

North Carolina State Bureau of Investigation

121 East Tryon Rd
Raleigh, NC 27603

External DNA Audit Report on Compliance with the FBI Director's Quality Assurance Standards for Forensic DNA Testing Laboratories

Conducted on October 19 – 21, 2009

Kristine Deters, NFSTC Lead Auditor
Jeremy Sanderson, NFSTC Lead Auditor
Kathleen Lobato, NFSTC Technical Auditor
Meredith Chambers, NFSTC Technical Auditor
Lynn Langford, NFSTC Technical Auditor



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National Institute of Justice
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**"This document is to be used for pre-decisional purposes only by the
laboratory audited and NDIS in determining compliance with these
standards".**

National Forensic Science Technology Center Inc
7881 114th Avenue N.
Largo FL 33773
Tel (727) 549-6067 Fax (727) 549-6070

THE FBI QUALITY ASSURANCE STANDARDS AUDIT FOR FORENSIC DNA TESTING LABORATORIES

IN ACCORDANCE WITH
THE QUALITY ASSURANCE STANDARDS
FOR
FORENSIC DNA TESTING LABORATORIES
EFFECTIVE JULY 1, 2009

An Audit of: North Carolina State Bureau of Investigation
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Auditor(s): Kristine Deters
(Name)
Jeremy Sanderson
(Name)
Kathleen Lobato
(Name)
Meredith Chambers
(Name)
Lynn Langford
(Name)

Kristine S Deters
(Signature)
Jeremy Sanderson
(Signature)
Kathleen M Lobato
(Signature)
Meredith A Chambers
(Signature)
Lynn Langford
(Signature)

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Checklist of General Laboratory Information

1. Name of Laboratory: North Carolina State Bureau of Investigation

2. Federal / **State** / Regional / County / Local / Other: _____
 Laboratory (Choose one)

3. Approximate Population Size Served: 9 million

4. Uses a Contract Laboratory: Yes / **No**
 Name of Contract Laboratory(ies): _____

5. NDIS Participant: **Yes** / No

6. Applying for NDIS Participation: Yes / No / **NA** (Choose one)

7. Technologies Used: (Choose those that apply)
 STRs X
 YSTRs X
 MtDNA
 Other: _____

8. Number of staff:
 DNA analysts: 22
 DNA trainees: 3
 DNA technicians: 0
 Laboratory support personnel: 0
 DNA technical leader: David Freeman
 On site: **Yes** / No
 Casework CODIS administrator: Amanda Fox

9. Last audit conducted on: December 8 – 10, 2008
 External / **Internal Audit** (Choose one)

10. Audit Document Discussion Used (Revision Date): 07/04 (Rev. #6)

Standard 3. Quality Assurance Program

	Yes	No	N/A
3.1 For the DNA laboratory’s quality assurance program:	<u>X</u>		
a. Does the DNA laboratory have an established and maintained documented quality system that is appropriate to the testing activities?	<u>X</u>		
b. Is the quality system equivalent to or more stringent than what is required by these Standards?	<u>X</u>		

Comment

	Yes	No	N/A
3.1.1 Is the quality system documented in a manual that includes or references the following elements:	<u>X</u>		
3.1.1.1 Goals and objectives?	<u>X</u>		
3.1.1.2 Organization and management?	<u>X</u>		
3.1.1.3 Personnel?	<u>X</u>		
3.1.1.4 Facilities?	<u>X</u>		
3.1.1.5 Evidence control?	<u>X</u>		
3.1.1.6 Validation?	<u>X</u>		
3.1.1.7 Analytical procedures?	<u>X</u>		
3.1.1.8 Equipment calibration and maintenance?	<u>X</u>		
3.1.1.9 Reports?	<u>X</u>		
3.1.1.10 Review?	<u>X</u>		
3.1.1.11 Proficiency testing?	<u>X</u>		
3.1.1.12 Corrective action?	<u>X</u>		
3.1.1.13 Audits?	<u>X</u>		
3.1.1.14 Safety?	<u>X</u>		
3.1.1.15 Outsourcing?	<u>X</u>		

Comment

Standard 4. Organization and Management

	Yes	No	N/A
4.1 Does the laboratory have:	<u>X</u>		
4.1.1 A managerial staff with the authority and resources needed to discharge its duties and meet the requirements of the Standards in this document?	<u>X</u>		
4.1.2 A technical leader who is accountable for the technical operations?	<u>X</u>		
a. Have at least one technical leader in a multi-laboratory system?			<u>X</u>
4.1.3 A casework CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility using CODIS?	<u>X</u>		
4.1.4 At least two full-time employees who are qualified DNA analysts?	<u>X</u>		
4.1.5 Documentation that specifies the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the validity of the DNA analysis?	<u>X</u>		
4.1.6 A documented contingency plan that is approved by laboratory management if the technical leader position is vacated?	<u>X</u>		

Comment

Standard 4.1.2.a was rated as N/A as the laboratory is not part of a multi-laboratory system.

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?		<u>X</u>	

Comment

Standard 5.1 - see Appendix A findings section.

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

Comment

	Yes	No	N/A
5.1.2 Does the laboratory have a documented training program for qualifying all analyst(s) and technician(s)?		<u>X</u>	

5.1.2.1 Does the training program contain at a minimum the following components:			
a. A training manual that covers all applicable DNA analytical procedures that the analyst/technician will perform?		<u>X</u>	
b. Practical exercises that include the examination of a range of samples routinely encountered in casework?	<u>X</u>		

5.1.2.2 Does the laboratory's training program teach and assess the technical skills and knowledge required to perform DNA analysis and include, at a minimum, the following?	<u>X</u>		
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5.1.2.2.1 Does the training program require the documentation of the successful completion of a competency test(s)?	<u>X</u>		
---	----------	--	--

5.1.2.2.2 For an analyst or technician with previous forensic experience:			
---	--	--	--

- a. Did the technical leader assess and document the adequacy of the previous training of the analyst and/or technician? X
- b. Did the analyst and/or technician complete a modified training program that was assessed and documented by the technical leader? X
- 5.1.2.2.3** Prior to participating in independent casework did all analysts and technicians, regardless of previous experience, successfully complete a competency test(s) covering the routine DNA methodologies to be used? X

Comment

Standards 5.1.2 and 5.1.2.1.a- see Appendix A findings section.

		Yes	No	N/A
5.1.3	Does the laboratory have a documented program to ensure that technical qualifications are maintained through continuing education?	<u>X</u>		
5.1.3.1	Does the technical leader, casework CODIS administrator, and each analyst have documented attendance at seminars, courses, professional meetings, or documented training sessions/classes that consist of:	<u>X</u>		
	a. Subject areas relevant to the developments in DNA typing?			
		Yes	<u>X</u>	No
	b. Cumulative minimum of eight hours per calendar year?			
		Yes	<u>X</u>	No
5.1.3.1.1	For continuing education conducted internally, does the laboratory's retained documentation include the following:			<u>X</u>
	a. Title of the program?	Yes	No	
	b. A record of the presentation?	Yes	No	
	c. Date of the training?	Yes	No	
	d. Attendance list?	Yes	No	

	e. Curriculum vitae of the presenter(s)?	Yes	No	
5.1.3.1.2	For continuing education conducted externally, does the laboratory's retained documentation include one or more of the following:			
	a. Certificate of attendance?			<u>X</u>
	b. Program agenda/syllabus?			
	c. Travel documentation?			
5.1.3.1.3	For continuing education that is based on multimedia or Internet delivery:			<u>X</u>
	a. Was the training subject to the review of, and approved by, the technical leader?			
		Yes	<u>X</u>	No
	b. Was the time required to complete the program formally recorded in the laboratory's retained document?			
		Yes	<u>X</u>	No
	c. Was the completion submitted to the technical leader for review and approval?			
		Yes	<u>X</u>	No
5.1.3.2	For the review of scientific literature:			
	a. Does the laboratory have a program, approved by the technical leader, for the annual review of scientific literature that documents the ongoing reading of scientific literature?			<u>X</u>
	b. Does the laboratory maintain or have physical or electronic access to a collection of current books, reviewed journals, or other literature applicable to DNA analysis?			<u>X</u>

Comment

Standard 5.1.3.1.1 was rated as N/A as all continuing education was conducted externally.

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

Comment

		Yes	No	N/A
5.2	Does the technical leader satisfy the requirements for degree/education, experience, and duties listed in Standards 5.2.1 through 5.2.4.1?	<u>X</u>		
5.2.1	Does the technical leader of the laboratory meet or exceed the following degree/educational requirements?	<u>X</u>		
	a. A master's degree in a biology-, chemistry-, or forensic science-related area or have a waiver as stated in Standard 5.2.1.4?	<u>X</u>		
	b. Twelve semester hours or equivalent credit hours including a combination of graduate and undergraduate course work or classes covering the following subject areas:	<u>X</u>		
	1. Biochemistry? Yes <u>X</u> No			
	2. Genetics? Yes <u>X</u> No			
	3. Molecular biology? Yes <u>X</u> No			
	4. Statistics or population genetics? Yes <u>X</u> No			
5.2.1.1	Of the 12 semester or equivalent credit hours required, do they include at least one graduate-level course registering 3 or more semester or equivalent credit hours?	<u>X</u>		
5.2.1.2	Do each of the specific subject areas listed in Standard 5.2.1 constitute an integral component of any coursework used to demonstrate compliance with this Standard?	<u>X</u>		
5.2.1.3	For individuals who have completed coursework with titles other than those listed in Standard 5.2.1, have they successfully demonstrated compliance with this Standard through a combination of pertinent materials such as a transcript, syllabus, letter from the instructor, or other documentation that supports the course content?			<u>X</u>

Comment

Standard 5.2.1.3 was rated as N/A as the courses used to satisfy the technical leader's educational requirements have the course titles listed in 5.2.1.b.

	Yes	No	N/A
5.2.1.4 If the degree requirements of Standard 5.2.1 are not met, does the technical leader possess a waiver from the American Society of Crime Laboratory Directors (ASCLD)?			<u>X</u>

Comment

Standard 5.2.1.4 was rated as N/A as the technical leader meets the degree requirements.

	Yes	No	N/A
5.2.2 Technical leader minimum experience requirements:			
a. Does the technical leader have three years of forensic DNA laboratory experience obtained at a laboratory where forensic DNA testing was conducted for the identification and evaluation of biological evidence in criminal matters?	<u>X</u>		
b. Does any technical leader, appointed or hired on or after July 1, 2009, have a minimum of three years human-DNA experience (current or previous) as a qualified analyst on forensic samples?			<u>X</u>
c. Has the technical leader successfully completed, or will successfully complete within one year of appointment, the FBI-sponsored auditor training?	<u>X</u>		

Comment

Standard 5.2.2.b was rated as N/A as the technical leader was appointed prior to July 1, 2009.

	Yes	No	N/A
5.2.3 Does the technical leader of the laboratory have responsibility for the following:			
5.2.3.1 Does the technical leader have the following general duties and authority:			
5.2.3.1.1 Oversee the technical operations of the laboratory?	<u>X</u>		
5.2.3.1.2 Authority to initiate, suspend, and resume DNA analytical operations for the laboratory or an individual?	<u>X</u>		

5.2.3.2	Does the technical leader perform the following specific responsibilities:		
5.2.3.2.1	Evaluate and document approval of all validations and methods used by the laboratory and propose new or modified analytical procedures to be used by analysts?	<u>X</u>	
5.2.3.2.2	Review and document the review of the academic transcripts and training records for newly qualified analysts and approve their qualifications prior to their conducting independent casework analysis?	<u>X</u>	
5.2.3.2.3	Approve the technical specifications for outsourcing agreements?		<u>X</u>
5.2.3.2.4	Review and document the review of internal and external DNA audit documents and, if applicable, approve corrective action(s).	<u>X</u>	
5.2.3.2.5	Review annually the procedures of the laboratory and document such review?	<u>X</u>	
5.2.3.2.6	Review and approve the training, quality assurance, and proficiency testing programs in the laboratory?		<u>X</u>

Comment

Standard 5.2.3.2.3 was rated as N/A as the laboratory does not outsource casework.

Standard 5.2.3.2.6 - see Appendix A findings section.

		Yes	No	N/A
5.2.4	Technical leader accessibility:			
	a. Is the technical leader accessible to the laboratory to provide on-site, telephonic, or electronic consultation as needed?	<u>X</u>		
	b. If the technical leader oversees a system of separate laboratories, has the technical leader conducted semiannual on-site visits of each of the laboratories?			<u>X</u>

5.2.4.1	Is the technical leader a full-time employee of the laboratory or laboratory system?	<u>X</u>	
5.2.4.1.1	a. If the technical leader position of the laboratory had been vacant since the last audit, was there a qualified individual immediately appointed as technical leader?		<u>X</u>
	b. If a qualified individual was not available/ appointed, did the laboratory immediately contact the FBI and submit its contingency plan within 14 days of the vacancy for the FBI's approval?		<u>X</u>
	c. Was all new casework suspended until the plan was approved by the FBI?		<u>X</u>
5.2.5	Did each technical leader appointed or hired on or after July 1, 2009, document a review of the following:		
	5.2.5.1 Validation studies and methodologies currently used by the laboratory?		<u>X</u>
	5.2.5.2 Educational qualifications and training records of currently qualified analysts?		<u>X</u>

Comment

Standard 5.2.4.b was rated as N/A as the laboratory is not a part of a multi-laboratory system.

Standards 5.2.4.1.1.a, 5.2.4.1.1.b, and 5.2.4.1.1.c were rated as N/A as the technical leader position has not been vacant since the last audit.

Standards 5.2.5.1 and 5.2.5.2 were rated as N/A as the technical leader was appointed prior to July 1, 2009.

		Yes	No	N/A
5.3	Is the casework CODIS administrator an employee of the laboratory and does he or she meet the following qualifications?	<u>X</u>		
5.3.1	Education:			
	Does the casework CODIS administrator meet the minimum education requirements?	<u>X</u>		

- a. Does the casework CODIS administrator meet the minimum education requirements as defined in Standard 5.4 or X
- b. Was the casework CODIS administrator appointed or hired prior to July 1, 2009, with supporting documentation from the FBI?

5.3.2 Experience:

Does the casework CODIS administrator meet the experience requirements?

- a. Is a current or previously qualified casework DNA analyst with documented mixture interpretation training, or X
- b. Was the casework CODIS administrator appointed or hired prior to July 1, 2009 with documented mixture-interpretation training and completion of FBI-sponsored CODIS training?

Comment

	Yes	No	N/A
5.3.3 Has the casework CODIS administrator:			
a. Successfully completed the FBI auditor training within one year of appointment, if not previously attended such training?	<u>X</u>		
b. Participated in the FBI sponsored CODIS software training within six months of appointment, if not previously attended such training?	<u>X</u>		
5.3.4 Is the casework CODIS administrator responsible for the following:	<u>X</u>		
5.3.4.1 Administering the laboratory's local CODIS network?	<u>X</u>		
5.3.4.2 Scheduling and documenting the CODIS computer training of casework analysts?	<u>X</u>		
5.3.4.3 Assuring that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures?	<u>X</u>		

5.4.1.2 For analysts appointed or hired on or after July 1, 2009, do the required subject areas consist of nine or more cumulative semester or equivalent hours? X

5.4.1.3 For individuals who have completed coursework with titles other than those listed in Standard 5.4.1:

a. Have they successfully demonstrated compliance with this Standard through a combination of pertinent materials such as a transcript, syllabus, letter from the instructor, or other documentation that supports the course content? X

b. Has the technical leader documented his or her approval of compliance with this Standard? X

Comment

	Yes	No	N/A
5.4.2 Does each analyst have six months of documented, forensic human-DNA laboratory experience?	<u>X</u>		

5.4.2.1 Prior to independent work using DNA technology, has each analyst completed the analysis of a range of samples routinely encountered in forensic casework?	<u>X</u>		
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5.4.2.2 Has each analyst successfully completed a competency test before beginning independent DNA analysis?	<u>X</u>		
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Comment

	Yes	No	N/A
5.5 Has each technician successfully completed each of the following:			

5.5.1 Documented training specific to his or her job function(s)?			<u>X</u>
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5.5.2 A competency test before participating in DNA analysis on evidence?			<u>X</u>
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5.6 Do all laboratory technical support personnel have documented training specific to their job function(s)?			<u>X</u>
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Comment

Standards 5.5.1 and 5.5.2 were rated as N/A as the laboratory does not utilize casework technicians.

Standard 5.6 was rated as N/A as the laboratory does not utilize support personnel.

Standard 6. Facilities

	Yes	No	N/A
6.1 Is the laboratory designed to ensure the integrity of the analyses and the evidence?	<u>X</u>		
6.1.1 Is access to the laboratory controlled and limited in a manner that prevents access by unauthorized personnel?	<u>X</u>		
a. Do all exterior entrance/exit points have security control?	<u>X</u>		
b. Is the distribution of all keys, combinations, and other security devices, documented and limited to the personnel designated by laboratory management?	<u>X</u>		

Comment

	Yes	No	N/A
6.1.2 Except as provided in Standard 6.1.4, are techniques performed prior to polymerase chain reaction (PCR) amplification-- to include evidence examinations, DNA extractions, and PCR setup-- conducted at separate times or in separate spaces from one another?	<u>X</u>		
6.1.3 Except as provided in Standard 6.1.4, is amplified DNA product-- including real-time PCR-- generated, processed, and maintained in a room(s) separate from the evidence examination, DNA extractions, and PCR-setup areas?	<u>X</u>		
a. Are the doors between rooms containing amplified DNA and other areas closed at all times except for passage?	<u>X</u>		
6.1.4 If a robotic workstation is used to carry out DNA extraction, quantification, PCR setup, and/or amplification in a single room, has the laboratory validated the analytical process in accordance with Standard 8?			<u>X</u>
a. If the robot performs analysis through amplification, is the robot housed in a separate room from that used for initial evidence examinations?			<u>X</u>

Comment

Standards 6.1.4 and 6.1.4.a were rated as N/A since the laboratory does not use a robotic workstation for casework.

	Yes	No	N/A
6.1.5 Does the laboratory have and follow written procedures for cleaning and decontaminating facilities and equipment?	<u>X</u>		

Comment

Standard 7. Evidence Control

	Yes	No	N/A
7.1 Does the laboratory have and follow a documented evidence control system to ensure the integrity of physical evidence?	<u>X</u>		
7.1.1 For evidence and sample identification:			
a. Is all evidence marked with a unique identifier on the evidence package?	<u>X</u>		
b. Does the laboratory clearly define what constitutes evidence and what constitutes work product?	<u>X</u>		
c. Does the laboratory have and follow a method to distinguish each sample throughout processing?	<u>X</u>		

Comment

	Yes	No	N/A
7.1.2 Does the laboratory document and maintain a chain of custody, in hard or electronic format, for all evidence, to include the following:	<u>X</u>		
a. Signature or initials or the electronic equivalent of each individual receiving or transferring the evidence?			
	Yes	<u>X</u>	No
b. The corresponding date for each transfer?			
	Yes	<u>X</u>	No
c. Evidentiary item(s) transferred?			
	Yes	<u>X</u>	No

Comment

	Yes	No	N/A
7.1.3 Does the laboratory have and follow documented procedures designed to minimize loss, contamination, and/or deleterious change of evidence and work product in progress?	<u>X</u>		

7.1.4 Does the laboratory have secure, controlled-access areas for evidence storage and work product in progress?	<u>X</u>		
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Comment

	Yes	No	N/A
7.2 Does the laboratory retain or return a portion of the evidence sample or extract where possible?	<u>X</u>		

Comment

	Yes	No	N/A
7.3 Does the laboratory have and follow documented policies for the disposition of evidence and sample consumption?	<u>X</u>		

Comment

	Yes	<u>X</u>	No	
3. Effects of multiplexing?				
	Yes	<u>X</u>	No	
4. Assessment of appropriate controls?				
	Yes	<u>X</u>	No	
5. Product detection studies?				
	Yes	<u>X</u>	No	
8.2.2 Are peer-reviewed publication(s) of the underlying scientific principle(s) of a technology available?				<u>X</u>

Comment

	Yes	No	N/A
8.3 Except as provided in Standard 8.3.1.1, have internal validation of all manual and robotic methodologies been conducted by each laboratory and reviewed and approved by the laboratory's technical leader prior to use?	<u>X</u>		
8.3.1 For Internal Validation Studies:			
a. Have internal validation studies been documented and summarized?	<u>X</u>		
b. Have all internal validation studies conducted on or after July 1, 2009, included, as applicable:	<u>X</u>		
1. Known and non probative evidence samples or mock evidence samples?			
	Yes	<u>X</u>	No N/A
2. Reproducibility and precision?			
	Yes	<u>X</u>	No N/A
3. Sensitivity and stochastic studies?			
	Yes	No	N/A <u>X</u>
4. Mixture studies?			
	Yes	No	N/A <u>X</u>
5. Contamination assessment?			
	Yes	No	N/A <u>X</u>

8.3.1.1	For multilaboratory systems:		
	a. Has each laboratory in a multi-laboratory system completed, documented, and maintained applicable site-specific precision, sensitivity, and contamination assessment studies?		<u>X</u>
	b. Are the summaries of all applicable validation data available at each site?		<u>X</u>
8.3.2	Have quality assurance parameters and interpretation guidelines, including, as applicable, guidelines for mixture interpretation, been defined pursuant to internal validation?	<u>X</u>	
8.3.3	If a laboratory has had a change in detection platform or test kit, have internal validation studies been performed?	<u>X</u>	
8.4	Has the analyst or examination team successfully completed a competency test using the DNA analysis procedure prior to its incorporation into casework applications?	<u>X</u>	

Comment

See appendix E for a list of those validation studies in compliance with Standard 8.1.

Standards 8.3.1.b (3-5) were rated as N/A as the laboratory has not completed any internal validation since July 1, 2009.

Standards 8.3.1.1.a and 8.3.1.1.b were rated as N/A as the laboratory is not a part of a multi-laboratory system.

		Yes	No	N/A
8.5	Have modified procedures been evaluated by comparison with the original procedures using similar DNA samples prior to their incorporation into casework applications?			<u>X</u>
8.6	Has the laboratory evaluated each additional or modified critical instrument by conducting a performance check prior to its use in casework?	<u>X</u>		
8.7	Has the laboratory evaluated software upgrades by conducting a performance check prior to use in casework?			<u>X</u>
	a. Has new software or significant software modifications been documented and subjected to validation testing prior to use in casework?			<u>X</u>

Comment

Standard 8.5 was rated as N/A as the laboratory has not made any modifications to their procedures since their last external audit.

Standard 8.6 - Performance checks of the upgrade of 3130xl Genetic Analyzers (serial numbers 1455-010 and 1352-020) were completed.

Standards 8.7 and 8.7.a were rated as N/A as the laboratory has not made any software upgrades, not added any software or made any significant software modifications since their last external audit.

Standard 9. Analytical Procedures

	Yes	No	N/A
9.1 Does the laboratory have and follow written analytical procedures approved by the technical leader?		<u>X</u>	
a. Are the laboratory’s standard operating procedures reviewed annually by the technical leader, and is this review documented?	<u>X</u>		
9.1.1 Does the laboratory have a documented standard operating procedure for each analytical method used?	<u>X</u>		
a. Do the analytical procedures specify reagents, sample preparation, extraction methods, equipment, and controls that are standard for DNA analysis and data interpretation?	<u>X</u>		
b. Does the laboratory have a procedure for the differential extraction of stains that contain sperm?	<u>X</u>		

Comment

Standard 9.1 - see Appendix A findings section.

	Yes	No	N/A
9.2 Does the laboratory use reagents that are suitable for the methods employed?	<u>X</u>		
9.2.1 Does the laboratory have written procedures for documenting commercial reagents and for the formulation of in-house reagents?	<u>X</u>		
9.2.2 Are commercial reagents labeled with:	<u>X</u>		
a. The identity of the reagent?			
Yes <u>X</u> No			
b. The expiration date as provided by the manufacturer or as determined by the laboratory?			
Yes <u>X</u> No			
9.2.3 Are in-house reagents labeled with:	<u>X</u>		
a. The identity of the reagent?			
Yes <u>X</u> No			
b. The date of the preparation or expiration or both?			
Yes <u>X</u> No			

	c. The identity of the individual preparing the reagent?			
	Yes <input checked="" type="checkbox"/> No			
9.3	Critical reagents shall include, but are not limited to, the reagents listed in Standards 9.3.1 and 9.3.2.			
	a. Has the laboratory identified critical reagents?			<input checked="" type="checkbox"/>
	b. Has the laboratory evaluated critical reagents prior to use in casework?			<input checked="" type="checkbox"/>
9.3.1	Has the laboratory identified and evaluated the following:			<input checked="" type="checkbox"/>
	a. Test kits or systems for performing quantitative PCR?			
	Yes <input checked="" type="checkbox"/> No N/A			
	b. Test kits or systems for performing genetic typing?			
	Yes <input checked="" type="checkbox"/> No N/A			
9.3.2	Has the laboratory identified and evaluated the following:			<input checked="" type="checkbox"/>
	a. Thermostable DNA polymerase (if not tested as test kit components under Standard 9.3.1)?			
	Yes <input checked="" type="checkbox"/> No N/A			
	b. Primer sets (if not tested as test kit components under Standard 9.3.1)?			
	Yes No N/A <input checked="" type="checkbox"/>			
	c. Allelic ladders used for genetic analysis (if not tested as test-kit components under Standard 9.3.1)?			
	Yes No N/A <input checked="" type="checkbox"/>			

Comment

Standards 9.3.2.b and 9.3.2.c were rated as N/A as the test kit components were rated under Standard 9.3.1.

		Yes	No	N/A
9.4	Does the laboratory quantify the amount of human DNA in forensic samples prior to nuclear DNA amplification?	<input checked="" type="checkbox"/>		

Comment

	Yes	No	N/A
9.5.5 Does the laboratory check its DNA procedures either annually or whenever substantial changes are made to a procedure against an appropriate and available NIST standard reference material (SRM) or standard traceable to a NIST standard?	<u>X</u>		

Comment

	Yes	No	N/A
9.6 Does the laboratory have and follow written guidelines for the interpretation of data?	<u>X</u>		
9.6.1 Does the laboratory verify that all control results meet the laboratory's interpretation guidelines for all reported results?	<u>X</u>		
9.6.2 Has the 1996 National Research Council report and/or a court-directed method been used for the statistical interpretation of a DNA profile for a given population and/or hypothesis or relatedness, and are these calculations derived from an established population database(s) appropriate for the calculation?	<u>X</u>		
9.6.3 Does the laboratory have and follow specific documented statistical interpretation guidelines if genetic analyses that are not addressed by Standard 9.6.2 are being performed?	<u>X</u>		
9.6.4 Does the laboratory have and follow documented procedures for mixture interpretation to include the following:	<u>X</u>		
a. Major and minor contributors?	Yes	<u>X</u>	No
b. Inclusions and exclusions?	Yes	<u>X</u>	No
c. Policies for reporting results and statistics?	Yes	<u>X</u>	No

Comment

	Yes	No	N/A
9.7 Does the laboratory have and follow a documented policy for detecting and controlling contamination?	<u>X</u>		

Comment

Standard 10. Equipment Calibration and Maintenance

	Yes	No	N/A
10.1 Does the laboratory use equipment that is suitable for the methods employed?	<u>X</u>		
10.2 Does the laboratory have and follow a documented program for conducting performance checks and calibrating equipment and instruments?	<u>X</u>		
10.2.1 At a minimum, are the following critical instruments or equipment performance-checked at least annually:	<u>X</u>		
10.2.1.1 A thermometer that is traceable to national or international standard(s) and is used for conducting performance checks?	<u>X</u>		
10.2.1.2 Balance/scale?	<u>X</u>		
10.2.1.3 Thermal cycler temperature-verification system?	<u>X</u>		
10.2.1.4 Thermal cycler including quantitative-PCR?	<u>X</u>		
10.2.1.5 Electrophoresis detection systems?			<u>X</u>
10.2.1.6 Robotic systems?			<u>X</u>
10.2.1.7 Genetic analyzers?	<u>X</u>		
10.2.1.8 Mechanical pipettes?	<u>X</u>		
10.3 Does the laboratory have a schedule and follow a documented program to ensure that instruments and equipment are maintained properly?	<u>X</u>		
a. Has documentation been retained for maintenance, service, and/or calibration?	<u>X</u>		
10.4 Does the laboratory performance check new critical instruments and equipment, or critical instruments and equipment that have undergone repair, service or calibration, before their use in casework analysis?	<u>X</u>		
10.4.1 At a minimum, are the following critical instruments or equipment performance-checked following repair, service, or calibration:			
10.4.1.1 Electrophoresis detection systems?			<u>X</u>
10.4.1.2 Robotic systems?			<u>X</u>
10.4.1.3 Genetic analyzers?	<u>X</u>		
10.4.1.4 Thermal cycler including quantitative-PCR?	<u>X</u>		

Comment

Standards 10.2.1.5 and 10.4.1.1 were rated N/A as the laboratory does not use an electrophoresis detection system other than genetic analyzers.

Standards 10.2.1.6 and 10.4.1.2 were rated as N/A as the laboratory does not use robotic systems for casework.

Standard 11. Reports

	Yes	No	N/A
11.1 a. Does the laboratory have and follow written procedures for taking and maintaining case notes to support the conclusions drawn in laboratory reports?	<u>X</u>		
b. Does the laboratory maintain all analytical documentation generated by analysts related to case analyses?	<u>X</u>		
c. Does the laboratory retain, in hard copy or electronic format, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual could interpret and evaluate the data?	<u>X</u>		

Comment

	Yes	No	N/A
11.2 Do the laboratory reports include the following elements:	<u>X</u>		
11.2.1 Case identifier?	<u>X</u>		
11.2.2 Description of evidence examined?	<u>X</u>		
11.2.3 Description of technology?	<u>X</u>		
11.2.4 Locus or amplification system?	<u>X</u>		
11.2.5 Results and/or conclusions?	<u>X</u>		
11.2.6 A quantitative or qualitative interpretative statement?	<u>X</u>		
11.2.7 Date issued?	<u>X</u>		
11.2.8 Disposition of evidence?	<u>X</u>		
11.2.9 Signature and title, or equivalent identification, of the person accepting responsibility for the content of the report?	<u>X</u>		

Comment

	Yes	No	N/A
11.3 Does the laboratory maintain the confidentiality of reports, case files, DNA records, and databases, except as otherwise provided by applicable state or federal law?	<u>X</u>		

- 11.3.1 Does the laboratory have and follow written procedures to ensure the privacy of reports, case files, DNA records, and databases? X
- 11.3.2 Does the laboratory have and follow written procedures for the release of reports, case files, DNA records, and databases in accordance with applicable state or federal law? X
- 11.3.3 Does the laboratory release personally identifiable information in accordance with applicable state and federal law? X

Comment

Standard 12. Review

	Yes	No	N/A
12.1 Does the laboratory conduct and document administrative and technical reviews of all case files and reports to ensure that conclusions and supporting data are reasonable and within the constraints of scientific knowledge?	<u>X</u>		
12.1.1 Are all technical reviews conducted by an individual that is, or has been, a qualified analyst in the methodology being reviewed?	<u>X</u>		

Comment

	Yes	No	N/A
12.2 Does the laboratory document the completion of the technical review of forensic casework, and does it include the following elements:	<u>X</u>		
12.2.1 A review of all case notes, worksheets, and electronic data (or printed electropherograms/images) that support the conclusions?	<u>X</u>		
12.2.2 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images)?	<u>X</u>		
12.2.3 A review of all profiles to verify correct inclusions and exclusions (if applicable) as well as a review of any inconclusive result for compliance with laboratory guidelines?	<u>X</u>		
12.2.4 A review of all controls, internal lane standards, and allelic ladders to verify that the expected results were obtained?	<u>X</u>		
12.2.5 A review of statistical analysis, if applicable?	<u>X</u>		
12.2.6 A review of the final report to verify that the results/conclusions are supported by the data?	<u>X</u>		
a. Does the report address each tested item or its probative fraction?	<u>X</u>		
12.2.7 For verification of CODIS eligibility. Has there been verification that all profiles entered into CODIS are eligible and have the correct DNA types and correct specimen category?	<u>X</u>		

- 12.2.7.1 Prior to upload to or search of SDIS, have the following been verified for DNA profiles: X
 - a. Eligibility for CODIS? Yes X No
 - b. Correct DNA types? Yes X No
 - c. Appropriate specimen category? Yes X No
- 12.2.7.2 Prior to entry of a DNA profile into a searchable category of SDIS, were the following criteria verified by two concordant assessments by a qualified analyst or technical reviewer: X
 - a. Eligibility for CODIS? Yes X No
 - b. Correct DNA types? Yes X No
 - c. Appropriate specimen category? Yes X No

Comment

	Yes	No	N/A
12.3 Does the administrative review include the following elements (any or all of which may be included within the technical-review process):			
12.3.1 A review of the case file and final report for clerical errors and for the presence and accuracy of the information specified in Standard 11.2?	<u>X</u>		
12.3.2 A review of the chain of custody and disposition of evidence?	<u>X</u>		
12.3.3 A procedure to document the completion of the administrative review?	<u>X</u>		

Comment

	Yes	No	N/A
12.4 Does the laboratory document the elements of a technical and administrative review?	<u>X</u>		
a. Are case files reviewed and documented according to the laboratory's procedures?	<u>X</u>		
12.5 Does the laboratory have and follow a documented procedure to address unresolved discrepant conclusions between analysts and reviewers?	<u>X</u>		

12.6 Does the laboratory have and follow a documented procedure for the verification and resolution of database matches? X

Comment

	Yes	No	N/A
12.7 Does the laboratory have and follow a program that documents the annual monitoring of the testimony of each analyst?	<u> X </u>		

Comment

Standard 13. Proficiency Testing

	Yes	No	N/A
13.1 Do analysts, technical reviewers, technicians, and other personnel designated by the technical leader undergo semiannual external proficiency testing in each technology performed to the full extent in which they participate in casework?	<u>X</u>		

Comment

	Yes	No	N/A
13.1.1 Are individuals using both manual and automated methods proficiency-tested in each, at least once per year, to the full extent in which they participate in casework?			<u>X</u>
13.1.2 Have newly qualified individuals entered the external proficiency-testing program within six months of the date of their qualification?	<u>X</u>		
13.1.3 Has the laboratory defined, documented, and consistently used the date that the proficiency test is performed as the received date, assigned date, submitted date, or due date?	<u>X</u>		
13.1.4 Except as provided in Standard 13.1.4.1, has each analyst been assigned and completed his or her own external proficiency test?	<u>X</u>		
13.1.4.1 If a team approach is used, have all analysts, technicians, and technical reviewers been proficiency-tested according to Standard 13.1?			<u>X</u>
13.1.5 Has the typing of all CODIS core loci or CODIS core sequence ranges been attempted for each technology performed as applicable?	<u>X</u>		
13.1.6 Does the laboratory maintain the following records for proficiency tests:			
13.1.6.1 The test-set identifier?	<u>X</u>		
13.1.6.2 Identity of the analyst, and other participants, if applicable?	<u>X</u>		
13.1.6.3 Date of analysis and completion?	<u>X</u>		
13.1.6.4 Copies of all data and notes supporting the conclusions?	<u>X</u>		
13.1.6.5 The proficiency test results?	<u>X</u>		

	13.1.6.6 Any discrepancies noted?	<u>X</u>	
	13.1.6.7 Corrective actions taken?		
13.1.7	Does the laboratory include, at a minimum, the following criteria for evaluating proficiency test results:	<u>X</u>	
	13.1.7.1 Evaluation:		
	a. Are all reported inclusions correct?	<u>X</u>	
	b. Are all reported exclusions correct?	<u>X</u>	
	c. Are all reported genotypes and/or phenotypes correct or incorrect according to consensus results or within the laboratory's interpretation guidelines?	<u>X</u>	
	13.1.7.2 Are results that are reported as inconclusive or not interpretable consistent with written laboratory guidelines?		<u>X</u>
	13.1.7.2.1 Has the technical leader reviewed any inconclusive result for compliance with laboratory guidelines?		<u>X</u>
	13.1.7.3 Have all discrepancies/errors and subsequent corrective actions been documented?		<u>X</u>
	13.1.7.4 Have all final reports been graded as satisfactory or unsatisfactory?	<u>X</u>	
	13.1.7.4.1 When a final report was graded satisfactory, was it shown that no analytical errors were observed for the DNA profile typing data?	<u>X</u>	
	13.1.7.4.1.1 If present, were administrative errors and corrective actions documented?		<u>X</u>
13.1.8	Have all proficiency-test participants been informed of their final test results, and has this notification been documented?	<u>X</u>	
13.1.9	Has the technical leader been informed of the results of all participants, and has this notification been documented?	<u>X</u>	
	a. If applicable, did the technical leader inform the casework CODIS administrator of all nonadministrative discrepancies that affect the typing results and/or conclusions at the time of discovery?		<u>X</u>

Comment

Standard 13.1.1 was rated as N/A as automated methods are not used in casework.

Standard 13.1.4.1 was rated as N/A as the laboratory does not use a team approach to casework.

Standards 13.1.7.2 and 13.1.7.2.1 were rated as N/A as the laboratory has not reported any inconclusive or not interpretable results.

Standard 13.1.7.3 was rated as N/A as the laboratory did not have any discrepancies/errors.

Standards 13.1.7.4.1.1 and 13.1.9.a were rated as N/A as the laboratory did not have any administrative errors or corrective actions.

	Yes	No	N/A
13.2 Does the laboratory use an external proficiency-test provider(s) that is in compliance with the current proficiency-testing manufacturing guidelines established by the American Society of Crime Laboratory Directors/Laboratory Accreditation Board or is in compliance with the current International Organization for Standardization?	<u>X</u>		

Comment

Standard 15. Audits

	Yes	No	N/A
15.1 Has the laboratory been audited annually in accordance with the FBI DNA Quality Assurance Standards?	<u>X</u>		
Has the laboratory maintained documentation that the auditor(s) for this inspection include:	<u>X</u>		
15.2 Has an external audit been conducted at least once every two years?	<u>X</u>		
a. By a qualified auditor? Yes <u>X</u> No			
b. By a current or previously qualified analyst in the laboratory’s current DNA technologies and platform? Yes <u>X</u> No			
15.2.1 Has the laboratory maintained audit documentation of those individuals (i.e., casework CODIS administrator, technical leader, and analysts) that have had their education, experience, and training qualifications evaluated and approved during two external audits?	<u>X</u>		
15.2.2 Has the laboratory maintained the documentation for those validations previously evaluated and approved during one external audit?	<u>X</u>		
15.3 For internal audits, has the laboratory maintained documentation that the auditor(s) for this inspection include:	<u>X</u>		
a. A qualified auditor? Yes <u>X</u> No			
b. A current or previously qualified analyst in the laboratory’s current DNA technologies and platform? Yes <u>X</u> No			
15.4 Have the internal and/or external audits performed pursuant to Standard 15.1 been conducted using the FBI DNA Quality Assurance Standards Audit Document in effect at that time?	<u>X</u>		
15.5 Have internal and external DNA audit documents and, if applicable, corrective action(s) been submitted to the technical leader for review to ensure that findings, if any, were appropriately addressed?	<u>X</u>		
15.5.1 For NDIS-participating laboratories, did the laboratory provide all external audit documentation and laboratory responses to the FBI within 30 days of the laboratory’s receipt of the audit documents or report?	<u>X</u>		

15.6 Are previous internal and external audit documents retained and available for auditor inspection?

X

Comment

Standard 16. Safety

	Yes	No	N/A
16.1 Does the laboratory have and follow a documented environmental health and safety program that includes, at a minimum, the following:	<u>X</u>		
16.1.1 A bloodborne pathogen and chemical hygiene plan?	<u>X</u>		
16.1.2 Documented training on the bloodborne pathogen and chemical hygiene plan?	<u>X</u>		
16.2 Has the laboratory’s environmental health and safety program been reviewed annually?	<u>X</u>		
a. Has such review been documented?	<u>X</u>		

Comment

Standard 17. Outsourcing

	Yes	No	N/A
17.1 Has the vendor laboratory complied with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories and the accreditation requirements of federal law?			<u>X</u>
17.1.1 Has the NDIS laboratory that outsources DNA sample(s) for entry into CODIS required and maintained the following documentation from the vendor laboratory:			<u>X</u>
a. Compliance with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories?			
	Yes	No	
b. Compliance with the accreditation requirements of federal law?			
	Yes	No	
17.2 Except as provided in Standard 17.2.1, since the laboratory’s last external audit, did the NDIS laboratory’s technical leader document and maintain the approval of the technical specifications of the outsourcing agreement before it was awarded?			<u>X</u>
17.2.1 For a vendor laboratory that is performing forensic DNA analysis for a law enforcement agency or entity other than the NDIS laboratory, was documented approval obtained by the vendor laboratory from the technical leader of the NDIS laboratory, accepting ownership of the DNA data generated, prior to the initiation of analysis?			<u>X</u>
17.3 Did the NDIS laboratory accept, upload to, or search in CODIS, profiles generated by a vendor laboratory?			<u>X</u>
a. Prior to the NDIS laboratory’s uploading or accepting data to upload or search in CODIS from any vendor laboratory or agency, did the technical leader of the NDIS laboratory document the prior approval of the technical specifications of the outsourcing agreement and/or document the approval of acceptance of ownership of the DNA data?			<u>X</u>
17.4 Does the NDIS laboratory have and follow a procedure to verify the integrity of the data received from a vendor laboratory through the performance of a technical review?			<u>X</u>

- 17.5** Prior to the upload or search of the data generated by the vendor laboratory to SDIS, did the NDIS laboratory perform a technical review of the vendor laboratory's data? X

 - a. Was the technical review performed by an NDIS laboratory-employed analyst or technical reviewer who is qualified, or was previously qualified, in the technology, platform, and typing amplification test kit used to generate the data and who participates in the NDIS laboratory's proficiency-test program? X
- 17.5.1** Do the technical review procedures include, at a minimum, the following elements:

 - 17.5.1.1** A review of all DNA types to verify that they are supported by the raw and/or analyzed data? X
 - 17.5.1.2** A review of all associated controls, internal lane standards and allelic ladders to verify that the expected results were obtained? X
 - 17.5.1.3** A review of the final report (if provided) to verify:

 - a. That the results/conclusions are supported by the data? X
 - Yes No

b. That each tested item (or its probative fraction) submitted to the vendor laboratory is addressed?
 - Yes No

17.5.1.4 Verification of the DNA types, eligibility, and the correct specimen category for entry into CODIS? X
- 17.6** For an on site visit:

 - a. Does the NDIS laboratory have and follow a procedure for performing an on-site visit? X
 - b. Does the procedure include, at a minimum, the following elements? X
- 17.6.1** A documented on-site visit prior to the initiation of analysis? X

 - 17.6.1.1** Has the on-site visit been performed by either the technical leader or a designated employee of the NDIS laboratory who is a qualified or previously qualified analyst in the technology, platform, and typing amplification test kit used to generate the DNA data? X

- 17.6.2 If the NDIS laboratory’s outsourcing agreement extended beyond one year, was an annual on-site visit conducted? X
- 17.6.2.1 If an on-site visit conducted by another NDIS laboratory was used by the NDIS laboratory, did the technical leader document the review and acceptance of that on-site visit? X

Comment

Standard 17 and all of its subcategories were rated as N/A as the laboratory does not outsource casework.

Appendix A: Findings and Responses

To be completed by the audit team (Findings) and laboratory (Responses).

Auditors shall reference any Standard found to be in non-compliance in the Findings below. Following the Standard, a detailed description of the non-compliance shall be provided.

Comments and/or recommendations shall **not** be included in Appendix A.

Additional pages may be attached, as needed.

Findings:

- 5.1 Do laboratory personnel have the education, training, and experience commensurate with the examination and testimony provided?

Note:

To successfully satisfy Standard 5.1, compliance must be demonstrated with all of the subcategories of Standard 5. There is no separate finding against this standard, only that the laboratory was not in compliance for Standards 5.1.2, 5.1.2.1.a, and 5.2.3.2.6.

- 5.1.2 Does the laboratory have a documented training program for qualifying all analyst(s) and technician(s)?

Note:

To successfully satisfy Standard 5.1.2, compliance must be demonstrated with all of the subcategories of Standard 5.1.2. There is no separate finding against this standard, only that the laboratory was not in compliance for Standard 5.1.2.1.a.

- 5.1.2.1 Does the training program contain at a minimum the following components:
- a. A training manual that covers all applicable DNA analytical procedures that the analyst/technician will perform?

Objective proof:

The training manual for STRs was not updated at the annual review following implementation of Y STR testing.

5.2.3.1 Does the technical leader have the following general duties and authority:

5.2.3.2.6 Review and approve the training, quality assurance, and proficiency testing programs in the laboratory?

Objective proof:

The technical leader did not document the approval of newly qualified analysts.

9.1 Does the laboratory have and follow written analytical procedures approved by the technical leader?

Objective proof:

The laboratory is not consistently following its procedure for reporting the upload of forensic unknown CODIS samples as outlined in the laboratory's Appendix E STR Interpretations Guidelines Section 3.5.1.3. The laboratory's STR interpretation guidelines require that when samples are added to the forensic unknown index of CODIS, the report will reflect this by including standard wording in the report.

Responses:

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:

Laboratory being audited: NCSBI Crime Laboratory - Raleigh As of [date] Sept 24, 2009
 Technologies currently in use: Autosomal STRs and Y-STRs
 Platforms currently in use: AB 3130xl, AB 3100, AB 7000
 Validations needing to be memorialized: Y-STRs
 Outsourcing agreements in place or in process: none for caseworking

The laboratory being audited may request documentation for the information reported in Section 2 below.

Section 2 – to be completed by the auditor who will sign the attestation statement below the questions and (a) for external audits, return to the laboratory prior to the scheduled audit date; or (b) for internal audits, maintain in the laboratory's files.

Auditor Qualifications:

Name of Auditor: Kristine Deters
 Auditor's Employer: MN BCA Forensic Science Laboratory
 Auditor's Title or Position: Forensic Scientist Supervisor
 Qualified Auditor²: Yes No (Circle One)
 Year Completed FBI DNA Auditor Class: 2003 (original), 2004 (refresher) and 2009 (refresher)
 Current or Previously Qualified DNA Analyst: Yes No (Circle One)
 Current or Previously Qualified in Casework, Database Analysis, or Both³:
 Casework Database Both (Circle One)
 Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List):
STR
 Platforms Currently or Previously Qualified In (e.g., Gel based/CE) (Please List): CE

I verify that:

**I understand the requirements of Standard 15.2⁴ ; and
 I have no conflicts of interest with the laboratory being audited; and
 The information contained in Section 2 above is correct.**

Signed By Kristine Deters Date 10/2/09

² A Qualified Auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor training course.

³ If the laboratory being audited performs both casework and database analyses, then the audit team or auditor must be qualified in both casework and database analyses.

⁴ Standard 15.2 requires that "at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform."

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:

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 Platforms currently in use: AB 3130xl, AB 3100, AB 7000
 Validations needing to be memorialized: Y-STRs
 Outsourcing agreements in place or in process: none for caseworking

The laboratory being audited may request documentation for the information reported in Section 2 below.

Section 2 – to be completed by the auditor who will sign the attestation statement below the questions and (a) for external audits, return to the laboratory prior to the scheduled audit date; or (b) for internal audits, maintain in the laboratory’s files.

Auditor Qualifications:

Name of Auditor: Jeremy Sanderson
 Auditor’s Employer: Washington State Patrol - Forensic Services Bureau
 Auditor’s Title or Position: Forensic Scientist 4
 Qualified Auditor²: Yes No (Circle One)
 Year Completed FBI DNA Auditor Class: 2005
 Current or Previously Qualified DNA Analyst: Yes No (Circle One)
 Current or Previously Qualified in Casework, Database Analysis, or Both³:
 Casework Database Both (Circle One)
 Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List):
STR
 Platforms Currently or Previously Qualified In (e.g., Gel based/CE)
 (Please List): 310, 3130 CE

I verify that:

I understand the requirements of Standard 15.2⁴ ; and
 I have no conflicts of interest with the laboratory being audited; and
 The information contained in Section 2 above is correct.

Signed By Jeremy Sanderson Date 9/30/09

² A Qualified Auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor training course.

³ If the laboratory being audited performs both casework and database analyses, then the audit team or auditor must be qualified in both casework and database analyses.

⁴ Standard 15.2 requires that “at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory’s current DNA technologies and platform.”

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:

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 Technologies currently in use: Autosomal STRs and Y-STRs
 Platforms currently in use: AB 3130xl, AB 3100, AB 7000
 Validations needing to be memorialized: Y-STRs
 Outsourcing agreements in place or in process: none for caseworking

The laboratory being audited may request documentation for the information reported in Section 2 below.

Section 2 – to be completed by the auditor who will sign the attestation statement below the questions and (a) for external audits, return to the laboratory prior to the scheduled audit date; or (b) for internal audits, maintain in the laboratory's files.

Auditor Qualifications:

Name of Auditor: Kathleen Lobato
 Auditor's Employer: Colorado Bureau of Investigation
 Auditor's Title or Position: Criminal Investigator II
 Qualified Auditor²: Yes No (Circle One)
 Year Completed FBI DNA Auditor Class: Oct 2002, Georgia; Refresher Class Feb 2009, Denver
 Current or Previously Qualified DNA Analyst: Yes No (Circle One)
 Current or Previously Qualified in Casework, Database Analysis, or Both³:
Casework Database Both (Circle One)
 Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List):
Autosomal STRs and YSTRs
 Platforms Currently or Previously Qualified In (e.g., Gel based/CE)
 (Please List): AB 310, AB 3100, AB 3130, AB 7000, AB 7500

I verify that:

I understand the requirements of Standard 15.2⁴ ; and

I have no conflicts of interest with the laboratory being audited; and

The information contained in Section 2 above is correct.

Signed By Kathleen Lobato Date 10/2/09

² A Qualified Auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor training course.

³ If the laboratory being audited performs both casework and database analyses, then the audit team or auditor must be qualified in both casework and database analyses.

⁴ Standard 15.2 requires that "at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform."

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 Validations needing to be memorialized: Y-STRs
 Outsourcing agreements in place or in process: none for caseworking

The laboratory being audited may request documentation for the information reported in Section 2 below.

Section 2 – to be completed by the auditor who will sign the attestation statement below the questions and (a) for external audits, return to the laboratory prior to the scheduled audit date; or (b) for internal audits, maintain in the laboratory’s files.

Auditor Qualifications:

Name of Auditor: Meredith A. Chambers
 Auditor’s Employer: West Virginia State Police Forensic Laboratory/ Biochemistry Section
 Auditor’s Title or Position: Forensic Scientist/ Evidence Coordinator
 Qualified Auditor²: Yes No (Circle One)
 Year Completed FBI DNA Auditor Class: 2006
 Current or Previously Qualified DNA Analyst: Yes No (Circle One)
 Current or Previously Qualified in Casework, Database Analysis, or Both³:
Casework Database Both (Circle One)
 Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List):
STR
 Platforms Currently or Previously Qualified In (e.g., Gel based/CE)
 (Please List): ABI 377, AB 3130/ 3130XL

I verify that:

**I understand the requirements of Standard 15.2⁴ ; and
 I have no conflicts of interest with the laboratory being audited; and
 The information contained in Section 2 above is correct.**

Signed By Meredith A. Chambers Date 9/30/2009

² A Qualified Auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor training course.

³ If the laboratory being audited performs both casework and database analyses, then the audit team or auditor must be qualified in both casework and database analyses.

⁴ Standard 15.2 requires that “at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory’s current DNA technologies and platform.”

Appendix C – Auditor Self-Certification for QAS Audits

Section 1 – to be completed by the laboratory being audited:

Laboratory being audited: NCSBI Crime Laboratory - Raleigh As of [date] Sept 24, 2009
 Technologies currently in use: Autosomal STRs and Y-STRs
 Platforms currently in use: AB 3130xl, AB 3100, AB 7000
 Validations needing to be memorialized: Y-STRs
 Outsourcing agreements in place or in process: none for caseworking

The laboratory being audited may request documentation for the information reported in Section 2 below.

Section 2 – to be completed by the auditor who will sign the attestation statement below the questions and (a) for external audits, return to the laboratory prior to the scheduled audit date; or (b) for internal audits, maintain in the laboratory's files.

Auditor Qualifications:

Name of Auditor: Lynn Langford
 Auditor's Employer: Georgia Bureau of Investigation/Northeastern Regional Crime Lab
 Auditor's Title or Position: Lab Manager
 Qualified Auditor²: Yes No (Circle One)
 Year Completed FBI DNA Auditor Class: 2002 with refresher courses in 2004, 2006, 2007, 2009
 Current or Previously Qualified DNA Analyst: Yes No (Circle One)
 Current or Previously Qualified in Casework, Database Analysis, or Both³:
 Casework Database Both (Circle One)
 Technologies Currently or Previously Qualified In (e.g., STR, mtDNA) (Please List):
STRs
 Platforms Currently or Previously Qualified In (e.g., Gel based/CE)
 (Please List): CE 310, 3100, 3130xl

I verify that:

**I understand the requirements of Standard 15.2⁴ ; and
 I have no conflicts of interest with the laboratory being audited; and
 The information contained in Section 2 above is correct.**

Signed By Lynn Langford Date 093009

² A Qualified Auditor is a current or previously qualified DNA analyst who has successfully completed the FBI DNA Auditor training course.

³ If the laboratory being audited performs both casework and database analyses, then the audit team or auditor must be qualified in both casework and database analyses.

⁴ Standard 15.2 requires that "at least once every two years, an external audit shall be conducted by an audit team comprised of qualified auditors from a second agency(ies) and having at least one team member who is or has been previously qualified in the laboratory's current DNA technologies and platform."

Appendix D – Personnel Meeting Minimum Education, Experience, and Training Qualifications As Assessed By External Audit

To be completed by the audit team.

In accordance with Standards 15.1 and 15.2.1, this form shall be used to document the evaluation and approval of analysts, casework CODIS administrators and technical leaders during an external audit. Section 1 is for documenting personnel who have received two successive separate external audit approvals of their education, experience, and training qualifications. Section 1 should be used to document all individuals who have received two successive separate audit approvals of their education, experience, and training qualifications, regardless of whether the individual is still employed by the laboratory. The date of the prior audit approvals should be noted in this Section, when known.

Section 2 is for documenting personnel who are receiving the **first** external audit approval of their education, experience, and training qualifications.

Section 1 documents those personnel who have received two successive external audit approvals of their education, experience, and training qualifications.

Section 1. (a) – Approvals Between July 1, 2004 and June 30, 2009

Laboratory personnel who have been evaluated after July 1, 2004, and approved under two successive, separate external audits as meeting the education, experience, and training qualifications required under Standard 5.1 of the 1998 Quality Assurance Standards for Forensic DNA Testing Laboratories¹:

Analyst(s):

Amanda Thompson (2004, 2005), Amanda Fox (2004, 2005), Carolyn Speas 2004, 2005), Chris Parker (2004, 2005), Christiana Fischer (2006, 2007), Cortney Cowan (2005, 2006), David Freeman (2004, 2005), Ivy McMillian (2006, 2007), Jenny Elwell (2004, 2005), Karen Wunningham (2004, 2005), Michelle Hannon (2006, 2007), Sharon Hinton (2004, 2005), Timothy Baize (2006, 2007), Zachary Kallenbach (2005, 2006), Mike Budzynski (2004, 2005).

Technical Leader(s): ***David Freeman (2004, 2007)***

Section 1. (b) – Approvals After July 1, 2009

¹ Laboratory personnel qualified by the technical leader on or before June 30, 2009, and evaluated after July 1, 2009, should be listed in this section.

Laboratory personnel who have been evaluated after July 1, 2009, and approved under two successive, separate external audits as meeting the education, experience, and training qualifications required under Standard 5.1 of the 2009 Quality Assurance Standards for Forensic DNA Testing Laboratories:

Analyst(s): ***Kristin (Meyer) Hughes***

Casework CODIS administrator(s):

Technical Leader(s):

Section 2 documents those personnel who are receiving the first external audit approval of their education, experience, and training qualifications.

Section 2. (a) – For Personnel Appointed or Hired Prior to July 1, 2009
Laboratory personnel who were appointed or hired prior to July 1, 2009, and approved for the first time as meeting the education, experience, and training qualifications required under Standard 5.1 of the 1998 Quality Assurance Standards for Forensic DNA Testing Laboratories:

Analyst(s):

Erin Ermish, Jody West, Mackenzie Dehaan, Sarah Johnson, Suzi Barker, Tanisha Walker

Casework CODIS administrator:

Technical Leader(s):

Section 2. (b) – For Personnel Appointed or Hired On or After July 1, 2009
Laboratory personnel who have been evaluated after July 1, 2009, and approved for the first time as meeting the education, experience, and training qualifications required under Standard 5.1 of the 2009 Quality Assurance Standards for Forensic DNA Testing Laboratories:

Analyst(s):

Casework CODIS administrator(s): ***Amanda Fox***

Technical Leader(s):

Appendix E – Approved Validations

This form may be used to document the evaluation and approval of validations by the external audit team according to Standard 8; this documentation to be maintained by the audited laboratory to comply with Standard 15.2.2.

To be completed by the audit team:

List of validations, if any, evaluated and approved during this audit:

Validation of the Applied Biosystems 3130 XL Genetic Analyzer (SN 17208-005) using the Applied Biosystems Identifiler Amplification Kit.

Sensitivity
Mixtures
Reproducibility
Concordance
Increased injection time

Validation of Quantifiler Human Male DNA Quantitation Kit

Sensitivity
Reproducibility
Precision

Validation of Yfiler Amplification Kit using the Applied Biosystems 3100 Genetic Analyzer

Stutter
Reproducibility
Sensitivity
Precision
Mixtures (male:female and male:male mixtures)
NIST
Adjudicated cases and mock case samples