AMERICAN SOCIETY OF CRIME LABORATORY DIRECTORS
LABORATORY ACCREDITATION BOARD (ASCLD/LAB)

APPLICATION FOR ACCREDITATION

Please provide the following information and return with the requested documentation to the ASCLD/LAB Executive Director, 139 J Technology Drive, Garner, NC 27529. All information must be placed in a ring binder with labeled tabs which designate the location of the required documentation or in an organized electronic format using software which is approved by the ASCLD/LAB office. Additional copies will be sent by the Applicant Laboratory to Inspectors after coordination with the Team Captain.

1. Organization Name North Carolina State Bureau of Investigation

2. Name of the laboratory Raleigh Laboratory

3. Laboratory Director Jerry Richardson Title Assistant Director

   Address 121 East Tryon Road

   City Raleigh State NC Country U.S.A. Postal Code 27603

   Telephone (919) 662-4500 Fax (919) 662-4475 E-mail jrichardson@mail.jus.state.nc.us

4. If someone other than the laboratory director is the contact:

   Name _____ *Title* _____

   Telephone( ) _____ Fax( ) _____ E-mail _____

5. The Laboratory is: _____

   X Governmental (Fed ___ State X County ___ City ___ Regional ___ Private ___)

   ___ Private (not for profit) ___ Proprietary (privately owned)

6. Specific disciplines in which accreditation is sought:

X	Controlled Substances	X	Toxicology
X	Trace Evidence	X	Firearms/Toolmarks
X	Biology	X	Latent Prints
X	Questioned Documents	___	Crime Scene (Optional)
X	Digital Evidence		

If service is limited in any discipline, please list the sub-disciplines: _____

7. Total positions in laboratory including vacancies:
   Testifying 95 *Non-Testifying* 24

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8. List all personnel by completing the following tables, "Professional Staff Testifying" and "Other Personnel". Use additional sheets if necessary. (Computerized printouts of similar format are acceptable. The form may be downloaded at www.ascld-lab.org)

9. Submit a current Statement of Qualifications form for each person other than clerical staff (Appendix 2).

10. Provide a copy of:

- *table of organization covering all positions*
- labeled, dimensional floor plan of the laboratory
- the laboratory objectives
- the laboratory budget
- the laboratory quality manual or manuals
- a job description for each job category in the laboratory
- procedures for handling and preserving evidence
- procedures on case records
- security procedures
- a list of the management training courses/seminars taken by the manager(s)
- other documents of director's choice such as monthly or annual reports which give laboratory work statistics.

13. Submit a copy of Grade Computation Sheets (Appendix 3) completed through self-evaluation.

As the Director of the applicant laboratory, I have verified that all required information and documentation for application is included with this application and that all statements made on this application are correct *to the best of my knowledge and belief. I have reviewed the conditions for accreditation* as outlined in the Accreditation Manual and agree to all of the stated conditions. I understand that ASCLD/LAB has the right to return my application without taking action, if it is not properly completed or does not contain the required documentation. I also understand that ASCLD/LAB is not required to accredit any laboratory unless it is determined that an applicant laboratory has met all standards and criteria required for accreditation.

Director's Signature

6-3-03
Date

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GRADE COMPUTATION SHEETS

CRITERIA	ESSENTIAL Y	ESSENTIAL N	ESSENTIAL N/A	IMPORTANT Y	IMPORTANT N	IMPORTANT N/A	DESIRABLE Y	DESIRABLE N	DESIRABLE N/A
1.1.1.1 (I)				X	—	—			
1.1.1.2 (I)				X	—	—			
1.1.1.3 (D)							X	—	—
1.1.2.1 (I)				X	—	—			
1.1.2.2 (I)				X	—	—			
1.1.2.3 (E)	X	—	—						
1.1.2.4 (E)	X	—	—						
1.1.2.5 (E)	X	—	—						
1.1.2.6 (D)							X	—	—
1.1.2.7 (E)	X	—	—						
1.1.2.8 (D)							X	—	—
1.1.2.9 (I)				X	—	—			
1.1.2.10 (I)				X	—	—			
1.1.2.11 (D)							X	—	—
1.1.2.12 (D)							X	—	—
1.1.2.13 (D)							X	—	—
1.1.2.14 (I)				X	—	—			
1.2.1.1 (D)							X	—	—
1.2.1.2 (D)							X	—	—
E/I/D = 4/7/8									
TOTALS	4	0	0	7	0	0	8	0	0

LABORATORY_____

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CRITERIA	ESSENTIAL Y	ESSENTIAL N	ESSENTIAL N/A	IMPORTANT Y	IMPORTANT N	IMPORTANT N/A	DESIRABLE Y	DESIRABLE N	DESIRABLE N/A
1.2.2.1 (I)				X	—	—			
1.2.2.2 (I)				X	—	—			
1.2.2.3 (I)				X	—	—			
1.2.2.4 (I)				X	—	—			
1.2.2.5 (I)				X	—	—			
1.2.2.6 (I)				X	—	—			
1.3.1.1 (D)							X	—	—
1.3.1.2 (I)				X	—	—			
1.3.1.3 (D)							X	—	—
1.3.2.1 (D)							X	—	—
1.3.2.2 (D)							X	—	—
1.3.2.3 (D)							X	—	—
1.3.3.1 (E)	X	—	—						
1.3.3.2 (I)				X	—	—			
1.3.3.3 (I)				X	—	—			
1.3.3.4 (I)				X	—	—			
1.4.1.1 (E)	X	—	—						
1.4.1.2 (E)	X	—	—						
1.4.1.3 (E)	X	—	—						
1.4.1.4 (E)	X	—	—						
1.4.1.5 (E)	X	—	—						
1.4.2.1 (E)	X	—	—						
E/I/D = 7/10/5									
TOTALS	7	0	0	10	0	0	5	0	0

LABORATORY_____

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CRITERIA	ESSENTIAL Y	ESSENTIAL N	ESSENTIAL N/A	IMPORTANT Y	IMPORTANT N	IMPORTANT N/A	DESIRABLE Y	DESIRABLE N	DESIRABLE N/A
1.4.2.2 (E)	X	—	—						
1.4.2.3 (E)	X	—	—						
1.4.2.4 (E)	X	—	—						
1.4.2.5 (E)	X	—	—						
1.4.2.6 (E)	X	—	—						
1.4.2.7 (E)	X	—	—						
1.4.2.8 (E)	X	—	—						
1.4.2.9 (E)	X	—	—						
1.4.2.10 (E)	X	—	—						
1.4.2.11 (I)				X	—	—			
1.4.2.12 (I)				X	—	—			
1.4.2.13 (E)	X	—	—						
1.4.2.14 (E)	X	—	—						
1.4.2.15 (E)	X	—	—						
1.4.2.16 (E)	X	—	—						
1.4.2.17 (E)	X	—	—						
1.4.2.18 (E)	X	—	—						
1.4.2.19 (E)	X	—	—						
1.4.3.1 (E)	X	—	—						
1.4.3.2 (E)	X	—	—						
1.4.3.3 (I)				X	—	—			
1.4.3.4 (I)				—	X	—			
E/I/D = 18/4/0									
TOTALS	18	0	0	3	1	0	0	0	0

LABORATORY_____

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CRITERIA	ESSENTIAL Y	ESSENTIAL N	ESSENTIAL N/A	IMPORTANT Y	IMPORTANT N	IMPORTANT N/A	DESIRABLE Y	DESIRABLE N	DESIRABLE N/A
2.1.1 (I)				X	—	—			
2.1.2 (D)							X	—	—
2.1.3 (D)							X	—	—
2.1.4 (D)							X	—	—
2.2.1 (E)	X	—	—						
2.2.2 (E)	X	—	—						
2.2.3 (E)	X	—	—						
2.2.4 (E)	X	—	—						
2.3.1 (E)	X	—	—						
2.3.2 (E)	X	—	—						
2.3.3 (E)	X	—	—						
2.3.4 (E)	X	—	—						
2.4.1 (E)	X	—	—						
2.4.2 (E)	X	—	—						
2.4.3 (E)	X	—	—						
2.4.4 (E)	X	—	—						
2.5.1 (E)	X	—	—						
2.5.2 (E)	X	—	—						
2.5.3 (E)	X	—	—						
2.5.4 (E)	X	—	—						
2.5.5 (E)	X	—	—						
2.5.6 (E)	X	—	—						
E/I/D = 18/1/3									
TOTALS	18	0	0	1	0	0	3	0	0

LABORATORY_____

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CRITERIA	ESSENTIAL Y	ESSENTIAL N	ESSENTIAL N/A	IMPORTANT Y	IMPORTANT N	IMPORTANT N/A	DESIRABLE Y	DESIRABLE N	DESIRABLE N/A
2.6.1 (I)				X	—	—			
2.6.2 (E)	X	—	—						
2.6.3 (E)	X	—	—						
2.6.4 (E)	X	—	—						
2.6.5 (E)	X	—	—						
2.7.1 (I)				X	—	—			
2.7.2 (E)	X	—	—						
2.7.3 (E)	X	—	—						
2.7.4 (E)	X	—	—						
2.7.5 (E)	X	—	—						
2.8.1 (I)				—	X	—			
2.8.2 (E)	X	—	—						
2.8.3 (E)	X	—	—						
2.8.4 (E)	X	—	—						
2.8.5 (E)	X	—	—						
2.9.1 (E)	X	—	—						
2.9.2 (E)	X	—	—						
2.9.3 (E)	X	—	—						
2.9.4 (E)	X	—	—						
2.9.5 (E)	X	—	—						
2.10.1 (E)	—	—	X						
E/I/D = 18/3/0									
TOTALS	17	0	1	2	1	0	0	0	0

LABORATORY_____

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CRITERIA	ESSENTIAL Y	ESSENTIAL N	ESSENTIAL N/A	IMPORTANT Y	IMPORTANT N	IMPORTANT N/A	DESIRABLE Y	DESIRABLE N	DESIRABLE N/A
2.10.2 (E)	—	—	X						
2.10.3 (E)	—	—	X						
2.10.4 (E)	—	—	X						
2.10.5 (E)	—	—	X						
2.11.1 (I)				—	X	—			
2.11.2 (E)	X	—	—						
2.11.3 (E)	X	—	—						
2.11.4 (E)	X	—	—						
2.11.5 (E)	X	—	—						
3.1.1 (I)				X	—	—			
3.1.2 (D)							X	—	—
3.1.3 (I)				X	—	—			
3.1.4 (I)				X	—	—			
3.1.5 (I)				X	—	—			
3.1.6 (D)							X	—	—
3.2.1 (I)				X	—	—			
3.2.2 (D)							X	—	—
3.2.3 (I)				X	—	—			
3.2.4 (I)				X	—	—			
3.2.5 (I)				X	—	—			
3.2.6 (I)				X	—	—			
3.3.1 (E)	X	—	—						
E/I/D = 9/10/3									
TOTALS	5	0	4	9	1	0	3	0	0

LABORATORY_____

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CRITERIA	ESSENTIAL Y	ESSENTIAL N	ESSENTIAL N/A	IMPORTANT Y	IMPORTANT N	IMPORTANT N/A	DESIRABLE Y	DESIRABLE N	DESIRABLE N/A
3.3.2 (E)	X	—	—						
3.3.3 (E)	X	—	—						
3.3.4 (E)	X	—	—						
3.3.5 (E)	X	—	—						
3.3.6 (I)				X	—	—			
3.4.1 (I)				X	—	—			
3.4.2 (I)				X	—	—			
3.4.3 (I)				X	—	—			
3.4.4 (I)				X	—	—			
3.4.5 (I)				X	—	—			
3.4.6 (I)				X	—	—			
3.4.7 (I)				X	—	—			
3.4.8 (I)				X	—	—			
3.4.9 (I)				X	—	—			
3.4.10 (I)				X	—	—			
3.4.11 (I)				X	—	—			
3.4.12 (D)							X	—	—

E/I/D = 4/12/1

TOTALS	4	0	0	12	0	0	1	0	0

LABORATORY_____

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SUMMATION OF CRITERIA RATINGS

	Total Possible	Total Yes	Total No	Total N/A	Total Number Yes/No
Essential	78	73	0	5	73
Important	47	44	3	0	44
Desirable	20	20	0	0	20

Calculations

Percent Essential = $\frac{\text{Total Yes}}{\text{(Total Yes + Total No)}} \times 100 =$ 100 %

Percent Important = $\frac{\text{Total Yes}}{\text{(Total Yes + Total No)}} \times 100 =$ 93.62 %

Percent Desirable = $\frac{\text{Total Yes}}{\text{(Total Yes + Total No)}} \times 100 =$ 100 %

Standards

Essential	100%
Important	75%
Desirable	50%

NOTE: N/A answers will not be counted in above calculations, but each N/A answer must be explained in writing.

Inspection Team: _____

_____

_____

_____

_____

_____

Laboratory Director Assistant Director Jerry Richardson

Date 6-5-03

LABORATORY N.C. State Bureau of Investigation

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PROFESSIONAL STAFF TESTIFYING (INCLUDING TRAINEES)

NAME/JOB TITLE	CS	TOX	TRA	BIO	F/T	QD	LP	CrSc	DE
David Mishoe - Forensic Computer Analyst									X
John Dilday - Forensic Computer Analyst									X
Eric Hicks - Forensic Computer Analyst									

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AMERICAN SOCIETY OF CRIME LABORATORY DIRECTORS
LABORATORY ACCREDITATION BOARD

September 9, 2003

Jerry Richardson, Assistant Director
North Carolina State Bureau of Investigation
Crime Laboratory
121 East Tryon Road
Raleigh, NC 27603

Dear Assistant Director Richardson:

In accordance with an agreement signed between ASCLD/LAB and the FBI, whenever ASCLD/LAB inspects a laboratory in the discipline of DNA, the FBI Quality Assurance Audit For Forensic DNA and Convicted Offender DNA Databasing Laboratories document is used in addition to the ASCLD/LAB standards. The primary purpose of this agreement is to eliminate the necessity for a laboratory to undergo two audits of their DNA unit in the same year.

A copy of the completed and signed Quality Assurance Audit document for the North Carolina State Bureau of Investigation Crime Laboratory is enclosed.

Sincerely,

Ralph M. Keaton

Ralph M. Keaton
Executive Director

cc: Michael Johnston, Staff Inspector

Ralph Keaton, Executive Director • 139 J Technology Drive, Garner, NC 27529 • Phone (919) 773-2600 • FAX (919) 773-2602 • E-mail rkeaton@ascld-lab.org

ASCLD/LAB
INSPECTION REPORT

NORTH CAROLINA STATE BUREAU OF INVESTIGATION
WESTERN REGIONAL CRIME LABORATORY

Inspected: August 27-28, 2003

STANDARDS AND CRITERIA

All of the criteria were scored YES with the following exceptions:

1.1.2.7 (E) CALIBRATION OF EQUIPMENT AND INSTRUMENTS.

The calibration procedures for the balances and FTIR in the Drug Chemistry Section do not include accuracy tolerance limits.

The Drug Chemistry Section does not have written procedures for the calibration of the Gas Chromatograph portion of the Gas Chromatograph/Mass Spectrometer when the Gas Chromatograph portion is used in the identification of controlled substances.

1.4.2.9 (E) IS THE QUALITY OF THE STANDARD SAMPLES AND REAGENTS ADEQUATE FOR THE PROCEDURE USED?

No source documentation was available in the Drug Chemistry section for the verification of controlled substance reference standards used for infrared and mass spectral comparisons.

1.4.2.8 (E) ARE APPROPRIATE CONTROLS AND STANDARDS SPECIFIED IN THE PROCEDURES AND ARE THEY USED AND DOCUMENTED IN THE CASE RECORD TO ENSURE THE VALIDITY OF EXAMINATION RESULTS?

On page A-1 of the Western Regional Laboratory Drug Chemistry Procedure Manual it states that the Marquis Reagent will be checked with Heroin. This lab is using other drugs such as Methamphetamine.

All criteria for 2.3 Toxicology, 2.4 Trace Evidence, 2.5 Biology, 2.6 Firearms/Toolmarks, 2.7 Questioned Documents and 2.9 Technical Support, and 2.11 Digital Evidence were scored N/A because the laboratory does not perform work in the disciplines.

All criteria for 2.10 Crime Scene were scored N/A because the laboratory elected not to apply for Crime Scene accreditation.

ASCLD/LAB
INSPECTION REPORT

NORTH CAROLINA STATE BUREAU OF INVESTIGATION
RALEIGH CRIME LABORATORY

Inspected: August 24-29, 2003

INTRODUCTION

This is the report of the ASCLD/LAB inspection of the North Carolina State Bureau of Investigation Raleigh Crime Laboratory. This inspection was conducted August 24 – 29, 2003.

The ASCLD/LAB inspection team consisted of the following members:

***Mike Johnston**, Staff Inspector, ASCLD/LAB, Austin, TX*
John Barbara, Florida Dept. of Law Enforcement, Tampa, FL
Craig Ogino, San Bernardino County Crime Lab, San Bernardino, CA
Robyn Ragsdale, Florida Dept. of Law Enforcement, Tampa, FL
Charles Quenzer, Federal Bureau of Investigation, Quantico, VA
Marie Samples, Office of Chief Medical Examiner, New York, NY
Cary Oien, Federal Bureau of Investigation, Quantico, VA
Steve Meagher, Federal Bureau of Investigation, Quantico, VA
Ingrid Dearmore, Washington State Patrol, Marysville, WA
Tom Darnell, South Carolina Law Enforcement Division, Columbia, SC
Ed Moilanen, Staff Inspector, ASCLD/LAB, Roscommon, MI
Doreen Hudson, Los Angeles Police Department, Los Angeles, CA

This report and the findings, observations, conclusions and recommendations are for pre-decisional purposes only. The inspection was performed using the principles, standards and criteria established in the 2003 version of the ASCLD/LAB Accreditation Manual and the FBI "Quality Assurance Audit For Forensic DNA and Convicted Offender DNA Databasing Laboratories".

LABORATORY OVERVIEW

The North Carolina State Bureau of Investigation Raleigh Crime Laboratory is located at 121 East Tryon Road in Raleigh, North Carolina and is a state laboratory which provides services for the State of North Carolina. Assistant Director Jerry Richardson is director of the Crime Laboratory System. He reports to State Bureau of Investigation Director Robin Pendergraft. The Laboratory provides services in Controlled Substances, Toxicology, Trace Evidence, Biology (Molecular Genetics), Firearms/Toolmarks, Latent Prints, Questioned Documents and Digital Evidence and has a staff of 92 testifying analysts and 24 support staff.

The Laboratory also provides Crime Scene services but has elected not to apply for accreditation in this discipline.

STANDARDS AND CRITERIA

All of the criteria were scored YES with the following exceptions:

1.1.2.7 (E) CALIBRATION OF EQUIPMENT AND INSTRUMENTS.

The calibration procedures for the balances in the Drug Chemistry and Biology sections do not include accuracy *tolerance limits*.

The Drug Chemistry Section does not have written procedures for the calibration of the Gas Chromatograph portion of the Gas Chromatograph/Mass Spectrometer when the Gas Chromatograph portion is used in the identification of controlled substances.

1.4.1.3 (E) IS EVIDENCE STORED UNDER PROPER SEAL?

Electrostatic Detection Apparatus (ESDA) results are being stored as examination documentation in the Document Section case records.

1.4.2.5 (E) ARE THE PROCEDURES USED GENERALLY ACCEPTED IN THE FIELD OR SUPPORTED BY DATA GATHERED AND RECORDED IN A SCIENTIFIC MANNER?

The written procedures in the Drug Chemistry Section are not specific to meet minimum identification requirements for phenalkylamines in regard to mass spectroscopy. If GC/MS is used, the procedure does not specify that a verified gas chromatographic retention time must be used in conjunction with the mass spectrometer results for the identification of phenalkylamines.

A conclusion in one ink examination case in the Questioned Documents Section reported that two ink samples had matching formulas. Case examination documentation revealed only physical examination techniques (fluorescence, luminescence and reflectance) were used to arrive at the conclusion. Questioned Document Section procedures for the analysis of ink include physical examination, chemical examination and thin layer chromatography. The technical procedures do not include minimum standards for reporting conclusions.

1.4.2.8 (E) ARE APPROPRIATE CONTROLS AND STANDARDS SPECIFIED IN THE PROCEDURES AND ARE THEY USED AND DOCUMENTED

IN THE CASE RECORD TO ENSURE THE VALIDITY OF EXAMINATION RESULTS?

Appropriate controls and standards are being used in the Digital Evidence Section, but are not specified in the Computer Forensics, Audio, or Video procedures, nor is their use being documented in the Computer Forensic case records.

The quantitation procedure in Biology uses a serial dilution to create a set of standards ranging from 10 ng to 0.15 ng, as well as two calibration controls intended to assess the performance of the standards. The technical procedures specify the use of these standards and calibrators but does not address the expected results, acceptable performance of the standards or calibrators, or the interpretation of results (DNA Audit Document standard 9.1, 9.1.2.). The procedure does not specify a minimum number of visible standards (or minimal DNA concentration) as well as data interpretation to ensure uniformity among analysts.

The gas chromatographic portion of the Drug Chemistry gas chromatograph-mass spectrometers is not being checked with controls or standards.

1.4.2.9 (E) IS THE QUALITY OF THE STANDARD SAMPLES AND REAGENTS ADEQUATE FOR THE PROCEDURE USED?

No source documentation was available in the Drug Chemistry section for the verification of controlled substance reference standards used for infrared and mass spectral comparisons.

1.4.2.13 (E) ARE THE INSTRUMENTS/EQUIPMENT PROPERLY CALIBRATED?

The Drug Chemistry Quality Assurance Manual (4.A.7, page 4-2) states that electronic balances "will be calibrated or have the calibration certified by the chemists on a monthly basis using standard weights". The weights used for calibration by the chemists have no authenticating certifying documentation.

1.4.2.14 (E) DO THE EXAMINERS GENERATE AND DOES THE LABORATORY MAINTAIN, IN A CASE RECORD, ALL THE NOTES, WORKSHEETS, PHOTOGRAPHS, SPECTRA, PRINTOUTS, CHARTS AND OTHER DATA OR RECORDS USED BY EXAMINERS TO SUPPORT THEIR CONCLUSIONS?

In the Biology Section, Administrative Order 01-PRO-4 dated April 24, 2001 requires that mandatory steps be followed when case samples are batched. During analyst interviews, it was determined that samples from different cases may be "batched" for extraction, quantitation, and/or amplification. However, there is no documentation in individual case records when samples are batched, making it impossible to compare results obtained between cases should the need for such comparison arise (i.e. for trouble-shooting). (DNA Audit Document standard 11.1, 11.1.1).

2.8.1 (I) DOES EACH EXAMINER POSSESS A BACCALAUREATE DEGREE WITH SCIENCE COURSES?

Not all examiners possess a baccalaureate degree.

2.11.1 (I) DOES EACH EXAMINER POSSESS A BACCALAUREATE DEGREE WITH SCIENCE COURSES?

Not all examiners possess a baccalaureate degree.

3.4.11 (I) ARE THE EMERGENCY EXITS FROM THE LABORATORY ADEQUATE FOR SAFE EXIT IN AN EMERGENCY?

Personal work areas in the Trace Evidence, Drug Chemistry, Biology and Latent Evidence sections are divided by common (shared) instrument/processing rooms. Access to these common rooms is from adjacent work areas. Exit from these rooms is by key only. If an analyst enters these rooms without the key, and the door(s) should happen to close while they are in the room, there is no way to exit or notify another person other than by pounding on the door to attract attention.

All criteria for 2.10 Crime Scene were scored N/A because the laboratory elected not to apply for Crime Scene accreditation.

SUMMATION OF CRITERIA RATINGS

	Total Possible	Total Yes	Total No
Essential	73	66	7
Important	47	44	3
Desirable	20	20	0

Percent Essential:	90
Percent Important:	94
Percent Desirable:	100

Areas sought for accreditation are as follows:

Controlled Substances
Toxicology
Biology
Trace Evidence
Firearms/Toolmarks
Latent Prints
Questioned Documents
Digital Evidence

Prepared by: Mike Johnston, Staff Inspector

Ralph M. Keaton
Ralph M. Keaton, Executive Director

9-5-03
Date

AMERICAN SOCIETY OF CRIME LABORATORY DIRECTORS
LABORATORY ACCREDITATION BOARD

September 9, 2003

Jerry Richardson, Assistant Director
NC State Bureau of Investigation Crime Laboratory
121 East Tryon Road
Raleigh, NC 27603

Dear Assistant Director Richardson:

On September 5, 2003, an ASCLD/LAB audit committee reviewed the draft inspection reports for the North Carolina State Bureau of Investigation Headquarters Laboratory and the Western Regional Laboratory which were inspected during the period of August 24-29, 2003. The audit committee reviewed each report for consistency with past Board decisions in order to expedite the process of remediation for your laboratories. Copies of the audited reports are being provided to you with this letter.

In its consideration of the draft report for the Headquarters Laboratory, the audit committee concluded that an appropriate correction had been made to the finding for Desirable criterion 1.1.2.8 and the scoring was changed to YES. The audit committee also concluded that the finding related to Essential criterion 1.4.1.4 was more appropriately reported under criterion 1.4.1.3. Therefore the scoring for criterion 1.4.1.4 was changed to YES. The audit committee concurred with all other findings of the inspection team.

In auditing the Western Regional Laboratory draft report, the audit committee concluded that the finding for Essential criterion 1.4.2.10 is valid but would be more appropriately assigned to Essential criterion 1.4.2.8. Therefore the scoring for criterion 1.4.2.10 was changed to YES and the scoring for criterion 1.4.2.8 was changed to NO. The audit committee concurred with all other findings of the inspection team.

These reports have not been considered by the Board and remain pre-decisional until the Board takes action concerning the accreditation of the laboratories. The Board will next meet on October 26 and 27. If you take exception with findings in either of the reports, you may appeal to the Board. Should you wish to appeal, you should advise me concerning the basis of your appeal and I will place the matter on the agenda for the upcoming meeting.

If you do not take issue with findings in the reports, you should begin taking the necessary actions to bring all Essential criteria into compliance with the requirements of the 2003 version of the Accreditation Manual. Typically, the Board wishes to see a 90 day history of compliance with standards involving documentation and procedures. Due to the nature of the findings, a

Ralph Keaton, Executive Director • 139 J Technology Drive, Garner, NC 27529 • Phone (919) 773-2600 • FAX (919) 773-2602 • E-mail rkeaton@ascld-lab.org

revisit to one or both of the laboratories may be required to verify compliance with all Essential criteria.

The inspection team found each of the North Carolina State Bureau of Investigation laboratories to be in compliance with the required percentage of Important and Desirable criteria. Therefore your laboratories will not be required to take corrective measures concerning any of these criteria. However, you do have the option to take corrective actions on any of these criteria, if you so choose. In the event that you wish to remediate any Important and/or Desirable criteria, you should advise staff inspector Michael Johnston.

Although you should work directly with Mr. Johnston in arranging for review of documentation of compliance, please feel free to contact me if I might be of assistance to you.

Best wishes,

Ralph M. Keaton

Ralph M. Keaton
Executive Director

cc: Michael Johnston, Staff Inspector
ASCLD/LAB Board

1-2-04
I

ASCLD/LAB®
INSPECTION REPORT

NORTH CAROLINA STATE BUREAU OF INVESTIGATION
RALEIGH CRIME LABORATORY

Inspected: August 24-29, 2003
Supplemental Inspection Report: December 4, 2003

INTRODUCTION

This is the Inspection Report of the ASCLD/LAB inspection of the North Carolina State Bureau of Investigation Raleigh Crime Laboratory. The initial inspection was performed on August 24-29, 2003 using the principles, standards and criteria established in the 2003 version of the ASCLD/LAB Accreditation Manual and the FBI "Quality Assurance Standards for Forensic DNA Testing Laboratories and Convicted Offender DNA Databasing Laboratories". Staff inspector Mike Johnston conducted a follow-up review of documentation on December 4, 2003.

The **ASCLD/LAB** inspection team consisted of the following members:

Mike Johnston, Staff Inspector, ASCLD/LAB, Austin, TX
John Barbara, Florida Dept. of Law Enforcement, Tampa, FL
Craig Ogino, San Bernardino County Crime Lab, San Bernardino, CA
Robyn Ragsdale, Florida Dept. of Law Enforcement, Tampa, FL
Charles Quenzer, Federal Bureau of Investigation, Quantico, VA
Marie Samples, Office of Chief Medical Examiner, New York, NY
Cary Oien, Federal Bureau of Investigation, Quantico, VA
Steve Meagher, Federal Bureau of Investigation, Quantico, VA
Ingrid Dearmore, Washington State Patrol, Marysville, WA
Tom Darnell, South Carolina Law Enforcement Division, Columbia, SC
Ed Moilanen, Staff Inspector, ASCLD/LAB, Roscommon, MI
Doreen Hudson, Los Angeles Police Department, Los Angeles, CA

LABORATORY OVERVIEW

The North Carolina State Bureau of Investigation Raleigh Crime Laboratory is located at 121 East Tryon Road in Raleigh, North Carolina and is a state laboratory which provides services for the State of North Carolina. Assistant Director Jerry Richardson is director of the Crime Laboratory System. He reports to State Bureau of Investigation Director Robin Pendergraft. The Laboratory provides services in Controlled Substances, Toxicology, Trace Evidence, Biology, Firearms/Toolmarks, Latent Prints, Questioned Documents and Digital Evidence. The laboratory has a staff of 92 testifying analysts and 24 support staff.

The Laboratory also provides Crime Scene services but elected not to apply for accreditation in this discipline.

INSPECTION TEAM FINDINGS

The following document lists each of the ASCLD/LAB Accreditation Standards and Evaluation Criteria from the 2003 Accreditation Manual. Each criterion for which the inspection team determined the laboratory to be in compliance is scored "Yes." Criteria for which the inspection *team found the laboratory to not be in total compliance* are scored "No." *Criteria which* are not applicable to the inspection of this laboratory are scored "N/A."

The Summary portion of the report documents the basis for all non-compliance and all non-applicable findings of the Inspection Team.

STANDARDS AND CRITERIA

The laboratory should establish objectives which are relevant to the community that it serves and communicate them to all employees orally and in written form.

		Yes	No	N/A
1.1.1.1 (I)	Does the laboratory have a written statement of its objectives?	✓		
1.1.1.2 (I)	Do the objectives appear to be relevant to the needs of the community serviced by the laboratory?	✓		
1.1.1.3 (D)	Does the laboratory staff understand and support the objectives?	✓		

A laboratory or its parent agency should have a formal written budget which is consistent with the forensic services provided by it.

1.1.2.1 (I)	Does the laboratory or its parent agency have a formal written budget?	✓		
1.1.2.2 (I)	Is the budget adequate to meet the written objectives?	✓		

Clearly written and well understood procedures must exist for handling and preserving the integrity of evidence; laboratory security; preparation, storage, security and disposition of case records and reports; and for maintenance and calibration of equipment and instruments. Clearly written and well understood procedures should also exist for control of materials and supplies; inventory of equipment and instruments; duty hours; leave time; job requirements and descriptions; personnel evaluations and objectives; and for employee grievances.

Do clearly written and well understood procedures exist for the following:

1.1.2.3 (E)	Handling and preserving the integrity of evidence.	✓		
1.1.2.4 (E)	Laboratory security.	✓		
1.1.2.5 (E)	Preparation, storage, security and disposition of case records or reports.	✓		
1.1.2.6 (D)	Control of materials and supplies.	✓		
1.1.2.7 (E)	Calibration of equipment and instruments.	✓		
1.1.2.8 (D)	Inventory of equipment and instruments.	✓		
1.1.2.9 (I)	Duty hours.	✓		
1.1.2.10 (I)	Leave time.	✓		
1.1.2.11 (D)	Job requirements and descriptions.	✓		

		Yes	No	N/A
1.1.2.12 (D)	Personnel evaluations and objectives.	✓		
1.1.2.13 (D)	Employee grievances.	✓		

A laboratory should have a management information system which provides information which assists the laboratory in accomplishing its objectives.

1.1.2.14 (I)	Does the laboratory have and use a management information system?	✓		

The laboratory manager should be able to relate the organizational structure to interacting variables such as those stated in the principle.

1.2.1.1 (D)	Does the organizational structure group the work and personnel in a manner that allows for efficiency of operation, taking into account the interrelation of various forensic disciplines?	✓		
1.2.1.2 (D)	Has the laboratory director considered and taken appropriate action to correct any discrepancies with regard to numbers of personnel when grouping work and resources?	✓		

The laboratory director should have authority commensurate with the assigned responsibilities.

1.2.2.1 (I)	Is the laboratory director's authority well defined?	✓		
1.2.2.2 (I)	Does the laboratory director have authority commensurate with responsibilities?	✓		

Delegation of authority within the laboratory should follow the organizational process outlined in the principle.

1.2.2.3 (I)	Is there sufficient delegation of authority?	✓		
1.2.2.4 (I)	Is authority of supervisors commensurate with their responsibilities?	✓		
1.2.2.5 (I)	Is each subordinate accountable to one and only one immediate supervisor per function?	✓		
1.2.2.6 (I)	Are performance expectations established and are they understood by laboratory personnel?	✓		

Constructive discussion should occur between supervisors and subordinates.

1.3.1.1 (D)	Is there constructive discussion between supervisors and subordinates?	✓		

Supervisors should carefully and objectively review laboratory activities and personnel.

		Yes	No	N/A
1.3.1.2 (I)	Do supervisors carefully and objectively review laboratory activities and personnel?	✓		

Supervisory techniques should encourage creative thinking and objectivity and should recognize meritorious performance of subordinates.

1.3.1.3 (D)	Do the supervisory techniques encourage creative, objective thinking and recognize meritorious performance?	✓		

Channels of communication within the laboratory should exist for coordination of case work and to ensure wide dissemination of technical information. Vertical, horizontal and diagonal channels of communication should exist within and external to the laboratory.

1.3.2.1 (D)	Do clear vertical, horizontal and diagonal channels of communication exist within and external to the laboratory?	✓		

Vertical channels of communication should normally be used for administrative functions.

1.3.2.2 (D)	Are vertical channels of communication used for administrative functions?	✓		

Staff meetings should be conducted on a regular basis.

1.3.2.3 (D)	Are staff meetings held on a regular basis?	✓		

A training program to develop the technical skills of employees is essential in each applicable functional area.

1.3.3.1 (E)	Does the laboratory have and use a documented training program in each functional area for employees who are new, untrained or in need of remedial training?	✓		

A formalized personnel development program is important to prepare employees to assume more responsible jobs.

1.3.3.2 (I)	Does the laboratory have an employee development program?	✓		

The laboratory should maintain an adequate forensic library to include literature published in the applicable functional areas.

1.3.3.3 (I)	Does the forensic library contain current books, journals, and other literature dealing with each functional area?	✓		

A system or procedure should exist to encourage a review of appropriate new literature by personnel.

		Yes	No	N/A
1.3.3.4 (I)	Does a system exist to encourage each examiner to review appropriate new literature?	✓		

A chain of custody record (e.g., signature, date, description of evidence) must be maintained which provides a comprehensive, documented history of each evidence transfer over which the laboratory has control.

1.4.1.1 (E)	Does the laboratory have a written or secure electronic chain of custody record with all necessary data which provides for complete tracking of all evidence?	✓		

Each individual item of evidence must be marked for identification, when practical. If the item does not lend itself to marking, its proximal container or identifying tag must be marked.

1.4.1.2 (E)	Is all evidence marked for identification?	✓		

Evidence seals must be designed and used to protect the integrity of the evidence.

1.4.1.3 (E)	Is evidence stored under proper seal?	✓		

Procedural precautions must exist which reduce the risk of evidence loss, cross transfer, contamination and /or other deleterious change.

1.4.1.4 (E)	Is evidence protected from loss, cross transfer, contamination and/or deleterious change?	✓		

A secure area for overnight and/or long-term storage of evidence must be available.

1.4.1.5 (E)	Is there a secure area for overnight and/or long-term storage of evidence?	✓		

All elements of a laboratory's quality system must be clearly documented in a quality manual which is kept current under the responsibility of a quality manager.

1.4.2.1 (E)	Does the laboratory have a comprehensive quality manual?	✓		

A laboratory must have an individual designated as the Quality Manager.

1.4.2.2 (E)	Is an individual designated as the quality manager?	✓		

To verify that its operations continue to comply with the requirements of its quality system and the standards under which ASCLD/LAB accreditation was granted, each laboratory must conduct an annual audit of its operations and submit an Annual Accreditation Audit Report (Appendix 6) to ASCLD/LAB, by April 1, each year.

		Yes	No	N/A
1.4.2.3 (E)	Did the laboratory conduct and document an annual audit of its operations and submit an annual accreditation audit report to ASCLD/LAB by the required deadline?	✓		

The quality system requires that laboratory management conduct a review at least once yearly to ensure the continued suitability and effectiveness of such a system.

1.4.2.4 (E)	Does the laboratory conduct and document an annual review of its quality system?	✓		

Procedures used must be generally accepted in the field or supported by data gathered and recorded in a scientific manner.

1.4.2.5 (E)	Are the procedures used generally accepted in the field or supported by data gathered and recorded in a scientific manner?	✓		

New technical procedures must be validated to prove their efficacy in examining evidence material before being implemented on casework.

1.4.2.6 (E)	Are new technical procedures scientifically validated before being used in casework and is the validation documentation available for review?	✓		

The laboratory must maintain written copies of appropriate technical procedures.

1.4.2.7 (E)	Are the technical procedures used by the laboratory documented and are the documents available to laboratory personnel for review?	✓		

Controls and standard samples must be used and documented in the case record to ensure the validity of the testing parameters and, thereby, the conclusion.

1.4.2.8 (E)	Are appropriate controls and standards specified in the procedures and are they used and documented in the case record to ensure the validity of examination results?	✓		

The quality of the standard samples and reagents must be adequate for the procedure used.

1.4.2.9 (E)	Is the quality of the standard samples and reagents adequate for the procedure used?	✓		

All reagents must be routinely tested for their reliability.

1.4.2.10 (E)	Does the laboratory routinely check the reliability of its reagents?	✓		

Instruments/equipment should be adequate for the procedures used.

1.4.2.11 (I)	Are the instruments/equipment adequate for the procedures used?	✓		

Instruments/equipment should be maintained in proper working order.

		Yes	No	N/A
1.4.2.12 (I)	Are the instruments/equipment in proper working order?	✓		

Instruments/equipment must be properly calibrated and calibration records maintained for all calibrated instruments.

1.4.2.13 (E)	Are the instruments/equipment properly calibrated?	✓		

The laboratory must create and maintain a case record for administrative and examination documentation generated or received by the laboratory on each case which it receives. Examination documentation such as notes, worksheets, photographs, spectra, printouts, charts, and other data or records which support conclusions must be generated and kept in the case record.

1.4.2.14 (E)	Do the examiners generate and does the laboratory maintain, in a case record, all the notes, worksheets, photographs, spectra, printouts, charts and other data or records used by examiners to support their conclusions?	✓		
1.4.2.15 (E)	Does the laboratory maintain case related administrative documentation generated and received, in a retrievable form?	✓		

It is essential that a representative number of reports be subjected to a technical review.

1.4.2.16 (E)	Does the laboratory have, use and document a system of technical review of the reports to ensure that the conclusions of its examiners are reasonable and within the constraints of scientific knowledge?	✓		

Administrative reviews must be conducted to ensure the completeness and correctness of the reports issued.

1.4.2.17 (E)	Does the laboratory conduct and document administrative reviews of all reports issued?	✓		

The laboratory must have and follow a written procedure whereby the testimony of each examiner is monitored at least once every year.

1.4.2.18 (E)	Does the laboratory monitor the testimony of each examiner at least annually and is the examiner given feedback from the evaluation?	✓		

The laboratory must have a written procedure which it uses to initiate a review and to take corrective action when the laboratory has an indication of a significant problem with a technical procedure or the work of an analyst.

		Yes	No	N/A
1.4.2.19 (E)	If the laboratory has an indication of a significant technical problem, is there a procedure in writing and in use whereby the laboratory initiates a review and takes any corrective action required?	✓		

Each laboratory must have a documented program of proficiency testing which measures the capability of its examiners and the reliability of its analytical results.

1.4.3.1 (E)	Does the laboratory have a documented program of proficiency testing?	✓		

The laboratory must participate in proficiency testing programs in which samples are provided by an external test provider. ASCLD/LAB approved providers must be used where available.

1.4.3.2 (E)	Does the laboratory participate in proficiency testing programs conducted by approved test providers or by other external provider(s) when no approved provider is available?	✓		

Each Examiner should be proficiency tested annually in each subdiscipline in which casework is performed.

1.4.3.3 (I)	Was each examiner proficiency tested annually in each *subdiscipline in which casework was performed?*	✓		

The laboratory should conduct annual proficiency testing in each discipline using re-examination or blind techniques.

1.4.3.4 (I)	Does the laboratory conduct proficiency testing using re-examination or blind techniques?	✓		

MANAGEMENT

The laboratory director should have a minimum of a baccalaureate degree in a natural science, criminalistics or a closely related field. If the director lacks a scientific background, then there should be support within management by personnel with appropriate scientific background.

2.1.1 (I)	Does the laboratory director possess a degree in a natural science, criminalistics or in a closely related field, or is the laboratory director supported by scientific personnel of sufficient managerial rank and authority?	✓		

A laboratory director should have at least five years of forensic science experience performing casework in one of the ASCLD/LAB accredited disciplines.

2.1.2 (D)	Does the laboratory director have at least five years of forensic science experience?	✓		

Additional education in management or business administration by college course work or short training courses (or both) is recommended.

		Yes	No	N/A
2.1.3 (D)	Does the laboratory director have some formal training in management?	✓		

The laboratory director should have at least two years of experience in management.

2.1.4 (D)	Does the laboratory director have at least two years of managerial experience?	✓		

CONTROLLED SUBSTANCES

Examiners must have education and experience/training commensurate with the examinations and testimony provided. A baccalaureate degree in a natural science, criminalistics or in a closely related field is required.

2.2.1 (E)	Does each examiner possess a baccalaureate degree in a natural science, criminalistics or in a closely related field and does each have experience/training commensurate with the examinations and testimony provided?	✓		

Examiners must have a good understanding of the principles, uses and limitations of the instruments, and the methods and procedures as applied to the tasks performed.

2.2.2 (E)	Does each examiner understand the instruments, and the methods and procedures used?	✓		

Examiners must have successfully completed a competency test.

2.2.3 (E)	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	✓		

A proficiency test must be successfully completed by each examiner at least annually.

2.2.4 (E)	Did each examiner successfully complete an annual proficiency test?	✓		

TOXICOLOGY

Examiners must have education and experience/training commensurate with the examinations and testimony provided. A baccalaureate degree in a natural science, toxicology, criminalistics or in a closely related field is required.

2.3.1 (E)	Does each examiner have a baccalaureate degree in a natural science, toxicology, criminalistics or in a closely related field and does each have experience/training commensurate with the examinations and testimony provided?	✓		

Examiners must have a good understanding of the principles, uses and limitations of the instruments, and the methods and procedures applied to the tasks performed.

		Yes	No	N/A
2.3.2 (E)	Does each examiner understand the instruments, and the methods and procedures used?	✓		

Examiners must have successfully completed a competency test.

2.3.3 (E)	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	✓		

A proficiency test must be successfully completed by each examiner at least annually.

2.3.4 (E)	Did each examiner successfully complete an annual proficiency test?	✓		

TRACE EVIDENCE

Examiners must have education and experience/training commensurate with the examinations and testimony provided. A baccalaureate degree in a natural science, criminalistics or in a closely related field is required.

2.4.1 (E)	Does each examiner possess a baccalaureate degree in a natural science, criminalistics or in a closely related field and does each have experience/training commensurate with the examinations and testimony provided?	✓		

Examiners must have a good understanding of the principles, uses and limitations of the instruments, and the methods and procedures applied to the tasks performed.

2.4.2 (E)	Does each examiner understand the instruments, and the methods and procedures used?	✓		

A competency test must be successfully completed prior to working cases of each evidence type.

2.4.3 (E)	Did each examiner successfully complete a competency test in each of the subdisciplines processed prior to assuming casework responsibility?	✓		

A proficiency test must be successfully completed by each examiner at least annually.

2.4.4 (E)	Did each examiner successfully complete an annual proficiency test?	✓		

BIOLOGY

Examiners must have education and experience/training commensurate with the examinations and testimony provided. A baccalaureate degree in a natural science, criminalistics or in a closely related field is required.

		Yes	No	N/A
2.5.1 (E)	Does each examiner possess a baccalaureate degree in a natural science, criminalistics or in a closely related field and does each have experience/training commensurate with the examinations and testimony provided?	✓		
2.5.2 (E)	Does each examiner performing DNA analysis have education, training and experience consistent with those required by the *quality assurance audit document*?	✓		

Examiners must have a good understanding of the principles, uses and limitations of the instruments, and the methods and procedures applied to the tasks performed.

2.5.3 (E)	Does each examiner understand the instruments, and the methods and procedures used?	✓		

Examiners must have successfully completed a competency test.

2.5.4 (E)	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	✓		

A proficiency test must be successfully completed by each examiner at least annually?

2.5.5 (E)	Did each examiner successfully complete an annual proficiency test?	✓		

Two proficiency tests must be successfully completed by each DNA examiner annually.

2.5.6 (E)	Did each examiner performing DNA analysis successfully complete two annual proficiency tests from an approved test provider?	✓		

FIREARMS/TOOLMARKS

Firearms/toolmarks examiners should have a baccalaureate degree with science courses.

2.6.1 (I)	Does each examiner possess a baccalaureate degree with science courses?	✓		

Examiners must have a good understanding of the principles, uses and limitations of the instruments, and the methods and procedures used as applied to the tasks performed.

2.6.2 (E)	Does each examiner understand the instruments, and the methods and procedures used?	✓		

Examiners must have education and experience/training commensurate with the examinations and testimony provided. Independent case examinations must not be undertaken until extensive instruction from a qualified examiner has been completed.

		Yes	No	N/A
2.6.3 (E)	Did each examiner have extensive training from a qualified examiner and does each have experience commensurate with the examinations and testimony provided?	✓		

Examiners must successfully complete a competency test.

2.6.4 (E)	Did each examiner successfully complete a competency test prior to assuming case work responsibility?	✓		

A proficiency test must be successfully completed by each examiner at least annually.

2.6.5 (E)	Did each examiner successfully complete an annual proficiency test?	✓		

QUESTIONED DOCUMENTS

Questioned document examiners should have a baccalaureate degree with science courses.

2.7.1 (I)	Does each examiner possess a baccalaureate degree with science courses?	✓		

Examiners must have a good understanding of the principles, uses and limitations of the instruments, and the methods and procedures used as applied to the tasks performed.

2.7.2 (E)	Does each examiner understand the instruments, and the methods and procedures used?	✓		

Examiners must have education and training/experience commensurate with the examinations and testimony provided. Independent case examinations must not be undertaken until extensive instruction from a qualified document examiner has been completed.

2.7.3 (E)	Did each examiner have extensive training from a qualified examiner and does each have experience commensurate with the examinations and testimony provided?	✓		

Examiners must have successfully completed a competency test.

2.7.4 (E)	Did each examiner successfully complete a competency test prior to assuming case work responsibility?	✓		

A proficiency test must be successfully completed by each examiner at least annually.

2.7.5 (E)	Did each examiner successfully complete an annual proficiency test?	✓		

LATENT PRINTS

Latent print examiners should have a baccalaureate degree with science courses.

		Yes	No	N/A
2.8.1 (I)	Does each examiner possess a baccalaureate degree with science courses?	___	✓	___

Examiners must have a good understanding of the concept of individualization and the principles, uses and limitations of the instruments, and the methods and procedures used as applied to the tasks performed.

2.8.2 (E)	Does each examiner understand the instruments, and the methods and procedures used?	✓	___	___

Examiners must have education and training/experience commensurate with the examinations and testimony provided. Independent case examinations must not be undertaken until extensive instruction from a qualified latent print examiner has been completed.

2.8.3 (E)	Did each examiner have extensive training from a qualified examiner and does each have experience commensurate with the examinations and testimony provided?	✓	___	___

Examiners must have successfully completed a competency test.

2.8.4 (E)	Did each examiner successfully complete a competency test prior to assuming casework responsibility?	✓	___	___

A proficiency test must be successfully completed by each examiner at least annually.

2.8.5 (E)	Did each examiner successfully complete an annual proficiency test?	✓	___	___

TECHNICAL SUPPORT

The individual must meet the specification of the job description.

2.9.1 (E)	Do technical support personnel meet the requirements of their job descriptions?	✓	___	___

The job description and the duties performed must be in agreement.

2.9.2 (E)	Are the job descriptions and the duties performed in agreement?	✓	___	___

Technical support staff must have successfully completed an appropriate competency test.

2.9.3 (E)	Did each member of the technical support staff successfully complete an appropriate competency test prior to assuming casework responsibility?	✓	___	___

Technical support personnel must successfully complete an appropriate proficiency test annually.

		Yes	No	N/A
2.9.4 (E)	Did all technical support personnel successfully complete an appropriate proficiency test, annually?	✓		

Two proficiency tests must be successfully completed annually by all technical support personnel performing DNA analysis.

2.9.5 (E)	Did all technical support personnel performing DNA analysis successfully complete two annual proficiency tests from an approved test provider?	✓		

CRIME SCENE

The examiner must meet the requirements of the job description.

2.10.1 (E)	Do examiners meet the requirements of their job descriptions?			✓

Examiners must have a good understanding of the concept and theory of scene security and integrity, and the uses and limitations of the equipment, methods and procedures used to document and process crime scenes, as applied to the tasks performed.

2.10.2 (E)	Does each examiner understand the equipment, methods and procedures used?			✓

Examiners must have training and experience commensurate with the examinations, documentation and testimony provided, as applied to the tasks performed. Independent examinations and documentation at crime scenes must not be undertaken until extensive instruction from a qualified examiner has been completed.

2.10.3 (E)	Did each examiner have extensive training from a qualified examiner and does each have experience commensurate with the examinations/documentation and testimony provided?			✓

Examiners must have successfully completed a competency test(s) as applied to the task(s) performed.

2.10.4 (E)	Did each examiner successfully complete a competency test(s) prior to primary responsibility for the examination, documentation and processing of a crime scene?			✓

A proficiency test must be completed by each person conducting crime scene examinations at least annually. The proficiency test should reflect the types of procedures, methods and equipment as applied to the typical task(s) performed.

2.10.5 (E)	Did each examiner successfully complete an annual proficiency test?			✓

DIGITAL EVIDENCE

Digital evidence examiners should have a baccalaureate degree with science courses.

		Yes	No	N/A
2.11.1 (I)	Does each examiner possess a baccalaureate degree with science courses?	✓	___	___

Examiners must have a good understanding of the principles, uses and limitations of the hardware, software, and the methods and procedures as applied to the tasks performed.

2.11.2 (E)	Does each examiner understand the equipment, programs, methods and procedures used?	✓	___	___

Examiners must have education and training/experience commensurate with the examinations and testimony provided. Independent case examinations must not be undertaken until extensive instruction from a qualified examiner has been completed.

2.11.3 (E)	Does each examiner have experience commensurate with the examinations/documentation and testimony provided?	✓	___	___

Examiners must have successfully completed a competency test.

2.11.4 (E)	Did each examiner successfully complete a competency test in each subdiscipline prior to assuming casework responsibility?	✓	___	___

A proficiency test must be successfully completed by each examiner at least annually.

2.11.5 (E)	Did each examiner successfully complete an annual proficiency test?	✓	___	___

Each employee should have adequate work space to accomplish assigned tasks.

3.1.1 (I)	Does each employee have adequate work space to accomplish assigned tasks?	✓	___	___

Sufficient space should be provided for storage of supplies, equipment and tools.

3.1.2 (D)	Is there sufficient space provided for storage of supplies, equipment and tools?	✓	___	___

Examiners should have space available for writing reports and other official communications.

3.1.3 (I)	Is there adequate space available for examiners for writing reports and other official communications?	✓	___	___

Adequate and appropriate space should exist for records and reference materials.

		Yes	No	N/A
3.1.4 (I)	Is there adequate and appropriate space available for records, reference works and other necessary documents?	✓		

Sufficient space should be available for instrumentation/equipment to facilitate its operation.

		Yes	No	N/A
3.1.5 (I)	Is adequate space available for instrumentation/equipment to facilitate its operation?	✓		

Accessories should be stored near instrumentation/equipment to facilitate its use and operation.

		Yes	No	N/A
3.1.6 (D)	Are accessories stored near instrumentation/equipment to facilitate its use and operation?	✓		

The physical design should permit the efficient flow of evidence from the time of its acceptance until its proper disposal.

		Yes	No	N/A
3.2.1 (I)	Does the physical design permit the efficient flow of evidence from the time of its acceptance until its proper disposal?	✓		

The relative locations of functional areas should facilitate the use of equipment and instruments.

		Yes	No	N/A
3.2.2 (D)	Do the relative locations of functional areas facilitate the use of equipment and instruments?	✓		

Adequate and proper lighting should be available for personnel to carry out assigned tasks.

		Yes	No	N/A
3.2.3 (I)	Is there adequate and proper lighting available for personnel to carry out assigned tasks?	✓		

Adequate and proper plumbing and wiring should be available and accessible to carry out assigned tasks.

		Yes	No	N/A
3.2.4 (I)	Is there adequate and proper plumbing and wiring available and accessible to carry out assigned tasks?	✓		

The laboratory should have proper general ventilation.

		Yes	No	N/A
3.2.5 (I)	*Does the laboratory have proper general ventilation?*	✓		

There should be adequate heating, cooling and humidity control in the laboratory.

		Yes	No	N/A
3.2.6 (I)	Is the heating, cooling and humidity control in the laboratory adequate?	✓		

Access to the operational area of the laboratory must be controllable and limited to those individuals who are assigned to routinely work in the area or to those individuals designated by the laboratory director to have access.

		Yes	No	N/A
3.3.1 (E)	Is access to the operational area of the laboratory controllable and limited?	✓		

All exterior entrance/exit points require adequate security control.

3.3.2 (E)	Do all exterior entrance/exit points have adequate security control?	✓		

Internal areas requiring limited/controlled access must have a lock system.

3.3.3 (E)	Do all internal areas requiring limited/controlled access have a lock system?	✓		

Accountability of all keys, magnetic cards, etc., must be documented and their distribution limited to those individuals designated by the laboratory director to have access.

3.3.4 (E)	Is distribution of all keys, magnetic cards, etc., documented and is distribution limited to those individuals designated by the laboratory director to have access?	✓		

The laboratory must be monitored during vacant hours by an intrusion alarm or by security personnel.

3.3.5 (E)	Is the laboratory secured during vacant hours by means of an intrusion alarm or by security personnel?	✓		

The laboratory should have a fire detection system.

3.3.6 (I)	Does the laboratory have a fire detection system?	✓		

All elements of a laboratory's health and safety program must be clearly documented in a manual. The program should be monitored and the manual kept current by a health and safety manager.

3.4.1 (I)	Does the laboratory have an effective health and safety program documented in a manual?	✓		
3.4.2 (I)	Is an individual designated as the health and safety manager?	✓		
3.4.3 (I)	Is the health and safety program monitored regularly and reviewed annually to ensure that its requirements are being met?	✓		

The laboratory should have available and encourage the use of safety devices (particularly those required in its health and safety manual). Examples of such devices are goggles, face protectors, ear protectors, gloves and fire extinguishers.

		Yes	No	N/A
3.4.4 (I)	Does the laboratory have available and encourage the use of safety devices, particularly those required by its health and safety manual?	✓		

Proper equipment and material should be available for the handling of carcinogenic, toxic and/or other dangerous material spills.

3.4.5 (I)	Does the laboratory have proper equipment and material available for the handling of carcinogenic, toxic and/or other dangerous material spills?	✓		

The laboratory should have safety shower and eye wash equipment in appropriate locations and in good working condition.

3.4.6 (I)	Does the laboratory have safety shower and eye wash equipment in appropriate locations and in good working condition?	✓		

Exhaust hoods must be available to maintain a safe work environment.

3.4.7 (I)	Are sufficient exhaust hoods available to maintain a safe work environment?	✓		

Sufficient first-aid kits should be available and strategically located.

3.4.8 (I)	Are sufficient first-aid kits available and strategically located?	✓		

An adequate number of personnel should hold current certification in first-aid.

3.4.9 (I)	Does the laboratory have an adequate number of personnel holding current certification in first-aid?	✓		

Space should be provided for safe storage of volatile, flammable, explosive and other hazardous materials.

3.4.10 (I)	Is appropriate space provided for safe storage of volatile, flammable, explosive and other hazardous materials?	✓		

Emergency exits from the laboratory should be in compliance with safe working requirements.

3.4.11 (I)	Are the emergency exits from the laboratory adequate for safe exit in an emergency?	✓		

General cleanliness and good-housekeeping should be apparent.

3.4.12 (D)	Is there general cleanliness and apparent good-housekeeping in the laboratory?	✓		

FINDINGS

The following summarizes the criteria for which the Inspection Team determined the laboratory was not in compliance at the time of the inspection and the basis for the finding. The summary also identifies criteria which were determined to be not applicable and the basis for that determination:

1.1.2.7 (E) CALIBRATION OF EQUIPMENT AND INSTRUMENTS.

Original inspection finding:
The calibration procedures for the balances in the Drug Chemistry and Biology sections do not include accuracy tolerance limits.

The Drug Chemistry Section does not have written procedures for the calibration of the Gas Chromatograph portion of the Gas Chromatograph/Mass Spectrometer when the Gas Chromatograph portion is used in the identification of controlled substances.

Supplemental finding:
Accuracy tolerance limits have been added to the calibration procedures in the Drug Chemistry and Biology Sections (See section 8.7 for Biology). Certified weights have been purchased and are available to these sections and other disciplines in the Crime Laboratory.

Written procedures are now included in Drug Chemistry Section procedures manual for the calibration of the gas chromatography portion of the Gas Chromatograph/Mass Spectrometer when the gas chromatography portion is used in the identification of controlled substances.

1.4.1.3 (E) IS EVIDENCE STORED UNDER PROPER SEAL?

Original inspection finding:
Electrostatic Detection Apparatus (ESDA) results are being stored as examination documentation in the Document Section case records.

Supplemental finding:
The procedure for storage of Electrostatic Detection Apparatus (ESDA) has been modified **to treat these exhibits as evidence. A new "Positive ESDA Lift" policy has been instituted. The policy requires positive ESDA lifts to be treated as evidence and stored as such in the property room until returned to the submitting agency. A review of a case file requiring ESDA analysis confirmed that the ESDA exhibits are treated as evidence and stored in the property room until it is returned to the submitting agency.**

1.4.2.5 (E) ARE THE PROCEDURES USED GENERALLY ACCEPTED IN THE FIELD OR SUPPORTED BY DATA GATHERED AND RECORDED IN A SCIENTIFIC MANNER?

Original inspection finding:
The written procedures in the Drug Chemistry Section are not specific to meet minimum identification requirements for phenalkylamines in regard to mass spectroscopy. If GC/MS is used, the procedure does not specify that a verified gas chromatographic retention time must be used in conjunction with the mass spectrometer results for the identification of phenalkylamines.

A conclusion in one ink examination case in the Questioned Documents Section reported that two ink samples had matching formulas. Case examination documentation revealed only physical *examination techniques (fluorescence, luminescence and reflectance) were used to arrive at the* conclusion. Questioned Document Section procedures for the analysis of ink include physical examination, chemical examination and thin layer chromatography. The technical procedures do not include minimum standards for reporting conclusions.

Supplemental finding:
The procedures in Drug Chemistry have been modified to meet the minimum identification requirement and specifications for phenalkylamines in regard to mass spectroscopy. Gas chromatograph interpretation is now required when using the mass spectrometer to identify phenylalykamines.

A corrected report has been issued for the ink examination case and a copy of the report was submitted to the inspection team for review. Crime Laboratory Directive 03-05 was *issued to suspend all ink analysis in the Questioned Documents section. All future ink* comparison requests will be referred to other agencies for analysis.

1.4.2.8 (E) ARE APPROPRIATE CONTROLS AND STANDARDS SPECIFIED IN THE PROCEDURES AND ARE THEY USED AND DOCUMENTED IN THE CASE RECORD TO ENSURE THE VALIDITY OF EXAMINATION RESULTS?

Original inspection finding:
Appropriate controls and standards are being used in the Digital Evidence Section, but are not specified in the Computer Forensics, Audio, or Video procedures, nor is their use being documented in the Computer Forensic case records.

The quantitation procedure in Biology uses a serial dilution to create a set of standards ranging from 10 ng to 0.15 ng, as well as two calibration controls intended to assess the performance of the standards. The technical procedures specify the use of these standards and calibrators but does not address the expected results, acceptable performance of the standards or calibrators, or the interpretation of results (DNA Audit Document standard 9.1, 9.1.2.). The procedure does not specify a minimum number of visible standards (or minimal DNA concentration) as well as data interpretation to ensure uniformity among analysts.

The gas chromatographic portion of the Drug Chemistry gas chromatograph-mass spectrometers is not being checked with controls or standards.

Supplemental finding:
Appropriate controls and standards are now specified in the Computer Forensics, Audio, or *Video procedures for the Digital Evidence disciplinee and the use of standards and controls* is being documented in the examination documentation.

The technical procedures for the Biology Section have been revised to address the expected results, acceptable performance of the standards or calibrators, and the interpretation of results. The procedures also specify a minimum number of visible standards (or minimal DNA concentration) as well as *data interpretation to ensure uniformity among analysts.*

The procedures for the gas chromatographic portion of the Drug Chemistry gas chromatograph-mass spectrometers have been revised to include checking with controls or standards. A review of the monthly retention time standard checks confirmed that the procedure is being followed.

1.4.2.9 (E) IS THE QUALITY OF THE STANDARD SAMPLES AND REAGENTS ADEQUATE FOR THE PROCEDURE USED?

Original inspection finding:
No source documentation was available in the Drug Chemistry section for the verification of controlled substance reference standards used for infrared and mass spectral comparisons.

Supplemental finding:
Certified drug standards have been obtained for the Drug Chemistry Section. Invoices were reviewed as the source documentation for the drug standards received. Review of several standard sample confirmation checks confirmed that has been done.

1.4.2.13 (E) ARE THE INSTRUMENTS/EQUIPMENT PROPERLY CALIBRATED?

Original inspection finding:
The Drug Chemistry Quality Assurance Manual (4.A.7, page 4-2) states that electronic balances "will be calibrated or have the calibration certified by the chemists on a monthly basis using standard weights". The weights used for calibration by the chemists have no authenticating certifying documentation.

Supplemental finding:
Certified weights have been purchased and are currently available to the Drug Chemistry Section of the Crime Laboratory. Review of the October and November standard weight certification confirmation checks confirmed that has been done.

1.4.2.14 (E) DO THE EXAMINERS GENERATE AND DOES THE LABORATORY MAINTAIN, IN A CASE RECORD, ALL THE NOTES, WORKSHEETS, PHOTOGRAPHS, SPECTRA, PRINTOUTS, CHARTS AND OTHER DATA OR RECORDS USED BY EXAMINERS TO SUPPORT THEIR CONCLUSIONS?

Original inspection finding:
In the Biology Section, Administrative Order 01-PRO-4 dated April 24, 2001 requires that mandatory steps be followed when case samples are batched. During analyst interviews, it was determined that samples from different cases may be "batched" for extraction, quantitation, *and/or amplification. However, there is no documentation in individual case records* when samples are batched, making it impossible to compare results obtained between cases should the need for such comparison arise (i.e. for trouble-shooting). (DNA Audit Document standard 11.1, 11.1.1).

Supplemental finding:
Administrative Order 01-PRO-4 dated April 24, 2001 in the Biology Section has been revised and now includes the steps to be followed when case samples are batched. Additional notation areas have been added to the pre-printed case notes to show which cases have been batched. The revised pre-printed forms were submitted for review to reflect that this documentation is currently being used in the individual case records. Review of three "batch sample confirmation" case record reviews confirmed that is now being done.

2.11.1(I) DOES EACH EXAMINER POSSESS A BACCALAUREATE DEGREE WITH SCIENCE COURSES?

Original inspection finding:
Not all examiners possess a baccalaureate degree.

Supplemental finding:
One analyst in the Digital Evidence discipline did not possess a baccalaureate degree during the on-site audit. The analyst has since retired.

3.4.11 (I) ARE THE EMERGENCY EXITS FROM THE LABORATORY ADEQUATE FOR SAFE EXIT IN AN EMERGENCY?

Original inspection finding:
Personal work areas in the Trace Evidence, Drug Chemistry, Biology and Latent Evidence sections are divided by common (shared) instrument/processing rooms. Access to these common rooms is from adjacent work areas. Exit from these rooms is by key only. If an analyst enters these rooms without the key, and the door(s) should happen to close while they are in the room, there is no way to exit or notify another person other than by pounding on the door to attract attention.

Supplemental finding:
Keys have been placed in all personal work areas in the Trace Evidence, Drug Chemistry, Biology, Firearms and Latent Evidence Section which have been divided by common instrumentation/processing areas. A key box or sealed container has been placed in a secure location in each of these areas, and secured with an initialed taped seal. When the key is needed in an emergency situation, the employee using the key must break the seal to obtain the key and is required to notify his/her supervisor as soon as possible. This action will be documented by the supervisor and it will be the responsibility of the supervisor to ensure that the key is returned to the appropriate location and sealed accordingly. Photographs of the key boxes and individual keys for each section were reviewed and substantiated that successful remediation has been accomplished.

The inspection team was not presented with documentation of compliance for the following Important criterion which was scored NO during the initial inspection:

2.8.1 (I) DOES EACH EXAMINER POSSESS A BACCALAUREATE DEGREE WITH SCIENCE COURSES?

Original inspection finding:
Not all examiners possess a baccalaureate degree.

All criteria for 2.10 Crime Scene were scored N/A because the laboratory elected not to apply for Crime Scene accreditation.

SUMMATION OF CRITERIA RATINGS

	Total Possible	Total Yes	Total No	Total N/A	Total Number Yes/No
Essential	78	73	0	5	73
Important	47	46	1	0	47
Desirable	20	20	0	0	20

Percent Essential: 100%

Percent Important: 98%

Percent Desirable: 100%

Areas sought for accreditation are as follows:

Controlled Substances	Firearms/Toolmarks
Toxicology	Latent Prints
Biology	Questioned Documents
Trace Evidence	Digital Evidence

Prepared by: Mike Johnston, Staff Inspector

Ralph M. Keaton
Ralph M. Keaton, Executive Director

12-18-03
Date

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 Crime Lab

Dates of Audit: August 25 - 29, 2003

Auditor(s):

Robyn L. Ragsdale			
(Name)		(Signature)	
Marie Samples			
(Name)		(Signature)	
(Name)		(Signature)	

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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?	✓		

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	✓		
b.	Organization and management structure	✓		
c.	Personnel Qualifications and Training	✓		
d.	Facilities	✓		
e.	Evidence control	✓		
f.	Validation	✓		
g.	Analytical procedures	✓		
h.	Calibration and maintenance	✓		
i.	Proficiency testing	✓		
j.	Corrective action	✓		
k.	Reports	✓		
l.	Review	✓		
m.	Safety	✓		
n.	Audits	✓		

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?	✓		

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?	✓		

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)	✓		
4.1c (CO)	Does the laboratory have a CODIS manager or custodian who is accountable for CODIS operations?	✓		

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?	✓		

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?	✓		

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?	✓		

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?	✓		
5.1.3.1(a)	Over the last year, has the technical manager or leader read current scientific literature?	✓		
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?	✓		
5.1.3.1(c) (CO)	Over the last year, has the CODIS manager read current scientific literature?	✓		
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?	✓		
5.1.3.1(e)	Over the last year, has each examiner/analyst read current scientific literature?	✓		
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?	✓		

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:

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

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?	✓	___	___

		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?	✓		
	A. A graduate degree in a biology, chemistry, or forensic science related area	✓		
	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	✓		
	(b) Genetics	✓		
	(c) Molecular biology	✓		
	(d) Statistics and/or population genetics	✓		

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?			✓

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?	✓		

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?	✓		
5.2.3.1	Does the technical manager or leader manage the technical operations of the laboratory?	✓		
5.2.3.2 (a-1)	Is the technical manager or leader responsible for evaluating all methods used by the laboratory?	✓		
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?	✓		
5.2.3.2 (b-1)	Is the technical manager or leader responsible for technical problem solving of analytical methods?	✓		
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?	✓		
5.2.3.3	Is the technical manager or leader accessible to the laboratory to provide onsite, telephonic or electronic consultation as needed?	✓		

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?		✓		
5.3.1	Does each examiner/analyst meet the following degree/educational requirements		✓		
	A..	A B.A./B.S. degree or its equivalent in a biology, chemistry, or forensic science related area	✓		
	B.	College course work or classes covering the subject areas of:			
		(a) Biochemistry	✓		
		(b) Genetics	✓		
		(c) Molecular biology	✓		
	C.	College course work or training which covers the subject area of statistics and/or population genetics	✓		

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?	✓		
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?	✓		

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?	✓		

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?	✓		
5.3.1	Does the CODIS manager or custodian possess a Bachelor's degree in a natural science or computer science?	✓		
5.3.2 (a)	Does the CODIS manager or custodian have a working knowledge of the following:			
	(a) Computers	✓		
	(b) Computer networks	✓		
	(c) Computer database management	✓		
5.3.2 (b)	Does the CODIS manager or custodian have an understanding of DNA profile interpretation?	✓		
5.3.3	Does the CODIS manager or custodian meet the duty requirements of this position?	✓		
5.3.3 (a-1)	Does the CODIS manager or custodian function as the system administrator of the laboratory's CODIS network?	✓		
5.3.3 (a-2)	Is the CODIS manager or custodian responsible for the security of the DNA profile data stored in CODIS?	✓		
5.3.3 (b)	Is the CODIS manager or custodian responsible for oversight of the CODIS computer training and quality assurance of data?	✓		
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?	✓		

		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?	✓		

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?	✓		
5.4.1	Did each technician receive on the job training specific to their job function?	✓		
5.4.2	Did each technician successfully complete a qualifying test before participating in forensic DNA typing responsibilities?	✓		
5.5	Do all laboratory support personnel meet the requirements as stated in standard 5.5.1?	✓		
5.5.1	Do all laboratory support personnel possess the training, education and experience commensurate with their responsibilities as outlined in their job descriptions?	✓		

Comment:

STANDARD 6 - FACILITIES

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

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?	✓		
6.1.2 (CO)	Are evidence examinations, liquid sample examinations, DNA extractions and PCR setup conducted at separate times or in separate spaces?	✓		
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?	✓		
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?			✓
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?			✓

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?	✓	___	___

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?	✓	___	___
7.1.1	Is each evidence sample (including Convicted Offender samples) labeled with a unique identifier in accordance with established agency policy?	✓	___	___

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?	✓	___	___

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?	✓	___	___
7.1.3	Does the laboratory follow documented procedures that minimize loss, contamination, and/or deleterious change of evidence?	✓	___	___

		Yes	No	N/A
7.1.4	Does the laboratory have secure areas for evidence storage?	✓		
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?	✓		

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?	✓		
7.2.1 (FO)	Does the laboratory have a procedure requiring that evidence samples/extract(s) be stored in a manner that minimizes degradation?	✓		

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?	✓		

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?			✓

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?			✓
8.1.2.1	Is there documentation and is it available which defines and characterizes each locus?			✓
8.1.2.2 (FO)	Have species' specificity, sensitivity, stability and mixture studies been conducted?			✓
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?	✓		

		Yes	No	N/A
8.1.2.3.1 (FO-a)	Where appropriate, has the database been tested for independence expectations?	✓		
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?	✓		
8.1.3	Has the laboratory completed and documented internal validation studies?	✓		

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?	✓		
8.1.3.1 (a-CO)	Has the procedure been tested using known samples?	✓		
8.1.3.1(b)	Has the reproducibility and precision of the procedure been monitored and documented using human DNA control(s)?	✓		
8.1.3.2 (FO)	Based on empirical data, have match criteria been established and documented?	✓		
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)	✓		
8.1.3.4	Have material modifications to analytical procedures been documented and subjected to validation testing?	✓		
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	✓		

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?	___	✓	___
9.1.1	Does the laboratory have a documented standard operating protocol for each analytical technique used?	✓	___	___
9.1.2	Do the analytical procedures describe reagents, sample preparation, extraction, equipment, and controls which are standard for DNA analysis and data interpretation?	___	✓	___
9.1.3 (FO)	Does the laboratory have a procedure for the differential extraction of stains which contain semen?	✓	___	___

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:

See Findings for comments.

		Yes	No	N/A
9.2	Does the laboratory use reagents that are suitable for the methods employed?	✓	___	___
9.2.1	Does the laboratory have written procedures for documenting commercial supplies and for the formulation of reagents?	✓	___	___
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?	✓	___	___
9.2.3 (a)	Has the laboratory identified and evaluated the reagents critical to the analysis process prior to use in casework?	✓	___	___
9.2.3 (b)	Has the laboratory identified and evaluated the following critical reagents:			
	(a) Restriction enzyme	___	___	✓
	(b) Commercial kits for performing genetic typing	✓	___	___

		Yes	No	N/A
(c)	Agarose for analytical RFLP gels	___	___	✓
(d)	Membranes for Southern blotting	___	___	✓
(e)	K562 DNA or other human DNA controls	✓	___	___
(f)	Molecular weight markers used as RFLP sizing standards	___	___	✓
(g)	Primer sets	✓	___	___
(h)	Thermostable DNA polymerase	✓	___	___

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?	✓	___	___

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

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)	✓	___	___

		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)	✓		
9.4.2.2	Positive and negative amplification controls (CO 9.3.2.2)	✓		
9.4.2.3 (FO)	Reagent blanks	✓		
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)	✓		
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)	✓		

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)	✓		
9.6.1	Does the laboratory verify that all control results are within established tolerance ranges? (CO 9.5.1)	✓		
9.6.2	Where appropriate, are visual matches supported by a numerical match criterion?			✓
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 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?	✓		
10.2	Does the laboratory have a documented program for calibration of equipment and instruments?	✓		
10.2.1	Where available and appropriate, are standards traceable to *national or international standards used in the calibration* of equipment?	✓		
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?	✓		
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?	✓		
10.3	Does the laboratory have a documented program to ensure that instruments and equipment are properly maintained?	✓		
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?	✓		
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?	✓		

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?	___	✓	___
11.1 (CO)	Does the laboratory have and follow written procedures for generating and maintaining documentation for database samples?	✓	___	___
11.1.1 (FO)	Does the laboratory maintain in a case record, all documentation generated by examiners related to case analyses?	___	✓	___
11.1.1 (CO)	Does the laboratory have written procedures for the release of database sample information?	✓	___	___

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:

See Findings for comments.

			Yes	No	N/A
11.1.2 (FO)	Do the laboratory reports include the following criteria:				
	(a)	Case identifier	✓	___	___
	(b)	Description of evidence examined	✓	___	___
	(c)	A description of methodology	✓	___	___
	(d)	Locus	✓	___	___
	(e)	Results and/or conclusions	✓	___	___
	(f)	An interpretative statement (either quantitative or qualitative)	✓	___	___
	(g)	Date issued	✓	___	___
	(h)	Disposition of evidence	✓	___	___
	(i)	A signature and title or equivalent identification of the person(s) accepting responsibility for the	✓	___	___

		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?	✓	____	____

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?	✓		
12.1 (CO)	Does the laboratory have and follow written procedures for reviewing database sample information, results and matches?	✓		
12.1.1	Does the laboratory have a mechanism in place to address unresolved discrepant conclusions between analysts and reviewers?	✓		

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?	✓		
12.2 (CO)	Does the laboratory have and follow a written program that documents the annual monitoring of the testimony of laboratory personnel?	✓		

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?	✓		

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	✓		
	(b)	Identity of the examiner	✓		
	(c)	Date of analysis and completion	✓		
	(d)	Copies of all data and notes supporting the conclusions	✓		
	(e)	The proficiency test results	✓		
	(f)	Any discrepancies noted	✓		
	(g)	Corrective action taken	✓		

			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.	✓		
	(b)	All reported exclusions are correct or incorrect.	✓		
	(c)	All reported genotypes and/or phenotypes are correct or incorrect according to consensus genotypes/phenotypes or within established empirically determined ranges.	✓		
	(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.	✓		
	(e)	All discrepancies/errors and subsequent corrective actions			

		Yes	No	N/A
	must be documented.	✓		
(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.	✓		
(g)	All proficiency test participants shall be informed of the final test results.	✓		

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?	✓	—	—
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?	✓	—	—
14.1.1	Does the laboratory maintain documentation for corrective actions and is such documentation retained in accordance with applicable Federal or state law?	✓	—	—

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?		✓		
15.1.1	Did the audit procedures address the following:				
	(a)	Quality assurance program	✓		
	(b)	Organization and management	✓		
	(c)	Personnel	✓		
	(d)	Facilities	✓		
	(e)	Evidence control	✓		
	(f)	Validation	✓		
	(g)	Analytical procedures	✓		
	(h)	Calibration and maintenance	✓		
	(i)	Proficiency testing	✓		
	(j)	Corrective action	✓		
	(k)	Reports	✓		
	(l)	Review	✓		
	(m)	Safety	✓		
	(n)	Previous audits	✓		
15.1.2	Has the laboratory retained all documentation pertaining to audits in accordance with relevant legal, agency, and state requirements?		✓		
15.2	Did a second agency (external) participate in an annual audit of the laboratory at least once every two years?		✓		

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?	✓		

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?	___	___	✓
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?	___	___	✓
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	___	___	✓
	(b) Visual inspection and evaluation of results/data	___	___	✓
	(c) Inclusion of QC samples	___	___	✓
	(d) On-site visits	___	___	✓

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:

Although this lab is the state database laboratory, no offender samples have been typed in the past year.

Appendix A: FINDINGS AND RESPONSES

Findings:

Standard 9.1, 9.12 -The quantitation procedure uses a serial dilution to create a set of standards ranging from 10 ng to 0.15 ng, as well as two calibration controls intended to assess the performance of the standards. The technical procedures specify the use of these standards and calibrators but does not address the expected results, acceptable performance of the standards or calibrators, or the interpretation of results. The procedure needs to specify a minimum number of visible standards (or minimal DNA concentration) as well as data interpretation to ensure uniformity among analysts.

Standard 11.1, 11.1.1- In Molecular Genetics, Administrative Order 01-PRO-4 dated April 24, 2001 requires that mandatory steps be followed when samples are batched. During analysts interviews, it was determined that samples from different cases are "batched" together for extraction, quantitation, and/or amplification. However, there is no indication on the paperwork in each individual case record that samples were batched, making it impossible to compare results obtained between cases should the need for such comparison arise, i.e. for trouble-shooting .

Responses:

Comments:

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

December 2, 2003

NDIS Custodian
FBI Laboratory
Room 1120
2501 Investigation Parkway
FBI Academy Complex
Quantico, VA 22135

Dear NDIS Custodian:

I certify that the NDIS Participating and contract laboratories in the State of North Carolina have undergone the required audits. A list of laboratories and the results of the audit follow:

North Carolina State Bureau of Investigation
External Audit
August 25 - 29, 2003

Corrective Actions Were Required and
Corrective Actions Were Taken

Sincerely,

Mark Boodee
Designated State Official
Assistant Special Agent in Charge
Forensic Biology Section

(Enclosures)

December 2, 2003

Audit of North Carolina State Bureau of Investigation Crime Laboratory

Appendix A: Responses

Standard 9.1, 9.12 - In response to this finding, the Technical Leader produced written guidelines for DNA Quantitation and Interpretation. See attached sheets labeled NCSBI MOLECULAR GENETICS SECTION Quality Assurance Manual - Revision 04 Appendix F - STR Interpretation Guidelines.

Standard 11.1, 11.1.1 - In response to this finding, the Technical Leader created new analysis forms which contain areas for writing down batched case numbers. Copies of actual case notes are attached which show the use of these new forms.

NOTE: The original audit document was submitted without responses to NDIS by the auditors. This audit document copy is the one present in the lab and is being used to illustrate the Findings and Responses.

STR Interpretation Guidelines

1 DNA Quantitation Interpretation Guidelines

1.1 Background:

1.1.1 DNA quantitation results are interpreted by comparing the signal intensity for the DNA test sample to the signal intensity obtained for the DNA Standards. The signal intensity for a sample reflects the total amount of DNA spotted on the membrane: 10, 5, 2.5, 1.25, 0.625, 0.3125, and 0.15625 ng. The concentration of the Standards are 2, 1, 0.5, 0.25, 0.125, 0.0625, and 0.031 ng/μl respectively.

1.1.2 The DNA Quantitation is an estimation of the DNA concentration of the DNA in the Test Samples. There are factors that may effect the ability of a specific sample to quantitate and it is possible for a sample to show no DNA or low levels of DNA on the Quanti-Blot but actually contain enough DNA for PCR amplification. Since this is an estimation of the DNA concentration, all efforts will be made to utilize a specific Quant-blot so that samples will not wasted on re-testing.

1.2 DNA Calibrators:

1.2.1 The DNA Calibrators are used to provide DNA of known concentration to verify that the DNA Standards were correctly diluted and are providing correct results.

1.2.2 "DNA Calibrator 1" (stock concentration of 0.7 ng/μl or 3.5 ng/5 μl). The signal for this calibrator should have a signal strength between the 5 and 2.5 ng (1 and 0.5 ng/μl) DNA Standards.

1.2.3 "DNA Calibrator 2" (stock concentration of 0.1 ng/μl or 0.5 ng/5 μl). The signal for this calibrator should have a signal strength between the 0.625 and 0.3125 ng (0.25 and 0.1.25 ng/μl) DNA Standards.

1.2.4 If the DNA Calibrators do not quantitate correctly with respect to the DNA Standards but at least three (2.0, 1.0, and 0.5 ng/μl) of the

DNA Standards can be observed, then the test does not have to be repeated. To save limited DNA test samples for PCR analysis, the quantitation of the DNA test samples may be estimated by comparing the DNA Standards to the DNA Calibrators and determining how far the DNA Standards deviate from the DNA Calibrators and then estimate the concentration of the DNA test sample.

1.3 DNA Standards

To save DNA test samples for PCR analysis, the Quantitation does not have to be repeated if the 2.0, 1.0, 0.5, and 0.25 ng/μl DNA Standards are observed. If the 2.0, 1.0, 0.5, and 0.25 ng/μl DNA Standards are not observed, increased exposure times for the film should be attempted. If this does not cause the 2.0, 1.0, 0.5, and 0.25 ng/μl DNA Standards to be observed, then the Quantitation must be repeated.

1.4 Estimation of DNA Test Samples:

1.4.1 The quantity of DNA test sample spotted on the membrane will be estimated by directly comparing it's signal strength to the intensity of the DNA Standards. The concentration of the DNA Standard that is closest to the intensity of a DNA test sample will be used for calculating the volume needed for PCR analysis.

1.4.2 Since it is possible for a DNA test sample to show no DNA or very low levels of DNA on the Quanti-Blot, but actually contain enough DNA for PCR amplification, then if a DNA test sample does not show any DNA, then that sample will still be amplified.

2 PCR STR Interpretation

2.1 Introduction: The interpretation of results in casework is necessarily a matter of professional judgment and expertise. Not every situation can or should be covered by a pre-set rule. It is important that this laboratory develop and adhere to criteria for the interpretation of analytical results. These criteria are based on our validation studies, literature, and over 10

North Carolina State Bureau Of Investigation
Crime Laboratory Division

FORENSIC BIOLOGY SECTION

CASE NOTES COVER SHEET

SBI LAB FILE NUMBER	R2002-8998
ANALYST	David Freeman DF
DATE ANALYSIS STARTED	10/13/03
DATE ANALYSIS COMPLETED	11/19/03

ADMINISTRATIVE REVIEW	
(Initials)	(Date)
TECHNICAL REVIEW	
See last page of the attached notes	

PAGE NUMBER	2
SBI LAB FILE NUMBER	B0027997
ANALYST	[illegible]
DATE	5/22/02

DNA SAMPLE SUBMISSION DATA FORM

ITEM #	DESCRIPTION OF EVIDENCE AND PACKAGING CONTAINERS
1-2	T man env c̄ bloodstain from Brittany Ferguson
1-12	T white env c̄ control swabs
1-13	T white env c̄ swab of labia
1-14	T man env c cuttings from pantries (Item 1-5)
2-2	T man env c̄ bloodstain from Thomas Lee
3-1	T man env c̄ cutting from pantries (Item 3)

DNA profiles for the following items have been entered in CODIS:

none

Only the following categories will be uploaded to CODIS:

[ ] *Suspect Standard* - Item # _____

[ ] Unsolved/unidentified forensic unknown profile - Item # _____

[ ] Transfer of suspect's DNA to victim or scene (forensic unknown) - Item # _____

[ ] Mixture of victim/suspect or unknown profile - Item # _____ (as much of victim profile as possible has been removed)

First Reader _____ Second Reader _____

Verification of sample identity and samples marked for upload to CODIS by:

Second Reader _____

forms/casenotes/bodyfluid/strsub2.wpd

PAGE NUMBER	2 3
SBI LAB FILE NUMBER	R2002-8998
ANALYST	[illegible]
DATE	10/13/03

DNA Extraction Worksheet

***NOTE:** Extractions for Question and Known Samples are separated by time or space.*

Question Samples	Date/ Time	Extraction Type	Final Volume	Area and Equip. Decon.
1-13, 1-14, 3-1, -f/m	10/13/03 5:50 A	differential	m = 25 µl f - 150 µl	[illegible]

Known Samples	Date/Time	Extraction Type	Final Volume	Area and Equip. Decon.
1-2, 2-2, -K, MJB	10/13/03 6:35 A	organic	200 µl	[illegible]

Phenol/Chloroform Lot # 112K0583

Extracted with following Cases R2002-20743

Notes: 1-12 not analyzed

PAGE NUMBER	4
SBI LAB FILE NUMBER	R2002-8998
ANALYST	CD
DATE	10/14/03

Quant Blot Sample Location Worksheet

	1	2	3	4	5	6
A	A	Cal 1	-f	[redacted]		
B	B	Cal 2	-m			
C	C	1-13f	1-2			
D	D	1-13m	2-2			
E	E	1-14f	-K			
F	F	1-14m	mJB			
G	G	3-1f	\			
H	H	3-1m				

Notes:

Quantiblot kit lot # Ec3747 ECL kit lot # 90

Quantitated with following Cases R2002-26743

PAGE NUMBER	5
SBI LAB FILE NUMBER	R2002-8998
ANALYST	CD
DATE	11/0/02

SAMPLE AMPLIFICATION WORKSHEET: PowerPlex 1.1

All amount in µl (DNA + water = 13.5)

Sample	DNA amt	H2O	Sample	DNA amt	H2O
K562	0.25	13.25			
Neg. Control	-0-	13.5			
MJB	0.5	13.0			
1-13-f	13.5	-0-			
1-13m	13.5	-0-			
1-14f	1µl 1:10 dil	12.5			
1-14m	0.5	13.0			
3-1f	1µl 1:10 dil	12.5			
3-1m	1µl - 1:10 dil	12.5			
~~3-K0~~					
-f	13.5	-0-			
-m	13.5	-0-			
1-2	0.3	13.2			
2-2	0.3	13.2			
-K	13.5	-0-			

Master Mix Components:

Component	Lot#	Amount used
10 X Buffer	13268201	2.5 ul/sample
10X Pplex 1.1 Primer	142490c1	2.5 ul/sample
10X D16S539 Primer	13258601	2.5 ul/sample
10X Amelo. Primer	13150701	2.5 ul/sample
BSA	116 #1375	1.0 ul/sample
Taq*	E05155	0.5 ul/sample

Add 11.5 µl master mix to 13.5 µl sample + dH2O. Total reaction volume is 25 µl.

Thermocycler# 96a-3 **K562 Lot #** 12478503

Area and Equipment Decontaminated Before Use CD

Amplified with following Cases R2002-26743

PAGE NUMBER	6
SBI LAB FILE NUMBER	R2002-8998
ANALYST	DB
DATE	11/19/03

ELECTROPHORESIS WORKSHEET

PowerPlex 1.1

Conditions: Approximately 1hour 30 minutes @ 55W for Long Plates

Lane	Sample #	Description	Lane	Sample #	Description
1	XXXXX	XXXXXXXXXXXX	16	3-1f	
2	XXXXX	XXXXXXXXXXXX	17	3-1m	
3	L		18	L	
4	-		19	-f	
5	+		20	-m	
6	L		21	L	
7	MJB		22	1-2	
8	-K		23	2-2	
9	L		24	L	
10	1-13f		25		
11	1-13m		26		
12	L		27		
13	1-14f		28		
14	1-14m		29	XXXXX	XXXXXXXXXXXXX
15	L		30	XXXXX	XXXXXXXXXXXXX

Allelic Ladder lot # 13224202

Amelogenin ladder lot # 1417451

Load dye lot # 13389103

Tracking dye lot # 13670105

Electrophoresed with following Cases _____

North Carolina State Bureau Of Investigation
Crime Laboratory Division

FORENSIC BIOLOGY SECTION

CASE NOTES COVER SHEET

SBI LAB FILE NUMBER	R2002-26743
ANALYST	David Freeman DF
DATE ANALYSIS STARTED	10/13/03
DATE ANALYSIS COMPLETED	11/19/03

ADMINISTRATIVE REVIEW	
(Initials)	(Date)
TECHNICAL REVIEW	
See last page of the attached notes	

PAGE NUMBER	2
SBI LAB FILE NUMBER	R2003-26743
ANALYST	SLB/JHW
DATE	3-27-03

DNA SAMPLE SUBMISSION DATA FORM

18 S.tiss ē small piece of tissue like material

ITEM #	DESCRIPTION OF EVIDENCE AND PACKAGING CONTAINERS
1-3/1-4	S.M.env.ē S.W.env.ē vaginal smears and swabs previously analyzed (Rare Sperm)
14-1	S.M.env.ē 1swabbing from inner edge of fire safe from Crime Scene (phen+)
19-1	S.M.env.ē 1swabbing from stains on VCR collected from crime scene. (phen+)
21	S.B.P.B ē 1swab id'd as collected from innermost rear door (Northside-interior) (phen+)
22	S.B.P.B ē 1swab id'd as collected from exterior south door - eastside of frame (phen+)
23	S.B.P.B. ē 1swab id'd as collected from mop handle next to rear door (phen+)
24	S.B.P.B. ē 1swab from exterior door handle to bathroom (phen+)
25	S.W.env.ē bloodstain prepared by Medical Examiner from Latisha Kornegay
20-1	S.M.env ē swabbing from straw of Hardee's cup left at crime scene.

28 SBPB id'das ē saliva sample from Antonio Young.

DNA profiles for the following items have been entered in CODIS:

None

Only the following categories will be uploaded to CODIS:

[ ] Suspect Standard - Item # _____

[ ] Unsolved/unidentified forensic unknown profile - Item # _____

[ ] Transfer of suspect's DNA to victim or scene (forensic unknown) - Item # _____

[ ] Mixture of victim/suspect or unknown profile - Item # _____ (as much of victim profile as possible has been removed)

First Reader _____ Second Reader _____

Verification of sample identity and samples marked for upload to CODIS by:

Second Reader _____

PAGE NUMBER	3
SBI LAB FILE NUMBER	R2002-26743
ANALYST	
DATE	10/13/03

DNA Extraction Worksheet

NOTE: Extractions for Question and Known Samples are separated by time or space.

Question Samples	Date/ Time	Extraction Type	Final Volume	Area and Equip. Decon.
14-1, 19-1, 21, 22, 23, 24, 26-1, 18-1, -2	10/13/03 5:50 pm	organic	~30µl 40µl others	
1-3, 1-4, -1/-2	10/13/03 6:00 pm	differential	~30µl ~100µl	

Known Samples	Date/Time	Extraction Type	Final Volume	Area and Equip. Decon.
25, 28, -K, MJB	10/13/03 6:35 pm	organic	200µl	

Phenol/Chloroform Lot # 112K0583

Extracted with following Cases R2002-8998

Notes: The 1-3 not analyzed.

DJ

PAGE NUMBER	4
SBI LAB FILE NUMBER	R2002-26743
ANALYST	CB
DATE	10/14/03

Quant Blot Sample Location Worksheet

	1	2	3	[redacted]		6
A	A	Cal 1	24			
B	B	Cal 2	20-1			
C	C	14-1	-Q			
D	D	18	c-p			
E	E	19-1				
F	F	21	1-4f			
G	G	22	1-4m			
H	H	23	-f			

Notes:

Quantiblot kit lot # E03749 ECL kit lot # 90

Quantitated with following Cases R2002-8998

PAGE NUMBER	5
SBI LAB FILE NUMBER	R2002-26743
ANALYST	
DATE	11/7/03

SAMPLE AMPLIFICATION WORKSHEET: PowerPlex 1.1

All amount in µl (DNA + water = 13.5)

Sample	DNA amt	H2O	Sample	DNA amt	H2O
K562	0.25	13.25	-~	13.5	-0-
Neg. Control	-0-	13.5	25	0.5	13.0
MJB	0.5	13.0	28	0.5	13.0
14-1	1	12.5	-K	13.5	-0-
18	13.5	-0-			
19-1	13.5	-0-			
21	2.0	11.5			
22	13.5	-0-			
23	13.5	-0-			
24	13.5	-0-			
20-1	13.5	-0-			
-9	13.5	-0-			
1-4f	1µl 1:10 dil.	12.5			
1-4~	0.5	13.0			
-4	13.5	-0-			

Master Mix Components:

Component	Lot#	Amount used
10 X Buffer	13268201	2.5 ul/sample
10X Pplex 1.1 Primer	1424900	2.5 ul/sample
10X D16S539 Primer	13256801	2.5 ul/sample
10X Amelo. Primer	13150701	2.5 ul/sample
BSA	116H1375	1.0 ul/sample
Taq*	E05155	0.5 ul/sample

Add 11.5 µl master mix to 13.5 µl sample + dH2O. Total reaction volume is 25 µl.

Thermocycler# 9600-3 **K562 Lot #** 12478K1

Area and Equipment Decontaminated Before Use

Amplified with following Cases R2002-8998

PAGE NUMBER	03 ~~8~~ 6
SBI LAB FILE NUMBER	R2002-26743
ANALYST	03
DATE	11/18/03

ELECTROPHORESIS WORKSHEET

PowerPlex 1.1

Conditions: Approximately 1hour 30 minutes @ 55W for Long Plates

Lane	Sample #	Description	Lane	Sample #	Description
1	XXXXX	XXXXXXXXXXXX	16	21	
2	XXXXX	XXXXXXXXXXXX	17	22	
3	L		18	L	
4	–		19	23	
5	+		20	24	
6	L		21	L	
7	MJB		22	1-4f	
8	-K		23	1-4m	
9	L		24	L	
10	14-1		25	-f	
11	18		26	-m	
12	L		27	L	
13	19-1		28		
14	20-1		29	XXXXX	XXXXXXXXXXXXXX
15	L		30	XXXXX	XXXXXXXXXXXXXX

Allelic Ladder lot # 13224202
Amelogenin ladder lot # 14174501
Load dye lot # 13389103
Tracking dye lot # 13070105

Electrophoresed with following Cases ——

I never ever more than one case @ a time or load gels together. MJB

UMBER
B FILE NUMBER 3 R2001-27701
T MJB
10/28/03

traction Worksheet

own Samples are separated by time or space.

	Date/ Time	Extraction Type	Final Volume	Area and Equip. Decon.
-Q, 22-2, 23-1, 23-2	10/27/03 5:00P	Org	30	✓

Known Samples	Date/Time	Extraction Type	Final Volume	Area and Equip. Decon.
-K, MJB	10/27/03 5:00P	Org	150	✓

Phenol/Chloroform Lot # 43K0616

Extracted with following Cases R2003-2944, R2001-5433, R2002-2451

Notes:

PAGE NUMBER	3
SBI LAB FILE NUMBER	R2002-24251
ANALYST	MJB
DATE	10/27/03

DNA Extraction Worksheet

NOTE: Extractions for Question and Known Samples are separated by time or space.

Question Samples	Date/ Time	Extraction Type	Final Volume	Area and Equip. Decon.
-Q, 6-1, 7-1	10/27/03 5:00P	Org	30	✓

Known Samples	Date/Time	Extraction Type	Final Volume	Area and Equip. Decon.
-K, MJB, 15-1V, 16-1S	10/27/03 5:30P	Org	150	✓

Phenol/Chloroform Lot # 43K0616

Extracted with following Cases R2003-2944, R2001-5433, R2001-27701

Notes:

PAGE NUMBER	3
SBI LAB FILE NUMBER	R2003-2944
ANALYST	MJB
DATE	10/27/03

DNA Extraction Worksheet

NOTE: Extractions for Question and Known Samples are separated by time or space.

Question Samples	Date/ Time	Extraction Type	Final Volume	Area and Equip. Decon.
-F, -M, 1-3, 1-11, 1-12	10/27/03 5:04P	Diff	F = 150	✓
			M = 30	

Known Samples	Date/Time	Extraction Type	Final Volume	Area and Equip. Decon.
-K, MJB, 1-1V, 4-25	10/27/03 5:05P	Org	150	✓

Phenol/Chloroform Lot # 43K0616

Extracted with following Cases R2001-5433, R2002-24251, R2001-27701

Notes:

PAGE NUMBER	3
SBI LAB FILE NUMBER	R2001-5433
ANALYST	MJB
DATE	10/28/03

DNA Extraction Worksheet

NOTE: Extractions for Question and Known Samples are separated by time or space.

Question Samples	Date/ Time	Extraction Type	Final Volume	Area and Equip. Decon.
-Q, 7-1, 7-2	10/27/03 5:20pm	Org	30	✓

Known Samples	Date/Time	Extraction Type	Final Volume	Area and Equip. Decon.
-K, MJB	10/27/03	Org	150	✓

Phenol/Chloroform Lot # 43K0616

Extracted with following Cases R2003-2944, R2002-24251, R2001-2701

Notes: No DNA profile was entered into CODIS

North Carolina State Bureau Of Investigation
Crime Laboratory Division

FORENSIC BIOLOGY SECTION

CASE NOTES COVER SHEET

SBI LAB FILE NUMBER	R2003[illegible]7
ANALYST	AcP
DATE ANALYSIS STARTED	11/17/03
DATE ANALYSIS COMPLETED	

ADMINISTRATIVE REVIEW	
(Initials)	(Date)
TECHNICAL REVIEW	
See last page of the attached notes	

PAGE NUMBER	
SBI LAB FILE NUMBER	R2002177117
ANALYST	Acp
DATE	11/17/03

DNA Extraction Worksheet

NOTE: Extractions for Question and Known Samples are separated by time or space.

Question Samples	Date/ Time	Extraction Type	Final Volume	Area and Equip. Decon.
1-4, 1-13, -F, -M	11/17/03 5:50pm	Differential	M-30ul F-150ul	✓

Known Samples	Date/Time	Extraction Type	Final Volume	Area and Equip. Decon.
1-2, 2-2, MJB, -K	11/17/03 6:15pm	Organic	150ul	✓

Phenol/Chloroform Lot # 013K0102

Extracted with following Cases N/A

Notes:

PAGE NUMBER	
SBI LAB FILE NUMBER	E200417717
ANALYST	ALF
DATE	11/18/03

Quant Blot Sample Location Worksheet

	1	2	3	4	5	6
A	A	Cal 1	MJB	[redacted]		
B	B	Cal 2	-K			
C	C	1-2	-F			
D	D	2-2	-M			
E	E	1-4F				
F	F	1-4M				
G	G	1-13F				
H	H	1-13M				

Notes:

Quantiblot kit lot # E07410 ECL kit lot # 59

ntitated with following Cases N/A

PAGE NUMBER	
SBI LAB FILE NUMBER	K2002 1717
ANALYST	Arp
DATE	11/18/03

SAMPLE AMPLIFICATION WORKSHEET: PowerPlex 1.1

All amount in µl (DNA + water = 13.5)

Sample	DNA amt	H2O	Sample	DNA amt	H2O
K562	0.25	13.25			
Neg. Control	-0-	13.5			
MJB	.5	13.0			
1-2	.25	13.25			
2-2	.25	13.25			
1-4F	.25	13.25			
1-4M	.25	13.25			
1-13F	.25	13.25			
1-13M	.25	13.25			
-K	13.5	0			
-F	13.5	0			
-M	13.5	0			

Master Mix Components:

Component	Lot#	Amount used
10 X Buffer	132L022 3	2.5 ul/sample
10X Pplex 1.1 Primer	142980D1	2.5 ul/sample
10X D16S539 Primer	132 5L80 1	2.5 ul/sample
10X Amelo. Primer	131507L1	2.5 ul/sample
BSA	116H1305	1.0 ul/sample
Taq*	E05155	0.5 ul/sample

Add 11.5 µl master mix to 13.5 µl sample + dH2O. Total reaction volume is 25 µl.

Thermocycler# 9600 #3 **K562 Lot #** 12478900

Area and Equipment Decontaminated Before Use ✓

Amplified with following Cases N/A

PAGE NUMBER	
SBI LAB FILE NUMBER	R2002 17717
ANALYST	Acp
DATE	11/19/03

ELECTROPHORESIS WORKSHEET

PowerPlex 1.1

Conditions: Approximately 45 minutes @ 40W for Short Plates
Approximately 1hour 30 minutes @ 55W for Long Plates

Lane	Sample #	Description	Lane	Sample #	Description
1	XXXXX	XXXXXXXXXXXX	16	1-13F	1.5ul
2	XXXXX	XXXXXXXXXXXX	17	1-13M	1.5ul
3	L		18	L	
4	-		19	-F	
5	+		20	-M	
6	L		21	L	
7	MJB		22		
8	-K		23		
9	L		24		
10	1-2	1.5ul	25		
11	2-2	1.5ul	26		
12	L		27		
13	1-4F	1.5ul	28		
14	1-4M	1.5ul	29	XXXXX	XXXXXXXXXXXXXX
15	L		30	XXXXX	XXXXXXXXXXXXXX

Allelic Ladder lot # 13224202
Amelogenin ladder lot # 14174501
Load dye lot # 13389603
Tracking dye lot # 13070105

Electrophoresed with following Cases N/A

PAGE NUMBER	
SBI LAB FILE NUMBER	R2002-1717
ANALYST	ALP
DATE	11/19/03

SAMPLE AMPLIFICATION WORKSHEET: PowerPlex 2.1

All amount in µl (DNA + water = 18.5)

Sample	DNA amt	H2O	Sample	DNA amt	H2O
K562	.25	18.25			
Neg. Control	-0-	18.5			
MJB	.5	18.0			
1-2	.25	18.25			
2-2	.25	18.25			
1-4m	.25	18.25			
1-13m	.25	18.25			
-m	18.5	0			

Master Mix Components:

Component	Lot#	Amount used
10 X Buffer	144179C1	2.5 ul/sample
10X PPlex Primer	148104C1	2.5 ul/sample
BSA	116H3375	1.0 ul/sample
Taq*	EC5155	0.5 ul/sample

Add 6.5 µl master mix to 18.5 µl sample + dH2O. Total reaction volume is 25 µl.

Thermocycler# 9600#3 K562 Lot # 12478903

Area and Equipment Decontaminated Before Use ✓

Amplified with following Cases N/A

PAGE NUMBER	
SBI LAB FILE NUMBER	R2002 17717
ANALYST	Arp
DATE	11/19/03

ELECTROPHORESIS WORKSHEET

PowerPlex 2.1

Conditions: Approximately 45 minutes @ 40W for Short Plates
Approximately 1hour 30 minutes @ 55W for Long Plates

Lane	Sample #	Description	Lane	Sample #	Description
1	XXXXX	XXXXXXXXXXXX	16	- M	
2	XXXXX	XXXXXXXXXXXX	17	L	
3	L		18		
4	-		19		
5	+		20		
6	L		21		
7	M50		22		
8	-K		23		
9	L		24		
10	1-2	1 o L	25		
11	2-2	1.0 L	26		
12	L		27		
13	1-4M	1.0L	28		
14	1-13M	1.0L	29	XXXXX	XXXXXXXXXXXXX
15	L		30	XXXXX	XXXXXXXXXXXXX

Allelic Ladder lot # 12952603
Load dye lot # 13359603
Tracking dye lot # 130 7c105

Electrophoresed with following Cases N/A

U.S. Department of Justice

Federal Bureau of Investigation

Washington, D. C. 20535-0001

December 8, 2003

Mr. Mark Boodee
North Carolina State Bureau of Investigation
Department of Justice
3320 Garner Road
P.O. Box 29500
Raleigh, North Carolina 27626

Dear Mr. Boodee:

This letter is to acknowledge receipt of your DNA Quality Assurance Standards (QAS) Audit Report, for the North Carolina State Bureau of Investigation, Raleigh, North Carolina, external audits for 2003. As you are aware, participation in the National DNA Index System (NDIS) requires an external audit on a bi-annual basis. An audit committee will be selected and copies of your audit will be submitted to them for review. Upon completion of this review, their copies of the audit documents will be returned to the FBI. All copies will be shredded and the original will be returned to you.

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

Sincerely,

Thomas F. Callaghan, PhD
Chief
CODIS Unit
Laboratory Division

U.S. Department of Justice

Federal Bureau of Investigation

Washington, D. C. 20535-0001

September 21, 2004

Mr. Mark Boodee
CODIS State Administrator
North Carolina State Bureau of Investigation
Department of Justice
3320 Garner Road
P.O. Box 29500
Raleigh, North Carolina 27626

Dear Mr. Boodee:

This is in response to the external Quality Assurance Standard audit conducted for the North Carolina State Bureau of Investigation, Raleigh, North Carolina, during August 25-29, 2003.

A review of your audit documentation, which is enclosed, found your laboratory to be in compliance with the external audit requirement and the FBI Director's Quality Assurance Standards.

Sincerely,

Thomas F. Callaghan, PhD
Chief, CODIS Unit
NDIS Custodian
Laboratory Division

Enclosure

1-2-04
JR

AMERICAN SOCIETY OF CRIME LABORATORY DIRECTORS
LABORATORY ACCREDITATION BOARD

December 19, 2003

RECEIVED
DEC 30 2003
ASSISTANT DIRECTOR-LAB

Jerry Richardson, Assistant Director
NC State Bureau of Investigation Crime Laboratory
121 East Tryon Road
Raleigh, NC 27603

Dear Assistant Director Richardson:

On December 18, 2003, the Board of Directors of ASCLD/LAB met and considered the applications for accreditation from the two (2) laboratories of the North Carolina State Bureau of Investigation. Based on the documentation provided and in accordance with the recommendation of Staff Inspector Michael Johnston, the Board is satisfied that both of the NC State Bureau of Investigation laboratories meet or exceed the standards for accreditation as set forth by ASCLD/LAB in the 2003 version of the accreditation manual. It is my pleasure to advise you that both of the laboratories have had accreditation renewed.

The Raleigh Laboratory was accredited in the disciplines of controlled substances, toxicology, trace evidence, biology, firearms/toolmarks, latent prints, questioned documents and digital evidence.

The Western Regional Laboratory in Asheville was accredited in the disciplines of controlled substances, and latent prints.

Final inspection reports for both laboratories are being provided to you with this letter. These accreditations are granted for a period of five (5) years effective at the expiration of the prior accreditations. Updated accreditation certificates for each of the laboratories will be provided to you in the near future. If you wish to hold an accreditation ceremony involving an ASCLD/LAB Board member, please contact Executive Director Ralph Keaton to arrange and schedule the ceremony.

It is noteworthy that the NCSBI laboratories are the first laboratories to be accredited under the standards of the 2003 manual and that the Raleigh Laboratory is the first laboratory to be accredited in the new ASCLD/LAB discipline of digital evidence. Accreditation is granted only after a thorough evaluation of a laboratory's management practices, personnel qualifications, technical procedures, quality assurance program and facilities. We recognize that accreditation is the result of much work and preparation by the management and personnel in each of your laboratories. On behalf of the Board of Directors, I extend sincere congratulations to you and to your entire staff for this significant accomplishment.

Accredited laboratories are expected to maintain the high standards which were required of them to achieve accreditation. The laboratories of the North Carolina State Bureau of Investigation will be expected to participate in external proficiency testing and to agree for test results to be reviewed by the appropriate Proficiency Review Committees (PRCs) as outlined in the accreditation manual. In addition, you will be expected to conduct annual audits of each of the laboratories and submit the Annual Accreditation Audit Reports (appendix 6 in the manual) to the Executive Director by April 1 of each year. Your laboratories will be invoiced near the end of each year for an annual accreditation fee which is based upon the budget approved by the Delegate Assembly at its annual meeting.

Ralph Keaton, Executive Director • 139 J Technology Drive, Garner, NC 27529 • Phone (919) 773-2600 • FAX (919) 773-2602 • E-mail rkeaton@ascld-lab.org

If you have not completed the post inspection evaluation form (Appendix 5 in the manual), you are encouraged to do so. Feedback from laboratories is essential to ensure that the program provides the quality of service expected by participating laboratories.

As the director of an accredited laboratory system, you and the directors of each of your laboratories are voting members of the Delegate Assembly. Each of you are invited and encouraged to participate in the accreditation process and to exercise your vote on issues which are presented to the Delegate either by mail ballot or at the annual meeting. If you are unable to attend, you are entitled to send a designee but you must notify the Executive Director in writing if you wish to designate someone to vote in your place.

On behalf of the Board, I extend my sincere congratulations to you and to all of the personnel of your laboratories. If you have any questions or if we might assist you in any way please feel free to get in touch with us.

My best wishes to you and your staff.

Sincerely,

Donald A. Wyckoff
Chair, ASCLD/LAB

cc: Michael Johnston, Staff Inspector
Ralph M. Keaton, Executive Director