

QUALITY ASSURANCE STANDARDS FOR DNA DATABASING LABORATORIES

INTRODUCTION

These Standards are applicable to databasing laboratories performing DNA analyses on DNA samples obtained from identified subject(s) for purposes of entering the resulting DNA profile or DNA record into a DNA database. If, in addition, the databasing laboratory is performing DNA analyses on known or casework reference samples considered evidence by that laboratory, the databasing laboratory shall:

- (1) Follow the Quality Assurance Standards for Forensic DNA Testing Laboratories for the known or casework reference samples; or
- (2) Follow these Standards including the additional requirements for known and casework reference samples in 5.1.2.1.1 and 7.1.2.1.

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.

EFFECTIVE DATE:

These standards shall take effect July 1, 2009.

REFERENCES:

Federal Bureau of Investigation, “Quality Assurance Standards for Forensic DNA Testing Laboratories” and “Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories,” Forensic Science Communications, July 2000, Volume 2, Number 3.

1. SCOPE

These Standards describe the quality assurance requirements that laboratories performing DNA testing on database, known or casework reference samples for inclusion in the Combined DNA Index System (CODIS) shall follow to ensure the quality and integrity of the data generated by the laboratory. These Standards also apply to vendor laboratories that perform DNA testing on database, known or casework reference samples in accordance with Standard 17. These Standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

2. DEFINITIONS

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

Accredited laboratory is a DNA laboratory that has received formal recognition that it meets or exceeds a list of standards, including the FBI Director's Quality Assurance Standards, to perform specific tests, 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 (42 U.S.C. §14132) or subsequent laws.

Accuracy is the degree of conformity of a measured quantity to its actual (true) value.

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

Analyst (or equivalent role, position, or title as designated by the Laboratory Director) is an employee that has successfully completed the laboratory's training requirements for database, known or casework reference sample analysis, passed a competency test, and has entered into a proficiency testing program according to these Standards. This individual conducts and/or directs the analysis of database, known or casework reference samples and interprets the resulting data from these samples.

Analytical documentation is the documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, 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.

Annual is once per calendar year.

Audit is an inspection used to evaluate, confirm, or verify activity related to quality.

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

Calibration is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.

Casework reference sample is biological material obtained from a known individual and collected for purposes of comparison to forensic samples.

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 obtained 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 labs; 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.

CODIS administrator (or equivalent role, position, or title as designated by the Laboratory Director) is an employee of the laboratory responsible for administration and security of the laboratory's CODIS at a laboratory that owns the database and/or known samples.

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

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

Contamination is the unintentional introduction of exogenous DNA into a DNA sample or PCR reaction.

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 a participant up to date in his/her relevant area of knowledge.

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

Critical equipment or instruments are those requiring calibration or a performance check prior to use and periodically thereafter.

Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use on database or known samples.

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

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

Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on database and known samples.

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

DNA type (also known as a DNA profile) is the genetic constitution of an individual at defined locations (also known as loci) in the DNA. A DNA type derived from nuclear DNA typically consists of one or two alleles at several loci (e.g., short tandem repeat loci). The DNA type derived from mitochondrial DNA is described in relation to the revised Cambridge Reference Sequence (Nature Genetics 1999, 23, 147).

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/local employment and eligible for the federal/state/local benefits of service; or (2) formerly in the service of a federal, state or local government who returns to service in that agency on a part-time or temporary basis. 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.

Expert System is a software program or set of software programs that interprets the data generated from a DNA analysis instrument platform in accordance with laboratory defined quality assurance rules and accurately identifies the data that does and does not satisfy such rules.

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

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

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

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

Internal validation is the accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

Known sample is biological material whose identity or type is established. An example of a known sample is a sample contributed by the close biological relative of a missing person.

Laboratory is a facility: (1) employing at least two full time employees who are qualified DNA analysts; and (2) having and maintaining the capability to perform the DNA analysis on database and/or known samples at that facility.

Laboratory support personnel (or equivalent role, position, or title as designated by the Laboratory Director) are employee(s) who perform laboratory duties exclusive of analytical techniques on database and/or known samples.

LDIS is the **L**ocal **D**N*A* **I**ndex **S**ystem; please see definition of CODIS.

Methodology is used to describe the analytical processes and procedures used to support a DNA typing technology: for example, extraction methods (manual vs. automated); quantitation methods (slot blot, fluorometry, real-time); typing test kit; and platform (capillary electrophoresis, real-time gel and end-point gel systems).

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

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

Multiplex system is a test providing for simultaneous amplification of multiple loci that is either prepared commercially or by a laboratory.

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

NDIS is the **N**ational **D**N*A* **I**ndex **S**ystem. NDIS is one component of CODIS – the national and highest level index containing the DNA records contributed from participating federal, state and local laboratories.

NIST is the **N**ational **I**nstitute of **S**tandards and **T**echnology.

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

On-site visit is a scheduled or unscheduled visit by one or more representatives of the outsourcing laboratory to the vendor laboratory work site to assess and document the vendor laboratory’s ability to perform analysis on outsourced database, known or casework reference samples.

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 for entry into CODIS. Outsourcing does not require the existence of a contractual agreement or the exchange of funds.

Ownership occurs when any of the following criteria are applicable:

- (1) the originating laboratory will use any samples, extracts or any materials from the vendor laboratory for the purposes of database testing (i.e. a vendor laboratory prepares an extract that will be analyzed by the originating laboratory);
- (2) the originating laboratory will interpret the data generated by the vendor laboratory;
- (3) the originating laboratory will issue a report on the results of the analysis; or
- (4) the originating laboratory will enter or search a DNA profile in CODIS from data generated by the vendor laboratory.

Performance check is a quality assurance measure to assess the functionality of laboratory instruments and equipment that affect the accuracy and/or validity of database, known or casework reference sample analysis.

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.

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 sample that is used to determine if the PCR performed properly. This control consists of the amplification reagents and 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 sampling of the two alleles present in a heterozygous locus primarily due to stochastic (random) fluctuation arising when only a few DNA molecules are used to initiate the polymerase chain reaction.

Procedure (protocol, SOP or other equivalent) is an established practice 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 may be open or blind, is a test obtained from an approved proficiency test provider.

Qualified auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor's training course.

Quality system is the organizational structure, responsibilities, procedures, processes 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.

Reagent blank control is an analytical control sample that contains no template DNA and is used to monitor contamination from extraction to final fragment or sequence analysis. This control is treated the same as, and parallel to, the database, known or casework reference samples being analyzed.

Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation that is issued by a certifying body.

Reproducibility is the ability to obtain the same result when the test or experiment is repeated.

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

SDIS is the State DNA Index System; please see definition of CODIS.

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.

Service is the performance of those adjustments or procedures specified which are to be performed by the user, manufacturer or other service personnel in order to ensure the intended performance of instruments and equipment.

State CODIS administrator is the CODIS Administrator who serves as the central point of contact for a State with the NDIS Custodian and is responsible for ensuring other participating laboratories in that State comply with the terms and conditions for participation in the National DNA Index System.

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

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 who is a current or previously qualified analyst in the methodology being reviewed that performs a technical review of analytical results and is not an author of the applicable report.

Technician (or equivalent role, position, or title as designated by the Laboratory Director) is an employee who performs analytical techniques on database, known or casework reference samples under the supervision of a qualified analyst. Technicians do not interpret data, reach conclusions on typing results, or prepare final reports.

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

Test kit is a pre-assembled set of reagents that allows the user to conduct a specific DNA extraction, quantitation or amplification.

Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

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.

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

- (1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on database, known or casework reference samples.
- (2) Internal validation 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 government or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for purposes of entry into CODIS.

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

3. QUALITY ASSURANCE PROGRAM

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

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

3.1.1.1 Goals and objectives

3.1.1.2 Organization and management

3.1.1.3 Personnel

3.1.1.4 Facilities

3.1.1.5 Sample control

3.1.1.6 Validation

3.1.1.7 Analytical procedures

3.1.1.8 Equipment calibration and maintenance

3.1.1.9 Documentation/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 Safety

3.1.1.15 Outsourcing

STANDARD 3.2 The laboratory shall maintain and follow a procedure regarding document retention that specifically addresses proficiency tests, analytical results, sample receipt and processing records, sample retention, hit confirmation, corrective action, audits, training records, continuing education 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 and the approval by the technical leader shall be documented.

4. ORGANIZATION AND MANAGEMENT

STANDARD 4.1 The laboratory shall:

- 4.1.1 Have a managerial staff with the authority and resources needed to discharge their duties and meet the requirements of the Standards in this document.
- 4.1.2 Have a technical leader who is accountable for the technical operations. Multi-laboratory systems shall have at least one technical leader.
- 4.1.3 Have a CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility utilizing CODIS.
- 4.1.4 Have at least two full time employees who are qualified DNA analysts.
- 4.1.5 Specify and document the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the validity of the DNA analysis.
- 4.1.6 Have a documented contingency plan that is approved by laboratory management if the technical leader position is vacated.

5. PERSONNEL

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

- 5.1.1 Have a written job description for personnel, that may be augmented by additional documentation that defines responsibilities, duties and skills.
- 5.1.2 Have a documented training program for qualifying all analyst/technician(s).
 - 5.1.2.1 The laboratory's training program shall include a training manual covering all DNA analytical procedures that the analyst/technician will perform. Practical exercises shall include the DNA methodologies used in the laboratory's database program.

5.1.2.1.1 If the databasing laboratory is processing known or casework reference sample(s) as evidence, the laboratory's training program shall also include evidence handling and courtroom testimony.

5.1.2.2 The training program shall teach and assess the technical skills and knowledge required to perform DNA analysis.

5.1.2.2.1 The training program shall require an individual's demonstration of competency. The laboratory shall maintain documentation of the successful completion of such competency test(s).

5.1.2.2.2 When hiring experienced analyst/technician(s), the technical leader shall be responsible for assessing their previous training and ensuring it is adequate and documented. Modification to the training program may be appropriate and shall be documented by the technical leader.

5.1.2.2.3 All analyst/technician(s), regardless of previous experience shall complete a competency test(s) covering the routine DNA methodologies to be used prior to participating in independent database analysis.

5.1.3 Have a documented program to ensure technical qualifications are maintained through participation in continuing education.

5.1.3.1 Continuing education: The technical leader, CODIS administrator, and analyst(s) shall stay abreast of developments within the field of DNA typing by attending seminars, courses, professional meetings or documented training sessions/classes in relevant subject areas at least once each calendar year. A minimum of eight cumulative hours of continuing education are required annually and shall be documented.

5.1.3.1.1 If continuing education is conducted internally, the title of the program, a record of the presentation, date of the training, attendance list, and the curriculum vitae of the presenter(s) shall be documented and retained by the laboratory.

5.1.3.1.2 If the continuing education is conducted externally, the laboratory shall maintain documentation of attendance through a mechanism such as certificates, program agenda/syllabus, or travel documentation. Attendance at a regional, national or international conference shall be deemed to provide a minimum of 8 hours of continuing education.

5.1.3.1.3 Programs based on multimedia or internet delivery shall be subject to the approval of the technical leader. Participation in such programs shall be formally recorded and its completion shall be submitted

to the technical leader for review and approval. The documentation shall include the time required to complete the program.

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

5.1.4 Maintain records on the relevant qualifications, training, skills and experience of the technical personnel.

STANDARD 5.2 The technical leader shall meet the following qualifications:

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

5.2.1.1 The 12 semester or equivalent credit hours shall include at least one graduate level course registering three (3) or more semester or equivalent credit hours.

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

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

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

5.2.2 Minimum experience requirements: The technical leader shall have three years of forensic, databasing or human identification DNA laboratory experience obtained at a laboratory where DNA testing was conducted for identification, databasing or forensic purposes. As of the effective date of this revision, any newly appointed technical leader shall have a minimum of three years of human DNA (current or previous) experience as a qualified analyst on database or forensic samples. The technical leader shall have previously completed the FBI sponsored auditor training or successfully complete the FBI sponsored auditor training within one year of appointment.

5.2.3 The technical leader shall be responsible for the following:

5.2.3.1 General duties and authority

5.2.3.1.1 Oversee the technical operations of the laboratory.

5.2.3.1.2 Authority to initiate, suspend and resume DNA database operations for the laboratory or an individual.

5.2.3.2 The minimum specific responsibilities to be performed by the technical leader include the following:

5.2.3.2.1 To evaluate and document approval of all validations and methods used by the laboratory and to propose new or modified database procedures to be used by analysts.

5.2.3.2.2 To review the academic transcripts and training records for newly qualified analysts and approve their qualifications prior to independent database analysis and document such review.

5.2.3.2.3 To approve the technical specifications for outsourcing agreements.

5.2.3.2.4 To review internal and external DNA Audit documents and, if applicable, approve corrective action(s) and document such review.

5.2.3.2.5 To review, on an annual basis, the procedures of the laboratory and document such review.

5.2.3.2.6 To review and approve the training, quality assurance and proficiency testing programs in the laboratory.

5.2.4 Accessibility: The technical leader shall be accessible to the laboratory to provide onsite, 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 a site visit to each laboratory at least semi-annually.

5.2.4.1 The technical leader shall be a full time employee of the laboratory or multi-laboratory system.

5.2.4.1.1 In the event that the technical leader position of a laboratory is vacated and there is no individual in the laboratory or multi-laboratory system who meets the requirements of this Standard and will serve as a technical leader, the laboratory shall immediately contact the FBI and submit their contingency plan within 14 days to the FBI for its approval.

Work in progress by the laboratory may be completed during this 14 day period but new database DNA analysis shall not be started until the plan is approved by the FBI.

5.2.5 Newly appointed technical leaders shall be responsible for the documented review of the following:

5.2.5.1 Validation and methodologies currently used by the laboratory; and

5.2.5.2 Educational qualifications and training records of currently qualified analysts.

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

5.3.1 Minimum educational requirements. The CODIS administrator shall meet the educational requirements for an analyst as defined in Standard 5.4. A CODIS administrator appointed prior to the effective date of this revision shall be deemed to have satisfied the minimum educational requirements; satisfaction of these minimum educational requirements shall be applicable to the specific laboratory the CODIS administrator is employed by prior to the effective date of this revision and shall not be portable.

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

5.3.3 Minimum CODIS training requirements. The CODIS administrator shall participate in FBI sponsored training in CODIS software within six months of assuming CODIS administrator duties if the administrator had not previously attended such training. The CODIS administrator shall successfully complete the FBI sponsored Auditor training within one year of assuming their administrator duties if the administrator had not previously attended such training.

5.3.4 The CODIS administrator shall be responsible for the following:

5.3.4.1 Administration of the laboratory's CODIS network.

5.3.4.2 Scheduling and documentation of the CODIS computer training of database analysts.

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

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

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

5.3.5 The CODIS administrator shall be authorized to terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified.

5.3.5.1 The state CODIS administrator shall have the authority over all CODIS sites under his/her jurisdiction to terminate an analyst's or laboratory's participation in CODIS until the reliability and security of the computer data can be assured in the event an issue with the data is identified.

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

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

5.4.1 Minimum educational requirements. The analyst shall have a bachelor's (or its equivalent) or an advanced degree in a biology-, chemistry- or forensic science- related area and shall have successfully completed college course work (graduate or undergraduate level) covering the following subject areas: biochemistry, genetics, molecular biology; and course work and/or training in statistics and/or population genetics as it applies to forensic or databasing DNA analysis.

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

5.4.1.2 Analysts appointed or hired after the effective date of these revisions shall have a minimum of nine cumulative semester hours or equivalent that cover the required subject areas.

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

5.4.2 Minimum experience requirements. The analyst shall have six (6) months of human DNA laboratory experience with at least three (3) months in a forensic or database

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

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

5.4.2.2 The analyst shall successfully complete a competency test(s) before beginning independent DNA analysis.

STANDARD 5.5 The technician shall meet the following qualifications:

5.5.1 Documented training specific to their job function(s).

5.5.2 Successful completion of a competency test(s) before participating in DNA analysis.

STANDARD 5.6 Laboratory technical support personnel shall have documented training specific to their job function(s).

6. FACILITIES

STANDARDS 6.1 The laboratory shall have a facility that is designed to ensure the integrity of the analyses and the samples.

6.1.1 Access to the laboratory shall be controlled and limited in a manner to prevent access by unauthorized personnel. All exterior entrance/exit points require security control. The distribution of all keys, combinations, etc..., shall be documented and limited to the personnel designated by laboratory management.

6.1.2 Except as provided in 6.1.4, techniques performed prior to PCR amplification such as sample accessioning, DNA extractions, and PCR setup shall be conducted at separate times or in separate spaces from each other. Standard 6.1.4 is applicable if robotic workstations are used by the laboratory.

6.1.3 Except as provided in 6.1.4, amplified DNA product, including real time PCR, shall be generated, processed and maintained in a room(s) separate from the sample accessioning, DNA extractions and PCR setup areas. The doors between rooms containing amplified DNA and other areas shall remain closed.

6.1.4 A robotic workstation may be used to carry out DNA extraction, quantitation (if applicable), PCR setup and/or amplification in a single room, provided that the analytical process has been validated in accordance with Standard 8. If the robot performs analysis

through amplification, the robot shall be housed in a separate room from that used for initial sample accessioning.

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

7. SAMPLE CONTROL

STANDARD 7.1 The laboratory shall have and follow a documented sample inventory control system to ensure the integrity of database and known samples. This system shall ensure that:

7.1.1 Database, known and casework reference samples shall be marked with a unique identifier or the laboratory shall have and follow a method to distinguish each sample throughout the processing (such as plate or rack mapping) that may not require the assignment of unique identifiers.

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

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

7.1.3 The laboratory shall have and follow documented procedures designed to minimize loss, contamination, and/or deleterious change of samples and work product in progress.

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

STANDARD 7.2 Where possible, the laboratory shall retain the database sample for retesting for quality assurance and sample confirmation purposes.

8. VALIDATION

STANDARD 8.1 The laboratory shall use validated methodologies for DNA analyses. There are two types of validations: developmental and internal.

STANDARD 8.2 Developmental validation shall precede the use of a novel methodology for DNA database analysis.

8.2.1 Developmental validation studies shall include, where applicable, characterization of the genetic marker, species specificity, sensitivity studies, stability studies,

reproducibility, database-type samples, population studies, mixture studies, precision and accuracy studies, and PCR-based studies. PCR-based studies include reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies. All validation studies shall be documented.

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

STANDARD 8.3 Except as provided in Standard 8.3.1.1, internal validation of all manual and robotic methods shall be conducted by each laboratory and reviewed and approved by the laboratory's technical leader prior to using a procedure for database applications.

8.3.1 Internal validation studies conducted after the date of this revision shall include as applicable: database-type samples, reproducibility and precision, sensitivity and stochastic studies, and contamination assessment. Internal validation studies shall be documented and summarized. The technical leader shall approve the internal validation studies.

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

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

8.3.3 A complete change of detection platform or test kit (or lab assembled equivalent) shall require internal validation studies.

8.3.4 For inclusion into NDIS of profiles reviewed by an expert system, the expert system shall be validated in accordance with applicable NDIS operational procedures.

8.3.5 Internal validation of robotics shall be conducted and documented to the extent they are used by the database laboratory.

STANDARD 8.4 Before the introduction of a methodology into the database laboratory, the analyst or examination team shall successfully complete a competency test(s) to the extent of his/her participation in database analyses.

STANDARD 8.5 The performance of a modified procedure shall be evaluated by comparison with the original procedure using similar DNA samples.

STANDARD 8.6 Each additional critical instrument shall require a performance check. Modifications to an instrument, such as a detection platform, that do not affect the analytical portion of the instrument shall require a performance check.

STANDARD 8.7 Modifications to software, such as an upgrade, shall require a performance check prior to implementation. New software or significant software changes that may impact interpretation or the analytical process shall require a validation prior to implementation.

9. ANALYTICAL PROCEDURES

STANDARD 9.1 The laboratory shall have and follow written analytical procedures approved by the technical leader. The standard operating procedures are to be reviewed annually by the technical leader independent of the audit required by Standard 15 and this review shall be documented.

9.1.1 The laboratory shall have and follow a standard operating procedure for each analytical method used by the laboratory. The procedures shall specify reagents, sample preparation, extraction, equipment and controls which are standard 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 written 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 the database laboratory. These critical reagents shall include, but are not limited to, the following:

9.3.1 Test kits for performing quantitative PCR and genetic typing

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.

STANDARD 9.4 The laboratory shall have and follow a documented procedure for the resolution, verification and reporting/notification of database matches.

STANDARD 9.5 The laboratory shall monitor the analytical procedures using the following controls and standards.

9.5.1. Where quantitation is used, quantitation standards shall be used.

9.5.2 Positive and negative amplification controls associated with samples being typed shall be amplified concurrently in the same instrument with the samples at all loci and with the same primers as the database, known and casework reference samples. All samples typed shall also have the corresponding amplification controls typed.

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

9.5.3.1 Extracted concurrently;

9.5.3.2 Amplified utilizing the same primers, instrument model and concentration conditions as required by the sample(s) with the most sensitive volume conditions of the extraction set; and

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

9.5.4 Allelic ladders and internal size makers for variable number tandem repeat sequence PCR based systems.

9.5.5 The laboratory shall check its DNA procedures annually or whenever substantial changes are made to a procedure against an appropriate and available NIST standard reference material or standard traceable to a NIST standard.

STANDARD 9.6 The laboratory shall have and follow written guidelines for the interpretation of data. An NDIS approved and internally validated Expert System may be used to complete the data interpretation process.

9.6.1 The laboratory shall verify that all control results meet the laboratory's interpretation guidelines for all data to be entered into CODIS.

STANDARD 9.7 The laboratory shall have and follow a documented policy for the detection and control of contamination.

10. EQUIPMENT CALIBRATION AND MAINTENANCE

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

STANDARD 10.2 The laboratory shall have and follow a documented program for conducting performance checks, calibration and recertification of instruments and equipment.

10.2.1 At a minimum, the following critical instruments or equipment shall require annual performance checks:

10.2.1.1 Thermometer traceable to national or international standard(s) that is used for conducting performance verification checks.

10.2.1.2 Balances/scales

10.2.1.3 Thermal cycler temperature verification system

10.2.1.4 Thermal cycler including quantitative-PCR system where utilized

10.2.1.5 Electrophoresis detection systems

10.2.1.6 Robotic systems

10.2.1.7 Genetic analyzers

10.2.1.8 Mechanical pipettes

10.2.2 The following critical equipment require quarterly recertification:

10.2.2.1 Expert systems approved for use at NDIS

STANDARD 10.3 The laboratory shall have a schedule and follow a documented program to ensure that instruments and equipment are properly maintained. The laboratory shall retain documentation of maintenance, service or calibration.

STANDARD 10.4 New critical instruments and equipment, or critical instruments and equipment that have undergone repair, service or calibration shall undergo a performance check before use in database analysis.

10.4.1 At a minimum, the following critical equipment shall undergo a performance check and/or recertification following repair, service or calibration:

10.4.1.1 Electrophoresis detection systems

10.4.1.2 Robotic systems

10.4.1.3 Genetic analyzers

10.4.1.4 Thermal cycler including quantitative-PCR where utilized

10.4.1.5 Expert systems approved for use at NDIS

11. DOCUMENTATION/REPORTS

STANDARD 11.1 The laboratory shall have and follow written procedures for maintaining documentation for database, known or casework reference samples. The laboratory shall

maintain all analytical documentation generated by analysts related to database analyses. The laboratory shall retain, in hard or electronic format, sufficient documentation for each technical analysis to support the profile data such that another qualified individual could evaluate and interpret the data.

STANDARD 11.2 Except as otherwise provided by state or federal law, the laboratory shall have and follow written procedures to ensure the confidentiality of the database, known or casework reference samples and the information in DNA databases and DNA records.

11.2.1 The laboratory shall have and follow written procedures for the release of DNA records and database, known or casework reference samples in accordance with applicable state and federal law.

11.2.2 The laboratory shall have and follow written procedures for the release of personally identifiable information relating to DNA records in accordance with applicable state and federal law.

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

12. REVIEW

STANDARD 12.1 The laboratory shall have and follow written procedures for reviewing DNA records and DNA database information, including the verification and resolution of database matches. The review of DNA data generated external to the laboratory is governed by Standard 17.

12.1.1 An individual conducting technical reviews shall be or have been an analyst qualified in the methodology being reviewed.

STANDARD 12.2 The laboratory shall perform a technical review of all DNA records prior to uploading or searching in SDIS. Completion of the technical review shall be documented and the technical review of a DNA record shall include the following elements:

12.2.1 A review of all notes, all worksheets, and the electronic data (or printed electropherograms or images) supporting the results.

12.2.2 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images). The review of the DNA types may be accomplished by an NDIS-approved and internally validated expert system.

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

12.2.4 A review to confirm that reworked samples have appropriate controls.

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

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

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

12.3.3 The laboratory shall have and follow a procedure to document the completion of the administrative review.

STANDARD 12.4 The laboratory shall document the elements of a technical and administrative review.

STANDARD 12.5 The laboratory shall have and follow a documented procedure to address unresolved discrepant conclusions between analysts and reviewer(s).

STANDARD 12.6. The laboratory shall have a system in place to ensure that the correct CODIS specimen categories have been assigned.

STANDARD 12.7 The laboratory shall have and follow a program that documents the annual monitoring of the testimony of laboratory personnel.

13. PROFICIENCY TESTING

STANDARD 13.1 Analysts, technical reviewers, technicians, and other personnel designated by the technical leader, shall undergo semi-annual external proficiency testing in each technology performed to the full extent in which they participate in database analysis. 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 the calendar year and the second event taking place in the second six months of that calendar year and where the interval between the two events is at least four months and not more than eight months. Such 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.

13.1.1 Individuals routinely utilizing both manual and automated methods shall be proficiency tested in each method at least once per year to the full extent in which they participate in database analysis.

13.1.2 Newly qualified individuals shall enter the external proficiency testing program within six months of the date of their qualification.

13.1.3 For purposes of tracking compliance with the semi-annual proficiency testing requirement, the laboratory shall define, document and consistently use the date that the proficiency test is performed as the received date, assigned date, submitted date, or the due date.

13.1.4 Except as provided in Standard 13.1.4.1, each analyst shall be assigned and complete his/her own external proficiency test.

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

13.1.5 Typing of all CODIS core loci or CODIS core sequence ranges shall be attempted for each technology performed.

13.1.6 The laboratory shall maintain the following records for proficiency tests:

- 13.1.6.1 The test set identifier,
- 13.1.6.2 Identity of the analyst, and other participants, if applicable,
- 13.1.6.3 Date of analysis and completion,
- 13.1.6.4 Copies of all data and notes supporting the conclusions,
- 13.1.6.5 The proficiency test results,
- 13.1.6.6 Any discrepancies noted, and
- 13.1.6.7 Corrective actions taken.

13.1.7 The laboratory shall include, at a minimum, the following criteria for evaluating proficiency test results:

13.1.7.1 Inclusions and exclusions, if applicable, as well as all reported genotypes and/or phenotypes are correct or incorrect according to consensus results or are within the laboratory's interpretation guidelines.

13.1.7.2 All results reported as inconclusive or not interpretable are consistent with written laboratory guidelines.

13.1.7.2.1 The technical leader shall review any inconclusive result for compliance with laboratory guidelines.

13.1.7.3 All discrepancies/errors and subsequent corrective actions shall be documented.

13.1.7.4 All final reports are graded as satisfactory or unsatisfactory.

13.1.7.4.1 A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data.

13.1.7.4.1.1 Administrative errors and corrective actions, as applicable, shall be documented.

13.1.8 All proficiency test participants shall be informed of his/her final test results and this notification shall be documented.

13.1.9 The technical leader shall be informed of the results of all participants and this notification shall be documented. The technical leader shall inform the CODIS administrator of all non-administrative discrepancies that affect the typing results and/or conclusions at the time of discovery.

STANDARD 13.2 The laboratory shall use an external proficiency test provider that is in compliance with the current proficiency testing manufacturing guidelines established by the American Society of Crime Laboratory Directors/ Laboratory Accreditation Board or be in compliance with the current International Organization for Standardization.

14. CORRECTIVE ACTION

STANDARD 14.1 The laboratory shall establish and follow a corrective action plan to address when discrepancies are detected in proficiency tests and database analysis. A laboratory corrective action plan shall define what level/type of discrepancy are applicable to this practice and identify (when possible) the cause, effect of the discrepancy, corrective actions taken and preventative measures taken (where applicable) to minimize its reoccurrence. Documentation of all corrective actions shall be maintained in accordance with Standard 3.2.

STANDARD 14.2 Corrective actions shall not be implemented without the documented approval of the technical leader.

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 6 months and no more than 18 months apart.

STANDARD 15.2 At least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform and one team member who is currently or was previously a qualified analyst from a databasing laboratory.

15.2.1 Each analyst, CODIS administrator and technical leader shall have his/her education, experience and training qualifications evaluated and approved during two successive, separate external audits conducted after July

1, 2004. Approval of an individual's education, experience and 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 For internal audits, the auditor or audit team shall have the following expertise: currently qualified auditor and currently or previously qualified as an analyst in the laboratory's current DNA technologies and platform.

STANDARD 15.4 Internal and external audits shall be conducted utilizing the FBI DNA Quality Assurance Standards Audit Document.

STANDARD 15.5 Internal and external DNA Audit documents and, if applicable, corrective action(s) shall be submitted to the technical leader for review to ensure that findings, if any, were appropriately addressed.

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

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

16. SAFETY

STANDARD 16.1 The laboratory shall have and follow a documented environmental health and safety program. This program shall include the following:

16.1.1 A blood borne pathogen and chemical hygiene plan

16.1.2 Documented training on the blood borne pathogen and chemical hygiene plan.

STANDARD 16.2 The laboratory's environmental health and safety plan shall be reviewed once each calendar year and such review shall be documented.

17. OUTSOURCING

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

17.1.1 An NDIS participating laboratory that outsources DNA sample(s) to a vendor laboratory to generate DNA data that will be entered into or searched in CODIS shall require the vendor laboratory to provide documentation of compliance with these

Standards and the accreditation requirements of federal law. The NDIS participating laboratory shall maintain such documentation.

STANDARD 17.2 Except as provided in Standard 17.2.1, an NDIS participating laboratory's technical leader shall document approval of the technical specifications of the outsourcing agreement with a vendor laboratory before it is awarded. Such documentation shall be maintained by the NDIS participating laboratory.

17.2.1 A vendor laboratory that is performing DNA analysis for a law enforcement agency or other entity and generating DNA data that may be entered into or searched in CODIS shall not initiate analysis for a specific sample or set of samples until documented approval has been obtained from the appropriate NDIS participating laboratory's technical leader of acceptance of ownership of the DNA data.

STANDARD 17.3 An NDIS participating laboratory shall not upload or accept DNA data for upload to or to search in CODIS from any vendor laboratory or agency without the documented prior approval of the technical specifications of the outsourcing agreement and/or documented approval of acceptance of ownership of the DNA data by the NDIS participating laboratory's technical leader.

STANDARD 17.4 An NDIS participating laboratory shall have, follow and document appropriate quality assurance procedures to verify the integrity of the data received from the vendor laboratory including, but not limited to, the following:

17.4.1 Random reanalysis of database, known or casework reference samples;

17.4.2 Inclusion of QC samples;

17.4.3 Performance of an on-site visit by 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. The laboratory shall have and follow a procedure to perform an on-site visit(s) of the vendor laboratory that shall include, at a minimum, the following elements:

17.4.3.1 A documented initial on-site visit prior to the vendor laboratory's beginning of DNA analysis for the laboratory.

17.4.3.2 The on-site visit shall be performed by the technical leader or designated employee of the NDIS participating laboratory who is a qualified or was previously a qualified DNA analyst in the technology, platform and typing amplification test kit used to generate the DNA data.

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

17.4.3.3.1 An NDIS participating laboratory may accept an on-site visit conducted by another NDIS participating laboratory using the same technology, platform and typing amplification test kit, for the generation of the DNA data and shall document the review and approval of such on-site visit.

STANDARD 17.5 An NDIS participating laboratory shall have, follow and document appropriate technical review procedures to verify the integrity of the data received from the vendor laboratory.

17.5.1 A technical review of DNA data prior to the upload to or search of DNA data in SDIS shall include the following elements:

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

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

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

17.5.2 A technical review of a vendor laboratory's DNA data shall be performed by an analyst or technical reviewer employed by the NDIS participating laboratory who is qualified or was previously qualified in the technology, platform and test kit used to generate the DNA data and participates in the 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.