WASHINGTON STATE PATROL

DNA ANALYSIS QUALITY ASSURANCE MANUAL

CRIME LABORATORY DIVISION

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QUALITY ASSURANCE PROGRAM FOR THE DNA TYPING OF BIOLOGICAL MATERIAL

1 GOALS AND OBJECTIVES

1.1 GOALS OF THE WSP DNA AND CODIS LABORATORIES

- Provide state and local law enforcement agencies laboratory services for DNA typing of selected biological materials associated with official criminal investigations, missing persons/unidentified human remains, and post-conviction testing requests (as defined under RCW 10.73.170).
- Perform DNA typing on reference samples submitted from individuals convicted of qualifying crimes defined under RCW 43.43.752 through 43.43.759 (Convicted Offender Program), maintain the computerized data bank of the DNA typing results from these samples, and conduct searches of the data bank to assist law enforcement agencies in identifying possible suspects from DNA typing results obtained from samples recovered from a crime scene or related to missing persons/unidentified human remains.
- Ensure the quality, integrity, and scientific accuracy of the DNA typing data through the implementation of a detailed DNA Quality Assurance (QA) Program.

1.2 PROGRAM DEVELOPMENT

The DNA QA Program was developed by and is updated through input from the DNA functional area, including DNA analysts, tech leads, supervisors, and management. Any changes to the DNA QA Program will be applied throughout the system and will be approved by the DNA Technical Leader. Ultimate responsibility for all quality assurance-related functions resides with the Standards and Accountability Manager.

The Quality Assurance Standards approved by the FBI Director and the FBI DNA Quality Assurance Audit Document will provide the basis for the Washington State Patrol Crime Laboratory's DNA QA Program. Any revisions to the forensic or database laboratory standards will be reviewed for incorporation if applicable into the DNA QA Program.

1.3 PROGRAM SCOPE

The DNA QA Program described in this manual is intended to support the DNA typing of biological materials, to ensure that the DNA testing procedures are operating within established performance criteria, and to ensure that the quality and integrity of the data is maintained and is scientifically sound.

1.4 PROGRAM OBJECTIVES

- Ensure uniformity and accountability in records and analysis techniques.
- Monitor analysis methods by using known standards and evaluate test results based on the performance of the known standards.
- Ensure the accuracy of the data generated.
- Document corrective actions taken.
- Monitor personnel and equipment performance.
- Terminate nonconforming materials or work.
- Ensure the proper preparation and documentation of reagents used.
- Require testing of critical reagents prior to their use in casework.
- Ensure use of documented and valid materials and procedures.
- Provide feedback to management on quality assurance performance.
- Ensure that DNA typing results are technically sound and legally defensible.
- Provide guidelines and expectations to employees.
- Ensure that personnel performing this testing have the appropriate level of training and education.

- Ensure that analysts are competent in performing the testing and interpreting of test results through proficiency tests.
- Provide for a safe workplace.
- Provide for competent internal and external audits to check that the operating policies and procedures are followed and meet quality assurance standards set forth by the FBI and our accrediting body.

2 ORGANIZATION AND MANAGEMENT

2.1 ORGANIZATION AND MANAGEMENT STRUCTURE

See the Washington State Patrol (WSP) Crime Laboratory Division (CLD) Quality Operations Manual (QOM) for a full description of the Organization and Management Structure of the WSP CLD.

2.2 FUNCTIONAL RESPONSIBILITIES

Each casework DNA section and CODIS consists of DNA analysts (Forensic Scientists, class series 1-3) and at least one supervising DNA analyst (Forensic Scientist 5). A casework DNA section may have serology screening analysts who work independently to find and identify biological evidence and prepare DNA extracts for downstream DNA analysis. There may also be a Laboratory Technician 2 in the casework DNA section and CODIS who performs laboratory duties exclusive of analytical techniques on forensic or database samples. The supervisors will assign the responsibility of monitoring and documenting the quality control measures provided for in this DNA QA manual.

The DNA functional area also incorporates Technical Lead DNA analysts (Forensic Scientist 4) in various roles throughout the Division. These analysts are accountable for the quality of the casework/convicted offender (CO) sample work product, for compliance with all applicable accreditation and audit criteria, compliance documentation, validation of new technology and methods, validation of new personnel beginning casework/CO sample analysis, and investigation of casework errors, or other specialty functions. The Technical Leads do not act alone, but with consultations of the DNA Functional Area (DNA FA), the supervisors, and the DNA Technical Leader. There are two Technical Lead positions assigned to Standards and Accountability providing assistance to the DNA Technical Leader. The CODIS laboratory Forensic Scientist 5 is accountable for (including the delegation of) the aforementioned Technical Lead responsibilities in the absence of a Forensic Scientist 4.

Each casework DNA section has one DNA analyst who also functions as the casework CODIS administrator (LDIS Administrator) who is responsible for the operations of the CODIS system within their laboratory (reference *CODIS Program Standard Operating Procedures*).

The DNA Technical Leader manages the technical operations of the DNA FA within the Crime Laboratory Division. As such, this individual will be directly responsible for quality issues involving the DNA FA and will work with the DNA Operations Manager, QA and QP Managers on all quality matters. The DNA Technical Leader has technical oversight of the CODIS program and assists in planning and coordinating DNA audits along with the QA Manager.

The CODIS Manager manages and operates the CODIS Laboratory and is responsible for CODIS-related issues throughout the division including the security of the DNA profiles stored in CODIS. The CODIS Manager or designee reports to the DNA Technical Leader for CODIS technical/analytical related issues.

The DNA Operations Manager is responsible for the DNA Functional Area, overseeing technical and quality operations, supervising the DNA Technical Leader, and managing staffing, contracts, grants, and budgets that pertain to the casework and CODIS labs. The DNA Operations Manager will specialize in non-technical matters, while the DNA Technical Leader will specialize in technical matters, with some overlap, consultation, and coordination.

2.3 LEVELS OF AUTHORITY

Individuals in a DNA section are empowered by the section supervisor to carry out QA/QC responsibilities and to act in their place. The supervisor is to be informed of any action taken as soon as practical. This means, for example, that a DNA analyst may reject any reagent or material that fails to meet specifications.

Should an analyst feel that a technical problem is not being adequately addressed within their section, that person has the authority to go directly to the DNA Technical Leader.

Technical Leads (FS4s, or the CODIS FS5) have the responsibility to recommend suspension of testing in DNA in the event of a technical problem with a technical procedure, instrumentation, or equipment. Communication of such action must follow the appropriate chain of command.

The section supervisors have overall responsibility for the DNA/CODIS units and to mediate discrepancies that arise between the analyst and the reviewer in peer review. They are designated by the DNA Technical Leader with the authority to approve acceptable minor deviations from STR interpretation guidelines and protocols. Technical Leads (FS4s) are designated by their section supervisor with the authority to approve acceptable minor deviations from STR interpretation guidelines and protocols. Approved deviations shall be recorded in the casefile, as well as the designated tracking spreadsheet, and will be reviewed periodically by the DNA Technical Leader. Questions regarding acceptable FS4/5 approved deviations shall be directed to the DNA Technical Leader.

The CODIS Manager has the authority to terminate an analyst's or laboratory's participation in CODIS in the event of a problem until the reliability and security of the computer data can be assured in the event an issue with the data is identified. The DNA Technical Leader and the Quality Assurance Manager will be notified as soon as practical.

LDIS Administrators maintain the local CODIS network at each lab. LDIS Administrators are responsible for scheduling and documenting CODIS training for users, ensuring the security and quality of the data stored at the local lab, and managing match dispositions according to state and federal law, as well as NDIS operational procedures. They have the authority to terminate (via a request submitted through SDIS) an analyst's or their 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. Any such action shall require notification to the CODIS Manager, DNA Technical Leader and Quality Assurance Manager as soon as practical. The alternate LDIS Administrator may assume the LDIS Administrator responsibilities when the LDIS Administrator in unavailable, on a rotating basis, or as necessary in an effort to maintain operations.

The DNA Technical Leader has the authority to initiate, suspend, and resume DNA analytical operations for the laboratory or an individual. The Technical Leader will review potential conflicts of interest when contract employees are employed by multiple NDIS participating and/or vendor laboratories.

All proposed changes to the quality system and all reports of quality variances, will be reported to the CLD Standards and Accountability Section per the QOM.

3 PERSONNEL QUALIFICATIONS AND TRAINING

All persons involved in the actual recovery, evaluation, analysis, and interpretation of DNA evidence shall have a background and training appropriate to the duties assigned.

3.1 JOB DESCRIPTION

Job descriptions for personnel within the DNA FA can be found in the QOM.

3.2 EDUCATION AND GENERAL REQUIREMENTS

All forensic scientists in the Washington State Patrol Crime Laboratory DNA FA must possess a minimum of a Bachelor's degree in a biology, chemistry, or forensic science related area and shall have successfully completed coursework (graduate or undergraduate level) covering the following subject areas: biochemistry, genetics, molecular biology; and coursework and/or training (dependent upon the applicable FBI QAS version) in statistics and/or population genetics as it applies to forensic DNA analysis.

Staff start/hire date will be used to determine the applicable FBI Quality Assurance Standards (QAS) version for education, experience, and training requirements as outlined below.

- The DNA Technical Leader must have, at minimum, a Masters' degree in a biology, chemistry, or forensic science related area and successfully completed 12 semester or equivalent credit hours from a combination of undergraduate and graduate coursework covering the following subject areas: biochemistry, genetics, molecular biology, and statistics or population genetics, and a minimum of three years of experience as a forensic DNA analyst. Of the 12 semester hours (or equivalent), at least one graduate level course registering at least 3 semester (or equivalent) hours must be recorded. The DNA Technical Leader shall have previously completed or successfully complete the FBI-sponsored QAS auditor training within one year of appointment, and be currently or previously qualified in each technology utilized in the laboratory, or have documented training within one year of appointment.

- The CODIS Manager shall have, at a minimum, the general requirements listed above and at least three years of experience as a forensic DNA analyst with documented mixture interpretation training. It is also desirable that the CODIS Manager have a working knowledge of computers, networks, and computer database management.

- A DNA analyst (forensic scientist) shall have, at a minimum, the general requirements listed above. Analysts are subject to the forensic scientist class series requirements as outlined in the QOM.

- A DNA supervisor (Supervising Forensic Scientist) must meet the CLD requirements for a Forensic Scientist 5 and have a minimum of two years of experience in forensic biology as a Forensic Scientist 3 or five years full-time paid technical experience in a forensic laboratory which includes two years performing analyses of physical evidence and testifying as an expert witness in courts of law.

- A DNA Technical Lead must meet the CLD requirements for a Forensic Scientist 4 as outlined in the QOM, as well as requirements outlined above for a DNA analyst (if performing casework/CODIS analysis, and/or technical review).

- The LDIS Administrator/alternate Administrator must meet the qualifications outlined above for a DNA analyst. In addition, the LDIS Administrator must have documented mixture interpretation training, have completed FBI-sponsored CODIS software training within six months of appointment, and have completed FBI QAS auditor training within one year of appointment.

- The Laboratory Technician 2 must have, at a minimum, an associate's degree in biology, chemistry, lab technology, microbiology, or molecular biology. The lab tech 2 must also have a working knowledge of basic laboratory tools such as pipettes and balances.

3.3 TRAINING AND QUALIFICATIONS

All forensic scientists will have completed training in the fundamentals of forensic science, including training in the handling of biological evidence. The Biochemical Analysis Training Program and STR Training Program manuals outline the WSP CLD training program for the qualification of all analysts in the DNA functional area. Training may be accomplished in-house or with a combination of in-house work and outsourcing to outside vendors.

Before a forensic scientist is qualified to examine and identify biological evidence for DNA casework, the scientist must have demonstrated, either through successful completion of formal course work or through in-house training, knowledge in the following areas:

- Documentation and reporting procedures.
- Safe laboratory practices.
- Serology screening methodologies for various body fluids and mixtures of body fluids.
- DNA Quality Control and Quality Assurance systems and methods.
- Equipment operation, calibration and maintenance.
- Technical review requirements
- Courtroom demeanor and moot court testimony.

In addition, the forensic scientist must complete well-documented sets of serology screening training samples.

Before a forensic scientist is qualified to analyze DNA casework, the scientist must have demonstrated, either through successful completion of formal course work or through in-house training, knowledge in the following areas:

- Documentation and reporting procedures.
- Safe laboratory practices.
- DNA STR methodology and biochemical analysis methodologies.
- DNA Quality Control and Quality Assurance systems and methods.
- Equipment operation, calibration and maintenance.
- Quantitative and qualitative evaluation of DNA test results.
- CODIS Eligibility requirements
- DNA case acceptance policies.
- Interpretation of electropherograms.
- Mixture interpretation training
- Statistical interpretation of STR results.
- DNA troubleshooting.
- Technical review requirements
- Courtroom demeanor and moot court testimony.

In addition, the forensic scientist must complete well-documented sets of DNA training samples.

Before a forensic scientist is qualified to analyze convicted offender samples using STR analysis, the scientist must have demonstrated, either through successful completion of formal course work or through in-house training, knowledge in the following areas:

- Familiarity with convicted offender statutes.

- Processing, documentation and reporting procedures for convicted offender samples.
- Safe laboratory practices.
- DNA STR methodology.
- DNA Quality Control and Quality Assurance systems and methods.
- Equipment operation, calibration and maintenance.
- Quantitative and qualitative evaluation of DNA test results.
- Interpretation of electropherograms.
- DNA troubleshooting.
- Technical review requirements
- Statistical interpretation applicable to a CODIS database laboratory
- Courtroom demeanor and moot court testimony

In addition, the forensic scientist must complete well-documented sets of DNA training samples.

When an experienced forensic scientist is hired, the DNA Technical Leader shall be responsible for assessing their previous training and ensuring it is adequate and documented. Modification(s) to the training program may be appropriate and shall be documented by the DNA Technical Leader.

Upon completion of an approved training program, the forensic scientist will be authorized to perform casework following the procedures in the QOM. The DNA Technical Leader shall review the trainee's training records and qualifications prior to approving the trainee for independent casework or technical review responsibilities.

Before a laboratory technician is qualified to prepare reagents and perform QC checks on reagents, instruments, and DNA kits, the technician must complete training and demonstrate knowledge and competence in the following areas:

- Safe laboratory practices
- Documentation procedures
- Relevant sections of the Biochemical Analysis Training Manual
- Relevant sections of the STR Training Manual
- DNA Quality Control and Quality Assurance systems and methods
- Equipment operation, calibration, and maintenance
- Courtroom demeanor and moot court testimony

In addition, the lab technician must complete well-documented sets of DNA training samples.

Upon completion of an approved training program, the supervisor, Laboratory Manager, and DNA Technical Leader will authorize the lab tech to perform reagent preparation and QC checks on reagents, instruments, and DNA kits.

The DNA Laboratory Technician will not process evidence, convicted offender samples, or perform casework, and is designated as Laboratory Support Staff for the purposes of the FBI DNA QAS.

3.4 EXPERIENCE

Prior to any DNA typing and reporting on convicted offender or casework samples, the DNA analyst must have a minimum of six months of forensic DNA laboratory experience. Prior to any independent serology screening and reporting on casework samples, the serology screener must have a minimum of 3 months of forensic serology laboratory experience. The DNA Technical Leader is responsible for reviewing and documenting prior experience as it pertains to these requirements.

The casework DNA analyst or serology screener shall complete the analysis of a range of samples routinely encountered in forensic casework prior to independent work using DNA technology and shall successfully complete a competency test before beginning independent analysis.

The CODIS DNA analyst shall complete the analysis of a range of samples routinely encountered in the convicted offender program prior to independent work using DNA technology and shall successfully complete a competency test before beginning independent analysis.

3.5 CONTINUING EDUCATION

DNA analysts, DNA Tech Leads, DNA Supervisors, the DNA Technical Leader, and the CODIS Manager must stay abreast of developments within the field by reading current scientific literature and by annual attendance at seminars, college courses, professional meetings, or documented training sessions/classes in relevant subject areas at least once each calendar year.

Review of scientific literature shall be documented by each laboratory by recording journal club attendance and articles discussed or by initialing copies of relevant DNA articles read. Documentation of scientific literature review shall be maintained by the laboratory.

Each forensic scientist must receive a minimum of eight cumulative hours of continuing education annually. Training received as a part of the training program that are required for establishing competency shall not be counted as continuing education. The DNA Technical Leader must approve continuing education delivered online and determine the number of hours credited. Completion of continuing education by each forensic scientist shall be documented and retained in each laboratory.

3.6 TRAINING RECORDS

Supervisors have the responsibility of maintaining and routing documentation of all training received for each analyst. This includes training related to new staff as well as ongoing training for existing staff. Records documenting the completion of training plans and training manual modules for newly hired staff will be maintained at the laboratory, with final approvals maintained by the supervisor. Training records will be forwarded to the WSP Training Division, as appropriate, to be added to the employee transcript.

4 FACILITIES

Each laboratory shall be secured and have access limited to personnel and escorted/observed visitors. Each laboratory shall have an evidence storage vault, locked refrigerators and/or freezers, and evidence lockers for the secure storage of evidence pending or in the process of examination. The QOM outlines the process and procedures regarding security of the laboratory and evidence.

The DNA section of each laboratory shall have a room separate from the examination area in which amplified DNA product (including real-time PCR) is generated, processed and maintained. Additionally, evidence examinations, DNA extractions, and PCR setup shall occur in separate spaces, or at separate times.

When robotic workstations are used to carry out DNA extraction, quantitation, PCR setup, and/or amplification, a single room may be used provided that appropriate validation has been performed and documented. If the robot performs analysis through amplification, the robot shall be housed in a separate room from that used for initial evidence examinations.

Each DNA laboratory shall have and follow written procedures for cleaning and decontaminating facilities and equipment. The procedures for facilities cleaning shall be maintained in a DNA Lab Cleaning Log (or similar) for the particular laboratory. The procedures for equipment maintenance including cleaning shall be maintained in the appropriate STR Analysis Procedures Manuals (Crime Laboratory and CODIS Laboratory).

5 CASEWORK EVIDENCE AND SAMPLE CONTROL

5.1 RECEIPT, STORAGE, AND HANDLING OF EVIDENCE SUBMITTED TO THE CRIME LABORATORY

Evidence items will be received, stored and handled in such a manner to ensure integrity by protecting from loss, cross contamination or deleterious change. The guidelines for evidence receipt, storage and handling are outlined in the QOM.

5.2 SAMPLE LABELING AND DOCUMENTATION

Each DNA test sample will be labeled with a unique identifier (i.e., laboratory number and, if appropriate, an item number and/or item description). DNA samples are not considered evidence. The guidelines for handling samples are outlined in the QOM.

5.3 EVIDENCE AND TEST SAMPLE HANDLING

Evidence items and test samples shall be handled in a manner to prevent loss, alteration, contamination, or mixing. Examination areas should be cleaned thoroughly and regularly using 10% bleach or another appropriate laboratory cleaner. Each separate item shall be examined on a clean surface (e.g. bench paper, Labmat etc.), and caution should be taken to avoid placing exterior packaging on examination surfaces designated for evidence items.

Analysts will wear gloves and masks while handling evidence and test samples both to preserve the integrity of the evidence and for personal protection. When working with limited evidence or low level DNA samples (such as handler/touch/cellular cases), disposable sleeves or a disposable lab coat and a mask or plexiglass shield shall be used. When required, a new set of sleeves or disposable lab coat shall be used for each evidence item. Gloves will be changed between items. Bleaching/cleaning of gloves may be employed during examination (e.g. when switching between item handling and taking notes) in addition to changing gloves. Lab coats shall be routinely laundered or disposable coats shall be utilized. Contaminated lab coats shall be disposed of or placed in a laundry receptacle after use.

Analysts will use disposable filtered pipette tips, discarding tips after each use involving possible contact with DNA sample or controls; not have more than one sample open at a time (unless doing so is part of the procedure); and use quality-controlled reagents when necessary.

All items must be sufficiently cleaned prior to coming into contact with sample to prevent DNA cross contamination. Sample-handling tools such as scissors or scalpels must be cleaned between uses on each sample. Examples of cleaning techniques include but are not limited to using autoclaved or physically cleaned rinsed/wiped tools, or physically cleaned rinsed/wiped and Sterigard 250 treated sample-handling tools.

Evidence samples shall be prepared separately in time and/or space from known reference samples.

DNA samples will be stored under conditions to maintain shelf-life and reduce or prevent the degradation of DNA (refrigeration or freezing for liquid extracts). Refer to the Analytical Procedures section of this manual for guidelines regarding inadvertent deleterious changes (loss, mixing, contamination, etc.) to DNA extracts.

5.4 CONSUMPTION OF DNA EVIDENCE AND LIMITED SAMPLES

Forensic scientists shall exercise reasonable care to conserve sufficient DNA evidence, sample, or extract to allow for a reasonable chance of reproducing the test results obtained during analysis when possible. However, consuming a sample may sometimes be necessary to achieve a useful test result.

Visual observation of the size and density of a biological stain and serological tests of samples with no visible staining may be used to assess the expected DNA content of a sample in order to determine if consumption may be necessary. For visible samples and those for which positive serology results have been obtained, consumption is determined at the time of sampling based on the amount of material sampled.

Samples that cannot be visually assessed for DNA content, and for which serology testing may be important based on the available case information, shall be preserved for future testing (such as by preparation of a microscope slide for suspected semen samples) or subjected to serology testing prior to DNA extraction.

For evidence items that cannot be visually assessed for quantity of biological material and serological testing is not appropriate (e.g. cells left on a surface from touching, hairs), the sample may be taken in its entirety and consumption is determined at amplification based on the DNA quantification results.

Unrestricted consumption of the sample or DNA extract may proceed after receipt of an Authorization for Consumption form, written permission from the investigating officer or prosecuting attorney or court order.

Observation of testing by an outside expert is subject to the procedures in the QOM. If applicable, discuss with the prosecutor, as part of the consumption process agreement that, if during the analysis being observed by an outside expert, the quantification of the consumed evidence item shows sufficient DNA to allow for re-testing, the DNA analyst can stop the observation of the testing at that point.

5.5 STORAGE, DISPOSITION, AND DESTRUCTION OF EVIDENCE AND WORK PRODUCT

Evidence management procedures are specified in the QOM. Microscope slides, DNA extracts, and reference bloodstain cards generated as a result of evidence analysis are defined as work product. Amplicons, reference sample extracts, and Y-screen samples are not considered work product and may be discarded once testing in the case has concluded.

Historical work product such as DNA extracts, bloodstain cards (e.g. stains made from reference samples), stain excision cuttings, microscope slides, etc. may be retained for possible cold case and post-conviction DNA investigations. To maintain the integrity of some DNA analysis work products such as bloodstain cards and stain cuttings, it may be necessary to use the laboratory's evidence vault for storage due to suitable space limitations.

DNA extract work product will be stored as specified in the Casework STR Analysis Procedures manual. Prior to July 2010, any extracted DNA not utilized in analysis was typically retained by the laboratory. If not, the disposition was recorded in the case notes. After July 2010, any extracted DNA from evidence items not utilized during casework analysis was returned to the submitting agency upon completion of the case. After July 24, 2015, all DNA work product produced during sample analysis, including remaining DNA extracts from evidence (excluding reference samples), microscope slides, and sample cuttings or cellular material not subjected to DNA extraction, will be returned to the submitting law enforcement agency as a new item of evidence. The disposition for all work product will be recorded in the case notes. Reagent blanks from extractions where there is no remaining DNA may be discarded. Extracted DNA from reference items shall be discarded unless the reference DNA extract is being preserved for Y-STR testing. A reference DNA extract may be retained following Y-STR testing if that extract has been previously included in the new item of evidence created for the DNA work product.

The case notes and report will specify the new item which contains the returned DNA extracts and/or other work product. Additionally, where possible, evidence packaging will be labeled (i.e. stickers or other method) to indicate that DNA work product is enclosed.

6 CONVICTED OFFENDER SAMPLE CONTROL

6.1 RECEIPT, STORAGE, AND HANDLING OF OFFENDER SAMPLES SUBMITTED TO THE CODIS LABORATORY

Washington State Patrol CODIS Laboratory guidelines for the receipt, storage, and handling of samples submitted to the CODIS Laboratory are documented in the WSP CLD CODIS Laboratory STR Procedures Manual.

6.2 SAMPLE LABELING AND DOCUMENTATION

Each sample will be labeled with a unique identifier (i.e., laboratory number). For more information see the WSP CLD CODIS Laboratory STR Procedures Manual.

6.3 SPECIMEN HANDLING

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 bacterial or endonuclease attack and for personal protection. When working with low DNA level samples, disposable sleeves and a mask or plexiglass shield must be employed. Analysts will also discard disposable pipette tips after each use, and use quality controlled solutions and reagents when necessary. Any sample-handling tools used (such as scissors or forceps) will be rinsed and wiped off between the preparation of each sample.

Samples will be stored under conditions to maintain shelf-life and reduce or prevent the degradation of DNA (refrigeration or freezing for liquid extracts). Refer to the Non-Conforming Work section of this manual for guidelines regarding inadvertent deleterious changes (loss, mixing, contamination, etc.) to DNA extracts.

6.4 DESTRUCTION OF DNA

All extracted and amplified convicted offender DNA will be destroyed upon completion of typing.

7 METHODS VALIDATION

See the QOM for a full description of procedures for Methods Validation.

7.1 SOFTWARE VALIDATION AND TESTING

The DNA Technical Leader shall evaluate new software, new modules of existing software, or modifications to software to assess the suitability of the software for its intended use in the laboratory and to determine the necessity of validation studies or software testing. This evaluation shall include the determination of which studies will and will not be conducted and shall be documented. The validation and testing determined to be necessary as a result of the evaluation shall be completed, documented, and approved by the DNA Technical Leader prior to implementation of the software in casework or convicted offender sample testing.

8 ANALYTICAL PROCEDURES

Standard operating procedures are followed for reagent preparation, processing of convicted offender samples, sample extraction and analysis, controls and equipment maintenance. These procedures are documented in the WSP Crime Laboratory STR Analysis Procedures Manual and WSP CODIS Laboratory STR Analysis Procedures Manual.

8.1 DEFINITIONS

Chemicals – substances with a distinct molecular composition (e.g. ethanol, sodium chloride).

Reagents – substances prepared from chemicals or other reagents, or commercially available kits used in laboratory analysis that might not be considered standalone chemicals (e.g. TE, amplification kits).

8.2 PREPARATION OF REAGENTS

Reagents will be prepared according to the instructions in the appropriate STR Analysis Procedures Manuals. The quantities and lot numbers of the materials used to prepare the reagents will be recorded in the laboratory's reagent preparation log book (or stored electronically). Each batch of reagent will be uniquely identified and recorded in the laboratory's reagent log book. If the reagent is made to be used only during a single day, there is no need to record it in the laboratory's reagent log book. All single-day-use reagents will be discarded at the end of the day and the lot number of the component(s) will be recorded in the analytical notes.

8.3 LABELING OF REAGENTS USED FOR DNA TESTING

The stock containers of laboratory-prepared reagents shall be labeled with the following:

- The identity of the reagent.
- The date of preparation.
- The batch of the reagent.
- The expiration date or lot#.
- The initials of the individual preparing the reagent.
- The storage conditions of all reagents not stored at room temperature.

Individual aliquots of reagents, referred to as "working solutions," shall be labeled with the reagent name, the batch identifier, and expiration date.

Commercially-prepared reagents shall be labeled with the following:

- The identity of the reagent.
- The expiration date, if one is provided by the manufacturer or determined by the laboratory.
- The storage conditions of all reagents not stored at room temperature.

Additional information on reagents can be found in the QOM Traceability and Quality Control of Reagents. Refer to the WSP Safety and Wellness Manual Chapter 11– Hazardous Chemical Communication Plan and 4.0 Acquisition and Storage of Chemicals in the CLD Safety Manual for information on SDS labels and storage, respectively.

8.4 CRITICAL REAGENTS

A list of critical reagents can be found in the WSP Crime Laboratory STR Analysis Procedures Manual and WSP CODIS Laboratory STR Analysis Procedures Manual. These reagents will be evaluated prior to their use.

8.5 STANDARDS AND CONTROLS

All controls, internal lane standards and allelic ladders required for a given procedure will be run and checked to verify that the expected results were obtained. Further details are described in the appropriate STR Analysis Procedures manual sections.

8.6 COMPARISON TO KNOWN STANDARDS

Newly validated DNA methods (from amplification through characterization), typing test kits, or detection platform instrument models shall be checked against an appropriate certified reference material (or sample made traceable to the certified reference material) prior to implementation in forensic casework or database analysis. Comparison to the NIST DNA standard/s may be completed as part of the validation study.

8.7 GUIDELINES FOR THE PROPER RECORDING OF ALL ANALYTICAL DATA

The following information will be recorded in the casefile of every case submitted for DNA analysis and for each set of convicted offender samples typed:

- Request for Laboratory Examination (RFLE) Form for casework or a list of samples in the set for convicted offender samples.
- For casework, documentation of examination.
- Appropriate forms or worksheets filled out properly to document the analysis of each sample, including a sample description, extraction, quantitation, amplification, and capillary electrophoresis analysis. The appropriate reagent information for all reagents used, such as testing dates and lot numbers, shall be included to allow for traceability of materials used in analysis.
- Results of the estimation of the quantity of human DNA recovered (unless samples are processed by direct amplification).
- Analytical data (stored electronically) which includes as appropriate, digital photographs of evidence, sample lists or load sheets, 7500 .eds file(s), GeneMapper® ID-X files and projects, the raw data generated, size standard(s), and STRmix files.
- Additionally, it will be verified and recorded that all controls run with the samples gave expected results. This is generally accomplished by marking the tech review sheet, with additional comments noted in the file if necessary.

- Additional data to be recorded with criminal cases:
    - Any statistical analyses and/or data sheets.
    - Any appropriate CODIS search/upload/match paperwork.
    - A draft of the laboratory report bearing the technical reviewer's initials and the date of review on each page.
    - A copy of the final laboratory report.

All casefiles and convicted offender samples will be reviewed by at least one other DNA analyst. An approved peer review checklist will be used to facilitate the review process. This must be retained in the casefile for casework but can be retained in the case record for CODIS. Following the checklist will ensure adequate review of results at every step of analysis.

8.8 DATA HANDLING, STORAGE, AND RETRIEVAL

All casework documentation will be maintained according to laboratory policy as outlined in the QOM.

Electronic data will be stored as follows:

- For casework electronic data:
  - All original instrument data (i.e. data produced by a CE run and quantification) shall be backed up from the appropriate instrument computer hard drives to an approved agency server at least once per quarter.
  - Completed casework files will be placed in a Completed Cases (or equivalent) folder on the agency approved server.
- Reviewed offender sets, hit confirmations, and elimination sample sets will be backed up quarterly on an agency approved server.
- Electronic instrument maintenance and QC records will be backed up at least annually.
- CODIS data will be entered into and stored in the CODIS system according to CODIS procedures and protocols.
- Crime Laboratory validation studies, performance testing results and population study/statistical analysis work results and write-ups will be retained in the DNA section of each laboratory conducting DNA typing or in the CODIS Laboratory or on a shared server/portal. After the initial creation of the work results and write-ups, it will be the responsibility of the DNA Technical Leader to decide what is added to or deleted from these files. The DNA/CODIS supervisor or designee will have the responsibility of ensuring that the material is added to or removed from all the files in their laboratory.

The Standards and Accountability Section is responsible for maintaining historical files containing all outdated analytical testing methods, procedures, and operating guidelines formerly used in the STR testing program.

9 EQUIPMENT CALIBRATION AND MAINTENANCE

An inventory of all critical equipment used in DNA testing will be maintained according to laboratory policy as outlined in the QOM. Instruments or equipment that require calibration or performance testing prior to use and periodically thereafter are critical as they may affect DNA testing.

New analytical instruments, or instruments which have undergone repair/maintenance, will be performance tested before use in casework or convicted offender sample analysis.

Equipment service and maintenance shall be documented on the appropriate service form. All documentation of instrument service and maintenance shall be maintained in the appropriate instrument maintenance log book or electronic equivalent.

Equipment requiring calibration (such as pipettes, CEs, thermal cyclers, and their thermocouple probes), shall be calibrated according to the schedule found in the WSP Crime Laboratory STR Analysis Procedures Manual or CODIS Laboratory STR Analysis Procedures Manual. Calibration shall be performed using appropriate certified standards and documented in the appropriate equipment/instrument log book. A written procedure or set of instructions will be available for calibration of more complex instruments.

The Calibration of Instruments section of the WSP CLD STR Analysis Procedures Manual and the WSP CODIS Laboratory STR Analysis Procedures Manual outlines the performing of this quality assurance function.

The equipment/instrument maintenance procedure will clearly define the calibration source to be used and the frequency of calibration.

Temperature checks shall be performed each working day as specified in the Calibration of Instruments section of the WSP CLD STR Analysis Procedures Manual and the WSP CODIS Laboratory STR Analysis Procedures Manual. Each DNA section shall establish acceptable temperature ranges for their temperature controlled equipment. Acceptable temperature ranges can be established by reviewing the history of temperature ranges where the functional performance of the equipment was acceptable. These ranges shall be documented in each laboratory, and may be documented electronically or in the appropriate reference binder.

Refer to the QOM for information on microscope care and maintenance plan.

10 REPORTS AND THE RELEASE OF INFORMATION

Detailed information regarding procedures for the release of casefile information and reports are addressed in the QOM.

10.1 REPORTS

Analytical results released from the laboratory shall be contained in a formal written report prepared in accordance with existing Crime Laboratory Division policy. Each case shall be technically reviewed before the corresponding report can be released.

The following information will be included in all reports as applicable:

- Case identifier
- Description of evidence examined
- A statement addressing non-examined items
- A description of methodology and technology used
- Amplification kit used or loci tested
- Test results, conclusions, opinions and interpretations for each sample tested
- Quantitative or qualitative interpretation statement to support all inclusions
- Disposition of evidence
- Date issued
- A signature and title of the person accepting responsibility for the content of the report

In the first implementation phase of standardized report phrase wording for technical manuals, conclusions from the Biochemistry Procedures Manual must be used (with the addition of case specific information). A DNA Tech Lead, DNA Supervisor or the DNA Technical Leader must approve significant deviations from standard phrase wording (to ensure that the scientific meaning of the conclusion is preserved). Approved deviations will be recorded in a log for review by the DNA Technical Leader.

Reports shall only be released by laboratory staff to relevant criminal justice agencies for law enforcement purposes, in judicial proceedings, or for criminal defense purposes under 34 U.S.Code § 12592(b)(3)(A). Staff will maintain confidentiality of case information, including results, DNA records, and databases. Refer to the QOM for additional information regarding the release of information, including discovery and public disclosure.

10.2 DISCOVERY AND PUBLIC DISCLOSURE

The DNA analyst will notify their supervisor when a discovery or public disclosure request is received. If appropriate, the supervisor may notify the laboratory manager and/or DNA technical leader (e.g. for excessive requests, requests for staff DNA profiles).

Discovery requests received from the prosecutor can be handled by the assigned scientist by providing the requested documents. The Public Disclosure Tracking Coordinator (PDTC) shall be notified and coordinate the release of records for all public disclosure requests, discovery requests received directly from the defense, subpoenas duces tecum, and any discovery request requiring redaction or records maintained by OPS or HRD, regardless of the requestor.

Refer to the QOM for information regarding what may and may not be released via discovery and public disclosure.

11 REVIEW

See the QOM for a full description of case review procedures.

11.1 TECHNICAL REVIEW REQUIREMENTS

A technical reviewer shall be authorized to perform technical review according to the procedures in the QOM. The technical reviewer shall be qualified in the method, technology, typing test kit, platform, and interpretation software being reviewed.

Technical review may be accomplished by multiple technical reviewers, each responsible for reviewing a portion of the work performed in a case. Each technical reviewer must document their review on the case file documentation related to the analysis step(s) reviewed. The technical reviewer responsible for DNA profile interpretation and reporting will complete the technical review checklist and documentation of technical review as required by the QOM.

Technical review shall not be conducted by the person who performed the work being reviewed. Reports may not be technically reviewed by the author of the report.

Technical review procedures are specified in the Casework STR Analysis Procedures.

11.2 ADMINISTRATIVE REVIEW REQUIREMENTS

In addition to the review procedures outlined in the QOM, a qualified person performing a DNA casework administrative review shall review the chain of custody of item(s) for that case and reported disposition. The reviewer shall access the LIMS program to verify that the scientist had possession of the item(s) and supports the reported disposition of the evidence. The chain of custody review shall be documented on the review checklist within the casefile. The DNA administrative reviewer is additionally responsible for reviewing the report for accuracy with respect to the required report elements listed in section 10.1.

12 PROFICIENCY TESTING

Participation in a proficiency testing program is an important element of the Washington State Patrol CLD and DNA quality assurance programs. Proficiency tests are used to demonstrate the quality performance of the DNA functional area (FA) and its staff, as well as assuring that testing procedures are working properly.

12.1 OPEN PROFICIENCY TESTING

The DNA FA participates in open proficiency testing programs with samples provided by outside organizations (such as Collaborative Testing Services).

12.2 PERSONNEL

DNA FA staff who perform analysis on or technical review of DNA casework or database samples, staff performing ownership reviews of outsourced cases, and other personnel designated by the DNA technical leader, shall participate in the CLD proficiency testing program.

12.3 FREQUENCY

Personnel required to participate in proficiency testing as defined in section 12.2 shall undergo external proficiency testing twice per year, one between January 1st and June 30th and the other between July 1st and December 31st, with the interval between the two being at least four and not more than eight months. Newly qualified forensic scientists shall enter the external proficiency testing program within eight months of the date of their qualification.

The designated date for proficiency test tracking for each lab is as follows:

- Seattle – received date
- Tacoma – submitted date (results sent to manufacturer)
- Marysville – submitted date (results sent to manufacturer)
- Spokane – due date
- Vancouver – due date
- CODIS – received date
- Standards and Accountability – received date

12.4 TECHNOLOGY AND TYPING TEST KIT

Forensic scientists qualified in STR typing shall type all samples in every proficiency test using the approved STR typing kit. The typing of all CODIS core loci is required for each proficiency test.

Forensic scientists qualified in Y-STR typing shall type all applicable samples in at least one proficiency test per year using the approved Y-STR typing kit. Applicable samples are those containing male DNA, regardless of case scenario. Typing one fraction of a differential satisfies the requirement to type the sample.

12.5 METHODOLOGY

Forensic scientists qualified in both automated and manual methods should perform alternate analysis of proficiency tests between both analytical processes.

Forensic scientists shall perform at least one method in each methodology for which they are qualified at least once per year on a proficiency test. If a team approach is utilized in the laboratory, the person performing each step of analysis shall be documented in the case file.

12.6 SEROLOGY SCREENING

For those individuals involved in serology screening for biological evidence and preparation of DNA extracts for DNA analysis, the proficiency test will involve teaming with DNA analysts twice a year. Individuals involved in serology screening for biological evidence only will undergo annual external proficiency testing.

12.7 SPECIMENS

For those individuals responsible for DNA typing of convicted offender samples, the proficiency samples will consist of dried bloodstains or buccal samples. For those individuals involved in DNA analysis and/or Serology Screening on criminal casework, the proficiency samples will consist of dried specimens of blood and/or other physiological fluids either singly or in mixtures. For other individuals designated only for outsourced case technical review, the proficiency samples will consist of electronic data of analysis results from dried specimens of blood and/or other physiological fluids either singly or in mixtures. These proficiency samples will normally be presented as a case situation with specific questions to be answered.

12.8 SAMPLE PREPARATION, STORAGE, AND DISTRIBUTION

All internally developed proficiency test specimens should be uniformly prepared using materials and methods that ensure their integrity and identity. Each set and specimen must be labeled with a unique identifier.

Each proficiency test will be treated as a laboratory case and as such, will have an associated RFLE and assigned a unique laboratory number. Samples will be stored in an appropriate manner pending analysis. Proficiency tests will be assigned to individuals in the DNA section by the section supervisor. Proficiency tests will be assigned to individuals in the CODIS laboratory by either the section supervisor or the CODIS manager. Proficiency tests will be assigned to others designated only for outsourced case technical review by the DNA Technical Leader.

12.9 DOCUMENTATION OF PROFICIENCY TEST RESULTS

The analyst will, without assistance and as appropriate to their role

- Conduct analysis.
- Interpret analytical data.
- Form conclusions (as appropriate).
- Write a report or complete the proficiency test answer form as applicable.

If an analyst has questions or requires assistance, the immediate supervisor should be contacted. The proficiency test casefile shall include the same information as is included with a casework file or convicted offender file, including electronic data.

The proficiency test results shall be added to the proficiency test casefile. Records of discrepancies between the test results and corrective actions shall be documented and maintained in the proficiency test casefile. Additionally, all non-administrative discrepancies will be reported to the laboratory's casework CODIS administrator. The completed proficiency test casefile will be maintained in each lab.

12.10 REVIEW AND REPORTING OF PROFICIENCY TEST RESULTS

The casefile will undergo a technical peer review by a qualified analyst. An administrative review will also be completed by someone other than the individual being tested. Upon completion of a proficiency test, the casefile will be returned to the appropriate supervisor, who will ensure that all necessary reporting forms have been completed.

A copy of the required reporting forms will be sent to the organization providing the test materials. This may be done electronically through the test provider's website.

When reporting a genotype, attention must be paid to allele heights and the stochastic threshold. A homozygote will be reported as an "A, A" genotype. If the possibility exists for dropout of a second allele, a single allele or apparent homozygote will be reported as an A genotype. For mixed samples with expected dropout, the analyst should consider re-amplification depending on the overall peak heights in the profile, otherwise a note must be added to the comments section of the test to indicate alleles may have dropped out at some loci.

When reporting a mixture for a differential extraction proficiency result, an attempt shall be made to deconvolute and report the true fraction contributor (e.g. male and female contributors in the sperm and non-sperm fractions respectively). As an alternative, it is also acceptable to bracket minor alleles in the form A, [B]. If deconvolution is not possible then all alleles present in the sample/fraction will be reported.

When reporting a mixture for a non-differential extraction, all alleles present in the sample will be reported. Loci with only a single allele will not be reported out as a homozygote, and instead will use the "A" designation.

STRmix will be used for deconvolution of mixed samples in CTS tests for reporting purposes, including comparisons to reference samples when required by casework procedures. Use of STRmix for interpretation of and comparisons to single source samples is optional. Inclusion of peaks identified by STRmix as possible contributor alleles that may also be explained by stutter should be noted in the "additional comments" section of the CTS report.

When test results are available from the manufacturer, the DNA Technical Leader or designee will review the CTS Manufacturer's Information Report relative to the results reported by the DNA analyst to assist the Quality Process Manager. The Quality Process Manager will promptly notify the employee taking the test of the results, and a written summary of the results will be included in the file. Test results with an inconclusive result shall be reviewed by the DNA Technical Leader to ensure compliance with laboratory guidelines. Discrepancies resulting in a quality variance will be documented in the Quality Process Improvement Tracker (QPIT) as a proficiency test inquiry and in the casefile.

13 NON-CONFORMING WORK

The policies and procedures related to non-conforming work and corrective actions are outlined in the QOM. The Quality Process Improvement Tracker (QPIT) will be used to log all non-conforming work and corrective actions.

Non-conforming work is defined by the QOM. There are two levels of non-conforming work: substantive and non-substantive.

Staff working in the DNA/CODIS functional area will use the appropriate quality variance (QV) entry type in QPIT. Quality variance incidents in the DNA functional area include but are not limited to: contamination (confirmed or unconfirmed), sample switching, inadvertent sample loss (due to dropping or spilling), and sample mixing. Additionally, instrument errors that occur during casework analysis and result in loss of sample, or require re-work (other than CE reinjection or reload) should be documented in QPIT for tracking purposes.

The analyst shall document the incident in the casefile(s) and notify their section supervisor. Quality variance incidents will be documented. If identified as a finding during an audit, the audit document can be used and the finding is entered into QPIT. If identified during a testimony evaluation the testimony evaluation form can be used and the incident is entered into QPIT. Quality variances identified otherwise will be documented using the QPIT. Quality variance entries shall include the case number(s); incident date; the type of incident; if contamination, the deduced source of the DNA or the interpretable allele calls; description of circumstances; whether noted in the report or not; action(s) taken; and the analyst and supervisor names. The DNA Technical Leader is notified of quality variance entries in QPIT for system-wide monitoring.

The DNA Technical Leader, or designee, will review all reported quality variances and assess the severity. For those events determined to be substantive non-conformances, the CLD QOM policy regarding the Corrective Action Process and Non-Conforming work will be followed. All other events will be treated as minor variances and monitored, as appropriate. Should multiple minor events occur for a single individual or multiple similar minor events occur for a laboratory or across a laboratory system, the group of instances may rise to the level of a substantive non-conformance. Supervisors, or their designee, shall review their lab's quality variances quarterly and report the result to their staff either via email or at a unit meeting. The DNA Technical Leader shall also be notified of the quarterly variances summary via email.

If an event appears potentially substantive, where a formal Corrective Action would be required, the DNA Technical Leader will be notified as soon as practicable.

If no results can be reported due to a quality variance incident, the final laboratory report will indicate the reason(s) why.

Significant contamination incidents shall be noted in a case report. This would include reportable DNA profiles suspected of being introduced to evidence samples or control samples while conducting lab procedures. Refer to the WSP Crime Laboratory STR Analysis Procedures Manual for suggested wording of reports.

Unconfirmed contamination based on available data below the stochastic threshold is assessed by the DNA analyst, peer reviewer and supervisor on a case-by-case basis for plausibility of trace DNA contamination, potential for impact on DNA profile interpretation and as to whether it is sufficiently significant to be noted in the report.

Refer to Extraneous DNA Guidelines in Appendix 1 for assistance in casework contamination troubleshooting. For CODIS analysts, refer to Appendix 2 for assistance in contamination troubleshooting.

If an extraneous profile is attributable to an unknown source, the profile shall be attached to the quality variance entry in QPIT.

All contamination events will be thoroughly investigated with appropriate troubleshooting measures documented in QPIT. The DNA Technical Leader may request additional troubleshooting steps or investigation when reviewing such entries.

Corrective actions involving DNA analysis shall not be implemented without the documented approval of the DNA Technical Leader. The CODIS Administrator will be notified of nonconformities that impact DNA records entered into CODIS and this notification will be documented in the casefile or QPIT.

14 AUDITS AND QUALITY REVIEW

Audits are an important aspect of the DNA FA's QA Program. They are an independent review conducted to compare the DNA FA's performance with a standard for that performance.

The DNA and CODIS laboratories will be audited annually with an external audit in alternating years. The audit will be conducted in accordance with the FBI DNA QAS document. The annual audits occur every calendar year and will be at least 6 months and no more than 18 months apart.

Refer to the QOM for detailed information regarding the audit process.

14.1 OBJECTIVES

There are two primary objectives of an audit:

1. To provide management with an evaluation of the DNA FA's performance in meeting its quality assurance policies and objectives.
2. To identify the areas in which the DNA FA performance may be improved.

14.2 TYPES OF DNA FUNCTIONAL AREA AUDITS

14.2.1 Audits of the DNA Functional Area

The DNA Technical Leader conducts and documents an annual review of the DNA Quality Assurance Program.

On a biennial basis, each DNA laboratory undergoes an external audit designed to determine the extent to which the section meets the FBI DNA Quality Assurance Audit document.

The audit is conducted by a team comprised of at least two individuals from an external agency one of which must have successfully completed the FBI DNA Auditor Training and at least one audit team member is or has been qualified in each DNA technology used in the CLD DNA laboratory to be audited.

A record (including a summary report prepared by the DNA Technical Leader) of each external audit will be maintained and include the date of the inspection, the names of the members of the inspection team, the findings and problems identified by the team, and remedial action taken to resolve existing problems. Any findings of non-conforming work will be addressed through corrective action processes. External audit documentation and laboratory responses will be reported to the FBI within 30 days of the laboratory’s receipt of the audit report.

On years where an external audit is not performed, each DNA laboratory undergoes an internal audit designed to determine the extent to which the section meets the FBI DNA Quality Assurance Audit document.

The internal audit is conducted under the direction of the DNA Technical Leader by at least one qualified auditor and one qualified (or previous qualified) DNA Analyst from another CLD laboratory and/or the DNA Technical Leader. The CODIS laboratory will have at least one qualified database analyst in the audit team.

A record (including a summary report prepared by the DNA Technical Leader) of each internal audit will be maintained and include the date of the inspection, the names of the members of the inspection team, the findings and problems identified by the team, and remedial action taken to resolve existing problems. Any findings of non-conforming work will be addressed through corrective action processes and documented in the QPIT. Audit findings and documentation will be provided to

the Laboratory Manager, DNA Supervisor/s, CODIS administrators, and CODIS Laboratory Manager.

The annual DNA audits (both internal and external) will be incorporated in the FLSB quality internal audits and Management System Reviews.

14.2.2 FLSB Management System Review and Internal Quality Audits

The annual internal quality audit and Management System Review (MSR) are reviews of the laboratory's management and quality systems and testing activities to ensure continuing suitability and effectiveness. These reviews will be used as tools to introduce necessary changes or improvements by management.

As a part of the FLSB, the DNA section and its activities will be subject to the annual MSR to ensure the continued suitability and effectiveness of the quality system and laboratory operation, compliance with established FLSB policies, current accrediting body requirements, any supplemental document requirements, the FBI DNA Quality Assurance Standards, and applicable WSP policies, rules and regulations.

The procedures for the annual internal quality audit and MSR are outlined in the QOM.

14.2.3 DNA Technical Leader Site Visits

The DNA Technical Leader shall conduct semi-annual site visits to all DNA laboratories within the WSP CLD. The purpose of these visits is to maintain consistency between labs, verify proper quality control measures exist, and to promote discussion among analysts. Additionally, these visits may include an update and discussion regarding newly implemented procedures and validations, available funding/grant awards, and general functional area updates.

The DNA Technical Leader may choose to include other staff during these visits, including Forensic Scientist Tech Leads (FS4), as an opportunity to collaborate and enhance interlab relations and information sharing.

Documentation supporting completion of the site visits shall be maintained by the Standards and Accountability Section.

14.2.4 Annual Case Review

An annual review of DNA case files encompassing a representative sample of the cases worked shall be performed. The scope of the review shall be defined prior to each review and shall be approved by the DNA Technical Leader. This review shall be independent of the annual QAS audit. Documentation of the review shall be maintained by the Standards and Accountability Section.

14.3 ANAB INSPECTION

Each laboratory of the Crime Laboratory Division is accredited by ANAB. As part of the accreditation process, all sections of each laboratory are inspected every four years to ensure that current accreditation requirements are being met. An ANAB inspection fulfills the biennial external audit requirement.

15 OUTSOURCING

External laboratories may be contracted to perform DNA analysis to meet operational goals or in order to provide services not offered by the WSP CLD. External laboratories contracted to perform DNA analysis for WSP CLD shall comply with the FBI DNA Quality Assurance Standards.

15.1 ESTABLISHING AN OUTSOURCING CONTRACT

1) Acquire the vendor's analysis and quality assurance procedures, validation reports, the last external DNA audit document, and accreditation certificate.
2) Document the technical review by the DNA Technical Leader of analysis and quality assurance procedures, last external DNA audit document, accreditation certificate, and proficiency test records.
3) Perform an initial on-site visit of the vendor lab in accordance with FBI QAS requirements. The site visit will be used to assess quality assurance performance through review of current audit documents and corrective actions, resolve technical issues and assess any critical changes in work environment.
4) Document WSP CLD DNA Technical Leader approval of outsourcing contract technical specifications prior to issuance of contract.
5) Determine who will perform the casefile reviews.
6) Designate a lead casefile reviewer as the point person and project coordinator.
7) Design and implement a technical review SOP for the contracted casefiles, data interpretations and conclusions.
8) Provide training to case reviewers on vendor file organization and review process and on any major technical differences between the WSP CL and the vendor laboratory.
9) An annual on-site visit of the vendor laboratory must be performed if the outsourcing contract extends beyond one year. Alternatively, an on-site visit conducted by another NDIS participating laboratory using the same technology, platform and typing test kit for the generation of the DNA data, or coordinated by a designated FBI employee, may be reviewed and approved by the DNA Technical Leader.

15.2 OWNERSHIP OF OUTSOURCED CASES

Ownership is defined by the FBI QAS and occurs when any of the following conditions are met:

1) The NDIS participating laboratory will use any samples, extracts or materials from the vendor laboratory for the purposes of forensic DNA testing;
2) The NDIS participating laboratory will interpret the DNA data generated by the vendor laboratory;
3) The NDIS participating laboratory will issue a report describing or drawing conclusions on the results of the DNA analysis performed by the vendor laboratory; or
4) The NDIS participating laboratory will enter or search a DNA profile in CODIS from data generated by the vendor laboratory.

An outsourcing agreement should exist between the WSP CLD and the vendor laboratory before the vendor laboratory performs any analysis of which the WSP CLD is intended to take ownership. If no outsourcing agreement exists, the WSP CLD may not be able to take ownership due to the requirement to have a qualified ownership reviewer. In rare instances where no outsourcing agreement exists and the WSP CLD will accept ownership, the DNA Technical Leader shall document the following prior to accepting ownership:

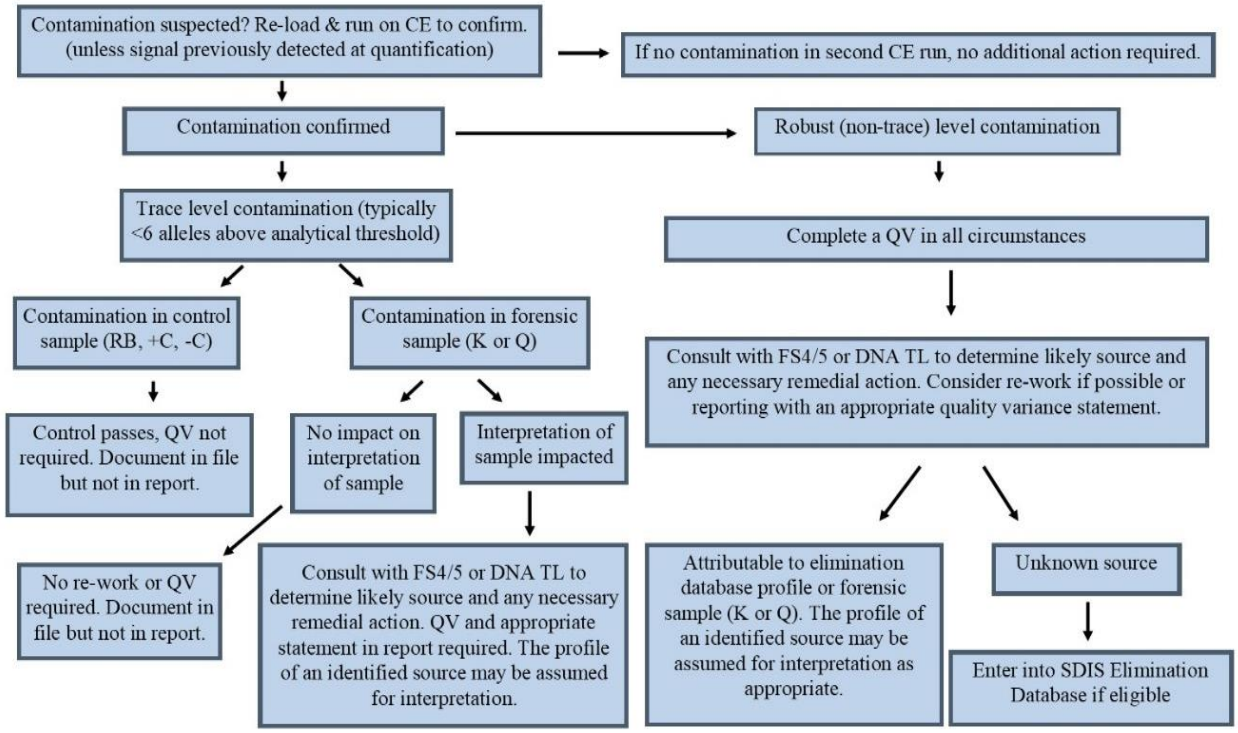
1) Approval of the casework CODIS administrator and written permission from the NDIS Custodian for any scenario that involves CODIS entry or searching.
2) Approval of the technical specifications of testing; and
3) Perform an on-site visit or review documentation of an acceptable on-site visit, as described above, within 18 months of the analysis being conducted by the vendor laboratory.

WSP CLD forensic scientists provide reports related to work performed by the WSP CLD. Vendor laboratory scientists are responsible for the contents of their reports and testifying to their analyses. Reference samples submitted to confirm CODIS hits should be submitted to the vendor laboratory when possible.

15.3 OWNERSHIP REVIEW

Ownership review is a technical review process used to ensure integrity of DNA data received from a vendor laboratory for the purposes of taking ownership. Ownership review shall be completed by a DNA forensic scientist authorized to perform technical review using the technology, platform, and typing test kit used to generate the data. Ownership reviews shall be performed in accordance with the procedures established in the Casework STR Analysis Procedures manual.

16 APPENDIX I – EXTRANEOUS DNA GUIDELINES



16.1 TROUBLESHOOTING CONTAMINATION

When possible contamination is detected in a DNA extract or control sample, an effort will be made to troubleshoot the source and mode of contamination. From the point where contamination is observed or suspected, the forensic scientist should work backwards to investigate if the contaminating step/activity can be determined. For example, if DNA is detected in a reagent blank at the quantification stage, the contaminating event occurred prior to or during this stage of analysis. Troubleshooting steps and results shall be documented in the appropriate casefile and/or QPIT entry.

The flowchart above outlines the contamination troubleshooting process. After contamination is confirmed via CE re-load and when possible or appropriate, analysis steps will be repeated to determine if the sample vs. the process (e.g. robot carryover) led to the contamination. This may include re-amplifying, re-quantifying, or re-extracting a sample as necessary. When DNA is detected in a reagent blank at quantification, re-loading on the CE is not necessary to confirm contamination prior to additional troubleshooting.

The source of the DNA profile shall be investigated using available DNA database searches or comparisons (STRmix elimination database, Y-STR profile records, vendor database searches/requests). If identified, the contaminating individual (or vendor) will be notified and discussion regarding possible quality assurance practices to limit reoccurrence should take place and be documented in the QPIT entry as appropriate.

When a signal is detected in a reagent blank at the quantification step, the reagent blank shall be amplified at 15 µL or, if any associated samples are concentrated, matching the most sensitive volume conditions in the associated batch. If DNA extracts will not be processed beyond the quantification step, the reagent blank may still be amplified to assist in troubleshooting efforts. If amplification of the reagent blank at 15 µL will reduce the necessary volume required for additional testing or negatively impact

downstream analysis of associated DNA samples (e.g. using a portion of a reagent blank needed for a Y-STR sample), the forensic scientist may document this in the file and continue analysis with amplification of the reagent blank matching the most sensitive volume conditions as the associated sample(s) in the extraction set.

For Casework Direct reagent blanks, an effort will be made to determine the source of the contaminant. If male DNA is present in the reagent blank, and also detected in the evidence samples, caution will be taken when determining downstream analysis. It is recommended that more than one Casework Direct reagent blank be quantified per plate/batch to aid in determination of reagent contamination.

Any reagent expected or presumed to be contaminated will be discarded. Contamination that cannot be resolved through re-testing or re-extraction will be reported as required in the flow chart above with the appropriate quality variance statement as referenced in the STR Casework Manual.

17 APPENDIX II – EXTRANEOUS DNA GUIDELINES - CODIS