

# DNA Quality Assurance Manual

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## DNA Quality Assurance Manual

The DNA Units in the FBI Laboratory conduct routine analysis of biological evidence and reference samples. The DNA Units are comprised of the Biometrics Analysis Section's (BAS) DNA Casework Unit (DCU), Federal DNA Database Unit (FDDU), and DNA Support Unit (DSU) and the Terrorist Explosive Device Analytical Center's (TEDAC) Scientific and Biometrics Analysis Unit DNA group (SBAU) as well as the DNA Technical Leader (TL) assigned to the BAS Front Office.

The DNA Units perform work in the biology discipline, commonly referred to in the FBI Laboratory as the DNA discipline. The DCU provides serological (sero), mitochondrial DNA (mtDNA), and nuclear DNA (nDNA) examination services in conjunction with criminal, counterterrorism, and missing person investigative matters. The SBAU performs exploitation of improvised explosive devices (IEDs) resulting in scientific information of biometric intelligence value and provides nuclear DNA (nDNA) examination services in conjunction with criminal, counterterrorism, and missing person investigative matters. Personnel in the DCU and the SBAU may also provide expert witness testimony in judicial proceedings on both a national and international level. The FDDU provides testing of biological reference samples obtained from individuals convicted of federal felonies and/or certain District of Columbia offenses, individuals who have been arrested on federal charges, and from non-U.S. citizens who have been detained under the authority of the United States government. Additionally, the FDDU supports federal agencies applicable to the Sexual Offense Registration and Notification Act (SORNA), to include federally recognized tribal agencies and U.S. Territories. The DSU facilitates the Quality Assurance (QA), Quality Control (QC), Validation and Research, and Training Programs in support of the DNA Units' examination efforts.

### 1 SCOPE

The DNA Quality Assurance Manual applies to personnel in the DNA Units and the casework and databasing operations over which DNA personnel have control. The DNA Units' level 2 documents (i.e., quality manual documents, technical procedures, training manuals, and their accompanying forms) supplement the level 1 documents (i.e., FBI Laboratory *Quality Assurance Manual* [QAM/LAB-100] and FBI Laboratory *Operations Manual* [LOM/LAB-200]) and serve as the cornerstone of DNA Units' operations. Additionally, these documents facilitate meeting the *Quality Assurance Standards for Forensic DNA Testing Laboratories* and the *Quality Assurance Standards for DNA Databasing Laboratories* (collectively referred to as QAS) issued by the FBI Director, as well as applicable accreditation requirements.

If laboratory activities are performed at sites outside of the FBI Laboratory permanent control facilities, these activities will be conducted by authorized DNA Unit personnel, using appropriately validated procedures that are approved by the DNA Technical Leader, using equipment under the permanent control of the DNA Units and/or that have been properly maintained in accordance with the DNA Procedures for Equipment Calibration and Maintenance (i.e., BIO-104), and using reagents that are under the permanent control of the DNA Units and prepared or evaluated in accordance with the DNA Procedures for Reagent Purchasing, Preparation, and Records (i.e., BIO-103) and/or the relevant DNA procedure.

## 2 GOALS AND OBJECTIVES

The DNA Units operate in accordance with the quality practices established by the FBI Laboratory. The DNA Units also follow the FBI and FBI Laboratory's policies and practices regarding administrative matters in addition to those addressed by unit specific procedures. Such administrative matters include, but are not limited to staffing, budget, job descriptions, duty hours and leave time.

- The DNA Units provide serological, mtDNA, nDNA, and convicted offender, arrestee, and detainee DNA testing services while striving to be a leading organization in the forensic DNA community through:
  - Continuously working to improve the overall quality and management of DNA laboratory operations.
  - Routinely reviewing unit procedures, quality control standards, expert witness testimony, proficiency testing, and audits.
  - Confirming that the analytical data and interpretation of DNA testing results are scientifically accurate and represented in a manner that is of high quality and consistent with the limits of the technical discipline.
  - Establishing and maintaining a system for documenting procedures and practices.
  - Providing on-site assistance and support to Evidence Response Teams (ERT) at crime scenes and natural disasters when directed by Executive Management.
  - Validating new methodologies and technologies and implementing those methodologies and technologies into forensic casework and DNA databasing operations.
  - Encouraging Examiners and Biologists to publish scientific articles regarding DNA analysis.
  - Liaising with other governmental, university, and private laboratories regarding DNA analysis through participation in the appropriate subcommittees of the Scientific Working Group on DNA Analysis Methods (SWGDM), the Organization of Scientific Area Committees for Forensic Science (OSAC), the Missing Persons Program, and the DNA Database Program.
  - Educating response personnel and/or contributors about DNA analysis and applicable precautions for collection and submission.
  - Educating officers of the court about DNA analysis, its forensic applications, and presenting DNA evidence in court.
  - Entering DNA profiles into the appropriate indices of the National DNA Index System (NDIS) using Combined DNA Index System (CODIS) software.
  - Maintaining compliance with the quality policies and practices established by the level 1 documents and the QAS.

### 3 QUALITY SYSTEM

DNA personnel will follow the DNA requirements and procedures referenced in this manual in addition to any unit specific or Laboratory-wide procedures, policies, and practices. Dissemination of information related to the Laboratory and the DNA QA Program is accomplished through staff meetings and through written and electronic mail communications. The level 1 documents and the DNA level 2 documents can be found at the FBI Laboratory intranet website.

- Records generated to fulfill the requirements in the level 1 documents, the DNA level 2 documents or the QAS will be retained in accordance with those documents, to include:
  - Proficiency Tests
  - Corrective Actions
  - Audits
  - Training Records
  - Court Testimony Monitoring
- All internal and external QAS Audit documents will be permanently retained.
- The Forensic Examiner training program records for Examiners will be retained permanently.
- Qualification and authorization electronic communications (ECs) will be maintained in Sentinel.
- Continuing education supporting records will be retained for at least the current accreditation cycle.
- Case file records will be retained as directed by the FBI Information Management Division.
- The following databasing records will be permanently retained:
  - Analytical Results
  - Sample Receipt and Processing Records
  - Match Confirmation Files
  - Expungement Records
- With the exception of case file records and database sample processing records, quality system records will generally be maintained by the DSU.
- Electronic records on Biometrics Analysis Section DNA Network (BASNET), to include those in the Sample Tracking and Control Software (STACS), are maintained and backed up according to the BASNET Information System Contingency Plan.

#### 3.1 Annual Review

The DNA quality system is reviewed annually in accordance with the level 1 documents. The annual review is facilitated by the DNA Quality Assurance Program Manager under the direction of the TL and approved by the TL.

### 3.2 Annual File Review

The annual review of case files and database sample processing records will be done in conjunction with the FBI Laboratory's annual file audit. Unless otherwise documented, the TL will utilize the representative sample and scope determined by the FBI Laboratory Audit Program Manager. Additional discipline specific audit questions may be added at the discretion of the TL and/or DNA unit management.

## 4 ORGANIZATION AND MANAGEMENT STRUCTURE

DNA personnel must comply with the responsibilities and requirements in the level 1 documents, the DNA level 2 documents, and the QAS. The organization of each DNA unit is presented in their organizational chart. DNA personnel may perform duties and responsibilities outside of their assigned unit provided they are trained and/or qualified and authorized to perform those tasks and are appropriately proficiency tested, when applicable.

### 4.1 Contingency Plans

The QAS requires a contingency plan for if the Technical Leader (TL) position is vacated or in the event the number of qualified analysts (i.e., Examiners) falls below two full-time employees who are qualified analysts (i.e., Examiners) at the laboratory.

- A. If the Technical Leader (TL) position is vacated, an acting TL will be designated as described below (See [Acting TL](#)).
- B. If at an FBI Laboratory location, the number of full-time employees that are qualified DNA examiners falls below two, an examiner(s) from the other FBI Laboratory location may be assigned a temporary duty (TDY) at the laboratory location without two examiners. Alternately, technical reviews will be performed by qualified and authorized FBI Laboratory personnel at the other laboratory facility until the number of qualified examiners returns to two full-time employees.
- C. If the number of qualified examiners falls below two full-time employees who are qualified examiners or if no one in the FBI Laboratory is qualified to fill the technical leader vacancy, the NDIS Custodian and State CODIS Administrator will be notified as required by the NDIS Operational Procedures Manual. The appropriate form in the QAS Audit Document(s) will be used to record the notification and any additional correspondence with the CODIS Unit regarding a contingency plan. If an additional contingency plan needs to be submitted to the CODIS Unit, DNA analytical procedures on new casework or new database analyses will not be initiated until CODIS Unit approval is granted. If the TL positions remains vacant (i.e., there is no FBI Laboratory employee qualified to fill the vacancy), casework or database analyses that were initiated prior to the technical leader's vacancy may be completed.

### 4.2 Date for QAS Personnel Requirements

As QAS are not to be applied retroactively, DNA examiners will comply with the education and experience requirements contained in the QAS in effect on the date of their initial qualification

and authorization to perform DNA analysis for the FBI Laboratory. If a qualified FDDU examiner gets additionally qualified and authorized to perform forensic DNA analysis, they must comply with the education and experience requirements contained in the Forensic QAS in effect on the date of their qualification and authorization to perform DNA analysis on casework. DNA personnel's initial and additional qualifications and authorizations will comply with the requirements for training contained in the QAS in effect at that time.

## **5 PERSONNEL**

DNA personnel must have the education, training, and experience commensurate with the examination, processing, and/or testimony provided. Requirements for Technical Leader, CODIS Administrator, analyst, technical reviewer, technician, and laboratory support personnel are detailed in the QAS. Individuals, however titled, may perform the duties associated with the role of analyst, technical reviewer, technician, and/or laboratory support personnel as defined by the QAS provided they have the applicable education and experience, and are appropriately trained and/or qualified and authorized as required in the QAS, the FBI Laboratory level 1 documents, and the DNA Training Manual (i.e., BIO-940). Position descriptions are maintained by the FBI Human Resources Division or the applicable contracting official. The duties and responsibilities of the positions in the DNA Units include, but are not limited to the following:

### **5.1 Biologist (Technical Leader)**

The Biologist (Technical Leader) is referred to as the Technical Leader (TL). The TL serves as a member of technical management and is accountable for all technical operations within the DNA Units. The TL may maintain proficiency as an analyst (i.e., examiner as defined by LOM) or technical reviewer as defined by the QAS. The duties and responsibilities of this position include, but are not limited to:

- Oversees all DNA technical operations and has the authority to initiate, suspend, terminate and/or resume such operations for any DNA unit or individual, as necessary.
- Evaluates and records approval of all validation studies and new or modified analytical methods utilized by the DNA Units and reviews proposals for new or modified analytical procedures, as appropriate.
- Assesses the previous training of an experienced Examiner or Biologist and approves a modified training program, as necessary.
- Reviews the academic transcripts of Forensic Examiner Trainees (FETs).
- Reviews training records for Examiners and Biologists, approves their qualification(s), and authorizes personnel prior to them performing independent analysis on forensic evidence and/or database samples. Reviews training records for other DNA personnel and authorizes personnel that influence the results of laboratory activities.
- Approves the technical specifications for outsourcing agreements and records this approval.
- Performs a recorded review of QAS audit documents from internal and external audits of the DNA Units and approves any resulting corrective actions, as applicable.

- Ensures that an annual review of the DNA level 2 documents is conducted under their direction and records approval of this review.
- Reviews and approves the training, quality assurance, and proficiency test programs within the DNA Units.
- Reviews potential conflicts of interest when a contract employee is employed by multiple National DNA Index System (NDIS) participating and/or vendor laboratories and approves the employment, as appropriate.
- Serves as an approving official on all DNA level 2 documents.
- Ensures there is a documented contingency plan to identify an individual(s) that will serve as the TL if the position is vacated.
- Approves continuing education programs based on multimedia or internet delivery.
- Approves the program for the annual review of scientific literature by DNA personnel.
- Reviews any inconclusive conclusion obtained on a proficiency test for compliance with laboratory guidelines.
- Ensures the Combined DNA Indexing System (CODIS) Administrator(s) is informed of all non-administrative discrepancies that affect the typing results and/or conclusions of proficiency tests at the time of their discovery.
- Reviews and records the approval of all corrective actions and DNA Unit deviations prior to implementation.
- Ensures he/she is accessible to all laboratory facilities to provide on-site, telephone, or electronic consultation, as needed, or ensures an acting TL is designated, when necessary.
- Ensures that the quality system within the DNA Units complies with the level 1 documents, as well as the QAS.

**5.1.1 Acting TL**

- A. If the TL is on temporary leave and is not available via phone or electronic means, then the TL will designate a temporary Acting TL (generally, the DNA QA Program Manager or DNA Unit Chief(s)) as a point of contact with the necessary authority to maintain (or suspend) technical operations (e.g., authorize deviations, evaluate nonconformities). One individual may be selected to serve as temporary Acting TL for all the DNA Units, or one may be selected for each unit. The TL will be informed of any reviews and authorizations performed by the temporary Acting TL(s) and follow-up as necessary.
- B. If the TL is on extended leave, an Acting TL(s) may be designated by the BAS Chief or designee. The named Acting TL(s) will temporarily assume all the duties and responsibilities of the position and must meet the qualification requirements stated in the QAS. The TL will be briefed of approvals and authorizations performed by the Acting TL(s) and follow-up as necessary.
- C. If the TL position becomes vacant, the BAS Chief or designee will immediately appoint an individual (or individuals) to serve as Acting TL(s). The Acting TL(s) must meet the qualification requirements stated in the QAS and will assume all the duties and responsibilities of the position until a new permanent TL can be appointed or

hired. A TL appointed or hired to fill a vacancy will record their review of the records required by the QAS.

## **5.2 Supervisory Biologist or Supervisory Physical Scientist (Unit Chief)**

The Supervisory Biologist/Physical Scientist (Unit Chief) is referred to as “Unit Chief (UC)”. The duties and responsibilities of the UC position include, but are not limited to:

- Functions as the head of a DNA Unit and is responsible for the overall management and coordination of operating programs to include future planning, staffing, scheduling, and budget within the respective unit.
- Determines mission-driven objectives and directs strategies and activities through which those objectives are met.
- Ensures all administrative, budgetary, equipment, and space needs are identified for the unit.
- Serves as the direct supervisor of DNA employees including Supervisory Biologists.
- Manages hiring, certifying time and attendance records, personnel and performance issues, and supervising appropriate unit members.
- Oversees the establishment, implementation, and review of administrative policies and procedures.
- Ensures a representative(s) is selected to approve level 2 and level 4 documents and delegates the initial review of level 3 documents to the TL.
- Approves unit administrative requirements and other unit specific documents, as necessary.
- Ensures that an appropriate individual is designated to serve as the Acting UC in their absence.

## **5.3 Supervisory Biologist (Forensic Examiner)**

- A Supervisory Biologist also referred to as “Supervisory Forensic Examiner (SFE)”, “Supervisory Examiner”, or “Supervisor” is an individual who has been assigned responsibility for the oversight of a group of personnel within their DNA unit. A Supervisor may be a qualified or previously qualified Examiner and therefore may be equivalent to an analyst or a technical reviewer as defined by the QAS. Supervisors who participate in the proficiency testing program will fulfill the requirements, duties, and responsibilities of an Examiner. The Supervisory Forensic Examiner duties and responsibilities may include, but are not limited to:
  - Ensures compliance with unit and FBI Laboratory policies, practices and procedures.
  - Participates in a documented training, continuing education and development program as required by the level 1 documents, accreditation standards, FBI policies, and/or the QAS.
  - Serves as the direct supervisor of a group of DNA employees which may include Forensic Examiners, Lead Biologists, Biologists, Technical Specialists, DNA Program Specialists, Management and Program Analysts, and/or Management and Program Assistants.

- Responsible for the management of various operational and/or administrative aspects of the unit, as directed by the UC.

#### 5.4 Biologist (Forensic Examiner)

A Biologist (Forensic Examiner) is also referred to as “Forensic Examiner (FE)” or “Examiner”. This position is equivalent to an analyst or technical reviewer as defined by the QAS. An Examiner may also be trained and qualified to perform laboratory activities as a Biologist (see section 5.8) and then will be proficiency tested accordingly. The Examiner duties and responsibilities include, but are not limited to:

- Ensures compliance with unit and FBI Laboratory policies, practices, and procedures.
- Participates in a documented training, continuing education and development program as required by the level 1 documents, accreditation standards, FBI policies, and the QAS.
- Directs and approves the analytical work generated by Biologist(s), reviews and interprets such data, generates *Laboratory Reports* or *Match Confirmation Letters*, testifies to the results in court, as necessary, and/or performs technical reviews of casework or databasing records, as authorized.
- Participates in the training of Biologists and Forensic Examiner Trainees (FETs) and interacts with training mentors, as appropriate.

#### 5.5 Biologist (Program Manager)

A Program Manager is assigned additional responsibilities for a specific program(s) in the DNA Unit(s) and/or serves as project manager over major projects and FBI Initiatives within the Laboratory. A Program Manager may be a qualified or previously qualified Examiner or Biologist and may maintain proficiency as a technician, an analyst, or a technical reviewer as defined by the QAS.

#### 5.6 CODIS Administrator

A CODIS Administrator and an alternate administrator will be designated by DCU and FDDU in accordance with the NDIS Operations Procedure Manual. The FBI Laboratory in Huntsville does not have CODIS access onsite; therefore, the CODIS Administrator in DCU is also responsible for the CODIS activities of SBAU. Each CODIS Administrator is responsible for the Local DNA Index System (LDIS) operated by their unit. The CODIS Administrator designated by DCU must meet the requirements of Casework CODIS Administrator as defined by the Forensic QAS and the CODIS Administrator designated by FDDU must meet the requirements of CODIS Administrator as defined by the DNA Databasing QAS. A CODIS Administrator is a qualified or previously qualified Examiner and may maintain proficiency as an analyst or technical reviewer as defined by the QAS. The CODIS Administrator duties and responsibilities include, but are not limited to:

- Administers the applicable local CODIS network.
- Schedules and records the CODIS computer training of Examiners.
- Ensures that the security and quality of data stored in CODIS is in accordance with state and/or federal law and the NDIS operational procedures.

- Ensures that matches are dispositioned in accordance with NDIS operational procedures.
- Authorized to terminate an Examiner or a DNA Unit's participation in CODIS until the reliability and security of the computer data can be assured if it is compromised.

### 5.6.1 State CODIS Administrator

The State CODIS Administrator serves as the point of contact for the NDIS Custodian and is responsible for ensuring that the laboratories participating in the FBI Laboratory's State DNA Index System (SDIS) comply with the terms and conditions for participation in the NDIS. In addition to the above responsibilities, the State CODIS Administrator has authority over the CODIS sites in their SDIS jurisdiction to terminate an Examiner's or LDIS laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified. The State CODIS Administrator may be a qualified or previously qualified Examiner and may maintain proficiency as an analyst or a technical reviewer as defined by the QAS.

## 5.7 Lead Biologist

A Lead Biologist is responsible for overseeing laboratory functions that support the casework and/or databasing operations of the DNA Units. This position is equivalent to a technician as defined by the QAS. The Lead Biologist responsibilities include, but are not limited to:

- Ensures compliance with unit and FBI Laboratory policies, practices, and procedures.
- Participates in a documented training, continuing education and development program as required by the level 1 documents, accreditation standards, FBI policies, and the QAS.
- Participates in the sample preparation stages prior to casework and/or database DNA processing to include collection of casework samples and/or front-end processing of database samples, and offender status requests, as needed.
- Performs specific analytical procedures in the laboratory to support casework and/or databasing activities and interacts with Examiners, as appropriate.
- Provides technical and operational support to Biologists regarding standard operational procedures and good laboratory practices.
- Participates in the training of Biologists and interacts with training mentors, as appropriate.
- Participates in troubleshooting, validation, and/or research projects, as needed.

## 5.8 Biologist

The Biologist position is equivalent to a technician as defined by the QAS. The Biologist duties and responsibilities include, but are not limited to:

- Ensures compliance with unit and FBI Laboratory policies, practices and procedures.
- Participates in a documented training, continuing education and development program as required by the level 1 documents, accreditation standards, FBI policies, and the QAS.

- Performs specific analytical procedures in the laboratory to support casework and/or databasing activities and interacts with Examiners, as appropriate.
- Serves as a mentor during the training of entry-level Biologists.
- Participates in troubleshooting, validation, and/or research projects as needed.

### 5.9 Biologist (Technical Specialist)

A Biologist (Technical Specialist) is also referred to as “Technical Specialist (TS)”. The TS is responsible for performing laboratory functions that are involved with quality assurance/quality control (QA/QC), validation, research, CODIS, and/or training efforts to support the technical operations of the DNA Units. TSs with QA/QC duties generally function as laboratory support personnel and will receive appropriate training specific to their job function. TSs that perform validation will demonstrate competence and be authorized to perform development, modification, verification, and validation of methods. TSs with CODIS and/or validation duties generally do not perform examinations on forensic samples or processing of database samples and therefore are not subject to the personnel requirements as defined by the QAS. TSs that perform examinations on forensic samples or process database samples will comply with the requirements of a technician as defined by the QAS and be authorized to perform laboratory activities. Responsibilities of a TS may include, but are not limited to:

- Ensures compliance with unit and FBI Laboratory policies, practices, and procedures.
- Participates in a documented training, continuing education and development program as required by the level 1 documents, accreditation standards, FBI policies, and the QAS.
- Performs specific analytical procedures in the laboratory that are involved with QA/QC, validation, and research efforts to support casework and/or databasing activities and interacts with Research Biologists, Program Managers, and Examiners, as appropriate.
- Provides guidance and/or direction to Biologists in support of the QA, training, validation, and/or research programs.
- Participates in the sample preparation stages prior to casework and/or database DNA processing to include collection of casework samples and/or front-end processing of database samples, and offender status requests, as needed.
- Identifies specific areas that require monitoring, including technical and quality control, problem solving, and research and validation, to improve the methods and processes carried out by the DNA Units.
- Assists the unit in administrative and/or CODIS duties, as needed.
- Functions as a CODIS Biologist by entering DNA profiles into CODIS following the prerequisite review and verification by appropriate DNA personnel. The CODIS Biologist uploads DNA profiles, maintains CODIS paperwork, coordinates potential Match evaluations, and operates the CODIS software on a daily basis. All individuals functioning as CODIS Biologists receive documented training in CODIS data entry, CODIS software, and CODIS operations.

### **5.10 Biologist (DNA Program Specialist)**

The DNA Units may refer to Biologist (DNA Program Specialist) as “Program Specialist (PS)”. The PS performs various levels of administrative tasks, laboratory support, case management, evidence management, and/or QA/QC duties in support of the DNA Units. PSs may also perform duties as listed above for a TS. PSs are typically equivalent to laboratory support personnel as defined by the QAS; however, PSs that perform examinations on forensic samples or process database samples will comply with the requirements of a technician as defined by the QAS.

### **5.11 Research Biologist**

A Research Biologist is responsible for identifying and/or conducting studies that will aid the DNA Units in using novel or improved analytical procedures, as well as conducting validation studies and transferring the knowledge pertaining to the validation of new methods and technologies to casework and database personnel. Research Biologists will demonstrate competence and be authorized to perform development, modification, verification, and validation of methods. A Research Biologist may be a qualified or previously qualified Examiner or Biologist and may maintain proficiency as a technician, an analyst, or a technical reviewer as defined by the QAS.

### **5.12 Management and Program Analyst**

A Management and Program Analyst is responsible for administrative tasks and the management and assessment of unit(s) program operations and projects. In addition, this position plans, develops, and conducts program analyses, identifies inefficiencies, evaluates performance measures, and provides recommendations to management, when necessary. A Management and Program Analyst may manage unit budget and financial matters by developing budget estimates and justifications and ensures unit funds are used appropriately. The Management and Program Analyst may also assist with time and attendance records.

### **5.13 Management and Program Assistant**

A Management and Program Assistant performs clerical and administrative duties. The Management and Program Assistant may also assist with the time and attendance records.

### **5.14 Temporary Duty Assignments**

In the event that additional personnel are needed to meet the changing operational needs of any of the DNA Units, a DNA UC may request that an individual, who possesses the necessary knowledge and skills, be transferred to the respective DNA Unit on temporary duty status. This request must be made in writing, approved by Executive Management and comply with current Laboratory Division (LD) policies. If the operational needs are technical in nature, the TL will determine and approve any necessary training and authorize personnel, as appropriate, in accordance with the level 1 documents.

## 5.15 Contractors

All DNA contractors will comply with the applicable requirements of the level 1 documents, accreditation standards, FBI policies, and the QAS. Prior to gaining employment by an additional NDIS participating and/or vendor laboratory, a contractor will obtain TL approval. Contractors will perform duties within the scope of the contract statement of work under the direction of the unit's Contracting Officer's Representative (COR). In addition to contractors with Biologist or Examiner titles, the following include possible contractor positions in the DNA Units.

### 5.15.1 Contractor Supervisor

The Contractor Supervisor (aka Operations Supervisor) provides on-site supervision to DNA contractors employed by their contracting agency assigned to the FBI Laboratory. The Contractor Supervisor is also responsible for assisting DNA Units in operational and support needs.

### 5.15.2 Supervisory Records Examiner/Analyst

A Supervisory Records Examiner/Analyst performs specific analytical procedures in the laboratory to support casework and/or database activities and interacts with Examiners, as appropriate. A Supervisory Records Examiner/Analyst must meet the qualifications and appropriate training requirements of a Biologist and is equivalent to a technician as defined by the QAS.

### 5.15.3 Records Examiner/Analyst

A Records Examiner/Analyst can be responsible for performing laboratory functions that are involved with quality assurance/quality control (QA/QC) or evidence management and sample preparation stages prior to casework and/or database DNA processing, as needed. A Records Examiner/Analyst can conduct QC procedures on the reagents and instruments used in casework and/or databasing. This includes performing the actual QC procedures as well as recording the results and assessing the performance of the reagents and instrumentation. A Records Examiner/Analyst can also function as the team leader for contractors assigned to the accessioning process, providing instruction and technical guidance, as needed. A Records Examiner/Analyst assigned to support the DCU Case Administration Group (CAG) manages items of evidence and is responsible for performing various levels of administrative tasks. A Records Examiner/Analyst may also perform Data Analyst tasks or act in support of other DNA Unit programs, as needed. Records Examiners/Analysts are equivalent to laboratory support personnel as defined by the QAS.

### 5.15.4 Data Analyst

A Data Analyst conducts various functions involving administrative and laboratory support. A Data Analyst may be responsible for retrieving database samples from storage and performing the plate preparation and plate creation process. This includes punching the samples into plates using automated punch workstations and returning samples to storage after analysis. Additional responsibilities include the receipt, check-in, and storage of the samples. A Data Analyst may also assist FDDU Examiners in the resolution of samples which contain missing

information, are potential duplicates, and/or potential rejects. A Data Analyst may assist with sample status requests and expedite requests. A Data Analyst in CAG will assist with the management of items of evidence. A Data Analyst may also conduct QC procedures on the reagents and instruments used in casework and/or databasing or perform validation studies. Data Analysts are generally equivalent to laboratory support personnel as defined by the QAS. Data Analysts may also provide administrative support such as Sentinel tasks and casefile management assistance or act in support of other DNA Unit programs, as needed.

#### 5.15.5 Clerical II

A Clerical II will assist with the receipt and check-in of collection kits, sample storage, and/or provide administrative support to the DNA Units.

#### 5.15.6 IT Support

IT Support personnel provide computer technical support and maintain the BASNET.

### **6 TRAINING, QUALIFICATION, AND AUTHORIZATION**

- A. All personnel that could influence the laboratory activities will act impartially, be competent, and work in accordance with the laboratory quality system.
- B. The TL will approve any modifications to required training based on the recorded assessment of the individual's previous training and experience.

#### **6.1 Training Programs**

- A. The DNA Units will administer and maintain documented training programs for personnel as required by the level 1 documents. The training programs will be outlined in a training manual which will identify the requirements necessary for achieving qualification and authorization in each respective position.
  - 1. All Examiners and Biologists must satisfactorily complete competency testing prior to assuming independent casework or databasing responsibilities. The competency test intended results must be achieved prior to performing the task(s) on casework items or databasing samples.
    - i. For Biologists training in an additional module, the additional training will be administered in accordance with the applicable section of the DNA Training Manual.
    - ii. Examiners training in an additional DNA technology or interpretation (e.g., kinship) will not reenter the Forensic Examiner Training Program but will complete the relevant training module in the DNA Training Manual.
  - 2. The DNA Training Manual will also address training for DNA personnel that handle evidence, laboratory support personnel that will perform laboratory duties exclusive of analytical procedures on forensic and/or database samples (e.g., sample accessioning, reagent preparation, instrument maintenance), and individuals that will perform development, modification, verification, and validation of methods.

## 6.2 Additional Training

- A. Prior to implementation of a new method in the laboratory for forensic examinations or DNA databasing, Biologists will be taught the technical skills and knowledge required to perform the method and Examiners will review the examination records generated using the method in order to authorize and report results.
  - 1. Before the use of the new method on evidence, reference, or database samples, the Biologists must successfully complete competency testing, including a practical component, to the extent of their participation in casework or databasing analyses.
- B. Prior to the implementation of a new technology, typing test kit, platform, or interpretation software, Examiners will be taught the technical skills and knowledge required to interpret data, reach conclusions, and generate reports.
  - 1. Before the use of a new technology, typing test kit, platform or interpretation software on evidence, reference, or database samples, Examiners must successfully complete competency testing, including a practical component, to the extent of their participation in casework or databasing analyses.
- C. For an Examiner to be qualified in reinterpretation of legacy data, for which they were not previously qualified within the laboratory, the Examiner must demonstrate the technical skills and knowledge required to interpret data, reach conclusions, and generate reports in the legacy technology, typing test kit, and/or platform.
  - 1. The Examiner must successfully complete competency testing, including a practical component, in the legacy technology, typing test kit, and/or platform to the extent of their participation in casework analyses. The competency testing will include practical components of reinterpretation.
- D. For an Examiner to be qualified to perform technical reviews for any method, technology, typing test kit, platform, or interpretation software or a legacy technology, typing test kit, platform and/or interpretation software on which they were not previously or are not currently qualified as an analyst in the laboratory, training will include the case notes, data analysis, interpretation, and reporting criteria, as applicable, required to perform a technical review.
  - 1. The Examiner must have successfully completed competency testing before completing a technical review of data and/or reports using the new or additional method, technology, typing test kit, platform or interpretation software used in casework analyses.

## 6.3 Qualification and Authorization

- A. The TL will review training records for Examiners and Biologists and approve an individual's successful completion of a training program.
- B. Qualification and authorization will be recorded in an EC in accordance with the level 1 documents and, if applicable, the DNA Training Manual.

1. Prior to use of a newly validated procedure (e.g., method, technology, typing test kit, platform, interpretation software), qualification and authorization is recorded in an EC for all individuals who successfully completed the additional training.
- C. When external proficiency testing does not include a legacy technology, typing test kit, or platform, an Examiner must maintain or reestablish the technical skills and knowledge necessary to perform reinter-pretation of the legacy data, as necessary, every two years. This is accomplished through a review of validation records, review of SOPs, and/or review of previous training records applicable to the legacy technology, typing test kit, or platform. The reviews will be recorded and provided to the TL to ensure authorization prior to reporting results requiring the reinter-pretation of legacy data.
  1. The TL will review the Examiner’s records of review and authorize the Examiner to reinter-pret legacy data for no more than a two-year period.
- D. When retraining of personnel is necessary, the technical leader will be responsible for evaluating the need for and assessing the extent of retraining. The retraining plan will be approved by the technical leader. The individual must successfully complete competency testing, including a practical component, prior to return to participation in forensic examinations or DNA databasing.

## 7 FACILITIES AND EVIDENCE/SAMPLE CONTROL

### 7.1 Facilities

- A. DNA laboratory areas in permanent control facilities are located separately from unit offices. Access to the laboratory area is obtained through a bio-vestibule.
  1. If laboratory activities are performed at sites outside of the FBI Laboratory permanent control facilities, DNA personnel will ensure requirements for facilities and environmental conditions of the applicable accreditation standards are met, to include verifying that the site is appropriate to ensure the integrity of the analyses and the evidence.
- B. DNA personnel will comply with all health and safety practices established in the [FBI Laboratory Safety Manual](#).
  1. DNA personnel will use appropriate protective equipment when performing sample check-in, laboratory examinations of evidence, or processing of samples that may contain potentially infectious biological substances.
  2. Food and/or drinks are not to be handled or consumed in any DNA laboratory space.
- C. DNA laboratory areas are arranged in a manner that ensures the physical separation of those used for evidence examination, sample accessioning, DNA extraction, amplification set-up and/or other pre-amplification processing from those used for DNA amplification and post-amplification processing.
  1. Evidence examination or sample accessioning, DNA extraction, and PCR setup are conducted at separate times or in separate spaces.

2. There are no specific environmental conditions necessary for the performance of DNA laboratory activities; however, extreme temperature fluctuations may impact the performance of capillary electrophoresis instruments.
- D. Amplified DNA product will be generated, processed, and maintained in rooms separate from evidence examination, sample accessioning, DNA extraction and amplification set-up. The doors to the amplification rooms will be kept closed except for passage.
1. Equipment and materials used in laboratory spaces where DNA is amplified or amplified DNA is stored or processed are not to be transferred to, used in, or stored in laboratory spaces where evidence is examined, database samples are processed, and/or unamplified DNA is extracted or stored unless decontaminated before transfer. These items include, but are not limited to:
    - Laboratory coats
    - Pipettes
    - PCR related supplies
    - Micro Amp Support Base (Amplification set-up racks)
    - General laboratory supplies and materials
  2. Rapid DNA instruments will be maintained in rooms outside of evidence examination or sample accessioning areas or those containing amplified DNA.
  3. Additional housekeeping procedures needed to ensure the quality of the examination or testing procedures are contained in the DNA procedures introduction (i.e., BIO-100).

## 7.2 Security

- A. The DNA Units will follow the level 1 documents and the security practices in the FBI Security Division Policy Directives and Policy Guides.
1. DNA personnel will ensure that individuals without unescorted access to the FBI Laboratory are escorted at all times while under their care and in the FBI Laboratory building.
- B. The FBI Laboratory buildings are secured areas. Laboratory space is accessed by the Security Access Control System (SACS) badge and/or a laboratory access key.
1. The LD Security Group is responsible for the control of access keys. Key lists will be reviewed at least annually. A UC, supervisor, or DSU personnel will ensure the LD Security Group and/or the individual are notified when an individual needs to be issued or is expected to relinquish a laboratory access key.
  2. The LD Security Group is responsible for making the appropriate changes to the access lists. Access lists will be reviewed annually. A UC, supervisor, or DSU personnel will ensure changes to the SACS badge access lists are requested, as needed.

- C. If laboratory activities are performed at sites outside of the FBI Laboratory permanent control facilities, DNA personnel are responsible for ensuring the security of the testing area.

### 7.3 Sample Control

- A. The FDDU does not handle forensic DNA evidence. The FDDU receives, stores, and processes DNA database samples (i.e., known blood or buccal samples) in accordance with the DNA databasing procedures.
  - 1. DNA database samples are stored in designated laboratory space and sample storage areas with restricted access. Database sample storage areas will be locked when unoccupied.
  - 2. The FDDU Chief will authorize the appropriate DNA personnel, and a limited number of other FBI Laboratory personnel and facilities maintenance employees, with unescorted access to database sample storage areas. Individuals not authorized by the FDDU Chief will be escorted.
  - 3. The FDDU will retain all DNA database samples (e.g., FTA cards) indefinitely unless otherwise directed by a legal expungement, as a result of an administrative removal or quantity not sufficient (QNS) removal, or for purposes of research, validation, and/or population databases.

### 7.4 Evidence Management

- A. DNA personnel will follow the relevant level 1 documents and the DNA evidence management procedures (i.e., BIO-201), when receiving, transferring, examining, storing, or returning evidence. When not under active examination, evidence will be stored, secured, and/or sealed in a manner to prevent loss, cross-transfer, contamination, or deleterious change.
  - 1. In general, evidence is stored at room temperature, refrigerated, or frozen. Evidence such as tissue, bones, and teeth are generally stored refrigerated, but may be stored frozen, if deemed necessary. DNA extracts and amplified DNA products may be stored refrigerated or frozen. For long term storage, DNA extracts may be dried and stored at room temperature.
  - 2. If a sample(s) is collected from evidence that is in the custody of another laboratory unit or a partner laboratory and therefore not in the custody of the DNA Units, the case record and/or chain of custody will appropriately reflect items or samples that are collected or created and preserved for future testing. Virtual transfers may be necessary to enter items and/or samples into STACS when an item of evidence is not received by the DCU or SBAU.
- B. The DCU and SBAU will maintain the security of Evidence Storage Rooms (ESR) in accordance with the appropriate level 1 documents.
  - 1. As appropriate, the DCU and SBAU Chief will authorize unit personnel, other FBI Laboratory personnel (e.g., EMU, EU, DSU), and facilities maintenance employees to enter the applicable ESR unescorted. Individuals not authorized

- by the applicable UC will be escorted and complete the appropriate log upon entry into the ESR.
- 2. The applicable UC will ensure the security group access lists are reviewed annually and necessary adjustments are requested.
- C. The DCU CAG centralizes DCU evidence management functions not related to examinations. An appropriately trained individual performs these functions for the SBAU.
  - 1. Appropriately trained individuals accept evidence into the DCU or SBAU and ensure appropriate entries are in STACS. The DNA Units use STACS for both Legacy and Forensic Advantage (FA) cases.
    - i. In general, CAG does not open evidence containers received as part of a Multiple Unit Submission (MUS). If necessary to separate evidence into different storage conditions (e.g., freezer, room temperature), the Chain-of-Custody will reflect this separation to include confirmation of the listed contents within the container upon opening.
- D. For evidence received as a Single Unit Submission (SUS), an appropriately trained individual will open evidence containers as necessary for evidence breakdown and inventory purposes in accordance with the appropriate practices and/or procedures.
- E. An appropriately trained individual will also ensure all items examined by the DNA Units are prepared (i.e., properly packaged) for forwarding to another Laboratory unit or returning to the contributor.

## 7.5 Evidence and Work Product

### 7.5.1 Databasing

- A. DNA database samples are not evidence. FDDU samples are considered work product at any stage of the analytical process commencing with punch. The FDDU utilizes STACS software for tracking the movement of samples through processing.
  - 1. STACS assigns a unique identifier (i.e., FDDU Sample Number) to each DNA database sample upon receipt/check-in, and that unique identifier is maintained through the analytical processes within the FDDU. Additionally, FDDU samples are RFID tagged for use in tracking the samples when moved within the laboratory and when placed in storage.
  - 2. Amplified FDDU samples will be stored refrigerated in the post-amplification laboratory. FDDU DNA extracts (if applicable) and amplified product may be disposed of once the data analysis is complete for the FDDU sample plate(s).
  - 3. Sample consumption is generally not necessary for FDDU sample processing. If continued attempts at testing to obtain a DNA profile are unsuccessful, the sample may require a Quantity Not Sufficient removal and a request for resubmission. (Refer to BIO-312)
  - 4. Unless a DNA database sample is expunged or removed according to the FDDU procedure, once DNA databasing is complete, the remaining sample is

retained for quality purposes (e.g., match confirmation) and may be used for training, validation, or other DNA unit needs.

### 7.5.2 Casework

- A. DNA extract tubes, DNA dilution tubes, and unprocessed collections (e.g., swabbings, bone powder) retained from items of evidence in the DCU and SBAU are considered secondary evidence.
  - 1. Secondary evidence may be retained by the DCU for future testing in support of the National Missing Person DNA Database (NMPDD) program. Once retained in the NMPDD repository storage, physical transfers will not be recorded until the sample is removed for subsequent testing.
  - 2. Secondary evidence in the SBAU will generally be transferred to the Evidence Management Unit (EMU) for retention with the evidence.
- B. Work product in the DCU and SBAU is material that is generated as a function of analysis of evidence or secondary evidence. Work product includes cuttings that have been processed for extraction, plates containing diluted DNA, amplification product, and material generated from serological analyses (e.g., slides prepared for Takayama hemochromogen testing). Work product is generally not retained or returned.
  - 1. Amplified DNA will be stored in a refrigerator/freezer in the post-amplification laboratory areas and physically separated from areas used for evidence examinations, DNA extractions, and PCR set-up. DCU or SBAU amplified DNA may be disposed of after the *Laboratory Report* has been issued for the case or at regular intervals as approved by the TL.

## 7.6 Examination of Evidence

- A. The Biologist, or an appropriately trained individual, that opens an evidence container or package will ensure the custody transfer was properly recorded. The item(s) transferred will be verified to the extent possible without unnecessarily opening packaging layers. Any necessary corrections will be made to the Chain of Custody. Any packaging discrepancy (e.g., torn bag, broken seal) will be noted.
  - 1. The contents of evidence containers or packages not opened by the DNA Units will not be verified.
  - 2. If a primary evidence package (i.e., packaging in contact with evidence) is opened but no examinations are conducted, a note will be made in the case file.
- B. The movement and location of all evidence and secondary evidence over which DNA personnel have custody will be tracked. STACS is used to track evidence and secondary evidence within the DCU and SBAU.
- C. Evidence is sealed and stored in accordance with the level 1 documents (Refer to LAB-200).
  - 1. Evidence may be considered under active examination during the time that items in a submission (or a group of submissions in a case) are being examined for serology and/or collected for DNA extraction. Evidence items

- may be unsealed in a lockable laboratory space (e.g., a laboratory suite) with proper signage while the items in the submission(s) are being examined.
2. Secondary evidence (e.g., extract tubes) may be considered under active examination from their creation until completion of the technical review when they are itemized in FA and packaged in a properly sealed container for return. Secondary evidence may be stored unsealed in a lockable laboratory space (e.g., a laboratory suite refrigerator or freezer) during this active exam period.
    - i. Secondary evidence may be removed from packaging for additional testing as needed (e.g., recall from EMU, resubmission) and will again be considered under active examination until completion of the additional testing.
  3. Personnel will ensure the laboratory rooms or areas containing evidence or secondary evidence are locked at the end of the day.
  4. Access to laboratory space is limited to FBI Laboratory employees, contractors, and limited maintenance and service personnel with SACS badge access; therefore, rooms containing only work product (i.e., post amplification labs) do not need to be individually locked.
  5. If laboratory activities are performed at sites outside of the FBI Laboratory permanent control facilities, DNA personnel are responsible for ensuring the security of the evidence and work product in progress. DNA personnel will remain present in the testing area or will record in the case notes the security measures taken to secure unattended items in order to preserve the integrity of the evidence and work product.
    - i. If secondary evidence must temporarily remain at a site outside of the FBI Laboratory permanent control facilities, DNA personnel will properly seal and ensure the items are stored in an appropriately secure, controlled access storage location.
    - ii. The storage location and a verification of the integrity of the items upon retrieval from the storage location will be recorded in the case notes and/or chain of custody.
- D. DNA personnel should use the amount of evidence considered necessary to provide DNA typing results. It is noted that while every attempt is made not to consume the entirety of any particular item of evidence to allow for possible reexamination of that evidence at a later date by another laboratory, the primary goal is to use the amount of evidence necessary to provide DNA typing results. When sample consumption is necessary, a concerted effort to obtain authorization from the prosecutor or contributor to consume evidentiary materials will be made prior to the initiation of DNA examinations (i.e., extraction) on the affected item(s). A record of these communications will be retained with the case records.
1. For TEDAC cases, samples will be consumed at the discretion of the DNA Units.
  2. Evidence material retained or used for non-casework procedures (e.g., for troubleshooting, validation) is considered work product. Collections made

for this purpose will be limited to items with sufficient material for future testing and must be approved by the contributor (for non-TEDAC cases) and recorded in the case notes and report.

## 8 VALIDATION

- A. All new technical procedures intended for DNA and/or serological analysis on casework and/or database samples will be validated in accordance with the level 1 documents and the QAS.
  - 1. Internal validation data may be shared by all locations. Each laboratory location will complete the applicable site-specific studies required by the QAS.
  - 2. Newly validated DNA methods (from amplification through characterization), typing test kit, or platform instrument model will be checked against an appropriate and available certified reference material (or sample made traceable to the certified reference material) prior to the implementation of the method for forensic examinations or DNA databasing.
- B. Procedural modification(s) (aka material modifications) made to a previously validated and approved technical procedure will be evaluated by comparison to the original procedure using similar samples. Such testing will be completed and approved prior to the issuance of the revised procedure.
- C. A Rapid DNA instrument used for modified Rapid DNA analysis will be validated in accordance with the level 1 documents and the QAS. An NDIS approved Rapid DNA System requires only a performance check prior to use on casework reference, known, or database samples.
- D. New software or modifications to software will be evaluated and appropriately validated or tested in accordance with the QAS and the applicable DNA procedures for equipment (i.e., BIO-104).
- E. Validation studies will be technically reviewed by an individual with the appropriate expertise in the subject matter. All developmental validation, internal validation, procedural modifications and software testing records will be reviewed and approved by the TL prior to implementation. Validation records will reflect the date of the review(s) and TL approval.
- F. The TL will ensure the applicable UC(s) are provided the results of an internal validation study and the validation summary before use in the laboratory. When a newly validated procedure will be implemented in a DNA Unit(s), the UC(s) of the applicable unit(s) will record agreement with the validation results and summary.
- G. Records associated with developmental validation, internal validation, procedural modifications and software testing will be maintained by DSU, typically via electronic records or in validation binders that are scanned into Laserfiche for retention. The summary of the shared validation data will be available at each site.

## 9 ANALYTICAL PROCEDURES

### 9.1 Standard Operating Procedures

- A. DNA personnel will follow the appropriate level 1 document when preparing, reviewing, issuing, distributing, and controlling DNA documents.
1. The DNA QAPM, in collaboration with subject matter experts in DCU, SBAU, FDDU, DSU, and the TL, will coordinate the revision and subsequent issuance of the DNA discipline level 2 documents, as appropriate.
    - i. Relevant level 2 documents are available in the applicable unit STACS.
    - ii. DSU maintains a list of controlled hard copies of level 2 documents.
  2. DNA level 3 documents (e.g., externally produced quality documents, equipment manuals, user guides) required to perform laboratory activities will be controlled in accordance with the appropriate level 1 document.
    - i. DSU maintains a list of controlled level 3 documents and their approvers.
    - ii. Typically, the DNA Units use externally produced quality documents for reference, maintenance, and/or troubleshooting purposes and, therefore, these will not be controlled.
    - iii. Electronic copies of equipment manuals may be retained in STACS or are generally available online.
  3. A list of DNA level 4 guidance documents (e.g., style guides, checklists) and the person(s) authorized to issue each document will be maintained by DSU.
    - i. DNA level 4 documents are available in Laserfiche on BASNet or on Sharepoint through the Unet OneDrive unless an alternative location is necessary (e.g., document is classified).
    - ii. The revision date and the representatives from each applicable unit who approve for adequacy will be recorded, usually on the first page of the document. The revision date may also be appended to the document name.
    - iii. Version control is used to track changes, when available. Otherwise, the changes and current revision status is identified.
    - iv. When practicable, the issuers will post PDFs, locked Word documents, or read only access versions of documents.
- B. If it is necessary to deviate from an FBI Laboratory quality system document (level 1, level 2, or level 3), DNA personnel will follow the appropriate level 1 document.
1. The TL will evaluate all technical deviation requests prior to approval.
  2. Approved minor deviation records will be tracked, generally through the QA ticketing system, and will be compiled for at least an annual review.
  3. Since level 4 documents do not contain requirements, deviations will not be tracked.

### 9.2 Quality Control of Reagents and Supplies

The DNA Units will follow the relevant level 1 and DNA level 2 documents and the QAS regarding the quality control of reagents and supplies.

- A. The use of analytical controls and standards to monitor analytical procedures used for examinations and DNA databasing are described in the applicable procedure(s).
- B. Reagents deemed critical are listed in the DNA procedures for reagents (i.e., BIO-103).

### 9.3 Detection and Control of Contamination

- A. DNA personnel follow guidance for cleaning and decontaminating facilities described in the DNA Procedures Introduction (i.e., BIO-100).
- B. Additional guidance for cleaning, when applicable, and the detection of contamination is contained in the applicable technical procedures.
- C. The FBI has a policy for an elimination DNA database to be used for the detection of contamination.

### 9.4 Sampling

- A. The types of forensic examinations performed by DNA personnel do not require a sampling plan. Sample collection guidance and sample preparation procedures are described in the appropriate DNA level 2 documents (e.g., BIO-501, BIO-301, BIO-511).
  - 1. A reasonable assumption of homogeneity can be made for database samples, casework reference samples (e.g., blood tubes, buccal samples), and various types of evidence (e.g., bones, teeth, hair and swabs) examined by the DNA Units.
  - 2. When a reasonable assumption of homogeneity cannot be assumed, the selection of samples or sites is based on an Examiner's knowledge, training, and experience to select the appropriate samples and/or stains to test. In addition, an Examiner may rely on the results of the serological testing and/or the Biologist observations, training, and experience regarding the selection of an appropriate stain/sample. If this information does not allow two stains/samples to be distinguished from one another, a stain/sample may be selected at random.
  - 3. In instances where a portion of an item of evidence may be selected for testing (e.g., one of multiple bloodstains on an item of evidence), the *Laboratory Report* will reflect the tested portion of the item of evidence, making no inference about the whole.
- B. Relevant sampling records are generally recorded in STACS.

### 9.5 Measurement Uncertainty

Measurement uncertainty does not apply to the examinations or DNA databasing conducted in the DNA Units.

## 10 EQUIPMENT CALIBRATION AND MAINTENANCE

All equipment having an effect on the accuracy and validity of DNA examinations or DNA databasing will be properly maintained and calibrated in compliance with the appropriate level 1 and DNA level 2 documents and the QAS. Equipment deemed critical are listed in the DNA procedures for equipment (i.e., BIO-104).

## 11 LABORATORY REPORTS AND MATCH CONFIRMATION LETTERS

- A. DNA personnel will prepare a *Laboratory Report* in accordance with the appropriate level 1 and DNA level 2 documents.
- B. The FDDU does not issue *Laboratory Reports*; however, it does provide *Match Confirmation Letters* in accordance with the appropriate DNA level 2 document (i.e., BIO-311).
- C. The resolution, verification and reporting/notification of database matches, including the release of personally identifiable information, is done in accordance with the NDIS procedures and the appropriate DNA level 2 document.

### 11.1 Records

- A. Case-related and database records will be generated and/or prepared by DNA personnel in accordance with the appropriate level 1 and DNA level 2 documents. Generally, laboratory activity records are generated and/or maintained in STACS.
- B. Abbreviations and notations may be used in records provided they are clearly documented and readily comprehensible to the reviewer. A list of commonly used abbreviations/symbols employed in case file and database records is available in [Appendix A: Commonly Used DNA Abbreviations](#).
- C. DNA Units maintain the confidentiality of case records and personally identifiable information (PII) according to the level 1 documents. DNA records or case files may be released upon request from an authorized entity (e.g., contributor, discovery request, another NDIS laboratory). DNA examination records (e.g., exam notes, DNA profiles) will be, at a minimum, technically reviewed, if applicable, prior to release.
  - 1. DNA databasing records (e.g., DNA profile, data required to manage and operate NDIS) are only released upon receipt of a written legal request for discovery or other legal request (e.g., Freedom of Information Act [FOIA]). With the FDDU Chief's approval, DNA records and associated metadata may be released to other FBI Laboratory units (e.g., DCU) in the absence of a written legal request.
  - 2. The Federal DNA Identification Act ('Federal DNA Act'; 34 U.S.C. §12592(b)(3)) provides for limited access to the DNA analyses and DNA samples to the following:
    - i. to criminal justice agencies for law enforcement identification purposes;
    - ii. in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;

- iii. 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
- iv. if personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes.

## 12 REVIEW

- A. *Laboratory Reports* (DCU and SBAU) and *Match Confirmation Letters* (FDDU), as well as case or database related administrative and examination records generated by the DNA Units will be reviewed in accordance with the appropriate level 1 and DNA level 2 documents and the QAS.
- B. Disagreements will be handled in accordance with the level 1 documents, except as described in the level 2 document for DNA Case Files, Reports, and Reviews (i.e., BIO-500).
- C. The release of personally identifiable information associated with a database hit requires at a minimum an administrative review of the *Match Confirmation Letter* or the *CODIS Laboratory Report*.
- D. STACS is typically used to assign CODIS specimen categories. For database samples, this is based on the sample contributor type. For casework samples, the specimen category is selected by the examiner within STACS. Specimen categories may be edited as necessary and appropriate upon entry of the sample into CODIS.

## 13 PROFICIENCY TESTING

- A. Personnel that perform laboratory activities on evidence or DNA databasing samples (i.e., Biologist and Examiners) or that handle evidence (i.e., CAG) will be monitored in accordance with the level 1 documents.
  - 1. Personnel that perform laboratory activities will be monitored through proficiency testing further described in the DNA procedures for administering proficiency tests (i.e., BIO-102).
  - 2. Personnel that do not perform laboratory activities, but handle evidence will be monitored through general performance feedback, direct observation audits, or other observation-based monitoring.
- B. DNA Units use external, open proficiency tests to monitor the performance of Examiners and Biologists according to the appropriate level 1 and DNA level 2 documents, and the QAS.
  - 1. Biologists that are qualified to perform laboratory methods on casework and/or databasing samples will be proficiency tested in each methodology in accordance with the QAS.
  - 2. Examiners will be tested on the interpretation and/or technical review of serological and/or DNA data in each technology and on each typing test kit in which they participate in casework and/or databasing in accordance with the QAS.

3. Proficiency testing requirements do not apply to the use of a Rapid DNA System; however, Examiners qualified to perform modified Rapid DNA analysis must be proficiency tested in accordance with the QAS.
- C. If an Examiner or Biologist is on leave or otherwise assigned for a period that takes them out of the proficiency test cycle, the Examiner or Biologist will complete any necessary training or retraining and will complete a competency test (aka a requalification test) in accordance with the retraining procedures above and the appropriate training manual prior to resuming casework or databasing and then return to the proficiency testing cycle within eight months.

#### 14 NONCONFORMITIES

- A. DNA Units will follow the appropriate level 1 documents when a potential nonconformity is identified in casework or DNA databasing analysis, proficiency testing, testimony, and/or audits.
- B. DNA personnel record nonconformities via the QA ticketing system. The requirement, the situation or condition, and any action taken should be included in the nonconformity record.
  1. DNA personnel evaluate a situation or condition and determine when a correction is practicable. If necessary, appropriate technical management in collaboration with the DNA QA program manager (QAPM) will assist with the evaluation.
  2. The QA ticketing system sends a notification to the TL and to other DNA personnel (e.g., assigned examiner, lab operations manager, supervisor, CODIS admin), when applicable.
  3. The QAPM (or other DSU personnel) reviews all reported nonconformities.
  4. Nonconformity records are maintained such that nonconformity records may be monitored for trends.
  5. At least quarterly, nonconformity records, including a notation of any trends and further actions taken, will be compiled for the TL and the applicable UCs and/or supervisors.
- C. The TL is responsible for determining if reported nonconformities potentially require corrective action and/or preventive action. Corrective actions and preventive actions in the DNA Units will be implemented in accordance with the appropriate level 1 documents. *Corrective Action Plans (7-254)* will be approved by the TL prior to implementation.
- D. When applicable, a copy of the nonconformity record (e.g., CAP), a communication log referencing the CAP and/or a note describing the action taken to address a nonconformity involving casework examinations or DNA databasing will be retained in the case file or database records.
- E. The appropriate CODIS administrator(s) will be notified when the nonconformity impacts DNA records entered into CODIS.

## 15 AUDITS

- A. DNA Units are audited annually in accordance with the QAS. The level 1 documents detailing internal audits do not apply to QAS audits.
  - 1. Audits performed as part of an accreditation assessment (i.e., ISO 17025, accrediting body requirements), will satisfy the external agency audit requirement for a specific year if conducted in accordance with the QAS and within the QAS required time interval.
- B. Under the direction of the TL, the DSU QA Program Manager will ensure all suggestions, recommendations, findings, and possible nonconformities as a result of the audit process are addressed. The TL is responsible for ensuring that, when necessary, nonconformities are appropriately addressed and recorded.
- C. The TL will ensure records of all external QAS audits are provided to the NDIS Custodian as required by the QAS and the NDIS Procedures. Internal and external QAS audit documentation, and if applicable, corrective action(s) will be provided to the appropriate CODIS administrator(s).
- D. In addition, the DNA Units are subject to periodic audits of the quality system conducted in accordance with the FBI Laboratory internal audit program. Records associated with these Forensic Analysis Support Unit (FASU) directed quality assurance audits are maintained according to the applicable level 1 documents.

## 16 PROFESSIONAL DEVELOPMENT

### 16.1 Continuing Education

- A. The DNA Units will comply with the continuing education requirements of the level 1 documents.
- B. The TL, CODIS Administrators, and currently qualified (i.e., proficiency tested) Examiners (i.e., analysts and/or technical reviewers) must stay abreast of topics relevant to the field of forensic and/or databasing DNA analysis in accordance with the QAS.
  - 1. Continuing education requirements of the QAS are fulfilled by attending seminars, courses, professional meetings, or other sessions/classes in relevant subject areas at least once a calendar year.
  - 2. Appropriate supporting records, as required by the QAS, for at least 8 hours per Examiner will be maintained by DSU.
- C. Supervisors will ensure personnel have the appropriate access to continuing education opportunities.

### 16.2 Scientific Literature

- A. The TL and currently qualified Examiners are responsible for the on-going review of scientific literature.
- B. The TL will ensure scientific journal articles or other relevant publications are distributed for review at least annually.
- C. The records of completion will be maintained by DSU.

- D. DNA personnel have ample access to scientific journal articles through the FBI Library.

**16.3 Testimony Monitoring**

- A. All DNA personnel who provide testimony or who review such testimony will follow the appropriate level 1 documents.
- B. A listing of all Forensic Examiners who did not testify over the course of a calendar year will be maintained by the DSU.

**17 OUTSOURCING**

The DNA Units do not outsource. If an external provider will be used for examinations or DNA databasing, the DNA Units will follow the requirements in the level 1 documents and/or will ensure compliance with the outsourcing requirements listed in the QAS prior to accepting ownership of any products for DNA testing.

**18 REFERENCES**

Biometrics Analysis Section DNA Network, Information System Contingency Plan (ISCP), latest version.

Federal Bureau of Investigation, Quality Assurance Standards for DNA Databasing Laboratories, latest version.

Federal Bureau of Investigation, Quality Assurance Standards for Forensic DNA Testing Laboratories, latest version.

National DNA Index System (NDIS) Operational Procedures Manual, latest version.

**19 REVISION HISTORY**

Revision	Issue Date	Changes
00	02/04/2022	Reformatted DNA 601-15 into new template and assigned new Doc ID. Revisions to align with LAB-100-00 and LAB-200-00 requirements. Added sections to ensure compliance with QAS2020.

## 20 APPENDIX A: COMMONLY USED DNA ABBREVIATIONS

<u>Abbreviations</u>	<u>Term</u>
↑	Elevated or High
↓	Decreased or Low
-	Deletion, Negative, or Negative Amplification Control
-A, -a	Non-Template Nucleotide Addition (Minus-A)
A	Adenine
AA	African American
ABNA	Analyzable But Not Alignable
AI	Allele Imbalance
ALS	Alternate Light Source
AMP	Amplify or Amplification
AMP BLANK	Amplification Blank
AP	Acid Phosphatase
BC	Barcode or Blood Card
BIS	Blood/Buccal Internal Standard
BKND, BKGND	Background
BL	Blank
BLK	Black
BP	Base Pairs
BT	Bleed-Through
C	Cytosine
CAU	Caucasian
CE	Capillary Electrophoresis or CE Instrument
CM or CMNG	Case Management or Case Management Next Generation
CO	COfiler
CODIS	Combined DNA Index System
CORE	Weak at 1 or more of the CODIS Core 13 loci
CS, CYC SEQ	Cycle Sequence(d)
CT	Cross talk or Cycle Threshold
D, DIL, DIL'N	Dilution
DA	Data Analysis
DB or DBASE	Database
DD	Dissociated Dye
DNA	Deoxyribonucleic Acid
EPG	Electropherogram
EPP	Electrophoresis Plate Preparation
EXBT	Excessive Bleed through
EXP	Extraction Plate
FB	Differential Female Reagent Blank
FBI	Federal Bureau of Investigation
FC	Female Control

FI	Failed Injection
FNC	Finger Nail Clipping(s)
FT	Faint
G	Guanine
GA	Genetic Analyzer
GF	GlobalFiler
GFE	GlobalFiler Express
GMID, GMIDX	GeneMapper ID or GeneMapper ID-X
GTT	Grey Top Blood Tube
HEMO	Hemochromogen
HETERO	Heteroplasmy
HV1, HVI	Hypervariable Region 1
HV2, HVII	Hypervariable Region 2
HV1A, HVIA	Hypervariable Region 1A
HV1B, HVIB	Hypervariable Region 1B
HV2A, HVIIA	Hypervariable Region 2A
HV2B, HVIIB	Hypervariable Region 2B
HV3	Hypervariable Region 3
I2	Second injection for a particular evidence extract
ID	Identifiler (FDDU), Identifiler Plus (DCU/SBAU), or Identification
ID+	Identifiler Plus
IDD	Identifiler Direct
INC	Inconclusive
INJ	Injection
IP	In Progress
K	Known Sample
KN	Known Negative
KP	Known Positive
LF	Laserfiche
LM	Left Message
LN	Lot Number
LR	Likelihood Ratio
LOR	Loss of Resolution
MB	Differential Male Reagent Blank
MINI	MiniFiler
MIX	Mixture
M MIX, MM	Master Mix
MP	Missing Persons or Miniprimer
MPS	Miniprimer Set
MORPH	Morphology
mtDNA	Mitochondrial DNA
NA	Not Analyzable or Not Applicable
NAV	Navajo
NC	Negative control

nDNA	Nuclear DNA
NEG	Negative or Negative Amplification Control
NFC	Not Further Characterized
NMPDD	National Missing Persons DNA Database
NP	Nucleotide Pair or Position
NR	No Results
NSP	Non-Specific Peak
OL	Off Ladder
ON, O/N	Overnight
OS	Off Scale
PC	Positive Control
PCR	Polymerase Chain Reaction
P2	Second amplification for a particular evidence extract
PHENO	Phenolphthalin
PH	Peak Height
PHR	Peak Height Ratio
POI	Person of Interest
POS, +, 9947A, 007	Positive or Positive Amplification Control
POST	Post PCR
PPID, PP, PRO+	Profiler Plus ID
PTT, PT(B)T	Purple Top Blood Tube
PU, PU (B, G, Y, R, or P)	Pull Up (in Blue, Green, Yellow, Red, or Purple channel(s))
PUN	Punch
Q	Questioned Sample
QCP	Quality Control Plate
QNS	Quantity Not Sufficient
QUANT, QNT	Quantify or Quantification
RB	Raised Baseline or Reagent Blank
rCRS	Revised Cambridge Reference Sequence
REC'D	Received
RE-INJ	Re-injection
RE-PREP	Re-prepared
REF	Reference
RES	Resolution
RFU	Relative Fluorescent Units
RGT, RGNT	Reagent
R/S	Resuspended
RT	Real-Time
RTT, RT, RT(B)T	Red Top Blood Tube
RTW	Ready To Work
RW	Rework
S2	Second cycle sequencing reaction for a particular extract
SAK	Sexual Assault Kit
SEH	Southeastern Hispanic

SEQ	Sequence or Sequenced
SEI	Secondary Evidence Inventory
SERO	Serology
SP	Spike
SPLIT	Split Peaks
SQ	Size Quality
SS	Single Source
ST, S	Stutter
STD	Standard
STR	Short Tandem Repeat
SUB	Subject
SWH	Southwestern Hispanic
T	Thymine
TC	Thermal Cycler
T/C	Telephone Call
TD	Trial Date
TF	Target Factor
TL	Technical Leader
TRI	Triallele
T/S	Tape Sealed
UD	User Defined
UHR	Unidentified Human Remains
VLD	Validation Plate
VM	Voicemail
UNSUB	Unidentified Subject
WCR	Whole Control Region
WI	Weak Injection
WK	Weak
WK1/2	Weak at only 1 or 2 loci
WK+	Weak at 1 or more of the expanded CODIS Core loci
VWK	Very Weak
X2	Second extraction for a particular item of evidence
Ys	Y-STRs
YF	Yfiler
YTT	Yellow Top Blood Tube

Additional abbreviations, acronyms, and chemical abbreviations may be defined in the DNA level 2 documents.