QUALITY ASSURANCE STANDARDS FOR DNA DATABASING LABORATORIES

EFFECTIVE DATE:

These standards shall take effect July 1, 2020 and shall not be applied retroactively.

1. SCOPE AND APPLICABILITY

This document consists of definitions and standards. The standards are quality assurance measures that place specific requirements on the laboratory. Equivalent measures not outlined in this document may also meet the standard if determined sufficient through an accreditation process.

The term 'year' refers to calendar year in these standards**.** Also, when used in these standards, the terms 'review', 'approve', 'document', 'define', 'schedule', 'policy', 'procedure', 'program', 'appoint', 'notify', 'inform', 'authorize', or 'designate' are intended to require written documentation to demonstrate compliance. In order to demonstrate compliance with these standards for purposes of the audit and accreditation process, the laboratory shall have available objective proof of satisfying each standard.

The standards describe the quality assurance requirements that laboratories performing DNA testing on samples obtained from identified subject(s) for the purpose of entering DNA profile(s) into the Combined DNA Index System (CODIS) shall follow to ensure the quality and integrity of the data generated by the laboratory. As it pertains to these standards, DNA testing begins at sample extraction or direct amplification. If, in addition, the databasing laboratory is performing DNA analyses on known or casework reference samples considered as evidence by that laboratory, the databasing laboratory shall follow these standards including the additional requirements for known and casework reference samples in Standards 7.3.2.1 and 12.3.2. DNA databasing laboratories performing DNA testing on known or casework reference samples shall be audited to these standards only and not the Quality Assurance Standards for Forensic DNA Testing Laboratories.

These standards are applicable to DNA databasing laboratories using Rapid DNA instruments/Systems on database, known or casework reference samples. The use of Rapid DNA instruments/Systems is not approved for use on forensic samples.

These standards also apply to vendor laboratories that perform DNA testing in accordance with Standard 17. These standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

2. DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

Accreditation is the formal recognition that a laboratory meets or exceeds a list of standards, including the FBI Director's Quality Assurance Standards, to perform specific tests. Accreditation is administered by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic science community in accordance with the provisions of the Federal DNA Identification Act (34 U.S.C. §12592) or subsequent laws.

Accuracy is the ability of a measurement to give results close to a true value.

Administrative review is an evaluation of the documentation for consistency with laboratory policies and for editorial correctness.

Analyst (or equivalent role, position, or title as designated by the laboratory) is an employee or contract employee, that has successfully completed the laboratory's training requirements for database analysis, passed a competency test, and has entered into a proficiency testing program according to these standards. This individual can conduct and/or direct the analysis of database, known or casework reference samples, interpret the resulting data from these samples and make conclusions.

Analytical control is a sample used to demonstrate that a method works correctly and to ensure the data are valid. See Positive amplification control, Positive sample control, Positive sequencing control, Negative amplification control, Negative sample control, Negative sequencing control, and Reagent blank control.

Analytical documentation is the documentation of procedural notes, controls, and instruments used; observations made; results of tests performed; and charts, graphs, photos, and other documentation generated which are used to support the analyst's conclusions.

Analytical procedure is an orderly, step-by-step process designed to ensure operational uniformity and to minimize analytical drift.

Analytical threshold is the minimum height requirement, determined through validation testing, at or above which detected peaks/signal can be reliably distinguished from background noise; peaks/signal at or above this threshold are generally not considered noise and are either artifacts or true alleles.

Annual is once per calendar year.

Audit is an on-site inspection used to evaluate, confirm, and/or determine the extent to which specified requirements are fulfilled.

Audit team is one or more individuals, including at least one auditor, that performs an inspection of a laboratory. At least one audit team member shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

Auditor is an individual who has successfully completed the FBI's DNA auditor training course.

Biochemistry is the study of the nature of biologically important molecules in living systems, DNA replication and protein synthesis, and the quantitative and qualitative aspects of cellular metabolism.

Casework reference sample is biological material (e.g., buccal swab, fingerprick, or blood draw) obtained directly from a known individual and used for purposes of comparison to forensic samples.

Certified reference material is a material for which values are obtained by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation which is issued by a certifying body (e.g., NIST).

CODIS is the Combined DNA Index System administered by the FBI. CODIS links DNA evidence obtained from crime scenes, thereby identifying serial criminals. CODIS also compares crime scene evidence to DNA profiles from offenders, thereby providing investigators with the identity of the putative perpetrator. In addition, CODIS contains profiles from missing persons, unidentified human remains, and relatives of missing persons. There are three levels of CODIS: the Local DNA Index System (LDIS), used by individual laboratories; the State DNA Index System (SDIS), used at the state level to serve as a state's DNA database containing DNA profiles from LDIS laboratories; and the National DNA Index System (NDIS), managed by the FBI as the nation's DNA database containing all DNA profiles uploaded by participating states. NDIS is the national and highest level index of CODIS containing the DNA records contributed from participating federal, state and local laboratories.

CODIS administrator (or equivalent role, position, or title as designated by the laboratory) is an employee of the laboratory responsible for administration and security of the laboratory's CODIS at a laboratory that owns the database and/or known samples. An alternate CODIS administrator must be designated by the laboratory as required by the NDIS operational procedures.

CODIS user is an employee or contract employee who has login access to the CODIS (i.e., State or Local) system and is authorized to read, add, modify and/or delete DNA records in CODIS.

Competency testing is a test or series of tests (practical, written, and/or oral) designed to establish that an individual has demonstrated achievement of technical skills and met minimum standards of knowledge necessary to perform DNA analysis.

Competency is the demonstration of technical skills and knowledge necessary to perform DNA analysis successfully.

Contamination is the unintentional introduction of exogenous DNA into a sample or analytical control during DNA testing.

Continuing education is an educational activity (such as a class, lecture series, conference, seminar, or short course) that is offered by a recognized organization or individual that brings participants up-to-date in their relevant area of knowledge.

Contract employee is an individual, not in the employ of the government or vendor laboratory, that performs DNA typing and/or analytical support services for a NDIS participating laboratory. The person performing these services must meet the relevant qualifications for the equivalent position in the NDIS participating laboratory. A contract employee cannot serve as a CODIS administrator or technical leader and cannot be counted as a full-time qualified analyst for purposes of satisfying the definition of a laboratory. Employment of a contract employee by multiple NDIS participating laboratories and/or vendor laboratories shall be disclosed to all employing laboratories and shall only be permitted subject to approval by the technical leader of the NDIS participating laboratory for which the contract employee is performing DNA typing and/or analytical services.

Corrective action plan evaluates and remediates a nonconformity with the goal to identify, correct, and/or prevent reoccurrence of the nonconformity, when possible.

Coursework is an academic class officially recognized and taught through a college or university program in which the participating student successfully completed and received one or more credit hours for the class.

Critical equipment or instruments are those equipment/instruments whose accurate functionality directly affects the results of the analysis and requires calibration, certification, or performance checks prior to use and periodically thereafter.

Critical reagents are those whose performance is vital to the success of the DNA testing and require testing on known samples before use on database or casework reference samples.

Database* or *databasing refers to the DNA analysis of database samples for entry into CODIS and, if eligible, for upload to the National DNA Index System (NDIS).

Database sample is a sample obtained from an individual who is legally required to provide a DNA sample for databasing purposes and whose identity is established at the time of collection of the sample**.**

Developmental validation - See Validation.

Differential amplification is the unequal amplification of one target region or locus over another during the polymerase chain reaction.

Disposition of samples is the documentation of the retention, return, or consumption of the samples upon completion of DNA testing.

DNA record is a database record that includes the DNA profile as well as data required to manage and operate NDIS, i.e., the Originating Agency Identifier, which serves to identify the submitting agency; the Specimen Identification Number; and DNA personnel associated with the DNA profile analyses.

DNA type (also known as a DNA profile) is the genetic constitution of an individual at one or more defined locations (also known as loci) in the DNA.

1) A DNA type derived from nuclear DNA typically consists of one or two alleles at several loci (e.g., short tandem repeat loci).
2) The DNA type derived from mitochondrial DNA is a specific sequence of nucleotides at a given mitochondrial region(s). In human DNA typing, the DNA type derived from mitochondrial DNA is described in relation to the revised Cambridge Reference Sequence (Nature Genetics [1999] 23:147).

Electrophoresis detection system is a platform that allows for the size separation of DNA molecules through a fluid or a gel under the influence of an electric field and the subsequent detection of the separated molecules by fluorescence or other means.

Employee is a person:

1) In the service of the applicable federal, state, or local government, subject to the terms, conditions, and rules of federal, state, or local employment and eligible for the federal, state, or local benefits of service; or
2) Formerly in the service of a federal, state, or local government who returns to service in the agency on a part-time or temporary basis.
3) For purposes of a vendor laboratory, an employee is a person in the service of a vendor laboratory and subject to the applicable terms, conditions, and rules of employment of the vendor laboratory.

Evidence is an item submitted for DNA testing and/or a derivative of an item as defined by the laboratory that is subject to a chain of custody.

Expert System is a software program or set of software programs designed to interpret single source DNA data in accordance with laboratory defined quality assurance rules and identify DNA data not satisfying laboratory defined quality assurance rules, without human intervention.

FBI is the Federal Bureau of Investigation, the federal agency authorized by the DNA Identification Act of 1994 to issue quality assurance standards governing DNA testing laboratories and to establish and administer the National DNA Index System (NDIS).

Forensic sample is a biological sample originating from and associated with evidence from a crime scene. A sample associated with evidence from a crime scene may include a sample that has been carried away from the crime scene.

Functional testing is a process to confirm that a software performs the tasks as expected.

Genetics is the study of inherited traits, genotype/phenotype relationships, and population/species differences in allele and genotype frequencies.

Guidelines are a set of general principles used to provide direction and parameters for decision making.

Integral component is that portion of an academic course that is so significant and necessary to the understanding of the subject matter as a whole that the course would be considered incomplete without it.

Internal validation - See Validation.

Interpretation software is a tool to assist the analyst in assessing the analyzed data by applying quality assurance rules, performing mixture deconvolution, and/or evaluating comparisons. Interpretation software may include probabilistic genotyping software or Expert Systems.

Known samples are biological material whose identity or DNA type is established.

Laboratory is a facility

1) Employing at least two full-time employees who are qualified analysts; and
2) Having and maintaining the capability to perform the DNA analysis of database, known and/or casework reference samples at that facility.

Laboratory support personnel (or equivalent role, position, or title as designated by the laboratory) are employees or contract employees who perform laboratory support duties exclusive of analytical procedures on database, known or casework reference samples.

Method is a combination of procedural steps used to perform a specific technical process. The method includes the validated steps, reagents, and critical instruments needed to perform the process or portion of a process. The same method may be conducted using different equipment (automated vs manual) when appropriately validated.

Methodology refers to the categories of methods used to perform a stage of a DNA typing technology or technologies. For example, methodologies for STR technology can include extraction, quantification, amplification, and detection.

Modified Rapid DNA analysis is the semi-automated (hands-free) process of developing a CODIS acceptable STR profile from a database, known or casework reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation,

and detection without human intervention but requires an analyst to perform manual interpretation and technical review.

Module is an independent but interrelated part of software that performs a distinct function.

Molecular biology is the study of the theories, methods, and techniques used in the study and analysis of gene structure, organization, and function.

Multi-laboratory system is used to describe an organization that has more than one laboratory performing DNA analysis.

Negative amplification control is an analytical control that is used to detect DNA contamination of the amplification reagents. This analytical control consists of only amplification reagents without the intentional addition of template DNA.

Negative sample control is an analytical control that is used to detect DNA contamination in Rapid DNA reagents and consumables.

Negative sequencing control is an analytical control that is used to detect DNA contamination of the sequencing reagents. This analytical control consists of only sequencing reagents without the intentional addition of template DNA. The negative amplification control can be used as the negative sequencing control.

NIST is the National Institute of Standards and Technology.

Nonconformity is not meeting, implementing, maintaining, or complying with one or more of the requirements of these standards or a laboratory's procedures, policies, or other quality system documents.

Offender is an individual who is required by statute to submit a sample for DNA analysis and databasing. The term "offender" includes individuals who are convicted of or arrested for a crime or juveniles adjudicated delinquent for an offense and required by state or federal law to provide a DNA sample for analysis and databasing.

On-site visit is a scheduled or unscheduled visit to the vendor laboratory work site by one or more representatives of an NDIS participating laboratory.

Outsourcing is the utilization of a vendor laboratory to provide DNA services in which the NDIS participating laboratory takes or retains ownership of the DNA data. Outsourcing does not require the existence of a contractual agreement or the exchange of funds.

Ownership is the process by which the responsibility for the products of DNA analyses provided by a vendor laboratory may pass to an NDIS participating laboratory. It applies if any of the following will occur:

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

Ownership review is the technical review of outsourced DNA data required by Standard 17. This review is to be distinguished from the technical and administrative reviews required by Standard 12. For outsourced DNA data, the vendor laboratory is responsible for conducting the technical and administrative reviews required by Standard 12.

Performance check is a quality assurance measure to assess the functionality of laboratory critical equipment and instruments.

Platform is the type of analytical system utilized to generate DNA profiles, such as capillary electrophoresis, real-time gel and end-point gel instruments or systems.

Policy is an organization's high level plan for a course of action or to address a requirement.

Polymerase Chain Reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles, which consist of the following:
1) Denaturation of the template;
2) Annealing of primers to complementary sequences at an empirically determined temperature; and
3) Extension of the bound primers by a DNA polymerase.

Positive amplification control is an analytical control that is used to determine if the PCR performed properly. This control consists of the amplification reagents and a known DNA sample.

Positive sample control is an analytical control that is used to determine if the Rapid DNA instrument/System is performing all steps of the process properly. This control consists of a known DNA sample.

Positive sequencing control is an analytical control that is used to determine if the sequencing performed properly. This control consists of the sequencing reagents and a known DNA sample. The positive amplification control can be used as the positive sequencing control.

Precision characterizes the degree of mutual agreement among a series of individual measurements, values, and/or results.

Preferential amplification is the unequal amplification of the two alleles present at a heterozygous locus during the polymerase chain reaction.

Procedure (protocol, standard operating procedure, or other equivalent) is a series of instructions to be followed in performing a specified task or under specific circumstances.

Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:

1) An internal proficiency test, which is produced by the agency undergoing the test.
2) An external proficiency test, which is a test obtained from a proficiency test provider accredited to the current applicable standard of the International Organization for Standardization and the applicable test is included on the proficiency test provider's scope of accreditation.

Program is a collection of policies, procedures, and/or instructions to fulfill a requirement.

Qualified is an adjective used to describe an individual who meets the requirements for the position, has successfully completed the laboratory's applicable training requirements, and is authorized to perform a specific task or role.

Quality system is the organizational structure, responsibilities, procedures, policies, and resources for implementing quality management.

Quantitative PCR is a method of determining the concentration of DNA in a sample by use of the polymerase chain reaction.

Rapid DNA analysis is the fully automated (hands-free) process of developing a CODIS acceptable STR profile from a database, known or casework reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation, detection and allele calling without human intervention.

Rapid DNA cartridge is a preassembled set of reagents and other analytical components (such as typing test kit) designed for use in a Rapid DNA instrument/System for the extraction, amplification and/or separation of DNA samples.

Rapid DNA instrument is an automated device that carries out Rapid DNA analysis or modified Rapid DNA analysis used to develop a CODIS acceptable STR profile from a database, known or casework reference sample.

Rapid DNA System is the collection of components that together performs a Rapid DNA analysis consisting of a Rapid DNA instrument, the PCR STR typing test kit/Rapid DNA cartridge, and an integrated Expert System used to develop a CODIS acceptable STR profile from a database, known or casework reference sample.

Reagent is a substance or mixture of substances used in the analysis process to detect, measure, produce, or interact with other substances.

Reagent blank control is an analytical control that is used to monitor contamination from extraction to DNA typing results and contains no intentionally added template DNA.

Regression testing is the process of testing an updated software program to confirm that modifications or new functionality do not unacceptably alter or terminate a desired functionality that behaved correctly before the change was implemented.

Reliability testing is the process of testing a software program beyond its functional aspects to ensure it works appropriately in the laboratory environment. This may include testing multi-user or multi-site scenarios, direct-access and network/server-access scenarios, and interaction with other software programs.

Review is an evaluation of documentation to check for consistency, accuracy, completeness, and compliance.

Second agency is an entity or organization external to and independent of the laboratory.

Semi-annual is used to describe an event that takes place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year, and where the interval between the two events is at least four months and not more than eight months.

Sensitivity studies (for the purposes of Standard 8.3) are used to assess the ability to obtain reliable results from a range of DNA quantities, to include the upper and lower limits of the assay.

Service (for the purposes of Standard 10) is the performance of adjustments or specified procedures by the user, manufacturer, or other service personnel in order to ensure the intended performance of instruments and equipment.

Specificity studies (for the purposes of Standard 8.3) are used to assess the ability to detect genetic information from non-targeted species (e.g., detection of microbial DNA in a human assay). The detection of genetic information from non-targeted species does not necessarily invalidate the use of the assay, but may help define the limits of the assay.

Stochastic threshold is the peak height or signal magnitude value, determined through validation studies, below which it is reasonable to assume that, at a given locus, allelic dropout of a sister allele in a heterozygous pair may have occurred.

Technical leader (or equivalent role, position, or title as designated by the laboratory) is an employee who is accountable for the technical operations of the laboratory and who is authorized to initiate, suspend, and resume laboratory operations.

Technical review is an evaluation of notes, data, and other documents to ensure there is an appropriate and sufficient basis for the scientific conclusions.

Technical reviewer is an employee or contract employee who is a current or previously qualified analyst that performs a technical review of analytical documentation which he/she did not create.

Technician (or equivalent role, position, or title as designated by the laboratory) is an employee or contract employee who performs analytical procedures on database, known or casework reference samples under the direction of a qualified analyst. Technicians do not interpret data to reach conclusions on typing results or prepare final documents.

Technology is used to describe the type of DNA analysis performed in the laboratory, such as RFLP, STR, YSTR, XSTR, SNP, microhaplotypes or mitochondrial DNA.

Test kit is a preassembled set of reagents (or laboratory assembled equivalent) that allows the user to conduct a specific DNA extraction, quantification, or amplification method. A laboratory assembled equivalent may be referred to as a test system.

Typing test kit is a preassembled set of reagents (or laboratory assembled equivalent) that is used to generate a DNA type.

Underlying scientific principle is a rule concerning a natural phenomenon or function that is a part of the basis used to proceed to more detailed scientific functions.

Uninterpretable is a determination that DNA data cannot be interpreted (e.g., due to poor or limited data quality, data that fail to meet laboratory quality requirements).

Validation is a process by which a method is evaluated to determine its efficacy and reliability for DNA analysis and includes the following:

1) Developmental validation, which is the acquisition of test data and determination of conditions and limitations of a new or novel DNA method for use on database samples.
2) Internal validation, which is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

Vendor laboratory is a governmental or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for purposes of entry into CODIS.

Work product is the material that is generated as a function of analysis, which may include extracts, amplified product and amplification tubes or plates as defined by the laboratory.

3. QUALITY ASSURANCE PROGRAM

STANDARD 3.1 The laboratory shall establish, follow, and maintain a documented quality system that is appropriate to the testing activities and is equivalent to, or more stringent than, what is required by these standards.

3.1.1 The quality system shall be documented in a manual that includes or references the following elements:

3.1.1.1 Goals and objectives

3.1.1.2 Organization and management

3.1.1.3 Personnel

3.1.1.4 Training

3.1.1.5 Facilities and sample control

3.1.1.6 Validation

3.1.1.7 Analytical procedures

3.1.1.8 Equipment

3.1.1.9 Documentation

3.1.1.10 Review

3.1.1.11 Proficiency testing

3.1.1.12 Corrective action

3.1.1.13 Audits

3.1.1.14 Professional development

3.1.1.15 Outsourcing ownership

3.1.2 Any document referenced within the quality manual shall be available on-site or be readily accessible.

STANDARD 3.2 The laboratory shall have and follow a policy regarding document retention that specifically addresses proficiency tests, analytical results, sample receipt and processing records, sample retention, hit confirmation, corrective action, audits, training records, testimony, and continuing education.

STANDARD 3.3 The quality system as applicable to DNA shall be reviewed annually independent of the audit required by Standard 15. The review of the quality system shall be completed under the direction of the technical leader. The quality system review shall be approved by the technical leader.

STANDARD 3.4 The laboratory shall annually review sample processing records, determined by the technical leader to be representative of the samples tested. This review of the sample processing records shall be independent of an external audit conducted under Standard 15. The scope of the review shall be defined prior to each annual review and shall be approved by the technical leader.

4. ORGANIZATION AND MANAGEMENT

STANDARD 4.1 The laboratory shall:

4.1.1 Have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the standards in this document.

4.1.2 Have a technical leader who is accountable for the technical operations. Multi-laboratory systems shall have at least one technical leader.

4.1.3 Have a CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility utilizing CODIS.

4.1.4 Have at least two full-time employees who are qualified analysts.

4.1.5 Specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis.

4.1.6 Have and follow a documented contingency plan that is approved by laboratory management if the technical leader position is vacated or if the number of qualified analysts falls below two full-time employees who are qualified analysts.

STANDARD 4.2 The laboratory shall have a policy that defines either the date of hire/appointment/promotion or the date of qualification to be used by the laboratory for determining the applicable version of the standard for education, experience and training requirements.

5. PERSONNEL

STANDARD 5.1 Laboratory personnel shall have the education, training, and experience commensurate with the examination and testimony provided.

5.1.1 The laboratory shall have a written job description for personnel, that may be augmented by additional documentation, which defines responsibilities, duties, and skills.

5.1.2 The laboratory shall maintain records on the relevant qualifications, training, skills, and experience of the technical personnel.

STANDARD 5.2 The technical leader shall be a full-time employee of the laboratory or multi-laboratory system and shall meet the following qualifications:

5.2.1 Minimum educational requirements: The technical leader of a laboratory shall have, at a minimum, a Master's degree in a biology-, chemistry-, or forensic science-related area and shall have successfully completed 12 semester or equivalent credit hours from a combination of undergraduate and graduate coursework covering the following subject areas: biochemistry, genetics, molecular biology, and statistics or population genetics.

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

5.2.1.2 The specific subject areas listed in Standard 5.2.1 shall constitute an integral component of any coursework used to demonstrate compliance with this standard.

5.2.1.3 Individuals who have completed coursework with titles other than those listed in Standard 5.2.1 shall demonstrate compliance with this standard through a combination of pertinent materials such as a syllabus, letter from the instructor, or other document that supports the course content.

5.2.1.4 If the degree requirements of Standard 5.2.1 were waived by the American Society of Crime Laboratory Directors (ASCLD) in accordance with criteria approved by the FBI Director, such a documented waiver shall be permanent and portable.

5.2.2 Minimum experience requirements: Any technical leader appointed prior to July 1, 2009, shall have three years of forensic, databasing or human identification DNA laboratory experience obtained at a laboratory where DNA testing was conducted for identification, databasing or forensic purposes. Any technical leader appointed on or after July 1, 2009, shall have a minimum of three years of human DNA (current or previous) experience as a qualified analyst on database or forensic samples.

5.2.3 Any technical leader appointed on or after July 1, 2020 shall be a currently or previously qualified analyst in each technology utilized in the laboratory, or have

documented training in each technology utilized in the laboratory within one year of appointment.

5.2.4 The technical leader shall have previously completed or will successfully complete the FBI's DNA auditor training course within one year of appointment.

5.2.5 The technical leader shall have the following authority and minimum responsibilities:

5.2.5.1 Oversee the technical operations of the laboratory.

5.2.5.2 Authority to initiate, suspend, and resume technical operations for the laboratory or an individual.

5.2.5.3 Evaluate and approve all validations and new or modified methods used by the laboratory.

5.2.5.4 Review the training records for newly qualified analysts, technicians and technical reviewers and approve their qualifications prior to independent database analysis. Review, verify, and approve the academic transcripts for newly qualified analysts and technical reviewers.

5.2.5.5 Approve the technical specifications for outsourcing agreements.

5.2.5.6 Review internal and external DNA Audit documents and, if applicable, approve corrective action(s).

5.2.5.7 Review, on an annual basis, the procedures of the laboratory.

5.2.5.8 Review and approve the training, quality assurance, and proficiency testing programs in the laboratory.

5.2.5.9 Review potential conflicts of interest when contract employees are employed by multiple NDIS participating and/or vendor laboratories.

5.2.6 The technical leader shall be accessible to the laboratory to provide on-site, telephone, or electronic consultation as needed. A multi-laboratory system may have one technical leader over a system of separate laboratory facilities. For multi-laboratory systems, the technical leader shall conduct and document a site visit to each laboratory at least semi-annually.

5.2.7 Newly appointed technical leaders shall be responsible for the review of the following within one year of appointment:

5.2.7.1 Validation studies and analytical procedures currently used by the laboratory; and

5.2.7.2 Educational and training records of currently qualified analysts and technical reviewers.

STANDARD 5.3 The CODIS administrator shall be an employee of the laboratory and meet the following qualifications:

5.3.1 Minimum educational requirements: The CODIS administrator shall meet the education requirements for an analyst as defined in Standard 5.4. A CODIS administrator appointed prior to July 1, 2020 shall be deemed to have satisfied the minimum educational requirements; satisfaction of these minimum educational requirements shall be applicable to the specific laboratory by which the CODIS administrator is employed by prior to July 1, 2020 and shall not be portable.

5.3.2 Minimum experience requirements: A CODIS administrator shall be a current or previously qualified forensic or database analyst as defined in Standard 5.4 with documented mixture interpretation training. A CODIS administrator appointed prior to July 1, 2009 who is not or has never been a qualified analyst (with documented training in mixture interpretation) shall be deemed to have satisfied the minimum experience requirements upon completion of FBI sponsored CODIS training; satisfaction of these minimum requirements shall be applicable to the specific laboratory the CODIS administrator is employed by prior to July 1, 2009 and shall not be portable.

5.3.3 Minimum CODIS training requirements: The CODIS administrator shall successfully complete the FBI-sponsored training in CODIS software within six months of assuming CODIS administrator duties if the administrator had not previously completed such training. The CODIS administrator shall successfully complete the FBI's DNA auditor training course within one year of assuming his/her administrator duties if the administrator had not previously completed such training.

5.3.4 The CODIS administrator shall have the following minimum responsibilities:

5.3.4.1 Administer the laboratory's CODIS network.

5.3.4.2 Schedule and document the CODIS computer training of database analysts.

5.3.4.3 Ensure that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.

5.3.4.4 Ensure that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures.

5.3.4.5 Ensure that matches are dispositioned in accordance with NDIS operational procedures.

5.3.5 The CODIS administrator shall be authorized to terminate 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.

5.3.6 A laboratory shall not upload DNA profiles to NDIS in the event that the CODIS administrator position is unoccupied.

STANDARD 5.4 The analyst shall be an employee or contract employee of the laboratory and meet the following qualifications:

5.4.1 Minimum educational requirements: The 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 coursework (graduate or undergraduate level) covering the following subject areas: biochemistry, genetics, and molecular biology. Any analyst hired/appointed/promoted or qualified (as defined by the laboratory per Standard 4.2) prior to July 1, 2020, shall have coursework and/or training in statistics and/or population genetics as it applies to forensic or databasing DNA analysis. Any analyst hired/appointed/promoted or qualified (as defined by the laboratory pursuant to Standard 4.2) on or after July 1, 2020, shall have successfully completed coursework covering statistics and/or population genetics.

5.4.1.1 The specific subject areas listed in Standard 5.4.1 shall be an integral component of any coursework for compliance with this standard.

5.4.1.2 Analysts appointed or hired on or after July 1, 2009 shall have a minimum of nine cumulative semester hours or equivalent that cover the required subject areas of biochemistry, genetics, and molecular biology.

5.4.1.3 Analysts who have completed coursework with titles other than those listed in 5.4.1 above shall demonstrate compliance with this standard through a combination of pertinent materials, such as a syllabus, letter from the instructor, or other document that supports the course content. The technical leader shall approve compliance with this standard.

5.4.2 Minimum experience requirements: The analyst shall have six months of human DNA laboratory experience with at least three months in a forensic or database DNA laboratory. If prior human DNA laboratory experience is accepted by a laboratory, the prior experience shall be documented and augmented by additional training, as needed. The analyst shall successfully complete the required training.

STANDARD 5.5 The technical reviewer shall be an employee or contract employee of the laboratory. The technical reviewer shall meet the education and experience requirements in Standard 5.4 and shall meet the following:

5.5.1 A current or previously qualified analyst.

5.5.2 Successful completion of documented training.

STANDARD 5.6 The technician shall be an employee or contract employee of the laboratory and shall successfully complete the laboratory's documented training program.

STANDARD 5.7 The technical leader shall verify and approve the education, to include a review of academic transcripts, of each analyst and technical reviewer.

6. TRAINING

STANDARD 6.1 The laboratory shall have a training program documented in a training manual for qualifying analysts and technicians. The training program shall:

6.1.1 Address all DNA analytical and interpretation procedures used in the laboratory.

6.1.2 Include practical exercises encompassing the examination of a range of samples routinely encountered in database analysis.

6.1.3 Teach and assess the technical skills and knowledge required to perform DNA analysis.

6.1.3.1 The training program for analysts shall include the skills and knowledge required to conduct a technical review.

6.1.4 Include an assessment of oral communication skills and/or a mock court exercise.

6.1.5 Include requirements for competency testing.

STANDARD 6.2 The technical leader shall approve any modifications to an analyst's, technical reviewer's, technician's, or laboratory support personnel's required training based on the documented assessment of the individual's previous training and experience.

STANDARD 6.3 All analyst/technician(s), regardless of previous experience, shall successfully complete competency testing covering the routine DNA methods and interpretation procedures that the analyst/technician will perform prior to participating in independent database analysis/processing.

6.3.1 Competency testing for a new analyst shall include a practical component, and written and/or oral components.

6.3.2 Competency testing for a new technician shall include a practical component.

STANDARD 6.4 For an analyst or technician, currently or previously qualified within the laboratory, to be qualified in a new or additional method, the laboratory shall teach and assess the technical skills and knowledge required to perform the additional method.

6.4.1 Before the use of a new or additional method on database, known or casework reference samples, the analyst and/or technician shall successfully complete competency testing to the extent of his/her participation in database analyses. The competency testing shall include a practical component.

STANDARD 6.5 For an analyst, currently or previously qualified within the laboratory, to be qualified to interpret data for a new or additional technology, typing test kit, platform, or interpretation software, the laboratory shall teach and assess the technical skills and knowledge required to interpret data using the additional technology, typing test kit, platform, or interpretation software.

6.5.1 Before the use of a new or additional technology, typing test kit, platform or interpretation software on database, known or casework reference samples, the analyst shall successfully complete competency testing using the additional technology, typing test kit, platform, or interpretation software to the extent of his/her participation in database analyses. The competency testing shall include a practical component.

STANDARD 6.6 A technical reviewer, who is not currently qualified as an analyst in the laboratory, shall receive training on processing records, data analysis and interpretation for any method, technology, typing test kit, platform, or interpretation software on which they will conduct reviews of data and/or records and for which they were not previously qualified as an analyst in the laboratory.

6.6.1 The technical reviewer shall successfully complete competency testing before completing a technical review of data and/or documentation using the additional method, technology, typing test kit, platform, or interpretation software used in database analyses.

6.6.1.1 For a technical reviewer who is a contract employee conducting reviews for an NDIS participating laboratory, the competency testing shall be administered by the NDIS participating laboratory.

STANDARD 6.7 The technical leader shall review the training records for the analyst, technician, and/or technical reviewer and approve his/her qualifications prior to independent database responsibilities.

STANDARD 6.8 The analyst, technician, and/or technical reviewer shall be authorized to independently perform assigned job responsibilities and the date(s) shall be documented.

STANDARD 6.9 Laboratory support personnel shall have documented training specific to their job function(s).

STANDARD 6.10 The laboratory shall have and follow a policy for addressing retraining of personnel when necessary. The technical leader shall be responsible for evaluating the need for and assessing the extent of retraining. The retraining plan shall be documented and approved by the technical leader.

6.10.1 The individual shall successfully complete competency testing prior to his/her return to participation in database analyses. This competency testing shall include a practical component.

STANDARD 6.11 The laboratory shall maintain records on the training, including successful completion of competency testing, of the laboratory personnel.

7. FACILITIES AND SAMPLE CONTROL

STANDARD 7.1 The laboratory shall have a facility that is designed to ensure the integrity of the analyses and the samples.

7.1.1 The laboratory shall have secure, controlled access areas for sample storage.

7.1.2 Except as provided in Standard 7.1.3.1, techniques performed prior to PCR amplification such as sample accessioning, DNA extractions, and PCR setup shall be conducted at separate times or in separate spaces from each other.

7.1.3 Except as provided in Standard 7.1.3.1, amplified DNA product, including real time PCR, shall be generated, processed, and maintained in a room(s) separate from the sample accessioning, DNA extractions, and PCR setup areas. The doors between rooms containing amplified DNA and other areas shall remain closed except for passage.

7.1.3.1 A Rapid DNA instrument/System used for processing database, known or casework reference samples shall be maintained in rooms outside of sample accessioning areas or those containing amplified DNA.

STANDARD 7.2 The laboratory shall have and follow procedures for laboratory security.

7.2.1 Access to the laboratory shall be controlled and limited in a manner to prevent access to the operational areas by unauthorized personnel. All exterior entrance/exit points require security controls that limit entry and access into the operational areas. The distribution of all keys, combinations, etc., shall be documented and limited to the personnel designated by laboratory management.

STANDARD 7.3 The laboratory shall have and follow a documented sample inventory control program to ensure the integrity of database, known and casework reference samples.

7.3.1 Database, known and casework reference samples shall be marked with a unique identifier. The laboratory shall clearly define what constitutes evidence and what constitutes work product. The laboratory shall have and follow a method to distinguish each sample throughout processing.

7.3.2 Documentation of sample identity, collection, receipt, storage, and disposition shall be maintained.

7.3.2.1 If the databasing laboratory is processing known or casework reference sample(s) as evidence, a chain of custody shall be documented and maintained in written, printed or electronic format. The chain of custody shall include the signature, initials, or electronic equivalent of each individual receiving or transferring the evidence, the corresponding date for each transfer, and the known or casework reference sample(s) transferred.

7.3.3 The laboratory shall have and follow procedures that address handling and preserving the integrity of samples and work product designed to minimize loss, contamination, and/or deleterious change.

7.3.3.1 The laboratory shall have and follow a policy or procedure for securing samples and work product in progress.

7.3.3.2 The laboratory shall have secure areas for sample storage including environmental control consistent with the form or nature of the sample.

STANDARD 7.4 The laboratory shall have a policy on sample consumption.

7.4.1. Where possible, the laboratory shall retain the database sample for retesting for quality assurance and sample confirmation purposes.

8. VALIDATION

STANDARD 8.1 The laboratory shall use validated methods for DNA analyses.

STANDARD 8.2 Developmental validation shall precede the implementation of any new methods used for DNA database analysis.

8.2.1 Developmental validation studies shall include, where applicable, characterization of the genetic marker, species specificity, sensitivity studies, stability studies, database-type samples, population studies, mixture studies, precision and accuracy studies, and PCR-based studies. PCR-based studies include reaction conditions, assessment of differential and preferential amplification, effects

of multiplexing, assessment of appropriate controls, and product detection studies. All validation studies shall be documented.

8.2.2 Peer-reviewed publication of the underlying scientific principle(s) of a method shall be required.

STANDARD 8.3 Except as provided in Standard 8.3.1.1, internal validation of all manual and robotic methods shall be conducted by each laboratory with the appropriate sample number and type to demonstrate the reliability and potential limitations of the method.

8.3.1 Internal validation studies shall include as applicable: known database-type samples, precision and accuracy studies, sensitivity and stochastic studies, and contamination assessment studies.

8.3.1.1 Internal validation data may be shared by all locations in a multi-laboratory system. The summary of the shared validation data shall be available at each site. Each laboratory in a multi-laboratory system shall complete, document and maintain applicable site-specific precision, sensitivity, and contamination assessment studies.

8.3.2 Internal validation shall define quality assurance parameters and interpretation guidelines.

8.3.3 Internal validation studies shall be conducted prior to implementing a change in platform instrument model or typing test kit.

8.3.4 Internal validation studies shall be documented and summarized. Internal validation shall be reviewed and approved by the technical leader prior to implementing a procedure for database applications.

STANDARD 8.4 Newly validated DNA methods (from amplification through characterization), typing test kit or platform instrument model shall 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 database analysis.

STANDARD 8.5 The performance of a modified procedure shall be evaluated by comparison to the original procedure using similar DNA samples and the evaluation documented. The evaluation shall be reviewed and approved by the technical leader prior to the implementation of the modified procedure into database applications.

STANDARD 8.6 An Expert System used to generate NDIS eligible DNA profiles shall be validated in accordance with Standard 8 and applicable NDIS operational procedures.

8.6.1 An Expert System shall be subject to recertification in accordance with NDIS operational procedures.

STANDARD 8.7 A Rapid DNA instrument used for modified Rapid DNA analysis on database, known or casework reference samples shall be validated in accordance with Standard 8.

STANDARD 8.8 An NDIS approved Rapid DNA System shall require a performance check prior to use on database, known or casework reference samples.

STANDARD 8.9 New software or new modules of existing software and modifications to software shall be evaluated to assess the suitability of the software for its intended use in the laboratory and to determine the necessity of validation studies or software testing. This evaluation shall include the determination of which studies will and will not be conducted and shall be documented.

8.9.1 New software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or statistical calculations shall be subject to developmental validation prior to implementation in DNA database analysis.

8.9.1.1 With the exception of legally protected information, the underlying scientific principle(s) utilized by software with an impact on the analytical process, interpretation, or statistical calculations shall be publicly available for review or published in a peer-reviewed scientific journal.

8.9.1.2 Developmental software validation studies for new software or new modules of existing software used as a component of instrumentation shall include at a minimum, functional testing and reliability testing.

8.9.1.3 Developmental software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include at a minimum, functional testing, reliability testing, and as applicable, accuracy, precision, sensitivity, and specificity studies.

8.9.1.4 Developmental software validation studies for new software or new modules of existing software for statistical calculations shall include at a minimum, functional testing, reliability testing, and as applicable, accuracy, and precision studies.

8.9.2 New software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations shall be subject to internal validation specific to the laboratory's intended use prior to implementation in DNA database analysis.

8.9.2.1 Internal software validation studies for new software or new modules of existing software used as a component of instrumentation shall include functional testing and reliability testing.

8.9.2.2 Internal software validation studies for new software or new modules of existing software for the analysis and/or interpretation of DNA data shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies, sensitivity, and specificity studies.

8.9.2.3 Internal software validation studies for new software or new modules of existing software for statistical calculations shall include functional testing, reliability testing, and, as applicable, precision and accuracy studies.

8.9.2.4 Software that does not impact the analytical process, interpretation, or statistical calculations shall require at a minimum, a functional test.

8.9.3 Modifications to software as described in Standards 8.9.1 and 8.9.2 shall be evaluated to determine if the modifications result in major or minor revisions to the software.

8.9.3.1 A major revision to software used as a component of instrumentation shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, and regression testing.

8.9.3.2 A major revision to software used for the analysis and/or interpretation of DNA data shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, regression testing, and, as applicable, precision and accuracy studies, sensitivity, and specificity studies.

8.9.3.3 A major revision to software used for statistical calculations shall require validation prior to implementation. Software validation studies shall include functional testing, reliability testing, regression testing, and, as applicable, precision and accuracy studies.

8.9.3.4 A minor revision to software that does not impact the analytical process, interpretation, or statistical calculations shall require at a minimum, a functional test.

8.9.4 Software validation studies and software testing may be shared by all locations in a multi-laboratory system. The summary of the shared validation data shall be available at each site. Each laboratory in a multi-laboratory system shall complete, document and maintain applicable site-specific reliability testing.

8.9.5 Software validation and testing shall be documented. Software validation and testing shall be reviewed and approved by the technical leader prior to implementation.

STANDARD 8.10 Developmental validation studies, internal validation studies, modified procedure evaluations, and software testing, including the approval of the technical leader, shall be retained and available for review.

9. ANALYTICAL PROCEDURES

STANDARD 9.1 The laboratory shall have and follow analytical procedures supported by the internal validations and approved by the technical leader.

9.1.1 The laboratory shall have and follow a standard operating procedure for each analytical method used by the laboratory including the appropriate analytical controls required for DNA analysis and data interpretation.

STANDARD 9.2 The laboratory shall use reagents that are suitable for the methods employed.

9.2.1 The laboratory shall have procedures for documenting commercial reagents and for the formulation of in-house reagents.

9.2.2 Commercial reagents shall be labeled with the identity of the reagent and the expiration date as provided by the manufacturer or as determined by the laboratory.

9.2.3 In-house reagents shall be labeled with the identity of the reagent, the date of preparation and/or expiration, and the identity of the individual preparing the reagent.

STANDARD 9.3 The laboratory shall identify critical reagents and evaluate them prior to use in database sample processing. The following shall be identified as critical:

9.3.1 Test kits or systems for DNA quantification or amplification.

9.3.2 Thermostable DNA polymerase, primer sets and allelic ladders used for genetic analysis that are not tested as test kit components under Standard 9.3.1.

9.3.3 Rapid DNA cartridges.

9.3.4 Other laboratory defined critical reagents.

STANDARD 9.4 Except for Rapid DNA instruments/Systems used to analyze database, known or casework reference samples pursuant to Standards 9.6 and 9.7, the laboratory

shall monitor the analytical procedures using the following analytical controls and standards.

9.4.1 Reagent blank controls associated with each extraction set being analyzed shall be:

9.4.1.1 Extracted concurrently and treated with the most sensitive conditions as the samples;

9.4.1.2 Amplified utilizing the same typing test kit, instrument model, and sensitivity conditions as required by the sample(s) containing the least amount of DNA; and

9.4.1.3 Typed utilizing the same instrument model, injection conditions and most sensitive volume conditions of the extraction set.

9.4.2 Where quantification is used, quantification standards shall be used. If a virtual or external standard curve is utilized, a calibrator must be run concurrently with the samples.

9.4.3 Positive and negative amplification controls associated with samples being typed shall be amplified concurrently using the same typing test kit on the same instrument as the samples.

9.4.3.1 Except as provided in Standard 9.4.4.1, all samples typed shall also have the corresponding amplification controls typed.

9.4.4 For laboratories performing sequencing, the laboratory shall use positive and negative sequencing controls concurrently sequenced using the same typing test kit on the same instrument as the samples.

9.4.4.1 If the positive amplification control is not used as the positive sequencing control, the laboratory shall have and follow procedures for the evaluation of the positive amplification control.

9.4.5 Allelic ladders and internal size standards for PCR-based systems, as applicable.

STANDARD 9.5 The laboratory shall have and follow written guidelines for the interpretation of data that are based on and supported by internal validation studies. An NDIS approved and internally validated Expert System may be used to complete the data interpretation process. The laboratory shall:

9.5.1 Have criteria to evaluate internal size standards, allelic ladders and analytical controls.

9.5.2 Have criteria for the interpretation of non-allelic peaks/signal.

9.5.3 Have criteria for the interpretation of allelic peaks/signal.

9.5.4 Define the thresholds used for interpretation. As appropriate to the interpretation model utilized, the laboratory shall establish the following thresholds:

9.5.4.1 Analytical Threshold

9.5.4.2 Stochastic Threshold

9.5.5 Define criteria for uninterpretable data.

STANDARD 9.6 For modified Rapid DNA analysis, a laboratory shall:

9.6.1 Have and follow written guidelines for the manual interpretation of data.

9.6.1.1 The laboratory shall verify that the internal size standard and allelic ladder results meet the laboratory's interpretation guidelines.

9.6.2 Have and follow procedures to address the use of positive sample controls and negative sample controls.

STANDARD 9.7 For Rapid DNA analysis, a laboratory shall have and follow procedures to address the use of positive sample controls and negative sample controls.

9.7.1 The Rapid DNA cartridge shall include an internal size standard with each sample.

STANDARD 9.8 The laboratory shall have and follow a procedure for the detection and control of contamination.

9.8.1 The laboratory shall have and follow procedures for cleaning and decontaminating facilities and equipment.

10. EQUIPMENT

STANDARD 10.1 The laboratory shall use equipment suitable for the methods employed.

STANDARD 10.2 The laboratory shall identify critical equipment or instruments and have and follow a program to ensure they are maintained.

10.2.1 At minimum, the following shall be identified as critical:

10.2.1.1 Handheld mechanical pipettes

10.2.1.2 A thermometer traceable to national or international standard(s)

10.2.1.3 Incubators/heat blocks used in analytical procedures

10.2.1.4 Robotic systems

10.2.1.5 Thermal cyclers, including quantitative PCR

10.2.1.6 Thermal cycler temperature verification systems

10.2.1.7 Electrophoresis detection systems, including Genetic Analyzers

10.2.1.8 Rapid DNA instruments/Systems

10.2.1.9 Any additional instruments or equipment that produces DNA typing results

STANDARD 10.3 The laboratory shall have procedures for conducting performance checks and evaluating results of critical equipment or instruments.

10.3.1 New critical equipment or instruments, not requiring validation, shall undergo a performance check before use in database analysis. Each additional critical instrument, of the same instrument model validated for use in the laboratory, shall require a performance check prior to use in database analysis.

10.3.2 The following critical equipment or instruments shall require annual performance checks:

10.3.2.1 Handheld mechanical pipettes

10.3.2.2 Incubators/heat blocks used in an analytical procedure

10.3.2.3 Robotic systems

10.3.2.4 Thermal cyclers, including quantitative-PCR

10.3.2.5 Thermal cycler temperature verification systems

10.3.2.6 Electrophoresis detection systems, including Genetic Analyzers

10.3.2.7 Any additional instruments or equipment that produces DNA typing results

10.3.2.8 Other critical equipment or instruments defined by laboratory

10.3.3 The following critical equipment or instruments shall require a performance check after repair or service:

10.3.3.1 Robotic systems

10.3.3.2 Thermal cyclers, including quantitative-PCR

10.3.3.3 Electrophoresis detection systems, including Genetic Analyzers

10.3.3.4 Rapid DNA instruments/Systems

10.3.3.5 Any additional instruments or equipment that produces DNA typing results

10.3.3.6 Other laboratory defined critical equipment or instruments

10.3.4 A Rapid DNA instrument/System shall require a performance check upon installation.

10.3.5 A Rapid DNA instrument/System shall undergo a performance check if the Rapid DNA instrument remains idle longer than the period recommended in the instrument specifications or as established by the laboratory.

STANDARD 10.4 The laboratory shall maintain documentation of maintenance, service, repair, and performance checks.

11. DOCUMENTATION

STANDARD 11.1 The laboratory shall have and follow procedures for maintaining documentation for database, known or casework reference samples. The laboratory shall maintain all analytical documentation generated by technicians and/or analysts related to database analyses. The laboratory shall retain, in written, printed, or electronic format, sufficient documentation for each technical analysis to support the profile data such that another qualified individual can evaluate what was done and interpret the data.

STANDARD 11.2 The laboratory shall have and follow a documented procedure for the resolution, verification and reporting/notification of database matches.

STANDARD 11.3 Except as otherwise provided by state or federal law, the information in DNA records and DNA databases shall be confidential.

11.3.1 The laboratory shall have and follow policies and/or procedures for the release of DNA records and databases, in accordance with applicable state or federal law.

11.3.2 The laboratory shall have and follow policies and/or procedures for the release of personally identifiable information in accordance with applicable state and federal law.

11.3.2.1 The laboratory shall have and follow a procedure for the release of personally identifiable information in connection with a database hit.

12. REVIEW

STANDARD 12.1 The laboratory shall have and follow procedures for reviewing DNA records and database information, including the verification and resolution of database matches.

12.1.1 An individual conducting technical reviews shall be an analyst or technical reviewer qualified in the method, technology, typing test kit, platform and interpretation software being reviewed.

STANDARD 12.2 The laboratory shall perform a technical review of all DNA records, except when using an NDIS approved Rapid DNA System to analyze database, known or casework reference samples. Completion of the technical review shall be documented and the technical review of a DNA record shall include the following elements:

12.2.1 A review of all notes, all worksheets, and the electronic data (or printouts of such data) supporting the results.

12.2.2 A review of all analytical controls, internal size standards, and allelic ladders to verify that the expected results were obtained, except when using an NDIS approved and internally validated Expert System.

12.2.3 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images), except when using an NDIS approved and internally validated Expert System.

STANDARD 12.3 The release of personally identifiable information associated with a database hit shall require an administrative review of the official correspondence. Completion of the administrative review shall be documented and shall include the following elements, any or all of which may be included within the technical review:

12.3.1 A review of the supporting administrative documentation and the correspondence for clerical errors, accuracy of information and adherence to agency policy.

12.3.2 A review of chain of custody for known or casework reference samples processed as evidence.

12.3.3 A review of the individual's biographical data, qualifying offense, and DNA profile generated from reanalysis, as applicable.

STANDARD 12.4 The laboratory shall have and follow a policy and/or procedure to address unresolved discrepant interpretations or conclusions between analysts and reviewer(s).

STANDARD 12.5 The laboratory shall have a system in place to ensure that the correct CODIS specimen categories have been assigned.

13. PROFICIENCY TESTING

STANDARD 13.1 Analysts, technical reviewers, technicians, and other personnel designated by the technical leader, shall undergo semi-annual external proficiency testing.

13.1.1 Analysts qualified in more than one technology shall be proficiency tested in each technology at least once per calendar year.

13.1.1.1 Typing of all CODIS core loci or CODIS core sequence ranges shall be attempted for each technology at least once per calendar year.

13.1.2 Analysts qualified in more than one typing test kit shall be proficiency tested in each typing test kit at least once per calendar year.

13.1.2.1 Analysts qualified to perform modified Rapid DNA analysis shall be externally proficiency tested on the interpretation of data generated by each Rapid DNA instrument model for each PCR STR typing test kit at least once per calendar year.

13.1.3 Individuals that perform analytical procedures on database, known, or casework reference samples shall be proficiency tested on at least one method in each methodology at least once per calendar year.

13.1.4 Except as provided in Standard 13.1.4.1, each external proficiency test shall be assigned to and completed by one analyst.

13.1.4.1 Laboratories that employ technicians and/or use a team approach for database analysis may do so on external proficiency tests. However, each analyst shall be assigned a proficiency test to complete the interpretation and report the results.

13.1.5 Individuals whose sole responsibility is technical review[1] shall be proficiency tested in the technical review of each technology and typing test kit at least once per calendar year.

13.1.5.1 The proficiency testing shall cover the CODIS core loci or CODIS core sequence ranges attempted for each technology at least once per calendar year.

13.1.5.2 Technical reviewers qualified to review modified Rapid DNA analysis shall be externally proficiency tested on the technical review of data generated by each Rapid DNA instrument model for each PCR STR typing test kit at least once per calendar year.

13.1.5.3 If the technical reviewer is a contract employee conducting technical reviews for an NDIS participating laboratory the proficiency testing shall be administered by an NDIS participating laboratory and shall be reviewed and approved by the technical leader of the NDIS participating laboratory for which the technical reviewer is conducting reviews.

13.1.6 Newly qualified individuals shall undergo semi-annual external proficiency testing within eight months of the date of their authorization.

STANDARD 13.2 The laboratory shall use an external proficiency test provider that is accredited to the current applicable standard of the International Organization for Standardization and the applicable test is included on the proficiency test provider's scope of accreditation. External proficiency testing shall be an open proficiency testing program and shall be submitted to the proficiency testing provider in order to be included in the provider's published external summary report.

STANDARD 13.3 For purposes of tracking compliance with the proficiency testing requirements, the laboratory shall define and consistently use the date that the proficiency test is performed as the received date, assigned date, submitted date, or the due date.

STANDARD 13.4 The laboratory shall maintain the following records for proficiency tests:

13.4.1 The test set identifier;

13.4.2 Identity of the analyst, and other participants, if applicable;

13.4.3 Date of analysis and completion;

13.4.4 Copies of all data and notes supporting the interpretations or conclusions;

[1] A qualified analyst proficiency-tested in the specific technology is qualified to serve as a technical reviewer without needing to take an additional proficiency test as a technical reviewer.

13.4.5 The proficiency test results;

13.4.6 Any discrepancies noted; and

13.4.7 Corrective actions taken.

STANDARD 13.5 The laboratory shall evaluate proficiency test results and shall include, at a minimum, the following criteria:

13.5.1 All reported genotypes, phenotypes, and/or sequences are correct or incorrect according to consensus results or are compliant with the laboratory's interpretation guidelines.

13.5.2 All reported uninterpretable results are compliant with written laboratory guidelines.

13.5.3 All final proficiency tests shall be evaluated as satisfactory or unsatisfactory.

13.5.3.1 All discrepancies or errors and subsequent corrective actions, as applicable, shall be documented.

STANDARD 13.6 The following shall be informed of the results of the proficiency test:

13.6.1 The proficiency test participant(s)

13.6.2 The technical leader

13.6.3 The CODIS administrator in the event of non-administrative discrepancies that affect the typing results.

14. CORRECTIVE ACTION

STANDARD 14.1 The laboratory shall have and follow a policy and/or procedure to address nonconformities detected in database analysis, proficiency tests, testimony, and audits. The laboratory policy and/or procedure shall define when a nonconformity requires documentation and/or a corrective action plan.

14.1.1 Corrective action plans shall be documented.

STANDARD 14.2 The laboratory's documented corrective action plan shall include the identification (when possible) of the cause(s) of the nonconformity, corrective actions taken with time frames (where applicable), and preventive measures taken (where applicable) to minimize its reoccurrence.

14.2.1 Corrective action plans shall be approved by the technical leader prior to implementation.

14.2.2 The CODIS administrator shall be notified when the nonconformity impacts DNA records entered into CODIS.

15. AUDITS

STANDARD 15.1 The laboratory shall be audited annually in accordance with these standards. The annual audits shall occur every calendar year and shall be at least six months and no more than 18 months apart.

STANDARD 15.2 At least once every two years, an external audit shall be conducted by one or more auditor(s) from a second agency(ies). At least one auditor shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

15.2.1 Each analyst, technical reviewer, CODIS administrator, and technical leader shall have his/her education, experience, and training qualifications evaluated and approved during two successive, separate external audits. Approval of an individual's education, experience, and training qualifications shall be documented in the Audit Document.

15.2.1.1 An analyst or technical reviewer that receives additional qualification in an additional technology(ies), typing test kit(s), or platform(s) shall have the additional training qualifications evaluated and approved during one external audit. Approval of additional training qualifications shall be documented in the Audit Document.

15.2.2 Each validation study shall be evaluated and approved during one external audit. Approved validation studies shall be documented in the Audit Document.

STANDARD 15.3 Internal audits shall be conducted by an audit team that includes at least one auditor. At least one team member shall be or have been an analyst previously qualified in the laboratory's current DNA technologies and platforms.

STANDARD 15.4 Internal and external audits shall be conducted utilizing the FBI *DNA Quality Assurance Standards* Audit Document in effect at the time of the audit.

STANDARD 15.5 Internal and external audit documentation and, if applicable, corrective action(s) shall be reviewed by the technical leader to ensure that findings, if any, were appropriately addressed and this review shall be documented.

15.5.1 Internal and external audit documentation, and if applicable, corrective action(s), shall be provided to the CODIS administrator.

15.5.2 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 Document or report.

STANDARD 15.6 Internal and external audit documentation shall be retained and available for inspection during subsequent audits.

16. PROFESSIONAL DEVELOPMENT

STANDARD 16.1 The laboratory shall have and follow a program to ensure technical qualifications are maintained through participation in continuing education.

16.1.1 The technical leader, CODIS administrator, analyst(s), and technical reviewers shall stay abreast of topics relevant to the field of forensic or databasing DNA analysis by attending seminars, courses, professional meetings, or other documented lectures or classes in relevant subject areas for a minimum of eight cumulative hours each calendar year.

16.1.1.1 The continuing education hours shall be documented. Attendance at a regional, national, or international conference with content including topics relevant to the field of forensic or databasing DNA analysis shall be deemed to provide a minimum of eight hours of continuing education.

16.1.1.2 The laboratory shall maintain documentation of attendance through a mechanism such as certificates, attendance list, or travel documentation.

16.1.1.3 With the exception of a regional, national, or international conference, the laboratory shall maintain documentation of content through a mechanism such as agenda/syllabus, record of presentation content, or the curriculum vitae of the presenter.

16.1.1.4 Continuing education based on multimedia or internet delivery shall be subject to the approval of the technical leader.

16.1.2 The laboratory shall have and follow a program approved by the technical leader for the annual review of scientific literature that documents the analysts' ongoing reading of scientific literature.

16.1.2.1 The laboratory shall maintain or have physical or electronic access to a collection of current books, reviewed journals, or other literature applicable to DNA analysis.

STANDARD 16.2 The laboratory shall have and follow a program that documents the annual review of the testimony of each analyst.

16.2.1 The program shall define elements and methods for testimony review.

16.2.2 The testimony review shall be documented and provided to the testifying individual.

16.2.2.1 Any deficiency and subsequent corrective actions, as applicable, shall be documented.

17. OUTSOURCING OWNERSHIP

STANDARD 17.1 A vendor laboratory performing database DNA analysis shall comply with these standards and the accreditation requirements of federal law.

17.1.1 An NDIS participating laboratory that outsources to a vendor laboratory shall require the vendor laboratory to provide documentation of compliance with these standards and the accreditation requirements of federal law. The NDIS participating laboratory's technical leader shall review the vendor laboratory's compliance with these standards and the accreditation requirements of federal law.

17.1.2 A vendor laboratory performing Rapid DNA analysis using an NDIS approved Rapid DNA System shall have a system in place to ensure that the correct CODIS specimen categories have been assigned.

STANDARD 17.2 Except as provided in Standards 17.2.1 and 17.2.2, the NDIS participating laboratory's technical leader shall approve the technical specifications of the outsourcing agreement with the vendor laboratory before it is awarded.

17.2.1 A vendor laboratory that is performing DNA analysis on behalf of a law enforcement agency or other entity for the purposes of ownership by an NDIS participating laboratory, shall not initiate analysis until approval has been obtained from the appropriate NDIS participating laboratory's technical leader.

17.2.2 An NDIS participating laboratory shall not upload or accept DNA data for upload to CODIS from any vendor laboratory or agency without the prior approval of the technical specifications of the outsourcing agreement and/or approval of acceptance of ownership of the DNA data by the NDIS participating laboratory's technical leader.

STANDARD 17.3 An NDIS participating laboratory shall have and follow a procedure to verify the integrity of the DNA data received for the purposes of taking ownership of DNA data from a vendor laboratory.

17.3.1 The NDIS participating laboratory shall have and follow quality assurance procedures to verify the integrity of the DNA data received from a vendor laboratory including, but not limited to, the following:

17.3.1.1 Random reanalysis of database, known or casework reference samples; and

17.3.1.2 Inclusion of quality control samples.

17.3.2 Prior to the search of DNA data in SDIS, an analyst, CODIS administrator or technical reviewer employed by an NDIS participating laboratory shall review the DNA data to verify the correct specimen category for entry into CODIS.

17.3.3 Prior to the upload of DNA data to SDIS or the reporting of search results, an ownership review of a vendor laboratory's DNA data shall be performed by an analyst or technical reviewer employed by an NDIS participating laboratory who is qualified in the technology, platform and typing test kit used to generate the data and participates in an NDIS participating laboratory's proficiency testing program. A portion of this review may be accomplished through the use of an NDIS approved and internally validated Expert System.

17.3.3.1 If the proficiency testing is administered by another NDIS participating laboratory, the technical leader of the NDIS participating laboratory for which the reviewer is conducting ownership reviews shall review and approve the reviewer's participation in an NDIS participating laboratory's proficiency testing program.

17.3.4 Except as provided in Standard 17.3.5, the ownership review shall include the following elements:

17.3.4.1 A review of all DNA types that the NDIS participating laboratory will take ownership of to verify that they are supported by the raw and/or analyzed data (electropherograms or images).

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

17.3.4.3 For samples to be entered into CODIS, verification of the DNA types, eligibility, and the correct specimen category.

17.3.4.3.1 Verification of eligibility shall be performed by a current CODIS user.

17.3.5 For an NDIS participating laboratory that outsources to a vendor laboratory performing Rapid DNA analysis on database, known or casework reference samples using an NDIS approved Rapid DNA System, the ownership review for data generated by the Rapid DNA System shall include:

17.3.5.1 A review of the final report (if provided) to verify that the results are supported by the Rapid DNA System data.

17.3.5.2 For samples to be entered into CODIS, verification of the eligibility and the correct specimen category.

17.3.5.2.1 Verification of eligibility shall be performed by a current CODIS user.

17.3.5.3 A review of the data associated with applicable Rapid DNA System performance checks.

STANDARD 17.4 An NDIS participating laboratory or multi-laboratory system outsourcing DNA sample(s) to a vendor laboratory or accepting ownership of DNA data from a vendor laboratory shall have and follow a procedure to perform an on-site visit(s) of the vendor laboratory, provided, however, that an on-site visit shall not be required when only technical review services are being provided. The procedure to perform an on-site visit shall include, at a minimum, the following elements:

17.4.1 A documented initial on-site visit, to assess the vendor laboratory's ability to perform analysis on outsourced database samples, prior to the vendor laboratory's beginning of DNA analysis for the NDIS laboratory.

17.4.1.1 The on-site visit shall be performed by the technical leader, or a designated employee of an NDIS participating laboratory, who is a qualified or previously qualified analyst in the technology, platform and typing test kit used to generate the DNA data. Alternatively, the technical leader of the NDIS participating laboratory shall evaluate and approve an on-site visit coordinated by a designated FBI employee.

17.4.2 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 six months and no more than 18 months apart.

17.4.2.1 An NDIS participating laboratory may accept an on-site visit conducted by another NDIS participating laboratory using the same technology, platform and typing test kit for the generation of the DNA data, or coordinated by a designated FBI employee, and shall document the review and approval of such on-site visit.