OSBI CODIS Unit Policy Manual

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Reference Forensic Biology Unit Policy Manual

Conforming to the ASCLD/LAB International Standards, as ISO 17025 Program of Accreditation

CODIS Unit Quality Manual

ATTENTION: If any portion(s) of the CODIS Unit Policy Manual is/are unclear to any analyst or if a circumstance arises outside the scope of this document, it is the responsibility of each analyst/technician to immediately notify the Technical Manager and the respective Supervisor to seek clarification/approval or obtain guidance on the issue BEFORE proceeding.

Per requirements in the FBI's Quality Assurance Standards for DNA Databasing Laboratories 11.2 and the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories Standard 11.3, *"Except as otherwise provided by state or federal law, the laboratory shall have and follow written procedures to ensure the confidentiality of the database, known or casework reference samples and the information in DNA databases and DNA records. Except as otherwise provided by state or federal law, reports, case files, DNA records, and databases shall be confidential."* DNA profiles are not to be transmitted outside the OSBI network electronically. The OSBI network (e-mail and server) is secure; therefore, NDIS allows these electronic transmissions. However, DNA profiles will not be e-mailed outside of the OSBI network without prior authorization from the Technical Manager.

CODIS Unit Quality Manual

CODISQM_1 SCOPE (top ↑)

1.1 The CODIS Unit Policy Manual shall apply to work specifically performed by analysts/technicians working within an officially defined CODIS Unit or by analysts/technicians working in the capacity as a CODIS analyst or associated technician.

1.2 The purpose of this Policy Manual is to establish and maintain a documented quality system that is appropriate to the CODIS Unit of the Oklahoma State Bureau of Investigation (OSBI). The Forensic Biology Unit maintains a separate quality manual which can be found in the Forensic Biology Unit Policy Manual.

1.3 Any document referenced within the policy manual shall be available to each Forensic Biology Casework/CODIS laboratory within the OSBI multi-laboratory system (per FBI Quality Assurance Standards (QAS) Audit Document discussion).

1.4 Hyperlink and attachment maintenance (removal, addition, or correction of hyperlinks and attachments) shall not constitute a new document revision.

ATTACHMENT(S):
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

REFERENCE(S):
OSBI Forensic Biology Unit Policy Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_2 DEFINITIONS (top ↑)

Terms in this document follow the definitions set forth in Section 2 of the Quality Assurance Standards (QAS). In addition, the OSBI CODIS Unit establishes the following definitions:

Analytical Threshold - the relative fluorescence units (RFU) value above which an observed well-formed peak that is not the result of a diagnosable issue such as stutter, pull-up, spike, minus A, etc. can be assumed to be observed due to the presence of an allele
Annual – once per calendar year
Concurrent – taking place at the same time with the same conditions [as clarified by the Federal Bureau of Investigation (FBI)]
Differential Extraction – process for extracting DNA from all samples testing presumptive or confirmatory positive for seminal fluid in the (performed in the Forensic Biology Units of the OSBI).
DNA Analysis - using the Polymerase Chain Reaction (PCR) to examine Short Tandem Repeats (STR) utilizing capillary electrophoresis
Dye blobs - disassociated primer dyes which are reproducible artifacts often observed with a particular lot of amplification kits
Instrument Spike - non-reproducible artifacts which occur occasionally within an electophoretic run resulting in the appearance of anomalous peak(s) on the electropherogram. A peak resulting from an instrument spike is easily identified as such upon close examination. Such a peak will usually be composed of all colors of approximately equal apparent fluorescent intensity and occur at the same data point and/or scan number in GeneMapper ID-X.

Intimate Sample - originating from the body (i.e. vaginal swabs, swab of hand, oral swabs, etc.)

Low Copy Number (LCN) DNA Analysis – as referred to at the OSBI, LCN DNA analysis shall be defined as any DNA analysis where additional amplification cycles beyond the OSBI's internal validation, post-amplification purification, reduced reaction volume, nested PCR, or an increased injection time or voltage outside the scope of the OSBI's internal validation were performed; the OSBI does not perform LCN DNA analyses and, as such, any sample subjected to these conditions will not be submitted to NDIS.

Microvariant Alleles - alleles which contain an incomplete repeat unit (i.e. 9.3 at TH01)

Minus A (-A) – a reproducible artifact of the PCR process generated by the inability of AmpliTaq Gold™ to catalyze the addition of a single nucleotide (predominantly adenosine) to the 3' end of the PCR product during the final extension step

Mixture – two or more contributors are present in a DNA profile

Off-ladder Allele (OL) - an allele whose size is not represented within the allelic ladder

Off-scale Peaks (OS) - those reproducible peaks above the linear detection of the instrument; any fluorescence signal that exceeds the detection threshold of the instrument. The OS quality flag indicates if the camera is saturated at any data point within the analysis range. It is not based on an absolute RFU value (peak height).

Peak Height Ratio (PHR) - the ratio of the peak with the lowest RFU to that of the peak with the highest RFU of a heterozygous pair expressed as a percent (truncated)

Peak Stochastic Threshold (PST) – the RFU value above which it can be assumed that peak "drop-out" does not occur and any observed allelic peak that has no sister allele present can reasonably be believed to be homozygous **Process Step** – this refers to each step in a process of analysis. This would include, but is not limited to, adding protocol specific reagents at listed volumes, use of Microcons, or use of any other equipment in the analysis process, and, as such, an associated blank must also be taken through the process concurrent to any samples. However, in some process steps such as the concentrating of a sample, although a questioned sample and its associated reagent blank(s) must both be placed into the device, it is acceptable to remove any associated blank(s) from the process step while allowing the sample to continue in the step until an appropriate volume is achieved. Adding reagent to bring any volumes to a working volume is not considered a process step.

Pull-up (PU) - when the matrix cannot compensate for an excess of one color, causing the "pulling up" of peaks in another color; in other words, the instrument is not able to resolve spectral overlap. This may be observed as a small peak at a similar scan number as a large peak in another color.

Reagent - any substance or mixture used in the analysis process of the Forensic Biology Discipline. Chemicals used to make reagents are not considered "reagents", but rather chemicals (i.e. NaOH). Reagents will have an expiration date of one year from the date of receipt, unless otherwise specified by the manufacturer or in the FBU Policy Manual and/or its attachments.

Review Date - the completion date of the review of the protocols

Single Source - one contributor is present in a DNA profile

Standard Extraction - all samples except those requiring a differential extraction (performed in the Forensic Biology Units of the OSBI).

Stutter (ST) - a reproducible artifact of the PCR process; a minor product peak longer or shorter than the corresponding main allele peak. The stutter peak may be various sizes in relation to the main allele peak dependent on the repeat structure and the amplification kit.

Technical Manager – equivalent to "Technical Leader" as defined by QAS

Trailing Primer Peak – peaks associated with the primer peak that fall within the size calling range

Trainee – an analyst or technician undergoing training in a particular discipline (i.e. serology or DNA analysis)

Trisomy – three alleles at a single source STR locus

True Allelic Peak (allele) - a relatively symmetric pointed arch in an upward direction. It is wider at the base than at the summit and shows an area of non-linear taper to and from the highest point. Generally, the peak should have a height:width ratio of >1. True allelic peaks should be present in only a single color unless pull-up has occurred.

Virtual Allele - an allele that is labeled by the software, even though it is not present in the allelic ladder. For example, if using the Identifiler® Plus panel in GMID-X, there is an allelic bin for an 11 at D3S1358, although the ladder alleles range from 12 to 19. Thus, an allele labeled as an 11 at D3S1358 would be considered a virtual allele. The term "virtual allele" does not in any way indicate that the allele is not a true allele, but simply

indicates it is an off-ladder allele that has been assigned a label.

Work product - the material utilized in testing and/or generated as a function of the analysis process

REFERENCE(S):

FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories

FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_3 QUALITY ASSURANCE PROGRAM (top ↑)

3.1 The OSBI Criminalistics Services Division (CSD) maintains a general, unit-neutral Quality Manual. The OSBI CODIS Unit maintains this unit-specific quality manual to specifically address the quality system for offender sample analysis.

3.1.1 The Quality System will address the following areas:

- 3.1.1.1 Goals and Objectives
- 3.1.1.2 Organization and Management
- 3.1.1.3 Personnel
- 3.1.1.4 Facilities
- 3.1.1.5 Evidence Control
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- 3.1.1.11 Proficiency Testing
- 3.1.1.12 Corrective Action
- 3.1.1.13 Audits
- 3.1.1.14 Safety
- 3.1.1.15 Outsourcing

3.2 **Retention of Records**

The CODIS Unit shall follow OSBI CSD Quality Procedure (QP) 16.1 – Control of Records for quality and technical records to include the following areas:

- Proficiency Tests
- Corrective Action
- Audits
- Training Records
- Continuing Education
- Court Testimony Monitoring

According to the OSBI CSD Quality Procedures, the above listed areas are all quality records.

3.3 **Annual Review** - The CODIS Unit shall conduct an annual review to be inclusive of the overall quality assurance program, analytical procedures, quality control procedures, training manual, and any other division (CSD) or agency (OSBI) procedures that are applicable to the quality of DNA analysis.

3.3.1 CODIS Level Documents: The Technical Manager shall direct and document his/her approval of the annual review of the CODIS Unit Quality Assurance Program. This review may be an ongoing process of incorporating any deviations or suggestions submitted through OSBI CSD QP 3 – Deviations and QP 15 – Preventive Action into the next revision of the CODIS Policy Manual. A final review of the incorporated changes will be completed before issuance, and

approval documented in the Approval section of the document. The Technical Manager will conduct the annual review by requesting assistance through the Biology Subcommittee, as needed.

3.3.1.1 The final, documented approval of the Annual Review shall correspond sequentially or identically in date with either the issuance of a new policy revision, approved by the Technical Manager, to the current policy or by the insertion of the "Review Date" and the phrase "Annual Review" within the History section of the current policy. Changes to the policy shall be outlined in the History section.

3.3.2 CSD/OSBI level documents: Review of these policies/procedures will be documented in a memo, and any proposed deviations/changes will be submitted to the appropriate authority.

3.4 **Goals and Objectives** - The CODIS Unit shall strive to accomplish the following goals and objectives:

3.4.1 The goals and objectives for the OSBI's Criminalistics Services Division (CSD) are outlined in the CSD Quality Manual. In addition, the specific goals and objectives of the CODIS Unit include ensuring the quality of data entered into and/or searched against CODIS, timely entry of offender and casework data into CODIS, routine searches of profiles maintained in CODIS, and timely verification of hits.

3.4.2 Pursuant to Oklahoma Statute Title 74 Section 150.27a, the Oklahoma State Bureau of Investigation (OSBI) is charged with the task of implementing the Combined DNA Index System (CODIS) for the state of Oklahoma. To ensure the quality of the database, it is the policy of the OSBI that all data entered into and/or searched against CODIS is generated in a manner consistent with the FBI's Quality Assurance Standards for DNA Databasing Laboratories, the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories, and the FBI's National DNA Index System (NDIS) Procedures.

REFERENCE(S):

OSBI CSD Quality Manual

FBI's Quality Assurance Standards for DNA Databasing Laboratories

FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories

FBI's National DNA Index System (NDIS) Procedures

CODISQM_4 ORGANIZATION AND MANAGEMENT (top ↑)

4.1 The OSBI CODIS Unit managerial staff shall:

4.1.1 The CODIS Unit shall have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the standards in this document and the FBI's Quality Assurance Standards for DNA Databasing Laboratories (September 1, 2011).

4.1.1.1 In the event that the managerial staff does not have the authority or resources to ensure that the standards are being met, the Technical Manager shall suspend DNA laboratory operations, utilizing OSBI CSD QP 13 – Non-Conforming Work, until such time that the DNA testing at one laboratory or multiple laboratories re-establishes the managerial authority or resources necessary to meet or exceed these standards.

4.1.2 The Technical Manager of the OSBI Forensic Biology discipline is responsible for all Technical aspects of the OSBI's multi-laboratory Forensic Biology discipline. The Forensic Biology discipline is comprised of two separate laboratories: Forensic Science Center — FSC Forensic Biology (FBU - major crimes), FSC Specialized Forensic Biology (SFBU - property crimes and cold cases), and CODIS Units and the Northeast Regional Laboratory — NERL Forensic Biology.

4.1.3 There is a single casework CODIS Administrator responsible for the entire OSBI multi-laboratory system.

4.1.4 The CODIS Unit shall have at least two full time employees who are qualified DNA analysts.

4.1.4.1 In the event that a laboratory ceases to have two full time DNA analysts, the Technical Manager shall immediately suspend the processing of any new analyses and only perform required quality procedures until a second full time DNA analyst is qualified.

4.1.5 OSBI Policy 103 – Authority and Responsibility and OSBI CSD QP 1 – Responsibilities and Authority specify the responsibility and authority of each position within the OSBI CODIS Unit chain of command. In addition, the CODISQM_5 section titled "Personnel" reflects the responsibilities associated with each position.

4.1.5.1 The Organization and Management Structure of the OSBI Criminalistics Services Division (CSD) is detailed in the OSBI CSD Quality Manual. The CODIS Unit "Organization and Management Structure" chart (CODISQM_OrgChart) maintained by the OSBI CODIS Unit reflects the interrelation of all appropriate personnel.

4.1.6 The document titled "Technical Manager Contingency Plan" reflects the plan to maintain uninterrupted Technical leadership over the DNA testing operations within the OSBI Forensic Biology discipline. Exclusion from the document shall not exclude qualified individuals from participating in a contingency plan during a Technical Manager position vacancy.

ATTACHMENT(S):
CODISQM_OrgChart – CODIS Unit Organizational Chart
OSBI Memo titled "Forensic Biology Discipline Technical Manager Contingency Plan"

REFERENCE(S):
OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_5 PERSONNEL (top ↑)

5.1 The OSBI CODIS Unit shall be staffed with personnel employed by the agency that meet the qualifications contained within this section as well as within any documents referenced herein and the qualifications listed in the QAS.

5.1.1 Analyst duties and responsibilities are outlined in a general written job description for each of the Criminalist (I, II, III, IV, and V) positions including responsibilities, duties, and skills necessary for the position. The general written job description is maintained by the Office of Personnel Management of the State of Oklahoma. Additional Selective Qualifications for analysts within the OSBI Forensic Biology discipline are on file with the OSBI Human Resources Division. Criminalist IVs in regional facilities may or may not also serve as DNA analysts.

5.1.2 OSBI CSD personnel shall meet the education and competency requirements detailed in the ASCLD/LAB Supplemental Requirements.

5.1.3 Laboratory personnel shall have the education, training, and experience commensurate with the examination and testimony provided.

5.1.3.1 Each CODIS Analyst shall complete the OSBI CODIS training program. If the employee has had documented prior academic or on-the-job training in CODIS software, DNA analysis, or database sample analysis, the initial training program may be modified accordingly.

5.1.3.2 The documentation of progression through training programs is detailed in CSD QP 19 – Training and in the CODIS Unit Training Manual.

5.1.3.3 Any analysts who are hired to perform DNA analysis that do not meet the qualifications listed in the general job description for a Criminalist position, the Selective Qualifications for the Forensic Biology Discipline, or the QAS will be brought into compliance with these requirements prior to commencing any independent DNA analysis. For required higher education classes, a passing grade will be a "C" or higher. QAS-required classes previously completed with a grade lower than "C" will have to be retaken. Failure to successfully complete with a grade of "C" or higher may result in progressive discipline up to and including termination.

5.1.4 A passing grade for all exams and quizzes in the training program will be 80%, unless deemed otherwise and documented by the Technical Manager.

5.1.4.1 Trainees will be required to successfully complete all applicable sections of the OSBI CODIS Unit Training Manual, including a range of samples routinely encountered in offender analysis, a competency assignment, and technical question assessment before release for independent analysis. The Memo releasing the analyst or technician for analysis will include the scope of the release including testing while the "Authorization to Work" Memo will include testing, instrumentation, equipment, testimony, etc. as required by ASCLD/LAB.

5.1.4.2 The competency assignment and technical question assessment is considered "competency test(s)". The successful completion of the competency assessment will be documented by the Technical Manager in the trainee's training materials. If an analyst or technician has previous forensic/databasing experience, the previous experience will be reviewed by the Technical Manager for adequacy and applicability to OSBI CODIS procedures. Adequate previous training may result in documented modifications to the CODIS Training Program for the trainee.

5.1.5 All analysts qualified to perform DNA analysis will be required to attend continuing education training as outlined in the QAS.

5.1.5.1 All training attended, whether conducted internally, externally, through multi-media, or internet delivery, to meet continuing education requirements must meet the standards listed in the QAS and attendance must be documented. The laboratory will maintain records associated with any such training, as required by the QAS.

5.1.5.2 The literature review program approved by the Technical Manager per OSBI CSD QP 19 – Training shall consist of quarterly literature reviews over topics relevant to forensic biology. Literature review documentation will be maintained by the Technical Manager.

5.1.5.3 The OSBI laboratory will maintain physical or electronic access to a collection of current books, reviewed journals, and/or other literature applicable to DNA analysis.

5.1.6 Records for qualifications, training, skills, and experience shall be retained in accordance with OSBI CSD QP 16.1 – Control of Records. The Technical Manager shall have access to documentation of qualifications, training, skills and experience that is pertinent for the analysis of DNA and should have access to the same documentation as is pertinent for serology.

5.2 Technical Manager

5.2.1 The Technical Manager has the authority to suspend work performed in the CODIS Unit which does not comply with the OSBI CSD Quality System or any applicable quality standards. The Technical Manager will assign and approve forensic/databasing procedures utilized in the CODIS Unit. All procedures will address and include practices consistent with quality standards. The Technical Manager has the authority to initiate, suspend, and resume DNA database operations for the entire CODIS Unit or an individual member of the CODIS Unit.

5.2.2 Any individual filling the position of OSBI Forensic Biology Discipline Technical Manager must meet the minimum education, experience, training requirements, and qualifications as per the QAS; in addition, all requirements of the Criminalist IV classification maintained by the Office

of Management and Enterprise Services (OMES): Human Capital Management (HCM) of the State of Oklahoma shall also be met. The Technical Manager position shall be filled by a full time employee of the OSBI.

5.2.2.1 The Technical Manager must have, at minimum, a Master's 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 course work covering the subject areas of biochemistry, genetics, molecular biology, and statistics or population genetics.

5.2.2.2 The 12 semester or equivalent credit hours shall include at least one graduate level course registering three or more semester or equivalent credit hours.

The subject areas listed above shall constitute an integral component of any course work in order to be accepted. If the course work completed has a title other than those listed above, a combination of pertinent materials such as a transcript, syllabus, letter from the instructor, or other documentation that supports the course content must be provided.

If the degree requirements listed above were waived by the American Society of Crime Laboratory Directors (ASCLD) in accordance with criteria approved by the Director of the FBI, the documented waiver is sufficient. This documented waiver is permanent and portable with the individual.

5.2.3 The OSBI Forensic Biology Discipline Technical Manager shall have at least three years of forensic, databasing, or human identification DNA laboratory experience obtained at a laboratory where forensic DNA testing was conducted for the identification, databasing, or forensic purposes. Any Technical Manager appointed or hired on or after July 1, 2009, shall have a minimum of three years of human-DNA experience as a qualified analyst on database or forensic samples. The OSBI Forensic Biology Discipline Technical Manager shall complete (within one year of appointment) the FBI-sponsored auditor training.

5.2.4 The duties, responsibilities and authority of the OSBI Forensic Biology Discipline Technical Manager will, at a minimum, be those designated by the QAS. Additional duties, responsibilities and authorities can be required of the Technical Manager as necessary to meet the needs of the agency:

5.2.4.1 Oversee the technical operations of the CODIS Unit.

5.2.4.2 Evaluate and document approval of all validations and methods used by the laboratory and to propose new or modified database procedures to be used by CODIS analysts.

5.2.4.3 Review and document the review of the academic transcripts and training records for newly qualified analysts and approve their qualifications prior to independent database analysis.

5.2.4.4 Approve the technical specifications for outsourcing agreements.

5.2.4.5 Review and document the review of internal and external DNA Audit documents and, if applicable, approve corrective action(s).

5.2.4.6 Review, on an annual basis, the procedures of the laboratory and document such review.

5.2.4.7 Review and approve the training, quality assurance and proficiency testing programs in the CODIS Unit.

5.2.4.8 Assist with management reviews as described in QP 18 – Management Reviews.

5.2.4.9 Review and approve all technical procedures within the CODIS Unit.

5.2.4.10 Implement and review quality documentation within the CODIS Unit.

5.2.4.11 Stay abreast of recommendations made by Forensic Biology Scientific Working Groups and incorporate appropriate recommendations.

5.2.4.12 Educate all members of the CODIS Unit in the implementation of the quality assurance program and confirm that all members of the discipline understand the importance of

the program.

5.2.4.13 Participate in audits and inspections.

5.2.5 The Technical Manager will be available to provide on-site, telephone or electronic consultation as needed. The Technical Manager shall conduct a site visit semi-annually to all satellite labs performing DNA analysis in a laboratory system.

5.2.5.1 The Technical Manager shall be a full time employee of the laboratory or multi-laboratory system.

5.2.5.2 In the event that the Technical Manager position of a laboratory is vacated and there is no individual in the laboratory or multi-laboratory system who meets the requirements listed in this policy, the laboratory shall immediately contact the FBI and submit their contingency plan within 14 days to the FBI for approval. Work in progress may be completed during this 14 day period, but new database DNA analysis shall not be started until the plan is approved by the FBI.

5.2.6 A newly appointed Technical Manager will be responsible for the documented review of the following: analyst qualifications (training records and education), validation studies, and methodologies currently used in the laboratory within the first year.

5.3 Casework CODIS Administrator

5.3.1 Any individual filling the position of OSBI Casework CODIS Administrator shall be an employee of the OSBI who meets or exceeds the minimum education and experience requirements as detailed in this policy and must meet the minimum educational, experience, and CODIS training requirements listed in the QAS.

5.3.2 The OSBI CODIS Administrator shall serve as the central point of contact with the FBI and be responsible for the use of CODIS software and submissions of DNA records to the National DNA Index System (NDIS). The CODIS Administrator shall be authorized to author and sign all correspondence and required reports for the FBI and NDIS Custodian. *[ref. FBI NDIS, Operational Procedures]*

5.3.3 In the event an issue with the data is identified, the CODIS Administrator shall be authorized to terminate an analyst's or a laboratory's participation in CODIS until the reliability and security of the data can be assured.

5.3.4 The CODIS Administrator for the OSBI shall also serve as the State CODIS Administrator for the entire CODIS network for the State of Oklahoma. In the event an issue with the data is identified, the state CODIS Administrator shall have the authority over all CODIS sites under his/her jurisdiction to terminate an analyst's or a laboratory's participation in CODIS until the reliability and security of the data can be assured.

5.3.5 In the extended absence of the CODIS Administrator, a designated Acting CODIS Administrator will perform CODIS related duties as needed. The Technical manager, CODIS Supervisor, or any qualified CODIS analyst can be assigned as the Acting CODIS Administrator.

5.3.6 In the event the CODIS Administrator position is unoccupied, the laboratory shall not upload profiles to NDIS.

5.3.7 The CODIS Administrator shall complete the FBI auditor training within one year of appointment, if not previously attended, and shall participate in the FBI-sponsored CODIS software training within six months of appointment, if not previously attended.

5.3.8 Responsibilities of the CODIS Administrator include:

5.3.8.1 Administration of the OSBI's CODIS network.

5.3.8.2 Scheduling and documenting the CODIS computer training of all database analysts.

5.3.8.3 Ensuring the quality and security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.

5.3.8.4 Coordinating database searches.

5.3.8.5 Ensuring matches are dispositioned in accordance with NDIS operational procedures.

5.3.8.6 Ensuring CODIS users are notified of and provided access to revised NDIS Operational Procedures and other documentation necessary to properly participate in NDIS. *[ref. FBI NDIS, Operational Procedures]*

5.3.8.7 In conjunction with the Technical Manager, develops, implements, and coordinates procedures applicable to the OSBI's participation in the state and national CODIS programs.

5.3.8.8 Makes recommendations to the Technical Manager for personnel approved to perform independent analysis of offender samples and hit verifications, as well as release to perform technical review of such.

5.3.8.9 Determines which individuals will be released to perform independent CODIS database software functions.

5.3.8.10 Assists in the acquisition and monitoring of grants for DNA Offender Database samples and laboratory equipment. This may include locating potential sources of funding, grant writing, grant monitoring, evaluation of contractor bid responses, and on-site evaluations of contract laboratories.

5.3.8.11 Coordinating all activities with private contractors performing analysis on offender DNA samples for the OSBI in accordance with procedures outlined in this policy.

5.3.8.12 Serving as liaison between the state CODIS system and criminal justice agencies, other OSBI personnel, and the public.

5.3.8.13 Complies with the Quality Assurance Program, the Safety Program, and all other policies and procedures applicable to the OSBI's CODIS Unit.

5.3.8.14 May also serve as the CODIS Supervisor. If so, the CODIS Administrator shall fulfill the requirements of a CODIS Supervisor as specified in this policy.

5.3.8.15 May also serve as a CODIS Analyst. If so, the CODIS Administrator shall fulfill the requirements of a CODIS Analyst as specified in this policy.

5.3.8.16 May also serve as a Casework Analyst. If so, the CODIS Administrator shall fulfill the requirements of a Casework Analyst, as specified in CSD FBU Policy Manual Quality Manual (FBU Policy Manual QM_5 Personnel).

5.3.8.17 Performs other duties, as assigned.

5.3.9 The CODIS Administrator shall meet the education requirements for an analyst as defined by this policy. In addition, a working knowledge of computers, computer networks, and computer database management is desired.

5.3.10 The CODIS Administrator shall be or have been a current or previously qualified forensic or database DNA analyst (as defined in this policy) with documented mixture interpretation training.

5.3.11 For the OSBI, the Casework CODIS Administrator position will be filled by the CODIS State Administrator. In the event that the Casework CODIS Administrator position is unoccupied, no casework profiles will be uploaded to NDIS.

5.4 CODIS Supervisor

The CODIS Supervisor has the authority to suspend any work performed in the CODIS Unit which does not comply with the OSBI CSD Quality System or any applicable quality standards.

5.4.1 Responsibilities:

5.4.1.1 Assist with management reviews as described in CSD QP 18 – Management Reviews and disseminate information regularly to members of the CODIS Unit.

5.4.1.2 Ensure each member of the CODIS Unit understands and follows all quality assurance procedures.

5.4.1.3 Know and follow the CSD Quality Assurance program.

5.4.1.4 Educate all members of the CODIS Unit in the implementation of the quality assurance and safety programs and confirm that all members of the Unit understand the importance of the program.

5.4.1.5 Monitor administrative review for the CODIS Unit.

5.4.1.6 To be knowledgeable regarding the quality of work produced by his/her staff.

5.4.1.7 Prepare administrative reports.

5.4.1.8 Assist in the coordination of administrative and fiscal activities.

5.4.1.9 Coordinate with the Technical Manager on assignment of DNA training.

5.4.1.10 Comply with the policies applicable to the OSBI CODIS Unit.

5.4.1.11 Act as a liaison with the courts, district attorneys, police agencies, other laboratories, private attorneys, and the public.

5.4.1.12 May also serve as the CODIS Administrator. If so, the CODIS Supervisor shall fulfill the requirements of a CODIS Administrator as specified by policy.

5.4.1.13 May also serve as a CODIS Analyst. If so, the CODIS Supervisor shall fulfill the requirements of a CODIS Analyst as specified by policy.

5.4.1.14 May also serve as a caseworking analyst. If so, the CODIS Supervisor shall fulfill the requirements of a Casework Analyst as specified in the FBU Policy Manual Quality Manual QM_5 Personnel.

5.4.1.15 Perform other duties, as assigned.

5.4.1.16 Make recommendations to improve quality within the Forensic Biology discipline and Criminalistics division.

5.4.2 Qualifications

The CODIS Supervisor shall meet the educational requirements for an analyst as defined in this policy. The CODIS Supervisor must have the education, training, and experience commensurate to perform duties as specified by the OSBI concerning the particular type(s) of analytical testing performed.

5.5 CODIS Analyst

5.5.1 A CODIS analyst shall be an employee of the OSBI who meets or exceeds the minimum education requirements as detailed in this policy. All analysts performing CODIS analysis must meet the minimum educational and experience requirements listed in the QAS.

5.5.2 A CODIS Analyst shall have a bachelor's (or its equivalent) or an advanced degree in a biology, chemistry, or forensic science related area and shall have successfully completed college course work (graduate or undergraduate level) covering the subject areas of biochemistry, genetics, molecular biology, and course work and/or training in statistics and/or population genetics as it applies to forensic or databasing DNA analysis.

5.5.2.1 The subject areas listed above shall constitute an integral component of any course work in order to be accepted.

5.5.2.2 Analysts appointed or hired after July 1, 2009 shall have a minimum of nine cumulative semester hours or equivalent that cover the required subject areas listed above.

5.5.2.3 Analysts who have completed course work with titles other than those listed above can still receive credit for the course through a combination of pertinent material, such as a transcript, syllabus, letter from an instructor, or other document that supports the course content. The Technical Manager must document approval of compliance with the subject area requirements.

5.5.2.4 For successful completion of college course work, a grade of "C" or above must be

obtained.

5.5.3 Each analyst will have at least 6 months of documented, human-DNA laboratory experience with at least 3 months in a forensic or database DNA laboratory before release for independent analysis.

5.5.3.1 If prior human DNA laboratory experience is accepted by the OSBI, the prior experience shall be documented and augmented by additional training, as needed, in the analytical methodologies, platforms and interpretations of human DNA results used by the OSBI.

5.5.4 The analyst shall complete the analysis of a range of samples routinely encountered in database analysis prior to independent work using DNA technology.

5.5.5 Typically, this requirement shall be satisfied by the successful completion of the CODIS Training Program. If the analyst has prior experience with analysis methods performed by the CODIS Unit, a modified training program can be implemented by the Technical Manager.

5.5.6 The analyst shall successfully complete a competency test before beginning an independent DNA analysis related tasks.

5.5.7 The analyst will receive in-house training and, if possible, training hosted by the Federal Bureau of Investigation (FBI) covering CODIS software.

5.5.8 The analyst will receive written notification from the Technical Manager and/or CODIS Administrator once he/she is considered competent to perform independent DNA analysis related tasks (hit verifications, offender sample analysis, data review, CODIS database software functions).

5.5.9 The analyst must participate in a proficiency testing program as per CSD QP 30 – Proficiency Tests.

5.6 Technical Reviewers

5.6.1 Each Technical Reviewer shall be a current or previously qualified analyst in the methodologies being reviewed.

5.6.2 Each Technical Reviewer shall participate in the external proficiency testing on the same technology, platform, and typing amplification kit used to generate the DNA data being reviewed.

5.7 CODIS Laboratory Technicians

5.7.1 Laboratory technicians shall have a high school diploma with some laboratory experience preferred.

5.7.2 Laboratory technicians shall have documented training specific to their job function(s).

5.7.3 Laboratory technicians shall successfully complete a competency test before participating in CODIS analysis.

5.7.4 General job functions include but are not limited to general housekeeping, accessioning of offender samples, shipping offender kits, inventory, and clerical duties.

5.7.5 Laboratory technicians shall know, understand, and apply quality procedures that are applicable to the CODIS Unit and notify the Technical Manager and/or CODIS Supervisor of any concerns relating to the quality assurance program of the Division. *[ref. CSD QM, QP 1]*

5.8 Laboratory Support Personnel

5.8.1 Any laboratory support personnel shall have documented training specific to their job function(s).

ATTACHMENT(S):
OSBI Memo titled: "Additional Selective Qualifications for Biologist Position with the OSBI"

REFERENCE(S):
OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories
Forensic Biology Selective Qualifications Memo
FBI's National DNA Index System (NDIS) Procedures

CODISQM_6 FACILITIES (top ↑)

The OSBI's CODIS Unit shall have facilities that are designed to ensure the integrity of the analyses performed and the samples maintained.

6.1 The procedures for cleaning and decontaminating facilities and equipment are specifically addressed in QC_1.

6.2 Access to the CODIS Unit Laboratory shall be controlled and limited in a manner to prevent access by unauthorized personnel.

6.3 Only persons authorized by the laboratory director will have access to the CODIS Unit Laboratory. This is done in accordance with procedures outlined in CSD QP 20 – Lab Security.

6.4 Techniques performed prior to PCR amplification (such as sample accessioning, DNA extraction (as applicable), and PCR setup) shall be conducted at separate times or in separate spaces from each other.

6.5 Amplified DNA product (including real-time PCR) shall be generated, processed and maintained in a room(s) separate from the sample accessioning, DNA extractions (as applicable) and PCR setup areas. The doors between rooms containing amplified DNA and other areas shall remain closed.

6.6 A robotic workstation may be used to carry out DNA extraction (if applicable), quantitation (if applicable), PCR setup and/or amplification in a single room, provided that the analytical process has been validated in accordance with Standard 8 of the FBI's Quality Assurance Standards for DNA Databasing Laboratories. If the robot performs analysis through amplification, the robot shall be housed in a separate room from that used for initial sample accessioning.

6.7 The CODIS Unit shall follow written procedures for cleaning and decontaminating facilities and equipment as specified by policy.

REFERENCE(S):
OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_7 SAMPLE CONTROL (top ↑)

The OSBI's CODIS Unit shall have and follow a documented sample inventory control system to ensure the integrity of database samples.

7.1 All database samples shall be marked with a unique identifier.

7.1.1 This will be performed upon receipt of the samples when logged into the OSBI Laboratory Information Management System (LIMS). The CODIS Analyst or Technician entering the samples into CoDNA is required to check each sample to ensure the samples are in numerical

order with no duplicates or missing numbers at the end of each accessioning session.

7.2 The number assigned by the LIMS system will be according to the following guidelines: Sample Type (last two digits of the year received) – (sequential number for that year).

7.2.1 The sample types used in the CODIS Unit are "C" (convicted offender), "A" (arrestee), and "P" (proficiency). For example, a CODIS sample labeled C15-001000 would represent convicted offender sample number 1000 received in the year 2015.

7.3 Documentation of sample identity, collection, receipt, storage and disposition shall be maintained by the CODIS Unit.

7.3.1 Offender database samples maintained by the OSBI's CODIS Unit are considered reference materials, not evidence, and therefore so not have a chain of custody associated with them.

7.4 Offender samples shall be stored in a secure area with environmental control consistent with the form or nature of the samples being stored.

7.5 The OSBI will permanently retain all offender samples unless meeting the requirements for expungement as outlined in this document. This is done to allow retesting of offender samples for quality assurance purposes (such as validations, quality control, and future testing due to technological advances) and sample confirmation purposes, as needed (such as hit verification procedures).

7.5.1 Duplicate offender samples may be retained at the discretion of the CODIS Administrator. Failed samples for which a suitable replacement has been received may be discarded at the discretion of the CODIS Administrator (or designee).

7.6 According to Oklahoma Statute Title 74 § 150.27a, offender samples are obtained for the purpose of DNA databasing only. An offender sample shall not be analyzed as a substitute for a legally obtained known reference sample.

7.7 The CODIS Unit shall follow written procedures designed to minimize loss, contamination, and/or deleterious change of samples and work product in progress.

REFERENCE(S):

OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_8 VALIDATION (top ↑)

8.1 The OSBI Forensic Biology discipline shall use only validated methodologies for DNA analyses. The OSBI CODIS Unit shall define within the validation plan, in addition to the requirements of QP 21.2 – Validations, whether the proposed validation is developmental or internal and conduct validations in accordance with CSD QP 21.1 – Research and/or CSD QP 21.2 – Validations.

8.2 If the validation is developmental, the OSBI CODIS Unit shall follow QAS Standard 8.2.

8.2.1 Developmental validation shall be performed prior to the use of a novel methodology used for DNA database analysis.

A. Developmental validation studies shall include (where applicable) characterization of the genetic marker, species specificity, sensitivity studies, stability studies, reproducibility, database-type samples, population studies, mixture studies, precision and accuracy studies, and PCR-based studies.

B. PCR based studies include reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies.

C. All validation studies performed shall be documented.

D. Peer reviewed publication of the underlying scientific principle(s) of the technology being tested shall be required.

8.3 Internal Validations

If the validation is internal, the OSBI CODIS Unit shall follow QAS Standard 8.3. For internal validations, the OSBI CODIS Unit may obtain the developmental validation documentation from the original laboratory or company or establish through citation and publications that the original developmental validation sufficiently addressed Standard 8.2.1 prior to beginning the internal validation.

8.3.1 In accordance with the QAS and the OSBI CSD QP 21.2 – Validations, the OSBI CODIS Unit shall complete internal validations utilizing the following general order of events: (1) submit validation plan per OSBI CSD QP 21.2 – Validations, (2) perform system and site-specific validation studies, (3) submit documentation and summary for approval, (4) complete individual competencies, and (5) release validated procedure for use in forensic or databasing DNA analysis.

8.3.2 Internal validation of all methods shall be reviewed and approved by the Technical Manager prior to implementing a new procedure.

8.3.3 All validation studies shall be documented, summarized, and made available to all members of the CODIS Unit and the Technical Manager.

8.3.4 Each internal validation study shall define the quality assurance parameters and interpretation guidelines.

8.3.5 A complete change in detection platform or test kit shall require an internal validation.

8.3.6 If an expert system is used to review profiles, the expert system shall be validated in accordance with applicable NDIS operational procedures prior to uploading these profiles to NDIS.

8.3.7 Internal validation of robotics shall be conducted and documented to the extent they are used by the CODIS Unit.

8.3.8 Internal validation studies shall include the following, as applicable:

- Database Type Samples
- Reproducibility and Precision Studies
- Sensitivity and Stochastic Studies
- Contamination Assessment
- NIST Traceable Samples

8.4 Individual Competency – Before a validated methodology is introduced into the CODIS Unit, each analyst shall successfully complete a competency test(s) to the extent of the analyst's participation in database analyses.

8.5 Introduction of a Modified Procedure – The performance of any modified procedure shall be evaluated by comparison with the original procedure using similar DNA samples prior to the modified procedure being used on database samples. The Technical Manager will decide if a procedural change is truly a modification. Modifications to procedures shall be handled in accordance with procedures in CSD QP 21.1 – Research and/or CSD QP 21.2 – Validations.

8.6 Critical Instruments

8.6.1 Introduction of Critical Instruments - Each additional critical instrument (of the same model as another critical instrument previously validated) requires a performance check. Purchase of a new critical instrument (of a different model or with a change in the analysis software, etc.) requires internal validation of the new instrument.

8.6.2 Modification to Critical Instruments - The Technical Manager should evaluate each critical instrument modification to determine the level of evaluation (performance check versus internal validation) required prior to using the modified critical instrument in casework. Modifications that do not affect the analytical process by the instrument require only a performance check.

Modifications to Instrument Software - Software modifications that do not impact interpretation or the analytical process require a performance check prior to implementation. New software or software modifications that impact interpretation, the analytical process, or sizing algorithms require internal validation prior to implementation. The Technical Manager should evaluate each software modification to determine the level of evaluation (performance check versus internal validation) required prior to using the modified software in casework.

REFERENCE(S):
OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_9 ANALYTICAL PROCEDURES (top ↑)

9.1 This document and corresponding documents represent the CODIS Unit's analytical procedures. This document will be reviewed and approved annually by the Technical Manager and CSD Division Director independent of internal and/or external audits. The documented review shall be conducted in accordance with CSD QP 2 – Document Control. Documentation of changes will be noted in the history section, and previous revisions will be archived.

9.2 The "Start Date" for analysis will be the date the sample is punched and the "End Date" will be the date the technical review form is signed.

9.3 The CODIS Unit shall follow the standard operating procedures outlined in this document and the corresponding documents. OSBI CODIS Unit analytical procedures shall contain the following, as applicable:

- Reagents and Supplies
- Sample Preparation
- Extraction Method
- Equipment (Critical Equipment as listed in CODISQM_10)
- Controls
- Individual Steps of the Procedure
- Interpretation of Results (section CODIS_7)

9.4 Reagents

9.4.1 The OSBI CODIS Unit shall follow the OSBI CSD QP 8 – Ordering, Receiving, and Verifying Reagents and Supplies.

9.4.2 In addition to the labeling requirement of OSBI CSD QP 8 – Ordering, Receiving, and Verifying Reagents and Supplies, the name of the reagent must be on the container.

- If changes have been made to the product insert, the Technical Manager shall be notified.
- Items that are too small to legibly record all the required information are exempt from the labeling and date opened requirements, as long as the storage container is labeled with all the appropriate information. Generally, this only applies to tubes

from kits.

- Reagents shall be considered expired at 11:59 p.m. on the expiration date. Reagents with a manufacturer's expiration date of month/year shall expire at 11:59 pm on the last day of the month.

All supporting documentation for function verification tests should include the reagent name or set of reagents (if tested together), date, initials, and page number.

9.5 Critical Reagents

9.5.1 Critical Reagents - DNA

PowerPlex® Fusion Direct Amplification Kits

The CODIS Unit shall have and follow a documented procedure for the resolution, verification, and reporting/notification of database matches.

The criteria for monitoring analytical procedures through the evaluation of controls and standards shall be specified in the applicable analytical procedures. The OSBI CODIS Unit shall, at a minimum, adhere to the following requirements.

9.5.2 Positive and Negative (Reagent Blank) Amplification Controls associated with the database samples being typed shall be amplified concurrently in the same instrument with the samples and typed at all loci using the same primers as the database samples on the sample instrument model, injection conditions, and the most sensitive volume of the sample set.

9.5.3 The CODIS Unit shall use allelic ladders and internal size markers for variable number tandem repeat sequence PCR based systems.

9.5.4 The CODIS Unit will check its DNA procedures annually or whenever substantial changes are made to a procedure against an appropriate and available NIST standard reference material or standard traceable to a NIST standard.

- The annual check, at a minimum, shall be from amplification to characterization.

9.6 For interpretation of data and verification of control results see CODIS_6 and CODIS_7. The interpretation can be performed by a qualified CODIS analyst or by an NDIS approved and internally validated expert system.

9.7 Detection and Control of Contamination

The OSBI CODIS Unit shall monitor contamination, follow decontamination protocols to minimize/prevent contamination, and follow procedures for interpreting data potentially affected by contamination.

Following any contamination event, the CODIS Unit will follow a decontamination procedure (as determined by the Technical Manager) that is proportional to the type of contamination event.

REFERENCE(S):

OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_10 EQUIPMENT CALIBRATION AND MAINTENANCE (top ↑)

10.1 The OSBI CODIS Unit shall use equipment suitable for the methods employed.

10.1.1 In the event that the OSBI CODIS Unit does not have suitable equipment for the methods used

at the OSBI, the Technical Manager shall suspend DNA laboratory operations, utilizing OSBI CSD QP 13 – Non-Conforming Work, until such time that the DNA testing at the laboratory re-establishes the suitability of the equipment.

10.1.2 The OSBI CODIS Unit shall follow OSBI CSD QP 24 – Calibration and Handling of Equipment.

10.1.3 Equipment will be checked (i.e. function verification) or calibrated before being placed into service. This check can be accomplished by completed the Performance Check as outlined in the section of this Policy titled "Performance Checks on Critical Instruments and Equipment" or by reviewing and archiving the calibration certificate received, as long as the company issuing the certificate is ISO 17025 compliant. A review and archiving of a calibration certificate is not sufficient to satisfy the requirements of a performance check as required for new critical instruments or equipment or equipment that has undergone repair, service, or calibration. These categories require a performance check before use in database analysis.

10.2 Documentation

10.2.1 Any service, maintenance, calibration, or repair performed on laboratory equipment must be recorded on the equipment and maintenance log and maintained by the laboratory.

10.2.2 A performance check/calibration must be documented.

10.2.3 Laboratory equipment shall be used as recommended by the manufacturer or as specified in analytical protocols.

10.3 Unsatisfactory Equipment or Instrument Performance

- If laboratory equipment does not function as expected, OSBI CSD QP 24 – Calibration and Handling of Equipment will be followed.
- The Technical Manager, supervisor, or designee shall make arrangements for needed service or replacement of the unit.
- Service performed on a unit shall be recorded on the equipment maintenance log and maintained by the laboratory.

10.4 Critical Equipment

10.4.1 The following will be considered critical instruments/equipment and shall require annual performance checks as per the quality control procedures:

- Thermometer traceable to national or international standard(s) that is used for conducting performance checks
- Balance/scale
- Robotic Systems
    - The Preventive Maintenance (PM) from a Beckman Coulter technician is not considered to be "repair, service, or calibration" and does not require a full performance check prior to offender analysis.
- Thermal Cycler temperature verification system
- Thermal Cycler including quantitative-PCR
- Electrophoresis Detection Systems
- Genetic Analyzers
    - The PM visit from an Applied Biosystems technician is not considered to be "repair, service, or calibration" (unless the laser is replaced or the optics are adjusted) and does not require a full performance check prior to offender analysis. The plate documentation and the electropherograms of a positive control, negative control, and a ladder from the first plate run subsequent to a PM will be copied and placed into the 3500xL Maintenance network folder.
- Mechanical pipettes
- Expert Systems
    - Any expert system used requires a quarterly recertification.

10.4.2 New critical instruments and equipment or critical instruments that have undergone repair, service, or calibration shall undergo a performance check before use in database analysis. For the CODIS Unit, this includes:

- Electrophoresis Detection Systems
- Robotic Systems
- Genetic Analyzers
- Thermal Cyclers (including quantitative-PCR)
- Expert Systems

10.5 Schedule and Maintenance Program

10.5.1 The schedule and maintenance program for instruments and equipment shall follow the requirements in the quality control procedures for equipment.

10.5.2 The records associated with the instrument or equipment should be portable for permanent instrument or equipment transfers within the multi-laboratory system.

10.5.3 In the event an instrument or equipment is permanently removed from service, the records should be archived and accessible for historical purposes.

REFERENCE(S):

OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_11 DOCUMENTATION/REPORTS (top ↑)

11.1 The OSBI CODIS Unit shall have and follow written procedures for maintaining documentation for database samples.

11.2 The CODIS Unit shall maintain all analytical documentation generated by analysts related to database analysis. This documentation can be retained in electronic and/or hard copy format. Documentation retained must be sufficient to support the profile data such that another qualified individual could evaluate and interpret the data.

11.2.1 The OSBI CODIS Unit "Abbreviation List" shall be maintained according to OSBI CSD QM.

11.3 Confidentiality of Database Samples, Records, and Information

11.3.1 Except as otherwise provided by state or federal law, the CODIS Unit shall have and follow written procedures to ensure the confidentiality of the database samples, DNA records, and the information contained in the CODIS database.

11.3.2 The OSBI CODIS Database is specifically exempt from any statute requiring disclosure of information to the public. The information contained in the database is privileged from discovery and inadmissible as evidence in any civil court proceeding. The information in the database in confidential and shall not be released to the public.

11.3.3 Any person charged with the custody and dissemination of information from the database shall not divulge or disclose any such information except to federal, state, county, or municipal law enforcement or criminal justice agencies. Any person violating the provisions of this section upon conviction shall be deemed guilty of a misdemeanor punishable by imprisonment in the county jail for not more than one year.

11.3.4 The OSBI shall promulgate rules concerning the collection, storage, expungement, and dissemination of information and samples for the OSBI CODIS Database. *[Oklahoma Statute Title 74 Section 150.27a]*

11.4 Release of DNA Samples and Records

11.4.1 In accordance with the Oklahoma Statute Title 74 Section 150.27a, and the Memorandum of Understanding between the OSBI and the Federal Bureau of Investigation (FBI), stored DNA samples and analyses may be released only:

- To criminal justice agencies for identification purposes;
- In judicial proceedings, if otherwise permissible pursuant to applicable statutes or rules;
- For criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or
- If personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes.

11.5 Release of Personally Identifying Information

11.5.1 In accordance with Oklahoma Statute Title 74 Section 150.27a, and the Memorandum of Understanding between the OSBI and the Federal Bureau of Investigation (FBI), the following information may be released to individuals representing any law enforcement agency (included but not limited to the Department of Corrections, Probation and Parole, court clerks, and the District Attorney's Office):

- Information regarding whether or not an offender sample was received;
- The date the sample was received; or
- Whether or not the profile from that sample has been entered into the CODIS database

  Note: Procedures regarding the release of personally identifiable information in connection with a database hit are detailed in the section of this manual titled "CODIS Hit Verification Procedures".

REFERENCE(S):

OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_12 REVIEW (top ↑)

12.1 The CODIS Unit shall have and follow written procedures for reviewing DNA records and database information, including the verification and resolution of database matches. An individual conducting Technical Reviews shall meet the requirements as described in CSD QP 31 – Reviews.

12.1.1 Offender Sample Analysis

12.1.1.1 Prior to uploading into or searching against the CODIS database, every sample within a batch of offender DNA samples analyzed shall be subjected to technical review.

- The Offender Sample Analysis Technical Review Form will be used to document the technical review of offender samples analyzed in-house. The review shall include the following, as minimum:
  - A review of all notes, worksheets, and the electronic data (or printed electropherograms or images) supporting the results.
  - A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images). The review of the DNA types may be accomplished by an NDIS approved and internally validated expert system.
  - A review of the controls, internal lane standards, and allelic ladders to verify the expected results were obtained.
  - A review to confirm that re-worked samples have appropriate controls.

- A review that the correct CODIS specimen category is assigned to all samples included in the cmf file.

12.1.2 The Offender Sample Analysis Technical Notes will be used to document which samples (analyzed in-house) need further analysis, if applicable.

12.1.3 Hit Verifications

12.1.3.1 Prior to the release of personally identifying information associated with a database hit, the official correspondence (hit letter) shall be subjected to an administrative review.

- The Offender Hit Verification Administrative Review Form will be used to document the administrative review of hit verifications. The review shall include the following, at minimum:
  - A review of the supporting documentation and the correspondence for clerical errors, accuracy of information, and adherence to CODIS Policy.
  - A review of the individual's biographical data, qualifying offense, and DNA profile generated from re-analysis (as applicable).

12.1.4 Unresolved Discrepant Conclusions

12.1.4.1 The CODIS Unit shall have and follow a documented procedure to address unresolved discrepant conclusions between analysts and reviewers.

- Discrepancies between CODIS Analysts and reviewers shall be handled on an individual basis. If a CODIS Analyst does not agree with the opinion of the technical reviewer, he/she must make it known to that reviewer at the time. Unresolved discrepant conclusion will be resolved using the following methods:
  - In cases where the issue can be resolved by re-analysis of the sample(s) in question, that remedy should be performed first.
  - In cases where the issue cannot be resolved by re-analysis, the Technical Manager will make the final determination.
  - In accordance with CSD QP 31 – Reviews, any issues that cannot be resolved by the Supervisor and/or Technical Manager, will be brought to the Criminalistics Administrator assigned to the CODIS Unit for further evaluation.

12.2 The OSBI CODIS Unit shall follow OSBI CSD QP 32 – Testimony to document annual monitoring of courtroom testimony.

REFERENCE(S):
OSBI CSD Quality Manual
OSBI Forensic Biology Unit Policy Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_13 PROFICIENCY TESTING (top ↑)

13.1 The OSBI CODIS Unit shall follow OSBI CSD QP 30 – Proficiency Tests.

13.2 Proficiency testing records will be maintained and evaluated in accordance with the procedures outlined in CSD QP 30 – Proficiency Tests.

13.3 The CODIS Unit shall use an external proficiency testing provider as detailed in CSD QP 30 – Proficiency Tests.

13.4 Analysts, technical reviewers, technicians, and other personnel designated by the Technical Manager, shall undergo semi-annual external proficiency testing in each technology performed to the fullest

extent in which they participate in database analysis.

13.4.1 Individuals using both manual and automated methods shall be proficiency tested in each, at least once per year, to the full extent in which they participate in casework.

13.4.2 Newly qualified analysts and technicians shall enter the external proficiency testing program within six months of the date of their qualification.

13.4.3 Each analyst shall be assigned to complete his/her own external proficiency test.

- Laboratories that use a team approach to database analysis may do so for external proficiency tests. However, all analysts, technical reviewers, and technicians shall be proficiency tested at least once per year in each of the DNA technologies (including test kits for DNA typing and each platform in which they perform database analyses) to the fullest extent in which they participate in database analyses.

13.4.4 The OSBI CODIS Unit shall use the **due date** as the date that the proficiency test was performed.

13.4.5 Analysts and technicians shall type all CODIS core loci for each technology performed during each proficiency test.

13.4.6 Proficiency tests will be tracked in accordance with CSD QP 30 – Proficiency Tests.

13.4.7 Proficiency Tests will be submitted to the manufacturer using the online submission option available.

13.4.7.1 Each analyst will notify the Quality Manager of the completion of their test by sending an e-mail to the Quality Manager with the completed Manufacturer's results forms attached.

13.4.8 Evaluation of Proficiency Test Results shall include the following:

- Reported inclusions and exclusions were correct (if applicable);
- All reported genotypes and/or phenotypes are correct according to consensus results or are within the laboratory's interpretation guidelines;
- Inconclusive or not interpretable results are consistent with written laboratory guidelines and have been reviewed by the Technical Manager;
- All discrepancies/errors and subsequent corrective actions are documented; and
- All final reports are graded as satisfactory or unsatisfactory
  - A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data
  - Administrative errors and corrective actions are documented

13.4.9 Notification of Proficiency Test Results - Analysts shall be informed of his/her final test results and the notification documented prior to issuance of a subsequent proficiency test.

13.4.10 The Technical Manager shall be informed of the results of all participants and this notification shall be documented as per OSBI CSD QP 30 – Proficiency Tests. The Technical Manager shall inform the casework CODIS administrator of all non-administrative discrepancies that affect the typing results and/or conclusions at the time of discovery.

13.5 External Proficiency Test Provider Stipulation - The laboratory shall use an external proficiency test provider approved by the American Society of Crime Laboratory Directors/ Laboratory Accreditation Board (ASCLD/LAB).

REFERENCE(S):

OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

CODISQM_14 CORRECTIVE ACTION (top ↑)

14.1 The OSBI CODIS Unit shall establish and follow a corrective action plan to address when discrepancies are detected in proficiency tests and database sample. The corrective action plan shall define what level/type of discrepancy, corrective actions taken, and preventative measures taken (when applicable) to minimize its recurrence. The CODIS Unit will follow OSBI CSD QP13 – Non-Conforming Work and QP 14.1 – Simple Corrections, QP 14.2 – Corrective Action and QP 14.3 – Non-Conforming Results policies, as well as OSBI Agency Policy #110 – OSBI Progressive Discipline, as needed.

14.2 All corrective actions applicable to database analysis or proficiency tests shall not be implemented without the documented prior approval of the Technical Manager.

- Discrepancies detected during proficiency tests shall be handled in accordance with the procedures outlined in CSD QP 30 – Proficiency Tests, and if necessary, CSD QP 13 – Non-Conforming Work and CSD QP 14 – Corrective Action.
- Discrepancies detected during database analysis shall be reported to the Technical Manager for evaluation. If the discrepancy is determined to be non-conforming work, procedures outlined in CSD QP 13 – Non-Conforming Work and CSD QP 14 – Corrective Action shall be followed. All other discrepancies shall be handled at the discretion of the Technical Manager.

14.3 The Technical Manager shall maintain access to a final version of all corrective actions involving analysts within the Forensic Biology discipline for corrective actions applicable to casework or proficiency tests.

REFERENCE(S):
OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_15 AUDITS (top ↑)

15.1 The OSBI CODIS Unit laboratory shall be audited annually against the QAS Audit Document, at minimum. The annual audits must occur every calendar year and be at least 6 months and no more than 18 months apart.

15.2 At least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors (as per the QAS) from an outside agency. At least one team member shall be currently or previously qualified in the current DNA technologies and platform(s) utilized in the CODIS Unit, and at least one team member who is currently or was previously a qualified analyst from a databasing laboratory. The audit team may consist of one or more individuals.

- Each analyst, CODIS Administrator, and Technical Manager shall have his/her education, experience, and training qualifications evaluated and approved during two successive, separate external audits conducted after July 1, 2004. Approval shall be documented in the audit document.
- Each validation shall be evaluated and approved during one external audit. Approved validation studies shall be documented in the audit document.

15.3 For internal audits, at least one auditor or member of the audit team shall be a currently qualified auditor and a currently or previously qualified analyst in the laboratory's current DNA technologies, methods and platform. All internal audits shall be conducted according to OSBI CSD QP 17 – Audits. Internal Audits will be conducted by an audit team comprised of at least one currently qualified auditor, and one currently or previously qualified analyst in the current technologies and platform(s) used in the CODIS Unit. The audit team may consist of one or more individuals.

15.4 Internal and external DNA Audit documents and, if applicable, corrective action(s) shall be submitted to the Technical Manager for review to ensure that findings, if any, were appropriately addressed.

15.4.1 For NDIS participating laboratories, all external audit documentation and laboratory responses shall be provided to the FBI within 30 days of laboratory receipt of the audit documents or report.

15.5 Internal and external audit documentation shall be retained and available for inspection during subsequent audits.

ATTACHMENT(S):
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories – Audit Document
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories – Audit Document

REFERENCE(S):
OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_16 SAFETY (top ↑)

16.1 The OSBI CODIS Unit shall follow the agency wide OSBI Safety Plan - Policy 121 and all subsections.

16.2 The OSBI's environmental health and safety program shall be reviewed once each calendar year and such review shall be documented in the History Section of the policy.

REFERENCE(S):
OSBI Safety Policy 121
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

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CODISQM_17 OUTSOURCING (top ↑)

The Forensic Biology Discipline Technical Manager will be consulted during bid specification composition for input and approval. The bid specifications shall include a statement indicating that the vendor laboratory is responsible for providing analysis as well as testimony on their analyses of the evidence.

17.1 The OSBI CODIS Unit will ensure the vendor laboratory complies with the FBI Quality Assurance Standards for DNA Databasing Laboratories and the accreditation requirements of ASCLD/LAB Legacy or ASCLD/LAB International Program. The OSBI CSD Quality Manager will be provided a copy of the accreditation certificate for any vendor laboratory utilized by the CODIS Unit.

17.1.1 The following documentation will be maintained from the vendor laboratory:

17.1.1.1 Proof of compliance with the FBI Quality Assurance Standards for DNA Databasing Laboratories and compliance with the accreditation requirements of federal law.

17.1.1.2 A copy of the vendor laboratory's most recent external audit document (relative to the time period the contract lab is performing analysis for the OSBI) and accreditation certificate shall be provided by the vendor laboratory and maintained at the OSBI.

17.1.1.3 An audit conducted by OSBI personnel may be required (at the discretion of the Technical Manager) prior to the acceptance of data for inclusion in the CODIS database.

17.1.1.4 Prior to DNA analysis being conducted, the vendor laboratory must guarantee compliance with confidentiality requirements as set forth by the OSBI.

17.1.1.5 The vendor laboratory will only use procedures approved by the OSBI CODIS Administrator and/or Technical Manager to analyze OSBI offender samples.

17.1.1.6 Contract analysis of offender samples will be performed at all CODIS core loci. Offender samples will not be considered complete unless results are obtained for all CODIS core loci.

17.2 The Technical Manager of the Forensic Biology discipline will document and maintain approval of the technical specifications of the outsourcing agreement before it is awarded. The OSBI shall maintain these documents.

17.2.1 No DNA generated by a vendor laboratory shall be entered into or searched against the CODIS database without the documented prior approval of the technical specifications of the outsourcing agreement and/or documented approval of acceptance of ownership of the DNA data.

17.3 The CODIS Unit shall have, follow and document appropriate quality assurance procedures to verify the integrity of the data received from the vendor laboratory including (but not limited to): *[ref. FBI QAS DDL, Standard 17.4]*

17.3.1 **Random re-analysis of samples** *[ref. FBI QAS DDL, Standard 17.4.1]*

For the purpose of Quality Control (QC), samples analyzed by the contract labora**to***ry may be randomly re-analyzed in* the OSBI laboratory or by a contract laboratory. The result obtained for this analysis must be the same as the initial result reported by the contract laboratory. Any discrepancy must be resolved to the satisfaction of the CODIS Administrator before the profile(s) will be accepted by the OSBI. The OSBI laboratory will maintain documentation of the re-analysis. If the same contract laboratory performs the re-analysis as performed the original analysis, the sample numbers will be changed so the result will not be known beforehand.

17.3.2 **Inclusion of QC Samples**

New batches of OSBI offender samples sent to a contract laboratory for analysis must contain a random selection of samples with a known DNA profile (e.g. blood/buccal sample from persons whose DNA profile is already known) included for the purpose of Quality Control. Other QC samples may be sent at the CODIS Administrator's discretion. The result of the QC analysis must be the same as the result of the original analysis. If not, the issue must be resolved to the CODIS Administrator's satisfaction before the data set will be accepted by the OSBI.

Note: The sum of any QC samples provided to the contract laboratory and those samples randomly re-analyzed will be approximately five (5) percent of the total number of offender samples analyzed by the contract laboratory. The OSBI may use either or both methods to assess the quality of the work produced by the contract laboratory.

17.4 On-site Visits

17.4.1 A documented initial in-site visit shall be performed prior to the vendor laboratory's beginning of DNA analysis for the CODIS Unit.

17.4.2 The on-site visit shall be performed by the Technical Manager or designated employee of an NDIS participating laboratory who is currently or previously qualified in the technology, platform, and typing amplification kit used to generate data. Alternatively, the Technical Manager may accept an on-site visit conducted by a designated employee of the FBI.

17.4.3 If the outsourcing agreement extends beyond one year, an annual on-site visit shall be required. Each annual on-site visit shall occur every calendar year and shall be at least 6 months and no more than 18 months apart.

17.4.4 The OSBI may accept an on-site visit conducted by the FBI or another NDIS participating laboratory using the same technology, platform, and typing amplification kit used for the generation of DNA data as long as it was conducted within the last 12 months. This on-site visit shall be reviewed, approved, and documented by the Technical Manager.

17.5 To ensure the integrity of data received from the vendor laboratory, the OSBI shall perform a technical review of all DNA data generated by the vendor laboratory prior to upload to or search against SDIS.

17.5.1 The technical review will be performed by an analyst or technical reviewer in the CODIS Unit (or Forensic Biology discipline) qualified in the same technology, platform, and typing amplification kit used to generate the data and who participates in the OSBI proficiency testing program in DNA analysis.

17.5.2 Technical reviews will include, at a minimum, the following elements:

17.5.2.1 A review of all DNA types to verify that they are supported by the raw and/or analyzed data (electropherograms or images).

17.5.2.2 A review of all associated controls, internal lane standards, and allelic ladders to verify that the expected results were obtained.

17.5.2.3 Verification of the DNA types and the correct specimen category for entry into CODIS.

17.5.2.4 Verification that peak height ratios, artifacts, allele designations, etc. are handled in accordance with the terms and conditions outlined in the contract between the OSBI and the vendor laboratory.

17.6 A portion of the technical review may be accomplished through the use of an NDIS approved and internally validated expert system.

17.6.1 The use of an internally validated NDIS approved expert system for outsourced samples is allowed only if the data was produced using the sample amplification kit, instrument model, and data collection software as the NDIS laboratory. Additional validation studies may be necessary before the use of an expert system on outsourced data.

17.7 Any profile not meeting standards will either be re-analyzed by the contract laboratory or analyzed in-house to obtain an acceptable result prior to uploading to or searching against SDIS.

17.8 All vendor laboratories must be accredited through the ASCLD/LAB Legacy or ASCLD/LAB International program or an organization that follows the ISO/IEC 17025 guidelines.

17.9 Ownership of Data

17.9.1 A vendor laboratory that is performing DNA analysis for a law enforcement agency (other than the OSBI) or other entity, and generating DNA data that may be entered into or searched against CODIS, shall not initiate analysis until documented approval has been obtained from the Technical Manager of acceptance of the ownership of the DNA data.

17.9.2 The vendor laboratory will destroy all DNA extracts, dilutions, and amplified products (as applicable) after the analysis has been completed. Documentation of this destruction must be provided to the OSBI.

17.9.3 All OSBI offender samples and data generated from analysis of these samples by a contract laboratory are the property of the State of Oklahoma and will be returned to the OSBI after analysis is complete. The data may include , but is not limited to:

17.9.3.1 The original run data files generated during the course of analysis;

17.9.3.2 Software (GeneMapper ID, GeneMapper ID-X) files;

17.9.3.3 Common Message Format (CMF) data files

After receiving the data files from the vendor laboratory, the OSBI CODIS Unit, within a reasonable amount of time will scan and/or copy the data and store it on the CODIS server in an appropriately named file. Hard copies may still be maintained, but they will not be destroyed or discarded until after the transfer of the data has been confirmed.

17.10 **Quality Control of Casework Data** - The vendor laboratory casework data (case records) must be handled in accordance with the procedures outlined in the Forensic Biology Unit Policy Manual prior to entry into or search against SDIS.

REFERENCE(S):

OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

CODISQM_18 DATA MANAGEMENT (top ↑)

18.1 Storage of Electronic Data

A. The original run data files and GeneMapper ID-X files generated during the course of analysis will be recorded in an electronic format (such as CD-R, DVD, etc) and/or maintained in a dedicated storage server.

B. When possible, DNA profile data to be imported directly into CODIS will be recorded sequentially in an electronic format, in Windows-compatible Common Message Format (CMF).

C. The original electronic data will be archived by the OSBI laboratory.
Note: A designated storage server can be utilized to store archived electronic data on a long term basis. However, it is important that the server is backed up on a regular basis. This may include daily tape backups stored on site, weekly tape backups stored on site, and/or monthly tape backups stored off site.

18.2 Storage of Hard Copy Data

A. All offender data and/or records received in hard copy form from a vendor laboratory will be archived by the OSBI and maintained for inspection. If both electronic and hard copy data exists, the hard copy data may be destroyed and the electronic data and documentation retained for inspection.

B. All offender data and/or records generated in hard copy form by the OSBI laboratory during analysis may be archived electronically and maintained for inspection.

Note: A designated storage server can be utilized to store archived electronic data on a long term basis. However, it is important that the server is backed up on a regular basis. This may include daily tape backups stored on site, weekly tape backups stored on site, and/or monthly tape backups stored off site.

18.3 CODIS Database Security Measures

It is the responsibility of the CODIS Administrator (or designee) to ensure the integrity and security of the CODIS database. This will be accomplished by ensuring the following procedures/practices are followed.

A. Only CODIS users shall have access to the CODIS database. A CODIS user is defined as a government employee who: *[ref. FBI NDIS, Security Requirements]*

1. Has login access to the CODIS database and is authorized to read, add, modify or delete DNA records in CODIS; or
2. Is a qualified DNA analyst responsible for producing DNA profiles stored in CODIS

B. The CODIS Administrator, or designee, will issue each CODIS user his/her own CODIS user account and password. It will be the responsibility of the CODIS user to change the password on first login. CODIS users shall not release their password to any other individual, including the CODIS Administrator; however, the CODIS Administrator, or designee, can reset passwords when necessary.
Note: Each CODIS user shall change his/her password to CODIS at least once every six months. For best practices, it is recommended the password be changed every 90 days.

C. Each CODIS user shall use his/her individual user name and password to login to the CODIS terminal and/or server containing the CODIS software. CODIS users are not permitted to share user names or passwords.

D. For CODIS users not authorized to access CODIS software applications, but still requiring access to the CJIS-WAN (Criminal Justice Information Services Wide Area Network), their individual account permissions will be set to prevent them access to modify CODIS data.

E. When logged onto the CODIS terminal and/or server, the CODIS user shall lock their screen or log off before moving to an area in which the user can no longer visually observe the CODIS terminal/server. All CODIS terminals and/or servers shall be set to lock the screen after ten minutes of non-use and require the CODIS user's password to unlock the screen.

F. Concurrent logins (logging onto two separate terminals or a server and a terminal with the same user name and password simultaneously) shall be prohibited.
Note: For administrative purposes, the CODIS Administrator or backup CODIS Administrator shall be permitted to log onto multiple computers concurrently if the computer(s) not directly in use is locked and requires a password for use. *[ref. FBI NDIS, Security Requirements]*

G. The CODIS software shall be installed on a computer that does not have internet access unless prior written approval for the use of a firewall has been obtained from the FBI.

H. CODIS software enhancements provided by the FBI will be implemented in accordance with NDIS Policy and Procedures.

I. The CODIS Unit shall conduct backups of the CODIS data on a routine schedule, but not less than once per week.

J. On a routine schedule, but not less than once per month, this backup media shall be stored at a secure physical location other than the OSBI's Forensic Science Center. This may include another NDIS participating laboratory, another building within the OSBI that is subject to the same security requirements, or a bank safety deposit box.
Note: Electronic media on which CODIS data is stored shall be maintained in a lockable container.

K. It is also recommended that anti-virus definitions be updated regularly (weekly or monthly, depending on upload frequency) to prevent corruption of critical CODIS data.

18.4 Removal Procedures / Expungements

The OSBI recognizes the need to remove from the CODIS database all DNA profiles which may have been improperly included in the database, or the known DNA profile of an individual whose qualifying offense has been removed by court action. The following procedures are designed to ensure the rights of individuals are protected by allowing for removal of any DNA profile which does not meet the Oklahoma statutory requirements for inclusion in the CODIS database.
Note: A known DNA profile can be from any legally obtained known reference sample, including convicted offender samples, arrestee samples, and/or legal samples.

A. **Removal of Non-Qualifying Samples**
Any known DNA profile from an individual included in the database through erroneous collection by an authorized collection facility may be administratively removed from the OSBI CODIS Database by one of two mechanisms:

1. By letter from the authorized collection facility, signed by the appropriate official, stating a blood or buccal sample was erroneously collected from the individual in question and sent to the OSBI for inclusion in the database.

2. The OSBI Laboratory Director, or designee, can order removal of a DNA profile from the database, if, after review by an OSBI CODIS Analyst, it is determined no qualifying offense exists to justify inclusion in CODIS.

3. An individual wishing to petition the OSBI for removal of their DNA profile from CODIS must provide such a request in writing to the OSBI. The OSBI CODIS Analyst will make a determination as to the requestor's status in CODIS and provide the Laboratory Director, CODIS Administrator, or designee, a recommended course of action to assure the OSBI and CODIS are in compliance with applicable statutes.

B. **Court Reversal of a Qualifying Conviction**
In accordance with the DNA Analysis Backlog Elimination Act of 2000 (42 U.S.C. Section 14132(d)(2)), in the event the courts overturn the qualifying offense of a convicted individual whose DNA profile is included in CODIS, the DNA profile may be expunged from CODIS. The OSBI must be notified, in writing, of the reversal and the subsequent need to expunge for each conviction of the person. This may be accomplished in writing from:

1. The District Attorney prosecuting the case stating that the qualifying offense has been removed. A certified copy of the final court order overturning the conviction must be provided to the OSBI. *[ref. 42 U.S.C. Section 14132(d)(2)]*

2. An individual (or legal counsel thereof) whose conviction has been overturned may request the DNA profile be expunged. Such a request must be in writing. A certified copy of the final court order overturning the qualifying offense must accompany the request. *[ref. 42 U.S.C. Section 14132(d)(2)]*

3. For these purposes, a court order is not considered "final" if time remains for an appeal or application for discretionary review with respect to the order. *[ref. 42 U.S.C. Section 14132(d)(2)]*

C. **Removal of a Non-Offender Sample**

In accordance with the amendments made by the DNA Fingerprint Act of 2005 (P.L. 109-162 (see 42 U.S.C. Section 14132(d)(2)(A)(ii)), individuals whose DNA sample was collected as the result of arrest, indictment, or other legal authority (such as suspect samples) may have their DNA profile expunged from CODIS in the event no charges were filed within the applicable time period, or the charge is dismissed or results in an acquittal. The OSBI must be notified, in writing, of the subsequent need to expunge for each charge against the person. This may be accomplished in writing from:

1. The District Attorney prosecuting the case stating that the qualifying offense has been removed. A certified copy of the final court order establishing that no charge was filed within the applicable time period, or that such charge has been dismissed or has resulted in an acquittal, must be provided to the OSBI. *[ref. 42 U.S.C. Section 14132(d)(2)(A)(ii)]*

2. An individual (or legal counsel thereof) whose sample was collected may request the DNA profile be expunged. Such a request must be in writing. A certified copy of the final court order establishing that no charge was filed within the applicable time period, or that such charge has been dismissed or has resulted in an acquittal, must accompany the request. *[ref. 42 U.S.C. Section 14132(d)(2)(A)(ii)]*

3. For these purposes, a court order is not considered "final" if time remains for an appeal or application for discretionary review with respect to the order. *[ref. 42 U.S.C. Section 14132(d)(2)(A)(ii)]*

D. **Laboratory Removal and Expungement Procedures**

Upon receipt of a proper written request for removal of a known DNA profile from CODIS (as described above), the CODIS Administrator or designee will verify through a criminal history check no other qualifying offense exists which would justify retention of the individual's profile in CODIS. If no other qualifying offense exists, the CODIS Administrator or designee will ensure the administrative removal or expunction of all information related to the DNA profile in question. This will include:

1. Removal of all identifying information from the Laboratory Information Management System (LIMS) associated with the sample number assigned to the individual in question. If applicable, the sample number record will be amended to indicate the reason the identifying information was expunged and the date of expungement.

2. Removal, if applicable, of all DNA profile information from all levels of the CODIS DNA database, including the State CODIS Database (SDIS) and the National CODIS Database (NDIS).
   Note: Removal of DNA profile information from NDIS may be requested in accordance with NDIS Operational Procedures.

3. Destruction of the original known reference DNA sample retained on file by the OSBI.

4. Completion of the Administrative Removal & Expungement Form.

E. **Notification**

Notification of administrative removal or expungement will be in writing from the CODIS Administrator or designee to the requestor on Official OSBI letterhead.

Note: In the event the DNA profile being expunged has generated a match through the CODIS database, the CODIS Administrator or designee will notify the CODIS Administrator from the other laboratory involved in the match, and inform them that an expungement is being performed.

F. **Documentation of Removal / Expungement**

The OSBI CODIS Unit will retain a copy of all documents relating to the removal or expungement including, but not limited to:

1. All correspondence and associated documentation, such as court orders, removal and/or expungement requests, criminal history, letters from NDIS, etc.

2. Completed Administrative Removal & Expungement Form

3. Letter(s) of notification to the requestor(s)

G. **Removal of Casework Profiles**

1. A Casework Analyst shall request that a forensic casework profile, which is found to be improperly included in the database, be removed from the CODIS database. The analyst must forward a completed CODIS Request for Profile Removal form to the OSBI CODIS Unit as specified in this policy.

2. The OSBI CODIS Unit will retain a copy of all documents relating to the removal of the forensic casework profile including, but not limited to the CODIS Request for Profile Removal form and a delete specimen report.

REFERENCE(S):

OSBI CSD Quality Manual
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories
FBI's National DNA Index System (NDIS) Procedures

CODIS Unit Policy Manual

CODIS Data Entry and Search Procedures (top ↑)

Policy
Procedure
- Indexes Maintained
  - Forensic, Unknown/Forensic Index
  - Forensic Partial/Forensic Partial Index
  - INC. Forensic STR/Incomplete Forensic Index
  - Forensic Mixture/Forensic Mixture Index
  - INC. For. Mixture/Incomplete Forensic Mixture Index
  - Missing Person/Deduced Missing Person/Missing Person Index
  - Relatives of Missing Person Index
  - INC. Unid. Remains/Inc Unidentified Human (Remains) Index
  - Unidentified Person/Unidentified Human (Remains) Index
  - Convicted Offender/Offender Index
  - INC. Offender STR/Incomplete Convicted Offender Index
  - Arrestee/Arrestee Index
  - Inc. Arrestee/Incomplete Arrestee Index
  - Multi-Allelic Offender
  - Legal/Legal Index
  - INC. Legal/Incomplete Legal Index
  - Staff/Employee Index
  - Contaminant Profile/Contaminant Index
  - Y-STR Profiles
- Definition of Acceptable Profiles
- Analysis of Casework Samples
- Analysis of Offender Samples
- Creating Specimen ID Numbers
- Request and Documentation of CODIS Data Entry
  - OSBI Casework Profile Data Entry
  - OSBI Casework Profile Notification of Database Entry
  - Local CODIS Laboratory Casework Profiles
  - Offender Profiles
- Conducting CODIS Searches
  - Remote Search Requests
  - Batch Target Searches
  - Familial Searches / Partial Matches
  - Routine Index to Index Searches
- Processing CODIS Matches
- Profile Removal

Annual Review/Updates

1.0 POLICY

This protocol defines allowed profiles, indexes, and searches of the State CODIS database (SDIS). This policy also specifically addresses the procedures a CODIS User must follow to request the entry of DNA data in SDIS.

A CODIS User is defined as a government employee who has login access to the CODIS system and is authorized to read, add, modify or delete DNA records in CODIS; or is a qualified DNA analyst responsible for producing DNA profiles stored in the National CODIS database (NDIS). *[ref. FBI NDIS, Terms and Abbreviations]*

2.0 PROCEDURE

2.1 Specimen Categories and Indexes Maintained:

In order to facilitate proper database searches, DNA profiles stored at SDIS are organized into several categories or indexes. Each index has certain criteria that must be met before a profile may be entered into the database or searched against other profiles stored in the database. A list of indexes maintained at SDIS and acceptable profiles for each index is listed below.

Note: New indexes may be added at the discretion of the CODIS Administrator or as provided by state statute (including but not limited to samples obtained from elimination reference samples, victim reference samples, and reference samples voluntarily provided by the public); however, such samples may not be eligible for inclusion in NDIS. *[ref. FBI NDIS, DNA Data Accepted at NDIS]*

A. **Forensic, Unknown/Forensic Index**

Single Source DNA profiles originating from and associated with evidence found at crime scenes, with no locus or allelic dropout at any of the CODIS Core Loci belong in the **Forensic, Unknown** specimen category.

The **Forensic Index** consists of DNA profiles in the Forensic, Unknown specimen category. The profiles must be single source with no locus or allelic dropout at any of the CODIS core loci (excluding Amelogenin). Profiles maintained in the Forensic Index will be forwarded to the FBI for inclusion in NDIS.

Note: Careful consideration should be taken to ensure these profiles meet all applicable NDIS guidelines before entry into the database. To help with this determination, the FBI's "Guide to Determining What is Allowable in the Forensic Index at NDIS" should be used. No profile from an evidentiary sample that matches the victim known or an exclusionary known (i.e. husband, boyfriend) shall be entered into CODIS. A profile which matches a suspect, obtained from an item belonging to that suspect (e.g. clothing or other article that would be expected to yield the owner's profile) is not considered an evidentiary sample and shall not be entered into CODIS.

B. **Forensic Partial/Forensic Partial Index**

Single Source DNA profiles originating from and associated with evidence found at crime scenes that have locus or allelic dropout at any of the CODIS Core Loci belong in the **Forensic Partial** specimen category. Forensic Partial profiles consist of at least 10 of the 13 CODIS core loci (excluding Amelogenin). Analysis at all core loci must be attempted. Forensic Partial Profiles shall be reviewed to ensure the DNA record satisfies a statistical threshold for match rarity of approximately one in the size of the NDIS database (NDIS match rarity statistical threshold). Loci where a partial profile is indicated shall be referenced with a "(p)" on the CODIS Data Entry Form. Casework analysts should keep in mind the reported inclusions/statistical values should a match occur to entries in this specimen category. If there would be no inclusion/statistical value for any profile matching to this specimen, the profile should not be entered into the CODIS database.

The **Forensic Partial Index** consists of DNA profiles in the Forensic Partial specimen category. The profiles must be single source and contain 10 to 13 of the CODIS core loci and meet the NDIS match rarity statistical threshold. Profiles maintained in the Forensic Partial Index will be forwarded to the FBI for inclusion in NDIS.

Forensic Partial profiles that exist in the CODIS database prior to January 25, 2013 are not required to meet the NDIS match rarity statistical threshold.

C. **INC. Forensic STR/Incomplete Forensic Index**

Partial, single source DNA profiles with results at more than 8 loci, but with less than 10 loci or that do not meet the NDIS match rarity threshold that originate from and are associated with evidence found at crime scenes belong in the **INC. Forensic STR** specimen category. Loci where a partial profile is indicated shall be referenced with a "(p)" on the CODIS Data Entry Form. Casework analysts should keep in mind the reported inclusions/statistical values should a match occur to entries in this specimen category. If there would be no inclusion/statistical value for any profile matching to this specimen, the profile should not be entered into the CODIS database.

The **Incomplete Forensic Index** consists of DNA profiles in the INC. Forensic STR specimen category. These single source profiles contain 8 to 9 of the 13 CODIS core loci (excludes Amelogenin) or do not meet the NDIS match rarity statistical threshold. Analysis at all 13 core loci must be attempted if sufficient DNA template is available. Profiles maintained in the Incomplete Forensic Index will be searched routinely against SDIS only and **will <u>not</u> be uploaded to NDIS**.

D. **Forensic Mixture/Forensic Mixture Index**

DNA profiles from forensic samples that contain DNA contributed from more than one source belong in the **Forensic Mixture** specimen category. Major and/or minor components of mixture DNA profiles, or deduced profiles from an intimate sample are also stored in the Forensic Mixture specimen category.

The **Forensic Mixture Index** consists of DNA profiles in the Forensic Mixture specimen category. Samples in the Forensic Mixture Index must have reported alleles for at least 10 CODIS core loci, must not have more than 4 alleles at any locus, and shall be reviewed to ensure the DNA record satisfies a statistical threshold for match rarity of approximately one in the size of the NDIS database.

Alleles which are unambiguously attributed to a victim will not be allowed. Casework analysts should keep in mind the reported inclusions/statistical values should a match occur to entries in this specimen category. If there would be no inclusion/statistical value for any profile matching to this specimen, the profile should not be entered into the CODIS database.

Profiles maintained in the Forensic Mixture Index will be forwarded to the FBI for inclusion in NDIS. *[ref. FBI NDIS, DNA Data Acceptance Standards]*

Forensic Mixture profiles that exist in the CODIS database prior to January 25, 2013 are not required to meet the NDIS match rarity statistical threshold.

E. **INC. For. Mixture/Incomplete Forensic Mixture Index**

Mixture DNA profiles from forensic samples with results from at least 8 but less than 10 CODIS core loci, or that do not meet the NDIS match rarity statistical threshold belong in the **INC. For. Mixture** specimen category. INC. For. Mixture profiles cannot have more than 4 alleles at any locus, and alleles which are unambiguously attributed to the victim shall not be included. Casework analysts should keep in mind the reported inclusions/statistical values should a match occur to entries in this specimen category. If there would be no inclusion/statistical value for any profile matching to this specimen, the profile should not be entered into the CODIS database.

INC. For. Mixture profiles shall be reviewed to ensure the DNA record satisfies a statistical threshold for match rarity of approximately 20 in the size of the SDIS database (SDIS match rarity statistical threshold).

INC. For. Mixture profiles that exist in the CODIS database prior to January 25, 2013 are not required to meet the SDIS match rarity statistical threshold.

The **Incomplete Forensic Mixture Index** consists of DNA profiles in the INC. For. Mixture specimen category. Samples in the Incomplete Forensic Mixture Index only contain results from 8 to 9 of the 13 CODIS core loci (excludes Amelogenin) or do not meet the NDIS match rarity statistical threshold. Analysis at all core loci must be attempted if sufficient DNA template is available. Profiles maintained in the Incomplete Forensic Mixture Index will be searched routinely against SDIS only and **will not be uploaded to NDIS**.

F. **Missing Person/Deduced Missing Person/Missing Person Index**

A DNA profile developed from a sample known to have been collected from the missing person (e.g. medical specimens) belongs in the **Missing Person** specimen category.
A DNA profile obtained from an intimate item purported to belong to the missing person (e.g. toothbrush) belong in the **Deduced Missing Person** specimen category.

The **Missing Person Index** consists of DNA profiles in the Missing Person and Deduced Missing Person specimen categories. The profiles must be single source and consist of at least 8 of the 13 CODIS core loci **plus** Amelogenin. Analysis at all core loci and Amelogenin must be attempted. Any locus with known dropout (an allele visible below threshold) will not be used for entry. Profiles maintained in the Missing Person Index will be forwarded to the FBI for inclusion in NDIS. *[ref. FBI NDIS, DNA Data Acceptance Standards]*

G. **Relatives of Missing Person Index**

DNA profiles from the known reference samples of biological relatives are stored in the specimen category that describes the relationship between the missing person and the relative. The following specimen categories are available: **Biological Child**, **Biological Father**, **Biological Mother**, **Biological Sibling**, **Maternal Relative** and **Paternal Relative**. The Maternal Relative specimen category contains profiles provided from a maternal biological relative who is not a child, mother or sibling of the missing person. The Paternal Relative specimen category contains profiles provided from a paternal biological relative who is not a child, father or sibling of the missing person.

The **Relatives of Missing Person Index** consists of DNA profiles belonging to the following specimen categories: Biological Child, Biological Father, Biological Mother, Biological Sibling, Maternal Relative and Paternal Relative. The profiles must be single source and consist of all CODIS core loci **plus** Amelogenin. Profiles maintained in the Relatives of Missing Person Index will be forwarded to the FBI for inclusion in NDIS. Once the individual corresponding to this reference sample has been identified, the specific DNA profile must be removed from this index. *[ref. FBI NDIS, DNA Data Acceptance Standards]*

H. **Unidentified Person/Unidentified Human (Remains) Index**

DNA profiles obtained from recovered deceased individuals (including body parts and tissue) or from an individual who is unidentified (e.g., children who can't and others who can't or won't identify themselves) belong in the **Unidentified Person** specimen category.

The **Unidentified Human (Remains) Index** consists of DNA profiles in the Unidentified Person specimen category. The profiles must be single source and consist of at least 8 of the 13 CODIS core loci **plus** Amelogenin. Analysis at all core loci and Amelogenin must be attempted. Loci with apparent dropout shall not be included in the profile. Profiles maintained in the Unidentified Human (Remains) Index will be forwarded to the FBI for inclusion in NDIS. *[ref. FBI NDIS, DNA Data Acceptance Standards]*

I. **INC. Unid. Remains/Inc Unidentified Human (Remains) Index**

Partial DNA profiles (between 6-7 CODIS core loci, or are missing Amelogenin) obtained from recovered deceased individuals (including body parts and tissue) or from an individual who is

unidentified (e.g., children who can't and others who can't or won't identify themselves) belong in the **INC. Unid. Remains** specimen category.

The Inc. Unidentified Human (Remains) Index consists of DNA profiles from unidentified remains or from individuals who are unable to or refuse to provide their identity (e.g. children). The profiles must be single source and consist of at 6 to 7 of the CODIS core loci **or are missing Amelogenin**. Analysis at all 13 core loci and Amelogenin must be attempted. Loci with apparent dropout shall not be included in the profile. Profiles maintained in the Inc. Unidentified Human (Remains) Index will be will be searched routinely against SDIS only and **will <u>not</u> be uploaded to NDIS**. *[ref. FBI NDIS, DNA Data Acceptance Standards]*

J. **Convicted Offender/Offender Index**

DNA profiles obtained from individuals convicted of a state qualifying offense as indicated in Oklahoma Statute Title 74 Section 150.27a belong in the **Convicted Offender** specimen category.

The **Offender Index** consists of DNA profiles from in the Convicted Offender specimen category. The profiles must be single source and consist of all CODIS core loci (excluding Amelogenin), therefore profiles with dropout at only D19 and/or D2 may be included. Profiles maintained in the Convicted Offender Index will be forwarded to the FBI for inclusion in NDIS. *[ref. FBI NDIS, DNA Data Acceptance Standards]*

K. **INC. Offender STR/Incomplete Offender Index**

Partial DNA profiles (between 8-12 CODIS core loci, excluding Amelogenin) obtained from individuals convicted of a state qualifying offense as indicated in Oklahoma Statute Title 74 Section 150.27a belong in the **INC. Offender STR** specimen category. These profiles may be temporarily assigned to this specimen category until additional analysis is performed. Loci where a partial profile is indicated shall be referenced with a "(p)" on the CODIS Data Entry Form. The specimen will be re-assigned to the Offender specimen category once results at all core loci have been obtained.

The **Incomplete Offender Index** consists of DNA profiles in the INC. Offender STR specimen category. Profiles maintained in the Incomplete Offender Index will be searched routinely against SDIS only and **will <u>not</u> be uploaded to NDIS**.

L. **Arrestee/Arrestee Index**

DNA profiles from individuals arrested of a state qualifying offense as indicated in Oklahoma Statute Title 74 Section 150.27a belong in the **Arrestee** specimen category.

The **Arrestee Index** consists of DNA profiles in the Arrestee specimen category. The profiles must be single source and consist of all CODIS core loci (excluding Amelogenin), therefore profiles with dropout at only D19 and/or D2 may be included. Profiles maintained in the Arrestee Index will be forwarded to the FBI for inclusion in NDIS. *[ref. FBI NDIS, DNA Data Acceptance Standards]*

M. **Inc. Arrestee/Incomplete Arrestee Index**

Partial DNA profiles (between 8-12 CODIS core loci, excluding Amelogenin) obtained from individuals arrested of a state qualifying offense as indicated in Oklahoma Statute Title 74 Section 150.27a belong in the **Inc. Arrestee** specimen category. These profiles may be temporarily assigned to this specimen category until additional analysis is performed. Loci where a partial profile is indicated shall be referenced with a "(p)" on the CODIS Data Entry Form. The specimen will be re-assigned to the Arrestee specimen category once results at all 13 core loci have been obtained.

The **Incomplete Arrestee Index** consists of DNA profiles in the Inc. Arrestee specimen category. Profiles maintained in the Incomplete Arrestee Index will be searched routinely against SDIS only and **will not be uploaded to NDIS.**

N. **Multi-Allelic Offender/Multi-Allelic Offender Index**

DNA profiles obtained from individuals arrested or convicted of a state qualifying offense as indicated in Oklahoma Statute Title 74 Section 150.27a that have three or more alleles at two or more loci belong in the **Multi-Allelic Offender** specimen category.

The **Multi-Allelic Index** consists of DNA profiles from in the Multi-Allelic Offender specimen category. The profiles must consist of all CODIS core loci (excluding Amelogenin), therefore profiles with dropout at only D19 and/or D2 may be included. Profiles maintained in the Multi-Allelic Offender Index will be forwarded to the FBI for inclusion in NDIS. *[ref. FBI NDIS, DNA Data Acceptance Standards]*

O. **Legal/Legal Index**

DNA profiles obtained from known suspect in a criminal investigation, and other DNA samples from individuals collected under applicable legal authorities belong in the **Legal** specimen category. As of January 1, 2006, suspect profiles are eligible for entry into the state CODIS database (SDIS) in accordance with Oklahoma Statute Title 74 Section 150.27a. Suspect samples may include known reference samples collected from the person, or secondary reference samples such as cigarette butts, chewing gum, razors, and toothbrushes. If the suspect profile matches a casework profile (which will be entered into CODIS), or the suspect profile is in CODIS from an arrestee or convicted offender sample, the suspect profile will not be added to the Legal Index.

The **Legal Index** consists of DNA profiles in the Legal specimen category. The profiles must be single source and consist of all 13 CODIS core loci (excluding Amelogenin). Profiles maintained in the Legal Index will be searched routinely and uploaded to NDIS per approval from the NDIS Custodian. *[ref. FBI NDIS, DNA Data Acceptance Standards]*

Note: For the purpose of this policy, a suspect is defined as any individual listed as a suspect or subject in a Criminalistics Examination Report. This does not include exclusionary samples collected from individuals for elimination purposes only. Exclusionary samples shall **not** be entered into CODIS. Suspect name and date of birth (if available) should be sent to the CODIS Unit for the purpose of determining if the sample already exists in the CODIS database.

Note: If a Legal Specimen is entered into CODIS, and subsequent analysis yields a CODIS eligible forensic profile that matches or is consistent with the Legal Specimen, the Legal Specimen will be removed from CODIS. A CODIS Request for Profile Removal Form should be filled out for the Legal Specimen and submitted with the CODIS Data Entry Form for the forensic sample.

P. **INC. Legal/Incomplete Legal Index**

Partial DNA profiles (between 8-12 CODIS core loci, excluding Amelogenin) obtained from known suspect in a criminal investigation, and other DNA samples from individuals collected under applicable legal authorities belong in the **INC. Legal** specimen category. These profiles may be temporarily assigned to this index until additional analysis is performed. Loci where a partial profile is indicated shall be referenced with a "(p)" on the CODIS Data Entry Form. The specimen will be re-assigned to the Legal Index once results at all core loci have been obtained.

The **Incomplete Legal Index** consists of DNA profiles in the INC. Legal specimen category. These profiles contain 8 to 12 of the CODIS core loci (excluding Amelogenin). Profiles maintained in the Incomplete Legal Index will be searched routinely against SDIS only and **will not be uploaded to**

NDIS.

Q. **Staff/Employee Index**

DNA profiles from known reference samples voluntarily provided by employees of the law enforcement agencies belong in the **Staff** specimen category.

The **Employee Index** consists of DNA profiles in the Staff specimen category. The profiles must be single source and consist of all CODIS core loci (excluding Amelogenin). Profiles maintained in the Employee Index will be searched routinely at SDIS only and **will <u>not</u> be uploaded to NDIS**. This search is conducted to exclude the possibility that a forensic DNA profile originated from a law enforcement employee who was in close proximity to the sample at the crime scene or during analysis of the evidence.

R. **Contaminant Profile/Contaminant Index**

DNA profiles originating from sample contamination in one of the Oklahoma CODIS participating DNA laboratories belong in the **Contaminant Profile** specimen category.

The **Contaminant Index** consists of DNA profiles in the Contaminant Profile specimen category. The profile eligibility for this index is determined by the CODIS Administrator on a case-by-case basis. Profiles maintained in the Contaminant Index will be searched at SDIS only and **will <u>not</u> be uploaded to NDIS**. This search is conducted to expedite identification and remediation of the contamination problem.

S. **Y-STR Forensic Unknown/Y-STR Forensic Index**

DNA profiles from forensic samples consisting solely of alleles derived from Y-STR genetic markers can be included at SDIS. These DNA samples belong in the **Y-STR Forensic Unknown** specimen category.

The **Y-STR Forensic Index** consists of DNA profiles in the Y-STR Forensic Unknown specimen category. The profiles must be single source (or a full major component profile originating from a mixture) and consist of at least 15 of the 16 Y-STR loci. Profiles maintained in the Y-STR Forensic Index will be searched routinely against other Y-STR profiles maintained at SDIS and **will not be uploaded to or searched at NDIS.**

T. **Y-STR Legal/Y-STR Legal Index**

DNA profiles from suspects containing alleles derived from Y-STR genetic markers can be included in SDIS, even if there is an existing STR profile in CODIS from an offender or previous legal sample. The DNA samples belong in the **Y-STR Legal** specimen category.

Note: Legal profiles with Y-STR alleles should only be entered in the Y-STR Legal specimen category if there is already an STR profile in CODIS from an offender sample. Otherwise, the profiles should be entered in the Legal Index, where they will be searched against all other STR profiles and uploaded to NDIS.

If the STR profile is associated with a specimen already in the Legal Index, the Y-STR profile will be added to that specimen. If the Y-STR profile is associated with an individual who has been entered as an offender or arrestee, then a new specimen consisting of only the Y-STR profile will be added to the Y-STR Legal Index.

The **Y-STR Legal Index** consists of DNA profiles in the Y-STR Legal specimen category. The profiles must be single source and consist of all 16 Y-STR loci. Profiles maintained in the Y-STR Legal Index will be searched routinely against other Y-STR profiles maintained at SDIS only and **will not be uploaded to or searched against NDIS.**

Y-STR Indices searches will be performed on a monthly basis.

2.2 Definition of Acceptable Profiles:

Before a DNA profile can be uploaded, entered into, or searched against SDIS, the following criteria must be met: *[ref. FBI NDIS, DNA Data Acceptance Standards (Operational Procedures)]*

A. The DNA profile must be developed by an accredited Forensic DNA Laboratory.

B. The DNA profile must be developed in compliance with the DNA Identification Act of 1994 and FBI Approved Quality Assurance Standards.

C. The DNA profile must be subjected to a thorough technical review by a qualified DNA analyst.

D. All DNA profiles must be associated with an accurate result for PCR DNA controls and reagent blanks.

E. All DNA profiles must be derived from analysis using an NDIS accepted PCR kit.

F. Low template or low copy DNA analyses shall not be submitted to SDIS.
   1. Low template or low copy DNA analyses has been defined as: based on a laboratory's internal validation, any DNA typing results generated from limited quantity and/or quality DNA template using conditions that have demonstrated increased stochastic effects.
      i. Stochastic effects may include: allelic drop-in or drop-out, increased stutter, and increased intra-locus peak height imbalance.

2.3 Analysis of Casework Samples

The following applies to DNA analysis performed at the OSBI Laboratory on casework samples.

A. Analysis performed on casework samples will comply with all applicable OSBI policies and the Forensic Biology Unit Policy Manual.

   Note: In the event the OSBI uses a contract laboratory for analysis, the contract laboratory will only use procedures approved by the OSBI Forensic Biology Discipline Technical Manager.

B. In addition, analysis at all CODIS core loci will be attempted on the victim reference sample and any other reference sample necessary to deduce a suspect profile from a mixture.

C. Casework profiles must be subjected to a thorough technical review by qualified OSBI personnel (according to the Forensic Biology Unit Policy Manual) prior to entry or search against SDIS.

D. A casework DNA profile must be referenced in a Criminalistics Examination Report to be eligible for entry into or search against SDIS.

E. For any profile that must meet a match rarity statistical threshold, the "Match Estimator 3.2 (ID) OSBI" excel spreadsheet or the CODIS 7.0 Popstats Match Estimation calculation will be used to determine the match rarity.
   1. D2S1338 and D19S433 will not be used in the calculation
   2. Instructions are provided with the "Match Estimator 3.2 (ID) OSBI" excel spreadsheet
   3. The results should be provided in the case record for review by the Technical Reviewer.

2.4 Analysis of Offender Samples

The following applies to analysis performed at the OSBI Laboratory on offender database samples

(including convicted offender and arrestee samples).

A. All analysis performed on offender database samples will comply with all applicable OSBI policies and the CODIS Policy Manual.
Note: In the event a contract laboratory is used for analysis, the contract laboratory will only use procedures approved by the OSBI CODIS Administrator and OSBI Forensic Biology Discipline Technical Manager.

C. Offender profiles must be subjected to a thorough technical review by qualified OSBI personnel (according to the CODIS Policy Manual) prior to entry or search against SDIS.

2.5 Creating Specimen ID Numbers

A. If an offender database sample is analyzed by the OSBI, the CODIS Specimen ID number will consist of the offender sample number. If a contract laboratory analyzes an offender sample, a prefix identifying the vendor and the year of the contract may be added to this Specimen ID to identify the vendor laboratory.

Example (In-House Analysis): C15-001000
Example (Outsourced Analysis): XX06-C15-001000

B. If a casework sample is analyzed by the OSBI, the CODIS Specimen ID number will consist of the state abbreviation, the DNA analyst's initials, the OSBI case number and item number. If a vendor laboratory analyzes a casework sample, a prefix identifying the vendor and the year of the contract may be used instead of the state abbreviation and analyst's initials.

Example (In-House Analysis): OK-RLP-15-1000-B1
Example (Contract Analysis): XX06-15-1000-B1

2.6 Request and Documentation of CODIS Data Entry

The CODIS Unit is responsible for the integrity and security of all data into SDIS. Any discrepancies will be forwarded to the CODIS Administrator for determination of profile eligibility prior to entry into or search against SDIS.

A. **OSBI Casework Profile Data Entry**

1. The Casework Analyst will fill out an electronic version of the CODIS Data Entry Form for each profile determined to be eligible for entry into SDIS and/or NDIS. The "Description of Profile Entered" will match the description of evidence in the report (forensic) or the full name of the individual (legal, parentage), if available.
Note: A deduced profile from a mixture, whether it is major, minor, or indistinguishable will be considered a Forensic Mixture profile. A "clean" sperm or epithelial fraction will be considered a single source profile or Forensic Unknown profile.

2. The following guidelines should be used in determining profile eligibility, in conjunction with the FBI's "Guide to Determining What is Allowable in the Forensic Index at NDIS" flowchart:
   a. If there are multiple, similar profiles from a case, **ONLY** the most complete and probative profile will be put into CODIS
      1. If there are mixtures with clear major and minor profiles, it is preferable to put in the clear major or minor profile than to put in an indistinguishable mixture profile which has consistent information.

Example: Mixture on jacket, clear major/minor, major not consistent w/ victim. Mixture on jeans, not distinguishable, with 2 additional alleles (1 each at 2 loci) than major profile from jacket. Put in major profile from jacket.

b. A known DNA profile can be subtracted from an otherwise indistinguishable mixture IF the mixture profile is from an INTIMATE sample. For our purposes, we will consider any sample from a person's body to be intimate (i.e. vaginal swabs, oral swabs, fingernail scrapings, etc).

Note: A known profile cannot be subtracted out from an intimate, indistinguishable mixture if that known has been excluded from the mixture.

c. A mixture profile may be entered in its entirety provided that there are no more than 4 alleles at any locus and it meets the appropriate match rarity statistical threshold.

d. Provided that there is documentation that a known sample has been requested from any consensual partner, an unknown male profile from a sexual assault case may be entered into CODIS, as long as the profile meets all other eligibility criteria.

e. Obligate alleles: In deducing mixture profiles, if it is possible that a portion of the locus contains an allele shared between the victim and suspect, any portion of the locus that could not be contributed by the victim should be marked as obligate by marking that allele with a plus (+) sign.

3. During the technical review, the reviewer will verify the accuracy of the profile and specimen category listed on each CODIS Data Entry Form and ensure the appropriate supporting documentation is present in the case record. Once verified, the reviewer will electronically sign and date the appropriate section on each the CODIS Data Entry Form. This form will be forwarded to the CODIS Unit for entry and then forwarded back to the case analyst so the case assignment can be closed out and a report issued.

4. Once each CODIS Data Entry Form is completed, all eligible profiles will be entered into SDIS. Once completed, the CODIS Data Entry Form(s) will be electronically signed and dated by the analyst entering the profile(s) into CODIS.

5. A Specimen Detail Report will be provided to the case analyst and made available in the BEAST system for each profile entered in the case record to document that each profile was correctly entered into the CODIS database.

6. The Casework Analyst will be provided the completed CODIS Data Entry Forms and the Specimen Detail Report(s) in the BEAST case record.

7. **It is the responsibility of the Casework Analyst to verify that the profile shown on the Specimen Detail Report is accurate.** Once verified, the Casework Analyst will electronically sign and date the bottom portion of the CODIS Data Entry Form. The CODIS Data Entry Form(s) and Specimen Detail Report(s) will be retained electronically in the BEAST case record. Any hard-copy documentation can be shredded after it is entered into the BEAST and verified it uploaded correctly.

B. **Local CODIS Laboratory Casework Profiles**

1. All other casework profiles will be entered into SDIS by processing an upload from an approved local CODIS laboratory (LDIS), such as Tulsa Police Department or Oklahoma City Police Department.

2. Each LDIS laboratory must complete and return a Memorandum of Understanding to the OSBI CODIS Administrator guaranteeing compliance with the same standards and procedures regarding acceptable data prior to uploading data to the OSBI.

C. **Offender Profiles**

1. Offender data received from a contract laboratory or processed in-house will be uploaded in bulk using CODIS Import (.cmf file). The CODIS Unit will maintain a copy of the CODIS Import Reports.

2. Individual offender profiles may be entered into CODIS by keyboard instead of .cmf file. This will be documented by filling out a CODIS Data Entry Form for each profile entered.

C. Release of DNA Profile for John Doe Warrant

1. To facilitate notification of DNA profile release, the BEAST LIMS program will be used.
   a. The CODIS Unit will not release mixture profiles for use in John Doe warrants. The major component of a mixture may be released.
   b. Deduced profiles or minor components of a mixture may be released in consultation with the CODIS Administrator and the Technical Manager.
   c. The CODIS Analyst will create an assignment for the CODIS Unit (C) within the BEAST. This can be done on the "Assignments" tab.
   d. To ensure consistency, the description of the evidence in the Profile Release Letter should match the description of evidence used in the Forensic Biology Unit DNA Report.
   e. The CODIS Analyst will generate a "Notification of Profile Release for John Doe Warrant" letter clearly listing the DNA profile to be used in the John Doe warrant. **Note**: The "Notification of Profile Release for John Doe Warrant" letter is NOT a report.
   f. The CODIS Analyst will route the assignment to the Casework Analyst (or designee) that developed the DNA profile for Administrative Review.
   g. The Administrative Review will be performed as per CSD QP 31 – Reviews. Care should be taken to ensure the correct DNA profile is released.
   h. If corrections are necessary, the Casework Analyst will route the assignment back to the CODIS Analyst.
   i. After completion of the Administrative Review, the Casework Analyst will approve the "Notification of Profile Release for John Doe Warrant" letter and mail any required hard copy letters to the submitting agency.
   j. Clicking the "Approve" button will document the completion of the Administrative Review.

2.7 Conducting CODIS Searches

This section describes the possible searches of SDIS using the FBI approved CODIS software. Before a DNA profile may be searched against SDIS, the criteria listed in section 2.2 of this policy must be met. The DNA profiles maintained at SDIS will only be searched using approved FBI CODIS software. **Intentional viewing of a specimen record with the intent of performing a manual DNA comparison to another profile (not eligible to otherwise be searched) is not permitted.** The CODIS Unit will maintain a record (paper or electronic) of any search conducted unless deemed not necessary by the CODIS Administrator (e.g. searches conducted during training).

A. **Remote Search Requests**

Remote search requests (also known as keyboard searches) are designed to expedite a search

against DNA profiles maintained at SDIS that are not part of the routine Autosearch. A keyboard search is a manual search of SDIS executed after receipt of a written request, and will be performed at the discretion of the CODIS Administrator (or designee). If requests are received from any source other than a criminal justice agency, the keyboard search will only be performed if pursuant to a court order. A copy of the court order must be provided to the CODIS Administrator for approval prior to conducting the search.

1. The search request form shall be completed and submitted to the CODIS Administrator for approval.

2. Before performing the search, the CODIS Administrator will ensure the search request is in compliance with all applicable laws and OSBI policy. If the request does not comply with these provisions, the CODIS Administrator will send a letter to the requestor (on official OSBI letterhead) explaining why the search was not conducted.

3. If the search request has been approved by the CODIS Administrator, the DNA profile(s) may be searched against SDIS using the same search combinations as allowed in a routine index to index search.

4. If the search is conducted, a letter will be produced (on official OSBI letterhead) and returned to the requestor, along with a copy of any potential CODIS Match Reports generated as a result of the search.

5. A keyboard search against NDIS is performed in accordance with NDIS Operational Procedures.

B. **Batch Target Searches**

Batch Target Searches are designed to search a specific group of DNA profiles against SDIS (such as training samples). These types of searches may be executed at the discretion of the CODIS Administrator (or designee). The search stringency and minimum number of loci to report a match are determined by the CODIS Administrator or designee on case-by-case basis.

C. **Familial Searches / Partial Matches**

Familial searching is a term applied to intentionally searching a forensic DNA profile against an offender DNA profile in the attempt to identify a potential family member of the offender. These types of searches are not performed at the OSBI. However, a familial search is very different from a partial match.

A partial match is defined as a moderate stringency match between two single source profiles having at each locus at least one allele in common. A partial match is not an exact match of the two profiles in question, but in certain cases, the partial match may indicate a potential familial relationship exists between the offender sample and the forensic DNA profile.

Although an exceptional event, partial matches may be reported to law enforcement agencies if they are discovered during a normal routine search of the CODIS database. The procedure for reporting partial matches is outlined in the CODIS Hit Verification Procedures section of this policy.

D. **Routine Index to Index Searches**

At the discretion of the State CODIS Administrator, Table 1 lists the routine SDIS Autosearches and the match criteria for each. Tables 2 -6 lists the indices searched in each Autosearch of SDIS. These routine Autosearches should be performed weekly, at minimum, following the addition of

new DNA profiles to SDIS.

Note: The CODIS Administrator may change the search stringency and minimum number of loci to report a match on a case-by case basis.

Table 1: **Routine SDIS Autosearch criteria**

Autosearch name	Min # Loci	Stringency	# of Allowed Mismatches
Inc Offender to Offender	8	Moderate	0
New Against Employee	8	Moderate	1
New Offender to Offender	13	High	1
New STR Specimens 1 Mismatch	8	Moderate	1
Inc. Unid. Human Remains	6	Moderate	0

Table 2: **Inc Offenders to Offender Autosearch**

Index	Offender	Inc Offender	Legal	Inc Legal	Arrestee	Inc Arrestee	Multi-Allelic Offender
Offender	X	X	X	X	X	X	X
Inc Offender	X	X	X	X	X	X	X
Legal	X	X	X	X	X	X	X
Inc Legal	X	X	X	X	X	X	X
Arrestee	X	X	X	X	X	X	X
Inc Arrestee	X	X	X	X	X	X	X
Multi-Allelic Offender	X	X	X	X	X	X	X

Table 3: **New Against Employee Autosearch**

Index	Forensic	Forensic Partial	Inc Forensic	Forensic Mixture	Inc Forensic Mixture	Offender	Inc Offender	Unidentified Human (Remains)	Missing Person	Relatives of Missing Person	Employee	Legal	Inc Legal	Arrestee	Inc Arrestee	Multi-Allelic Offender
Employee	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Table 4: **New Offender to Offender Autosearch**

Index	Offender	Legal	Arrestee	Multi-Allelic Offender
Offender	X	X	X	X
Legal	X	X	X	X
Arrestee	X	X	X	X
Multi-Allelic Offender	X	X	X	X

Table 5: New STR Specimens 1 Mismatch Autosearch

Index	Forensic	Forensic Partial	Inc Forensic	Forensic Mixture	Inc Forensic Mixture	Offender	Inc Offender	Unidentified Human (Remains)	Missing Person	Relatives of Missing Person	Legal	Inc Legal	Arrestee	Inc Arrestee	Multi-Allelic Offender
Forensic	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Forensic Partial	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Inc Forensic	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Forensic Mixture	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Inc Forensic Mixture	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Offender	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Inc Offender	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Unidentified Human (Remains)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Missing Person	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Relatives of Missing Person								X	X						
Legal	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Inc Legal	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Arrestee	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Inc Arrestee	X	X	X	X	X	X	X	X	X		X	X	X	X	X
Multi-Allelic Offender	X	X	X	X	X	X	X	X	X		X	X	X	X	X

Table 6: **Incomplete Unidentified Human Remains Autosearch**

Index	Offender	Inc Offender	Legal	Inc Legal	Arrestee	Inc Arrestee	Missing Person	Relatives of Missing Person	Forensic	Forensic Partial	Inc Forensic	Employee	Contaminant	Multi-Allelic Offender
Inc Unidentified Human (Remains)	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Table 7: **Y-STR Autosearch**

Index	Y-STR Forensic	Y-STR Legal	Legal	Forensic	Forensic Partial	Inc Forensic	Forensic Mixture	Incomplete Forensic Mixture
Y-STR Forensic	X	X	X	X	X	X	X	X
Y-STR Legal	X	X	X	X	X	X	X	X

2.8 Processing CODIS Matches

The CODIS Unit shall carefully examine any potential database match prior to releasing any identifying information to law enforcement personnel.

Note: The terms **match** and **hit** are used throughout this document. Matches and hits are not interchangeable terms or events. A match occurs when the CODIS software makes an association between two or more DNA profiles. A hit occurs when a match adds value to the investigation of a criminal case.

A. The CODIS Unit or a casework DNA analyst will review any potential CODIS matches and disposition each match appropriately.
   Note: The FBI's flowchart titled "Hit Disposition Quick Reference" should be used when dispositioning potential CODIS matches.

B. Any matches for which the disposition is unknown will be dispositioned as "Pending" until further information is obtained.

C. When possible, comments should be added in Match Manager explaining the disposition once the permanent disposition has been assigned.

D. Matches that are deemed to be Offender, Forensic or Familial Hits will be verified according to the CODIS Hit Verification Procedures section of this policy.

E. In order to provide statistical data from CODIS hits, the OSBI will also record the number of investigations aided for each CODIS hit obtained.
   Note: The FBI's flowchart titled "Investigations Aided Quick Reference" should be used when counting investigations aided.

2.9 Profile Removal

A. It is the responsibility of the Casework Analyst to notify the CODIS Unit if a previously entered profile matches to a known sample from an elimination or victim analyzed after the fact.

1. The CODIS Request for Profile Removal Form shall be completed and forwarded to the CODIS Unit after the technical review is complete.

2. The original CODIS Request for Profile Removal Form and a Delete Specimen Report (if the profile is removed from CODIS) will be returned to the Casework Analyst to be added to the case record.

3. It is the responsibility of the Casework Analyst to verify that the profile shown on the Delete Specimen Report is accurate by completing the appropriate section of the CODIS Request for Profile Removal Form. It is also the responsibility of the Casework Analyst to notify the customer of the removal of the profile from CODIS via amended report or a new report listing the specific item's profile that was removed.

B. CODIS Match to Ineligible Forensic Profile

1. If, during the course of a match evaluation, it is found that the forensic profile involved is no longer CODIS eligible due to changes in eligibility criteria, the profile in question will be removed from CODIS as outlined above.
2. If the match in question is determined to need verification, verification will be requested and completed. A statement will be added to the verification report to reflect the fact that the profile has been removed from the database due to it no longer being eligible.
3. For matches to samples ineligible for other reasons, the profile in question will be removed from CODIS, as outlined above. Hit verification reporting will be determined on a case-by-case basis by the State CODIS Administrator and/or the CODIS Technical Manager.

Removal of Duplicate Offender and Legal Samples

Duplicate Offender and Legal Samples may be removed at the discretion of the CODIS Administrator, and a "CODIS Request for Profile Removal Form" does not need to be completed.

2.10 Annual Review/Updates

In accordance with NDIS Procedures, all CODIS Users will certify annually that they have reviewed and comply with requirements for DNA profiles acceptable at NDIS. To satisfy this requirement, each CODIS User must successfully complete the FBI's training module located on the CJIS-WAN within the time designated by the CODIS Administrator. Once complete, a certificate may be printed for each CODIS User as proof the training was successfully conducted.

The CODIS Administrator is responsible for ensuring this required annual training is completed for all OSBI CODIS Users.

CODIS Unit Policy Manual

CODIS Hit Verification Procedures (top ↑)

1.0 POLICY

This protocol outlines the proper course of action to be taken in the event a hit is obtained to the State CODIS database (SDIS) or the National CODIS database (NDIS). This policy includes the procedures to be used in the verification of database sample(s), the release of information to other laboratories and/or investigative agencies, and the proper documentation maintained at the OSBI laboratory. In all cases, the CODIS Laboratory will make the best effort to resolve matches within 30 business days of the match report. This includes verifications and dispositions.

2.0 PROCEDURE

2.1 Forensic Hits

A Forensic Hit occurs when two or more DNA profiles developed from crime scene evidence match one another, and the match provides new or confirms existing information to an unsolved crime.

A. **Forensic Hit Verification**

The following procedures are to be used in the event the match involves a DNA profile developed by the OSBI Forensic Biology Unit. When selecting the proper disposition for a database match, the CODIS Unit will refer to the FBI's "Hit Disposition Quick Reference Flowchart".

Note: If two or more cases are submitted and analyzed with the prior knowledge that they are associated, and a CODIS match occurs, this is not considered a forensic hit, and should instead be dispositioned as a "benchwork match".

1. A qualified Analyst will examine the matched forensic profiles and determine if they may have originated from the same source. If the potential match has any loci matching at less than High Stringency or contains a mismatch, the Analyst must be currently or previously qualified in mixture interpretation. For mixture profiles, this determination may require careful examination of the original electropherogram(s). If the matching profiles may have originated from the same source, proceed to step 2. If not, mark the Match Detail Report "No Match," and return it to the CODIS Unit if applicable so the match may be dispositioned accordingly.

2. If the match evaluation was performed by a CODIS Analyst, the casework analyst will be notified that a match has occurred and is being verified.

3. The CODIS Analyst responsible for verifying the hit will fill out a Forensic Hit Verification Request form for each OSBI case involved in the forensic match. The CODIS Unit will then contact the appropriate personnel from other laboratories, if necessary, and compile the necessary information for reporting the forensic hit.

B. **Reporting Forensic Hits**

For cases in which the forensic DNA profiles are assigned in CODIS to an OSBI DNA casework analyst, the requesting officer will be contacted directly to communicate the hit information. If the officer cannot be reached directly, another appropriate individual in the agency shall be contacted. In addition, in all cases, a Forensic Hit letter will be sent (by mail, fax, and/or e-mail) by the CODIS Unit to each agency involved in the hit. Information in the letter shall include, at minimum, the investigating agency, type of case, and point of contact for each case. The

Forensic Hit Letter should clearly state if the casework profile was either incomplete or a mixture. This may be accomplished by amending the first sentence of the Forensic Hit Letter to read "…a potential DNA match was obtained between your mixture/partial profile, specimen ID…"

C. **Documenting Forensic Hits**

1. All Forensic Hit documentation will be retained in the laboratory DNA case record(s) in the BEAST system corresponding to the forensic specimen(s) involved in the hit. This includes, at minimum, the following:

   a. A copy of the CODIS Match Detail Report
   b. A copy of the Forensic Hit letter(s)
   c. A copy of the forensic hit verification request
   d. All conversation correspondence (phone, fax, and/or e-mail)
   e. Any additional information as determined by the CODIS Administrator

2. Information reported by telephone must be documented as a narrative in the BEAST system.

3. Forensic Hits obtained at NDIS will be handled in the same manner as SDIS Forensic Hits; however, additional documentation may be required according to NDIS Procedures. A copy of any additional documentation will be retained electronically in the appropriate laboratory DNA case record(s).

2.2 Offender Hits

An Offender Hit occurs when a DNA profile from crime scene evidence (forensic profile) matches an offender's DNA profile and the match provides new or confirms existing information to an unsolved crime.

B. **Offender Hit Verification**

When selecting the proper disposition for a database match, the CODIS Unit will refer to the FBI's "Hit Disposition Quick Reference Flowchart".

1. When a potential Offender Hit is identified, a CODIS analyst (or designee) will evaluate the match. If the potential match has any loci matching at less than High Stringency or contains a mismatch, the Analyst must be currently or previously qualified in mixture interpretation. The analyst will examine the matched profiles and determine if they may have originated from the same source. If the answer is yes, proceed to step 2. If not, mark the Match Detail Report "No Match," and return it to the CODIS Unit so the match will be dispositioned accordingly.

2. If the match evaluation was performed by a CODIS Analyst, the Casework Analyst may be consulted when needed.

3. Once the match has been determined to be an Offender Hit, the CODIS Analyst assigned to verify the hit will fill out the Offender Hit Verification Request Form.

4. If the offender associated with the hit is an Oklahoma offender, the CODIS Analyst will re-analyze the offender sample as indicated below. If the hit involves an out-of-state offender, the CODIS Analyst will establish contact with the appropriate CODIS laboratory, and facilitate the reporting of the hit according to NDIS Procedures.

C. **Re-Analysis of the Offender Samples**

1. The offender specimen in question will be pulled from storage and re-analyzed to verify the result. Analysis will be performed on all CODIS core loci to ensure that no error occurred due to a sample being switched. All re-analyses of offender samples will be performed according to applicable OSBI Quality Assurance Policies and CODIS Policies and Procedures. Offender samples being processed for hit verification purposes will be named HV-(offender number) to distinguish from original sample analysis.
   Ex: HV-C15-001000

2. If the verification analysis of the offender sample in question does not yield the same result, it will be assumed a sample switch error occurred. An attempt will be made to identify the correct convicted offender sample by first determining the number(s) of the convicted offender samples analyzed immediately before and after the sample in question. These convicted offender sample(s) will be analyzed to determine which one matches the forensic profile in question. Additional convicted offender samples will be re-analyzed, as needed, to identify the correct match. Once the correct convicted offender sample is identified, the result will be properly verified.

   Note: Variations in profile results due to amplification kit differences, mutations, etc., are still considered to be consistent with each other. These types of variations will be carefully evaluated by the CODIS Technical Manager. Likewise, any partial profiles obtained during the verification process will be handled in consultation with the Technical Manager for determination of what, if any, troubleshooting should be performed.

3. If an offender sample has previously been re-analyzed by qualified OSBI personnel and documented as part of a hit verification or validation, then re-analysis is not necessary. Documentation of the previous re-analysis will be referenced or included in the case record and a letter regarding the new hit will be sent. If the offender sample was re-analyzed as part of a validation, the fingerprint and qualifying offense will still need to be verified and the offender hit verification reported in letter format as specified in this protocol.

D. **Verification of the Offender Fingerprints**

1. A qualified OSBI Latent Evidence Analyst will check the fingerprint exemplar of the offender specimen to verify the identity of the sample donor.

2. The Latent Evidence Analyst will sign off on the appropriate line of the CODIS Offender Hit and Fingerprint Verification Form after indicating the result of the examination.

3. If the identity of the fingerprint donor is found to be different than the person listed on the offender specimen card, a request will be made to search the offender exemplar through AFIS in an effort to determine the donor of the Offender sample.

4. If the fingerprint is of insufficient quality for comparison purposes, it will be noted on the CODIS Offender Hit and Fingerprint Verification Form that a comparison was attempted, but the print was of insufficient quality. This will not preclude the CODIS Unit from reporting the identity of the offender, but it shall also be noted in the Offender Hit letter that the print could not be verified.

E. **Verify the Qualifying Offense and Biographical Information**

1. A copy of the Oklahoma and National Criminal History Reports of the offender in question will be requested in an attempt to verify that the offender specimen was collected in accordance with Oklahoma Statue Title 74 Section 150.27a. If no criminal history record(s) exists for the offender, this will be noted in the Hit Verification file.

2. In the event that no qualifying offense can be identified for the offender, the hit information may still be reported pursuant to Oklahoma Statutes Title 74 Section 150.27a (known as the "Good Faith Clause").

3. The verifying analyst will compare the biographical information on the offender record in CoDNA with the information available on State and National Criminal History reports and on the Department of Corrections (DOC) web page for the offender. An initial comparison shall be made to ensure that the correct records have been obtained. Aliases found on the State Criminal History report will be included on the hit letter. If no DOC number is available on the CoDNA record or the State Criminal History Reports, it will be included from the DOC page, if applicable.

F. **Reporting Offender Hits**

1. For cases in which the forensic DNA profile is assigned in CODIS to an OSBI DNA casework analyst, following verification and administrative review, the requesting officer will be contacted directly to communicate the hit information. If the officer cannot be reached directly, another appropriate person in the agency shall be contacted. In addition, in all cases, the Offender Hit letter will be sent (by mail, fax and/or e-mail) by the CODIS Unit to the investigative agency involved with the hit. Information in the letter shall include (if available) the offender's name, date of birth, race, sex, Social Security number, Department of Corrections number, State ID number, FBI number, OSBI number, and the qualifying offense. This information can be obtained from the offender specimen card or from the LIMS system. The Offender Hit Letter should clearly state if the casework profile was either incomplete or a mixture. This may be accomplished by amending the first sentence of the Offender Hit Letter to read "…a potential DNA match was obtained between your mixture/partial profile, specimen ID…". A .pdf version of the Offender Hit letter, CODIS Match Report, and the Offender Hit Request Form should be attached to the appropriate electronic case record in the BEAST system.

   Note: Additional identifying information from the criminal history report(s) may also be included in the report at the discretion of the CODIS Administrator.

   Note: Information reported by telephone must be documented as a narrative in the BEAST system.

2. **Offender hits are investigative leads only!** The investigative agency will be requested to use this information as probable cause to obtain a court order compelling the individual identified by the database search to provide a known reference sample for forensic testing. A Casework Analyst will report the result of this subsequent DNA testing to the requesting agency in the form of a Criminalistics Examination Report.

3. For Offender Hits where the offender sample is from another state, the hit will be reported by sending (by mail, fax, and/or e-mail) a copy of the Offender Hit letter (from

the state that verified the offender sample) to the investigating agency in Oklahoma. A .pdf version of the hit letter should be attached to the appropriate electronic case record in the BEAST system along with a copy of the appropriate CODIS Match Report.

4. If a collection error is identified through the hit verification process (this will likely be characterized by a confirmation of the DNA profile, but a print belonging to someone other than is identified on the card) the hit may still be reported at the CODIS Administrator's discretion. In this event, the Offender Hit letter will include the identity of the offender as indicated on the collection card, as well as the identification of the individual determined to be the source of the print after the AFIS search conducted by the Latent Evidence Unit. The letter will contain language indicating that a potential error at the collection site has been identified and the source of the DNA from the evidence could be either one of the individuals associated with the card. The letter will request that the investigating agency collect known DNA reference samples from both individuals for submittal to the appropriate casework laboratory for determination of the actual potential contributor.

5. At the discretion of the State CODIS Administrator, information regarding an offender's identity may be released prior to the completion of the verification and administrative review, especially in circumstances where the offender is not incarcerated, or if the verification will take more than 30 days. If the offender's identity is released prior to verification, the individual notified shall be informed that the verification procedure has not been completed and the conversation will be documented in the BEAST system (narrative) – if possible. Note: If possible, the fingerprints should be checked before the release of an offender's identity prior to the completion of verification.

F. **Documenting Offender Hits**

All Offender Hit documentation will be retained in the appropriate CODIS Hit Verification file(s).

1. For hits involving an Oklahoma offender, the CODIS Unit will retain required documents in Offender Hit Verification files. These files will include, at minimum, the following:
   a. A copy of the CODIS Match Detail Report,
   b. A copy of the Offender Hit letter(s),
   c. A copy of the offender hit verification request,
   d. Offender Hit Verification Administrative Review Form,
   e. CODIS Offender Hit and Fingerprint Verification Form,
   f. Photo(s) of the offender specimen card showing identifying information, or the appropriate CoDNA data sheet,
   g. A copy of the signed technical review form from the plate on which the offender sample was re-analyzed,
   h. A copy of the electropherograms(s) from the DNA verification,
   i. All appropriate conversation correspondence (phone, fax, and/or e-mail),
   j. Any additional information as determined by the CODIS Administrator.
2. Also for hits involving an Oklahoma offender, the following documents will be maintained as attachments to the electronic hit verification record in CoDNA. In addition, they may be included in the Hit Verification file at the analyst's discretion:
   a. A copy of the Oklahoma Department of Corrections offender look-up sheet (if available),
   b. A copy of the Oklahoma Criminal History Report for the offender (if available),
   c. A copy of the National Criminal History Report for the offender (if available).

3. For hits involving offenders from another state, the information will be retained in the

laboratory DNA case record(s) corresponding to the forensic specimen that was involved in the hit. These records will include, at minimum, the following:

a. A copy of the CODIS Match Detail Report,
b. A copy of the Offender Hit letter from the respective offender laboratory,
c. A copy of the offender hit verification request,
d. All appropriate conversation correspondence (phone, fax, and/or e-mail),
e. Any documentation required according to NDIS procedures,
f. Any additional information as determined by the CODIS Administrator.

2.3 Familial Hits (also known as Partial Matches)

A partial match occurs when a single source DNA profile from crime scene evidence (forensic profile) matches an offender's DNA profile at moderate stringency, having at least one allele in common at each locus. Upon careful examination of other information associated with the two profiles, it may be determined that a potential familial relationship exists between the two profiles (known as a Familial Hit).

A. **Familial Hits:**

Potential Familial Hits (Partial Matches) at SDIS or NDIS will be handled on a case-by-case basis, according to any current Scientific Working Group on DNA Analysis Methods (SWGDAM) and NDIS guidelines. Partial Matches will only be reported in the event that all other investigative options have been exhausted.

3.0 HIT TRACKING

Whenever possible, hit information should be recorded for statistical purposes. At a minimum, the match date, specimen ID's, laboratory names and/or ORI numbers, qualifying offense, and type of case aided should be noted.

CODIS Unit Policy Manual
Setup of Direct Amplification of DNA from FTA®/non-FTA® Punches using PowerPlex® Fusion Half Reaction Volume (top ↑)

Principle of the Protocol
- Sample Requirements
- Controls
- Reagents

Individual Steps of the Protocol
- Punch Samples

Protocol Notes

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is for the direct amplification of DNA from storage card punches (including buccal cells collected on FTA® cards and blood collected on non-FTA® cards) using the PowerPlex® Fusion System and GeneAmp® PCR System 9700 thermal cycler with silver 96-well blocks.

1.1 Sample Requirements

Offender samples consist of dried blood or buccal stains on FTA® paper and blood on non-FTA® paper. Following is a table detailing the appropriate number of punches for each sample type. The quantity and quality of DNA recovered from each specimen will vary.

Sample Type and Punches Used

Sample Type	Harris Punch Size	# of Punches	Notes
Blood Card on FTA	1.2 mm	1	One punch should be used as an increase to two punches can inhibit the reaction with half-reaction volume.*
Buccal Card on FTA	1.2 mm	1	An alternate light source may be used to aid in locating the stain. One punch should be used as an increase to two punches can inhibit the reaction with half-reaction volume.*
Blood Card on non-FTA	1.2 mm	1	One punch should be used as an increase to two punches can inhibit the reaction with half-reaction volume.*

*for samples exhibiting drop-out or incomplete profiles, an increased amplification cycle number may need to be used once validated

NOTE: Take care while punching to NOT include any paper backing from the sample into the well as this may cause issues with the analysis of the sample.

1.2 Controls

A negative control (NC) must be included with every plate of samples. A negative control is defined as the reagents used in the direct amplification process without adding any biological sample (reagent blank control). A negative control is subjected to the same analysis process used during direct amplification of offender database samples. It is included to detect possible contamination of the analytical reagents.

If a plate contains sample(s) requiring PunchSolution™ reagent to be used, the PunchSolution™ will be included in the negative control (NC) for the plate.

1.3 Reagents/Supplies/Equipment

PowerPlex® Fusion Direct Amplification Kit	Thermo Mixer	Adhesive Plate Seal
PunchSolution™ Kit	96-well plate	Centrifuge
AmpSolution™ Kit	Harris Punch	

2.0 INDIVIDUAL STEPS OF PROTOCOL

Using the following procedure, prepare all samples and reagent blank(s) for lysis. Fill out the appropriate sections of the Offender Sample Analysis Lot Numbers Worksheet.

2.1 Punch Samples

A. All non-FTA samples will be punched into the 96-well plate first and pre-treated with PunchSolution™ to lyse non-FTA samples before adding PCR amplification mix. Add 10 µl PunchSolution™ to each well containing non-FTA samples and incubate the plate at 70˚C until the well is dry (~30 minutes). Failure to pre-treat these samples may result in incomplete profiles.
Note: If a plate contains sample(s) requiring PunchSolution™ reagent to be used, the PunchSolution™ will be included in the negative control (NC) for the plate.

B. Label the 96-well plate with the appropriate "Plate Name" as defined below:

1. **First Pass Plates**
Original analysis plates will be labeled as "calendar year-first pass (FP)-plate number". Plate numbers will be in sequential numerical order. This plate number will be assigned when samples are punched, and will remain the same throughout amplification and capillary electrophoresis. Ex: "**2015-FP-0001**"

2. **Re-Punch Plates**
Samples which are to be re-punched will be placed on the next available re-punch plate. The plate will be named by "calendar year-re-punch (RP)-plate number". Plate numbers will be in sequential numerical order. Ex: **"2015-RP-0001"**

3. **Re-Inject Plates**
Entire plates which need to be re-setup for genetic analysis will be assigned as a re-inject plate. The plate will be named by "calendar year-re-inject (RI)-plate number". Plate numbers will be in sequential numerical order. Ex: **"2015-RI-0001"**

4. **Last Try Plates**
Samples which have been previously analyzed 2 times and still fail to produce a full DNA profile will be analyzed for a third and final time. These samples will be placed on the next available last try plate, named by "calendar year-last try (LT)–plate number". Ex: **"2015-LT-0001"**.

C. Make the appropriate volume of PCR amplification mix according to the volumes below[1]:

Water[1], Amplification Grade 5.0 µl	5.0 µl
5X AmpSolution™ 2.5 µl	2.5 µl
PowerPlex® Fusion 5X Master Mix	2.5µl
PowerPlex® Fusion 5X Primer Pair Mix	2.5µl
Total Reaction Volume	12.5µl

[1]*Add amplification grade water to the tube first; then Master Mix and Primer Pair Mix.*

For one full plate of samples, the following totals can be used:

Water[1], Amplification Grade 5.0 µl	500 µl
5X AmpSolution™ 2.5 µl	250 µl
PowerPlex® Fusion 5X Master Mix	250 µl
PowerPlex® Fusion 5X Primer Pair Mix	250 µl
Total Reaction Volume	1250 µl

[1]*Add amplification grade water to the tube first; then Master Mix and Primer Pair Mix.*

D. Vortex the PCR amplification mix for 5-10 seconds, and then place 12.5µl of PCR amplification mix into each reaction well.

E. Place the appropriate number of punches (see Sample Type and Punches Used) into the designated well of the 96-well plate. To clean the punch between samples, take two punches of a clean area of the sample card and discard the blank punches.

1. For the positive amplification control, vortex the tube of 2800M control DNA and add 1µl (10ng) to a reaction well containing 12.5µl of PCR amplification mix. The reagent blank will also serve as the negative amplification control.

2. Seal the plate. Briefly centrifuge the plate to bring the storage card punches to the bottom of the wells and remove air bubbles.

3. Record the sample number(s) on the Offender Sample Analysis Summary Table and the Offender Sample Analysis Set-Up Worksheet.

3.0 PROTOCOL NOTES

Analysts should pay careful attention during punching to avoid the accidental addition of the paper backing into the sample wells, as this can affect the quality of the profile obtained, as observed in the OSBI Internal Validation.

Failure to vortex the PCR amplification mix sufficiently can result in poor amplification or locus-to-locus imbalance.

CODIS Unit Policy Manual
Amplification of DNA Using the PowerPlex® Fusion Kit Half Reactions on the GeneAmp® 9700 Thermal Cycler (top ↑)

Principle of the Protocol

Individual Steps of the Protocol
Amplification Using the 9700 Thermal Cycler

Protocol Notes

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is for the direct amplification of DNA from storage card punches (including buccal cells collected on FTA® cards and blood collected on non-FTA® cards) using the PowerPlex® Fusion System and GeneAmp® PCR System 9700 thermal cycler.

1.1 Sample Requirements, Controls, and Reagents

The CODIS Unit uses direct amplification of offender samples. For sample requirements and controls refer to the previous section (Setup of Direct Amplification of DNA from FTA®/non-FTA® Punches using PowerPlex® Fusion Half Reaction Volume).

PowerPlex® Fusion Direct Amplification Kit
PunchSolution™ Kit
AmpSolution™ Kit
96-well plate from CODIS_1 procedure
GeneAmp® 9700 Thermal Cycler

2.0 INDIVIDUAL STEPS OF THE PROTOCOL

2.1 Amplification using the 9700 Thermal Cycler

A. Program the GeneAmp® 9700 Thermal Cycler according to the appropriate schedule:

Instrument Used	Times and Temperatures for PowerPlex® Fusion Kit					
	Initial Step	Melt	Anneal	Extend	Final Extension	Final Step
GeneAmp® 9700 Thermal Cycler	1 CYCLE	26 CYCLES			1 CYCLE	SOAK
	96°C 1 min	94°C 10 sec	59°C 1 min	72°C 30 sec	60°C 20 min	4°C ∞

B. Place the 96-well plate in the thermal cycler, close the lid, and start the "pp fusion" amplification program.

C. After the amplification is complete, remove the plate from the instrument block. The amplified DNA is now ready to be set up for analysis on the 3500xL Genetic Analyzer.

D. Sealed plates of amplified DNA product may be stored at -20°C (or frozen) in a light protected box for short periods of time. Long periods of storage of amplified samples at 4°C or higher may produce artifacts.

3.0 PROTOCOL NOTES

Amplification plates will be discarded after technical review is complete. If the plate contains samples that are to be re-injected, the plate will be retained and stored as stated in this protocol until this process has been completed and then discarded.

For troubleshooting purposes, the sample can be re-punched and re-amplified or 2µL of amplicon can be added to the 3500xL plate. In the future (after the completion of the 27 cycle amplification stochastic threshold determination study), re-punch and/or last-try samples may be amplified using 27 amplification cycles at the analyst's discretion in an attempt to bring peaks above the analytical threshold.

The appropriate Biomek 3000 method should be used.

Capillary Electrophoresis of DNA Using the 3500xL Genetic Analyzer and the Biomek Automated Workstation (top ↑)

Principle of the Protocol
- Sample Requirements
- Controls
- Reagents

Individual Steps of the Protocol
- Instrument Preparation
- Manual Setup
- Setup Using the Biomek 3000
- Heat Denature / Snap Cool
- Loading the Instrument
- Instrument Preparation

Protocol Notes

1.0 PRINCIPLE OF THE PROTOCOL

This protocol shall establish the procedures to be used for capillary electrophoresis of offender DNA database samples on the 3500xL Genetic Analyzer.

The 3500xL Genetic Analyzer separates fluorescently labeled DNA fragments based on size using capillary electrophoresis. Utilizing a multi-component fluorescent detection system, this instrument allows for simultaneous detection of DNA fragments on a 24 capillary array. The data collection software stores the raw fluorescent intensity data in the instrument's oracle database, which can later be retrieved for genetic typing utilizing sophisticated software packages such as GeneMapper ID-X (GMID-X).

1.1 Sample Requirements

Samples shall consist of offender DNA database samples previously extracted (if applicable) and amplified following the procedures in the CODIS Unit Policy Manual.

Note: A plate that is to be re-injected due to original genetic analysis set-up failure is to be named as a re-inject plate:

Re-Inject Plates
If a plate contains samples that are to be re-injected, the plate will be named by "calendar year-reinjection (RI)-plate number". Plate numbers will be in sequential numerical order. Ex: "**2015-RI-0001**"

1.2 Controls

All positive amplification controls and reagent blank/negative amplification controls shall be injected with every plate as required by the CODIS Unit Policy Manual.

1.3 Reagents

Hi-Di™ Formamide
Anode Buffer Container
Cathode Buffer Container
Performance Optimized Polymer 4 (POP-4®) for the 3500xL Genetic Analyzer
CC5 Internal Lane Standard 500 (CC5)
PowerPlex® Fusion Allelic Ladder

Supplies/Equipment

96-well Optical Plate	Biomek 3000	Freezer, Ice, or Cold Block
Microcentrifuge Tube	96-well Septa Mat	Plate Base and Plate Retainer
Centrifuge	Thermal Cycler	3500xL Genetic Analyzer

2.0 INDIVIDUAL STEPS OF PROTOCOL

Fill out the appropriate sections of the Offender Sample Analysis Lot Number Form.

2.1 Instrument Preparation

Refer to the section of this Policy and Procedures Manual titled Maintenance and Calibration of the 3500xL Genetic Analyzer for steps to prepare the instrument for operation, including maintenance, spatial and spectral calibrations.

2.2 Manual Setup

A. Manual sample setup shall only be performed with prior approval from either the CODIS Supervisor or the Technical Manager. Approval should be documented on the Offender Sample Analysis Lot Number Form.

B. Prepare the appropriate volume of master mix according to the volumes below:

CC5 ILS 500	1.0µl
Hi-Di™ Formamide	10.0µl
Total Volume per Well	11µl

Vortex the master mix for 10-15 seconds. Aliquot 11ul of the master mix solution into the appropriate wells of the 96-well plate.

C. Add 1.0µl of PCR product or PowerPlex® Fusion Allelic Ladder to the appropriate well. Cover wells with appropriate septa.

D. Centrifuge plate briefly to remove air bubbles from the wells.

2.3 Setup using the Biomek 3000

Prepare a tube of Master Mix containing 1050 µl of formamide and 105 µl of CC5 ILS 500.

A. On the Biomek 3000 software, open “Amp Setup” deck and save changes.

B. Open the Setup program titled “3500 Fusion”. (If setting up a last try plate with increased amplicon volume, choose “Last Try Fusion”)

C. Arrange the deck as indicated in the deck layout in the 3500 fusion program

D. Start the program and mark tips which are to be used as prompted by the software program.

E. After the program has completed, discard the microcentrifuge tube which contained the Master Mix and all used tips which were marked. Seal the amplification plate for storage and cover the 3500xL plate with a new 96-well septa mat.

F. Briefly centrifuge the 96-well plate to ensure the samples are seated at the bottom of the wells.

2.4 Heat Denature / Snap Cool

A. Denature the samples by heating the 96-well plate in a 9700 thermal cycler at 95°C for ~3 minutes.
Note: The lid on the 9700 thermal cycler should not be locked down during this step. The heated lid can melt the plate septa on the reaction plate.

B. Quickly chill the tray in a cold block, ice, or freezer for ~3 minutes.

C. Briefly spin the 96-well plate in a centrifuge to ensure no air bubbles are trapped at the bottom of each well. (Bubbles can interfere with the electrokinetic injection process.)

2.5 Loading the Instrument

A. Place the 96-well plate onto the 96-well plate base. Snap the plate retainer onto the optical plate and plate base. Verify that the holes of the plate retainer and the 96-well septa mat are aligned.

2.6 Instrument Preparation

A. Open the 3500xL Data Collection Software. The Dashboard screen will launch. Press the Refresh button to ensure the most up-to-date information is being displayed.

B. Set the oven temperature to 60˚C, then select "Start Pre-Heat". When the Oven Temperature and Detection Cell Temperature turn green, you may proceed with the first injection.

C. To import a plate from the CODIS worksheet excel template:

a. Click on the tab in the excel workbook titled template
b. Ensure that all cells have been properly filled and click the windows button.
c. Click "save as" and in the "save as" dialogue box select "Text (Tab delimited)(*.txt)" in "Save as type" drop down list.
d. Make sure the file name is the plate name.
e. Select the appropriate location to which you want to save the file
f. Click "save" and click OK and Yes on the two following dialogue boxes in that order.
g. On the computer workstation for the 3500xL instrument, launch the 3500 collection software and log in.
h. Click the "library" tab from the dashboard.
i. Select "import" from the toolbar.
j. Navigate to the location of the saved file. It may be necessary to choose .txt for the file extension dropdown in order to have your saved plate record be visible.
k. Select the appropriate plate record and choose OK.
l. The dialogue box will indicate whether or not the plate was imported successfully.
m. Select "edit" from toolbar to bring up the plate record. If any injections need to be deleted due to a partial plate etc, highlight the cells to be deleted and right click to select delete.
n. Select "Link Plate for Run"
o. Once the Load Plate window appears, select "Yes"
p. In the Run Information window, assign the plate name for "Run Name" and select "Start Run"

D. To create a new plate:

a. navigate to the Library and from the Manage menu, select "Plates", then "Create".
b. Assign a Plate Name. Select the plate type "HID" from the drop-down menu.
c. Select "Assign Plate Contents" and assign sample names and sample types to wells.
d. Select the appropriate Assay, File Name Convention, and Results Group for the samples.
e. Select "Link Plate for Run".
f. Once the Load Plate window appears, select "Yes".
g. In the Run Information window, assign the plate name for "Run Name" and select "Start Run".

Each injection will take about 40 minutes.

Upon completion of the plate run, refer to the sections of this Policy Manual titled Analysis and Management of DNA Data and Interpretation Guidelines for Offender Database Samples for details on analysis and management of data.

3.0 PROTOCOL NOTES

Samples will be injected for standard injection times of 18 and 24 seconds. Based on validation data, the 18 second injection will be used for the stochastic evaluation. The 24 second injection may be used if there are alleles that are below analytical threshold in the 18 second injection or the 18 second injection has undesirable artifacts.

Last try plates may be set up for 3500xL analysis with increased amplicon volume of 2.0µl at the analyst's discretion.

The Biomek 3000 workstation should be cleaned weekly using a 1:10 bleach solution and documented on the Decontamination Log.

PowerPlex® Fusion Allelic Ladder should be stored protected from light at -15°C to -25°C upon receipt, then stored protected from light at 2-8°C after initial use.

CC5 Internal Lane Size Standard (ILS) 500 is to be stored at 2-8°C.

Performance Optimized Polymer (POP-4) is to be stored at 2-8°C.

Hi-Di™ Formamide should be stored at -15°C to -25°C upon receipt, then stored at 2-8°C after initial use. Unless otherwise indicated by the manufacturer, Hi-Di™ Formamide does not have an expiration date.

CODIS Unit Policy Manual

Analysis and Management of DNA Data (top ↑)

Principle of the Protocol
- Sample Requirements

Individual Steps of the Protocol
- Data Analysis
  - GeneMapper ID-X Analysis Software
  - Create a New GeneMapper ID-X Project
    - General Tab Settings
    - Allele Tab Settings
    - Peak Detector Tab Settings
    - Peak Quality Tab Settings
    - SQ and GQ Tab Settings
  - View Raw Data for Each Ladder
  - Analyze Sample Files
  - Examine Samples for Missing ILS 500 Peaks
  - View Sample Plots
  - Evaluate Process-Component Based Quality Values (PQV)
- Data Management
  - Create a *.cmf file for CODIS Import
  - Data Storage on the CODIS Server

Protocol Notes

1.0 PRINCIPLE OF THE PROTOCOL

The purpose of this protocol is to provide information on how to analyze and manage electronic data pertaining to offender database samples.

1.1 Sample Requirements

Electronic data captured by the CCD camera on a 3500xL Genetic Analyzer.

Supplies/Equipment

GeneMapper ID-X Analysis Software
3500xL Run Folders

2.0 INDIVIDUAL STEPS OF THE PROTOCOL

2.1. Data Analysis

A. **GeneMapper ID-X Analysis Software**

The 3500xL Genetic Analyzer detects DNA fragments by automated fluorescence scanning detection. The GeneMapper ID-X (GMID-X) software analyzes the data collected by the instrument to size and quantify the DNA fragments. GeneMapper ID-X analysis includes:

1. Establishing a baseline,
2. Adjusting for spectral overlap of dye emission,
3. Peak detection,
4. Peak size calling,
5. Finding the lane or injection containing the allelic ladder,
6. Creating allele size categories based on imported allelic ladder data,
7. Removing labels from stutter peaks by applying a filter,

8. Assigning the appropriate allele label to sample alleles,
9. Process Component-Based Quality Values (PQV),
10. Automated concordance checks, and
11. Building a table containing genotypes for all samples.

The project window is the primary window for GeneMapper ID-X. It allows for adding samples, initiating analysis, and exporting data to various databases and reports.

B. **Create a New GeneMapper ID-X Project**

1. Launch the **GeneMapper ID-X** application. Each analyst must log on under his/her GMID-X user name to ensure that the analyzed samples and *.cmf files have the correct "read by" and "assigned to" user. The GMID-X user name must be the same as the CODIS database user name to allow importing of data.

2. Select **File**, then **New Project.**

3. Select **Edit**, then **Add Samples to Project**.

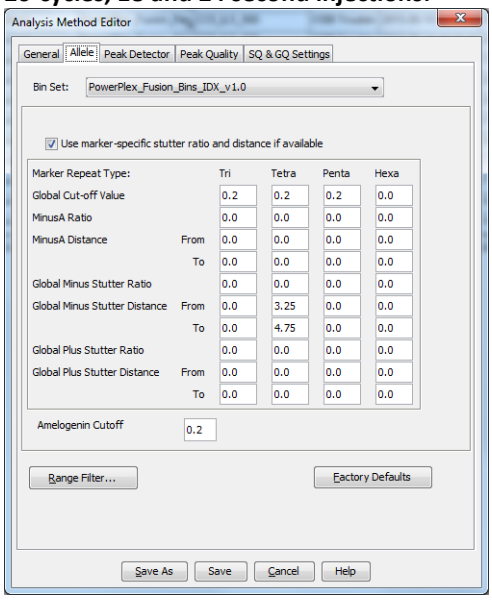
4. Browse to the location of the run files. Highlight the desires file(s) and then select **Add to List** followed by **Add**.

5. In the Sample Type column, use the drop down menu to select **Allelic Ladder**, **Sample**, **Positive Control** or **Negative Control** as appropriate for the sample.

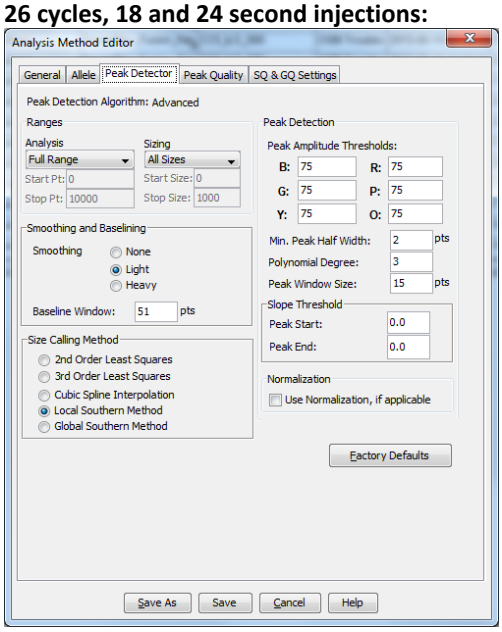
6. In the **Analysis Method** column, select "**OSBI Fusion**". All settings have been pre-determined during CODIS validations. Double click the Analysis Method to confirm the following settings:

   a. **General Tab Settings**:
      26 cycles, 18 and 24 second injections:
      - Name: **OSBI Fusion**
      - Instrument: **3500xL**
      - Analysis Type: **HID**

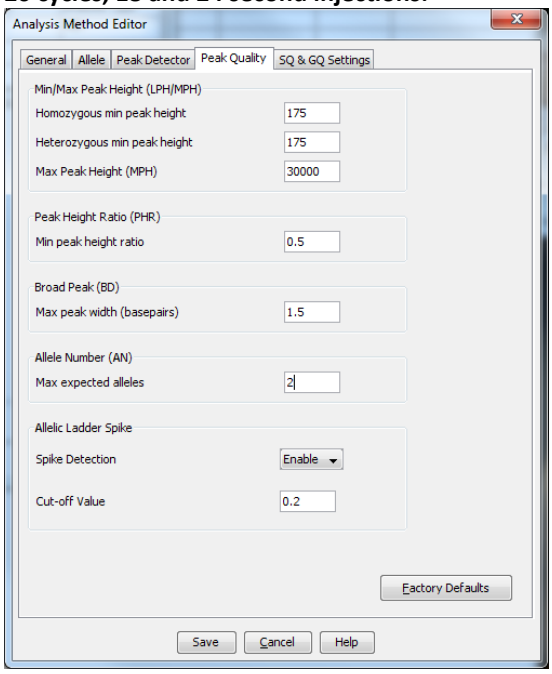
b. **Allele Tab Settings**:
26-cycles, 18 and 24 second injections:



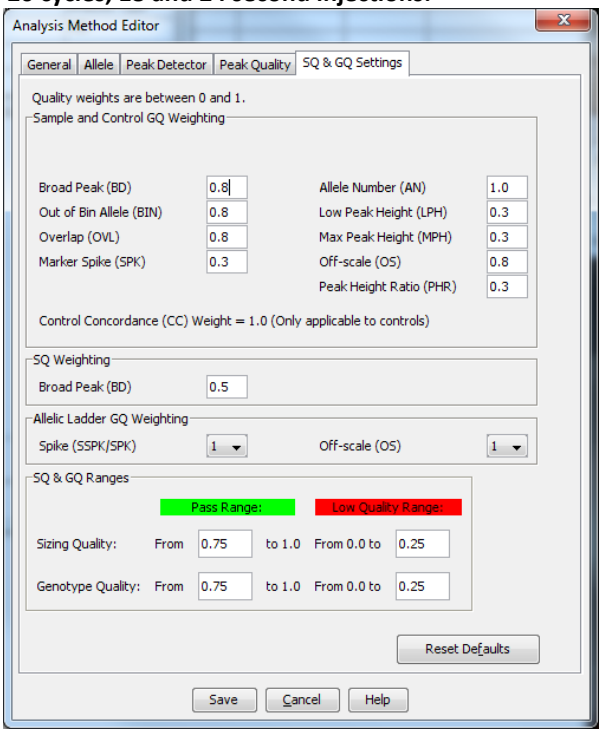
c. **Peak Detector Tab Settings**:
26 cycles, 18 and 24 second injections:



d. **Peak Quality Tab Settings:**
26 cycles, 18 and 24 second injections:



e. **SQ and GQ Tab Settings:**
26 cycles, 18 and 24 second injections:



7. Ensure that the "**Fusion_CODIS_v1.0**" Panel is selected.

8. Ensure that the "**3500_CC5_ILS_500_IDX**" Size Standard is selected. Double click to confirm the following settings:

   a. Size Standard Dye: **Orange**
   b. Size in Base Pairs: **60, 65, 80, 100, 120, 140, 160, 180, 200, 225, 250, 275, 300, 325, 350, 375, 400, 425, 450, 475, 500**

C. **View Raw Data for each Ladder**

1. Click **View > Raw Data**. Look at each ladder for bad injections. If any are found, they should be removed from the project and listed in the Offender Sample Analysis Technical Notes.

D. **Analyze Sample Files**

1. Select **Analyze** (green arrow button) to start data analysis. A new window will open asking for a **Project name:** Enter the appropriate Plate Name, as specified in the following sections of this Policy and Procedures Manual: Setup of Direct Amplification of DNA from FTA / Non FTA Punches Using PowerPlex® Fusion Half Reaction Volume, Amplification of DNA using the PowerPlex® Fusion Kit, Biomek Automated Workstations and the ABI 9700 Thermal Cycler, or Capillary Electrophoresis Using the ABI 3500xL Genetic Analyzer and the Biomek Automated Workstations.

26 cycle Analytical Thresholds		
Dye	18 sec	24 sec
Blue	75	75
Green	75	75
Yellow	75	75
Red	75	75
Orange	75	75

26 cycle Peak Stochastic Threshold
175

Note: Each analyst will save two types of projects. The first one contains the unedited GMID-X data prior to any changes being made (other than size quality overrides). The second one contains the reported GMID-X data and only includes passed samples (if multiple injections are performed, only one passed sample should be saved). Each project should be named as follows:

Ex: "**Plate Name (Unedited)**" and "**Plate Name (Reported)**"

In the event a plate fails analysis and no data is accepted, a "Reported" project will not be created. Also, there may be times when more than 1 "Reported" project is needed. In this case, each "Reported" project should also include a sequential number at the end to distinguish them apart.

Ex: "**Plate Name (Reported)**" and "**Plate Name (Reported 2)**"

2. Click **OK**. The progress status bar at the bottom of the window will fill in as the samples are analyzed.

3. After the analysis is complete, confirm that the sizes for the peaks in the CC5 ILS 500 size standard have been correctly assigned. This may be quickly accomplished by highlighting all the samples in the **Sample** window and clicking the **Size Match Editor** under the **Tools** menu.

Note: Only 21 peaks from 60 to 500 bp. should be found within the analysis range of each sample's CC5 ILS 500 peaks. Additional peaks should be carefully examined to ensure they do not interfere with sample profiling.

4. If the SQ column (located at the far right of the **Samples** window) has a green square, then the size quality meets the predetermined requirements. Skip to step "F". Otherwise, the samples need to be examined for missing CC5 ILS 500 peaks.

E. **Examine Samples for CC5 ILS 500 Peaks**

1. Examine the CC5 ILS 500 of each sample for any failures of sample sizing due to the presence of artifacts such as pull-up. Any ILS that is overridden must be documented in the file in the technical notes section and approved by the Technical Reviewer. Any discrepancies will be brought to the attention of the Technical Manager. Samples with size quality overrides must be re-analyzed; this re-analysis must be performed in the unedited GMID-X project. The data for these samples will be closely examined for any uncalled/unlabeled peaks.

2. If a CC5 ILS 500 peak has been excluded at either end of the analysis range, the analysis range may need to be expanded to include the peaks in question. This will affect the analysis range of all samples and controls within the project.
Note: An alternative method is to re-analyze the problem sample(s) in a new project with a new analysis range to include the peak(s) in question. If this alternate method is performed, at least one allelic ladder must be included in the new project. This new project should be named in a manner to distinguish it from the other projects.
Ex: "**Plate Name (Reported 2)**"

3. Determine the correct analysis range for the first sample by highlighting the sample on the **Samples** tab. Examine the raw data for the sample by choosing **Raw Data** in the **View** menu. Alternately, the sample can be highlighted in the navigation pane on the left side of the window. **The object is to exclude the over-blown primer peak typically found at < 1600 scan numbers while including the size standard range from 60 to 500 bp.**

4. A closer examination can be made by placing the cursor on the left or top scale until the magnifying glass appears. Click and drag the magnifying glass to include the area desired. To return to the original scale double click the appropriate scale. This will aid in choosing scan number values less than the 60 base pairs (bp) and greater than the 500 bp. CC5 ILS 500 standard peaks as observed in the raw data. The other scans can be evaluated after highlighting the first scan and placing the cursor on the correct scan number and using the down arrow (**↓**) to scroll.

5. Once these values have been determined, return to the **Samples** window by clicking on the **Project** icon in the navigation pane or by clicking on **Samples** in the **View** menu.

6. Modify the analysis range values accordingly and re-analyze the sample files according to step "D" above. No other GMID-X setting should be modified!
   Note: Once the analysis range values have been changed, they will become the new default settings for future projects. If this is not desired, ensure the original default settings are re-entered when analyzing future projects.

F. **View Sample Plots**

1. From the **Samples** tab, highlight each allelic ladder and select **Display Plots** from the **Analysis** menu. Carefully evaluate each ladder to determine if all ladder alleles are called appropriately. Remove any incorrect or failed ladders from the GMID-X project and document in the Offender Sample Analysis Technical Notes.

2. From the **Samples** tab, highlight the controls and select **Display Plots** from the **View** menu. Carefully evaluate each control according to the section of this policy manual titled Interpretation Guidelines for Offender Database Samples.

3. From the **Samples** tab, highlight the samples and select **Display Plots** from the **View** menu. Carefully evaluate each sample according to the section of this policy manual titled Interpretation Guidelines for Offender Database Samples.

4. Document the results of sample analysis on the Offender Sample Analysis Technical Notes and determine if re-analysis is needed. Individual samples which do not pass guidelines for reasons that do not extend to the entire plate will typically be assigned to the next available re-punch plate. The most common reason for re-punch is dropout. If a sample fails again after being assigned to a re-punch plate, it will be assigned to a last try plate. If a sample on a last try plate fails to produce a full DNA profile it will be considered failed. All reasonable attempts to remediate samples not meeting reporting guidelines will be made. Failed samples will be documented on the Offender Sample Analysis Technical Notes for the plate on which they failed. Failed samples may be manually entered into the Incomplete Offender or Incomplete Arrestee Index if meeting the eligibility requirements as listed in this policy. A comment for all failed samples should be entered into the BEAST indicating the sample failed analysis and requesting an additional sample be collected from that offender. If an entire plate fails due to amplification failure, or electrophoresis failure, the plate may be re-amplified as a re-punch plate or re-injected as a re-inject plate.

G. **Evaluate Process-Component Based Quality Values (PQV)**
After careful examination of all samples, ladders and controls, the analyst should use the GeneMapper ID-X PQV flags as an additional quality check of the reported data. The PQV markers are not to be used as a substitute for the analyst's evaluation of the data, but as a tool to help ensure no additional sample problems went undetected.

1. From the **Genotypes** tab in the **Project** window, the samples will be separated by marker. The available PQVs will be displayed at the far right side of the table. Each PQV will be marked with a green square (Pass), a yellow triangle (Check), or a red octagon (Low Quality).

2. The samples can be sorted with the low quality samples taken to the top by clicking **Low Quality to Top** under the **View** menu. This will sort the samples into low quality, check and pass.

3. Each sample with a red octagon (Low Quality) or a yellow triangle (Check) must be examined to determine what action needs to be taken. Highlight the sample and click **Display Plots** under the **View** menu.

2.2 Data Management

A. Create a *.cmf file for CODIS Import

A *.cmf file must be created from each Reported GMID-X project that contains offender database samples which need to be imported into the CODIS database.

1. All offender database samples that have been successfully profiled will be marked for export. In the **Samples** tab, select "**Convicted Offender,**" "**Arrestee**," or "**Proficiency,**" as appropriate, from the **Specimen Category** menu. This marks the specimen to be assigned to the appropriate index in the CODIS database.
   Note: This does not include Hit Verification samples or samples previously entered into the CODIS database. These samples should not be marked for export.

2. All controls and ladders will be set to "No Export". Any sample that does not meet the requirements outlined in Interpretation Guidelines for Offender Database Samples will not be added to the *.cmf file. This will prevent any unacceptable samples from being entered into the CODIS database.

3. After all samples have been marked appropriately, they should be exported following these steps:

   a. Click **File > Export Table for CODIS** and make the following selections:

      - Export File As: **CMF 3.2 (.xml)**
      - Source: **OKOBI0000**
      - Destination: **OKOBI0000**
      - File name: **"GMID-X Project Name (cmf file)"**
      - Files of type: **CODIS formats CMF 1.0, CMF, 3.0, CMF 3.2 (*.dat, *.xml)**

   b. Select the appropriate destination you want the file to be saved and Click **Export**.

4. If the "Reported" project is edited during technical review, a new *.cmf file must be created.

B. Data Storage on the CODIS Server

1. The DNA_Profiles partition of the CODIS Storage Server (\\osbi-codis\DNA_Profiles) will be organized by year. Each completed plate will have its own subfolder in the year folder.
   Example: 2015 > 2015-FP-0001

2. After the completion of sample analysis, the following data should be made available electronically to the technical reviewer:
   a. GMID-X project(s)
   b. *.cmf file(s) exported from GMID-X
   c. 3500xL run folder(s)
   d. Plate record(s) exported from the 3500xL Data Collection software

3. Upon completion of the Technical Review, the completed plate folder in \\osbi-codis\DNA Profiles will contain the items listed above.

3.0 PROTOCOL NOTES

All 3500xL analysis plates will be discarded after the Technical Review has been completed. If the plate contains samples that are to be re-injected, the plate should be retained and stored appropriately until this process has been completed.

For 26 cycle amplifications, the stochastic threshold was determined to be 175rfu during the OSBI Internal Validation. 27 cycle amplifications will not be used at this time – but will be used in the future pending the approval of a subsequent report from Promega detailing the 27 cycle amplification stochastic threshold determination.

Interpretation Guidelines for Offender Database Samples (top ↑)

Principle of the Protocol
- Sample Requirements

Individual Steps of the Protocol
- Interpretation of Data
- Acceptability Criteria
  - Oversaturation
  - Heterozygous Peak Height Ratios
  - Unidentified Peaks
  - Off-Ladder Alleles
  - Trisomy / Tri-allelism

Known Artifacts Defined
- Pull-up
- Spikes
- Minus A
- Stutter
- Dye Blobs

Frequency and Tolerance of Controls
- Control Requirements
- Failure of Controls
- Unexplained Peaks

Protocol Notes
- Complete Offender Profiles
- Incomplete Offender Profiles
- Technical Issues and Non-Conforming Work
- Peak Amplitude Threshold
- Precision and Size Window

1.0 PRINCIPLE OF THE PROTOCOL

The purpose of this protocol is to provide STR interpretation guidelines for DNA profiles generated from Offender Database Samples.

1.1 **Sample Requirements**

Samples shall consist of DNA profiles generated from Offender Database Samples.

2.0 INDIVIDUAL STEPS OF THE PROTOCOL

2.1 **Interpretation of Data**

A. A true peak (**allele**) is defined as a relatively symmetric pointed arch in an upward direction. It is wider at the base than at the summit and shows an area of non-linear taper to and from the highest point. Generally, the peak should have a height to width ratio of >1. True peaks should be present in only a single color unless pull-up has occurred.

B. **Heterozygous** loci are identified by the presence of two separate peaks. Only one peak, generally greater in height (approximately twice the size) than adjacent heterozygous pairs, will be observed for any **homozygous** locus.

C. The final product of each sample analysis is a profile genotype. It is defined by the alleles present at each locus. With the exception of the Amelogenin locus, alleles are assigned number designations defined by the number of repeat sequences present. The genotype of a sample is represented by a series of one or more alleles associated with each locus analyzed:

PowerPlex® Fusion Positive Control 2800M Allele Designation:

Locus	Alleles	Locus	Alleles
Amelogenin	X,Y	TH01	6, 9.3
D3S1358	17, 18	vWA	16, 19
D1S1656	12, 13	D21S11	29, 31.2
D2S441	10,14	D7S820	8, 11
D10S1248	13, 15	D5S818	12, 12
D13S317	9, 11	TPOX	11, 11
Penta E	7, 14	DYS391	10, 10
D16S539	9,13	D8S1179	14, 15
D18S51	16,18	D12S391	18, 23
D2S1338	22,25	D19S433	13, 14
CSF1PO	12,12	FGA	20, 23
Penta D	12,13	D22S1045	16, 16

D. The allele designations provided in the table above are the genotype of 2800M Control DNA (PowerPlex™ Fusion positive control). The locus genotype of heterozygotes is given by two different numbers representing two discrete alleles, such as "11, 12". Those loci, which are homozygous, possessing identical alleles on each homologous chromosome, are characterized by repeated numbers, such as "11, 11".

E. The genotype of the sex-identifying locus, Amelogenin, is not defined numerically. Only two genotypes are possible, X, X and X, Y. A genotype of X, X at this locus indicates the sex to be female. The genotype X, Y is that of a male. These results are observed graphically on the electropherogram as a single peak for the X, X genotype and two peaks for the X, Y genotype.

Note: If an apparent null allele exists (no X detected, for example), the sample will be re-analyzed and documented in the Offender Sample Analysis Technical Notes.

F. A sample can be determined to have originated from a single source if no more than two alleles

are present at all loci examined, recognizing that three peak (trisomy/tri-allele) patterns can occur.

2.2 **Acceptability Criteria**

By nature, Offender Database Samples are single source and the profiles should be carefully evaluated for indications of a mixture, which could indicate contamination. DNA profiles from all samples, controls, and ladders must meet the following criteria to be considered acceptable:

A. **Alleles Below Peak Stochastic Threshold**

Peak Stochastic Threshold (PST) is defined as "the RFU value above which it can be assumed that peak dropout does not occur and any observed allelic peak that has no sister allele present can reasonably be believed to be homozygous". Alleles present in offender samples that are below the established peak stochastic threshold may signify that there is drop out of a sister allele at a locus. The 18 second injection of all offender samples will be used for the peak stochastic threshold evaluation. Samples exhibiting potential drop out (peaks below PST) may be acceptable if the locus is heterozygous and both peaks are present. If the sample has apparent homozygous peaks below PST, the sample should be further analyzed by re-punching/re-amplifying the sample. The 24 second injection of the sample may be analyzed as well; however, the 18 second injection is used for PST determinations. Other troubleshooting techniques for alleles below PST include adding 2µL of amplicon to the 3500xL Genetic Analyzer plate or an increased amplification cycle number (to be approved for use on offender samples in the future once the supplemental 27 cycle validation work is completed and approved).

Note: The PST determination for the locus DYS391 does not apply.

B. **Over Saturation / Off Scale**

Check each sample to see if the Over Saturation / Off Scale (OS) PQV in the 'Genotypes' tab is flagged as Pass. If the PQV is anything other than Pass, a closer examination of the sample is required, and the determination will be according to analyst discretion. If the analyst believes that the data may be affected by the over saturation, the sample shall be re-analyzed and documented in the Offender Sample Analysis Technical Notes.

B. **Heterozygote Peak Height Ratios (PHR)**

A peak height ratio is defined as the ratio of the peak with the lowest relative fluorescence unit (RFU) to that of the peak with highest RFU of a heterozygous pair expressed as a percent. Examination of the Low Peak Height (LPH) PQV in the 'Genotypes' tab will indicate whether the peak height ratio meets the appropriate percentage. Offender Database Sample profiles will be accepted with peak height ratios 50% or more.

Note: Samples displaying less than 50% peak height ratios at one or more locations will be re-injected to verify results. If after re-injection the sample is still below 50%, the sample will be accepted. Results must be documented on the Offender Sample Analysis Technical Notes and approved by an analyst qualified to perform a technical review on CODIS database samples.

C. **Unidentified Peaks**

Unless approved by the Technical Manager, an Offender Database Sample shall not contain any unexplained peaks (which exceed the peak detection threshold) within the allele calling range. This does not include known artifacts defined in section 3.0 of this policy. Samples containing unexplained peaks will be re-injected and/or re-amplified to verify the result. However, if possible contamination is present, the incident will be evaluated in accordance with procedures outlined in CSD QP 13. In this case, no profiles from the affected plate will be imported into CODIS until the evaluation of the incident has been finalized.

D. **Off-Ladder Alleles**

An off-ladder allele is defined as an allele whose size is not represented within the allelic ladder. The GeneMapper ID-X software (GMID-X) is unable to assign an allele value to these peaks, so a manual calculation may be required. Unless otherwise indicated, samples containing off-ladder alleles will be re-injected and/or re-amplified to verify the result.

There are three main types of off-ladder alleles.

1. First, there are alleles which fall **outside** the range of ladder alleles. These alleles are smaller than the smallest allele of the ladder or larger than the largest allele of the ladder of a particular dye. The GMID-X software labels these alleles as "< (smallest ladder peak)" or "> (largest ladder peak)".

   Since the CODIS database software does not recognize allele values outside the range of ladder alleles, the label assigned will be accepted once the result has been verified. The approximate base size may be calculated if desired and documented on the Offender Sample Analysis Technical Notes.

2. Second, there are alleles which may fall **inside** the range of the smallest and largest ladder alleles of a particular dye. These microvariant alleles contain an incomplete number of repeats (such as X.1, X.2, or X.3), and are labeled as “OL” by the GMID-X software if not present in the allelic ladder.

   After the sample is re-analyzed, if the software has assigned an allele label, the sample will be accepted as valid. If the allele is still labeled as “OL”, the sizing value will be calculated and the appropriate allele value assigned. All verified microvariant alleles shall be documented on the Offender Sample Analysis Technical Notes.

3. Third, there are alleles that are labeled by the GMID-X software, even though they are not present in the allelic ladder. These “**virtual alleles**” are labeled due to the presence of a bin outside the minimum or maximum allele for a particular dye. The term virtual allele does not in any way indicate that the allele is not a true allele, but simply indicates it is an off-ladder allele that has been assigned a label. Virtual alleles will be accepted with no additional analysis required.

4. Occasionally an allele may be labeled as OL by the software, even though it is a value that is recognized within the ladder, due to the sample not lining up satisfactorily with the average bins calculated from the ladder. When this happens, the analyst should analyze the sample in a separate project with a different combination of ladder(s) to try and reconcile the sample. This action shall be documented on the Offender Sample Analysis Technical Notes.

5. Occasionally an allelic peak may be observed which falls outside or in between two locus bins. In these instances, the software will not label the peak as an allele, nor can the analyst add a label. When this is observed and the analyst feels the peak represents a true allele, the analyst will note the out of bin allele in the technical notes and indicate the locus to which the allele is believed to belong.

   Additionally, an allele may be labeled in the wrong locus. These instances may be observed as false tri-alleles or have inconsistent peak heights. To confirm the suspected incorrect assignment, the analyst should calculate the value of the allele from the ladder of the correct locus and verify the previous observation in STRbase. The analyst may then delete the allele to reduce the chance of an erroneous no-match due to incorrect

profiling at the affected locus. This deletion must be noted in the technical notes and must be approved by the technical reviewer. If there is a discrepancy, the Technical Manager will be consulted.

E. **Trisomy/Tri-allelism**

If a profile is suspected to have trisomy or be tri-allelic at a locus, the sample shall be re-injected, and then re-amplified to verify this event. Once verified, the tri-allele can be accepted as valid.

Note: Peak height ratios may not be calculated for a locus with a verified tri-allele.

3.0 KNOWN ARTIFACTS DEFINED

There are known artifacts identified that are a naturally occurring phenomenon of the DNA analysis process. At times, these artifacts are labeled by the GMID-X software as allele peaks, thus interfering with the true sample profile. If a known artifact is observed during data analysis, the electropherograms should be examined with care. If there is no indication of a possible mixture on the electropherograms, and the artifact is clearly not a true allele peak, the analyst may delete the allele call from the artifact peak. Deleted peaks must be documented on the Offender Sample Analysis Technical Notes and approved by an analyst qualified to perform a technical review on CODIS database samples. If the artifact interferes with a true allele peak, the sample shall be re-injected or re-amplified.

3.1 Pull-up

Pull-up may be observed with loci that have large peaks due to an amplification of excess template DNA. The spectral may not be able to compensate for an excess of one color, causing the "pulling up" of peaks in another color. In other words, the instrument is not able to resolve spectral overlap. Pull up peaks will have nearly identical GeneMapper ID-X data point values to their source peaks.

3.2 Spikes

Instrument spikes occur occasionally within an electrophoretic run resulting in the appearance of anomalous peak(s) on the electropherograms. A peak resulting from an instrument spike is easily identified as such upon close examination. Such a peak will usually be composed of all colors (blue, green, yellow, red, and orange) of approximately equal apparent fluorescent intensity and occur at the same data point and/or scan number in GeneMapper ID-X. Spikes are believed to be caused by scattering of incident light due to the passage of dust particles through the excitation laser beam.

3.3 Minus A

Minus A is an artifact of the PCR process. Thermostable non-proofreading DNA polymerase included with the PowerPlex® Fusion amplification kit can catalyze the addition of a single nucleotide (predominantly adenosine ‘A’) to the 3' end of the PCR product. The PCR processes used in this policy manual facilitate the addition of the ‘A’, with an extended 60°C soak for 20 minutes. With higher than recommended amount of template DNA, minus A (n-1) peaks may be observed as a “shoulder” of the main allele peak. If minus A is observed, the amplification plate may be extended at 60°C for an additional 20 minutes to attempt to decrease the amount of minus A present in the sample.

3.4 Stutter

Stutter is an artifact of the PCR process. It is a minor product peak a repeat unit (i.e. four bases shorter [n-4]) than the corresponding main allele peak. With higher than recommended amount of template DNA, stutter may sometimes be labeled as an allele peak by GMID-X software.

3.5 Dye Blobs

A dye blob is an artifact of the PCR process. Although it is not entirely clear why dye blobs occur, it is believed to be caused when the fluorescent dye tags attached to the amplification primers begin to break down over time. These disassociated primer dyes are carried through the PCR amplification step, and

when injected onto the capillary array can appear as peaks during data analysis. Dye blob peaks are usually wider than real peaks and are typically only seen in one color (but can be seen in multiple dye colors).

4.0 FREQUENCY AND TOLERANCE OF CONTROLS

4.1 Control Requirements

A. Each set of amplified samples must include negative and positive amplification controls. All samples and controls shall then be analyzed using the 3500xL Genetic Analyzer.

Note: It is the default procedure for offender plates to be injected one time at 18 seconds and one time at 24 seconds. If offender sample data from an 24 second injection is accepted (in lieu of the data from the 18 second injection), the reagent blank / negative amplification control injected at 24 seconds must also be evaluated and produce the expected results. If the reagent blank / negative amplification control injected at 24 seconds fails, no offender sample injected at 24 seconds shall be considered valid and shall be re-analyzed accordingly.

B. A sample, control, or allelic ladder shall not contain any unexplained peaks (which exceed the peak amplitude threshold) within the allele calling range.

C. Any control with unexplained peaks below the peak amplitude threshold will be evaluated in consultation with the Technical Manager. The use of data from any affected plate may only be used with Technical Manager approval.

D. The positive amplification control must yield the genotype listed in Section 2.1.C.

4.2 Failure of Controls

In the event a control fails one of the above criteria, the control will be re-injected to verify the result. If the re-injection is acceptable, the control will be considered valid. If the same condition is observed in the second injection, the entire set of samples processed with the same reagents is considered invalid. The source of the problem must be determined and corrective action taken.

Note: If a plate contains more than one of each control and only one fails (due to a bad injection, artifact, drop-out, low peak height ratio or possible contamination), the failed control does not need remediation, as long as a second control was good. However, if possible contamination is present, the incident will be evaluated in accordance with procedures outlined in CSD QP 13 – Non-Conforming Work and/or CSD QP 14 – Corrective Action. In this case, no profiles from the affected plate will be imported into CODIS until the evaluation of the incident has been finalized.

4.3 Unexplained Peaks

If a positive amplification control reagent blank / negative amplification control fails due to the presence of unexplained peaks, the possibility of contamination shall be evaluated. This may be confirmed by examining sample profiles for the presence of peaks consistent with those observed in the contaminated control(s). Such contamination must be eliminated by either immediately replacing all reagents currently in use or by systematically replacing one reagent at a time until the control in question shows no contamination.

A. If the source of the contamination is found to be in the PowerPlex® Fusion kit, then all samples will be re-amplified using a new kit.

B. If the source of the contamination is found to be in something other than the PowerPlex® Fusion kit, all samples must be re-amplified using uncontaminated reagents.

5.0 PROTOCOL NOTES

5.1 Complete Offender Profiles

A profile is considered to be complete when all alleles are above analytical and stochastic thresholds at the core CODIS loci and otherwise meet the requirements of the Interpretation Guidelines for Offender Database Samples. Upon completion of Technical review, all complete profiles will be entered into the Offender or Arrestee Index as applicable (see the section of this policy manual titled CODIS Data Entry and Search Procedures).

5.2 Incomplete Offender Profiles

A profile is considered to be incomplete when all alleles are not above analytical and stochastic thresholds at each of the core CODIS loci. These samples shall be re-analyzed in the attempt to obtain a full profile. Re-analysis may include re-punching of the sample using the same number of amplification cycles or increased amount of amplification product. In the future, an increased amplification cycle number for troubleshooting will be validated and approved for use on offender samples. If a complete profile is not obtained after 3 attempts, the sample will be considered failed.

5.3 Technical Issues and Non-Conforming Work

All technical issues and non-conforming work must be brought to the attention of the Technical Manager immediately. This includes (but not limited to) contamination, sample-switch, plate record linked to incorrect plate, Biomek instrument problems, etc. The Technical Manager will determine the appropriate response per CSD QP 13 – Non-Conforming Work and/or CSD QP 14 – Corrective Action.

5.4 Peak Amplitude Threshold

The sensitivity of the 3500xL Genetic Analyzer is based on the average background noise observed for a negative control injected multiple times for all capillaries. The analytical threshold determined from internal validation studies for the OSBI's 3500xL Genetic Analyzer is 75 RFU for 26 cycle amplifications. No peaks below this analytical threshold will be sized as alleles.

5.5 Precision and Size Window

The precision and size window validated by the OSBI follows the manufacturer's recommendation of $\pm$ 0.5 bp.

Quality Control Procedure for PowerPlex® Fusion Amplification Kits (top ↑)

Principle of the Protocol
- Specimen Requirements
- Controls
- Reagents

Individual Steps of the Protocol
- Purchase of Kits
- Receiving Kits
- Quality Testing of Kits
- Documentation of Quality Testing

Frequency and Tolerance of Controls
- Expected Values
- Repeated Testing
  - Known Samples
  - Positive Control
  - Negative Control
- Persistent Problems

1.0 PRINCIPLE OF THE PROTOCOL

This protocol shall establish a quality control procedure for the critical reagents contained within the PowerPlex® Fusion Amplification Kit used to amplify the genomic DNA from offender database samples.

1.1 **Specimen Requirements (sample handling and preservation)**

5 different NIST traceable DNA samples from known human sources in which genotypes for all PowerPlex® Fusion loci plus Amelogenin have been determined. These samples are those designated by the Technical Manager for use in quality control testing.

1.2 **Controls**

Positive Control (Control DNA 2800M)
Negative Control (TE^{-4})

1.3 **Reagents**

Promega PowerPlex® Fusion Direct Amplification Kit containing:

A. PowerPlex® Fusion Reaction Mix
B. PowerPlex® Fusion Primer Set
C. Control DNA 2800M
D. PowerPlex® Fusion Allelic Ladder

CCE-ILS-500 Internal Lane Size Standard
PowerPlex® 5 dye Matrix Standards (CC5, CXR-ET, TMR-ET, JOE, Fluorescein, and nuclease-free water)
Hi-Di Formamide
3500xL Anode and Cathode Buffer
3500xL Performance Optimized Polymer 4 (POP-4®)

2.0 INDIVIDUAL STEPS OF PROTOCOL

2.1 Purchase of Kits

Purchases should be made such that all kits ordered at one time are from the same lot number (if possible), and the expiration date for that lot is as close as possible to one year (or greater) from the date of delivery.

2.2 Receiving Kits

A. Upon receipt of the shipment, all kit boxes will be examined for damage, leaks, or other problems. Any problems observed will be documented on the PowerPlex® Fusion PCR Amplification Kit Information Form and reported to the Technical Manager.

B. The kit components will be dated, sequentially numbered (1 of 6, 2 of 6, etc.), initialed by the receiving personnel, and stored appropriately.
Note: In order to conserve storage space, when large numbers of kits from the same lot are received at once, individual kit components may be removed from their boxes, placed into appropriate containers, and stored according to policy. In these cases, the outer storage container will be labeled with the lot number, expiration date, the date of receipt, and the initials of the receiving personnel. Individual tubes will be marked with sequential numbers so that all components of a single kit are labeled with the same number.

C. The receiving personnel will complete the attached PowerPlex® Fusion Direct Amplification Kit Information Form.

D. PowerPlex® Fusion kits will be stored frozen (between -15°C and -25°C) and protected from light until initial use, at which time individual kits will be stored refrigerated (between, 2°C and 8°C) protected from light. Pre and post amplification reagents will be stored in separate containers.

2.3 Quality Testing of Kits

Quality testing of all new kit lots will be performed by a qualified CODIS Analyst or Technician (following current OSBI CODIS Unit Policy and Procedures) prior to use on offender database samples. One kit from each lot must be quality checked. All individual components of the kit will be examined to make sure each container has the correct amount of material in it, and none have leaked or were damaged.

A. Amplification and Genetic Analysis will be performed on at least 5 different NIST traceable DNA samples from known human sources, the Positive Control DNA provided in the kit, and a Negative Control (TE^{-4}). In order to preserve reagents, this analysis may be performed manually without prior approval from the Technical Manager.

B. A second qualified analyst will verify the results and document acceptance of the quality check by signing the Quality Testing Evaluation Form for PowerPlex® Fusion Kits.

2.4 Documentation of Quality Testing

A notebook containing the complete records of the quality analysis for each lot of PowerPlex® Fusion Direct Amplification Kits shall be maintained by the CODIS Unit. These records shall include:

- Completed PowerPlex® Fusion Direct Amplification Kit Information Form
- Manufacturer's quality information (if provided)
- Analysis worksheets
- Completed Quality Testing Evaluation Form for PowerPlex® Fusion Kits

3.0 FREQUENCY AND TOLERANCE OF CONTROLS AND CORRECTIVE ACTION TO BE TAKEN IF TOLERANCES ARE EXCEEDED

3.1 Expected Values

Careful examination of the DNA results should be performed during quality testing of new amplification kits. This includes ensuring that:

A. The correct profile was obtained from the positive control and all NIST traceable DNA samples analyzed during the quality check.

B. No unexplained peaks exceeding the analytical threshold (75 RFU) are observed in the 60bp to 500bp range.

C. Peak height ratios for all loci are balanced (≥50%).

D. All allele peaks heights are between the analytical threshold (75 RFU – 26 cycle amplification) and the instrument detection saturation point.

E. Stutter peaks observed are in the correct position and not of excessive height.

F. The negative control is free of contaminating DNA.

3.2 Repeated Testing

If any of the expected values are not met, the testing shall be repeated using all of the same components. If the second run meets all expected values, the lot will be accepted for analysis of offender database samples. If any of the criteria are not met in the second run, the following procedures will be followed (as needed):

A. **Known Samples**

On the second run, if any of the known samples are not satisfactory (while the other samples in the same run are satisfactory), a new sample from that individual shall be punched, amplified, and tested. If the new analysis meets the quality criteria, the old sample will be discarded and the kit lot will be accepted.

B. **Positive Control**

On the second run, if the positive control is not satisfactory (while the other samples in the same run are satisfactory), a vial of Control DNA 2800M from a previously quality checked kit lot shall be amplified and analyzed. If the previous Control DNA meets the quality criteria when amplified with the components of the new kit, proceed to step 3.3. If no Control DNA from the previous kit lot is available, the Control DNA from a second box of the new lot kit will be tested. If the second Control DNA from the new lot meets quality criteria, the kit lot will be accepted.

C. **Negative Control**

On the second run, if the negative control shows contaminating DNA, the other samples from that same run shall be examined to see if the same contaminating DNA is also present. If the contamination does not appear in the other samples, a new control will be amplified and analyzed. If the new control shows no contaminating DNA, the lot will be accepted. If the same contaminating DNA appears in the other samples, a second kit or different tube will be opened and a new amplification blank, the positive control, and the reference samples will be retested. If the contamination does not appear in the amplification blank and the other samples meet criteria, the kit lot will be accepted. The tube or kit with the contamination problem will be discarded.

3.3 **Persistent Problems**

If the expected values are still not met after repeated testing is performed, the Technical Manager will be notified. If the problem is suspected to be due to a component of the new kit lot, the kit supplier will be contacted to inform them of the problem and a request made to replace the problem kit(s).

ATTACHMENT(S):

QC_1_PowerPlex Fusion PCR Amplification Kit Information Form
QC_1_Quality Testing Evaluation Form for PowerPlex Fusion Kits

REFERENCE(S):

FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Maintenance and Calibration of the 3500xL DNA Analyzer (top ↑)

Principle of the Protocol
Reagents

Individual Steps of the Protocol
Daily Maintenance
Weekly Maintenance
Monthly Maintenance
Quarterly Maintenance
As-Needed Maintenance
Quarterly HID Install Performance Check
Performance Check following Installation of Capillary Array or Repair, Service, or Calibration
3500xL Genetic Analyzer Performance
Defragmenting the Computer Hard Drive

Protocol Notes

1.0 PRINCIPLE OF THE PROTOCOL

This protocol summarizes common tasks required to properly maintain and calibrate the 3500xL Genetic Analyzer under normal conditions. Other service work must be referred to a qualified technician. The tasks listed can be performed less often if the instrument is not in use, as long as the tasks are performed before the next use.

1.1 Reagents

Anode Buffer Container
Cathode Buffer Container
Performance Optimized Polymer 4 (POP-4®) for the 3500xL Genetic Analyzer
Conditioning Reagent
Hi-Di™ Formamide
CC5 Internal Lane Standard 500 (CC5)
HID Install Standard and LIZ Size Standard

2.0 INDIVIDUAL STEPS OF PROTOCOL

2.1 Daily Maintenance (or before each run when instrument is not used daily)

A. Check dashboard.

B. Visually inspect the fluid level in the buffer containers.

C. Record the number of runs.

2.2 Weekly Maintenance (7 days - when instrument is in use)

A. Check storage condition of used arrays to ensure array tip is covered in the reservoir.

B. Run Wash Pump and Channels Wizard.

C. Replace Anode and Cathode Buffer and the septa on the reservoirs.

D. Replace POP-4® pouch.

2.3 Monthly Maintenance (when instrument is in use)

A. Flush Pump Trap.

B. Empty the condensation container and water trap waste container.

2.4 Quarterly Maintenance

A. Archive the Library to the network.

B. Run a HID Install Standard Performance Check.

2.5 As Needed Maintenance

A. Restart the computer.

B. Install a new capillary array: Capillary arrays can be used until undesirable data such as poor sizing precision, poor allele calling poor resolution, or decreased signal intensity is consistently observed.

C. Perform a spatial calibration after replacing a capillary array, when a service engineer performs an optical service procedure such as realigning or replacing the laser, CCD cameras or mirrors, when you open the detector door or move the detection cell, or when you move the instrument.

D. Perform a spectral calibration if you change dye sets, change the capillary array, change polymer type, when a service engineer performs an optical service procedure such as realigning or replacing the laser , CCD cameras or mirrors or when you see an increase of spectral separation (pull-up/pull-down peaks) in the raw or analyzed data. Place this document in the desktop folder on the instrument computer.

E. Defragment the computer hard drive.

2.6 Quarterly HID Install Performance Check

A **HID install standard performance check** will be performed for the 3500xL Genetic Analyzer to verify the instrument conforms to analysis sizing precision, sizing range and peak height specifications at least **quarterly**.
If the performance check is not completed before the end of the quarter, the 3500xL Genetic Analyzer shall not be used for database analysis until a performance check is successfully completed (only takes about 30 minutes).
Document results of the performance check by saving it to the appropriate network folder.
Place this document in the desktop folder on the instrument computer.

2.7 Performance Check following Installation of Capillary Array or Repair, Service, or Calibration

A HID Install Standard performance check will be performed for the 3500xL Genetic Analyzer to verify the instrument conforms to analysis sizing precision, sizing range and peak height specifications after the replacement of the capillary array or after repair, service, or calibration. This performance check can also serve to satisfy the quarterly performance check requirement above.

If instrument sensitivity concerns are present, a dilution series shall be analyzed at the instruction of the Technical Manager.

Document the results of the performance check by saving it to the appropriate network folder. Note: If Preventive Maintenance visit from the manufacturer was performed which did not require alterations to the optics of the instrument (i.e. laser), then a performance check of the instrument consisting of an evaluation of the first positive and negative controls ran on the instrument will be performed and documented in the maintenance notebook (form X) before nay results from the run will be reported. Of the optics are adjusted, a HID install standard performance check will be successfully completed before offender samples are processed.

The same procedures used for the performance check of new amplification kits as described in the section of this policy manual titled Quality Control Procedure for PowerPlex® Fusion Amplification Kits will be used for the annual genetic analyzer performance check.

2.8 3500xL Genetic Analyzer Performance

If the 3500xL Genetic Analyzer fails to perform correctly, the instrument shall undergo troubleshooting to the extent of the technical skills of the laboratory personnel in an attempt to re-establish satisfactory performance.

If the 3500xL Genetic Analyzer continues to yield unsatisfactory performance, the instrument shall be removed from service and a qualified service technician shall be contacted.

2.9 Defragment the Hard Drive

The fragmentation of files decreases the performance of the Data Collection Software and the computer operating system. Programs take a longer time to access files by performing multiple search operations of the fragments.

Note: Do not manually delete spectral plate records or spectral information from the database. Doing so will permanently delete spectral information.

A. In the Windows desktop, select **Start > Programs > Accessories > System Tools > Disk Defragmenter and follow the prompts**.

Note: You can click **Analyze** to see if you should defragment or not.

B. Once complete, a dialog box will appear and allow you to view a report or close.

ATTACHMENT(S):
QC_2 3500xL Maintenance Log

REFERENCE(S):
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Maintenance and Calibration of the Biomek 3000 (top ↑)

Principle of the Protocol

Individual Steps of the Protocol
- Preventative Maintenance
- Cleaning the Biomek 3000
- Framing the Biomek 3000 Deck
- Performance Checks

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is written to ensure optimum operations of the Biomek 3000 utilized in the CODIS Unit.

The following maintenance and calibration procedures should be performed as indicated. All maintenance performed should be documented on the General Maintenance Record Form and stored in the appropriate laboratory location.

Any maintenance described in this protocol can be performed by a qualified CODIS Analyst, qualified CODIS Technician or by a Beckman Coulter service representative. Any maintenance not described in this protocol should be performed by a Beckman Coulter service representative.

2.0 INDIVIDUAL STEPS OF PROTOCOL

Chapter 1 of the Biomek 3000 User's Manual details the system components on the Biomek 3000. The analyst/technician should become familiar with these components prior to operating the system.

A. Preventive Maintenance

The Biomek 3000 requires little preventive maintenance; however, to ensure optimum operation, perform the following maintenance procedures:

1. Wipe up all spills immediately
2. At least once a year, schedule a Beckman Coulter service call to lubricate the belts that control the movement of the pod

B. **Cleaning the Biomek 3000**

The Biomek 3000 should be cleaned weekly with alcohol. In the event the Biomek 3000 and/or associated components become contaminated with biological materials, they should first be cleaned with a 1:10 bleach solution followed by an alcohol cleaning.

C. **Framing the Biomek 3000 Deck**

Framing is the procedure used to teach the Biomek software the location of the Automated Labware Positioners (ALPs) and devices positioned on the deck. The Biomek software uses this information to move the pod to the appropriate positions to perform liquid-handling operations and manipulate labware.

1. A Beckman Coulter Service Engineer frames the Biomek 3000 instrument during the initial system installation. However, it may be necessary to repeat the framing if:
   a. The robot pod crashes into the deck or deck components
   b. ALPs or devices are added, moved, or removed from the deck
   c. The pod is serviced or changed
   d. When an alignment problem is observed

2. Chapter 5 of the Biomek 3000 User's Manual outlines the procedures to be used when framing the Biomek 3000.

D. **Performance Checks**

The Biomek 3000 shall undergo a performance check after any repair, service, or calibration is performed by laboratory personnel or a Beckman Coulter Service Engineer. Certification by the service representative shall serve as the documentation for successful completion of the performance check following repair, service or calibration.

1. Certification will be documented using the "Certification of Robotic Repair" form.

ATTACHMENT(S):

QC_9_Certification of Robotic Repair Form
QC_9_Robotics Systems Pipetting Tools Performance Check Log

REFERENCE(S):

FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Quality Control for Thermometers (top ↑)

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is written to ensure optimum operations of the Thermometers utilized in the CODIS Unit.

The following maintenance and calibration procedures should be performed as indicated. All procedures performed should be documented on the QC_4 Thermometers Form and stored in the appropriate location.

2.0 INDIVIDUAL STEPS OF PROTOCOL

The following performance checks shall be conducted annually (at minimum) in accordance with the schedule listed below. All documentation of maintenance, service or calibration shall be retained in the appropriate laboratory location.

2.1 **Thermometer:**

A. A critical thermometer is one that is used for conducting performance verification checks or is used to monitor refrigerators and freezers used for storing critical chemicals. For the OSBI's CODIS Unit,

this consists of thermometers monitoring the refrigerators and freezers containing amplification kits or kit components.

Note: Freezer temperatures monitored by the laboratory's alarm system do not require additional verification checks (see e-mail from FBI).

B. All critical thermometers utilized in the CODIS Unit should be NIST traceable.

C. The performance check may be accomplished either through:
   1. Certification by an outside vendor
   2. In-house verification using the procedure outlined in the OSBI CODIS Unit Policy Manual, QC_4 Thermometers.

Performance Check

- An annual performance check will be performed on each NIST-traceable thermometer used for conducting performance checks.
- If the performance check is not completed within the anniversary month of the last check, the thermometer shall be removed from casework until a performance check is successfully completed.

Calibration

- Set a water bath to the desired temperature.
- Allow water to heat for at least 30 minutes.
- Place bulb of each thermometer to be checked into the water bath along with the NIST thermometer.
- Wait several minutes and record the temperature on the Thermometer Calibration Log (QC_4_Therm).
- Wait 15 minutes and record the temperature again.
- Alternatively, the calibrating digital thermometer can be placed into the same equipment as the thermometer, be allowed to equilibrate, and the reading documented.

Thermometer Performance

- If thermometer readings equal the NIST calibrated reading, no action is needed.
- If the NIST thermometer measurement is within ± one (1) degree of the thermometer being tested, then the amount of deviation shall be noted and all other readings adjusted by the same amount, and in the same direction. If deviation of more than ± one (1) degree is observed the thermometer shall be replaced or taken out of service.

ATTACHMENT(S):

CODIS Unit Policy Manual QC_4_Therm

REFERENCE(S):

FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Quality Control for Refrigerators and Freezers (top ↑)

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is written to ensure optimum operations of the Refrigerators and Freezers utilized in the CODIS Unit.

The following procedures should be performed as indicated. All monitoring performed should be documented on the QC_13_Temp Form and stored in the appropriate location.

2.0 Individual Steps of the Procedure

- At least once a week, temperatures shall be recorded on the Temperature Log (QC_13_Temp). The analyst recording the temperature shall check the records for any variances from the expected value that may show the performance of the unit over several measurements is not satisfactory.
- The monitoring probes should be placed such that they are not in an area where the temperature fluctuates enough to set off the alarm during defrost cycles.
- The alarm monitoring pad should be set to take the variance into account.
- The weekly temperature should not be recorded when the unit is in defrost mode.
- Equipment can be inspected at this time for mold, mildew, excess frost/ice buildup or any other possible deleterious condition that may require maintenance. Any maintenance shall be recorded on the equipment maintenance log.

Unsatisfactory Refrigerator or Freezer Performance

- The unit shall be inspected and the cause of any variance determined and corrected. If the cause cannot easily be determined or corrected by in-house personnel, the unit shall be emptied.
- The contents shall be transferred to a working unit (if possible) or to a temporary storage container until expedient arrangement can be made for proper storage.
- If a unit sets off an alarm, the alarm monitoring company, as per contract, should contact, in a timely manner, the designated contact person for that laboratory. The contact person shall notify, if necessary, the appropriate unit supervisor or his/her designee in a timely manner. The supervisor/designee shall take the action described above.

ATTACHMENT(S):
CODIS Unit Policy Manual QC_13_Temp

REFERENCE(S):
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Quality Control for Balances/Scales (top ↑)

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is written to ensure optimum operations of the Balances/Scales utilized in the CODIS Unit.
The following procedures should be performed as indicated. All calibrations/maintenance performed should be documented on the QC_11_General Equipment Maintenance Form and stored in the appropriate location.

1.1 **Balances/Scales*:***

A. All balances/scales utilized in the CODIS Unit shall undergo an annual performance check. If the performance check is not completed before the end of anniversary month of the last check, the balance/scale shall be removed from service until the performance check is successfully completed.

B. The performance check will be accomplished through an outside vendor.

ATTACHMENT(S):
CODIS Unit Policy Manual QC_11_General Equipment Maintenance

Quality Control for Thermal Cycler (top ↑)

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is written to ensure optimum operations of the Thermal Cyclers utilized in the CODIS Unit.
The following procedures should be performed as indicated. All procedures performed should be documented on the QC_7_9700_0.2 Form and stored in the appropriate location.

1.1 **Thermal cycler:**

A. All thermal cyclers utilized in the CODIS Unit shall undergo an annual performance check. If the performance check is not completed before the end of anniversary month of the last check, the thermal cycler shall be removed from service until the performance check is successfully completed.

B. Thermal cyclers shall also undergo a performance check and/or recertification following repair, service or calibration.

C. The minimum requirements of a performance check may be accomplished either through:
   1. Certification by an outside vendor
   2. In-house verification will be performed by comparison against a certified thermal cycler temperature verification system.

Performance Check

- An annual performance check on all 9700 thermal cyclers will be performed using a Temperature Verification System (TVS) [refer to 9700 User's Manual in the attachment of the FBU Policy Manual].
- If the performance check is not completed within the anniversary month of the last check, the 9700 Thermal Cycler shall be removed from casework until a performance check is successfully completed.
- The performance check will be performed using the Temperature Verification function under Diagnostics in the 9700 Thermal Cycler Software.

Performance Check following Repair, Service, or Calibration

- A performance check will be completed using a Temperature Verification System (TVS) after any repair, service, or calibration and before using in casework.

9700 Thermal Cycler Instrument Performance

Temperature Calibration Verification test

- If the block average is more than 1.0°C above or below the 45°C point or more than 1.0°C above or below the 85°C point, the test is to be run two more times.
- If the thermal cycler meets standards two of three attempts, then it shall be deemed acceptable.
- Record results on QC_9700_0.2 as needed.

Temperature Uniformity Test

- If the results of either calculation are greater than 1.0°C, the test is to be run two more times.
- If the thermal cycler meets standards two of three attempts, then it shall be

deemed acceptable.

- Record results on QC_9700_0.2 as needed.

If a 9700 thermal cycler fails to perform correctly, the instrument shall be removed from service and a qualified service technician shall be contacted.

ATTACHMENT(S):

QC_7_9700_0.2

REFERENCE(S):

FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Quality Control for Mechanical Pipettors (top ↑)

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is written to ensure optimum operations of the mechanical pipettors utilized in the CODIS Unit. The following procedures should be performed as indicated. All procedures performed should be documented on the FBU Policy Manual QC_PipetCal and/or FBU Policy Manual QC_PipetCalReprod Form and stored in the appropriate location.

1.1 **Mechanical Pipettes:**

Performance Check-Annual

All mechanical pipettes utilized in the CODIS Unit shall undergo an annual performance check. If the performance check is not completed before the end of anniversary month of the last check, the pipette shall be removed from service until the performance check is successfully completed. The annual performance check may be completed in-house or by an external vendor.

Pipettor Type Requirements

- Adjustable pipettors shall be checked at the minimum and maximum values, with the exception of the 2 µL and 10 µL pipettors, which will be checked using 1 µL for the minimum value. For Rainin pipettors, the range for P-2 is 0.1 to 2 µL, P-10 is 0.5 to 10 µL, P100 is 10 to 100 µL, P-200 is 50 to 200 µL and P-1000 is 100 to 1000 µL.
- Repeat pipettors shall be checked at the minimum and maximum values based on the dispensing volume range associated with the attached tip. In addition, repeat pipettors will be checked at the aliquot volume desired. Repeat pipettors shall be labeled with the approved volume range and aliquot volume.
- Multichannel pipettors shall be checked at the minimum and maximum values with each channel being checked individually and the set of channels being checked collectively.

Individual Steps of the Performance Check

- Using a calibrated balance, place a weighing receptacle on the balance and tare.
- Deliver the desired volume of water to the weighing receptacle and record registered weight. At the FSC, this may be accomplished by using the Calibri software recording the measured volume.
- Calculate % error for each measurement using the formula: (Delivered weight - Expected weight) / Expected Weight x 100%, if taking measurements by hand.
- Document results for each pipettor on the Forensic Biology Unit Policy Manual Pipettor Calibration Log (QC_PipetCal) or archive the "Calibration Report" from the Calibri software in the appropriate QC folder on the network.

Pipettor Performance

- Determine whether the pipettor passed or failed the calibration. The tolerance for pipettor volumes greater than or equal to 10 µL is 3%. The tolerance range for volumes less than 10 µL is 10%.
- If the percent error is greater than that stated above, repeat measurement four more times. Average the volume of the five measurements and calculate the percent error using the Forensic Biology Unit Pipettor Calibration Reproducibility Log (QC_PipetCalReprod). If the percent error is within the established tolerance, the pipettor is accepted as meeting criteria.
- If the pipettor fails after 5 tries, adjustment/maintenance is necessary. This can be done in house or at an authorized service center.
- Certification from the external vendor may serve as the documentation for the successful completion of the performance check. The calibration certificates issued by these competent calibrating laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

  NOTE: Calibration labs fulfilling the requirements of ASCLD/LAB ISO 17025 are considered to be competent. Copies of ISO 17025 certificates shall be maintained with the calibration/test reports as sufficient evidence of traceability of the calibration data reported. A review of the certificate(s) by the TM (or designee) shall serve as documentation of this check of compliance regarding function and calibration.

ATTACHMENT(S):

FBU Policy Manual QC_PipetCal
FBU Policy Manual QC_PipetCalReprod

REFERENCE(S):

OSBI CSD QualityManual
ISO/IEC 17025:2005
ASCLD/LAB-*International* Supplemental Requirements – Testing
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Quality Control for Robotics Systems (top ↑)

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is written to ensure optimum operations of the robotics systems utilized in the CODIS Unit.
The following procedures should be performed as indicated. All procedures performed should be documented on the QC_9_Biomek FX Maintenance and Calibration, QC_9_Certification of Robotic Repair and/or QC_9_Roboticcs Systems Pipetting Tools Form and stored in the appropriate location.

1.1 **Robotics Systems:**

A. All robotics systems utilized in the CODIS Unit shall undergo an annual performance check. If the performance check is not completed before the end of anniversary month of the last check, the robotic system shall be removed from service until the performance check is successfully completed.

B. Robotics systems shall also undergo a performance check and/or recertification following repair, service or calibration. The procedures for performance checks subsequent to repair, service or calibrations are found in the maintenance and calibration policies for the appropriate robotics systems in this manual.

C. The minimum requirements of an annual performance check shall be defined by the laboratory. The performance check may be accomplished either through:
1. An outside vendor (accomplished during a scheduled PM visit)
2. In-house by the laboratory

D. If the performance check is performed in-house by the laboratory, it will be accomplished by performing amplification and genetic analysis on at least five (5) different NIST traceable DNA samples from known human sources.

1. The NIST Traceable samples will be analyzed according to current CODIS Policy and Procedure.

2. If the anniversary date of the previous annual performance check has not lapsed, the NIST Traceable samples may be run concurrently with offender samples. If the anniversary date is passed, the NIST samples must be run prior to analysis on new offender samples.

3. All NIST Traceable samples must yield the expected profiles. The quality of the profiles must meet requirements listed in the Acceptability Criteria section of the Interpretation Guidelines for Offender Database Samples procedure in this manual.

4. A second qualified analyst will verify the results and document acceptance of the performance check by signing the Offender Sample Technical Review Form for the Plate on which the NIST samples are being analyzed.

ATTACHMENT(S):
QC_9_Certification of Robotic Repair Form
QC_9_Biomek FX Maintenance and Calibration Form
QC_9_Robotics Systems Pipetting Tools Performance Check Log

REFERENCE(S):
OSBI CSD Quality Manual
ISO/IEC 17025:2005
ASCLD/LAB-*International* Supplemental Requirements – Testing
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Quality Control for NIST Certified Equipment (top ↑)

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is written to ensure optimum operations of the NIST Equipment utilized in the CODIS Unit.
The following procedures should be performed as indicated. All procedures performed should be documented on the QC_11 General Equipment Form and stored in the appropriate location.

Individual Steps of the Procedure

- The calibration for weights, timers, tachometers, and delegated temperature verification systems is to be performed annually or prior to the expiration date of the current NIST certificate, whichever is longer. Thermometers must be calibrated annually.
- Contact a company/business that is an authorized NIST certifying body, such as Chermac Services Corporation at (405) 340-9326, or the NIST Calibration Program at (301) 975- 2092 or calibrations@nist.gov to make arrangements for the calibration.
- Once IPR is approved, deliver to the agency directed by the NIST representative for the

calibration.

- The vendor shall ascertain and certify that the equipment is functioning appropriately. Notification should be given if repairs or replacement are required before service is performed and before instrument is returned for use.
- Calibration and maintenance records for NIST certified equipment are to be maintained.
- It may be more cost effective to replace NIST certified timers at the end of their current certificate rather than to send for recalibration.

REFERENCE(S):
OSBI CSD Quality Manual
ISO/IEC 17025:2005
ASCLD/LAB-*International* Supplemental Requirements – Testing
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

General Equipment: Documentation of Maintenance (top ↑)

Principle of the Protocol
Standards

Individual Steps of the Protocol

Corrective Action

Protocol Notes

1.0 PRINCIPLE OF THE PROTOCOL

Documentation must be maintained for all repairs, maintenance, calibration and other service performed on instrumentation and equipment in the laboratory. A system is established for recording such service performed on laboratory equipment / instrumentation that does not have a specific protocol(s) for maintenance, calibration, repairs or other procedures.

1.1 **Standards**

Laboratory equipment / instrumentation must perform to the manufacturer's specification and accommodate the laboratory procedure for which it is being used.

2.0 INDIVIDUAL STEPS OF PROTOCOL

2.1 Laboratory equipment / instrumentation shall be used as recommended by the manufacturer or as specified in analytical protocols.

2.2 Laboratory equipment / instrumentation shall be used in accordance with OSBI policies that include analytical protocols and safety policies.

3.0 CORRECTIVE ACTION TO BE TAKEN IF TOLERANCES ARE EXCEEDED

3.1 If laboratory equipment / instrumentation does not function as expected, it shall be inspected and the cause of the problem determined and corrected. If the cause cannot easily be determined or corrected by in-house personnel the unit of equipment / instrumentation shall be marked with a dated sign indicating it is "**OUT OF SERVICE**". The date on which equipment/instrumentation was placed out or in service will be recorded on the General Maintenance Record Form.

A. The CODIS Supervisor (or designee) shall make arrangements for needed service or replacement of the unit of equipment / instrumentation.

B. Service performed on equipment / instrumentation shall be recorded on the General Maintenance Record Form and maintained in the laboratory.

C. Any maintenance, calibration, repair, or other service performed on laboratory equipment / instrumentation shall be recorded on the General Maintenance Record Form and maintained in the laboratory.

4.0 PROTOCOL NOTES

Before being placed back into use, a verification of functional calibration must be performed after equipment / instrumentation has been serviced. This verification shall be recorded on the General Maintenance Record Form and maintained in the laboratory.

Note: The degree of functional calibration necessary will vary among different equipment / instrumentation and will be determined by the Technical Manager on a case-by-case basis.

ATTACHMENT(S):

QC_11_General Equipment Maintenance Form

REFERENCE(S):

FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Cleaning & Sterilization in the CODIS Laboratory (top ↑)

Principle of the Protocol

Individual Steps of the Protocol
- General Laboratory Glassware and Plasticware
- Glassware and Plasticware Used to Handle Biohazards and/or Human DNA Samples
- Solutions Requiring Sterilization
- Operation of Ultraviolet Crosslinker
- Operation of Autoclave
- Floor and Work Surface Decontamination

1.0 PRINCIPLE OF THE PROTOCOL

Thorough cleaning and sterilization of glassware, plasticware, floors and work surfaces in the laboratory can be achieved by use of detergent and water, a 1:10 household bleach solution, UV light, and/or cleaners labeled as tuberculocidal. Removal of material from plastic and glassware from everyday use ensures clean, uncontaminated containers for analytical procedures.

2.0 INDIVIDUAL STEPS OF PROTOCOL

2.1 **General Laboratory Glassware and Plasticware**

A. Glassware and plastic containers should be cleaned with detergent and completely rinsed with tap water by hand immediately after use.

B. Before use, these items should be rinsed with distilled water.

C. An automatic dishwasher may be used instead of hand washing

2.2 **Glassware, Plasticware, Equipment, and Instruments Used to Handle Biohazards and/or Human DNA Samples**

A. Clean and sterilize any item used to handle biological samples following such a procedure.

B. Rinse glassware and plasticware with 1:10 household bleach solution or cleaner labeled as tuberculocidal and then wash as above with detergent.

C. Ultraviolet light exposure for ~15-30 minutes can be used for sterilization on glassware and plasticware.

D. Steam and/or heat sterilization in an autoclave can be used for items that will not melt.

Instruments

- Instruments used to process biological samples (forceps, scissors, etc.) shall be cleaned with an approximate 1:10 bleach solution or alcohol before and after each sample is handled.
- Exposure to ultraviolet light for a minimum of 15 minutes in a UV crosslinker should be used to decontaminate articles which are small enough to fit into the unit and that will not be damaged by the ultraviolet light

Equipment

- Equipment shall be decontaminated with an approximate 1:10 bleach solution periodically.
- This shall be documented on the Decontamination Log (QC_DecontamLog) associated with the equipment or instrument.

2.3 **Solutions Requiring Sterilization**

A. Sterilization of solutions should be performed at the time they are made.

B. Steam autoclaving of solutions is performed at ~120°C for ~20 minutes. Each respective reagent preparation procedure shall indicate whether or not the solution requires sterilization by autoclaving.

C. Small aliquots of solutions are to be used at the bench and should be UV sterilized before use.

2.4 **Operation of Ultraviolet Crosslinker**

A. Follow instructions within the operations manual for use of crosslinker.

B. The crosslinker should be equipped with short wave (254 nm) tubes in order to ensure decontamination.

2.5 **Operation of the Autoclave**

A. Follow instructions within operations manual for use of autoclave.

B. The autoclave should reach a minimum temperature of 120°C for at least 20 minutes for

decontamination.

C. Use autoclave indicator tape to ensure the decontamination is complete.

D. After autoclaving is complete, check the indicator tape to make sure sterilization has taken place. If tape has not turned black, repeat the procedure.

2.6 **Floor and work surface decontamination**

Use a 1:10 household bleach solution for decontamination of floor (when needed) and work surfaces before and after each use.

Decontamination Following a Contamination Event

Following any contamination event, the OSBI CODIS Unit should perform a standardized decontamination procedure after the remediation method has been determined. The following may be utilized.

- Discard any facemasks and obtain new facemasks, if applicable.
- Remove laboratory coat(s) from the laboratory and have it/them cleaned or obtain new disposable lab coats.
- Dispose of aliquots of reagents that have been tested and shown to be contaminated.
- Decontaminate (with 1:10 bleach) all supplies (pipettors, racks, de-cappers) and equipment (centrifuges, hoods) used throughout the analysis process.
- Decontaminate (with 1:10 bleach) all work areas including common areas potentially used throughout the analysis process.
- UV crosslink all small supplies and reagents associated with the analysis process.

ATTACHMENT(S):

QC_12_Decontamination Log

REFERENCE(S):

FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Temperature Documentation of General Equipment (top ↑)

Principle of the Protocol
Standards

Individual Steps of the Protocol

Corrective Action

Protocol Notes

1.0 PRINCIPLE OF THE PROTOCOL

Certain laboratory reagents and chemicals may require storage or use within specific temperature ranges to preserve them. To ensure these items are maintained within the appropriate temperature ranges, a system of monitoring cooling and heating units is established.

1.1 **Standards**

To convert temperatures from Fahrenheit to Celsius, subtract 32 from degrees Fahrenheit, multiply by 5, and divide by 9. To convert temperatures from Celsius to Fahrenheit, multiply degrees Celsius by 9, divide

by 5, and add 32.

A. Standard refrigerators generally should maintain a temperature range of approximately 0˚C to 10˚C.

B. Standard freezers generally should maintain a temperature range of approximately 0˚C or below.

C. Water baths generally should maintain a temperature range of approximately 65˚C to 75˚C when in use.

D. Specific protocols which specify the temperature ranges for equipment or reagents shall supersede this protocol.

2.0 INDIVIDUAL STEPS OF PROTOCOL

2.1 At least once a week, refrigerator and freezer temperatures should be recorded on the Temperature Log. The person recording the temperature shall check the records for any variances from the expected value that may show the performance of the unit over several measurements is not satisfactory. At a minimum, the refrigerators and freezers storing critical chemicals shall be monitored.

2.2 Equipment can be inspected at this time for mold, mildew, excess frost/ice buildup or any other possible deleterious conditions that may require maintenance. Any maintenance shall be recorded on the General Maintenance Record Form.

2.3 Equipment should be disinfected with a 1:10 bleach solution as needed. This should be recorded on the Decontamination Log.

3.0 CORRECTIVE ACTION

3.1 If the specified tolerances are exceeded, the unit shall be inspected and the cause of any variance determined and corrected. If the cause cannot easily be determined or corrected by in-house personnel, the unit shall be emptied.

A. The contents shall be transferred to a working unit (if possible) or to a temporary storage container until expedient arrangements can be made for proper storage.

B. The unit shall be marked with an "**Out of Service**" sign. The date shall be recorded both on the sign and on the General Maintenance Record Form.

C. The Unit Supervisor (or designee) shall arrange to have the unit repaired or replaced.

3.2 If a unit sets off an alarm, the alarm monitoring company shall contact (as per contract) the OSBI Laboratory Building Maintenance Supervisor. The Building Maintenance Supervisor shall notify (in a timely manner) the appropriate Unit Supervisor and his/her designee. The Supervisor/designee shall take the corrective action described above.

4.0 PROTOCOL NOTES

4.1 Each thermometer should be placed in an easily visible location. The bulb, sensor, or probe portion should be free from contact with any other item or material.

4.2 Unless otherwise specified in superseding protocols, thermometers do not need to be NIST traceable or require any calibration.

The contents of each refrigerator / freezer unit should be arranged and reasonably limited so that the proper circulation of air within the unit is maintained.

4.3 Refrigerator/freezer units with frost free functions have short duration defrost cycles. Allowance for temperature variance during these cycles is acceptable. The monitoring probes should be placed such that they are not in an area where the temperature fluctuates enough to set off the alarm during these cycles. The alarm monitoring pad should be set to take variances into account, and the weekly temperature should not be recorded when the unit is in defrost mode.

ATTACHMENT(S):
QC_13_Temp

REFERENCE(S):
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Thermomixer Quality Control (top ↑)

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is written to ensure optimum operations of the Thermomixer(s) utilized in the CODIS Unit.
The following procedures should be performed as indicated. All procedures performed should be documented on the QC_14 Thermomixer Form and stored in the appropriate location.

Cleaning

- Use neutral cleaning agents to clean the thermomixer housing and thermo-blocks as needed.
- Ensure that all parts are dried thoroughly before use.

Performance Check - At a minimum, the OSBI CODIS Unit shall perform an annual performance check for each thermomixer consisting of both a temperature and timer verification. If the performance check is not completed within the anniversary month of the last check, the thermomixer shall be removed from service until a performance check is successfully completed.

Temperature verification

- Remove the 0.02mL well cover located in the middle of the smart block.
- Verify the appropriate temperatures used in policy (See DNA_1 and DNA_2) with a Temperature Verification System (TVS).
- Document the results on the Thermomixer Calibration Log (QC_Thermomixer).

Timer Calibration

- Measure the timer against a stopwatch or other calibrated timer set for the same time interval(s).
- Document timer calibration results on the Thermomixer Calibration Log (QC_Thermomixer).

Thermomixer Performance

Temperature

- If the temperature is more than 1.0˚C above or below the desired temperature, the test is to be run two more times.

- If the temperature verification fails two of the three times, the thermomixer shall be removed from service and a qualified service technician shall be contacted.

Timer

- If the timer varies more than 30 seconds in five minutes, the instrument shall be removed from service and a qualified service technician shall be contacted.

ATTACHMENT(S):
CODIS Policy Manual QC_14 Thermomixer

REFERENCE(S):
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

Quality Control for Thermal Cycler Temperature Verification System (TVS) (top ↑)

1.0 PRINCIPLE OF THE PROTOCOL

This protocol is written to ensure optimum operations of the TVS utilized in the CODIS Unit.
The following procedures should be performed as indicated. All calibrations/maintenance performed should be documented on the QC_11_General Equipment Maintenance Form and stored in the appropriate location.

1.1 **Thermal cycler temperature verification system (TVS):**

A. All TVS's utilized in the CODIS Unit shall undergo an annual performance check. If the performance check is not completed before the end of anniversary month of the last check, the TVS shall be removed from service until the performance check is successfully completed.

B. The performance check will be accomplished through certification by an outside vendor

TVS Performance Check Documentation

- Certification from the external vendor shall serve as the documentation for the successful completion of the performance check.

ATTACHMENT(S):
CODIS Unit Policy Manual QC_11_General Equipment Maintenance

REFERENCE(S):
OSBI CSD Quality Manual
ISO/IEC 17025:2005
ASCLD/LAB-*International* Supplemental Requirements – Testing
FBI's Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories
FBI's Quality Assurance Standards (QAS) for DNA Databasing Laboratories

CODIS Unit Policy Manual

History

Revision#	Issue Date	Document History
Rev. 0	02-15-2010	Original issue
Rev. 1	05-19-2011	Changed CODIS Manager to CODIS Administrator, “electropherrogram” to “electropherogram”, technical leader to technical manager, methanol to alcohol, off-scale to over-saturation, and thermalcycler to thermal cycler throughout document. Removed non-working hyperlinks to forms. Updated references to reflect changes to FBU Policies. Added required letter grade for college coursework. Added Job Duties and educational requirement for Laboratory Technician. Clarified the following: who can authorize access to laboratory; database samples are considered reference materials, not evidence; when offender samples may be discarded; comparison between modified and original procedures, use of amplification controls; that preventative maintenance was not considered “repair, service or calibration and didn’t need full performance check, and the retention of plate documentation after; requirement for technical reviewer; legal authority for expungement of CODIS sample; offender and arrestee profiles may have dropout at D19 and or D2 and still be in the Offender Index or Arrestee Index; eligibility for Legal Index; eligibility of Y-STR profiles; profiles must be associated with accurate results for reagent blanks; ability to retain records electronically or in paper form; partial matches (potential familial hits will be handled according to current SWGDAM and NDIS guidelines; what is required for passing spectral calibration; maintenance requirements for Biomek FX; performance checks on robotic workstations; pull-up; secondary stutter; reagent blanks and controls with peaks below threshold; date equipment taken out of or placed in service recorded; temperature monitoring requirements; performance checks; Added requirement to review that correct CODIS Specimen Category is assigned to offender samples. Removed reference to “CODIS Proficiency Testing Procedures Supplemental Guide.” Removed definition of semi-annual, and all definitions in Glossary that were from the QAS. Added definition for acronym CJIS-WAN. Added ability for backup CODIS Administrator to have concurrent login to multiple CODIS computers. Revised number of loci required for entry into SDIS to 8 for all indices that were previously at 6. Revised number of loci required for entry into Legal Index. Removed Incomplete Unidentified Human Remains Index and Incomplete Missing Person Index. Added explanation of low template DNA analysis. Removed reference to attempting analysis on all 13 CODIS core loci. Changed procedure for

		CODIS Data Entry of forensic samples. Added procedure for notification of entry into database. Allowed for batch target files to be generated externally but not downloaded from CJIS-WAN. Changed minimum loci required for match to 8. Changed procedure for evaluating matches. Added procedure for profile removal for casework samples. Addressed CODIS Matches to ineligible forensic profiles. Changed CODIS Hit Verification Procedures to allow for casework analysts to evaluate matches and request verification, removed requirement to call on cases with reports issued within 30 days. Added attaching hit letter to BEAST case file. Allow criminal history to be stored electronically, and not included in Offender Hit Verification file. Moved Punching, plate naming, and sample lysis to new procedure, and removed duplicate sections. Changed Removed Biomek FX deck layouts to Appendix A. Combined Amplification using Biomek 3000 and FX into one procedure. Combined Capillary Electrophoresis using Biomek 3000 and FX into one procedure. Changed all references to P20 tips to P50 tips. Removed defragmenting hard drive from monthly maintenance and added it to Long Term Storage of Data section . Combined changing buffer and water sections in 3730 maintenance. Changed performance check requirement for 3730 after replacement or service of CCD camera or laser. Changed references to “Biomek FX Maintenance and Calibration Log” and “Biomek 3000 Maintenance and Calibration Log” to “General Maintenance Record Form”. Changed all references to “General Equipment Documentation of Maintenance Form” to “General Maintenance Record Form” Added requirement to create new cmf file if reported data project is edited during TR. Added requirement for re-analysis of apparent null alleles. Simplified examination of over-saturated data. Added reference to non-conforming work and CSD QP 13 to Interpretation Guidelines. Allow for personnel other than analysts to receive amplification kits. Change requirement for Technical Manager to approve QC check of Identifiler Kits to second analyst. Added temperature range for water baths.
Rev. 2	10-01-2011	Fixed hyperlinks throughout document. Clarified that PM on robotics is not “maintenance, calibration, or repair.” Corrected Master Mix component volumes in Biomek 3000 Deck Layout. Corrected reference to Biomek 3000. Clarified critical thermometers. Referenced naming for re-amp and re-inject plates. Deleted unused/duplicate hyperlinks. Removed references to DNA IQ Kit Lot # on Chemical Formulation Worksheets for both Wash and Lysis Buffers. Clarified that Notification Letter was not a report. Added Identifiler Half Reaction method. Allow any employee to monitor temperatures. Modified Outsourcing to comply with latest QAS standards. Changed reference to QAS standard to reflect current standards revision.
Rev. 3	07-01-2012	Annual Review. Changed reference to QAS standard to reflect current standards revision [throughout document].

Added the following references to “References” section since they are listed in document:

ASCLD/LAB-International Supplemental Requirements
FBI’s Guide to Determining What is Allowable in the Forensic Index at NDIS
FBI’s Hit Disposition Quick Reference flowchart
FBI’s Investigations Aided Quick Reference flowchart

Correct “Minimal” to “minimum” in Table of Contents for QA Procedures.

Change “Leader” to “Manager” [QA Procedures, section 2.2, 2.3, 4.1].

Modified name of Training Manual to reflect title of Manual [QA Procedures, section 3.2]

Added name of CSD QP Procedures throughout document.

Added Yfiler kit reference [QA section 8.2].

Added “if applicable” [QA Procedures, section 11.1].

Added “and the accreditation requirements of federal law” [QA Procedures, section 16.1].

Added “as long as it was conducted within the last twelve months” [QA Procedures, section 16.3].

Added “in the BEAST system (narrative)” [CODIS Hit Verification Procedures, section 2.2.D.4].

Added reference to half-reaction procedure [DNA IQ Extraction and Isolation of DNA Using the Biomek 3000, DNA IQ Extraction and Isolation of DNA Using the Biomek FX, Capillary Electrophoresis of DNA Using the ABI 3730 DNA Analyzer and Biomek Automated Workstations

Change “should” to “may” in each amplification protocol (section 2.5.D).

Correct numbering in the half-reaction procedure.

Add “Manual Setup” to the Table of Contents for Capillary Electrophoresis of DNA Using the ABI 3730 DNA Analyzer and Biomek Automated Workstations.

Added Quality Flag “Tab” Settings and “for Each Ladder” to the Table of Contents for Analysis and Managements of DNA Data.

Added language referring to Y-STR analysis in Interpretation Guidelines for Offender Database Samples [section 3.4].

Added “or Technician” [Quality Control Procedure for Identifiler Amplification Kits, section 2.3].

		Add “Forensic Hit” specific Administrative Review form. Correct typo on “CODIS Keyboard Search Request Form”. Corrections to grammar/spelling throughout document and modifications for consistency. *Incorporate Deviations as follows:* QA Procedures, section 6.1 – add requirement to check for order and numbering of samples to ensure to duplication or missing numbers. Add 9700 Thermal Cycler Calibration Log 0.2mL Dual Block Form to list of forms. Change volumes of reagents on Biomek 3000 Deck Layout. Update CODIS Organizational Chart. Maintenance and Calibration of the ABI 3730 DNA Analyzer - change criteria for evaluation of spectral calibration to “no more than three capillaries may fail and these three cannot be consecutive”. Temperature Documentation of General Equipment – modify “analyst” to “person” to allow for other personnel trained to record temperatures may do so. Offender Analysis Worksheets – Add Amplification Method used to the Lot Number Worksheet. Add “Equipment will be checked (i.e. function verification) or calibrated before being placed into service…” for new equipment being placed into service [QA Procedures, section 9.0].
Rev. 4	10-01-2013	Annual Review. Add Amplification with Identifiler Half Reaction Procedure Add forms for 9700 Thermal Cycler Calibration Log 0.2mL Dual Block, Forensic Hit Verification Administrative Review Form and Abbreviation List. Update references and Quality Manual titles to reflect changes in most recent revision. Grammatical corrections. Add Yfiler amplification kits to list of critical reagents. Add clarification of Indices not uploaded to NDIS. Add “(or designee)” to Remote Search Request section.

		Add wording in the HV procedure addressing any partial profiles obtained during the verification process will be handled in consultation with the Technical Manager for determination of what, if any, troubleshooting should be performed as well as documentation required in the BEAST narrative. Add section regarding spinning the plate to remove air bubbles in the amplification procedures. Add "(partial box)" clarification to Biomek 3000 Deck Layout schematics. Add "Manual Setup" option to Capillary Electrophoresis section. Add "or Technician" to Quality Testing of Kits section. *Incorporate Deviations as follows:* Analysis and Management of Data, Create a *.cmf file for CODIS Import, 2.2.A.3.a – change to "Export File As: CMF 1.0 (.dat). CODIS Data Entry and Search Procedures, Section 2.7.D Routine Index to Index Searches – added moderate stringency, 8 loci, 1 mismatch autosearch Define Start and End dates of analysis in Quality Assurance Procedures, 8.0 Analytical Procedures section. CODIS Hit Verification Procedures, 2.1.A.1 Forensic Hit Verifications and 2.2.1 Offender Hit Verifications – allow CODIS analysts to evaluate matches. Change archival of data from 3730 and Long Term Storage on CD-R to electronic storage of data on the CODIS Storage server. Remove requirement for quarterly download and quarterly defragment for 3730. Defragmentation should be done annually or as needed. Remove requirement to contact agencies for Hit Verifications. Add John Doe warrant procedure to CODIS Data Entry and Search Procedures, section 2.6 Request and Documentation of CODIS Data Entry.
Rev. 5	December 15, 2014	Annual Review. Incorporate Deviations as follows: Add "ND" = "No Data" to the Abbreviation List. Add requirement to indicate dropout or partiality of a profile on the CODIS Data Entry Form. Add a check box with "Are partial/mixture profiles referenced appropriately per policy?" to the CODIS Offender Hit Verification Administrative Review Form.

Deleted section 2.6.B regarding CODIS Notification of Entry letters and update section 2.6.A to include the process change to the casework analysts holding their DNA report for approval until the CODIS profile(s) is/are entered.

Changes all instances of “case file” to “case record” to reflect electronic BEAST case records for casework.

Add check box addressing partial/mixture profiles references on Hit Verification Administrative Review form.

Add wording in Hit Verification sections to address requirement to contact agency heads via telephone regarding hit information.

Rev. 6 October 5, 2015 Annual Review.
Incorporate Deviations as follows:

Addition of how to address OL peaks that fall between bins or outside the appropriate locus. [Section 2.2.D.5]

Change of Hit Verification Procedures Policy section 1.0 to include NDIS requirement for resolving matches within 30 business days of match report.

Change of title of section 2.2.C to include “and Biographical Information” and addition of number 3 in this section to require the analyst to verify the biographical information on the offender record in CoDNA with the information available on the State and National criminal history reports and the Department of Corrections web page for the offender.

Add number 4. to section E. of Reporting Offender Hits in CODIS Hit Verification Procedures to address procedure to be used if possible sample collection error is identified during the hit verification procedure.

Add letter D. to section 16.4 of Quality Manual to address the storage of data received from contract laboratories.

Add section 2.1.S and 2.1.T to CODIS Data Entry and Search Procedures to allow entry of Y-STR only profiles in CODIS with certain eligibility requirements.

Incorporate Validation of PowerPlex® Fusion on 3500xL Genetic Analyzer.

Removal of Biomek FX procedures, related forms, and references from CODIS Policy & Procedures due to implementation of PowerPlex® Fusion direct amplification kit.

Removed “Dual” from the 9700 Thermal Cycler Calibration Log 0.2mL Block Form reference in the Table of Contents and on the form.

In Quality Assurance Manual, section 4.2 – modified language in letter D. to reflect NDIS Procedures Section 2.6 requirements for successful completion of the FBI sponsored CODIS software training within 6 months of assuming duties and successful completion of the QAS Auditor training within 1 year of assuming duties if not previously attended.

Added “Multi-Allelic Offender” to Table of Contents of CODIS Data Entry and Search Procedures and added language to letter N. addressing multi-allelic offenders.

Add language to Forensic Mixture and INC Forensic Mixture sections in CODIS Data Entry and Search Procedures to clarify alleles unambiguously attributed to the victim will not be allowed.

Modification of Tables 2-6 and addition of Table 7 in CODIS Data Entry and Search Procedures to account for Multi-Allelic Offenders and Y-STR Autosearches.

Added “if applicable” to the CODIS Hit Verification Procedures, section 2.1.A.1 regarding returns of the Match Detail Report to the CODIS Unit.

Modified language in CODIS Hit Verification Procedures, section 2.1.A.3 allowing the CODIS analyst responsible for verifying the hit to fill out the Hit Verification Request Form. Deleted the statement requiring the forwarding of the forms to the CODIS Unit.

Deleted the statement in CODIS Hit Verification Procedures, section 2.1.B stating that a copy of the forensic hit letter will also be returned with the completed Forensic Hit Verification Request Form to the original casework analyst to be retained in the case record.

Added “in the BEAST system” to CODIS Hit Verification Procedures, section 2.1.C.1.

Deleted CODIS Hit Verification Procedures, section 2.1.C.2 (“In addition, if possible, a .pdf copy of the hit letter should be attached to the appropriate electronic case record in the BEAST system.”) and renumbered the remainder of the section accordingly.

Modified language in CODIS Hit Verification Procedures, section 2.2.A.1, 2.2.A.2, 2.2.A.3, and 2.2.A.4 clarifying that a CODIS analyst (or designee) will evaluate matches

and that the casework analyst may be consulted.

Removed reference to “13 core CODIS loci” throughout document and modified to “core CODIS loci”.

Modify language in CODIS Hit Verification Procedures, section 2.2.E.1 deleting the requirement for a copy of the offender hit letter to be forwarded to the original caseworking analyst with the completed Offender Hit Verification Form to be retained in the appropriate case record. Additional wording added that a .pdf version of the Offender Hit letter, CODIS Match Report, and the Offender Hit Request Form should be attached to the appropriate case record in the BEAST system (CODIS analysts, or designee will do this now). Same modification for Section 2.2.E.3.

Change “these” to “required” in CODIS Hit Verification Procedures, section 2.2.F.1.

Maintenance and Calibration of the Biomek 3000:
Changed “is” to “may be” in section 2.0.B.1 regarding repeating the framing of the deck.

Delete section 2.0.C Framing the Gripper (also deleted from the Table of Contents).

Temperature Documentation of General Equipment:
Remove section 2.2 since the water bath will no longer be in use with the use of the PowerPlex® Fusion Direct Amplification kit.

Performance Checks on Critical Instrument and Equipment:
Section 2.1.A – delete “located in the water baths during the extraction process and the thermometers” since water baths/extraction will not be in use in the CODIS Unit.

Section 2.9.D – remove the word “extraction” since no extraction will be in use in the CODIS Unit.

Forms for Forensic Hit and Offender Hit Verification Requests:
Changed “Analyst Requesting Verification” to “Casework Analyst”

CODIS Data Entry and Search Procedures, section 2.1.B, 2.1.C, 2.1.D, and 2.1.E: Added statement regarding casework analysts keeping in mind the reported inclusions/statistical values of any potential hits for a specimen and stated that if there would be no inclusions or statistical value resulting, then the profile should not be entered into the database.

		Added section for Biomek 3000 setup of 3500xL plate in Capillary Electrophoresis Protocol. Added definition of reinject plate to section 2.1 of Setup of Direct Amplification of DNA from FTA / non-FTA Punches using PowerPlex® Fusion Half Reaction. Added clarification in CODIS Data Entry and Search Procedures for Profile Removal that it is the Casework Analysts' responsibility to notify the customer when a profile is removed from CODIS. [2.9.A.3] Add language to CODIS Data Entry and Search Procedures 2.6.A.1 that the Description of Profile Entered should match the description of evidence (forensic) or the full name (legal, parentage).
Rev. 7	November 1, 2015	Change Policy Manual formatting and incorporate changes necessary based on PowerPlex Fusion implementation including modification of 1-2 punches for non-FTA blood cards to 1 punch since only 1 punch was validated and add ILS override language in Analysis and Management of Data section. Format worksheets to PDF, add Thermomixer QC protocol and worksheet. Add Forensic Biology Selective Qualifications attachment, updated Orgainzational Chart and Abbreviation List, update temperature ranges for fridges and freezers to reflect OSBI CSD QP 8.1 deviation issued 10-28-15.

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CODIS Unit Policy Manual
Approval

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Per OSBI CSD QP 2 – Document Control, technical protocols/procedures, discipline quality manuals, and related attachments and references will be approved by the appropriate Technical Manager and the OSBI CSD Director or designee.

Forensic Biology Discipline Technical Manager	J. Janice Joslin	10/20/2015 Date
CSD Division Director	Andrea R. Swiech	10/28/2015 Date