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DEPARTMENT OF THE ARMY
US ARMY CRIMINAL INVESTIGATION LABORATORY
4930 N 31ST STREET
FOREST PARK, GA 30297-5205

October 24, 2007

Mr. Mike Budzynski, Special Agent in Charge
North Carolina State Bureau of Investigation
121 East Tryon Rd.
Raleigh, NC 27603

Dear Mr. Budzynski,

On October 16-17, 2007, staff from the United States Army Criminal Investigation Laboratory (USACIL) audited your laboratory according to the FBI Standards for Forensic DNA Testing and Convicted Offender DNA Databasing Laboratories. The audit team thanks you and your staff for their hospitality and cooperation throughout the audit.

Overall, the audit team was impressed by both the facility and the quality of your DNA operation. The findings that were identified in Standards 9 and 10 are detailed in the enclosed audit document.

Thank you,

Meredith Kitey

Meredith Kitey
DNA Technical Leader
USACIL

AN ASCLD/LAB ACCREDITED LABORATORY (SINCE 1985)

NORTH CAROLINA
STATE BUREAU OF INVESTIGATION
DEPARTMENT OF JUSTICE

3320 GARNER ROAD
PO BOX 29500
RALEIGH, NC 27626-0500
(919) 662-4500
FAX: (919) 662-4523

ROY COOPER
ATTORNEY GENERAL

ROBIN P. PENDERGRAFT
DIRECTOR

Dr. Douglas Hares
NDIS Custodian
FBI Laboratory
Room 1120
2501 Investigation Parkway
FBI Academy Complex
Quantico, VA 22135

Dear Dr. Hares:

I am writing to notify you that an external QAS audit was conducted of the N.C. State Bureau of Investigation Forensic Biology Section on October 16-17, 2007. The audit was conducted by Meredith Kitey (Lead) with Debra Glidewell, Nicole Carter and Chrisite Johnson (Technicals) of the U. S. Army Criminal Investigation Laboratory.

The audit report and responses are attached.

If you have any questions, I can be reached at 919-662-4500 (ext. 2527).

Sincerely,

Michael J. Budzynski
NCSBI Crime Laboratory

QUALITY ASSURANCE AUDIT

FOR

FORENSIC DNA AND CONVICTED OFFENDER

DNA DATABASING LABORATORIES

IN ACCORDANCE WITH

THE QUALITY ASSURANCE STANDARDS

FOR

FORENSIC DNA TESTING LABORATORIES

AND

CONVICTED OFFENDER DNA DATABASING LABORATORIES

ISSUED BY

THE FBI DIRECTOR

An Audit of: North Carolina State Bureau of Investigation

Dates of Audit: October 16-17, 2007

Auditor(s):

(Name)	(Signature)
Meredith Kitey	Meredith Kitey
Debra Glidewell	Debra Glidewell
Nicole Carter	Nicole R. Carter
Christie Johnson	Christie Johnson

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Introduction

The *DNA Identification Act of 1994* required the formation of a panel of distinguished professionals from the public and private sectors to address issues relevant to forensic DNA applications. This panel, titled the DNA Advisory Board, first convened in 1995. An early mission of the DNA Advisory Board was to develop and implement quality assurance standards for use by forensic DNA testing laboratories. The scope was quickly expanded to include forensic DNA databasing laboratories. The DNA Advisory Board fulfilled this role, recommending separate documents detailing quality assurance standards for both applications. The *Quality Assurance Standards for Forensic DNA Testing Laboratories* and the *Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories* were issued by the Director of the Federal Bureau of Investigation in October 1998 and April 1999, respectively. Both documents have become benchmarks for assessing the quality practices and performances of DNA laboratories throughout the country.

The *DNA Identification Act of 1994* also required the FBI Laboratory to ensure that all DNA laboratories that are federally operated, receive federal funds, or employ software prepared for the Combined DNA Index System (CODIS) demonstrate compliance with the standards issued by the FBI. Additional programs, such as the National DNA Index System, added further requirements for DNA laboratories that wish to enter data into the national DNA database also demonstrate compliance with such standards. Typically, documentation of a laboratory's compliance with a stated standard has been measured through an audit process. Such audits have been performed by forensic scientists, either internal or external to the laboratory, and serve to identify compliance with established standards.

Since the issuance of both quality assurance documents, confusion regarding the intent and subsequent interpretation for various standards has existed in the forensic science community. The lack of a defined, uniform interpretation guide for such standards has presented a potential problem among laboratories and auditors attempting to determine levels of compliance. In an effort to satisfy the responsibilities assigned through the *DNA Identification Act of 1994* and attempt to minimize interpretation variability, the FBI Laboratory has developed an audit document for assessing compliance with the required standards of both documents. Recognizing the broad application of such an undertaking, the FBI Laboratory has solicited input from many forensic DNA laboratories over the past year to assist in the document's design. This has included collaborating with members from two prominent international inspection/accreditation entities, the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) and the National Forensic Science Technology Center. To this end, the audit document has been created by the FBI Laboratory with the input, guidance, and consensus from the above-mentioned groups. The document defines and interprets each standard, with added discussion points clarifying the criteria necessary for compliance. Additionally, the document is structured such that criteria, which overlap between the FBI-issued standards and the corresponding ASCLD/LAB elements, share a consistent interpretative view.

Regarding the format of the audit document, each standard is listed numerically, combining the quality standards of the forensic DNA laboratories and the convicted offender DNA databasing laboratories into one document. Standards that apply exclusively to one application are identified as such, with the designation of either FO or CO, parenthetically adjacent to the standard. The absence of a designation identifies a shared application. Instances in which the wording of a standard is the same for both applications (FO and CO), but the corresponding number of the standard differs, the FO number will be parenthetically adjacent to the standard, and the CO designation, with its corresponding number, will follow the narrative of the standard. The rating system for assessing the laboratory with each standard is listed by the choices of Yes, No, or Not Applicable (N/A). As indicated earlier, discussion sections follow standards, as appropriate, and serve to clarify the interpretation necessary for compliance. Specific passages are bold to add emphasis to the intent associated with a standard. A comment section is also provided following the discussion areas, affording auditors the opportunity to reference information that may have value in the audit process (such as listing the reason for a Yes, No, or N/A).

Finally, in Appendix A, the findings associated with the audit will be detailed and summarized by the

auditor, with an area available for response to such findings by the laboratory. Notes or comments, including observations and recommendations are better suited to be mentioned during the exit briefing with laboratory personnel or in a separate letter/memorandum to the laboratory so that these comments are not confused with comments relating to a finding or an explanation of why a particular standard is not applicable.

The revised discussions are not to be applied retroactively and will take effect upon the approval of the FBI Director.

The following checklist should be completed and placed after the coversheet of the report:

INTRODUCTION HISTORY Revision 6 Issue Date July 1, 2004

Added instructions regarding notes and comments

- Added sentence regarding effective date of revisions
- Added "Checklist of General Laboratory Information"
- Added instruction for checklist placement

Checklist of General Laboratory Information

1. Name of Laboratory __NC State Bureau of Investigation__

2. Federal/State/Regional/County/Local/Other ___ Laboratory (Highlight one)

3. Covering Population of ___North Carolina_____

4. Casework and/or Offender Database Samples (Highlight those that apply)

5. Uses a Contract Laboratory Yes/No (Highlight those that apply)
   Casework Samples Yes/No
   Offender Database Samples Yes/No
   Name of Contract Laboratory(ies) __LabCorp and Bode_____

6. National DNA Index System Participant: Yes/No (Highlight one)

7. Applying for National DNA Index System Participation Yes/No/NA (Highlight one)

8. Technologies Used (Highlight those that apply and indicate if for casework or offender databasing)
   STRs: Casework or Offender Databasing
   YSTRs: Casework or Offender Databasing
   MtDNA: Casework or Offender Databasing
   RFLP: Casework or Offender Databasing
   Other_____: Casework or Offender Databasing

9. Number of staff
   DNA analysts/examiners _28__
   DNA trainees __2___
   DNA technicians _n/a_____
   DNA technical leader/manager _David Freeman_____
   On-site Yes/No (Highlight one)

   CODIS Manager __Chris Parker (State Administrator)____

10. Last audit conducted on___December 12-14, 2006_____
    External/Internal Audit (Highlight one)

References

American Society of Crime Laboratory Directors/Laboratory Accreditation Board, *ASCLD/LAB Accreditation Manual.* ASCLD/LAB, Garner, North Carolina, 2003.

Federal Bureau of Investigation DNA Advisory Board. Quality assurance standards for forensic DNA testing laboratories, (1998) *Forensic Science Communications* [Online]. (July 2000). Available: www.fbi.gov/hq/lab/fsc/backissu/july2000/codispre.htm.

Federal Bureau of Investigation DNA Advisory Board. Quality assurance standards for convicted offender DNA databasing laboratories, (1999) *Forensic Science Communications* [Online]. (July 2000). Available: www.fbi.gov/hq/lab/fsc/backissu/july2000/codispre.htm.

International Standards Organization/International Electrotechnical Commission. *ISO/IEC Guide 25:1990,* (1990) American National Standards Institute, New York.

Technical Working Group on DNA Analysis Methods. Guidelines for a quality assurance program for DNA analysis, *Crime Laboratory Digest* (1995) 22:(2)21-43.

42 Code of Federal Regulations, Chapter IV (10-1-95 Edition), Health Care Financing Administration, Health and Human Services.

REFERENCE HISTORY Revision 6 Issue Date July 1, 2004

- Changed version year of ASCLD/LAB Accreditation Manual

Definitions

As used in this document, the following terms have the meanings specified:

(a) Administrative review is an evaluation of the report (if applicable) and supporting documentation for consistency with laboratory policies and for editorial correctness.

(b) Amplification blank control consists of only amplification reagents without the addition of sample DNA. This control is used to detect DNA contamination of the amplification reagents.

(c) Analytical procedure is an orderly step-by-step procedure designed to ensure operational uniformity and to minimize analytical drift.

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

(e) Batch is a group of samples analyzed at the same time.

(f) Calibration is the set of operations that 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.

(g) CODIS is the Combined DNA Index System administered by the FBI. It houses DNA profiles from convicted offenders, forensic specimens, population samples, and other specimen types.

(h) Commercial test kit is a preassembled kit that allows the user to conduct a specific DNA identification test.

(i) Convicted offender is an individual who is required by statute to submit a standard sample for DNA databasing.

(j) Convicted offender database (CODIS) manager or custodian (or equivalent role, position, or title as designated by the laboratory director) is the person responsible for administration and security of the laboratory's CODIS.

(k) Convicted offender standard sample is biological material collected from an individual for DNA analysis and inclusion into CODIS. See also database sample.

(l) Critical equipment or instruments are those requiring calibration prior to use and periodically thereafter.

(m) Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use in order to prevent unnecessary loss of sample.

(n) Database sample is a known blood or standard sample obtained from an individual whose DNA profile will be included in a computerized database and searched against other DNA profiles.

(o) Examiner/analyst (or equivalent role, position, or title as designated by the laboratory director) conducts and/or directs the analysis of samples, interprets data, and reaches conclusions.

(p) Forensic DNA testing is the identification and evaluation of biological evidence in criminal matters using DNA technologies.

(q) Known samples are biological material whose identity or type is established.

(r) Laboratory is a facility where forensic DNA testing and/or convicted offender DNA testing is performed or a government facility that contracts with a second entity for such testing.

(s) Laboratory support personnel (or equivalent role, position, or title as designated by the laboratory director) are individuals who perform laboratory duties and do not analyze samples.

(t) NIST is the National Institute of Standards and Technology.

(u) Polymerase chain reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles that consist of (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.

(v) Proficiency test sample is biological material whose DNA type has been previously characterized and that is used to monitor the quality performance of a laboratory or an individual.

(w) 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) Internal proficiency test is one prepared and administered by the laboratory.

(2) External proficiency test, which may be open or blind, is one that is obtained from a second agency.

(x) A qualifying test measures proficiency in both technical skills and knowledge.

(y) Quality assurance includes the systematic actions necessary to demonstrate that a product or service meets specified requirements for quality.

(z) A quality manual is a document stating the quality policy, quality system, and quality practices of an organization.

(aa) Quality system is the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

(bb) Reagent blank control consists of all reagents used in the test process without any sample. This is to be used to detect DNA contamination of the analytical reagents.

(cc) 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.

(dd) Restriction fragment length polymorphism (RFLP) is generated by cleavage by a specific restriction enzyme, and the variation is due to restriction site polymorphism and/or the number of different repeats contained within the fragments.

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

(ff) Second agency is an entity or organization external to and independent of the laboratory and that performs DNA identification analysis.

(gg) Secure area is a locked space (e.g., cabinet, vault, room) with access restricted to authorized personnel.

(hh) Subcontractor is an individual or entity having a transactional relationship with a laboratory.

(ii) Technical manager/leader (or equivalent position or title as designated by the laboratory director) is the individual who is accountable for the technical operations of the laboratory.

(jj) Technical review is an evaluation of reports, notes, data, and other documents to ensure an

appropriate and sufficient basis for the scientific conclusions. This review is conducted by a second qualified individual.

(kk) Technician (or equivalent role, position, or title as designated by the laboratory director) is an individual who performs analytical techniques on samples under the supervision of a qualified examiner/analyst and/or performs DNA analysis on samples for inclusion in a database.

(ll) 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.

(mm) Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for DNA analysis and includes

(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 samples.

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

Standard 3: Quality Assurance Program

		Yes	No	N/A
3.1	Does the DNA laboratory have an established and maintained documented quality system that is appropriate to the testing activities?	_X_	____	____

Discussion

The laboratory must have a documented (hard copy or electronic copy) quality system, typically identified as a quality manual. The laboratory must demonstrate that it has maintained its quality system by conducting an annual review of that system. An annual review of the quality system is important for ensuring that measures are being taken by the laboratory to continually provide the highest quality of service. This review must include the review of the quality manual and standard operating procedures used by the laboratory and must be independent of the required annual audit. Audit reports may identify areas in need of attention and provide the basis for changes to the quality system. Such changes may include new or improved quality control activities for monitoring the quality of the laboratory work product. Additionally, significant modifications of forensic DNA testing, such as the incorporation of a new technology, may necessitate a review or updating of the quality system. The annual review must be documented (hard copy or electronic copy).

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Replaced "generally directed" with "must"
- Added wording that the quality manual review is independent of annual audit
- Added "hard copy or electronic copy" to last sentence

Comment

		Yes	No	N/A
3.1.1	Does the quality manual address (at a minimum) the following:			
a.	Goals and objectives	_X__	____	____
b.	Organization and management structure	_X__	____	____
c.	Personnel qualifications and training	_X__	____	____
d.	Facilities	_X__	____	____
e.	Evidence control	_X__	____	____
f.	Validation	_X__	____	____
g.	Analytical procedures	_X__	____	____
h.	Calibration and maintenance	_X__	____	____
i.	Proficiency testing	_X__	____	____
j.	Corrective action	_X__	____	____
k.	Reports	_X__	____	____
l.	Review	_X__	____	____
m.	Safety	_X__	____	____
n.	Audits	_X__	____	____

Discussion

The DNA laboratory quality system or quality manual must contain or reference each of the above listed criteria. Individual sections that deal with subject areas that are defined through laboratory-wide policies or procedures (e.g., evidence control, safety) may be located in documents that are separate from the quality manual; however, such information should be referenced in the quality manual. If such sections have been supplemented by DNA laboratory-specific practices, the quality manual must reflect such additions.

Any document that is referenced in the laboratory's DNA quality manual must be available on-site. Documents may be in hard copy, electronic files, or a combination of both formats.

Additionally, the quality system/quality manual must contain or reference practices that address continuing education (Standard 5.1.3) and monitoring court testimony (Standard 12.2).

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added paragraph requiring on-site availability of any referenced laboratory quality manual documents
- Added "monitoring" to last sentence

Comment

Standard 4: Organization and Management

		Yes	No	N/A
4.1.a	Has the managerial staff of the laboratory been provided the authority and resources needed to discharge their duties and meet the requirements of the standards in this document?	_X__	____	____

Discussion

Evidence of meeting this standard is assessed through interviews of staff and the review of laboratory documents such as job descriptions and organizational charts.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted last sentence of paragraph

Comment

		Yes	No	N/A
4.1.b	Does the laboratory have a designated technical manager/leader who is accountable for the technical operations?	_X__	____	____

Discussion

The role of a technical manager/leader does not preclude, for example, the existence of additional program managers, each of whom may be assigned a subset of clearly defined duties (e.g., training program manager, quality assurance program manager). The technical manager/leader will retain, however, the ultimate responsibility for such programs.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Replaced "specific" with "clearly defined"

Comment

		Yes	No	N/A
4.1.c	Does the laboratory specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis? (CO4.1c)	_X__	____	____
4.1c(CO)	Does the laboratory have a CODIS manager or custodian who is accountable for CODIS operations?	_X__	____	____

Discussion

As a tool in the evaluation of the management standards, laboratories must maintain a current organizational chart, referencing the members of the laboratory with their specific position assignments (e.g., technical manager/leader, CODIS manager). Additionally, current job descriptions must be available for all laboratory personnel, accurately defining the technical and/or administrative responsibilities associated with each position (Standard 5 - Personnel).

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted "various"

Comment

Standard 5: Personnel

		Yes	No	N/A
5.1	Do laboratory personnel have the education, training, and experience commensurate with the examination and testimony provided?	_X__	____	____

Discussion

To successfully satisfy Standard 5.1, compliance must be demonstrated with all of the subcategories of Standard 5. A list of the individuals in compliance with Standard 5.1 will be incorporated by the auditor into the Comment section below. The credentials for those individuals found to be in compliance with Standard 5.1 after two successive external audits do not need to be reviewed.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted reference to specific subcategories
- Added a sentence requiring a list of standard compliant individuals be placed in comment section
- Added statement that credentials of compliant listed individuals need not be reviewed after two successive external audits

Comment

The following Database analysts meet the education, training and experience requirements and have been reviewed for a second time: Gina Autry, Sarah Johnson, Elaine Staley, and Janis Matthews

The following Casework analysts meet the education, training and experience requirements and have been reviewed for a second time: Christiana Fischer, Jennifer Leyn, Michelle Hannon, Ivy McMillan, and Timothy Baize

The following Database analysts meet the education, training and experience requirements and have been reviewed for the first time: Regina Hedgepeth and Tanisha Ray

The following Casework analyst meets the education, training and experience requirements and have been reviewed for the first second time: Kristin Meyer

		Yes	No	N/A
5.1.1	Does the laboratory have written job descriptions for all personnel to include responsibilities, duties, and skills?	_X__	____	____

Discussion

Written job descriptions that are augmented by other documentation to include responsibilities, duties, and skills are acceptable.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording

Comment

		Yes	No	N/A
5.1.2	Does the laboratory have a documented training program for qualifying all technical laboratory personnel?	_X__	____	____

Discussion

A laboratory's training program must teach **and assess** the skills and knowledge required to achieve the minimum standards of competence and good laboratory practice in a specific area of work. Training must include all methods that the analyst will use in casework and/or convicted offender analysis.

The laboratory must have a documented training program that includes a training manual and training records for each trainee available for review. Additionally, the laboratory must have documentation that provides a formal means for recognizing an individual's successful completion of the training program (e.g., certificate, letter, memorandum) and demonstration of competency, typically through a test. For further information, refer to the discussion following Standard 5.3.3.

It is management's responsibility to establish and document the adequacy of the training of any staff member who has not completed the laboratory's formal training program. Examples may include (but are not limited to) the acquisition of fully trained personnel from a separate organization or the assignment of experienced forensic DNA caseworking examiners/analysts to validate a new DNA testing procedure. All individuals, regardless of previous training and experience, must successfully complete a qualifying test for the specific DNA technology to be used at the current laboratory prior to assuming convicted offender and/or casework responsibilities. Successful completion of an individual's qualifying test must be documented by the laboratory.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording, added sentence defining training and clarified document training program
- Deleted the SWGDAM note
- Added "convicted offender and/or" to last paragraph

Comment

		Yes	No	N/A
5.1.3	Does the laboratory have a documented program to ensure that technical qualifications are maintained through continuing education?	_X__	____	____
5.1.3.1(a)	Over the last year has the technical manager/leader read current scientific literature?	_X__	____	____
5.1.3.1(b)	Over the last year has the technical manager/leader attended at least one seminar, course, professional meeting, or training session/class that addresses subject matter related to DNA analysis?	_X__	____	____
5.1.3.1(c) (CO)	Over the last year has the CODIS manager read current scientific literature?	_X__	____	____
5.1.3.1(d) (CO)	Over the last year has the CODIS manager attended at least one seminar, course, professional meeting, or training session/class that addresses subject matter related to DNA analysis?	_X__	____	____
5.1.3.1(e)	Over the last year has each examiner/analyst read current scientific literature?	_X__	____	____
5.1.3.1(f)	Over the last year has each examiner/analyst attended at least one seminar, course, professional meeting, or training session/class that addresses subject matter related to DNA analysis?	_X__	____	____

Discussion

The laboratory's continuing education program must be documented, such as in the quality manual or training manual. To comply with this standard, laboratory management must provide technical personnel with the opportunity to stay abreast of new developments and issues in the field of DNA analysis. The laboratory must provide the technical manager/leader, CODIS manager, and all examiner/analysts with continuing education in a subject area related to DNA analysis annually as defined by the laboratory (e.g., fiscal or calendar). Continuing education shall be no less than a cumulative total of eight hours on an annual basis. While such continuing education should be formalized, requirements do not necessarily include earned credit hours or grade evaluations, although this would be acceptable. Participation and completion of programs based on multimedia or Internet delivery must be formally recorded and approved by the technical manager/leader. This documentation must include the time required to complete the program.

For laboratory external continuing education programs, a variety of methods may be used including attending local, national, and international meetings or symposia or external training courses. The laboratory must maintain documentation of such attendance.

For internal continuing education programs, the title, a record of the presentation, date of training, attendance list, and curriculum vitae of presenter(s) must be documented and retained by the laboratory.

The laboratory must maintain or have access (e.g., Internet) to a collection of current books, journals, or other literature applicable to DNA typing. The laboratory must have an established system that tracks reading of scientific literature.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted wording.
- Added sentence defining number of hours of continuing education
- Added clarification of use of multimedia or Internet delivery for continuing education
- Added definitions for required internal and external continuing education documentation
- Changed wording and deleted last sentence of last paragraph

Comment

		Yes	No	N/A
5.1.4	Does the laboratory maintain records on the relevant qualifications, training, skills, and experience of all technical personnel?	_X__	____	____

Discussion

The laboratory must verify the degree and course work for technical personnel. Transcripts must be available to the auditors for assessing an individual's qualifications. Technical personnel skills and experience must be documented through a curriculum vitae or other means, such as a statement of qualifications. Compliance with this standard is assessed through a review of documentation and staff interviews.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted "curriculum vitae"

Comment

		Yes	No	N/A
5.2	Does the technical manager/leader satisfy the degree/educational, experience, and duty requirements as listed in Standards 5.2.1 through 5.2.3?	_X_	____	____

		Yes	No	N/A
5.2.1	Does the technical manager/leader of the laboratory meet the following degree/educational requirements or have a waiver as stated in Standard 5.2.1.1?	_X__	____	____
	A. A graduate degree in a biology, chemistry, or forensic science-related area	_X__	____	____
	B. A minimum of 12 credit hours or its equivalent including a combination of graduate and undergraduate course work or classes covering the subject areas of	_X__		
	(a) Biochemistry	_X__	____	____
	(b) Genetics	_X__	____	____
	(c) Molecular biology	_X__	____	____
	(d) Statistics and/or population genetics	_X__	____	____

Discussion

A minimum of 12 semester or equivalent credit hours must be completed successfully (college- or university-determined passing grade) that address the general subject areas of biochemistry, genetics, molecular biology, as well as statistics and/or population genetics, or other subjects that provide a basic understanding of the foundation of forensic DNA analysis. **The 12 semester or equivalent credit hours requirement (5.2.1 B) must include, at a minimum, one graduate level class registering three or more semester or equivalent credit hours.** A variety of college course work may apply toward satisfying this standard and is not limited exclusively to the subject categories listed. However, the specific subjects area(s) listed must constitute an **integral component** of any class or course work for compliance with this standard. Individuals who have completed course work with titles other than those listed above must demonstrate compliance with this standard through transcripts, a letter from a university professor verifying course content, a course syllabus, or other appropriate documentation. The DNA training program previously offered by the FBI Laboratory, with graduate credit hours from the University of Virginia, may be applied toward the molecular biology course work requirement associated with this standard. However, courses such as the FBI's Basic Serology course or the FBI's Biochemical Methods of Bloodstain Analysis course would not be applicable toward the 12-hour credit requirement.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Wording changes
- Added last sentence of paragraph defining courses **not** applicable toward 12-hour credit requirement

Comment
Educational requirements of Technical Leader were previously reviewed by two prior audits.

		Yes	No	N/A
5.2.1.1	Does the technical manager/leader possess a waiver from the American Society of Crime Laboratory Directors or other organization designated by the Director of the FBI?	____	____	_X__

Discussion

Compliance with Standard 5.2.1.1 is necessary only if Standard 5.2.1 has not been satisfied. Otherwise the response to 5.2.1.1 is Not Applicable (N/A). Documentation of the waiver must be available.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording to require waiver documentation

Comment

		Yes	No	N/A
5.2.2	Does the technical manager/leader of the laboratory have a minimum of three years forensic DNA laboratory experience?	_X__	____	____

Discussion

The technical manager/leader of the laboratory must have a minimum of three years forensic DNA laboratory experience. This experience must have been gained at a **facility** where forensic DNA testing was performed for the identification and evaluation of **biological evidence in criminal matters**. This would include agencies where research/training and caseworking laboratories are separate entities but reside under the same facility-wide organizational umbrella. It should be noted that the experience time frame is measured not by the number of years with any particular employer, but rather by the number of years in a position specific for gaining the experience necessary to satisfy this standard. Although not required, the technical manager/leader should have successfully completed the DNA Auditing Workshop sponsored by the FBI.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added last sentence in paragraph recommending that a technical manager/leader successfully complete the FBI DNA Auditing Workshop

Comment

		Yes	No	N/A
5.2.3	Does the technical manager/leader of the laboratory meet the duty requirements of this standard?	_X__	____	____
5.2.3.1	Does the technical manager/leader manage the technical operations of the laboratory?	_X__	____	____
5.2.3.2 (a-1)	Is the technical manager/leader responsible for evaluating all methods used by the laboratory?	_X__	____	____
5.2.3.2 (a-2)	Is the technical manager/leader responsible for proposing new or modified analytical procedures to be used by the examiners?	_X__	____	____

5.2.3.2 (b-1)	Is the technical manager/leader responsible for technical problem solving of analytical methods?	_X__	____	____
5.2.3.2 (b-2)	Is the technical manager/leader responsible for the oversight of training, quality assurance, safety, and proficiency testing in the laboratory?	_X__	____	____
5.2.3.3	Is the technical manager/leader accessible to the laboratory to provide on-site, telephonic, or electronic consultation as needed?	_X__	____	____

Discussion

Auditors may assess whether a laboratory has satisfied the requirements listed in Standard 5.2.3 through a review of laboratory documentation (e.g, protocols, quality manual), staff interviews, and/or on-site evaluations. The technical manager/leader is not required to occupy physical (on-site) facility space. However, the technical manager/leader must demonstrate knowledge and oversight of the DNA program to ensure the laboratory is following standards and written protocols. If the laboratory system contracts for an off-site technical manager/leader, the laboratory must ensure that the technical manager/leader makes an initial on-site visit. The frequency of additional visits should be regular but not less than once a year and as needed, based on quality issues, after the initial visit. This individual must be readily accessible to the laboratory (telephonically or electronically) to fulfill the responsibilities and requirements of this position in an effective manner.

For compliance with the duty requirements of Standard 5.2.3, it is not necessary for the technical manager/leader to function (or to have functioned) as a qualified examiner/analyst. For those instances in which the technical manager/leader has an experience base in a specific DNA technology, which is different from the DNA technology currently used in convicted offender or casework analysis, the laboratory must demonstrate that the technical manager/leader has fulfilled his/her defined duties and keeps abreast of technical developments.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added requirements and responsibilities of off-site managers/leaders
- Deleted second sentence of second paragraph
- Deleted reference to RFLP testing
- Deleted last two sentences of second paragraph

Comment

		Yes	**No**	**N/A**
5.3	Does each examiner/analyst satisfy the degree/educational, experience, and duty requirements as listed in Standards 5.3.1 through 5.3.3 (CO5.4)?	_X__	____	____
5.3.1	Does each examiner/analyst meet the following degree/educational requirements:	_X__	____	____
	A. B.A./B.S. degree or its equivalent in a biology, chemistry, or forensic science-related area	_X__	____	____
	B. College course work or classes covering the subject areas of	_X__		

(a) Biochemistry	_X_	____	____
(b) Genetics	_X_	____	____
(c) Molecular biology	_X_	____	____
C. College course work or training that covers the subject area of *statistics and/or population genetics*	_X_	____	____

Discussion

A variety of college course work may apply toward satisfying this standard and is not limited exclusively to the subject categories listed. However, the specific subjects area(s) listed must constitute an integral component of any class or course work to satisfy this standard. Analysts who become qualified after the effective date of this document must have a minimum of six cumulative semester hours or equivalent that covers the required subject areas. Individuals who have completed course work with titles other than those listed above must demonstrate compliance with this standard through transcripts, a letter from a university professor verifying course content, a course syllabus, or other appropriate documentation. The technical leader must document his/her approval of compliance.

The DNA training program previously offered by the FBI Laboratory, with graduate credit hours from the University of Virginia, may be applied toward the molecular biology course work requirement associated with this standard. However, courses such as the FBI's Basic Serology course or the FBI's Biochemical Methods *of Bloodstain Analysis course would not be applicable.*

Examiners/analysts may satisfy the statistics and/or population genetics course work or training requirement (5.3.1) through internal or external training.

For external statistics and/or population genetics training, a variety of methods may be used including workshops at local, national, or international meetings or symposia or external training courses. The laboratory must maintain documentation of such attendance.

For internal statistics and/or population genetics training, the title, a record of the presentation, date of training, attendance list, and curriculum vitae of presenter(s) must be documented and retained by the laboratory.

STANDARD 5.3 HISTORY Revision 6 Issue Date July 1, 2004

- Deleted "(FO)"
- Added "(CO 5.4)"

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first paragraph and added sentence requiring six cumulative semester hours of course work in required subject areas
- Added sentence requiring technical leader's approval of compliance
- Added sentence defining nonapplicable courses for molecular biology course requirements
- Added statements requiring documentation of external and internal statistics and/or population genetics training

Comment

		Yes	No	N/A
5.3.2(a)	Does each examiner/analyst have a minimum of six months forensic DNA laboratory experience?	_X_	____	____
5.3.2(b)	Does the experience of each examiner/analyst include the successful analysis of a range of samples typically encountered in forensic casework prior to undertaking independent casework	_X_	____	____

analysis using DNA technology?

Discussion

An examiner/analyst must have a minimum of six months forensic DNA laboratory experience gained at a facility where forensic DNA testing was performed for the identification and evaluation of biological evidence in criminal matters. The experience time frame is measured not by the length of time spent with

any particular employer but rather by the number of months/years in a position specific for gaining the experience necessary to satisfy this standard. The experience gained by an individual must include the successful analysis of a range of samples typically associated with forensic casework. An individual's participation in a formal forensic DNA training program is acceptable for fulfilling or being applied toward fulfilling the experience requirement of this standard.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Wording changes

Comment

		Yes	No	N/A
5.3.3	Has each examiner/analyst successfully completed a qualifying test before beginning independent casework responsibilities?	_X__	____	____

Discussion

A qualifying test or competency test serves to test an individual's knowledge, skills, and abilities as they relate to his/her individual position. A laboratory may select from a variety of approaches for administering a qualifying test, including but not limited to a written, oral, or practical examination. If a laboratory uses an internal or external proficiency test as a qualifying test, the laboratory must have phenotyping/genotyping results to assess an individual's performance. The date of qualification of an individual must be documented. The qualification date has particular relevance to proficiency testing requirements discussed in Standard 13 (Proficiency Testing), which requires newly qualified individuals to participate in an external proficiency test within six months of their initial qualification date.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Wording changes
- Replaced "180 days" with "six months"

Comment

		Yes	No	N/A
5.3(CO)	Does the CODIS manager or custodian satisfy the degree/educational, experience, and duty requirements as listed in the convicted offender Standards 5.3.1 through 5.3.3?	_X_	____	____
5.3.1	Does the CODIS manager or custodian possess a Bachelor's degree in a natural science or computer science?	_X_	____	____
5.3.2(a)	Does the CODIS manager or custodian have a working knowledge of the following:	_X_		
	(a) Computers	_X_	____	____
	(b) Computer networks	_X_	____	____
	(c) Computer database management	_X_	____	____
5.3.2(b)	Does the CODIS manager or custodian have an understanding of DNA profile interpretation?	_X_	____	____
5.3.3	Does the CODIS manager or custodian meet the duty requirements of this position?	_X_	____	____
5.3.3(a-1)	Does the CODIS manager or custodian function as the system administrator of the laboratory's CODIS network?	_X_	____	____
5.3.3(a-2)	Is the CODIS manager or custodian responsible for the security of the DNA profile data stored in CODIS?	_X_	____	____
5.3.3(b)	Is the CODIS manager or custodian responsible for oversight of CODIS computer training and quality assurance of data?	_X_	____	____
5.3.3(c-1)	Does the CODIS manager or custodian have the authority to terminate the laboratory's participation in CODIS in the event of a problem until the reliability of the computer data can be assured?	_X_	____	____
5.3.3(c-2)	Does the state CODIS manager or custodian have this authority over all CODIS sites under his/her jurisdiction?	_X_	____	____

Discussion

A qualifying test is not required for the CODIS manager unless the CODIS manager performs examiner/analyst duties such as interpretation of data. Examiner/analysts and technicians associated with the convicted offender program are required to successfully complete a qualifying test specific to their duties prior to participating in DNA typing responsibilities. The responsibilities and authority of the CODIS manager must be documented.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted first sentence of paragraph
- Wording changes

Comment

		Yes	No	N/A
5.4	Does each technician meet the training and qualification requirements as stated in Standards 5.4.1 and 5.4.2 (CO5.5)?	____	____	_X_
5.4.1	Did each technician receive on-the-job training specific to the job function?	____	____	_X_
5.4.2	Did each technician successfully complete a qualifying test before participating in forensic DNA typing responsibilities?	____	____	_X_
5.5	Do all laboratory support personnel meet the requirements as stated in Standard 5.5.1 (CO5.6)?	____	____	_X_
5.5.1	Do all laboratory support personnel possess the training, education, and experience commensurate with their responsibilities as outlined in their job descriptions?	____	____	_X_

Comment
No trained support personnel in lab

Discussion
Technicians associated with the convicted offender program and/or casework are required to successfully complete a qualifying test specific to their duties prior to participating in DNA typing responsibilities.

STANDARD 5.4 HISTORY Revision 6 Issue Date July 1, 2004
- Added "(CO5.5)"

STANDARD 5.5 HISTORY Revision 6 Issue Date July 1, 2004
- Added "(CO5.6)"

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004
- Added discussion paragraph requiring a qualifying test

Standard 6: Facilities

		Yes	No	N/A
6.1	Is the laboratory designed to provide adequate security and minimize contamination?	_X__	____	____
6.1.1	Is access to the laboratory controlled and limited?	_X__	____	____

Discussion

To successfully satisfy Standard 6.1, compliance must be demonstrated with all of the subcategories of Standard 6.

Clearly written and well-understood procedures must exist for laboratory security. The laboratory's security system must control access and limit entry to the operational areas. All exterior entrance/exit points to the facility must be secured and controlled in a manner to prevent access by unauthorized personnel. Internal controlled areas should limit access to only authorized personnel. The distribution of all keys and combinations must be limited to appropriate laboratory personnel as designated by laboratory management. The distribution system must be current, accurate, clearly documented, and available for review. Many other control systems, which include card keys, surveillance cameras, and intrusion alarms, are acceptable when they complement the laboratory's security system by controlling unauthorized access and/or limiting authorized access to the operational laboratory and evidence storage areas.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Wording changes
- Replaced "should" with "must" as it applies to criteria for security access distribution systems

Comment

		Yes	No	N/A
6.1.2	Are evidence examinations, DNA extractions, and PCR setup conducted at separate times or in separate spaces?	_X__	____	____
6.1.2(CO)	Are evidence examinations, liquid sample examinations, DNA extractions, and PCR setup conducted at separate times or in separate spaces?	_X__	____	____
6.1.3	Is amplified DNA product generated, processed, and maintained in a room(s) separate from the evidence examination, DNA extractions, and PCR setup areas?	_X__	____	____
6.1.3(CO)	Is amplified DNA product generated, processed, and maintained in a room(s) separate from the evidence examination, liquid sample examinations, DNA extractions, and PCR setup areas?	_X__	____	____
6.1.4(CO)	If a robotic workstation is used to carry out DNA extraction and amplification in a single room, can it be demonstrated that contamination is minimized and equivalent to that when performed manually in separate rooms?	____	____	__X_

Discussion

Through a combination of clearly written technical procedures, casework notes, and/or personal observation, the laboratory's approach to sample processing for PCR-based procedures (extraction and amplification) must demonstrate a separation in time or physical space for each activity. The laboratory's design must demonstrate that evidence flow, through the various steps of DNA processing, does not compromise the integrity of the sample. The amplification room must be enclosed with walls from the floor to the ceiling and door(s) for passage. The amplification room(s) must physically separate amplified DNA from all other areas of the laboratory by maintaining doors in the closed position.

When robotic workstations are used to carry out DNA extractions through PCR setup on casework samples (Standards 6.1.2 and 6.1.3) a single room may be used. Internal validation must show that if contamination occurs, it is minimized, addressed, and less than or equivalent to that observed when these procedures are performed manually in separate rooms.

To successfully satisfy Standard 6.1.4(CO), robotic workstations may be used to carry out DNA extraction through amplification in a single room provided that they are separated from the casework extraction and casework amplification areas and that it can be demonstrated through internal validation that if contamination occurs, it is minimized, addressed, and less than or equivalent to that observed when these procedures are performed manually in separate rooms.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added clarification to description of amplification areas
- Added clarification to use of robotic workstations as they apply to casework contamination

Comment

		Yes	No	N/A
6.1.4	Does the laboratory follow written procedures for monitoring, cleaning, and decontaminating facilities and equipment?	_X__	____	____

Discussion

A laboratory may employ a variety of methods to monitor its facilities, such as the use of appropriate controls in the analysis process. Whichever approach(es) the laboratory selects to use, the method(s) must be documented. This may be accomplished through a variety of ways at the discretion of the laboratory.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted third sentence

Comment

Standard 7: Evidence or Sample Control

		Yes	No	N/A
7.1	Does the laboratory have and follow a documented evidence control system or sample inventory control system (convicted offender) for handling and preserving the integrity of physical evidence?	_X__	____	____
7.1.1	Is each evidence sample (including convicted offender samples) labeled with a unique identifier in accordance with established agency policy?	_X__	____	____

Discussion

To successfully satisfy Standard 7.1, compliance must be demonstrated with all of the subcategories of Standard 7.

Convicted offender samples are not considered evidence for the purposes of this document.

The DNA laboratory must have clearly written, well-understood procedures that address handling and preserving of the integrity of evidence and convicted offender samples. Key components of an evidence sample control procedure include proper labeling and sealing of evidence, a documented chain-of-custody record, and a secure area designated for evidence storage. Key components of a convicted offender sample control procedure include proper labeling and sample storage. Each item of evidence and each convicted offender sample (and/or its container) must be marked with a unique identifier.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added reference to convicted offender samples

Comment

		Yes	No	N/A
7.1.2	Does the laboratory maintain a chain of custody for all evidence?	_X__	____	____

Discussion

A written chain-of-custody record must include the signature or initials (written or electronic) of each individual receiving or transferring evidence, with the corresponding date for each transfer with a corresponding identifier that specifies each evidentiary item. This record must provide a comprehensive, documented history for each evidence transfer over which the laboratory has control. Electronic tracking of evidence is an acceptable alternative to a written record if the computerized data are sufficiently secure, detailed, and accessible for review and can be converted to a hard copy when necessary.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added " (written or electronic)" to first sentence

Comment

		Yes	No	N/A
7.1.2(CO)	Does the laboratory document and maintain the identity, collection, receipt, storage, and disposition for samples?	_X__	____	____
7.1.3	Does the laboratory follow documented procedures that minimize loss, contamination, and/or deleterious change of evidence?	_X__	____	____
7.1.4	Does the laboratory have secure areas for evidence storage?	_X__	____	____
7.1.4(CO)	Does the laboratory have secure areas for sample storage including environmental controls consistent with the form or nature of the sample?	_X__	____	____

Discussion

The laboratory must ensure that evidence stored under its custody is properly sealed and protected from loss, contamination, and/or deleterious change. An evidence container is properly sealed if its contents cannot readily escape and if entering the container results in a detectable alteration to the container or seal. The seal must be labeled in a manner that identifies an individual responsible for sealing the evidence. The immediate container need not be sealed (but securely closed) if it is enclosed in a larger container that meets the requirements of a proper seal. In such instances, the container must be securely closed so that its contents are protected from loss, contamination, and/or deleterious change. Secure areas for evidence storage must exist in the laboratory. This may include the use of temporary or short-term storage, demonstrating proper security through defined, controlled access to the evidentiary storage area. Short-term storage areas may vary from a locked file cabinet to an entire secured examination room housing large or bulky items of evidence on a temporary basis.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Replaced "desirable" with "must" in third sentence
- Added "secured" to last sentence

Comment

		Yes	No	N/A
7.2(FO)	Does the laboratory retain or return a portion of the evidence sample or extract when possible?	_X__	____	____
7.2.1(FO)	Does the laboratory have a procedure requiring that evidence samples/extract(s) be stored in a manner that minimizes degradation?	_X__	____	____

Standard 8: Validation

		Yes	No	N/A
8.1	Does the laboratory use methods and procedures for forensic DNA analysis that have been validated prior to casework implementation?	_X_	____	____

Discussion

To successfully satisfy Standard 8.1, compliance must be demonstrated with all of the subcategories of Standard 8.

Validation is the process used by the scientific community to acquire the necessary information for accessing a procedure's reliability to obtain a specific, desired result. The validation process also serves to identify critical aspects of a procedure that must be controlled and monitored, while defining the limitations of the procedure.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first sentence of first paragraph

Comment

No additional validation studies have been conducted since the last external audit.

		Yes	No	N/A
8.1.1	Have developmental validation studies been conducted and appropriately documented?	____	____	_X__

Discussion

Developmental validation must precede the introduction of a novel methodology for forensic DNA analysis. A novel methodology may include an existing technology or testing procedure that has been developed for a specific technology (e.g., medical testing, genetic analysis) that is not currently applied to forensic DNA analysis. Citations in peer-reviewed scientific journals that provide the underlying scientific basis for a novel methodology should be available.

		Yes	No	N/A
8.1.2	Have novel forensic or database DNA methodologies used by the laboratory undergone developmental validation to ensure the accuracy, precision, and reproducibility of the procedure?	____	____	_X__
8.1.2.1	Is there documentation and is it available that defines and characterizes each locus?	____	____	_X__
8.1.2.2(FO)	Have species' specificity, sensitivity, stability, and mixture studies been conducted?	____	____	_X__
8.1.2.3(FO)	Does the laboratory have access to a population database that is documented and available for use in population statistics?	___	____	_X__
8.1.2.3.1(FO-a)	Where appropriate, has the database been tested for independence expectations?	____	____	_X__
8.1.2.3.1(FO-b)	Does the database information include allele and frequency distributions for the locus or loci obtained from relevant populations?	____	____	_X__

8.1.3	Has the laboratory completed and documented internal validation studies?	____	____	_X__

Discussion

To successfully satisfy Standards 8.1.2 and 8.1.3, compliance must be demonstrated with all of the subcategories of these standards.

Prior to implementing a new DNA analysis procedure or an existing DNA procedure developmentally validated by another laboratory, the forensic or database laboratory must first demonstrate the reliability of the procedure internally. The internal validation studies conducted by the forensic laboratory should be sufficient to document the reliability of the technology as practiced by that laboratory. Summaries must be written for all internal validation studies and approved by the technical manager/leader.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first paragraph
- Added sentence requiring internal validation summaries.

Comment

		Yes	No	N/A
8.1.3.1(a)	Has the procedure been tested using known and nonprobative evidence samples?	____	____	_X__
8.1.3.1 (CO-a)	Has the procedure been tested using known samples?	____	____	_X__
8.1.3.1(b)	Has the reproducibility and precision of the procedure been monitored and documented using human DNA control(s)?	____	____	_X__
8.1.3.2 (FO)	Based on empirical data, have match criteria been established and documented?	____	____	_X__
8.1.3.3	Has the analyst or examination team successfully completed a qualifying test using the DNA analysis procedure prior to its incorporation into casework or database applications? (CO8.1.3.2)	____	____	_X__
8.1.3.4	Have material modifications to analytical procedures been documented and subjected to validation testing?	____	____	_X__
8.1.4(FO)	If methods are not specified, does the laboratory, wherever possible, select methods that have been published by reputable technical organizations or in relevant scientific texts or journals or that have been appropriately evaluated for a specific or unique application?	____	____	_X__

Discussion

For laboratory systems that consist of more than one laboratory, each of the laboratories must complete and maintain performance-based validations (e.g., sensitivity and precision), while basic validation studies may be shared among all locations in a laboratory system. The internal validation materials must be documented, summarized, and approved by the technical manager/leader. Summaries of a system's internal validation studies must be available at all sites.

Each new instrument or performance-based software change (including upgrades) requires a performance check. A performance check is an evaluation of a validated procedure existing in the laboratory system to ensure that it conforms to specifications and may include such studies as reproducibility and sensitivity.

However, if acquisition of new equipment leads to a method change (e.g., DNA detection from a gel-based to capillary-based system), internal validation studies must be performed.

A list of the validation studies in compliance with Standard 8.1 will be incorporated by the auditor into the comment section below. The validation studies found to be in compliance with Standard 8.1 after one external audit do not need to be reviewed.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added clarification to validation studies
- Added paragraph requiring performance checks
- Deleted note referencing SWGDAM
- Added paragraph requiring auditors to list validation studies reviewed. When compliant with standard, validation studies need not be reviewed in future audits

Comment

Standard 8.1.3.4 is rated N/A because the lab did not make any material modifications to the procedures.

Standard 8.1.4 is rated N/A because the lab did not create any new methods.

Standard 9: Analytical Procedures

		Yes	No	N/A
9.1	Does the laboratory have and follow written analytical procedures approved by laboratory management/technical manager/leader?	___	_X__	____
9.1.1	Does the laboratory have a documented standard operating protocol for each analytical technique used?	___	_X__	____
9.1.2	Do the analytical procedures describe reagents, sample preparation, extraction, equipment, and controls that are standard for DNA analysis and data interpretation?	_X__	____	____
9.1.3(FO)	Does the laboratory have a procedure for the differential extraction of stains that contain semen?	_X__	____	____

Discussion

To successfully satisfy Standard 9.1, compliance must be demonstrated with all of the subcategories of Standard 9.

Technical protocols for each analytical technology must be approved by the technical manager/leader. This approval must be documented. Technical protocols must be readily available to laboratory personnel and reflect the current practices employed by the laboratory.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording

Comment
Standard 9.1 is marked as 'No' due to 'No' for standard 9.1.1: DNA Database SOP (section 3.5.5.4) and CODIS SOP (section 3.2.1) do not reflect current practices (they still refer to PowerPlex 1.1/2.1 and gels)

		Yes	No	N/A
9.2	Does the laboratory use reagents that are suitable for the methods employed?	_X_	____	____
9.2.1	Does the laboratory have written procedures for documenting commercial supplies and for formulating reagents?	_X__	____	____
9.2.2	Are reagents labeled with the identity of the reagent, the date of preparation or expiration, and the identity of the individual preparing the reagent?	_X__	____	____
9.2.3(a)	Has the laboratory identified and evaluated the reagents critical to the analysis process **prior** to use in casework?	_X__	____	____
9.2.3(b)	Has the laboratory identified and evaluated the following critical reagents:			
	(a) Restriction enzyme	____	____	_X__
	(b) Commercial kits for performing genetic typing	____	____	_X__
	(c) Agarose for analytical RFLP gels	____	____	_X__
	(d) Membranes for Southern blotting	____	____	_X__
	(e) K562 DNA or other human DNA controls	____	____	_X__

(f)	Molecular weight markers used as RFLP sizing standards	___	___	_X__
(g)	Primer sets	_X__	___	___
(h)	Thermostable DNA polymerase	_X__	___	___

Discussion

To successfully satisfy Standard 9.2, compliance must be demonstrated with all of the subcategories of Standard 9.2.

Reagents must be labeled with the identity of the reagent and a tracking mechanism identifying preparation or expiration date and component sources. Records must be maintained that identify the preparer of the reagent and the quality control measures (if any) used to check the reliability of the reagent. The laboratory must identify the reagents critical to the analytical processes used and evaluate each, prior to their use on evidence and convicted offender samples. This list must include, at a minimum, those critical reagents listed in Standard 9.2.3(b). Laboratories must have written procedures detailing the quality control measures in place for evaluating reagents and materials, the acceptable range of results, procedures for acting upon data that are unacceptable, and the mechanisms used for documentation and the subsequent approval/rejection of quality control data. The critical reagents listed in Standard 9.2.3(b) are not applicable universally to all types of DNA methodologies.

Standard 9.2.3(b), part(a), (c), (d), and (f) refer to RFLP-based technology.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first paragraph
- Added reference to convicted offender samples
- Added sentence defining minimum requirements for listing critical reagents
- Replaced last sentence of paragraph with a reference to Standard 9.2.3(b)

Comment

		Yes	No	N/A
9.3(FO)	Does the laboratory have and follow a procedure for evaluating the quantity of human DNA in samples?	_X__	___	___

Discussion

When using PCR-based analysis techniques for nuclear DNA, the presence or absence of detectable human DNA must also be assessed with regard to the unknown evidentiary samples for compliance to Standard 9.3.

A less direct method for estimating or controlling the amount of recovered DNA, such as control of sample size (e.g., size of a hole punch, volume and length of a hair shaft) is an acceptable approach. These methods are suitable for use on known reference samples from casework, database samples, and evidentiary items that are subjected solely to mitochondrial DNA analysis. In such instances, the response to Standard 9.3 would be Not Applicable.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted first sentence in first paragraph
- Added reference to nuclear DNA in first paragraph
- Changed wording in second paragraph
- Deleted last paragraph

Comment

		Yes	No	N/A
9.3.1	Does the laboratory use procedures for establishing the presence of high molecular weight DNA from RFLP casework samples?	____	____	_X__
9.4	Does the laboratory monitor the analytical procedures using appropriate controls and standards? (CO9.3)	_X__	____	____
9.4.1	Does the laboratory use the following controls for RFLP casework analysis? (CO9.3.1)	____	____	_X__
9.4.1.1	Quantitation standards that estimate the amount of DNA recovered by extraction (CO9.3.1.1)	____	____	_X__
9.4.1.2	K562 as a human DNA control (CO9.3.1.2)	____	____	_X__
9.4.1.3	Molecular weight size markers at defined intervals for bracketing known and evidence samples (CO9.3.1.3)	____	____	_X__
9.4.1.4	Procedure to monitor the completeness of restriction enzyme digestion (CO9.3.1.4)	____	____	_X__

Discussion

Standards 9.4.1 through 9.4.1.4 apply to RFLP-based technology.

For database laboratories (convicted offender), pertaining to Standard 9.3.1.3, no more than five lanes may exist between marker lanes. Additionally, regarding Standard 9.3.1.4, these laboratories may monitor the completeness of a restriction enzyme digest through a test gel or other method.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added a standards reference line
- Changed wording
- Deleted reference to database laboratories and autoradiogram/lumigraph assessment methods
- Deleted last sentence of paragraph

Comment

		Yes	No	N/A
9.4.2	Does the laboratory use the following controls for PCR casework or database analysis? (CO9.3.2)	_X__	____	____
9.4.2.1	Quantitation standards that estimate the amount of human nuclear DNA recovered by extraction (CO9.3.2.1)	_X__	____	____
9.4.2.2	Positive and negative amplification controls (CO9.3.2.2)	_X__	____	____
9.4.2.3	Reagent blanks (CO9.3.2.3.1)	_X__	____	____
9.4.2.4	Allelic ladders and/or internal size markers for variable number tandem repeat sequence PCR-based systems (CO9.3.2.4)	_X__	____	____
9.5	Does the laboratory check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material (SRM) or standard traceable to a NIST standard? (CO9.4)	_X_	____	____

Discussion

Standards 9.4.2 through 9.4.2.4 apply to PCR-based technology.

Laboratories have the option of using one sample from the NIST SRM or to create/purchase a NIST traceable standard for the annual check of typing results for each genetic system (e.g., STRs, Y-STRs, mtDNA) used by the laboratory. Laboratories are not required to purchase a NIST SRM kit each year to comply with Standard 9.5. Laboratories may identify controls and run these against the NIST SRM, which in turn makes these controls NIST traceable. For those laboratories that use a bloodstain control, a "lot" is identified as the bloodstain(s) that is tested against the NIST SRM, not the person from whom the blood was drawn. This lot can be used annually to verify the controls and DNA procedures in use by the laboratory.

STANDARD 9.4.2.3 HISTORY Revision 6 Issue Date July 1, 2004
- Deleted "(FO)"
- Added "(CO9.3.2.3.1)"

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004
- Added standards reference paragraph
- Deleted first two paragraphs
- Added new paragraph regarding NIST SRMs

Comment

		Yes	No	N/A
9.6	Does the laboratory have and follow written general guidelines for the interpretation of data? (CO9.5)	_X__	____	____
9.6.1	Does the laboratory verify that all control results are within established tolerance ranges? (CO9.5.1)	_X__	____	____
9.6.2	Where appropriate, are visual matches supported by a numerical match criterion?	____	____	_X__
9.6.3	Has the 1996 National Research Council Report and/or a court-directed method been used for the statistical interpretation of a DNA profile for a given population and/or hypothesis or relatedness and are these calculations derived from an established population database appropriate for the calculation?	_X__	____	____

Discussion

For Standard 9.6.1, laboratories using RFLP-based technology must verify and document that controls fall within established tolerance ranges. For PCR-based technologies, laboratories must verify and document that the types of controls are correct.

Standard 9.6.2 applies to RFLP-based technology.

Standard 9.6.3 does not apply to mitochondrial or Y-STR DNA testing.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004
- Discussion paragraph deleted
- Added new discussion paragraph regarding verification and documentation of controls
- Added two sentences regarding application of Standards 9.6.2 and 9.6.3

Comment

Standard 10: Equipment Calibration and Maintenance

		Yes	No	N/A
10.1	Does the laboratory use equipment that is suitable for the methods employed?	_X__	____	____
10.2	Does the laboratory have a documented program for calibration of equipment and instruments?	____	_X__	____
10.2.1	When available and appropriate, are standards traceable to national or international standards used in the calibration of equipment?	_X__	____	____
10.2.1.1	Where traceability to a national standard of measurement is not applicable, does the laboratory provide satisfactory evidence of correlation of results?	_X__	____	____
10.2.2	For each instrument requiring calibration, has the frequency of calibration been documented and has such documentation been retained in accordance with applicable federal or state law?	____	_X__	____
10.3	Does the laboratory have a documented program to ensure that instruments and equipment are properly maintained?	_X__	____	____
10.3.1	Have new instruments and equipment, or instruments and equipment that have undergone repair or maintenance, been calibrated before being used in casework analysis?	_X__	____	____
10.3.2	Have written records or logs been maintained for maintenance service performed on instruments and equipment and has such documentation been retained in accordance with applicable federal or state law?	_X__	____	____

Discussion

To successfully satisfy Standards 10.2 and 10.3, compliance must be demonstrated with all of the subcategories of both standards.

To successfully satisfy the requirements listed in Standard 10.2, the laboratory's documentation must include the identification of all critical equipment and instruments that require calibration. The laboratory's documentation must include the schedules for and records of all calibrations for the critical equipment and instruments. Critical equipment or instruments are those requiring calibration prior to use and periodically thereafter when the accurate calibration of that instrument directly affects the results of the analysis. Critical equipment, calibration, and traceability are defined at the beginning of this document. Standard 10.3.1 does not apply to instruments and equipment that cannot be calibrated by laboratory personnel (e.g. fluorescence based detection instruments).

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first paragraph.
- Changed wording in second paragraph and defined requirements for equipment calibration.
- Added sentence regarding application of Standard 10.3.1.

Comment

Standard 10.2 is marked as 'No' due to 'No' for Standard 10.2.2.: Per SBI QA manual section 8.9.4: Calibration of thermalcyclers will be calibrated by an external agency twice a year; this was due in April, but was not completed.

Standard 11: Reports

		Yes	No	N/A
11.1(FO)	Does the laboratory have and follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory reports?	_X__	____	____
11.1(CO)	Does the laboratory have and follow written procedures for generating and maintaining documentation for database samples?	_X__	____	____
11.1.1(FO)	Does the laboratory maintain in a case record all documentation generated by examiners related to case analyses?	_X__	____	____
11.1.1(CO)	Does the laboratory have written procedures for the release of database sample information?	_X__	____	____

Discussion

The release of database sample information in Standard 11.1.1(CO) is specifically limited to database applications and does not apply to forensic (anonymous) population databases that are used by caseworking laboratories to estimate allele frequency information.

Laboratory case records may be in hard copy, electronic files, or a combination of both formats.

Materials contained in case records must demonstrate compliance with this standard.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added sentence defining formats for case records
- Added sentence requiring materials in case records to be in compliance with standard

Comment

		Yes	No	N/A
11.1.2(FO)	Do the laboratory reports include the following criteria:			
	(a) Case identifier	_X__	____	____
	(b) Description of evidence examined	_X__	____	____
	(c) Description of methodology	_X__	____	____
	(d) Locus	_X__	____	____
	(e) Results and/or conclusions	_X__	____	____
	(f) Interpretative statement (either quantitative or qualitative)	_X__	____	____
	(g) Date issued	_X__	____	____
	(h) Disposition of evidence	_X__	____	____
	(i) Signature and title or equivalent identification of the person(s) accepting responsibility for the content of the report	_X__	____	____
11.1.3(FO)	Does the laboratory have written procedures for the release of case report information?	_X__	____	____

Discussion

The laboratory must generate sufficient documentation for each technical analysis to support the reported conclusions such that in the absence of the examiner/analyst who directed the analysis, another qualified individual could evaluate and interpret the resulting data.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Replaced "assay" with "analysis"

Comment

Standard 12: Review

		Yes	No	N/A
12.1(FO)	Does the laboratory conduct administrative and technical reviews of all case files and reports to ensure conclusions and supporting data are reasonable and in the constraints of scientific knowledge?	_X__	____	____
12.1(CO)	Does the laboratory have and follow written procedures for reviewing database sample information, results, and matches?	_X__	____	____
12.1.1	Does the laboratory have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewers?	_X__	____	____

Discussion

The laboratory must have written procedures defining the elements associated with both administrative and technical reviews. The laboratory must define the qualifications and responsibilities of the administrative reviewer and technical reviewer. The administrative reviewer is not required to be a current or former qualified DNA examiner/analyst.

All individuals who perform technical reviews on DNA casework must have been previously qualified in the specific DNA technology that the review is encompassing. The laboratory must demonstrate that the technical reviewer has a basis of knowledge that will allow him/her to ensure the conclusions and supporting data are reasonable and within the constraints of scientific acceptance. The laboratory must describe the documentation method used for demonstrating completion of each review, as well as a procedure that defines the course of action necessary in the event of an unresolved discrepancy. This applies to both forensic casework as well as database laboratories.

To comply with Standard 12.1(CO) laboratories must demonstrate 100 percent review of database samples. A National DNA Index System-approved and internally validated expert system can be used to interpret and review.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Deleted "frequency" and "required" from first paragraph and changed wording
- Added paragraph requiring 100 percent database review for compliance with Standard 12.1(CO) and approval for use of expert systems to interpret and review

Comment

		Yes	No	N/A
12.2	Does the laboratory have and follow a written program that documents the annual monitoring of the testimony of each examiner?	_X__	____	____
12.2(CO)	Does the laboratory have and follow a written program that documents the annual monitoring of the testimony of laboratory personnel?	_X__	____	____

Discussion

In forensic DNA and convicted offender database laboratories, the testimony of individuals who provide expert witness testimony as part of their current positions must be monitored at least once annually. Several methods of monitoring are possible, and laboratories may select an appropriate approach. Laboratories must define the elements and standardize the method for capturing information necessary to review an individual's testimony. Supervisors must review the testimony monitoring results with each individual, serving to identify areas of strengths and weaknesses. The laboratory must provide clear documentation identifying individuals who did not testify over the course of the year.

Comment

Standard 13: Proficiency Testing

		Yes	No	N/A
13.1	Do examiners and other personnel designated by the technical manager/leader who are actively engaged in DNA analysis undergo open external proficiency tests at regular intervals not to exceed 180 days?	_X__	____	____

Discussion

All technical personnel who participate in DNA analysis (casework or convicted offender) must undergo two external proficiency tests per year. One test must be performed in the first six months of the calendar year and the second in the last six months of the calendar year. The interval between consecutive tests must be at least four months and not to exceed eight months. The laboratory must define and consistently use the date that the proficiency test is performed as the received date, submitted date, or the due date. An external proficiency test is defined as a test provided by a second agency. An external proficiency test provider must demonstrate compliance with the proficiency testing manufacturing guidelines established by the Technical Working Group on DNA Analysis Methods and American Society of Crime Laboratory Directors/Laboratory Accreditation Board (*Guidelines for DNA Proficiency Test Manufacturing and Reporting*, Technical Working Group on DNA Analysis Methods Quality Assurance Subcommittee and American Society of Crime Laboratory Directors/Laboratory Accreditation Board DNA Proficiency Review Committee Volume 21, Number 2, April 1994). Alternatively, the external proficiency test provider must demonstrate compliance with the International Standards Organization Guide 43.

The test results from each participant in the laboratory must be returned to the provider by the specified due date to ensure incorporation into the provider's external summary report. All external proficiency tests must have defined due dates for the return of testing information to the test provider. Regardless of whether the test provider is one who provides an external summary report or not, the laboratory must not have access to the proficiency test results until all participants have completed the test.

Newly qualified technical personnel must enter into the external proficiency testing program within six months of the date of qualification.

Technical personnel must be externally proficiency tested on an annual basis in each DNA technology (RFLP, PM/DQA1, STRs, mtDNA) to the full extent in which they perform casework examinations. Each qualified analyst must be assigned and complete his/her own proficiency test set. The laboratory must handle proficiency test samples in the same manner as their casework or database samples. Laboratories that routinely employ a team approach for conducting DNA examinations (such as several technicians, each performing a separate, dedicated aspect of the DNA process on evidentiary materials) may likewise employ a team approach for performing proficiency tests. However, all technical personnel must be proficiency tested in **each** aspect of the DNA process in which they performed DNA testing over the course of a year.

Individuals who perform both RFLP- and PCR-based analyses in casework or database applications must be externally proficiency tested for each method. One test may include only RFLP analysis with a second test that is limited to PCR analysis. This does not preclude the possibility that both technologies (RFLP and PCR) may be administered on a single proficiency test. In either case, the two external tests per year are required.

Individuals who perform multiple PCR testing methodologies (e.g., PM/DQA1, STR, mtDNA) in casework or database applications must be externally proficiency tested for each method. This does not preclude the possibility that all PCR methodologies may be administered on a single proficiency test. As stated previously, two external tests per year are required.

There are no proficiency test requirements for individuals who function solely as the technical manager/leader or the CODIS manager.

The laboratory's proficiency testing program must include testing for all genetic loci used by the laboratory in casework and database applications. For example, laboratories that conduct STR analysis at 13 genetic loci must include characterizations (or attempts at characterization) for all 13 genetic loci.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added clarification to the time interval between proficiency tests
- Added a statement requiring a defined and consistent date that a proficiency test is performed
- Changed wording that requires new technical personnel to be proficiency tested within six months after being qualified
- Changed wording that requires technical personnel to be proficiency tested annually
- Added statements that further clarify the handling of proficiency test samples in accordance with casework/database samples
- Deleted "180 day(s)"

Comment

			Yes	No	N/A
13.1.1	Does the laboratory maintain the following records for proficiency tests and is such documentation retained in accordance with applicable federal or state law?				
	(a)	Test set identifier	_X__	____	____
	(b)	Identity of the examiner	_X__	____	____
	(c)	Date of analysis and completion	_X__	____	____
	(d)	Copies of all data and notes supporting the conclusions	_X__	____	____
	(e)	Proficiency test results	_X__	____	____
	(f)	Any discrepancies noted	_X__	____	____
	(g)	Corrective action taken	_X__	____	____

		Yes	No	N/A
13.1.2	Has the laboratory established at a minimum the following criteria for evaluating proficiency tests:			
	(a) All reported inclusions are correct or incorrect.	_X__	____	____
	(b) All reported exclusions are correct or incorrect.	_X__	____	____
	(c) All reported genotypes and/or phenotypes are correct or incorrect according to consensus genotypes/phenotypes or within established empirically determined ranges.	_X__	____	____
	(d) All results reported as inconclusive or uninterpretable are consistent with written laboratory guidelines. The basis for inconclusive interpretations in proficiency tests must be documented.	_X__	____	____
	(e) All discrepancies/errors and subsequent corrective actions must be documented.	_X__	____	____

(f) All final reports are graded as satisfactory or unsatisfactory. A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data. Administrative errors shall be documented and corrective actions taken to minimize the error in the future.	_X__	____	____
(g) All proficiency test participants shall be informed of the final test results.	_X__	____	____

Discussion

The laboratory must have and use a documented program for evaluating proficiency testing data as listed in Standard 13. This must include documentation (such as a summary report) that addresses the evaluation of all participants. Additionally, such evaluations should identify any levels of administrative, analytical, or systemic errors and define what (if any) corresponding corrective actions are necessary. Such evaluations must be available to the participants.

Comment

Standard 14: Corrective Action

		Yes	No	N/A
14.1	Does the laboratory have and follow written procedures for taking corrective action whenever proficiency testing discrepancies and/or casework errors are detected?	_X__	____	____
14.1(CO)	Does the laboratory have and follow written procedures for taking corrective action whenever proficiency testing discrepancies and/or analytical errors are detected?	_X__	____	____
14.1.1	Does the laboratory maintain documentation for corrective actions and is such documentation retained in accordance with applicable federal or state law?	_X__	____	____

Discussion

The elements listed for Standard 14 may be assessed through a review of existing laboratory documentation.

Comment

Standard 15: Audits

			Yes	No	N/A
15.1	Are audits of the laboratory completed and documented annually?		_X_	____	____
15.1.1	Did the audit procedures address the following:				
	(a)	Quality assurance program	_X_	____	____
	(b)	Organization and management	_X_	____	____
	(c)	Personnel	_X_	____	____
	(d)	Facilities	_X_	____	____
	(e)	Evidence control	_X_	____	____
	(f)	Validation	_X_	____	____
	(g)	Analytical procedures	_X_	____	____
	(h)	Calibration and maintenance	_X_	____	____
	(i)	Proficiency testing	_X_	____	____
	(j)	Corrective action	_X_	____	____
	(k)	Reports	_X_	____	____
	(l)	Review	_X_	____	____
	(m)	Safety	_X_	____	____
	(n)	Previous audits	_X_	____	____
15.1.2	Has the laboratory retained all documentation pertaining to audits in accordance with relevant legal, agency, and state requirements?		_X_	____	____
15.2	Did a second agency (external) participate in an annual audit of the laboratory at least once every two years?		_X_	____	____

Discussion

The DNA laboratory must be audited annually. Every other year a qualified auditor from an external agency must conduct the audit. At least one participant of the external auditing team must be or have been a previously qualified analyst in the specific DNA technology (e.g., STRs, mtDNA) in which the external audit is encompassing. A qualified auditor is an individual who has successfully completed the DNA Auditing Workshop sponsored by the FBI. At least one participant in an internal audit must be a qualified DNA analyst or technical manager/leader. One of the individuals must be a qualified auditor.

Audits must be conducted once per calendar year, with the interval between audit dates not less than six months and not exceeding 18 months.

After the audit is completed, the auditor briefs DNA laboratory management regarding the results. This briefing should detail specific areas of findings (noncompliance), observations (general comments and/or recommendations), as well as recognitions of commendable performances.

A written report should be prepared within 30 days of an audit. The audit report consists of the completed checklist, with any areas of noncompliance listed under the findings section of Appendix A. All findings must be clearly identified and referenced to the appropriate standard. Recommendations must not be

included in the audit document. The laboratory must ensure that an adequate response has been generated with regard to all findings, detailing any incorporated corrective actions if appropriate within the response section of Appendix A. Prior audit reports must be available to auditors as a measure of the laboratory's response to previous findings. It is critical that findings identified in a previous audit report are thoroughly addressed and resolved (if possible) within the DNA laboratory's capabilities. **To fulfill the requirements associated with Standard 15.2, the laboratory must show evidence of an adequate response to all findings detailed in the previous audit.** A laboratory's written course of action or response to the findings in an audit report (document) should be maintained as part of the audit report (document).

The audit process criteria listed in Standard 15.1.1 must also include an evaluation of the laboratory's practices that relate to individual qualifications, training, continuing education, and court testimony.

Note: National DNA Index System participating laboratories must refer to the National DNA Index System - Laboratory Audits and External Proficiency Testing Operational Procedures.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Changed wording in first paragraph
- Added statements for qualification requirements of members of the external audit team
- Added wording to define a time frame of 30 days after the audit for the written report to be prepared
- Added sentence requiring that recommendations must not be included in the audit document
- Added note for National DNA Index System participating laboratories

Comment

Standard 16: Safety

		Yes	No	N/A
16.1	Does the laboratory have and follow a documented environmental health and safety program?	_X__	____	____

Discussion

All information addressing environmental health and safety must be current and available to laboratory staff. At a minimum, the laboratory must have bloodborne pathogen and chemical hygiene plans. This information must be updated to reflect changes in a technical procedure (e.g., radioisotopes) or the remodeling of laboratory space (e.g., changed evacuation plans) that may have an effect on the laboratory's environmental health and safety program. To fulfill the requirements associated with Standard 16.1, the laboratory must provide documentation that its environmental health and safety program has been reviewed to ensure that all practices are appropriate and contemporary.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added sentence requiring bloodborne pathogen and chemical hygiene plans

Comment

Standard 17: Subcontractors of Analytical Testing for Which Validated Procedures Exist

		Yes	No	N/A
17.1	Does the laboratory require certification of compliance with these standards when a subcontractor performs forensic DNA analyses for the laboratory?	_X__	____	____
17.1.1	Has the laboratory established and does the laboratory use appropriate review procedures to verify the integrity of the data received from the subcontractor?	_X__	____	____
17.1.1(CO)	Has the laboratory established and used review procedures that include but are not limited to each of the following:			
	(a) Random reanalysis of samples	_X__	____	____
	(b) Visual inspection and evaluation of results/data	_X__	____	____
	(c) Inclusion of quality control samples	_X__	____	____
	(d) On-site visits	_X__	____	____

Discussion

A subcontractor, as a forensic DNA laboratory or a convicted offender laboratory, must demonstrate compliance with Standard 17.1 by undergoing an audit with respect to the elements listed in this document. Compliance with Standard 17 is required if the forensic or convicted offender laboratory pays for a subcontractor to perform analysis using analytical methods currently employed by the forensic or convicted offender laboratory or the laboratory enters into an agreement (direct or indirect) with another laboratory for forensic DNA testing (e.g., criminal casework, paternity testing in criminal matters, convicted offender/database testing), in which the forensic or convicted offender laboratory will maintain "ownership" of the case. The forensic or convicted offender laboratory is said to maintain "ownership" and must comply with Standard 17.1.1, if any of the following criteria are applicable:

(a) The forensic/convicted offender laboratory will use any samples, extracts, or any materials from the subcontractor for the purposes of forensic testing (i.e., a subcontractor prepares an extract that will be analyzed by the forensic/database laboratory).

(b) The forensic/convicted offender laboratory will interpret the data generated by the subcontractor.

(c) The forensic/convicted offender laboratory will issue a report on the results of the analysis.

(d) The forensic/convicted offender laboratory will enter a DNA profile into CODIS from data generated by the subcontractor.

To minimize the redundancy of multiple audits (each requiring the same quality assurance elements as listed in this document) of the same subcontractor over the course of the year, contracting laboratories may elect to accept the audit documentation generated from an external audit conducted on the subcontractor laboratory. The audit documentation must include the audit checklist, audit report, and the subcontractors' responses, and/or follow-up actions to any findings detailed in the report. Such documentation or copies must be retained by the contracting laboratory. It is noted that an on-site visit is different from an external audit.

To minimize the redundancy of multiple on-site visits to the subcontracting laboratory (CO17.1.1[d]), contracting laboratories may elect to accept information/documentation generated from an on-site visit conducted on the subcontracting laboratory by a National Institute of Justice/Federal Bureau of Investigation-sponsored laboratory assessment team or public laboratory with similar analysis/contract criteria.

On-site visits (CO17.1.1[d]), if conducted following the external audit on database laboratories or as a component of the review process on a forensic DNA laboratory (FO Standard 17.1.1), should include a reevaluation of any findings detected during the audit. A minimum of one on-site visit is required per contract period.

All reviews associated with the criteria listed in Standard 17.1.1 (a-d) must be sufficient to thoroughly assess the integrity of the subcontractor's data. A National DNA Index System-approved and internally validated expert system can be used to interpret and review data.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added statements clarifying a subcontractor's compliance with Standard 17
- Added a list of criteria that defines a forensic/convicted offender laboratory maintaining ownership of a case
- Changed wording in second paragraph
- Added paragraph giving direction on minimizing redundancy of multiple on-site visits to subcontracting laboratories
- Added a sentence requiring one on-site visit minimum per contract period
- Deleted last sentence of second paragraph
- Added sentence approving the use of expert systems for data interpretation and review

Comment
The Database section subcontracts convicted offender samples to LabCorp and to Bode Technologies. No casework was subcontracted since the previous audit.

Appendix A: Findings and Responses

Note: Auditors should reference any standard found to be in noncompliance in the findings section below. Directly under the standard, describe the finding of noncompliance in terms of the standard. Recommendations must not be included in the audit document.

DISCUSSION HISTORY Revision 6 Issue Date July 1, 2004

- Added note to auditors regarding noncompliant standards

Findings

Standard 10.2 is marked as 'No' due to 'No' for Standard 10.2.2.: Per SBI QA manual section 8.9.4: Calibration of thermalcyclers will be calibrated by an external agency twice a year; this was due in April, but was not completed.

Standard 9.1 is marked as 'No' due to 'No' for Standard 9.1.1: DNA Database SOP (section 3.5.5.4) and CODIS SOP (section 3.2.1) do not reflect current practices (they still refer to PowerPlex 1.1/2.1 and gels)

Responses

Responses to Findings:

Standard 10.2 and 10.2.2
The requirement for biannual testing by an external vendor was deleted. I have enclosed Revision 10, page 40 of 59, which contains the reason for the finding (highlighted) and a portion of Revision 11, page 40 of 59, which has been approved and no longer has this requirement.

Standard 9.1 and 9.1.1
The reference to gel scans and Powerplex (3.5.5.4) was deleted. I have enclosed Revision 3, page 5 of 15, which contains the reason for the finding (highlighted) and a portion of Revision 4, page 5 of 14, which has been approved and no longer has this reference.

The reference to gel information (3.2.1) was deleted. I have enclosed Revision 6, page 6, which contains the reason for the finding (highlighted) and a portion of Revision 7, page 6, which has been approved and no longer has this reference.

microscopes).

8.7.3 Other equipment will be maintained by external vendors (i.e. water systems).

8.7.4 Each calibration log will clearly show the calibration source used and the frequency of calibration.

8.8 Equipment Needing Calibration: The equipment listed below shall be calibrated prior to coming online for use in the Section.

8.8.1 Balances: The electronic top loading and analytical balances are cleaned, calibrated, and serviced biannually by a contract vendor.

Balances also undergo a weight check monthly by designated analysts in each unit.

8.8.2 Pipettors: Pipettors will be calibrated biannually by a contract vendor.

8.8.3 Biological Safety Cabinets: Biological safety cabinets will be inspected and certified annually by a contract vendor.

8.8.4 Digital Thermometer, Probe and Meter: The thermal probe and meter used to monitor the thermocyclers will be calibrated yearly by an outside calibration laboratory.

8.8.5 Thermometers: Thermometers will either be factory calibrated using a NIST standard, verified yearly against a NIST-certified thermometer or verified yearly against a 0° C ice bath.

8.8.6 Waterbaths, heat blocks, and glass bead sterilizers: These instruments will undergo a calibration check be calibrated yearly against a NIST traceable thermometer.

8.8.7 NIST Thermometer: Will be calibrated yearly against a 0° C ice bath.

8.9 Equipment Needing Service/Preventative Maintenance

8.9.1 Chemical Fume Hoods: Chemical fume hoods will be inspected and have their face velocity checked annually.

8.9.2 Water System: At approximate 6 month intervals, a contract vendor will sanitize the units and change the cartridges and inspect the unit.

8.9.3 Microscopes: Microscopes are serviced annually by a contracted vendor.

8.9.4 Thermocyclers: Thermocyclers will be tested biannually by an external vendor and quarterly in-house for block temperature uniformity and for temperature verification quarterly or when concerns about performance occur.

8.9.5 3100 Genetic Analyzers (or equivalent): These instruments will be repaired or serviced as needed by the manufacturer.

8.9.6 7000 Sequence Detection Systems: The instruments will be repaired as needed by the manufacturer and serviced semiannually.

8.10 QC Requirements for Equipment Following Repairs or Preventative Maintenance

Before instruments can be used for analysis following repairs or preventative maintenance, the following instruments required Calibration checks.

8.10.1 Thermocyclers: Prepare, amplify, and separate positive control (9947A) and a negative reagent blank. The positive control must give the appropriate allelic values and the negative reagent blank must not show activity over the 75 RFU threshold.

8.10.2 3100/3130XL Genetic Analyzers (or equivalent): Prepare and run at least one amplified positive control (9947A) and a negative reagent blank. The positive control must give the appropriate allelic values and the negative reagent blank must not show activity over the 75 RFU threshold.

8.10.3 7000: Prepare and run duplicate standard dilutions. Standard Curve values should fall within the guidelines for use. The NTC should not show activity.

8.11 Instruments Out of Service: Any instrument that fails a calibration test, calibration verification, or is not working properly and cannot be repaired immediately, must be tagged with a label that states that it is out of service. This label must be readily apparent. If possible, the instrument should be moved to a location that it will not be used until repaired.

NCSBI Forensic Biology Section

Quality Assurance Manual

Approved by:

SAC, Michael J. Budzynski — Date: 12/7/07

Assistant Director, Jerry Richardson — Date: 12/7/07

DNA Technical Leader, David Freeman — Date: 12/7/07

Body Fluid Technical Leader, Jenny Elwell — Date: 12/7/07

8.9.3 Microscopes: Microscopes are serviced annually by a contracted vendor.

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Revision History		
Effective Date	Revision Number	Reason
Unknown	00	Original Document
April, 26, 1999	01	Manual Update
October 10, 2000	02	Manual Update
December 4, 2002	03	Procedure Update
March 1, 2003	04	Update to clarify Technicians training and responsibilities.
August 7, 2003	05	1) Update Evidence Handling Procedure to clarify when a) gloves should be changed during Body Fluid Identification and b) lab coats should or should not be worn; 2) Procedure change in the transfer of evidence to Trace Evidence; 3) Directions for Technical and Administrative Reviews added
November 17, 2003	06	1) Addition of Balance Limits and clarification of Placing Un-calibrated pipets out of service. 2) Replace "Molecular Genetics" with "Forensic Biology" due to Section name change. 3) Remove requirements for advanced course work for DNA Caseworking Analyst.
May 6, 2004	07	Addendum to STR Interpretation Guidelines to include Capillary Electrophoresis data.
December 23, 2004	08	1) Creation of Technical Leader for Body Fluids Section; 2) Change Molecular Genetics to Forensic Biology; 3) Incorporation of capillary electrophoresis and RT-PCR; 4) Taking out some duplicated policies; 5) Take out commentary portions of the manual;6) Revising proficiency testing section so that it refers to the federal standards; 7) Procedure change in hair transfer to Trace evidence; 8) Take out prohibition statement on outsourcing of casework; 9) change educational requirements of database analysts 10) Added "Procedure for Completion of Quality System Documents" and "Document Control Procedure in Appendices; 11) Updated Section 15
December 09, 2005	09	1) Added statement about labeling equipment that is not in use Section 8.9 2) Added statement in Section 12 that the

		Technical Reviewer could not be signed off until substantial changes were made and that the Administrative Reviewer could not approve case in LIMS unless personally observed that all changes had been made and that the Administrative Reviewer could not be same individual that performed the Technical Review.
January 30, 2007	10	Section 2: Rearranged Sections pertaining to specific duties; Section 2: Updated Technical Leader duties for DNA and Body Fluid; Section 3.4.8: removed large section regarding Interns; Section 5.4.2: Added statement clarifying procedure with cases containing hair evidence; Section 7.3: Updated Section on DNA controls; Section 7.4.11: Addition of QC Requirements for TE and Stain Extraction Buffer; Section 12: Added requirement for Technical Reviewer and Administrative Reviewers.
December 7, 2007	11	Section 8.9.4: Removed requirements for biannual external vendor testing.

3.5 ANALYSIS OF BLOODSTAINS TO DEVELOP DNA PROFILES

3.5.1 Samples will be processed using only approved technical procedures.

3.5.2 All lab notes and files will be kept in the DNA Database Unit files.

3.5.3 All gel scans will be closely checked by analysts before determining the genotype.

3.5.4 All STR results will be double read, and the DNA Database Manager and/or DNA Database Analyst II's will be the second reader at the time of CODIS entry and will upload the profiles to state and National Index.

3.5.5 Batch Samples

3.5.5.1 The Database Unit will processes samples in a batch format.

3.5.5.2 For example, 91 convicted offender samples are simultaneously extracted and amplified in a single 96 will format. One well is a negative extraction control and the other 4 wells are used for positive and negative amplification controls.

3.5.5.3 The current practice is to assign a batch number to this work which is represented by the year followed by a sequential number (i.e. 01-14)

3.5.5.4 Gel scans originating from a batch run will be given an identifier traceable to the root batch number. It typically takes 5 gels to run all samples on PowerPlex 1.1 and 5 gels to run all samples on PowerPlex 2.1. Gels and their associated runs are identified as (01-1-14A through 01-1-14E and as 01-2-14A through 01-2-14E. The first two digits refer to the year, the next digit denotes the particular PowerPlex 1 or 2 run, the next two digits denote the root batch number, and the final letter denotes the sequential gel identifier.

3.5.5.5 All sample, positive controls, and negative controls

are extracted and amplified simultaneously and are from one batch. The positive controls and negative controls are run on every gel. However, if one positive or negative control does not run on the gel as expected, the analyst does not have to re-run all the convicted offender samples, provided it is documented on other gels that the negative control or positive controls are correct.

4 LINES OF AUTHORITY AND RESPONSIBILITIES FOR INFORMATION AND SAMPLES IN THE DNA DATABANK AND DATABASE

4.1 The DNA Database Unit is one of the functional units in the Forensic Biology Section. The Forensic Biology Section is headed by a Special Agent In Charge.

4.2 The DNA Database Unit is composed of a Unit Manager and analysts.

4.3 The CODIS Manager is responsible for the day to day operations and security of the CODIS system. The designated CODIS manager may or may not be the DNA Database Unit Manager. He is assisted by DNA Database Analyst and team leader of the DNA Analysis Unit.

4.4 DNA Database Analysts have full authority to receive, run, and analyze the samples from convicted offenders received in the Database Unit. The only restrictions placed on this authority is to resolve problems with the samples received (this responsibility lies with the Unit Manager, but may be delegated to analysts) and to destroy samples received in error.

4.5 The DNA Database Unit Manager is responsible for the day to day operations of the unit and the time reports of all analysts within the unit. The Database Unit Manager is responsible for supervising the quality of the work entered into the local database, and for seeing that the Database Unit follows all quality assurance procedures found in the DNA Quality Assurance Manual. Work performance evaluations on analysts under the supervision of the DNA Database Unit Manager will be conducted by the DNA Database Unit Manager. The Database Unit Manager is also responsible for:

4.5.1 Maintaining the inventory of supplies within the Database Unit.

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Revision History		
Effective Date	Revision Number	Reason
Unknown	00	Original Document
November 26, 2002	01	Procedure Update; Insertion of Outline; Page Number Change; Add Rev. # in Header
December 30, 2004	02	Change in Section name in the header, lines of authority, match confirmation guidelines, use of Match Manager, page numbers
December 30, 2005	03	Changing of "gel scan" to "electropherogram." Changing of "gel electrophoresis" to "capillary electrophoresis." Removal of all information pertaining to the stain room.
December 7, 2007	04	Section 3.5.5.4 was removed

Revision 03 Approval Signature	Date
Name/Title Michael J. Budzynski / SAC	12/7/07
(Signature) Michael J. Budzynski	
Name/Title David Freeman / DNA Tech. Leader	12/7/07
(Signature)	
Name/Title	
(Signature)	

Elimination - A known sample from an individual known not to be a suspect in a case. Examples include, consensual sex partners (boyfriends or husbands), a witness who was injured at a scene, officers who may have inadvertently left DNA on evidence, etc. Elimination profiles WILL NOT be entered into any CODIS Index.

Convicted Offender - A sample from an individual CONVICTED of a felony in North Carolina that is specifically authorized by North Carolina General Statute §15A - 266. Convicted Offender profiles will be entered into SDIS and NDIS.

Employee - A sample from an employee of the North Carolina State Bureau Of Investigation. Employee profiles will only be entered into SDIS.

Mass Screening Samples - Samples submitted from known individuals that have been obtained by police DNA dragnets in an effort to solve a crime. The donors of these samples have not been listed as suspects on the SBI-5 form. Samples not listed on the evidence submission form as suspects (like in mass screening cases), will not be uploaded to any Index of CODIS.

Victim - A known sample from an individual identified as a victim on the evidence submission form (SBI-5) by the submitting officer. Victim profiles will not be uploaded to any CODIS Index.

Missing Persons - The known reference sample from and individual that is missing. The source of the DNA has been verified as originating from the missing person.

Unidentified Person - Samples obtained from human remains (i.e. body parts, bones and tissues) where the identity of the person is not known.

3.2 CODIS Identification Number

3.2.1 A standardized format for entering specimen and gel information into CODIS has been devised.

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Revision History

Effective Date	Revision Number	Reason
Dec. 14, 2000	-----	Draft
Dec. 28, 2000	00	Original Document
April 26, 2001	01	Section 3.10 - Expungement of Profiles added
September 13, 2001	02	Procedure Update
November 26, 2002	03	Update Page Numbers and Header. Add Revision # to Header. Procedure Update.
December 30, 2004	04	Updated Section name, deleted language re. target batch files, added search procedure, updated to include GDIS, updated backup procedure, updated new sample retention procedure, included new law in Appendix B
December 8, 2005	05	Casework Hit and Match Manager was rescinded from the DNA Database Unit: CODIS Search, Sample Entry Into Target Batch File and Match Manager Procedure Manual and placed into Section 3: Profile Managment of this document.
June 21, 2006	06	LDAS terminology deleted,, Added missing person and unidentified human remains under definitions for profile management, deleted population category from definitions, changed male/female fraction terminology to sperm/non-sperm fraction, other minor terminology changes, deleted obsolete practices,

June 21, 2006	06	changed sample retention from freezer to cabinet, updated DNA sample submission form in Appendix A, DNA Profile Removal Request form altered in Appendix A, added D2 and D19 to DNA search request form in Appendix A, Updated Appendix B
December 7, 2007	07	Deleted reference to "gel" in 3.1

Approval Signature	Date
Name/Title Michael Budzynski / SAC	12/12/07
(Signature)	
Name/Title David Fagan / DNA Tech Leader	12/7/07
(Signature)	
Name/Title	
(Signature)	

U.S. Department of Justice

Federal Bureau of Investigation

Washington, D. C. 20535-0001

December 21, 2007

Michael J. Budzynski
NCSBI Crime Laboratory
3320 Garner Road
Raleigh, North Carolina 27626-0500

Dear Mr. Budzynski:

This is to acknowledge receipt of your DNA Quality Assurance Standards (QAS) Audit Report for the North Carolina State Bureau of Investigation, Raleigh, North Carolina dated October 16 to 17, 2007, for the 2007 external audit. As you are aware, participation in the National DNA Index System (NDIS) requires an external audit bi-yearly. Copies of the audit report will be submitted to an audit committee for review. Upon completion of this review, the committee's copies of the audit documents will be destroyed by the FBI. The original will be returned to you.

For tracking purposes, the audit has been assigned number 2007111. Please refer to this number if you have any inquiries concerning this particular audit document.

Thank you for your assistance in this matter. If you have any questions, please call me at (703) 632-8315.

Sincerely,

Douglas R. Hares

Douglas R. Hares, PhD
NDIS Custodian
CODIS Unit
Laboratory Division

1 - Mr. Chris Parker (information only)