FBU is dedicated to serology and/or DNA testing only.

### 8.2. Calibration/Maintenance Procedures and Logs



A permanent log of calibration and maintenance procedures and/or records conducted on FBU equipment is kept in binders in the Laboratory or the FBU office area (i.e., the file room) and/or maintained electronically. The following list includes FBU equipment requiring periodic temperature checks, maintenance and/or calibration.

3500/3500xL Genetic Analyzers  
7500 Real-Time PCR Systems  
96-well GeneAmp® PCR System 9700s  
Balance(s)  
Centrifuges  
EZ1  
Thermomixers  
Freezers  
Hoods (fume, biological, PCR, etc)  
Heat blocks  
Microscopes  
Pipettes  
Refrigerators  
Thermometers and/or Temperature Monitoring System

Equipment that needs to leave the laboratory for calibration will be denoted within the SOP specific to that piece of equipment. If equipment (i.e., thermometers or temperature probes used with the temperature monitoring system) leaves the laboratory for calibration, it will be checked upon return to verify effectiveness. See the individual equipment SOP for procedures.

## 9. Reports and Documentation

Documentation of all significant aspects of the serology and/or DNA analysis procedures and other aspects of the laboratory operation related to the reliability and interpretation of analytical results are necessary to:

- Support the scientific conclusions in the laboratory report.
- Permit technical/administrative review of the work product.
- Allow reevaluation of the data by outside scientific observers.
- Provide a foundation for the introduction of the work product into a court of law.
- Provide an audit trail by which management can demonstrate and verify the continued quality of the laboratory's work.

### 9.1. Analytical Notes

Analytical notes will be made for all work performed.

- Note-keeping is defined as documentation of work as performed.
- "Documentation" is the recording of details and observations sufficient to both support conclusions and duplicate the experiment at another time if possible.
- "As performed" means both that the record is made at or near the time the work is done and that what is recorded is what was actually done.

Notes must be sufficiently detailed to support the conclusions in the report, refresh the analyst's memory during court proceedings and to allow duplication of the work at another time. Notes are to be made at or near the time the work is done and must accurately reflect what was actually done.

For casework, analytical notes will be recorded on notepaper, worksheets, or appropriate forms (electronically or manually). Each page will contain the case number, date, analyst's handwritten initials and page number. Handwritten notes will be made in ink. Corrections will be made by a single strikeout, leaving the original text visible with the analyst's initials and date to account for the correction. Notes on the initial examination of evidence items will note the packaging and whether it is sealed, describe the item and its condition, describe the presence of stains and/or other unusual features. Identifying marks observed on or added to the items (e.g., case number, date and analyst's initials) will be documented. Questioned stains and other pertinent features will be diagramed and/or photographed before and/or after sampling. The diagram will include the locations from which stain and control samples were collected for typing.

## 9.2. Report Writing

The function of the *Report of Examination* is to communicate the analytical results, conclusions, and interpretation of the analyst, conveying the essence of what the analyst would say if asked for his/her expert opinion in court. The conclusions in the report will be concise and worded in such a way as to be understood by an investigator or attorney. When applicable, the Examination Methods and/or Notes section of the Report of Examination will clearly state appropriate qualifications or limitations on the evidence interpretation.

The serology and/or DNA report will follow the standard laboratory format described in the *LOM02 – Procedures for Case Documentation and Report Writing* (Document Control Number: 1319).

## 9.3. Case Files

A case file with a unique laboratory number is established for each case in which evidence has been received in the laboratory. Upon completion of the analysis and report, all analytical notes and reports are entered into this file. The file will also contain documentation of technical and administrative review. Additional documentation such as chain of custody information, case contact information, police reports (as available), *Case Activities* logs, and correspondence are maintained electronically. Case files are archived according to the established laboratory schedule in the *FSL Quality Assurance Manual* (Document Control Number: 1300).

#### 9.4. Issuance of Case Reports

Copies of laboratory reports may be issued to: 1) the agency which submitted the evidence for analysis, 2) the United States Attorney's Office or other prosecuting agency, 3) as directed by court order, 4) to other persons as authorized by the submitting agency. Private parties requesting copies of case materials shall be directed to make their Freedom of Information Act (FOIA) request through DFS General Counsel; see *LOM02 – Procedures for Case Documentation and Report Writing* (Document Control Number: 1319).

### 10. Review

#### 10.1. Case Review

After completion of a non-discontinued case, the cases will be technically reviewed by approved qualified analysts for technical accuracy. Technical reviewers must successfully complete a competency test prior to participating in the technical review of DNA data. They must also participate in an external proficiency testing program on the same technology, platform and typing amplification test kit used to generate the DNA data being reviewed.

Discontinued cases require an administrative review only. Administrative reviews will be completed by qualified personnel.

Reports and supporting documentation (e.g., notes, charts) will be examined to verify the conclusions drawn are supported by the documentation and are scientifically appropriate. Completion of the technical review will be documented as set forth in *LOM03 – Procedures for Reviewing a Report of Examination* (Document Control Number: 1320).

##### 10.1.1. Elements of Technical Review

At a minimum, the technical review will include the following elements:

- A review of all case notes, worksheets and printed electropherograms (and/or electronic data) that support the conclusions in the Report of Examination.
- A review of all DNA profiles to verify that they are supported by the analyzed data depicted on the printed electropherograms (and/or the raw data, as necessary).
- A review of all profiles to verify correct inclusions and exclusions (if applicable), as well as a review of any inconclusive result for compliance with laboratory guidelines.
- A verification that a review of the core binder(s) containing all controls, internal lane standards and allelic ladders was performed to verify that the expected results for these controls were obtained and properly documented.
- A review of statistical analysis, when applicable.

- A review of the final report to verify that the results and conclusions are supported by the data and that the report addresses each tested item and/or its probative fraction.
- As applicable, verification prior to entry into a searchable category at SDIS that all profiles entered into CODIS are eligible, have the correct DNA types/profile, and the correct specimen category.
- As applicable, verification that appropriate profiles have been entered into the FBU QA Database and that the correct DNA type/profile is entered.

There may be instances where the analyst and reviewer(s) cannot resolve significant differences in results obtained or conclusions drawn. If, after discussion and review, the disagreement still remains, the problem will be forwarded to the Technical Leader. If this is necessary, the final determination of the Technical Leader will stand as the final interpretation of the results.

Following the technical review, all cases will be reviewed for clerical accuracy by personnel approved to perform administrative reviews. This level of review is to evaluate the report and supporting documentation for consistency with laboratory policies and for editorial correctness.

Refer to *LOM03 – Procedures for Reviewing a Report of Examination* (Document Control Number: 1320).

## 10.2. Testimony review

Effective testimony is an essential component of professional competence in forensic science. Analysts must be able to demonstrate:

- Familiarity with the literature related to forensic discipline employed
- Experience and training in forensic discipline employed
- Understanding of the scientific principles underlying the procedures used in the laboratory
- Knowledge of laboratory quality assurance policies and procedures
- Ability to explain the analysis procedure to a lay audience
- Ability to advise and assist attorneys in presentation of forensic evidence
- Professional appearance and demeanor

Analyst/technician readiness for testimony will be assessed prior to court testimony by performance in moot court situations. Subsequent to this initial qualification, testimony will be monitored in person, by witness feedback from judges, attorneys, supervisors or qualified peers. In the event external or internal witness feedback is not conducted, the Unit Manager will review an official court transcript of testimony and document their evaluation of

testimony. The Technical Leader will then review the documented testimony evaluations, at least once per calendar year.

Refer to *LOM04 - Practices for Court Testimony Monitoring* (Document Control Number: 1322).

## 11. Proficiency Testing

### 11.1.Purpose

The purpose of proficiency testing is to monitor the performance of individual analysts/technicians and of the laboratory as a whole. Proficiency tests provide a mechanism for critical self-review and a means by which others may evaluate the laboratory performance on an on-going basis. In general, the proficiency testing program of the Forensic Biology Unit will follow regulations set forth in the *Quality Assurance Standards for Forensic DNA Testing Laboratories*.

Because proficiency tests are intended to monitor work as normally performed in the laboratory, they are to be conducted using the currently approved procedures being applied to casework samples. Work is to be done independently by the analyst, supported by notes, photographs, other documentation, and summarized in a written report as required for casework. Prior to reporting the proficiency test results, the work is to receive the same level of technical and administrative review required for casework.

Proficiency tests may be “internal” (i.e., samples prepared in-house and/or results not reported to an external body) or “external” (i.e., samples acquired from, and results reported to, an independent outside source). Samples may be retained from previously completed external tests and reissued to other analysts as unknowns in subsequent internal tests. In any case, the “correct results” are to be unknown to the analyst until after the tests are completed and the results are reported.

Proficiency tests may be “open” (i.e., samples are known to the analyst to be a test) or “blind” (i.e., the analyst is unaware the samples are a test). Because analysts routinely confer with submitting agencies about the cases, a true “blind” test in casework can be difficult to construct.

### 11.2.Assignment, Frequency and Documentation

The FBU subscribes to external tests from various vendors (e.g., Forensic Assurance). In general, it is expected that each analyst/technician will complete and return proficiency test results within the applicable deadlines. The Deputy Director and/or Quality Specialist will ensure that test results are reported to the vendor within applicable deadlines.

Each analyst/technician qualified in DNA testing will complete at least two external proficiency tests per year (one to be conducted during the first six months of the calendar year and the second to occur in the last six months of the calendar year. The interval between consecutive tests must be at least four months and may not exceed eight months.) Each analyst/technician must enter the proficiency testing program within six months of the date of their competency/qualification.

The date the proficiency test is assigned is the date that is referred to when determining subsequent proficiency test assignment dates.

A file is created for each proficiency test and retained indefinitely. The proficiency file contains all analytical data (e.g., notes, photos, run sheets) generated in the analysis, a report of the analyst's conclusions, signature and comments of the technical and administrative reviewer(s) if applicable. If the results of a test are not satisfactory, then significant discrepancies and appropriate corrective action are documented in the proficiency file. For external tests, a separate file is maintained containing the summary report of the test provider regarding the particular test.

A Proficiency Test Evaluation Form (Document Control Number: 1280) is maintained by the Deputy Director or Quality Specialist for each proficiency test conducted and notes performance as satisfactory or unsatisfactory. Any corrective action required as a result of an individual's test will also be documented by the Quality team. (Refer to *FSL Quality Assurance Manual* (Document Control Number: 1300).

### 11.3. Verification of Performance

The Technical Leader or Quality Specialist will review all test materials and compare results to information supplied by the manufacturer of the test to determine if test performance is satisfactory. The analyst/technician will be notified in a timely fashion by the Technical Leader as to whether or not the performance is satisfactory and must acknowledge receipt of the results. All of the results will be forwarded to the Deputy Director and/or Quality Specialist.

Any discrepancies found will be addressed according to the *FSL Quality Assurance Manual*. Once the cause of the problem has been identified, all involved analysts/technicians will be made aware of any corrective action taken to minimize the recurrence of the discrepancy.

## 12. Corrective Action

### 12.1. Procedure

Immediate corrective action will be initiated in the event of an error, non-conformity, and/or problem such as encountered in casework or proficiency

testing, temperature monitoring, etc. The situation will be investigated to determine whether the problem is of a one-time nature or is systemic to the laboratory operation (e.g., methodology/ reagents/ instrumentation). All non-conformities will be evaluated and addressed according to *DOM07 – Practices for Quality Corrective Action* (Document Control Number: 1275).

Individual problems may be handled through a combination of remedial training, competency testing, proficiency testing, and close technical supervision of the involved employee. The individual responsible for the error may be suspended from further casework until the problem is corrected and rectified. The specific combination of corrective action will be determined by the type of non-conformity involved. In no instance will the employee be allowed to engage in future casework in the affected discipline until the Technical Leader has been assured the non-conformity has been corrected and future occurrences can be avoided.

Non-conformities which are judged to be systemic in nature and are the result of faulty laboratory methodology, bad reagents, and/or improperly calibrated equipment require the immediate suspension of all casework within that discipline or protocol until the problem is completely resolved. The Technical Leader is responsible for suspending analytical activity in this situation. All employees will be alerted to the problem and provided instructions and/or training in all new methodology, reagent or equipment use.

## 12.2. Clean Run

This procedure is used to confirm that corrective measures taken have eliminated the source of a typing problem. It may be useful in pinpointing the source(s) of contamination when a typing problem arises.

When a significant typing problem or contamination event arises, it may be necessary to evaluate all the steps involved in the body fluid identification and/or DNA typing procedure (e.g., extraction, amplification, typing). It may be useful to determine what components have been changed since the last successful set and work from there.

- samples: reagent blank/extraction control (negative control)
- whole blood or bloodstain samples of known types
- negative amplification control
- positive amplification control
- electrophoresis negative (formamide/internal standard)

Extract the samples according to the appropriate extraction procedures. The reagent blank is used to evaluate contamination from the reagents and equipment in the extraction area.

Amplify the samples with the positive amplification control from the kit and an amplification negative control according to the appropriate amplification procedure. No extract is added to the amplification negative control. The amplification negative control is used to evaluate contamination from the reagents and equipment in the extraction/PCR set-up areas. The positive amplification control evaluates the performance of the amplification reagents and the thermal cycler.

Electrophorese the amplified samples with an electrophoresis negative control according to the appropriate typing procedure. No amplified sample is added to electrophoresis negative controls. The electrophoresis negative control evaluates polymer, buffers and equipment.

Corrective measures are determined to be successful when all the negative controls are free of contamination and the positive control gives the proper typing result.

Contamination sources may be determined as follows:

- If the reagent blank (negative control) shows contamination, the problem has most likely occurred during the extraction step.
- If the amplification negative control shows contamination, the problem has most likely occurred during the amplification set-up. The reagent blank (negative control) may or may not appear contaminated as well.
- If only the positive control appears contaminated, the problem might be a contaminated positive control.
- If the electrophoresis negative control appears contaminated, the problem might be in the formamide or the internal size standard.

**Note:** The need for clean runs must be evaluated on a case-by-case basis with the Technical Leader, as many problems may be evaluated by repeating a single step in the DNA analysis procedure. All documentation concerning the contamination problem, corrective measures and clean run testing must be documented according to *DOM07 – Practices for Quality Corrective Action*.

### 13. Audits

Audits are an important aspect of the quality assurance program. They are an independent review conducted to compare the various aspects of the FBU's performance with a standard for that performance. The audits are not punitive in nature but are intended to provide management with an evaluation of the laboratory's performance in meeting its quality policies and objectives.

#### 13.1. Annual DNA Audit

At a minimum, every other year, a qualified auditor from an external agency must conduct an external DNA audit of the FBU. Auditors conducting the quality assurance audit must satisfy the requirements described in the



*Quality Assurance Standards for Forensic DNA Testing Laboratories.* The auditors will use the most recent revision of the *Quality Assurance Standards for Forensic DNA Testing Laboratories* for the audit. During years when an external audit is not being performed, the Technical Leader and/or an audit trained designee will conduct an internal audit to verify the laboratory continues to meet the accreditation and the quality assurance standards.

### 13.2. Quality Audit

The Deputy Director and/or Quality Specialist will request and schedule, respectively, an annual audit of the entire quality assurance program. The audit will include:

- Staff's awareness of the FSL and FBU Quality Assurance Manuals
- Analytical procedure selection, control and validation
- Control of reagents and standards
- Equipment calibration and maintenance records
- Adequacy of case reports, notes and their disposition
- Evidence handling procedures
- Proficiency testing and inter-laboratory comparison studies
- Personnel training records
- Handling of deficiencies and remedial action
- Laboratory orderliness, health and safety measures

### 13.3. Quality Review

The Deputy Director and/or Quality Specialist will meet annually with staff to assess the laboratory's quality assurance program. An in-depth review of the internal quality audit, external audits and laboratory inspection reports will be made. Recommendations for improvements in the quality assurance program will be considered. The Technical Leader will institute those changes necessary to improve and ensure the quality of the Forensic Biology Unit work product.

## 14. Safety

The FBU procedures and policies related to facility safety, emergency response and evacuation, illness and accident prevention, hazard communication, chemical hygiene and bloodborne pathogens are all contained in *DOM13 - DFS Health and Safety Manual (Document Control Number 1617)*.

## 15. Outsourcing Casework for DNA Analysis

### 15.1. Vendor Laboratory Requirements

The vendor laboratory performing the DNA analysis will comply with the current *Quality Assurance Standards for Forensic DNA Testing Laboratories* and the accreditation requirements of federal law. If the data obtained is to be entered into the Combined DNA Index System (CODIS), the vendor is

required to provide documentation of compliance with the Standards and the accreditation requirements of federal law.

The Technical Leader will document approval of the technical specifications of the outsourcing agreement with the vendor laboratory before it is awarded.

FBU will not upload or accept DNA data for upload to CODIS from any vendor laboratory or agency without the prior approval of the specifications of the outsourcing agreement and/or documented approval of acceptance of ownership of the DNA data by the Technical Leader.

## 15.2. On-Site Visits

An on-site visit is a scheduled or unscheduled visit to a vendor laboratory work site by one or more representatives of the FBU to assess and document the vendor laboratory's ability to perform analysis on outsourced casework.

A documented initial on-site visit of the vendor laboratory will be conducted prior to the beginning of casework analysis. This on-site visit is not required when only technical review services are being provided. The Technical Leader (or a designee who is a qualified or previously qualified DNA analyst in the technology, platform and typing amplification test kit used to generate the DNA data) will perform the on-site visit.

Alternatively, the Technical Leader may accept an on-site visit conducted by a designated FBI employee or another NDIS participating laboratory using the same technology, platform and typing amplification kit for the generation of the DNA data provided the on-site visit was conducted within the past twelve months. The Technical Leader must document the review and approval of such on-site visit.

If the outsourcing agreement extends beyond one year, an annual on-site visit is required. Each annual on-site visit will occur every calendar year and will be at least six months and no more than 18 months apart.

### 15.2.1. On-site Visit Process and Elements

When an on-site visit to a vendor laboratory is conducted by a representative(s) of the FBU, the representative(s) will complete and retain the following for review and approval by the FBU Technical Leader and retention by the FBU:

- The "For NDIS Participating Laboratories" section of the Checklist for the Use of a Vendor Laboratory (from the CODIS Administrator's Handbook, Appendix B).
- The FBU Outsourcing Vendor Laboratory Site Visit Checklist (Document Control Number: 4328) which evaluates the following criteria/elements:

- Accreditation status and dates of last surveillance visit/assessment.
- Organizational chart for inclusion of technical personnel, including the Technical Leader, as well as administrative and management personnel.
- Information from the most recent external QAS Audit, including whether all technical personnel, including the technical leader, were meeting all applicable requirements at that time including documentation of testimony experience.
- Contamination / Carry-over Logs for any documented events, including any which may be repetitive or systemic.
- The Corrective Action Log / Records.
- Proficiency test records to ensure all technical personnel have current documentation and have successfully completed at least two (2) proficiency tests within the last year, with at least one of those in the applicable DNA testing kit(s).
- Validation studies documentation with respect to its availability on-site, whether approved under the most recent external QAS Audit and if new validations were performed since the last external QAS Audit if they conform to the FBI DNA QAS.
- Reagent preparation and QC logs to determine if implemented procedures to address non-conformances are in place and whether any non-conformities have been documented.
- Instrument run and maintenance logs for any documented issues.
- Evidence control and storage adequacy.
- Laboratory space sufficiency for analysts.
- Safe laboratory practices evident.
- Contingency plan in place for technical leader absences.

The FBU representative(s) conducting the on-site visit will ensure that, at a minimum, the vendor laboratory provides the following documents or that the FBU is already in possession of current copies so they are available for review and approval by the FBU Technical Leader and retention by the FBU:

- The vendor laboratory's current accreditation certificate.
- The vendor laboratory's current organizational chart.
- A copy of the vendor laboratory's most recent external QAS Audit Document and responses.