QUALITY ASSURANCE STANDARDS FOR FORENSIC DNA TESTING LABORATORIES

EFFECTIVE DATE:

These standards shall take effect July 1, 2025, and shall not be applied retroactively.

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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 forensic DNA testing or utilizing the Combined DNA Index System (CODIS) shall follow to ensure the quality and integrity of the data generated by the laboratory. DNA data generated from forensic DNA testing performed outside of the scope of these standards are prohibited from entry into CODIS. As it pertains to these standards, forensic DNA testing begins at sample lysis or direct amplification.

These standards also apply to vendor laboratories that perform forensic 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.

These standards are applicable to forensic DNA testing laboratories establishing and operating a Forensic Rapid DNA Program. A Forensic Rapid DNA Program can consist of any combination of the following applications:

- Operation of a Rapid DNA System or instrument in the laboratory,
- Operation of a Rapid DNA System or instrument in a Rapid DNA partner agency facility that is recognized under the scope of accreditation of the laboratory,
- Operation of a Rapid DNA System or instrument in a temporary/mobile facility that is recognized under the scope of accreditation of the laboratory.

Standards 18 and 19 describe the Forensic Rapid DNA Program quality assurance requirements. Compliance with these standards is required for entry and/or searching of eligible DNA records in CODIS. Operation of a Forensic Rapid DNA Program requires that the accredited laboratory fulfill all of the applicable standards in Standard 18. The laboratory is the lead agency for any Forensic Rapid DNA Program established with a Rapid DNA partner agency under Standard 19. For a program that includes testing of forensic samples, validation of modified Rapid DNA analysis is required. A facility that has Rapid DNA as their only DNA capability does not satisfy the definition of a laboratory.

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. For a Forensic Rapid DNA Program, any Rapid DNA partner agency facility(ies) shall be included under the laboratory's scope of accreditation.

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

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

Advanced authentication is additional security to the typical user identification and authentication of login ID and password and is intended to meet the standards of two-factor authentication.

Analyst (or equivalent role, position, or title as designated by the laboratory) is an employee or contract employee, who has successfully completed the laboratory's training requirements for casework sample 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 forensic samples, interpret data, reach conclusions, and generate reports.

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.

Casework 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 performing DNA analysis on forensic and casework reference samples. An alternate Casework CODIS Administrator must be designated by the laboratory as required by the NDIS operational procedures.

Casework reference sample is biological material (e.g., buccal swab) 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 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 forensic DNA analysis.

Competency is the demonstration of technical skills and knowledge necessary to perform forensic 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 Casework CODIS Administrator, Laboratory Rapid DNA 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 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 check 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 forensic or casework reference samples.

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 evidence is the documentation of the retention, return, or consumption of the evidence item(s) 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 composition of an individual at one or more defined locations (also known as loci) in the DNA. Examples of DNA types:

1) For length-based short tandem repeats, the DNA type is a series of numerical alleles reflecting the number of repeats observed at the defined locations.
2) For mitochondrial DNA, the DNA type is a series of nucleotide sequence variants observed in specified region(s) and described in relation to the revised Cambridge Reference Sequence (Nature Genetics [1999] 23:147).

3) For single nucleotide polymorphisms, the DNA type is a series of nucleotide-based alleles observed at the defined locations.

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 forensic DNA testing laboratories and to establish and administer the National DNA Index System (NDIS).

Forensic DNA analysis (also referred to as Forensic DNA testing) is the process of isolation, detection, identification, and evaluation of biological evidence in criminal matters using DNA technologies.

Forensic Rapid DNA Lead Operator is

1) an employee of the Rapid DNA partner agency
2) a Forensic Rapid DNA Operator designated by the Rapid DNA partner agency to oversee the operation of a Rapid DNA instrument(s)/System(s) for their agency
3) the main point of contact to the laboratory.

Forensic Rapid DNA Operator is an employee of the Rapid DNA partner agency and is designated by the Rapid DNA partner agency as qualified and authorized to operate a Rapid DNA instrument/System with casework reference and/or forensic samples for that agency.

Forensic Rapid DNA Program is the application of a Rapid DNA instrument/System on casework reference and/or forensic samples. Applications can include operation of a Rapid DNA instrument/System in the laboratory, in a Rapid DNA partner agency, or in a

temporary/mobile location. All applications utilized by the laboratory must be recognized under the laboratory's scope of accreditation.

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.

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

Inconclusive is a determination that no conclusion can be drawn from the comparison of a casework reference sample to a forensic sample. An inconclusive conclusion could also be due to uninterpretable data or data determined by the laboratory as not suitable for comparisons.

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.

Intimate sample is a biological sample from an evidence item that is obtained directly from an individual's body; it is not unexpected to detect that individual's allele(s) in the DNA typing results.

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 forensic samples and/or casework reference samples at that facility that complies with these standards and the accreditation requirements of the Federal DNA Identification Act (34 U.S.C. §12592) or subsequent laws. Having Rapid DNA as the only DNA capability does not satisfy the definition of a laboratory.

Laboratory Rapid DNA 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 Forensic Rapid DNA Program involving Rapid DNA partner agencies operating a Rapid DNA instrument/System outside the laboratory on casework reference and/or forensic samples.

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 forensic or casework reference samples.

Legacy refers to a typing test kit, platform, or technology that is no longer in use by a laboratory.

Legacy data is data generated by a typing test kit, platform, or technology that is no longer in use by the laboratory that is used for the interpretation of DNA types.

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 casework reference or forensic 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.

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

Negative amplification control is an analytical control that is used to detect DNA contamination of the amplification process. This analytical control is a sample 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 in the sequencing process. This analytical control is a sample without the intentional addition of template DNA or a computational negative that monitors for signal from samples not intentionally added to the sequencing run.

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.

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 forensic DNA analyses provided by a vendor laboratory is accepted by an NDIS participating laboratory. It applies to any of the following circumstances:

1) The NDIS participating laboratory will use any samples, extracts or materials from the vendor laboratory for the purposes of forensic 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 drawing conclusions on a forensic sample analyzed 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 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 a known DNA sample.

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 in 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.

Qualitative statement is a description of the evidence (e.g., partial profile, mixture profile) or a conclusion of any comparisons that were performed without a statistical significance provided (e.g., source attribution, consistent with an intimate sample).

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.

Quantitative statement is a conclusion that provides a statistical measure of the DNA profile (e.g., random match probability) or comparison performed (e.g., likelihood ratio).

Rapid DNA analysis is the fully automated (hands-free) process of developing a CODIS acceptable STR profile from a casework reference or forensic sample. The "swab in – profile

out" process consists of automated extraction, amplification, separation, detection and allele calling without human intervention.

Rapid DNA cartridge/chip 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. For forensic samples, the cartridge/chip shall include internal quality controls and the ability to estimate the quantity of DNA in the forensic sample that was amplified.

Rapid DNA data are the electronic files produced by the Rapid DNA instrument/System associated with a sample run. Data includes the raw data (e.g., .fsa) files for potential re-analysis by a qualified analyst, sample outputs, and instrument log files.

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 casework reference or forensic sample.

Rapid DNA partner agency is a criminal justice agency, such as a law enforcement agency or medical examiner's office, which is operating a Rapid DNA instrument/System in conjunction with a laboratory and under that laboratory's scope of accreditation and is contributing the Rapid DNA data to the laboratory's Forensic Rapid DNA Program. This definition also applies to the laboratory's primary/parent agency when developing a Forensic Rapid DNA Program for use of Rapid DNA instruments by the parent agency outside of the DNA laboratory.

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/chip, and an integrated Expert System used to develop a CODIS acceptable STR profile from a casework reference sample or forensic 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.

Reinterpretation is the reassessment of legacy data that may change the previously documented results. This may be due to a reevaluation of any of the allele calls or genotype calls (to include potential allelic drop-out), removal of alleles (or entire loci) from statistical estimates, or a change in the assumptions.

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 8.1) 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.

Sensitivity studies (for the purposes of Standard 8.5) are used to assess the ability of the system to reliably determine the presence of a contributor's DNA over a broad variety of evidentiary typing results (to include mixtures and low-level DNA quantities).

Sequencing is a process to determine the nucleotide bases (i.e., A, C, G, or T) in a region of DNA for a technology. This process may also be referred to as cycle-sequencing.

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 8.1) 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.

Specificity studies (for the purposes of Standard 8.5) are used to evaluate the ability of the system to provide reliable results over a broad variety of evidentiary typing results (to include mixtures and low-level DNA quantities).

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 personnel (for the purposes of Standard 5) are laboratory employees or contract employees (however titled) involved in testing and support of testing of forensic or casework reference samples.

Technical review is an evaluation of reports, 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 currently or previously qualified analyst that performs a technical review.

Technician (or equivalent role, position, or title as designated by the laboratory) is an employee or contract employee who performs analytical procedures on forensic samples 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 reports.

Technology is used to describe the type of forensic 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 method (e.g., extraction, quantification, amplification, sequencing). 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). Uninterpretable data may result in an inconclusive conclusion.

Validation is a process by which a method is evaluated to determine its efficacy and reliability for forensic casework 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 forensic 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 that is not subject to a chain of custody.

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 evidence control

3.1.1.6 Validation

3.1.1.7 Analytical procedures

3.1.1.8 Equipment

3.1.1.9 Reports

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, corrective action, audits, training records, continuing education, case files, and court testimony monitoring.

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 case files determined by the Technical Leader to be a representative sample of the cases worked. This review of case files 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 Casework 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 interrelationship 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 standards for education, experience and training requirements.

5. PERSONNEL

STANDARD 5.1 Laboratory technical personnel shall have education, training, and experience commensurate with their authorized responsibilities.

5.1.1 The laboratory shall have documentation that 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.

5.2.1.1 The Technical Leader shall have successfully completed at least 9 credit hours of coursework in biology- or chemistry-related areas that provide an understanding of the foundation of DNA analysis.

5.2.1.2 In addition, the Technical Leader shall have successfully completed coursework in statistics or population genetics.

5.2.1.3 The required coursework shall include at least one graduate level course.

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.

5.2.1.5 If prior minimum educational requirements as a Technical Leader were accepted by the laboratory in accordance with Standard 15.2.1.1, this shall be documented through prior external audit documentation and shall be retained by the laboratory.

5.2.2 Minimum experience requirements: 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 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 current 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, and, when applicable, a Rapid DNA partner agency.

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 casework analysis. Review, verify, and approve the education and experience 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 Training records of currently qualified analysts and technical reviewers who have not yet been memorialized by an external audit.

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

5.3.1 Minimum educational requirements: The Casework CODIS Administrator shall have a bachelor's (or its equivalent) or an advanced degree in a biology-, chemistry-, or forensic science-related area.

5.3.2 Minimum experience requirements: A Casework CODIS Administrator appointed on or after July 1, 2009 shall be a currently or previously qualified analyst with documented mixture interpretation training.

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

5.3.4 If prior minimum educational, experience, or training requirements as a Casework CODIS Administrator were accepted by the Technical Leader in accordance with Standard 15.2.1.2, this shall be documented through prior external audit documentation and shall be retained by the laboratory.

5.3.5 The Casework CODIS Administrator shall have the following minimum responsibilities:

5.3.5.1 Administer the laboratory's local CODIS network.

5.3.5.2 Schedule and document the CODIS computer training of casework analysts.

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

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

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

5.3.6 The Casework CODIS Administrator shall be authorized to terminate an analyst's or laboratory's, and, when applicable, a Rapid DNA partner agency'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.

5.3.7 A laboratory shall not upload DNA profiles to NDIS in the event that the Casework 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.

5.4.1.1 The analyst shall have successfully completed at least 9 credit hours of coursework in biology- or chemistry-related areas that provide an understanding of the foundation of DNA analysis.

5.4.1.2 In addition, an analyst hired/appointed/promoted or qualified (however defined by the laboratory pursuant to Standard 4.2) on or after July 1, 2020, shall have successfully completed coursework covering statistics or population genetics.

5.4.1.3 If prior minimum educational requirements as an analyst were accepted by the Technical Leader in accordance with Standard 15.2.1.3, this shall be documented through prior external audit documentation and shall be retained by the laboratory.

5.4.2 Minimum experience requirements: The analyst shall have forensic human DNA laboratory experience commensurate with their authorized responsibilities. If prior forensic 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 and meet the following qualifications:

5.5.1 A currently 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, interpretation, and/or statistical procedures used in the laboratory.

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

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, interpretation, and/or statistical procedures that the analyst/technician will perform prior to participating in independent casework.

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 forensic samples or casework reference samples, the analyst and/or technician shall successfully complete competency testing to the extent of their participation in casework 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 and generate reports 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, reach conclusions, and generate reports 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 forensic samples 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 their participation in casework 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 the case notes, data analysis, interpretation, and reporting criteria for any method, technology, typing test kit, platform, or interpretation software or the legacy technology, typing test kit, platform and/or interpretation software on 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 reports using the additional method, technology, typing test kit, platform or interpretation software used in casework 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 For an analyst to be qualified in reinterpretation of legacy data, for which they were not previously qualified within the laboratory, the analyst shall 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.

6.7.1 The analyst shall successfully complete competency testing in the legacy technology, typing test kit, and/or platform to the extent of their participation in casework analyses. The competency testing shall include practical components of reinterpretation.

STANDARD 6.8 The laboratory shall have and follow procedures for maintaining or reestablishing the technical skills and knowledge of analysts and technical reviewers who reinterpret legacy data for which they are qualified or previously qualified and whose external proficiency testing does not include a legacy technology, typing test kit or platform.

6.8.1 The Technical Leader shall review the documentation of an analyst's or technical reviewer's maintenance or reestablishment of the technical skills and knowledge and authorize the analyst or technical reviewer to reinterpret legacy data for no more than a two-year period.

STANDARD 6.9 The Technical Leader shall review the training records for the analyst, technician, and/or technical reviewer and approve their qualifications prior to independent casework responsibilities.

STANDARD 6.10 The analyst, technician, and/or technical reviewer shall be authorized to independently perform assigned job responsibilities. The date(s) and authorized responsibilities shall be documented.

STANDARD 6.11 Laboratory support personnel shall have documented training specific to their job function(s).

STANDARD 6.12 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 approved by the Technical Leader.

6.12.1 The individual shall successfully complete competency testing prior to their return to participation in casework analyses. This competency testing shall include a practical component.

STANDARD 6.13 The laboratory shall maintain records on the training, including successful completion of competency testing, of the laboratory personnel.

7. FACILITIES AND EVIDENCE CONTROL

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

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

7.1.2 Except for Rapid DNA instruments/Systems, techniques performed prior to PCR amplification such as evidence examinations, DNA extractions, and PCR setup shall be conducted at separate times or in separate spaces from each other.

7.1.3 Except for Rapid DNA instruments/Systems, amplified DNA product, including real-time PCR, shall be generated, processed, and maintained in a room(s) separate from the evidence examination, DNA extractions, and PCR setup areas. The doors between rooms containing amplified DNA and other areas shall remain closed except for passage.

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 evidence control program to ensure the integrity of physical evidence.

7.3.1 Evidence shall be marked with a unique identifier on the evidence package. 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 the testing process.

7.3.2 Chain of custody for all evidence 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 evidentiary item(s) transferred.

7.3.3 The laboratory shall have and follow procedures that address handling and preserving the integrity of evidence 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 evidence and work product in progress.

7.3.3.2 The laboratory shall have and follow a policy or procedure for properly sealing evidence.

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

7.4.1 Where possible, the laboratory shall retain or return a portion of the evidence sample or extract.

STANDARD 7.5 The laboratory shall have and follow a policy for the disposition of evidence.

8. VALIDATION

STANDARD 8.1 Validation shall precede the implementation of any method used for forensic DNA analysis.

8.1.1 Developmental validation studies shall be conducted for a new technology, typing test kit, or platform and shall include, where applicable, characterization of the genetic marker, species specificity, sensitivity studies, stability studies, case-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. These studies shall be documented.

8.1.2 Except as provided in Standard 8.1.2.2, internal validation studies shall be conducted by each laboratory with the appropriate sample number and type to demonstrate the reliability and potential limitations of each method.

8.1.2.1 Internal validation studies shall include as applicable: known and non-probative evidence samples or mock evidence samples, precision and accuracy studies, sensitivity and stochastic studies, mixture studies, and contamination assessment studies.

8.1.2.2 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.

8.1.3 Validation data shall be used to establish quality assurance parameters.

8.1.4 Validation data shall be used to establish interpretation guidelines, mixture interpretation guidelines, and the application of appropriate statistical calculations, when applicable.

8.1.4.1 Validation studies for mixture interpretation shall include samples with a range of the number of contributors, template amounts, and mixture ratios expected to be interpreted in casework.

8.1.5 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 forensic applications.

STANDARD 8.2 With the exception of an NDIS-approved Rapid DNA instrument/System, a new technology, typing test kit, or platform instrument model used to generate a DNA type 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 forensic analysis.

STANDARD 8.3 The performance of a modified method shall be evaluated by comparison to the original method 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 method into casework applications.

STANDARD 8.4 An Expert System used to generate NDIS eligible DNA profiles shall be validated in accordance with Standard 8 and the *NDIS Operational Procedures Manual*.

8.4.1 An Expert System shall be subject to recertification in accordance with the *NDIS Operational Procedures Manual*.

STANDARD 8.5 Software used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations, shall be subject to validation prior to implementation in forensic DNA analysis.

8.5.1 The laboratory shall use software suitable for the intended use in the laboratory and within the limitations established during the internal validation.

8.5.2 New software, new modules of existing software, or a major revision to software that is 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 forensic DNA analysis.

8.5.2.1 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. A major revision shall also require regression testing.

8.5.2.2 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. A major revision shall also require regression testing.

8.5.2.3 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. A major revision shall also require regression testing.

8.5.3 A minor revision to software used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or statistical calculations shall require at a minimum, a functional test.

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

8.5.5 Software validation and testing shall be documented. Software validation shall be reviewed and approved by the Technical Leader prior to implementation.

STANDARD 8.6 Developmental validation studies, internal validation studies, modified method evaluations, and software validation and 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 casework. The following shall be identified as critical:

9.3.1 Test kits for DNA quantification, amplification, or sequencing.

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 Other laboratory defined critical reagents.

STANDARD 9.4 Except as provided in Standards 9.4.1 and 9.4.2, the laboratory shall quantify or otherwise calculate the amount of human DNA in forensic samples prior to nuclear DNA amplification.

9.4.1 Quantification of human DNA for casework reference samples shall not be required if a laboratory has a validated system demonstrated to reliably yield successful DNA amplification and typing without prior quantification.

9.4.2 If not performed prior to nuclear DNA amplification, calculation of the amount of human DNA for laboratory defined forensic sample types shall be performed after or simultaneously with nuclear DNA amplification. The typing test kit shall contain internal quality controls and the laboratory shall validate a method to calculate the quantity of DNA that was amplified. The laboratory validation shall demonstrate that the defined sample types yield comparable or improved DNA results with quantitation after or during amplification as they do when quantitation is done prior to amplification.

STANDARD 9.5 Except for Rapid DNA instruments/Systems used pursuant to Standard 18, the laboratory shall monitor the analytical procedures using the following analytical controls and standards.

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

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

9.5.1.2 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

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

9.5.2 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.

9.5.3 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.

9.5.3.1 Except as provided in Standard 9.5.4.1, all samples typed shall also have the corresponding amplification controls typed.

9.5.4 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.

9.5.4.1 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.

9.5.5 Allelic ladders and internal size standards shall be used for PCR-based systems, as applicable.

STANDARD 9.6 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 some or all of the data interpretation steps defined in Standards 9.6.1 through 9.6.4. The laboratory shall:

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

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

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

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

9.6.4.1 Analytical Threshold

9.6.4.2 Stochastic Threshold

9.6.5 Have criteria for uninterpretable data.

9.6.6 Have and follow procedures for mixture interpretation that address the following:

9.6.6.1 The assessment of the number of contributors.

9.6.6.2 The separation of contributors (e.g., major versus minor).

9.6.6.3 The criteria for deducing potential contributors.

STANDARD 9.7 The laboratory shall define criteria for the formulation of conclusions (e.g., inclusionary, exclusionary, inconclusive).

STANDARD 9.8 The laboratory shall have and follow procedures for statistical calculations and the reporting of results and conclusions that address the following:

9.8.1 The assumptions that can be made when formulating conclusions.

9.8.2 Performing statistical analysis in support of any inclusion that is determined to be relevant in the context of the case.

9.8.3 Documenting of the genetic loci and assumptions used for statistical calculations, at a minimum, in the case notes.

9.8.4 Not using uninterpretable data in statistical calculations.

9.8.5 The approaches to performing statistical calculations.

9.8.5.1 For autosomal STR typing, the procedure shall address homozygous and heterozygous typing results, multiple locus profiles, mixtures, minimum allele frequencies, and where appropriate, biological relationships.

9.8.5.2 For lineage marker testing, the procedure shall address parameters specific for the applicable lineage marker statistical calculations.

9.8.5.3 The laboratory shall use loci that are shown to be in Hardy-Weinberg equilibrium and statistically unlinked, when using the product rule for statistical calculations.

9.8.6 The source of the population database(s) used in any statistical calculations.

9.8.7 The criteria for source attribution declarations, when applicable.

STANDARD 9.9 The laboratory shall have and follow a procedure to address the reinterpretation of legacy data.

STANDARD 9.10 The laboratory shall have and follow a procedure for the detection and control of contamination.

9.10.1 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 Any additional instruments or equipment that produce 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 casework 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 casework 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 Electrophoresis detection systems, including Genetic Analyzers

10.3.2.6 Any additional instruments or equipment that produce DNA typing results

10.3.2.7 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 Any additional instruments or equipment that produce DNA typing results

10.3.3.5 Other laboratory defined critical equipment or instruments

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

11. REPORTS

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

STANDARD 11.2 Casework reports shall include the following elements:

11.2.1 Case identifier;

11.2.2 Description of evidence examined and identification of samples tested;

11.2.3 Technology used;

11.2.4 Loci, sequence region, or amplification system;

11.2.5 Results and/or conclusions for each forensic sample tested;

11.2.6 A quantitative or qualitative interpretative statement to support all inclusions;

11.2.7 Date of the report;

11.2.8 Disposition of evidence; and

11.2.9 A signature and title, or equivalent identification, of the person accepting responsibility for the content of the report.

STANDARD 11.3 Except as otherwise provided by state or federal law, reports, case files, DNA records, and databases shall be confidential.

11.3.1 The laboratory shall have and follow policies and/or procedures to ensure the privacy of the reports, case files, DNA records, and databases.

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

11.3.3 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.

12. REVIEW

STANDARD 12.1 The laboratory shall have and follow a procedure to conduct and document technical and administrative reviews of all case files and reports to ensure conclusions and supporting data are reasonable and within the constraints of scientific knowledge.

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. A technical reviewer shall not technically review their own work.

STANDARD 12.2 Completion of the technical review(s) shall be documented and the technical review of forensic casework shall include the following elements:

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

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 or an NDIS approved Rapid DNA 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 or an NDIS approved Rapid DNA System.

12.2.4 A review of all data to verify conclusions (e.g., inclusionary, exclusionary, inconclusive) are in compliance with laboratory guidelines.

12.2.5 A review of statistical analysis, if applicable.

12.2.6 A review of the final report's content to verify compliance with Standard 11.2 and that the results and/or conclusions are supported by the data.

12.2.7 Prior to upload to SDIS, entry into a searchable category of SDIS, or search of SDIS, verification that all profiles entered into CODIS are eligible, have the correct specimen category, and have the correct DNA types.

12.2.7.1 Verification of CODIS eligibility and specimen category shall be conducted by two concordant assessments by a qualified analyst or technical reviewer.

12.2.7.2 Verification of DNA types shall be conducted by two concordant assessments by a qualified analyst or technical reviewer unless an NDIS approved and internally validated Expert System is used in lieu of these two concordant assessments.

STANDARD 12.3 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 case file and final report for clerical accuracy and compliance with Standard 11.2.

12.3.2 A review of chain of custody and disposition of evidence.

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

STANDARD 12.5 The laboratory shall have and follow a procedure for the verification and resolution of database matches.

13. PROFICIENCY TESTING[1]

STANDARD 13.1 Analysts, technical reviewers, technicians, and other personnel designated by the Technical Leader, shall undergo semi-annual external proficiency testing. Where an external proficiency test is not available or appropriate for a technology, performance shall be monitored in accordance with the laboratory's accreditation requirements.

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

[1] The testing of legacy technologies, typing test kits and platforms shall be governed by Standard 6.8.

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.

13.1.3 Individuals that perform analytical procedures on forensic samples 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 casework examination 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[2] 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 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.

[2] 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.

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 conclusions;

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 Inclusions and exclusions are correct or incorrect.

13.5.3 All reported uninterpretable results and/or inconclusive conclusions are compliant with written laboratory guidelines.

13.5.3.1 The Technical Leader shall review any inconclusive conclusion for compliance with laboratory guidelines.

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

13.5.4.1 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 Casework CODIS Administrator in the event of non-administrative discrepancies that affect the typing results and/or conclusions.

14. CORRECTIVE ACTION

STANDARD 14.1 The laboratory shall have and follow a policy and/or procedure to address nonconformities detected in casework 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 Casework 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, Casework CODIS Administrator, and Technical Leader shall have their qualifications evaluated during one external audit. If evaluation and approval of minimum educational requirements from a previous employer are accepted by the laboratory, this shall be documented through prior external audit documentation and shall be retained by the laboratory.

15.2.1.1 The Technical Leader's education, experience, and required training in Standard 5.2 shall be evaluated and approved during one external audit and documented in the Audit Document. This may be portable for an equivalent position in another laboratory if accepted by the hiring laboratory.

15.2.1.2 The Casework CODIS Administrator and alternate casework CODIS Administrator's education, experience, and required training in Standard 5.3 shall be evaluated and approved during one external audit and documented in the Audit Document. This may be portable for an equivalent position in another laboratory if accepted by the Technical Leader.

15.2.1.3 The education and experience of each analyst and technical reviewer shall be evaluated and approved during one external audit and documented in the Audit Document. This may be portable for an equivalent position in another laboratory if accepted by the Technical Leader.

15.2.1.4 The training and authorization of each new analyst and technical reviewer shall be evaluated and approved during one external audit and documented in the Audit Document.

15.2.1.5 An analyst or technical reviewer that receives qualification in an additional technology(ies), typing test kit(s), platform(s), or interpretation software shall have the training 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 audit 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 Casework 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, Casework CODIS Administrator, analysts, and technical reviewers shall stay abreast of topics relevant to the field of forensic 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 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 lists, 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 mechanisms 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 forensic DNA analysis, to include modified Rapid 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.

STANDARD 17.2 Except as provided in Standards 17.2.1 through 17.2.3, 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 forensic 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 For rare instances where the NDIS participating laboratory is requested to take ownership and no outsourcing agreement exists between either the law enforcement agency, the vendor laboratory or that NDIS participating laboratory, the requested NDIS participating laboratory's Technical Leader shall document the following prior to acceptance of ownership of product(s) of forensic DNA analyses from the vendor laboratory:

17.2.2.1 Approval of the Casework CODIS Administrator and written permission from the NDIS Custodian for any scenario that involves CODIS entry or searching;

17.2.2.2 Approval of the technical specifications of testing; and

17.2.2.3 Review the documentation of or conduct an on-site visit of the vendor laboratory. The on-site visit shall have been within 18 months of the conducted analysis and in accordance with Standard 17.4.

17.2.3 In the event that an NDIS participating laboratory permanently ceases operations and another NDIS participating laboratory accepts ownership of this laboratory's DNA data, the NDIS participating laboratory taking ownership shall obtain written permission from the NDIS Custodian.

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

17.3.2 Prior to the upload of DNA data to SDIS or the reporting of search results, the 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, typing test kit, and platform 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.

17.3.2.1 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.

17.3.3 The ownership review shall include the following elements:

17.3.3.1 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).

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

17.3.3.3 A review of the final report (if provided) to verify that the results/conclusions are supported by the data.

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

17.3.3.4.1 Verification of eligibility must be performed by a current CODIS user.

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 casework, prior to the vendor laboratory's beginning of casework 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, typing test kit, and platform 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, typing test kit, and platform for the generation of the DNA data, or coordinated by a designated FBI employee, and the Technical Leader shall review and approve such on-site visit.

18. LABORATORY USE OF RAPID DNA[3]

STANDARD 18.1 The laboratory shall define the Rapid DNA applications to be used within the laboratory's Forensic Rapid DNA Program.

18.1.1 All Rapid DNA applications shall be covered under the scope of the laboratory's accreditation.

18.1.2 The laboratory's Forensic Rapid DNA Program shall define, establish, or reference the laboratory's and, if applicable, Rapid DNA partner agency's(ies') procedures for each application.

STANDARD 18.2 The laboratory shall document the responsibility, authority, and interrelationship of all personnel who manage, perform, or review work relating to Rapid DNA applications.

18.2.1 The Technical Leader's authority and minimum responsibilities shall include the technical operations of the Forensic Rapid DNA Program. Their interrelationship with the Laboratory Rapid DNA Administrator, if applicable, shall be documented.

18.2.2 The Casework CODIS Administrator shall have authority over the CODIS operations of the Forensic Rapid DNA Program. Their interrelationship with the Laboratory Rapid DNA Administrator, if applicable, shall be documented.

STANDARD 18.3 The training program for Rapid DNA shall include all Rapid DNA applications implemented by the laboratory.

18.3.1 Analysts shall have documented training for the operation of Rapid DNA instruments/Systems and interpretation of the resulting DNA data.

18.3.1.1 For Forensic Rapid DNA Programs that include modified Rapid DNA analysis, analysts and technical reviewers shall be trained and qualified

[3] Standard 18 applies to laboratories using Rapid DNA on casework reference samples and/or forensic samples either through operation of Rapid DNA in the laboratory or laboratory operation of a Rapid DNA instrument/System in a temporary/mobile facility that is recognized under the scope of accreditation of the laboratory.

in modified Rapid DNA analysis to the extent the laboratory uses modified Rapid DNA analysis.

18.3.2 Technicians shall have documented training for operating the Rapid DNA instrument/System.

STANDARD 18.4 Except as provided in Standard 18.4.1, a Rapid DNA instrument/System used for processing casework reference samples and/or forensic samples shall be maintained in areas outside of rooms containing amplified DNA.

18.4.1 If maintained inside a room containing amplified DNA, the sample cartridge/chip shall be loaded in an area that does not contain amplified DNA.

18.4.2 An uninterruptible power supply (UPS) capable of powering a run from start to finish shall be connected to the Rapid DNA instrument/System during use for temporary/mobile applications.

18.4.3 For temporary/mobile applications, the laboratory shall have procedures to ensure environmental conditions are appropriate for continuous operation of the Rapid DNA instrument/System in accordance with manufacturer specifications.

STANDARD 18.5 A laboratory's Forensic Rapid DNA Program shall have a policy for Rapid DNA evidence consumption and sample selection. The laboratory shall ensure sufficient sample from the same evidence item remains for potential forensic DNA analysis using non-Rapid DNA laboratory methods.

STANDARD 18.6 Modified Rapid DNA analysis shall be validated prior to the use of a Rapid DNA instrument/System with forensic samples. Modified Rapid DNA analysis shall also be validated prior to the use of a Rapid DNA instrument/System with casework reference samples if modified Rapid DNA analysis will be used for casework reference samples. In addition to Standard 8 requirements, validation of modified Rapid DNA Analysis on forensic samples shall include:

18.6.1 Representative forensic sample types that are appropriate for the laboratory's Forensic Rapid DNA Program.

18.6.2 Mixture samples to determine if or at what level mixture interpretation will be attempted on Rapid DNA data. If Rapid DNA mixtures will be interpreted, the laboratory shall have validation data to support the procedures under Standard 9.6.6 for Rapid DNA mixtures and shall define the limitations of modified Rapid DNA analysis mixture interpretation.

18.6.3 Evaluation of the raw Rapid DNA data.

STANDARD 18.7 An NDIS approved Rapid DNA System used for Rapid DNA analysis on casework reference samples shall require a performance check prior to its initial use.

STANDARD 18.8 The laboratory shall have and follow procedures for the use of Rapid DNA instruments/Systems. The laboratory procedures shall address:

18.8.1 Non-Rapid DNA laboratory forensic DNA analysis when testing of the additional sample collected from the same evidence item is necessary, as required by Standard 18.5 and if applicable Standard 19.5.1.

18.8.2 The use of NDIS approved Rapid DNA cartridges/chips and/or Rapid DNA Systems for CODIS entry.

18.8.3 Evaluating Rapid DNA critical reagents prior to use in casework. Positive and negative sample controls shall be run on new lot numbers of Rapid DNA critical reagents.

18.8.3.1 The laboratory's procedures shall define the acceptable criteria for positive and negative sample controls.

18.8.4 Requiring the following for Forensic Rapid DNA Programs that include forensic samples:

18.8.4.1 Rapid DNA cartridges/chips shall contain internal quality controls and the ability to estimate the quantity of DNA in the forensic sample that was amplified.

18.8.4.2 Forensic samples with quality flags generated by an NDIS approved Rapid DNA System shall be reviewed by an analyst qualified in modified Rapid DNA analysis.

18.8.5 Including the following for Forensic Rapid DNA Programs which include modified Rapid DNA analysis:

18.8.5.1 Guidelines for the manual interpretation of data in accordance with these standards and supported by the laboratory's validation studies.

18.8.5.2 Procedures to address if or at what level mixture interpretation will be conducted on Rapid DNA data.

18.8.5.3 Procedures to verify the internal size standard and allelic ladder results that satisfy the laboratory's interpretation guidelines. These procedures shall define the acceptable results for internal size standards and allelic ladders and the documented verification of their use.

18.8.5.4 Procedures to verify the internal controls and quantification results for forensic samples that satisfy the laboratory's interpretation guidelines. These procedures shall define the acceptable results for internal controls and quantification results and the documented verification of their use.

18.8.5.5 Procedures to address the use of positive sample controls and negative sample controls.

STANDARD 18.9 Rapid DNA instrument/Systems are critical equipment, and the laboratory shall have and follow a program to ensure they are properly maintained to include procedures for conducting performance checks, evaluating results, and acceptance criteria.

18.9.1 Rapid DNA instruments/Systems shall require a performance check prior to use in casework in accordance with the following criteria:

18.9.1.1 Upon installation;

18.9.1.2 After repair, service, or software update;

18.9.1.3 When the Rapid DNA instrument/System remains idle longer than the period recommended in the instrument specifications or as established by the laboratory and;

18.9.1.4 Following the relocation of the Rapid DNA instrument/System, if recommended by the manufacturer or as established by the laboratory.

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

STANDARD 18.10 Laboratory casework reports shall document the use of Rapid DNA to include the cartridge/chip type as well as loci tested or amplification system.

STANDARD 18.11 Verification of DNA types shall be conducted by two concordant assessments by a qualified analyst or technical reviewer on all samples processed using modified Rapid DNA analysis. Technical review of the case file must be in accordance with Standard 12.

STANDARD 18.12 Analysts and technical reviewers qualified to perform modified Rapid DNA analysis shall undergo proficiency testing in accordance with Standard 13. Their proficiency testing shall include the interpretation of data generated by each Rapid DNA instrument model for each PCR typing kit at least once per calendar year.

STANDARD 18.13 The laboratory's Forensic Rapid DNA Program shall include procedures for addressing nonconformities.

STANDARD 18.14 For an NDIS participating laboratory that outsources to a vendor laboratory performing Rapid DNA analysis on casework reference using an NDIS approved Rapid DNA System, the ownership review for data generated by the Rapid DNA System shall include:

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

18.14.2 Verification of the eligibility and the correct specimen category for CODIS eligible samples prior to entering into CODIS.

18.14.2.1 The verification of CODIS eligibility shall be performed by a current CODIS user.

18.14.3 A review of the data associated with applicable Rapid DNA System performance checks to include positive sample control and negative control for the cartridge/chip lot and any performance checks since the last preventative maintenance.

19. RAPID DNA PARTNER AGENCY FORENSIC RAPID DNA PROGRAM[4]

STANDARD 19.1 The laboratory shall have an executed agreement with the Rapid DNA partner agency defining the roles, responsibilities, information technology requirements, and sample acceptance criteria with each agency planning to establish a Forensic Rapid DNA Program.

19.1.1 The laboratory establishing a Forensic Rapid DNA Program with a Rapid DNA partner agency shall also comply with Standard 18.

STANDARD 19.2 The laboratory shall have a Laboratory Rapid DNA Administrator who is accountable for the administration and security of the laboratory's Rapid DNA partner agency Forensic Rapid DNA Program.

19.2.1 The Laboratory Rapid DNA Administrator shall be an employee of the laboratory and meet the following qualifications:

19.2.1.1 Minimum educational requirements: The Laboratory Rapid DNA Administrator shall have, at minimum, a bachelor's (or its equivalent) degree in a biology-, chemistry-, or forensic science-related area.

19.2.1.2 Minimum experience requirements: A Laboratory Rapid DNA Administrator shall be a currently or previously qualified analyst with documented mixture interpretation training.

[4] Standard 19 applies to laboratories that have established Forensic Rapid DNA Programs with Rapid DNA partner agencies outside the laboratory using Rapid DNA on casework either through operation of Rapid DNA at a stationary location in the Rapid DNA partner agency or the Rapid DNA partner agency operation of Rapid DNA in a temporary/mobile facility. All aspects of the Rapid DNA partner agency Forensic Rapid DNA Program shall be recognized under the scope of accreditation of the laboratory. Rapid DNA partner agencies under this standard do not meet the QAS definition of a laboratory as the Rapid DNA partner agency only operates the Rapid DNA instrument/System at their location under the accreditation umbrella of the laboratory. The laboratory is the lead agency for any Forensic Rapid DNA Programs established with a Rapid DNA partner agency. A laboratory shall also comply with Standard 18 to establish a Forensic Rapid DNA Program with a Rapid DNA partner agency outside the laboratory. A vendor laboratory cannot be considered a Rapid DNA partner agency and shall comply with the requirements of Standards 17 and 18 so that an NDIS laboratory can accept ownership for CODIS entry and/or searching.

19.2.1.3 Minimum training requirements: The Laboratory Rapid DNA Administrator shall comply with the training and continuing education requirements of the Casework CODIS Administrator in these standards.

19.2.2 The Laboratory Rapid DNA Administrator shall have the following minimum responsibilities:

19.2.2.1 Oversee the Rapid DNA partner agency Forensic Rapid DNA operations, including the following:

19.2.2.1.1 Authority to suspend the use of a Rapid DNA instrument/System, suspend Forensic Rapid DNA operations at a Rapid DNA partner agency if an issue with the data is identified, and with approval of the Technical Leader, enforce any corrective actions identified at the Rapid DNA partner agency.

19.2.2.1.2 Suspend or terminate a Forensic Rapid DNA Operator's participation in a Forensic Rapid DNA Program if an issue with their data is identified.

19.2.2.2 Provide and/or oversee training in accordance with these standards and the laboratory requirements.

19.2.2.3 Ensure that the security and quality of Rapid DNA data is in accordance with state and/or federal law and NDIS Operational Procedures and these standards.

19.2.2.4 Ensure a Rapid DNA partner agency provides required case documentation for the Rapid DNA data upon submission to the laboratory.

19.2.2.5 Review, on an annual basis, the procedures of the Forensic Rapid DNA Program, including the procedures of the Rapid DNA partner agency if in addition to or different than the laboratory's procedures.

19.2.2.6 Ensure the appropriate Rapid DNA partner agency documentation is available at the laboratory for review during the annual QAS audit of the laboratory.

STANDARD 19.3 The Rapid DNA partner agency shall have at least one Forensic Rapid DNA Lead Operator who is accountable for the operation of all the Rapid DNA instrument(s)/System(s) at the Rapid DNA partner agency and serves as the designated point of contact with the laboratory.

19.3.1 The Forensic Rapid DNA Lead Operator shall have the following minimum responsibilities:

19.3.1.1 Perform and/or oversee routine maintenance of Rapid DNA instrument(s)/System(s) in accordance with the requirements of the Rapid DNA instrument manufacturer and laboratory.

19.3.1.2 Conduct and/or oversee performance checks of each Rapid DNA instrument(s)/System(s) in accordance with these standards and laboratory requirements.

19.3.1.3 Ensure the Forensic Rapid DNA Program at the Rapid DNA partner agency complies with laboratory policies/procedures.

19.3.1.4 Maintain documentation of the following in accordance with laboratory requirements:

19.3.1.4.1 Rapid DNA instrument(s)/System(s) performance checks;

19.3.1.4.2 Rapid DNA instrument(s)/System(s) maintenance;

19.3.1.4.3 Rapid DNA instrument(s)/System(s) users and run logs;

19.3.1.4.4 Rapid DNA instrument(s)/System(s) cartridge/chip and reagent logs; and

19.3.1.4.5 Relocation logs, if applicable.

STANDARD 19.4 Rapid DNA partner agency personnel that conduct Rapid DNA operations shall successfully complete the laboratory's documented training program.

19.4.1 Forensic Rapid DNA Operators and Forensic Rapid DNA Lead Operators shall successfully complete the training requirements of the laboratory prior to approval as a qualified Forensic Rapid DNA Operator/Lead Operator.

19.4.1.1 Training shall include sample types that will be routinely processed at that location.

19.4.1.1.1 The initial Rapid DNA instrument/System and Forensic Rapid DNA Operator/Lead Operator training shall be conducted at the Rapid DNA partner agency site on the instrument(s) at that Rapid DNA partner agency location**.** This also applies to the initial setup of a Rapid DNA partner agency's operation of Rapid DNA in a temporary/mobile application, if applicable.

19.4.1.2 Forensic Rapid DNA Operators/Lead Operators shall successfully complete a competency test administered by the laboratory before being qualified to operate Rapid DNA instrument(s)/System(s) in accordance with the requirements of the laboratory.

19.4.1.3 Refresher training shall be conducted and documented in accordance with the laboratory requirements to include, but not be limited to, the following:

19.4.1.3.1 Forensic Rapid DNA Operators/Lead Operators shall successfully complete refresher training upon major changes to the Rapid DNA instrument(s)/System(s) or Forensic Rapid DNA procedures.

19.4.1.3.2 Forensic Rapid DNA Operators/Lead Operators shall successfully complete refresher training due to infrequent use, as defined by the laboratory.

19.4.1.3.3 Forensic Rapid DNA Operators/Lead Operators shall successfully complete refresher training due to improper use.

19.4.1.3.4 Forensic Rapid DNA Operators/Lead Operators shall successfully complete a competency test after refresher training and prior to their return to operation of the Rapid DNA instrument(s)/System(s).

19.4.2 The Technical Leader or Laboratory Rapid DNA Administrator, in accordance with Standard 18.2.1, shall review the training records for each Forensic Rapid DNA Operator/Lead Operator and approve their qualifications.

19.4.3 Forensic Rapid DNA Operator(s)/Lead Operators(s) shall be authorized to independently operate the Rapid DNA instrument(s)/System(s) and the date(s) of authorization(s) shall be documented.

STANDARD 19.5 The Rapid DNA partner agency shall have and follow a documented evidence control program to ensure the integrity of physical evidence.

19.5.1 The Rapid DNA partner agency shall follow the laboratory's policies for evidence consumption that address Forensic Rapid DNA sample selection and shall ensure enough sample from the same evidence item remains for potential forensic DNA analysis using non-Rapid DNA laboratory methods.

STANDARD 19.6 The Rapid DNA partner agency shall have a facility that is designed to ensure the integrity of the evidence and the Forensic Rapid DNA processing.

19.6.1 The Rapid DNA partner agency shall have secure, controlled access areas for evidence storage.

19.6.2 A Rapid DNA instrument/System shall be maintained in a secure area and access shall be limited to personnel designated by agreement of the laboratory and Rapid DNA partner agency.

19.6.2.1 Documentation of designated personnel shall be available to both the laboratory and Rapid DNA partner agency.

19.6.3 An uninterruptible power supply (UPS) capable of powering a run from start to finish shall be connected to the Rapid DNA instrument/System during use for temporary/mobile applications.

19.6.4 If procedures developed by the laboratory for temporary/mobile applications are not being used, the Rapid DNA partner agency shall have and follow procedures to ensure environmental conditions are appropriate for continuous operation of the Rapid DNA instrument/System in accordance with manufacturer specifications.

19.6.5 Only authorized Rapid DNA Operators/Lead Operators and designated laboratory personnel shall operate a Rapid DNA instrument/System. Rapid DNA Operators/Lead Operators shall use advanced authentication to log in to a Rapid DNA instrument/System.

STANDARD 19.7 The Rapid DNA partner agency shall maintain and operate the Rapid DNA instrument(s)/System(s) in accordance with manufacturer and/or laboratory requirements.

19.7.1 The Rapid DNA partner agency shall only use NDIS approved Rapid DNA instrument(s)/System(s) and cartridges/chips. Forensic samples require cartridges/chips approved specifically for forensic sample use.

19.7.2 The Rapid DNA partner agency shall follow the laboratory policies and procedures regarding relocation of the Rapid DNA instrument/System.

19.7.3 The Rapid DNA partner agency shall appropriately store Rapid DNA reagents in accordance with manufacturer specifications and/or laboratory procedures and requirements, as applicable.

19.7.4 The Rapid DNA partner agency shall have and follow a procedure to document the lot number and the expiration date of the Rapid DNA cartridge/chip and other reagents used for each Rapid DNA instrument/System run.

19.7.4.1 Rapid DNA cartridges/chips and reagents shall not be used beyond their manufacturer specified expiration dates.

19.7.4.2 Rapid DNA cartridges/chips, and any DNA sample remaining in Rapid DNA cartridges/chips, shall be disposed of in accordance with the procedures of the laboratory.

19.7.5 The laboratory shall establish procedures for approval of performance checks conducted at the Rapid DNA partner agency.

19.7.6 The Rapid DNA partner agency shall have and follow laboratory procedures to conduct performance checks of each Rapid DNA instrument/System. A Rapid DNA instrument/System shall successfully undergo a performance check, as defined by the laboratory, prior to use on casework reference and/or forensic samples in accordance with the following criteria:

19.7.6.1 Upon installation of a Rapid DNA instrument/System and before the use of new lot numbers of Rapid DNA cartridges/chips and/or reagents.

19.7.6.1.1 The performance check shall include a positive sample control and negative sample control.

19.7.6.2 Following the repair, service, and/or maintenance of a Rapid DNA instrument/System.

19.7.6.3 Following the relocation of the Rapid DNA instrument/System if recommended by the manufacturer or as established by the laboratory.

19.7.6.4 When a Rapid DNA instrument/System remains idle longer than the period recommended by the manufacturer or as established by the laboratory.

19.7.6.5 When a Rapid DNA instrument/System has experienced an extended power outage that exceeds recommendations by the manufacturer or as established by the laboratory.

STANDARD 19.8 The Rapid DNA partner agency shall provide case documentation for the NDIS participating laboratory to verify CODIS eligibility upon submission to the laboratory. Case documentation includes, but is not limited to, a case synopsis, including the criminal offense(s), description of how the evidence is from the crime scene and is attributed to the putative perpetrator of the crime, a description of the evidence sample(s) processed by the Rapid DNA instrument/System, and the data generated by the Rapid DNA instrument/System.

19.8.1 The laboratory shall review Rapid DNA data in accordance with the analytical procedures established in Standard 18.

19.8.1.1 The Rapid DNA data shall be available electronically from the Rapid DNA partner agency.

19.8.2 Any electronic transfer of Rapid DNA data and case documentation between the partner agency and the laboratory shall utilize a secure network.

19.8.3 Except as otherwise provided by state or federal law, all Rapid DNA data and case documentation shall be confidential.

19.8.3.1 The Rapid DNA partner agency shall have and follow policies and/or procedures to ensure the confidentiality and privacy of all Rapid DNA data and case documentation.

STANDARD 19.9 All Rapid DNA partner agency Forensic Rapid DNA Program documentation shall be available at the laboratory for inspection during the annual audit.

19.9.1 The Laboratory Rapid DNA Administrator's education, experience, and required training in Standard 19.2.1 shall be evaluated and approved during one external audit and documented in the Audit Document. This may be portable for an equivalent position in another laboratory if accepted by the Technical Leader.