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:	December 3-5, 2001	
Auditor(s):	R. Elizabeth Bush	R. Elizabeth Bush
	(Name)	(Signature)
	Karen Curtis Ambrozy	Karen Curtis Ambrozy
	(Name)	(Signature)
	(Name)	(Signature)

Audit of the North Carolina State Bureau of Investigation-Molecular Genetics Section

Table of Contents

INTRODUCTION 3

REFERENCES 5

DEFINITIONS 6

STANDARD 3 - QUALITY ASSURANCE PROGRAM 9

STANDARD 4 - ORGANIZATION AND MANAGEMENT 11

STANDARD 5 - PERSONNEL 13

STANDARD 6 - FACILITIES 22

STANDARD 7 - EVIDENCE OR SAMPLE CONTROL 24

STANDARD 8 - VALIDATION 26

STANDARD 9 - ANALYTICAL PROCEDURES 29

STANDARD 10 - EQUIPMENT CALIBRATION AND MAINTENANCE 34

STANDARD 11 - REPORTS 35

STANDARD 12 - REVIEW 37

STANDARD 13 - PROFICIENCY TESTING 39

STANDARD 14 - CORRECTIVE ACTION 42

STANDARD 15 - AUDITS 43

STANDARD 16 - SAFETY 45

STANDARD 17 -SUBCONTRACTORS OF ANALYTICAL TESTING FOR WHICH VALIDATED PROCEDURES EXIST 46

Appendix A: FINDINGS AND RESPONSES 47

QUALITY ASSURANCE AUDIT DOCUMENT

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 (DAB), first convened in 1995. An early mission of the DAB 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 as well. The DAB 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 which 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 (NDIS) 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 within the forensic science community. The lack of a defined, uniform interpretation guide for such standards has presented a potential problem between laboratories and auditors attempting to determine levels of compliance. In an effort to satisfy the responsibilities assigned through the DNA Identification Act 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 multiple forensic DNA laboratories over the past year to assist in the document's design. This has included a collaboration with members from two (2) prominent international inspection/accreditation entities, the American Society of Crime Laboratory Directors/ Laboratory Accreditation Board (ASCLD/LAB) and the National Forensic Science Technology Center (NFSTC). 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 which 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 such 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 underlined 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 which 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.

REFERENCES

American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD/LAB), *ASCLD/LAB Accreditation Manual,* 1999.

Federal Bureau of Investigation, *Quality Assurance Standards for Forensic DNA Testing Laboratories,* (1998)

Federal Bureau of Investigation, *Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories,* (1999)

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

Technical Working Group on DNA Analysis Methods, "Guidelines for a Quality Assurance Program for DNA Analysis," *Crime Laboratory Digest,* April 1995, Volume 22, Number 2, pp. 21-43.

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

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

(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) is an individual who 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 in which forensic DNA testing and/or convicted offender DNA testing is performed or a government facility which 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 individual(s) 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 which 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 which 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 which 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 which 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 which performs DNA identification analysis.

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

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

(ii) Technical manager or 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 within 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) 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 is generally directed to the quality manual and standard operating procedures used by the laboratory. 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.

Comment:

3.1.1	Does the quality manual address (at a minimum) the following:	**Yes**	**No**	**N/A**
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 which deal with subject areas that are defined through laboratory-wide policies or procedures (such as evidence control, safety, etc.) may be located in documents which are separate from the quality manual; however, such information should be referenced within the quality manual. If such sections have been supplemented by DNA laboratory-specific practices, the quality manual must likewise reflect such additions.

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

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, organizational charts, etc. Evidence of noncompliance with this standard would be a finding (Standard 15 - Audits) attributable to the lack of necessary authority and/or resources.

Comment:

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

Discussion:

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

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? (CO 4.1 c)	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 various members of the laboratory with their specific position assignments (technical manager or leader, CODIS manager, etc.). 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).

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 standards 5.1, 5.2, 5.3 and 5.4 and all of their subcategories.

Comment:

		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, augmented, if necessary, by other documentation, to include responsibilities, duties and skills, are acceptable.

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 emphasize and teach the skills and knowledge required to achieve the minimum standards of competence and good laboratory practice within a specific area of work (see note below).

The laboratory must have both a documented training program available for review (such as a training manual) as well as documentation which provides a formal means for recognition of an individual's successful completion of the training program (certificate, letter, memorandum, etc.) and demonstration of competency, typically through a test. For further information, refer to the discussion following Standard 5.3.3.

Note: The Scientific Working Group for DNA Analysis Methods (SWGDAM) Training Working Group is currently preparing a document for defining the specific elements of a DNA training program. When implemented, this document will serve as a reference for detailing the essential requirements in a DNA training program.

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 case working examiner/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 casework responsibilities. Successful completion of an individual's qualifying test must be documented by the laboratory.

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 or leader read current scientific literature?	X		
5.1.3.1(b)	Over the last year has the technical manager or leader attended at least one seminar, course, professional meeting or training session/class which 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 which 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 which addresses subject matter related to DNA analysis?	X		

Discussion:

The laboratory's continuing education (CE) program must be documented, such as in the quality manual or training manual. Additionally, the laboratory must demonstrate that its CE program has been utilized. Laboratories must provide documentation of the presence and use of its CE program to achieve compliance with Standard 5.1.3. Laboratory management must provide technical personnel with the opportunity to stay abreast of new developments and issues within the field of DNA analysis. The laboratory must provide the technical manager or leader, CODIS manager and all examiner/analysts with at least one session of documented CE in a subject area related to DNA analysis annually (as defined by the laboratory, e.g., fiscal or calendar). While such CE should be formalized, requirements do not necessarily

include earned credit hours or grade evaluations (although this would be acceptable). For laboratory internal CE programs, the title and date of training, attendance list and presenter(s) must be documented. The laboratory may administer an external CE program through a variety of methods; however, the records of staff attendance for such programs must be retained by the laboratory.

Additionally, 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 which demonstrates the review of scientific literature. Compliance with these standards is assessed through staff interviews and an evaluation of the laboratory's mechanism for scientific literature review.

Comment:

5.1.3.1 (f) No 2001 continuing education for two examiners. NCSBI interprets this standard on a fiscal year basis, not calendar year.

		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 vita (CV) or other means, such as a statement of qualifications. Compliance with this standard is assessed through a review of documentation as well as staff interviews.

Comment:

		Yes	No	N/A
5.2	Does the technical manager or 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 or 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:			
	(a) Biochemistry	X		
	(b) Genetics	X		
	(c) Molecular biology	X		
	(d) Statistics and/or population genetics	X		

Discussion:

A minimum of twelve semester or equivalent credit hours must be completed successfully(college- or university-determined passing grade) which 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 twelve semester or equivalent credit hours requirement (5.2.1 B) must include, at a minimum, one graduate level class registering three (3) 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 the primary 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 may demonstrate compliance with this standard through several methods, such as transcripts, a letter from a university professor verifying course content, or a course syllabus. 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.

Comment:

		Yes	No	N/A
5.2.1.1	Does the technical manager or leader possess a waiver from the American Society of Crime Laboratory Directors (ASCLD) 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). Additionally, application for the waiver process is available only until October 1, 2000.

Comment:

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

Discussion:

The technical manager or leader of the laboratory must have a minimum of three years forensic DNA laboratory experience. This experience must have been gained at a facility in which forensic DNA testing was performed for the identification and evaluation of biological evidence in criminal matters. This would include agencies in which research/training and case working 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.

Comment:

		Yes	No	N/A
5.2.3	Does the technical manager or leader of the laboratory meet the duty requirements of this standard?	X		
5.2.3.1	Does the technical manager or leader manage the technical operations of the laboratory?	X		
5.2.3.2 (a-1)	Is the technical manager or leader responsible for evaluating all methods used by the laboratory?	X		
5.2.3.2 (a-2)	Is the technical manager or 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 or leader responsible for technical problem solving of analytical methods?	X		
5.2.3.2 (b-2)	Is the technical manager or 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 or leader accessible to the laboratory to provide onsite, telephonic or electronic consultation as needed?	X		

Discussion:

Auditors may assess whether a laboratory has satisfied the requirements listed in 5.2.3 through a review of laboratory documentation (protocols, quality manual, etc.), staff interviews and/or on-site evaluations. Additionally, the technical manager or leader is not required to occupy physical (on-site) facility space; however, this individual must be 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 or leader to function (or to have functioned) as a qualified examiner/analyst. The technical manager or leader must, however, satisfy the management and responsibility requirements, as specified in Standards 5.2.3.1 and 5.2.3.2. For those instances in which the technical manager or leader has an experience base in a specific DNA technology (such as RFLP testing), which is different from the DNA technology currently utilized in case work applications (such as STR analysis), the laboratory must demonstrate that the technical manager or leader has fulfilled his/her defined duties. In the example mentioned, a technical manager or leader with an RFLP-only experience base may continue to function as the technical manager or leader, even as other DNA technologies are incorporated within the laboratory, provided that he or she keeps abreast of such technical changes through a documented continuing education program. In such instances the laboratory must also demonstrate that specific duties of the technical manager or leader have been delegated appropriately.

Comment:

			Yes	No	N/A
5.3 (FO)	Does each examiner/analyst satisfy the degree/educational, experience and duty requirements as listed in standards 5.3.1 through 5.3.3?		X	____	____
5.3.1	Does each examiner/analyst meet the following degree/educational requirements		X	____	____
	A..	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:			
		(a) Biochemistry	X	____	____
		(b) Genetics	X	____	____
		(c) Molecular biology	X	____	____
	C.	College course work or training which 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 the primary component of any class or course work to satisfy this standard. Individuals who have completed course work with titles other than those listed above may demonstrate compliance with this standard through several methods, such as transcripts, a letter from a university professor verifying course content, or a course syllabus. 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.

Laboratories may satisfy the statistics and/or population genetics course work or training requirement for examiner/analysts (5.3.1) through internal or external mechanisms. Regardless of which approach is adopted, the laboratory must retain an appropriate level of documentation that provides a summary of the content of the course work/training program.

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 case work prior to undertaking independent case work analysis using DNA technology?	X	____	____

Discussion:

An examiner/analyst must have a minimum of six months forensic DNA laboratory experience gained at a facility in which forensic DNA testing was performed for the identification and evaluation of biological evidence in criminal matters. It should be emphasized 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 case work. An individual's participation in a formalized forensic DNA training program is acceptable for fulfilling or being applied toward fulfilling the experience requirement of this standard.

Comment:

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

Discussion:

All examiner/analysts must have successfully completed a qualifying test in their respective technical areas prior to performing independent case-related or database analyses. 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 desired, a laboratory may also use an internal or external proficiency test. When a proficiency test (internal or external) is used as a qualifying test, the laboratory must have sufficient available test information (phenotyping/genotyping results) to thoroughly assess the 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 180 days of their initial qualification date.

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:			
	(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 the 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		

		Yes	No	N/A
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:

Based on the duties associated with the position of CODIS manager, a qualifying test is not required for an individual functioning in this role. It is noted that examiner/analysts and technicians associated with the convicted offender program are required, however, to successfully complete a qualifying test specific for their individual positions prior to participating in DNA typing responsibilities. The laboratory must retain documentation regarding the responsibilities of the CODIS manager which demonstrates compliance to the standards listed in Section 5.3.3.

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?	____	____	X
5.4.1	Did each technician receive on the job training specific to their 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?	____	____	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:

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 standard 6.1 and all of its subcategories.

Clearly written and understood procedures must exist for addressing key aspects of 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, combinations, must be limited to appropriate laboratory personnel as designated by laboratory management. Such a distribution should also 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.

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 work station 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, case work 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. Amplification areas are typically oriented as dead end rooms and not used for pass-through activities. The amplification room must be enclosed with walls, from the floor to the ceiling, and door(s) for passage. The amplification room must physically separate amplified DNA from the evidence examination, DNA extraction and PCR setup areas. A robotic work station may be used to carry out DNA extraction and amplification in a single room, provided that it is separated from the casework extraction and casework amplification areas and that it can be demonstrated that if contamination occurs, it is minimized, addressed and less than or equivalent to that performed manually in separate rooms.

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 within the analysis process. Whichever approach(es) the laboratory selects to use, the method(s) must be documented. Additionally, laboratories must also demonstrate that such practice(s) are being followed. This may be accomplished through a variety of ways, at the discretion of the laboratory.

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 standard 7.1 and all of its subcategories.

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

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 of each individual receiving or transferring evidence, with the corresponding date for each transfer with a corresponding identifier which 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 as long as the computerized data are sufficiently secure, detailed and accessible for review and can be converted to a hard copy when necessary.

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	____	____

		Yes	No	N/A
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. It is highly desirable for the seal to be labeled in a manner which identifies the 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 such that it's contents are protected from loss, contamination and/or deleterious change. Secure areas for evidence storage must exist within 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 examination room housing large or bulky items of evidence on a temporary basis.

Comment:

		Yes	No	N/A
7.2 (FO)	Does the laboratory retain or return a portion of the evidence sample or extract where 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 which have been validated prior to casework implementation?	X	____	____

Discussion:

To successfully satisfy standard 8.1, compliance must be demonstrated with standard 8.1 and all of its subcategories.

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 which must be controlled and monitored, while defining the limitations of the procedure.

Comment:

		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 which has been developed for a specific technology (medical testing, genetic analysis, etc.) which is not currently applied to forensic DNA analysis. Citations in peer-reviewed scientific journals which 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 utilized 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 which 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 data base which is documented and available for use in population statistics?	X	____	____

		Yes	No	N/A
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 data base 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 subcategories of both 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.

Comment:

		Yes	No	N/A
8.1.3.1(a)	Has the procedure been tested using known and non-probative evidence samples?	X		
8.1.3.1 (a-CO)	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 utilizing the DNA analysis procedure prior to its incorporation into case work or database applications? (CO 8.1.3.2)	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 which have been appropriately	X		

	Yes	No	N/A
evaluated for a specific or unique application?			

Discussion:

For larger laboratory systems which consist of multiple laboratories, internal validation criteria which may result in site-specific variations (instrument performance, precision measurements, etc.) that could impact consistency of analytical data between laboratories must be independently validated within each laboratory of the parent system. The corresponding internal validation materials must be documented and available for review for each location.

Note: The SWGDAM Validation Working Group is currently preparing a document for defining the specific elements of the validation process. When implemented, this document will serve as a reference for detailing the essential requirements for developmental as well as internal validation.

Comment:

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 or 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 which 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 which contain semen?	X		

Discussion:

To successfully satisfy standard 9.1, compliance must be demonstrated with standard 9.1 and all of its subcategories.

Technical protocols for each analytical technology must include documented approval by laboratory management. Technical protocols must be readily available to laboratory personnel and reflective of the current practices employed by the laboratory.

Comment:

			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 the formulation of 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		

		Yes	No	N/A
(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 standard 9.2 and all of its subcategories.

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 which identify the preparer of the reagent, along with the quality control measures (if any) utilized 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 case work samples. 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 which are unacceptable, and the mechanisms used for documentation and the subsequent approval/rejection of quality control data. Additionally, the critical reagents listed in Standard 9.2.3 (b) are not applicable universally to all types of DNA methodologies. For example, a laboratory which strictly performs RFLP testing would not employ critical reagents such as primer sets (g) or a thermostable DNA polymerase (h).

Comment:

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

Discussion:

Estimating or controlling the quantity of DNA in case work and convicted offender samples is important in the analytical process for generating quality DNA profile results. When utilizing PCR analysis techniques, 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.

Regardless of which DNA typing technology is utilized (RFLP or PCR), 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) may also be an acceptable approach, if adequately validated. Circumstances in which human DNA quantitation is not required for compliance with Standard 9.3, but

rather the use of a validated less direct estimation method is acceptable if it includes known reference samples (case work or data base applications) as well as evidentiary items which are subjected solely to mitochondrial DNA analysis. In such instances, the response to Standard 9.3 would be "Not Applicable".

For laboratories which select to use a less direct method for estimating DNA quantities in known reference or offender samples, it is acceptable to re-run such samples to obtain useable results. Laboratories which select such an approach must have a mechanism in place to evaluate each set of results and to identify samples which need to be reprocessed.

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? (CO 9.3)	_X_	____	____
9.4.1	Does the laboratory use the following controls for RFLP casework analysis? (CO 9.3.1)	____	____	_X_
9.4.1.1	Quantitation standards which estimate the amount of DNA recovered by extraction (CO 9.3.1.1)	____	____	_X_
9.4.1.2	K562 as a human DNA control (CO 9.3.1.2)	____	____	_X_
9.4.1.3	Molecular weight size markers, at defined intervals, for bracketing known and evidence samples. (CO 9.3.1.3)	____	____	_X_
9.4.1.4	Procedure to monitor the completeness of restriction enzyme digestion (CO 9.3.1.4)	____	____	_X_

Discussion:

For database laboratories (Convicted Offender), pertaining to Standard 9.3.1.3, no more than five lanes must exist between marker lanes. Additionally, regarding Standard 9.3.1.4, database laboratories (Convicted Offender) may monitor the completeness of a restriction enzyme digest through a test gel or other method; however, interpretation of the resulting autoradiogram/lumigraph is the ultimate method of assessment. As mentioned under the previous quantitation discussion (Standard 9.3), under appropriate situations, a "Not Applicable" response would be appropriate for Standard 9.4.1.1.

Comment:

		Yes	No	N/A
9.4.2	Does the laboratory use the following controls for PCR casework or database analysis? (CO 9.3.2)	_X_	____	____

		Yes	No	N/A
9.4.2.1	Quantitation standards which estimate the amount of human nuclear DNA recovered by extraction (CO 9.3.2.1)	X		
9.4.2.2	Positive and negative amplification controls (CO 9.3.2.2)	X		
9.4.2.3 (FO)	Reagent blanks	X		
9.4.2.4	Allelic ladders and/or internal size markers for variable number tandem repeat sequence PCR based systems (CO 9.3.2.4)	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? (CO 9.4)	X		

Discussion:

As mentioned in the previous quantitation discussion (Standard 9.3), under appropriate situations, a "Not Applicable" response would be appropriate for Standard 9.4.2.1.

It should be noted that a standard traceable to the NIST SRM must be established for use by the laboratory. This standard must be used as an annual check on all DNA procedures in use by the laboratory (or if a substantial change has been implemented) for which a standard is available. Laboratories may elect to use the NIST SRM or develop a secondary standard (traceable to the NIST SRM) to accomplish this requirement.

To successfully satisfy standard 9.4, compliance must be demonstrated with Standard 9.4 and all of its subcategories. Additionally, to successfully satisfy Standards 9.4.1 and 9.4.2, complaince must be demonstrated with all of their respective subcategories.

Comment:

		Yes	No	N/A
9.6	Does the laboratory have and follow written general guidelines for the interpretation of data? (CO 9.5)	X		
9.6.1	Does the laboratory verify that all control results are within established tolerance ranges? (CO 9.5.1)	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	X		

	Yes	No	N/A
relatedness and are these calculations derived from an established population data base appropriate for the calculation?			

Discussion:

It is noted that Standard 9.6.2 is applicable for RFLP testing and may not be applicable for other DNA technologies (such as PM/DQA1, STR analysis, mitochondrial DNA analysis, etc.). Also, Standard 9.6.3 does not apply to mitochondrial DNA testing applications ("N/A").

Comment:

STANDARD 10 - EQUIPMENT CALIBRATION AND MAINTENANCE

		Yes	No	N/A
10.1	Does the laboratory use equipment which 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	Where 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 instrument 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 standards 10.2, 10.3 and all of their subcategories.

To successfully satisfy the requirements listed in Standard 10.2, the laboratory's documentation must include the identification of all critical equipment which requires calibration. It is suggested that the laboratory's inventory of equipment include information describing calibration and maintenance schedules. The elements listed for Standard 10 may be assessed through a review of laboratory documentation.

Comment:

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 which are used by case working laboratories to estimate allele frequency information.

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)	A description of methodology	X		
	(d)	Locus	X		
	(e)	Results and/or conclusions	X		
	(f)	An interpretative statement (either quantitative or qualitative)	X		
	(g)	Date issued	X		
	(h)	Disposition of evidence	X		
	(i)	A signature and title or equivalent identification of the person(s) accepting responsibility for the	X		

		Yes	No	N/A
	content of the report.			
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 assay, another qualified individual could evaluate and interpret the resulting data.

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 within 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 and frequency associated with both administrative and technical reviews. The laboratory must define the required qualifications to function as an administrative reviewer as well as a technical reviewer. It is not required for the administrative reviewer to be a current or former qualified DNA examiner/analyst.

All individuals who perform technical reviews on DNA case work must have been previously qualified in the specific DNA technology which 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 which defines the course of action necessary in the event of an unresolved discrepancy. This applies to both forensic case work as well as database laboratories.

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 during the course of the year. 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 or 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 (case work or convicted offender) must undergo two external proficiency tests per year, at intervals not to exceed 180 days. The time span from the completion of the initial or first test (typically the providers' due date) until the initiation of the second test must not exceed 180 days. 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 (TWGDAM) and American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) ("Guidelines for DNA Proficiency Test Manufacturing and Reporting," Technical Working Group on DNA Analysis Methods (TWGDAM) Quality Assurance Subcommittee and American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) DNA Proficiency Review Committee Volume 21, Number 2, April 1994). Alternatively, the external proficiency test provider must demonstrate compliance with the International Standards Organization (ISO) 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 should enter into the external proficiency testing program at the laboratory's first available opportunity, not to exceed a time span of 180 days from the date of qualification.

Technical personnel should 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. Laboratories which 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 case work 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, two external tests per year, at 180 day intervals, are required.

Individuals who perform multiple PCR testing methodologies (for example, PM/DQA1, STR, mtDNA) in case work 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, at 180 day intervals, are required.

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

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

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)	The 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)	The 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 evaluation of 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	____	____

		Yes	No	N/A
(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) which 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 case work 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 conduct annual audits, with the participation of an external agency, at a minimum of every other year. Audits must be conducted once per year, with the interval between audits not less than six (6) months and not exceeding eighteen (18) months. After the audit is completed, the auditor briefs DNA laboratory management regarding the results. This discussion 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 shortly after the audit has been conducted. 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. 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 which relate to individual qualifications, training, continuing education and court testimony.

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 (EHS) must be current and available to laboratory staff. This information must be updated to reflect changes in a technical procedure (radioisotopes, etc) or the remodeling of laboratory space (changed evacuation plans) which may have an effect on the laboratory's EHS program. To fulfill the requirements associated with Standard 16.1, the laboratory must provide documentation that its EHS program has been reviewed to ensure that all practices are appropriate and contemporary.

Comment:

STANDARD 17 - SUBCONTRACTORS OF ANALYTICAL TESTING FOR WHICH VALIDATED PROCEDURES EXIST

			Yes	No	N/A
17.1	Does the laboratories 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 A (CO)	Has the laboratory established and used review procedures which include (but are not limited to) each of the following:				
	(a)	Random re-analysis of samples	X	____	____
	(b)	Visual inspection and evaluation of results/data	X	____	____
	(c)	Inclusion of QC samples	X	____	____
	(d)	On-site visits	X	____	____

Discussion:

A subcontractor, as a forensic DNA laboratory or a Convicted Offender database laboratory, must demonstrate compliance with standard 17.1 by undergoing an audit with respect to the elements listed in this document. 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 by a separate or different agency. The audit documentation must include the audit check list, audit report, and the subcontractors' responses and/or follow-up actions to any findings detailed in the report. Such documentation (or copies thereof) must be retained and available for review by each contracting laboratory which selects such an approach. It is noted that an on-site visit is different from an external audit.

On-site visits (part (d) of Convicted Offender Standard 17.1.1), 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. If an on-site visit reveals a finding not captured or resolved from the initial audit, the subcontractor must ensure such information (with the corresponding corrective actions, if appropriate) is documented and made available to the contracting laboratories which relied upon the previous audit report, as well as the individual auditor(s).

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.

Comment:

Appendix A: FINDINGS AND RESPONSES

Findings:

No deficiencies identified.

Responses:

COMMONWEALTH of VIRGINIA

DEPARTMENT OF CRIMINAL JUSTICE SERVICES

DIVISION OF FORENSIC SCIENCE
WESTERN LABORATORY
A Nationally Accredited Laboratory

6600 NORTHSIDE HIGH SCHOOL ROAD
ROANOKE, VIRGINIA 24019-2837
(540) 561-6600 FAX (540) 561-6608

December 10, 2001

Mark S. Nelson
Special Agent in Charge
Molecular Genetics Section
North Carolina State Bureau of Investigation
3320 Garner Road
P. O. Box 29500
Raleigh, North Carolina 27626-0500

Dear Mark,

Please find enclosed the report of the audit we conducted of your laboratory December 3-5, 2001. The Quality Assurance Audit was conducted in accordance with the Quality Assurance Standards for Forensic DNA Testing Laboratories and Convicted Offender DNA Databasing Laboratories as issued by the FBI Director. There were no deficiencies or areas of non-compliance.

You have a well-qualified staff, organized forensic DNA program and an excellent facility. In addition, the research endeavors of the Molecular Genetics Section are a credit to your organization and benefit the entire forensic DNA community.

We appreciate the hospitality extended by you and your staff during our visit. Please contact us if you have any questions or if we can be of further assistance.

Sincerely,

R. Elizabeth Bush
Forensic Scientist Supervisor
Western Laboratory
(540) 561-6600

Karen Curtis Ambrozy
Forensic Scientist Supervisor
Northern Laboratory
(703) 764-4600