THE FBI QUALITY ASSURANCE STANDARDS

AUDIT FOR

FORENSIC DNA TESTING LABORATORIES

IN ACCORDANCE WITH

THE QUALITY ASSURANCE STANDARDS

FOR

FORENSIC DNA TESTING LABORATORIES

EFFECTIVE _____

An Audit of: Click here to enter Laboratory

Address of Laboratory Click here to enter Laboratory contact address.

Dates of Audit: Click here to enter start date. to Click here to enter end date.

Type of Audit: External ☐ Internal ☐

Was the audit done in conjunction with an accreditation assessment? Yes ☐ or No ☐

Revision Date of Audit Guidance Document referenced Click here to enter a date.

Audit Team: Click here to enter name of Lead Auditor/Team Lead.

Click here to enter name of auditor.	Click here to enter name of auditor.
Click here to enter name of auditor.	Click here to enter name of auditor.
Click here to enter name of auditor.	Click here to enter name of auditor.
Click here to enter name of auditor.	Click here to enter name of auditor.
Click here to enter name of auditor.	Click here to enter name of auditor.

For Laboratory:

Date Final Audit Report Received: Click here to enter a date.

Does the Audit Document include findings? Yes ☐ or No ☐

If external, Date Audit Documentation Sent to NDIS: Click here to enter a date.

FORENSIC QAS 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, known as the DNA Advisory Board (DAB), first convened in 1995. The 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 its statutory responsibilities, recommending separate documents detailing quality assurance standards for both forensic and databasing 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. The “Quality Assurance Standards for Forensic DNA Testing Laboratories" and the retitled "Quality Assurance Standards for DNA Databasing Laboratories" have become benchmarks for assessing the quality practices and performances of DNA laboratories throughout the country. When the Federal DNA Advisory Board’s statutory term expired, it transferred responsibility for recommending revisions of these Quality Assurance Standards to the Scientific Working Group on DNA Analysis Methods (SWGDAM).

The DNA Identification Act of 1994 also required that the FBI Laboratory ensure that all DNA laboratories that receive federal grant funds or participate in the National DNA Index System (NDIS) demonstrate compliance with the FBI’s Quality Assurance Standards (QAS). A laboratory's documentation of compliance with the QAS is measured through an accreditation/audit process. Such accreditation inspections or audits are performed by forensic scientists, either internal or external to the laboratory, and are intended to evaluate and document compliance with established standards.

Since the issuance of the original QAS, the FBI Laboratory recognized that a uniform interpretation guide would minimize interpretation variability among auditors. For the initial QAS, the FBI Laboratory developed, in collaboration with inspection and accreditation agencies and other interested stakeholders, audit documents for assessing compliance with the required Forensic and Databasing Standards. Previous Audit Documents contained a checklist for assessing compliance with each standard and additional discussion sections with interpretation guidance for laboratories and auditors.

With the 2020 QAS revisions, the QAS discussion sections for the Forensic and Databasing Standards, formerly part of the Audit Documents, have been transitioned into the QAS Guidance Document. The Guidance Document clarifies standards, as needed, and provides additional guidance to assist the laboratory and auditors in determining compliance. **The Forensic and Databasing QAS and QAS Guidance**

Document will take effect on Janaury 1, 2020 and are not to be applied retroactively. The Forensic and Databasing QAS are the primary resource for the definitions and quality assurance standards and take precedence over the QAS Guidance Document which should be consulted only for additional clarification as a secondary resource.

The Forensic and Databasing Audit Documents now contain only the checklists for assessing compliance with each standard. In this Audit Document, the rating system for assessing the laboratory with respect to each standard contains the choices of "Yes" or "No", and, where appropriate, "Not Applicable (N/A)." In Appendix A, the findings associated with the audit will be detailed and summarized by the auditor, with an area available for response to such findings by the laboratory. Notes or comments, including observations and recommendations, are better suited to be mentioned during the exit briefing with laboratory personnel or in a separate letter/memorandum to the laboratory so that these comments are not confused with comments relating to a finding or an explanation of why a particular standard is not applicable.

Instructions to Audit Team

Thank you for participating in this important process intended to evaluate compliance with minimum standards for a quality program for performing forensic DNA analysis.

Starting with audits conducted in accordance with the Quality Assurance Standards effective July 1, 2009, separate Audit Documents are used for forensic and databasing laboratories. If a laboratory performs both functions, each Audit Document must be completed and submitted to the laboratory at the conclusion of the audit process.

Once an external audit has been scheduled, the laboratory should provide the laboratory being audited with the Checklist contained on the following pages as soon as possible. The Lead Auditor shall also request a certification (contained in Appendix C) from each auditor on the team and provide them to the laboratory prior to the beginning of the audit. The Lead Auditor shall review the checklist completed by the laboratory and the laboratory shall review the Appendix C or each auditor to ensure that the audit team contains the appropriate number of members to audit the laboratory and that the team members possess the necessary expertise required to audit that laboratory. An auditor or his or her employer who has a contractual relationship (exclusive of audits) with the laboratory being audited shall disclose this fact and recuse himself or herself from performing the audit. The laboratory shall review the auditors' certifications for any potential conflicts of interest.

As a general rule, compliance with a standard is assessed through a review of the laboratory's documentation and interviews with laboratory staff. Documents may be in hard copy, electronic or a combination of both formats. Certificates of qualifications shall not be considered documentation of compliance with these standards. Laboratory personnel's compliance with these standards shall be documented by the auditor(s) in Appendix D. A review of case reports for the laboratory shall include a number of case files randomly selected for each DNA analyst. As appropriate, a minimum of three to five cases per DNA analyst should be reviewed.

When conducting an audit, please keep in mind the following general guidelines:

- Potential issues concerning compliance should be directed to the laboratory's designated points of contact.
- Comments on the laboratory's operations should be reserved for the audit document if a "No" or "N/A" is marked and/or the exit interview with laboratory management; comments should not be made to laboratory staff.
- Contested or contentious issues should be brought to the attention of your Lead Auditor for follow-up, as necessary.

As a general rule,

- Issues deemed minor by the audit team that are addressed during the course of an audit (for example: date or position revisions of a laboratory's organizational chart) may be determined by the auditor to satisfy a non-compliance so that a "Yes" is marked for that standard.

- Non-compliance with a standard identified by the laboratory prior to the audit should be assessed by the audit team for adequate documentation and/or corrective action. If determined to have been appropriately addressed, the auditor may mark the corresponding standard as "Yes".

- Comments should not be included for standards marked "Yes".

- Comments shall be included for standards marked "No" or "N/A".

    - For a standard marked "No", the comment shall describe the non-compliance with sufficient detail so that the laboratory can develop an appropriate corrective action for compliance.

    - For a standard marked "N/A", the comment shall describe why that standard is not applicable to that laboratory.

For additional information pertaining to the interpretation of each standard refer to the QAS Guidance Document. Questions concerning this Audit Document or a specific standard should be directed to the FBI's Combined DNA Index System (CODIS) Unit at QAS@fbi.gov

After the audit is completed, the Lead Auditor or auditor(s) briefs DNA laboratory management and the DNA technical leader regarding the results. This briefing should verbally detail specific findings (non-compliances) and observations (general comments and/or recommendations), as well as recognize commendable performances. The written report should be prepared by the Lead Auditor and/or auditor(s) and sent to the laboratory within 30 days of the audit. The Audit Document Report consists of the completed Audit Document Checklist, with any areas of non-compliance listed under the Findings Section of Appendix A. All findings of non-compliance must be clearly identified and referenced to the appropriate standard.

Recommendations shall not be included in the Audit Document Report. Notes or comments, including observations and recommendations are better suited to be mentioned during the exit briefing with laboratory personnel or in a separate letter/memorandum to the laboratory so that these comments are not confused with comments relating to a finding of non-compliance or an explanation of why a particular standard is not applicable.

General Laboratory Information

For an External Audit, to be completed by the laboratory and provided to the audit team prior to the on-site visit.

1. Name of Laboratory: Click here to enter text.
2. Jurisdiction: Choose an item. If Other: Click here to explain.
3. Uses a Vendor Laboratory: ☐ Yes ☐ No
   If Yes, Click here to enter Vendor Laboratory(ies)
4. Uses contract employees: ☐ Yes ☐ No
5. NDIS Participant: ☐ Yes ☐ No
   If No, applying for NDIS Participation: ☐ Yes ☐ No
6. Technologies Used: (Choose those that apply)
   ☐ Autosomal STR ☐ Y STR ☐ Mito ☐ SNP
   ☐ Other: Click here to enter text.
   ☐ Other: Click here to enter text.
7. Test Typing Kits Used: Click here to enter text.
8. Platform Instrument Models Used: Click here to enter text.
9. Validations requiring review under Std 15: ☐ Yes ☐ No
10. Staff (to include contract employees)
    a. Total # of qualified DNA Analysts/Technical Reviewers: ###
       i. # of DNA Analysts requiring review under Std 15: ###
    b. # of DNA Technicians: ###
    c. # of Laboratory Support Personnel: ###
    d. DNA Technical Leader: Click here to enter text.
       i. On Site: ☐ Yes ☐ No
       ii. Hired or Appointed since last external audit: ☐ Yes ☐ No
    e. Casework CODIS Administrator: Click here to enter text.
       i. Hired or Appointed since last external audit: ☐ Yes ☐ No
11. Date of Last Audit: Click here to enter a date.
    a. ☐ External ☐ Internal
    b. If Internal, Date of Last External Audit: Click here to enter a date.
    c. Revision Date of Audit Guidance Document Used: Click here to enter a date.
12. Uses an Expert System: ☐ Yes ☐ No
    a. Name & Version of Expert System: Click here to enter text.
    b. Test Kit and Instrument: Click here to enter text.
    c. Version of Data Collection: Click here to enter text.
13. Uses a Rapid DNA System: ☐ Yes ☐ No
    a. Name of Rapid DNA System and Instrument: Click here to enter text.
    b. Typing Kit and Cartridge: Click here to enter text.
    c. System Software: Click here to enter text.
    d. Expert System Software: Click here to enter text.

Standard 1. Scope

No Auditable Requirements

Standard 2. Definitions

No Auditable Requirements

Standard 3. Quality Assurance Program

		Yes	No	N/A
3.1	Does the laboratory have, follow, and maintain a documented quality system:	☐	☐	
	a. Is the quality system appropriate to the testing activities?	☐	☐	
	b. Is the quality system equivalent to or more stringent than what is required by these Standards?	☐	☐	
NOTE:	*To successfully satisfy Standard 3.1, compliance must be demonstrated with all of the subcategories of Standard 3.1.*			
3.1.1	Is the quality system documented in a manual that includes or references the following elements:	☐	☐	
	3.1.1.1 Goals and objectives?	☐	☐	
	3.1.1.2 Organization and management?	☐	☐	
	3.1.1.3 Personnel?	☐	☐	
	3.1.1.4 Training?	☐	☐	
	3.1.1.5 Facilities and evidence control?	☐	☐	
	3.1.1.6 Validation?	☐	☐	
	3.1.1.7 Analytical procedures?	☐	☐	
	3.1.1.8 Equipment?	☐	☐	
	3.1.1.9 Reports?	☐	☐	
	3.1.1.10 Review?	☐	☐	
	3.1.1.11 Proficiency testing?	☐	☐	
	3.1.1.12 Corrective action?	☐	☐	
	3.1.1.13 Audits?	☐	☐	

3.1.1.14 Professional Development?	☐	☐	
3.1.1.15 Outsourcing Ownership?	☐	☐	
3.1.2 Does the laboratory maintain and have available on-site any documents referenced within the quality manual?	☐	☐	

		Yes	**No**	**N/A**
3.2	Does the laboratory have and follow a policy regarding document retention that specifically addresses:	☐	☐	

a. Proficiency tests?	Yes	☐	No	☐
b. Corrective action?	Yes	☐	No	☐
c. Audits?	Yes	☐	No	☐
d. Training records?	Yes	☐	No	☐
e. Continuing education?	Yes	☐	No	☐
f. Case files?	Yes	☐	No	☐
g. Court testimony monitoring?	Yes	☐	No	☐

		Yes	**No**	**N/A**
3.3	Does the laboratory perform annual review of its DNA quality system?	☐	☐	
	a. Is the review independent of the audit required by Standard 15?	☐	☐	
	b. Is the review completed under the direction of the technical leader?	☐	☐	
	c. Is the review approved by the technical leader?	☐	☐	
3.4	Does the laboratory annually review case files determined by the technical leader to be a representative sample of the cases worked?	☐	☐	
	a. Is the review independent of an external audit required by Standard 15?	☐	☐	
	b. Is the scope of the review defined prior to each annual review and approved by the technical leader?	☐	☐	

Comment

Standard 4. Organization and Management

		Yes	No	N/A
4.1	Does the laboratory have:	☐	☐	
	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?	☐	☐	
	4.1.2 A technical leader who is accountable for the technical operations?	☐	☐	
	a. Have at least one technical leader in a multi - laboratory system?	☐	☐	☐
	4.1.3 A casework CODIS administrator who is accountable for CODIS on-site at each individual laboratory facility using CODIS?	☐	☐	☐
	4.1.4 At least two full-time employees who are qualified DNA analysts?	☐	☐	
	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?	☐	☐	
	4.1.6 A documented contingency plan that is approved by laboratory management if the technical leader position is vacated or if the number of qualified DNA analysts falls below the two full-time analyst requirement?	☐	☐	
	a. If applicable, did the laboratory follow the documented contingency plan?	☐	☐	☐

NOTE: *For an NDIS participating lab, refer to Appendix B for the Contingency Plan Notification Form.*

		Yes	No	N/A
4.2	Does the laboratory define whether the date of hire/appointment/promotion or date of qualification will be used by the laboratory for determining the applicable QAS version for education, experience and training requirements?	☐	☐	

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?	☐	☐	
NOTE:	*To successfully satisfy Standard 5.1, compliance must be demonstrated with all of the subcategories of Standard 5.*			
5.1.1	Does the laboratory have written job descriptions for all personnel to include responsibilities, duties, and skills?	☐	☐	
5.1.2	Does the laboratory maintain records on the relevant qualifications, training, skills, and experience of all technical personnel?	☐	☐	

		Yes	No	N/A
5.2	Is the technical leader a full-time employee of the laboratory or multi-laboratory system?	☐	☐	
NOTE:	*To successfully satisfy Standard 5.2, compliance must be demonstrated with all of the subcategories of Standard 5.2.*			
NOTE:	*Standard 5.2 and Standards 5.2.1 through 5.2.4 may be marked "Yes" for a TL who has been reviewed and memorialized in at least 2 prior external audit documents.*			
5.2.1	Does the technical leader of the laboratory meet or exceed the following degree/educational requirements or have a waiver as allowed for in 5.2.1.4?	☐	☐	☐
NOTE:	*The subcategories of Standards 5.2.1 through 5.2.1.3 will be marked "N/A" for a TL who has a waiver as allowed for in 5.2.1.4*			
	a. A master's degree in a biology-, chemistry-, or forensic science-related area?	☐	☐	☐
	b. Twelve semester hours or equivalent credit hours including a combination of graduate and undergraduate coursework or classes covering the following subject areas:	☐	☐	☐
	1. Biochemistry? Yes ☐ No ☐			

2. Genetics? Yes ☐ No ☐

3. Molecular biology? Yes ☐ No ☐

4. Statistics / population genetics? Yes ☐ 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?	☐	☐	☐
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?	☐	☐	☐
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 syllabus, letter from the instructor, or other documentation that supports the course content?	☐	☐	☐
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)?	☐	☐	☐

		Yes	**No**	**N/A**
5.2.2	Does the technical leader meet or exceed one of the following minimum experience requirements?	☐	☐	
	a. If the technical leader was appointed prior to July 1, 2009, 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?	☐	☐	☐
	b. If the technical leader was appointed on or after July 1, 2009, does the technical leader have a minimum of three years human DNA experience (current or previous) as a qualified analyst on forensic samples?	☐	☐	☐

NOTE: *Standards 5.2.3 and 5.2.4 may be marked "N/A" if the technical leader has been in the position for less than one year.*

5.2.3	If the technical leader was appointed on or after [*the effective date of this revision]*, was the technical leader a currently or previously qualified analyst in each technology or have documented training in each technology utilized in the laboratory within one year of appointment?	☐	☐	☐
5.2.4	Has the technical leader successfully completed the FBI-sponsored auditor training within one year of appointment?	☐	☐	☐

		Yes	**No**	**N/A**
5.2.5	Does the technical leader of the laboratory have the following authority and minimum responsibilities:	☐	☐	
	5.2.5.1 Oversee the technical operations of the laboratory?	☐	☐	
	5.2.5.2 Authority to initiate, suspend, and resume DNA analytical operations for the laboratory or an individual?	☐	☐	
	5.2.5.3 Evaluate and approve of all validations and new or modified methods used by the laboratory?	☐	☐	
	5.2.5.4 Review the training records for newly qualified analysts, technicians and technical reviewers and approve their qualifications prior to independent casework analysis and review, verify, and approve the academic transcripts for newly qualified analysts and technical reviewers?	☐	☐	
	5.2.5.5 Approve the technical specifications for outsourcing agreements?	☐	☐	
	5.2.5.6 Review internal and external DNA audit documents and, if applicable, approve corrective action(s)?	☐	☐	
	5.2.5.7 Review annually the procedures of the laboratory?	☐	☐	
	5.2.5.8 Review and approve the training, quality assurance, and proficiency testing programs in the laboratory?	☐	☐	

	5.2.5.9 Review potential conflicts of interest when contract employees are employed by multiple NDIS participating and/or vendor laboratories?	☐	☐	☐

		Yes	No	N/A
5.2.6	Is the technical leader accessible to the laboratory to provide on-site, telephonic, or electronic consultation as needed?	☐	☐	
	a. If the technical leader oversees a system of separate laboratories, has the technical leader conducted and documented semi-annual on-site visits of each of the laboratories?	☐	☐	☐
NOTE:	*Standards 5.2.7, 5.2.7.1 and 5.2.7.2 may be marked "N/A" if the technical leader has been in the position for less than one year.*			
5.2.7	Has a newly appointed technical leader documented a review of the following within one year of appointment?	☐	☐	☐
	5.2.7.1 Validation studies and analytical procedures currently used by the laboratory?	☐	☐	☐
	5.2.7.2 Educational qualifications and training records of currently qualified analysts and technical reviewers?	☐	☐	☐

		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?	☐	☐	☐
NOTE:	*For an audit of a vendor laboratory, Standard 5.3 and all of its subcategories will be marked "N/A".*			
NOTE:	*To successfully satisfy Standard 5.3, compliance must be demonstrated with all of the subcategories of Standard 5.3.1 through 5.3.3.*			
NOTE:	*Standard 5.3 and Standards 5.3.1 through 5.3.3 may be marked "Yes" if the casework CODIS administrator has been reviewed and memorialized in at least 2 prior external audit documents.*			
NOTE:	*Standard 5.3.1 shall be marked "Yes" if the casework CODIS administrator was appointed prior to [the effective date of this revision].*			

5.3.1	Does the casework CODIS administrator meet or exceed the degree and educational requirements in Standard 5.4?	☐	☐	☐
NOTE:	*Standard 5.3.2 shall be marked "Yes" if the CODIS administrator was appointed prior to July 1, 2009.*			
5.3.2	Is the casework CODIS administrator a current or previously qualified analyst with documented mixture interpretation training?	☐	☐	☐
NOTE:	*Standard 5.3.3 a may be marked "N/A" if the* casework CODIS administrator *has been in the position for less than six months. Standard 5.3.3 and 5.3.3 b may be marked "N/A" if the* casework CODIS administrator *has been in the position for less than one year.*			
5.3.3	Has the casework CODIS administrator successfully completed the following training requirements?	☐	☐	☐
	a. FBI-sponsored CODIS software training within six months of appointment, if not previously completed such training?	☐	☐	☐
	b. FBI DNA auditor training within one year of appointment, if not previously completed such training?	☐	☐	☐

		Yes	**No**	**N/A**
5.3.4	Is the casework CODIS administrator responsible for the following:	☐	☐	☐
	5.3.4.1 Administer the laboratory's local CODIS network?	☐	☐	☐
	5.3.4.2 Schedule and document the CODIS computer training of casework analysts?	☐	☐	☐
	5.3.4.3 Ensure that the security of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures?	☐	☐	☐
	5.3.4.4 Ensure that the quality of data stored in CODIS is in accordance with state and/or federal law and NDIS operational procedures?	☐	☐	☐
	5.3.4.5 Ensure that matches are dispositioned in accordance with NDIS operational procedures?	☐	☐	☐

5.3.5	Is the casework CODIS administrator authorized to terminate an analyst's or the laboratory's participation in CODIS until the reliability and security of the computer data can be assured if an issue with the data is identified?	☐	☐	☐
5.3.6	If the casework CODIS administrator position has been unoccupied since the last audit, has the laboratory refrained from uploading new DNA profiles to NDIS during the vacancy?	☐	☐	☐

		Yes	**No**	**N/A**
5.4	Is each analyst an employee or contract employee of the laboratory and does he or she meet or exceed the following qualifications?	☐	☐	
NOTE:	*To successfully satisfy Standard 5.4, compliance must be demonstrated with all of the subcategories of Standards 5.4.1 through 5.4.2.*			
NOTE:	*Complete Standards 5.4.1 through 5.4.2 for analysts under review. Standard 5.4 and Standards 5.4.1 through 5.4.2 may be marked "Yes" if all analysts have been reviewed and memorialized in at least 2 prior external audit documents.*			
5.4.1	Does each analyst reviewed meet or exceed the following degree and educational requirements:	☐	☐	☐
	a. B.A./B.S. or advanced degree or its equivalent in a biology-, chemistry-, or forensic science- related area?	☐	☐	☐
	b. College coursework covering the subject areas of:	☐	☐	☐
	1. Biochemistry? Yes ☐ No ☐			
	2. Genetics? Yes ☐ No ☐			
	3. Molecular biology? Yes ☐ No ☐			
	c. For analysts hired/appointed/promoted or qualified (as defined by the laboratory per Standard 4.2) prior to [*the effective date of this revision]*, college coursework or training that covers the subject areas of statistics and/or population genetics as it applies to forensic DNA analysis? or For analysts hired/appointed/promoted or qualified (as defined by the Laboratory per Standard 4.2) on	☐	☐	☐

	or after [*the effective date of this revision*], successful completion of coursework covering statistics and/or population genetics?			
5.4.1.1	Does each of the specific subject areas listed in Standard 5.4.1 constitute an integral component of any coursework used to demonstrate compliance with this Standard?	☐	☐	☐
5.4.1.2	For analysts appointed or hired on or after July 1, 2009, do the required subject areas of biochemistry, genetics, and molecular biology consist of nine or more cumulative semester or equivalent hours?	☐	☐	☐
5.4.1.3	For individuals who have completed coursework with titles other than those listed in Standard 5.4.1, has compliance with this Standard been demonstrated through a combination of pertinent materials such as a syllabus, letter from the instructor, or other documentation that supports the course content, and has the technical leader approved compliance with this Standard?	☐	☐	☐
5.4.2	Does each analyst have six months of forensic human DNA laboratory experience?	☐	☐	☐
	a. Has each analyst successfully completed the laboratory's required training?	☐	☐	☐

		Yes	**No**	**N/A**
5.5	Is each technical reviewer an employee or contract employee of the laboratory and meet the education and experience requirements of Standard 5.4?	☐	☐	☐
NOTE:	*To successfully satisfy Standard 5.5, compliance must be demonstrated with all of the subcategories of Standards 5.5.1 through 5.5.2.*			
NOTE:	*Complete Standards 5.5.1 through 5.5.2 for technical reviewers under review. For qualified analysts under review that are authorized to conduct technical reviews, Standards 5.5 through 5.5.2 will be marked "Yes" if compliance with Standard 5.4 was demonstrated.*			
5.5.1	Is each technical reviewer a current or previously qualified analyst?	☐	☐	☐
5.5.2	Has each technical reviewer successfully completed documented training?	☐	☐	☐

		Yes	No	N/A
5.6	Is each technician an employee or contract employee of the laboratory and successfully completed laboratory's documented training program?	☐	☐	☐

		Yes	No	N/A
5.7	Has the technical leader verified and approved the education, to include a review of academic transcripts, of each analyst and technical reviewer?	☐	☐	☐

Comment

Standard 6. Training

		Yes	No	N/A
6.1	Does the laboratory have a training program documented in a training manual for qualifying all analyst(s) and technician(s)?	☐	☐	
NOTE:	*To successfully satisfy Standard 6.1, compliance must be demonstrated with all of the subcategories of Standards 6.1.*			
	Does the laboratory's training program:			
6.1.1	Address all DNA analytical, interpretation, and/or statistical procedures used in the laboratory?	☐	☐	
6.1.2	Include practical exercises encompassing the examination of a range of samples routinely encountered in casework?	☐	☐	
6.1.3	Teach and assess the technical skills and knowledge required to perform DNA analysis?	☐	☐	
	6.1.3.1 Does the laboratory's training program for analysts include the skills and knowledge required to conduct a technical review?	☐	☐	
6.1.4	Include an assessment of oral communication skills and/or a mock court exercise?	☐	☐	
6.1.5	Include requirements for competency testing?	☐	☐	

		Yes	No	N/A
6.2	Did the technical leader approve any modifications to an analyst's, technical reviewer's, technician's, or laboratory support personnel's required training based on a documented assessment of the individual's previous training and experience?	☐	☐	☐
6.3	Prior to participating in independent casework, did all analysts and technicians, regardless of previous experience, successfully complete competency testing covering the routine DNA methods, interpretation, and/or statistical procedures to be used?	☐	☐	
NOTE:	*Complete Standards 6.3.1 through 6.3.2 for analysts under review and technicians that completed the training program since the last external audit. Standards 6.3 through 6.3.2 may be marked "Yes" if all analysts have been reviewed and memorialized in at least 2 prior external audit documents and no technicians have completed training since the last external audit.*			
6.3.1	Did the competency testing for a new analyst include a practical component, and written and/or oral components?	☐	☐	☐
6.3.2	Did the competency testing for a new technician include a practical component?	☐	☐	☐

		Yes	No	N/A
6.4	For an analyst or technician (currently or previously qualified within the laboratory) to be qualified in a new or additional method:			
	Did the laboratory teach and assess the technical skills and knowledge required to perform the additional method?	☐	☐	☐
6.4.1	Before the use of a new or additional method on forensic samples or casework reference samples:	☐	☐	☐
	a. Did the analyst and/or technician successfully complete competency testing to the extent of his/her participation in casework analyses?	☐	☐	☐
	b. Did the competency testing include a practical component?	☐	☐	☐

6.5	For an analyst (currently or previously qualified within the laboratory) to be qualified to interpret data and generate reports for a new or additional technology, typing test kit, platform, or interpretation software:			
	Did the laboratory teach and assess the technical skills and knowledge required to interpret data, reach conclusions, and generate reports using the additional technology, typing test kit, platform, or interpretation software?	☐	☐	☐
6.5.1	Before the use of a new or additional technology, typing test kit, platform or interpretation software on forensic samples or casework reference samples:	☐	☐	☐
	a. Did the analyst successfully complete competency testing using the additional technology, typing test kit, platform or interpretation software to the extent of his/her participation in casework analyses?	☐	☐	☐
	b. Did the competency testing include a practical component?	☐	☐	☐
		Yes	**No**	**N/A**
NOTE:	*Standard 6.6 may be marked "N/A" for a laboratory that does not have individuals that solely conduct technical reviews.*			
6.6	Did a technical reviewer, who is not currently qualified as an analyst in the laboratory, receive training on the case notes, data analysis, interpretation, and reporting criteria for any method, technology, typing test kit, platform, or interpretation software or the legacy technology, typing test kit, platform and/or interpretation software on which they were not previously qualified as an analyst in the laboratory?	☐	☐	☐
6.6.1	Did the technical reviewer successfully complete competency testing before completing a technical review of data and/or reports using the additional method, technology, typing test kit, platform or interpretation software used in casework analyses?	☐	☐	☐
	6.6.1.1 For a contract technical reviewer conducting reviews for an NDIS participating laboratory, was the competency testing administered by the NDIS participating laboratory?	☐	☐	☐

		Yes	No	N/A
NOTE:	*Standards 6.7 through 6.8 may be marked "N/A" for a laboratory that does not reinterpret legacy data.*			
6.7	For an analyst to be qualified in reinterpretation of legacy data, for which they were not previously qualified within the laboratory, did the analyst demonstrate the technical skills and knowledge required to interpret data, reach conclusions, and generate reports in the legacy technology, typing test kit, and/or platform?	☐	☐	☐
6.7.1	Did the analyst successfully complete competency testing in the legacy technology, typing test kit, and/or platform to the extent of his/her participation in casework analyses?	☐	☐	☐
	a. Did the competency testing include practical components of reinterpretation?	☐	☐	☐
6.8	Does the laboratory have and follow procedures for maintaining or reestablishing the technical skills and knowledge of analysts and technical reviewers who reinterpret legacy data for which they are qualified or previously qualified and whose external proficiency testing does not include a legacy technology, typing test kit or platform?	☐	☐	☐
6.8.1	Does the technical leader review the documentation of an analyst's or technical reviewer's maintenance or reestablishment of the technical skills and knowledge and authorize the analyst or technical reviewer to reinterpret legacy data for no more than a two year period?	☐	☐	☐

		Yes	No	N/A
6.9	Does the technical leader review the training records for each analyst, technician, and/or technical reviewer and approve his/her qualifications prior to independent casework responsibilities?	☐	☐	
6.10	Are each analyst, technician, and/or technical reviewer authorized to independently perform the assigned job responsibilities and the date(s) documented?	☐	☐	

6.11	Do laboratory support personnel have documented training specific to their job function(s)?	☐	☐	☐
6.12	Does the laboratory have and follow a policy for addressing retraining of personnel when necessary?	☐	☐	
	a. Is the technical leader responsible for evaluating the need for and assessing the extent of retraining and approving the retraining plan?	☐	☐	
NOTE:	*Standard 6.12.1 will also be completed for any individual on extended leave for a period that takes them out of the proficiency test cycle.*			
6.12.1	Did the individual successfully complete competency testing prior to his/her return to participation in casework analyses?	☐	☐	☐
	a. Did the competency testing include a practical component?	☐	☐	☐
6.13	Does the laboratory maintain records on the training, including successful completion of competency testing, of the laboratory personnel?	☐	☐	

Comment

Standard 7. Facilities and Evidence Control

		Yes	No	N/A
7.1	Does the laboratory physical space ensure the integrity of the analyses and the evidence?	☐	☐	
NOTE:	*To successfully satisfy Standard 7.1, the laboratory must demonstrate compliance with all of the subcategories of Standard 7.1.*			
7.1.1	Does the laboratory have secure, controlled access areas for evidence storage?	☐	☐	
7.1.2	Except as provided in Standard 7.1.3.1, are techniques performed prior to polymerase chain reaction (PCR) amplification, such as evidence examinations, DNA extractions, and PCR setup, conducted at separate times or in separate spaces from each another?	☐	☐	

7.1.3	Except as provided in Standard 7.1.3.1, 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?	☐	☐	
	a. Are the doors between rooms containing amplified DNA and other areas closed at all times except for passage?	☐	☐	
	7.1.3.1 Is a Rapid DNA instrument/System used for processing casework reference samples maintained in rooms outside of evidence examination areas or those containing amplified DNA?	☐	☐	☐
7.2	Does the laboratory have and follow written procedures for laboratory security?	☐	☐	
7.2.1	Is access to the laboratory controlled and limited in a manner that prevents access to the operational areas by unauthorized personnel?	☐	☐	
	a. Do all exterior entrance/exit points have security control that limits entry and access into the operational areas?	☐	☐	
	b. Is the distribution of all keys, combinations, and other security devices, documented and limited to the personnel designated by laboratory management?	☐	☐	

		Yes	**No**	**N/A**
7.3	Does the laboratory have and follow a documented evidence control program to ensure the integrity of physical evidence?	☐	☐	
NOTE:	*To successfully satisfy Standard 7.3, the laboratory must demonstrate compliance with all of the subcategories of Standard 7.3.*			
7.3.1	For evidence and sample identification:	☐	☐	

a. Is all evidence marked with a unique identifier on the evidence package?

Yes ☐ No ☐

b. Does the laboratory clearly define what constitutes evidence and what constitutes work product?

Yes ☐ No ☐

c. Does the laboratory have and follow a method to distinguish each sample throughout processing?

Yes ☐ No ☐

7.3.2 Does the laboratory document and maintain a chain of custody, in written, printed, or electronic format, for all evidence, to include the following: ☐ ☐

a. Signature, initials, or the electronic equivalent of each individual receiving or transferring the evidence?

Yes ☐ No ☐

b. The corresponding date for each transfer?

Yes ☐ No ☐

c. Evidentiary item(s) transferred?

Yes ☐ No ☐

7.3.3 Does the laboratory have and follow procedures for handling and preserving the evidence and work product designed to minimize loss, contamination, and/or deleterious change of evidence and work product? ☐ ☐

7.3.3.1 Does the laboratory have and follow procedures for securing evidence and work product in progress? ☐ ☐

7.3.3.2 Does the laboratory have and follow procedures for properly sealing evidence? ☐ ☐

		Yes	No	N/A
7.4	Does the laboratory have a policy on sample consumption?	☐	☐	
7.4.1	Does the laboratory retain or return a portion of the evidence sample and/or extract, where possible?	☐	☐	
7.5	Does the laboratory have and follow documented policies for the disposition of evidence?	☐	☐	

Comment

Standard 8. Validation

		Yes	No	N/A
8.1	Does the laboratory use validated methods for DNA analyses?	☐	☐	

***NOTE**: To successfully satisfy Standard 8.1, the laboratory must demonstrate compliance with all of the subcategories of Standard 8.*

		Yes	No	N/A
NOTE: *Standards 8.2 and 8.3 and all of the subcategories may be marked "N/A" if there are no validations to review since the last external audit. Ensure Standard 8.3.3 is "N/A" prior to marking all Standards of 8.3 as "N/A".*				
8.2	Have developmental validation studies preceded the use of any new methods implemented for forensic DNA analysis since the last external audit?	☐	☐	☐
8.2.1	For all validations under review: Have developmental validation studies been performed and documented to include, where applicable:	☐	☐	☐

a. Characterization of the genetic marker?	Yes	☐	No	☐	N/A	☐
b. Species specificity?	Yes	☐	No	☐	N/A	☐
c. Sensitivity studies?	Yes	☐	No	☐	N/A	☐
d. Stability studies?	Yes	☐	No	☐	N/A	☐
e. Case-type samples?	Yes	☐	No	☐	N/A	☐
f. Population studies?	Yes	☐	No	☐	N/A	☐
g. Mixture studies?	Yes	☐	No	☐	N/A	☐
h. Precision and accuracy studies?	Yes	☐	No	☐	N/A	☐
i. PCR-based studies to include?	Yes	☐	No	☐	N/A	☐

1. Reaction conditions?

   Yes ☐ No ☐

2. Assessment of differential and preferential amplification?

   Yes ☐ No ☐

3. Effects of multiplexing?

   Yes ☐ No ☐

4. Assessment of appropriate controls?

   Yes ☐ No ☐

5. Product detection studies?

   Yes ☐ No ☐

		Yes	No	N/A
8.2.2	Are peer-reviewed publication(s) of the underlying scientific principle(s) of a method available?	☐	☐	☐

		Yes	No	N/A
8.3	Except as provided in Standard 8.3.1.1, have internal validation of all manual and robotic methods been conducted by each laboratory?	☐	☐	☐
	a. Were the appropriate sample number and type to demonstrate the reliability and potential limitations of the method used?	☐	☐	☐

***NOTE**: To successfully satisfy Standard 8.1, the laboratory must demonstrate compliance with all of the subcategories of Standard 8.*

8.3.1	Have internal validation studies included, as applicable:	☐	☐	☐

1. Known and non-probative evidence samples or mock evidence samples?

   Yes ☐ No ☐ N/A ☐

2. Precision and Accuracy studies?

   Yes ☐ No ☐ N/A ☐

3. Sensitivity and stochastic studies?

   Yes ☐ No ☐ N/A ☐

4. Mixture studies?

   Yes ☐ No ☐ N/A ☐

5. Contamination assessment studies?

   Yes ☐ No ☐ N/A ☐

8.3.1.1 For multi-laboratory systems:

		Yes	No	N/A
a.	Are the summaries of all shared validation data available at each site?	☐	☐	☐
b.	Has each laboratory in a multi-laboratory system completed, documented, and maintained applicable site-specific studies:	☐	☐	☐

1. Precision studies?

   Yes ☐ No ☐ N/A ☐

2. Sensitivity studies?

   Yes ☐ No ☐ N/A ☐

3. Contamination assessment studies?

Yes ☐ No ☐ N/A ☐

8.3.2 Have quality assurance parameters and interpretation guidelines been defined pursuant to internal validation? Including, as applicable: ☐ ☐ ☐

a. Guidelines for mixture interpretation?

Yes ☐ No ☐ N/A ☐

b. Application of appropriate statistical calculations?

Yes ☐ No ☐ N/A ☐

8.3.2.1 Do mixture interpretation validation studies include: ☐ ☐ ☐

a. A range of the number of contributors?

Yes ☐ No ☐ N/A ☐

b. A range of template amounts?

Yes ☐ No ☐ N/A ☐

c. Mixture ratios expected to be interpreted in casework?

Yes ☐ No ☐ N/A ☐

8.3.3 If a laboratory has had a change in platform instrument model or typing test kit (or laboratory assembled equivalent), have internal validation studies been performed? ☐ ☐ ☐

8.3.4 Have internal validation studies been documented and summarized? ☐ ☐ ☐

a. Were internal validation studies reviewed and approved by the laboratory's technical leader prior to implementation? ☐ ☐ ☐

		Yes	**No**	**N/A**
8.4	Have newly validated DNA methods (from amplification through characterization), typing test kit, or platform instrument model been checked against an appropriate and available certified reference material (or sample made traceable to the certified reference material) prior to the implementation of the method?	☐	☐	☐
8.5	Have modified procedures been evaluated by comparison with the original procedures using similar DNA samples?	☐	☐	☐
	a. Was the evaluation documented?	☐	☐	☐
	b. Was the evaluation reviewed and approved by the technical leader prior to the implementation of the modified procedure into casework applications?	☐	☐	☐

8.6	Were Rapid DNA instruments used for modified Rapid DNA analysis on casework reference samples validated in accordance with Standard 8?	☐	☐	☐
8.7	Have NDIS approved Rapid DNA Systems undergone a performance check prior to use on casework reference samples?	☐	☐	☐

		Yes	**No**	**N/A**
8.8	Is new software or new modules of existing software and modifications to software evaluated to assess the suitability of the software for its intended use in the laboratory and to determine the necessity of validation studies or software testing?	☐	☐	☐
	a. Is the evaluation documented and does it include the determination of which studies will and will not be conducted?	☐	☐	☐
NOTE:	*Standards 8.8.1 through Standards 8.8.2 and all of the subcategories may be marked "N/A" if there are no software validations to review since the last external audit.*			
8.8.1	Is new software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations subject to developmental validation prior to implementation in forensic DNA analysis?	☐	☐	☐
	8.8.1.1 With the exception of legally protected information, are the underlying scientific principle(s) utilized by software with an impact on the analytical process, interpretation, or statistical calculations publicly available for review or published in a peer-reviewed scientific journal?	☐	☐	☐
	8.8.1.2 Do the developmental software validation studies for new software or new modules of existing software used <u>as a component of instrumentation</u> include, at a minimum:	☐	☐	☐

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

8.8.1.3 Do the developmental software validation studies for new software or new modules of existing software <u>for the analysis and/or interpretation of DNA data</u> include: ☐ ☐ ☐

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Accuracy studies (as applicable)?

Yes ☐ No ☐ N/A ☐

d. Precision studies (as applicable)?

Yes ☐ No ☐ N/A ☐

e. Sensitivity studies (as applicable)?

Yes ☐ No ☐ N/A ☐

f. Specificity studies (as applicable)?

Yes ☐ No ☐ N/A ☐

8.8.1.4 Do the developmental software validation studies for new software or new modules of existing software <u>for statistical calculations</u> include: ☐ ☐ ☐

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Accuracy studies (as applicable)?

Yes ☐ No ☐ N/A ☐

d. Precision studies (as applicable)?

Yes ☐ No ☐ N/A ☐

		Yes	No	N/A
8.8.2	Is new software or new modules of existing software that are used as a component of instrumentation, for the analysis and/or interpretation of DNA data, or for statistical calculations subject to internal validation specific to the laboratory's intended use prior to implementation in forensic DNA analysis?	☐	☐	☐

8.8.2.1 Do the internal software validation studies for new software or new modules of existing software used <u>as a component of instrumentation</u> include: ☐ ☐ ☐

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

8.8.2.2 Do the internal software validation studies for new software or new modules of existing software <u>for the analysis and/or interpretation of DNA data</u> include: ☐ ☐ ☐

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Precision and accuracy studies (as applicable)?

Yes ☐ No ☐ N/A ☐

d. Sensitivity studies (as applicable)

Yes ☐ No ☐ N/A ☐

e. Specificity studies (as applicable)?

Yes ☐ No ☐ N/A ☐

8.8.2.3 Do the internal software validation studies for new software or new modules of existing software <u>for statistical calculations</u> include: ☐ ☐ ☐

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Precision and accuracy studies (as applicable)?

Yes ☐ No ☐ N/A ☐

8.8.2.4 Does software that does not impact the analytical process, interpretation, or statistical calculations undergo, at a minimum, a functional test? ☐ ☐ ☐

		Yes	No	N/A
NOTE:	*Standards 8.8.3 and all of the subcategories may be marked "N/A" if there are no modifications to software since the last external audit.*			
8.8.3	Are any modifications to software as described in Standards 8.8.1 and 8.8.2 evaluated to determine if the modifications result in major or minor revisions to the software?	☐	☐	☐
8.8.3.1	Are any major revisions to software used <u>as a component of instrumentation</u> validated prior to implementation, to include:	☐	☐	☐

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Regression testing?

Yes ☐ No ☐

8.8.3.2	Are any major revisions to software used <u>for the analysis and/or interpretation of DNA data</u> validated prior to implementation, to include:	☐	☐	☐

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Regression testing?

Yes ☐ No ☐

d. Precision and accuracy studies (as applicable)?

Yes ☐ No ☐ N/A ☐

e. Sensitivity studies (as applicable)?

Yes ☐ No ☐ N/A ☐

f. Specificity studies (as applicable)?

Yes ☐ No ☐ N/A ☐

8.8.3.3 Are any major revisions to software used <u>for statistical calculations</u> validated prior to implementation, to include: ☐ ☐ ☐

a. Functional testing?

Yes ☐ No ☐

b. Reliability testing?

Yes ☐ No ☐

c. Regression testing?

Yes ☐ No ☐

d. Precision and accuracy studies (as applicable)?

Yes ☐ No ☐ N/A ☐

8.8.3.4 Do any minor revisions to software that does not impact the analytical process, interpretation, or statistical calculations undergo, at a minimum, a functional test? ☐ ☐ ☐

		Yes	**No**	**N/A**
8.8.4	For multi-laboratory systems:	☐	☐	☐
	a. Are the summaries of shared software validation and software testing data available at each site?	☐	☐	☐
	b. Has each laboratory in a multi-laboratory system completed, documented, and maintained applicable site-specific reliability testing?	☐	☐	☐
8.8.5	Is all software validation and testing documented and reviewed and approved by the technical leader prior to implementation?	☐	☐	☐

		Yes	No	N/A
8.9	Are developmental validation studies, internal validation studies, modified procedure evaluations, and software testing, including the documented approval of the technical leader, available for review?	☐	☐	☐

Comment

Standard 9. Analytical Procedures

		Yes	No	N/A
9.1	Does the laboratory have and follow written analytical procedures supported by the internal validations and approved by the technical leader?	☐	☐	
NOTE:	*To successfully satisfy Standard 9.1, the laboratory must demonstrate compliance with all of the subcategories of Standard 9.1.*			
9.1.1	Does the laboratory have and follow a documented standard operating procedure for each analytical method used?	☐	☐	
	a. Do the analytical procedures include the appropriate analytical controls required for DNA analysis and data interpretation?	☐	☐	

		Yes	No	N/A
9.2	Does the laboratory use reagents that are suitable for the methods employed?	☐	☐	
NOTE:	*To successfully satisfy Standard 9.2, the laboratory must demonstrate compliance with all of the subcategories of Standard 9.2.*			
9.2.1	Does the laboratory have written procedures for documenting commercial reagents and for the formulation of in-house reagents?	☐	☐	
9.2.2	Are commercial reagents labeled with:	☐	☐	☐
	a. The identity of the reagent?			

Yes ☐ No ☐

b. The expiration date as provided by the manufacturer or as determined by the laboratory?

Yes ☐ No ☐

9.2.3 Are in-house reagents labeled with: ☐ ☐ ☐

a. The identity of the reagent?

Yes ☐ No ☐

b. The date of the preparation and/or expiration?

Yes ☐ No ☐

c. The identity of the individual preparing the reagent?

Yes ☐ No ☐

		Yes	No	N/A
9.3	Does the laboratory identify critical reagents and evaluate them prior to use in casework?	☐	☐	
9.3.1	Has the laboratory identified and evaluated the following:	☐	☐	☐

a. Test kits (or systems) for performing quantification?

Yes ☐ No ☐ N/A ☐

b. Test kits (or systems) for performing amplification?

Yes ☐ No ☐ N/A ☐

9.3.2 If not tested as test kit components under Standard 9.3.1, has the laboratory identified and evaluated the following: ☐ ☐ ☐

a. Thermostable DNA polymerase?

Yes ☐ No ☐ N/A ☐

b. Primer sets?

Yes ☐ No ☐ N/A ☐

c. Allelic ladders used for genetic analysis?

Yes ☐ No ☐ N/A ☐

9.3.3 Has the laboratory identified and evaluated Rapid DNA cartridges? ☐ ☐ ☐

9.3.4 Has the laboratory identified and evaluated other laboratory defined critical reagents? ☐ ☐ ☐

		Yes	No	N/A
9.4	Except as provided in Standard 9.4.1, does the laboratory quantify or otherwise calculate the amount of human DNA in forensic samples prior to nuclear DNA amplification?	☐	☐	☐
9.4.1	If quantification of human DNA for casework reference samples is not performed, does the laboratory have a validated system demonstrated to reliably yield successful DNA amplification and typing without prior quantification?	☐	☐	☐

		Yes	No	N/A
9.5	With all analytical procedures except Rapid DNA instruments/Systems used to analyze casework reference samples pursuant to Standards 9.7 and 9.8, does the laboratory monitor the analytical procedures using appropriate controls and standards?	☐	☐	
NOTE:	*The use of Rapid DNA instruments/Systems to analyze casework reference samples is pursuant to Standards 9.7 and/or 9.8.*			
9.5.1	Are reagent blank controls associated with each extraction set being analyzed as follows:	☐	☐	
	9.5.1.1 Extracted concurrently and treated with the most sensitive conditions as the samples?	☐	☐	
	9.5.1.2 Are the reagent blanks amplified using:	☐	☐	
	a. The same typing test kit as the sample(s)? Yes ☐ No ☐			
	b. The same instrument model as the sample(s)? Yes ☐ No ☐			
	c. The same sensitivity conditions as required by the sample(s) containing the least amount of DNA? Yes ☐ No ☐			
	9.5.1.3 Are the reagent blanks typed using:	☐	☐	
	a. The same instrument model as the sample(s)? Yes ☐ No ☐			

b. The same injection conditions as the sample(s)?

Yes ☐ No ☐

c. The most sensitive volume conditions of the extraction set?

Yes ☐ No ☐

9.5.2	When quantitation is used, are standards used?	☐	☐	☐
	a. If a virtual or external standard curve is utilized, is a calibrator run concurrently with the samples?	☐	☐	☐
9.5.3	Are the positive and negative amplification controls associated with the samples being typed amplified concurrently using the same typing test kit and on the same instrument as the samples?	☐	☐	
	9.5.3.1 Except as provided in 9.5.4.1, are the positive and negative amplification controls associated with the samples typed?	☐	☐	
9.5.4	For laboratories performing sequencing, are positive and negative sequencing controls concurrently sequenced using the same typing test kit on the same instrument as the samples?	☐	☐	☐
	9.5.4.1 If the positive amplification control is not used as the positive sequencing control, does the laboratory have and follow procedures for the evaluation of the positive amplification control?	☐	☐	☐
9.5.5	Are allelic ladders and internal size standards used for PCR-based systems?	☐	☐	☐

		Yes	**No**	**N/A**
9.6	Does the laboratory have and follow written guidelines for the interpretation of data that are based on and supported by internal validation studies?	☐	☐	
	Does the laboratory:			
9.6.1	Have criteria to evaluate quantitation standards, internal size standards, allelic ladders, and analytical controls?	☐	☐	
9.6.2	Have criteria for the interpretation of non-allelic peaks/signal?	☐	☐	☐
9.6.3	Have criteria for the interpretation of allelic peaks/signal?	☐	☐	☐
9.6.4	Define the thresholds used for interpretation?	☐	☐	
	As appropriate to the interpretation model utilized, does the laboratory establish the following thresholds:			
	9.6.4.1 Analytical Threshold?	☐	☐	☐

	9.6.4.2 Stochastic Threshold?	☐	☐	☐
9.6.5	Define criteria for uninterpretable data?	☐	☐	
9.6.6	Have and follow procedures for mixture interpretation to include the following:	☐	☐	☐
	a. Assessment of the number of contributors?	☐	☐	☐
	b. Separation of contributors (e.g. major versus minor)?	☐	☐	☐
	c. Criteria for deducing potential contributors?	☐	☐	☐

		Yes	No	N/A
9.7	For modified Rapid DNA analysis, does the laboratory:	☐	☐	☐
9.7.1	Have and follow written guidelines for the manual interpretation of data?	☐	☐	☐
	9.7.1.1 Does the laboratory verify that the internal size standard and allelic ladder results meet the laboratory's interpretation guidelines?	☐	☐	☐
9.7.2	Have and follow procedures to address the use of positive sample controls and negative sample controls?	☐	☐	☐

		Yes	No	N/A
9.8	For Rapid DNA analysis, does the laboratory have and follow procedures to address the use of positive sample controls and negative sample controls?	☐	☐	☐
9.8.1	Does the Rapid DNA cartridge include an internal size standard with each sample?	☐	☐	☐

		Yes	No	N/A
9.9	Does the laboratory define criteria for the formulation of inclusionary, exclusionary, and inconclusive conclusions?	☐	☐	

		Yes	No	N/A
9.10	Does the laboratory have and follow procedures for statistical calculations and the reporting of results and conclusions that address the following:	☐	☐	
9.10.1	The assumptions that can be made when formulating conclusions?	☐	☐	
9.10.2	Performing statistical analysis in support of any inclusion that is determined to be relevant in the context of the case?	☐	☐	
9.10.3	Documenting of the genetic loci and assumptions used for statistical calculations, at a minimum, in the case	☐	☐	

notes?

9.10.4	Not using uninterpretable data in statistical calculations?	☐	☐	
9.10.5	The approaches to performing statistical calculations?	☐	☐	
	9.10.5.1 For autosomal STR typing, does the procedure address:	☐	☐	☐

a. Homozygous and heterozygous typing results?

Yes ☐ No ☐

b. Multiple locus profiles?

Yes ☐ No ☐

c. Mixtures?

Yes ☐ No ☐

d. Minimum allele frequencies?

Yes ☐ No ☐

e. Where appropriate, biological relationships?

Yes ☐ No ☐ N/A ☐

	9.10.5.2 For lineage marker testing, does the procedure address parameters specific for the applicable lineage marker statistical calculations?	☐	☐	☐
	9.10.5.3 Does the laboratory use loci that are shown to be in Hardy-Weinberg equilibrium and statistically unlinked, when using the product rule for statistical calculations?	☐	☐	☐
9.10.6	The source of the population database(s) used in any statistical calculations?	☐	☐	
9.10.7	The criteria for source attribution declarations, when applicable?	☐	☐	☐

		Yes	**No**	**N/A**
9.11	Does the laboratory have and follow a procedure to address the reinterpretation of legacy data?	☐	☐	

		Yes	**No**	**N/A**
9.12	Does the laboratory have and follow a procedure for the detection and control of contamination?	☐	☐	
9.12.1	Does the laboratory have and follow procedures for cleaning and decontaminating facilities and equipment?	☐	☐	

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?	☐	☐	
NOTE:	*To successfully satisfy Standard 10.1, the laboratory must demonstrate compliance with all of the subcategories of Standard 10.*			
10.2	Does the laboratory identify critical equipment or instruments and have and follow a program to ensure they are maintained?	☐	☐	
10.2.1	At a minimum, are the following identified as critical:	☐	☐	
	10.2.1.1 Handheld mechanical pipettes?	☐	☐	☐
	10.2.1.2 A thermometer traceable to national or international standard(s)?	☐	☐	☐
	10.2.1.3 Incubator/Heat block, used in analytical procedures?	☐	☐	☐
	10.2.1.4 Robotic systems?	☐	☐	☐
	10.2.1.5 Thermal cycler, including quantitative-PCR?	☐	☐	☐
	10.2.1.6 Thermal cycler temperature verification system?	☐	☐	☐
	10.2.1.7 Electrophoresis detection systems, including Genetic Analyzers?	☐	☐	☐
	10.2.1.8 Rapid DNA instruments/Systems?	☐	☐	☐
	10.2.1.9 Any additional instruments or equipment that produce DNA typing results?	☐	☐	☐
10.3	Does the laboratory have procedures for conducting performance checks and evaluating results of critical equipment or instruments?	☐	☐	
10.3.1	Does the laboratory performance check new critical equipment or instruments, not requiring validation, before use in casework analysis?	☐	☐	☐

	a. Does the laboratory performance check each additional critical instrument, of the same instrument model validated for use in the laboratory, prior to use in casework analysis?	☐	☐	☐
NOTE:	*Equipment or instruments that require validation will be assessed under Standard 8.*			
10.3.2	Are the following critical equipment or instruments performance-checked at least annually:	☐	☐	
	10.3.2.1 Handheld mechanical pipettes?	☐	☐	☐
	10.3.2.2 Incubator/Heat block, used in analytical procedures?	☐	☐	☐
	10.3.2.3 Robotic systems?	☐	☐	☐
	10.3.2.4 Thermal cycler, including quantitative-PCR?	☐	☐	☐
	10.3.2.5 Thermal cycler temperature verification system?	☐	☐	☐
	10.3.2.6 Electrophoresis detection systems, including Genetic Analyzers?	☐	☐	☐
	10.3.2.7 Any additional instruments or equipment that produce DNA typing results?	☐	☐	☐
	10.3.2.8 Other critical equipment or instruments defined by the laboratory as needing annual performance check?	☐	☐	☐
10.3.3	Are the following critical equipment or instruments performance-checked after repair or service:	☐	☐	
	10.3.3.1 Robotic systems?	☐	☐	☐
	10.3.3.2 Thermal cycler, including quantitative-PCR?	☐	☐	☐
	10.3.3.3 Electrophoresis detection systems, including Genetic Analyzers?	☐	☐	☐
	10.3.3.4 Rapid DNA instruments/Systems?	☐	☐	☐
	10.3.3.5 Any additional instruments or equipment that produce DNA typing results?	☐	☐	☐
	10.3.3.6 Other critical equipment or instruments defined by the laboratory as needing performance check after repair or service?	☐	☐	☐
10.3.4	Are Rapid DNA instruments/Systems performance-checked upon installation?	☐	☐	☐

10.3.5	Are Rapid DNA instruments/Systems performance-checked if the Rapid DNA instrument remains idle longer than the period recommended in the instrument specifications or as established by the laboratory?	☐	☐	☐

		Yes	No	N/A
10.4	Does the laboratory maintain documentation of maintenance, service, repair, and performance checks?	☐	☐	

Comment

Standard 11. Reports

		Yes	No	N/A
11.1	Does the laboratory have and follow written procedures for taking and maintaining casework notes to support the conclusions drawn in laboratory reports?	☐	☐	
	a. Does the laboratory maintain all analytical documentation generated by technicians and/or analysts related to case analyses?	☐	☐	
	b. Does the laboratory retain, in written, printed, or electronic format, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual can evaluate what was done and interpret the data?	☐	☐	

		Yes	No	N/A
11.2	Do casework reports include the following elements:	☐	☐	
	11.2.1 Case identifier?	☐	☐	
	11.2.2 Description of evidence examined and identification of samples tested?	☐	☐	
	11.2.3 Technology used?	☐	☐	
	11.2.4 Loci, sequence region, or amplification system(s)?	☐	☐	
	11.2.5 Results and/or conclusions for each forensic sample tested?	☐	☐	
	11.2.6 A quantitative or qualitative interpretative statement to support all inclusions?	☐	☐	
	11.2.7 Date of the report?	☐	☐	
	11.2.8 Disposition of evidence?	☐	☐	

11.2.9	Signature and title, or equivalent identification, of the person accepting responsibility for the content of the report?	☐	☐	

		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?	☐	☐	
NOTE:	*To successfully satisfy Standard 11.3, the laboratory must demonstrate compliance with all of the subcategories of Standard 11.3.*			
11.3.1	Does the laboratory have and follow policies and/or procedures to ensure the privacy of reports, case files, DNA records, and databases?	☐	☐	
11.3.2	Does the laboratory have and follow policies and/or procedures for the release of reports, case files, DNA records, and databases in accordance with applicable state or federal law?	☐	☐	
11.3.3	Does the laboratory have and follow policies and/or procedures for the release of personally identifiable information in accordance with applicable state and federal law?	☐	☐	

Comment

Standard 12. Review

		Yes	No	N/A
12.1	Does the laboratory have and follow a procedure to conduct and document technical and administrative reviews of all case files and reports to ensure that conclusions and supporting data are reasonable and within the constraints of scientific knowledge?	☐	☐	
12.1.1	Are all technical reviews conducted by an analyst or technical reviewer that is qualified in the method, technology, typing test kit, platform, and interpretation software being reviewed?	☐	☐	

		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:	☐	☐	
	12.2.1 A review of all case notes, all worksheets, and the electronic data (or printouts of such data) supporting the results and/or conclusions?	☐	☐	
	12.2.2 A review of all analytical controls, internal size standards, and allelic ladders to verify that the expected results were obtained, except when using an NDIS approved Rapid DNA System on casework reference samples?	☐	☐	
	12.2.3 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images), except when using an NDIS approved Rapid DNA System on casework reference samples?	☐	☐	
	12.2.4 A review of all data to verify conclusions (i.e., inclusions, exclusions, inconclusive) are in compliance with laboratory guidelines?	☐	☐	
	12.2.5 A review of statistical analysis, if applicable?	☐	☐	
	12.2.6 A review of the final report's content to verify compliance with Standard 11.2 and that the results and/or conclusions are supported by the data?	☐	☐	
	12.2.7 Verification that all profiles entered into CODIS are eligible, have the correct DNA types, and correct specimen category?	☐	☐	☐
	12.2.7.1 Prior to upload to SDIS, entry of a DNA profile into a searchable category of SDIS, or search of SDIS, were the following criteria verified by two concordant assessments by a qualified analyst or technical reviewer:	☐	☐	☐
	a. Eligibility for CODIS? Yes ☐ No ☐			
	b. Correct DNA types? Yes ☐ No ☐			
	c. Appropriate specimen category? Yes ☐ No ☐			

		Yes	No	N/A
12.3	Does the laboratory document the completion of the administrative review and does it 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 accuracy and compliance with Standard 11.2?	☐	☐	
12.3.2	A review of the chain of custody and disposition of evidence?	☐	☐	

		Yes	No	N/A
12.4	Does the laboratory have and follow policy and/or procedure to address unresolved discrepant conclusions between analysts and reviewer(s)?	☐	☐	

NOTE: *Standard 12.5 shall be marked "N/A" for non-NDIS participating laboratories.*

		Yes	No	N/A
12.5	Does the laboratory have and follow a documented procedure for the verification and resolution of database matches?	☐	☐	☐

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 semi-annual external proficiency testing?	☐	☐	
13.1.1	Are analysts proficiency tested in each technology at least once per calendar year?	☐	☐	
13.1.1.1	Has the typing of all CODIS core loci or CODIS core sequence ranges been attempted for each technology performed at least once per calendar year?	☐	☐	
13.1.2	Are analysts proficiency tested in each typing test kit at least once per calendar year?	☐	☐	

	13.1.2.1 Are analysts that are qualified to perform modified Rapid DNA analysis externally proficiency tested on the interpretation of data generated by each Rapid DNA instrument model for each PCR STR typing test kit at least once per calendar year?	☐	☐	☐
13.1.3	Are individuals that perform analytical procedures on forensic samples or casework reference samples proficiency tested on at least one method in each methodology at least once per calendar year?	☐	☐	
13.1.4	Except as provided in Standard 13.1.4.1, is each external proficiency test assigned to and completed by one analyst?	☐	☐	
	13.1.4.1 If technicians and/or a team approach is used for casework examinations, has each analyst been assigned a proficiency test to complete the interpretation and report the results?	☐	☐	☐
NOTE:	*Standard 13.1.5 and the subcategories may be marked "N/A" for a laboratory that does not have individuals that solely conduct technical reviews.*			
13.1.5	Are individuals whose sole responsibility is technical review proficiency tested in the technical review of each technology and typing test kit at least once per calendar year?	☐	☐	☐
	13.1.5.1 Does the proficiency testing cover the CODIS core loci or CODIS core sequence ranges attempted for each technology at least once per calendar year?	☐	☐	☐
	13.1.5.2 Are technical reviewers qualified to review modified Rapid DNA analysis externally proficiency tested on the technical review of data generated by a Rapid DNA instrument model for each PCR STR typing test kit at least once per year?	☐	☐	☐
	13.1.5.3 If the technical reviewer is a contract employee conducting technical review for an NDIS participating laboratory, is the proficiency testing administered by an NDIS participating laboratory and reviewed and approved by the technical leader of the NDIS participating laboratory for which the technical reviewer is conducting reviews?	☐	☐	☐
13.1.6	Have newly qualified individuals undergone semi-annual external proficiency testing within eight months of the date of their authorization?	☐	☐	☐

		Yes	No	N/A
13.2	Does the laboratory use an external proficiency test provider that is accredited to the current applicable standard of the International Organization for Standardization and is the applicable test included on the proficiency test provider's scope of accreditation?	☐	☐	
	a. Is the external proficiency testing an open proficiency testing program and is it submitted to the proficiency testing provider in order to be included in the provider's published external summary report?	☐	☐	
13.3	For purposes of tracking compliance with the proficiency testing requirements, does the laboratory define and consistently use the date that the proficiency test is performed as the received date, assigned date, submitted date, or the due date?	☐	☐	

		Yes	No	N/A
13.4	Are the following records maintained by the laboratory for proficiency tests:	☐	☐	
	13.4.1 The test set identifier?	☐	☐	
	13.4.2 Identity of the analyst, and other participants, if applicable?	☐	☐	
	13.4.3 Date of analysis and completion?	☐	☐	
	13.4.4 Copies of all data and notes supporting the conclusions?	☐	☐	
	13.4.5 The proficiency test results?	☐	☐	
	13.4.6 Any discrepancies noted?	☐	☐	
	13.4.7 Corrective actions taken?	☐	☐	

		Yes	No	N/A
13.5	Does the laboratory evaluate proficiency test results? At a minimum, are the following criteria included in the evaluation of proficiency test results:	☐	☐	
	13.5.1 Are all reported genotypes, phenotypes, and/or sequences correct or incorrect according to consensus results or are compliant with the laboratory's interpretation guidelines?	☐	☐	
	13.5.2 Are inclusions and exclusions correct or incorrect?	☐	☐	

13.5.3 Are all reported uninterpretable results and/or inconclusive conclusions compliant with written laboratory guidelines?	☐	☐	
13.5.3.1 Has the technical leader reviewed any inconclusive conclusion for compliance with laboratory guidelines?	☐	☐	☐
13.5.4 Have all final reports been graded as satisfactory or unsatisfactory?	☐	☐	
13.5.4.1 Have all discrepancies/errors and subsequent corrective actions, as applicable, been documented?	☐	☐	☐

		Yes	No	N/A
13.6	Have the following been informed of the results of the proficiency test:	☐	☐	
	13.6.1 The proficiency test participant(s)?	☐	☐	
	13.6.2 The technical leader?	☐	☐	
	13.6.3 The casework CODIS administrator in the event of non-administrative discrepancies that affect the typing results and/or conclusions?	☐	☐	☐

Comment

Standard 14. Corrective Action

		Yes	No	N/A
14.1	Does the laboratory have and follow a policy and/or procedure to address nonconformities detected in casework analysis, proficiency tests, testimony, and audits?	☐	☐	
	a. Does the laboratory policy and/or procedure define when a nonconformity requires documentation and/or a corrective action plan?	☐	☐	
14.1.1	Are corrective action plans documented?	☐	☐	☐

		Yes	No	N/A
14.2	Does the laboratory's documented corrective action plan include the following: a. The identification (when possible) of the cause(s) of the nonconformity? Yes ☐ No ☐ N/A ☐ b. The corrective actions taken with time frames (where applicable)? Yes ☐ No ☐ N/A ☐ c. Preventative measures taken (where applicable) to minimize its reoccurrence? Yes ☐ No ☐ N/A ☐	☐	☐	☐
14.2.1	Are corrective action plans approved by the technical leader prior to implementation?	☐	☐	☐
14.2.2	Is the casework CODIS administrator notified when the nonconformity impacts DNA records entered into CODIS?	☐	☐	☐

Comment

Standard 15. Audits

		Yes	No	N/A
15.1	Has the laboratory been audited annually in accordance with the Quality Assurance Standards for Forensic DNA Testing Laboratories?	☐	☐	☐
	a. Have the annual audits occurred every calendar year at least six months and no more than 18 months apart?	☐	☐	☐
15.2	Has an external audit been conducted at least once every two years?	☐	☐	☐
	a. Was the external audit conducted by one or more auditor(s) who has successfully completed the FBI's DNA auditor training course from a second agency(ies)?	☐	☐	☐
	b. Was at least one auditor a current or former analyst previously qualified in the laboratory's current DNA technologies and platforms?	☐	☐	☐

NOTE:	*Auditor(s) and their applicable qualifications will be documented in Appendix C.*			
15.2.1	Has the laboratory maintained audit documentation of those analysts, technical reviewers, casework CODIS administrator(s), and technical leader(s) that have had their education, experience, and training qualifications evaluated and approved during two successive, separate external audits?	☐	☐	☐
NOTE:	*Approval of an individual's education, experience, and training qualifications shall be documented in Appendix D.*			
	15.2.1.1 As of [*the effective date of this revision*], has the laboratory maintained audit documentation of those individuals that have had their additional qualification in an additional technology(ies), typing test kit(s), or platform(s) evaluated and approved during one external audit?	☐	☐	☐
15.2.2	Has the laboratory maintained the audit documentation for validation studies previously evaluated and approved during one external audit?	☐	☐	☐
NOTE:	*Approved validation studies shall be documented in Appendix E.*			
15.3	For internal audits, was the internal audit conducted by an audit team with at least one auditor(s) who has successfully completed the FBI's DNA auditor training course?	☐	☐	☐
	a. Was at least one audit team member a current or former analyst previously qualified in the laboratory's current DNA technologies and platforms?	☐	☐	☐
NOTE:	*Auditor team member(s) and their applicable qualifications will be documented in Appendix C.*			
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?	☐	☐	
15.5	Have internal and external DNA audit documentation and, if applicable, corrective action(s) been reviewed by the technical leader to ensure that findings, if any, were appropriately addressed and has the review been documented?	☐	☐	☐
15.5.1	Have internal and external audit documentation, and if applicable, corrective action(s) been provided to the casework CODIS administrator?	☐	☐	☐

15.5.2	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 document or report?	☐	☐	☐
15.6	Are previous internal and external audit documents retained and available for inspection during subsequent audits?	☐	☐	☐

Comments

Standard 16. Professional Development

		Yes	No	N/A
16.1	Does the laboratory have and follow a documented program to ensure that technical qualifications are maintained through participation in continuing education?	☐	☐	
16.1.1	Does the technical leader, casework CODIS administrator, and each analyst and technical reviewer stay abreast of topics relevant to the field of forensic DNA analysis by having documented attendance at seminars, courses, professional meetings, or documented lectures or classes in relevant subject areas for a minimum of eight cumulative hours each calendar year?	☐	☐	
	16.1.1.1 Have continuing education hours been documented?	☐	☐	
NOTE:	*Attendance at regional, national, or international, conferences with content including topics relevant to the field of forensic DNA analysis shall be deemed to provide a minimum of eight hours of continuing education.*			
	16.1.1.2 Has the laboratory maintained documentation of attendance through a mechanism such as certificates, attendance lists, or travel documentation?	☐	☐	
	16.1.1.3 With the exception of a regional, national, or international conference, has the laboratory maintained documentation of content through a mechanism such as agenda/syllabus, record of presentation content, or curriculum vitae of the presenter?	☐	☐	☐

	16.1.1.4 Has continuing education based on multimedia or internet delivery received approval of the technical leader?	☐	☐	☐
16.1.2	Does the laboratory have and follow a program approved by the technical leader for the annual review of scientific literature that documents the analysts' ongoing reading of scientific literature?	☐	☐	
	16.1.2.1 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?	☐	☐	

		Yes	**No**	**N/A**
16.2	Does the laboratory have and follow a program that documents the annual review of the testimony of each analyst?	☐	☐	
16.2.1	Does this program define elements and mechanisms for testimony review?	☐	☐	
16.2.2	Is the testimony review documented and provided to the testifying individual?	☐	☐	☐
	16.2.2.1 Are any deficiencies and subsequent corrective actions, as applicable, documented?	☐	☐	☐

Comment

STANDARD 17. Outsourcing Ownership

		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?	☐	☐	☐

NOTE: *For a vendor laboratory, Standards 17.1.1, 17.2, 17.2.2, and Standards 17.3 and 17.4 and their subcategories shall be marked "N/A.".*

NOTE: *For an NDIS participating laboratory, if a contract for outsourcing is in place or outsourcing is occurring without a contractual agreement, Standard 17 must be assessed even if no samples were outsourced.*

NOTE: *For an NDIS participating laboratory, Standard 17 may be marked "N/A" if the NDIS participating laboratory has not outsourced any DNA-related services for the purposes of taking ownership in the scope of the audit.*

17.1.1 Has the NDIS participating laboratory that outsources to a vendor laboratory acquired the following documentation from the vendor laboratory, and has this documentation been reviewed by the NDIS participating laboratory's technical leader for: ☐ ☐ ☐

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 and 17.2.2, since the laboratory's last external audit, did the NDIS participating laboratory's technical leader approve the technical specifications of the outsourcing agreement before it was awarded? ☐ ☐ ☐

17.2.1 For a vendor laboratory that is performing forensic DNA analysis on behalf of a law enforcement agency or other entity for the purposes of ownership by an NDIS participating laboratory, was documented approval obtained by the vendor laboratory from the appropriate NDIS participating laboratory's technical leader prior to the initiation of analysis? ☐ ☐ ☐

17.2.2 For the rare instances where the NDIS participating laboratory is requested to take ownership and no outsourcing agreement exists between either the law enforcement agency, the vendor laboratory or that NDIS participating laboratory, prior to acceptance of ownership of product(s) of forensic DNA analyses from the vendor laboratory has the following been documented by the requested NDIS participating laboratory's technical leader: ☐ ☐ ☐

	17.2.2.1 Approval of the casework CODIS administrator and written permission from the NDIS Custodian for any scenario that involves CODIS entry or searching?	☐	☐	☐
	17.2.2.2 Approval of the technical specifications of testing?	☐	☐	☐
	17.2.2.3 Review of the documentation of an on-site visit that has occurred within 18 months of the conducted analysis or conduct an on-site visit of the vendor laboratory within 18 months of the conducted analysis?	☐	☐	☐
		Yes	**No**	**N/A**
17.3	Does the NDIS participating laboratory have and follow a procedure to verify the integrity of the DNA data received for the purposes of taking ownership of DNA data from a vendor laboratory?	☐	☐	☐
17.3.1	Prior to the search of DNA data in SDIS, did an analyst, casework CODIS administrator, or technical reviewer employed by an NDIS participating laboratory review the DNA data to verify specimen eligibility and the correct specimen category for entry into CODIS?	☐	☐	☐
17.3.2	Prior to the upload of DNA data generated by the vendor laboratory to SDIS or the reporting of search results, did an NDIS participating laboratory perform an ownership review of the vendor laboratory's data?	☐	☐	☐
	a. Was the ownership review performed by an analyst or technical reviewer employed by an NDIS participating laboratory who is qualified in the technology, platform, and typing test kit used to generate the data and who participates in an NDIS laboratory's proficiency testing program?	☐	☐	☐
	17.3.2.1 If the proficiency testing is administered by another NDIS participating laboratory, has the participation in an NDIS participating laboratory's proficiency testing program been reviewed and approved by the technical leader of the NDIS participating laboratory for which the reviewer is conducting ownership reviews?	☐	☐	☐
17.3.3	Except as provided in Standard 17.3.4, does the ownership review include the following elements:	☐	☐	☐

	17.3.3.1 A review of all DNA types of which the NDIS participating laboratory will take ownership to verify that they are supported by the raw and/or analyzed data (electropherograms or images)?	☐	☐	☐
	17.3.3.2 A review of all associated analytical controls, internal size standards and allelic ladders to verify that the expected results were obtained?	☐	☐	☐
	17.3.3.3 A review of the final report (if provided) to verify that the results/conclusions are supported by the data?	☐	☐	☐
	17.3.3.4 For samples to be entered into CODIS, verification of the DNA types, eligibility, and the correct specimen category?	☐	☐	☐
	17.3.3.4.1 Is verification of eligibility performed by a current CODIS User?	☐	☐	☐
17.3.4	For an NDIS participating laboratory that outsources to a vendor laboratory performing Rapid DNA analysis on casework reference samples using an NDIS approved Rapid DNA System, does the ownership review for data generated by the Rapid DNA System include:	☐	☐	☐
	17.3.4.1 A review of the final report (if provided) to verify that the results/conclusions are supported by the Rapid DNA System data?	☐	☐	☐
	17.3.4.2 For samples to be entered into CODIS, verification of the eligibility and the correct specimen category?	☐	☐	☐
	17.3.4.2.1 Is verification of eligibility performed by a current CODIS User?	☐	☐	☐
	17.3.4.3 A review of the data associated with applicable Rapid DNA System performance checks?	☐	☐	☐

		Yes	**No**	**N/A**
17.4	Does the NDIS participating laboratory or multi-laboratory system outsourcing DNA sample(s) to a vendor laboratory or accepting ownership of DNA data from a vendor laboratory have and follow a procedure to perform an on-site visit(s) of the vendor laboratory?	☐	☐	☐
NOTE:	*An on-site visit is not required when only technical review services are being provided.*			
	Does the procedure to perform an on-site visit include, at a minimum:			

17.4.1	A documented initial on-site visit, to assess the vendor laboratory's ability to perform analysis on outsourced casework, prior to the vendor laboratory's beginning of casework analysis for the NDIS laboratory?	☐	☐	☐
17.4.1.1	Has the on-site visit been performed by the technical leader or designated employee of an NDIS participating laboratory who is a qualified or previously qualified analyst in the technology, platform and typing test kit used to generate the DNA data or has an on-site visit coordinated by a designated FBI employee been evaluated and approved by the NDIS participating laboratory's technical leader?	☐	☐	☐
17.4.2	An annual on-site visit if the NDIS participating laboratory's outsourcing agreement extends beyond one year?	☐	☐	☐
a.	Did an annual on-site visit occur every calendar year, with each visit at least six months but no more than 18 months apart?	☐	☐	☐
17.4.2.1	If an on-site visit conducted by another NDIS participating laboratory using the same technology, platform and typing test kit used to generate the DNA data or coordinated by a designated FBI employee was accepted, did the technical leader of the NDIS participating laboratory document the review and approval of that on-site visit?	☐	☐	☐

Comments

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:

Responses:

Appendix B: Contingency Plan Notification Form

To be completed by the NDIS participating laboratory in the event of:

1. A vacancy in the technical leader position when there is no qualified individual available to serve as the technical leader.
2. The number of qualified analysts falls below two full-time employees who are qualified analysts.

This form shall be used to document various actions relating to the laboratory's contingency plan. In accordance with the FBI Quality Assurance Standards and the NDIS Operational Procedures Manual, the FBI's NDIS Custodian shall be notified of such vacancy within 5 days and provided with the laboratory's contingency plan within 14 days of the vacancy.

Date technical leader position vacated or number of qualified analysts fell below two full-time employees:	
Date NDIS Custodian and, if applicable, State CODIS Administrator Notified: (must be within 5 days of the vacancy)	
Date contingency plan submitted to the FBI: (must be within 14 days of the vacancy)	
Date FBI approval received:	

Contingency plan attached:

FBI conditions for approval attached, if applicable:

Date new casework/database analysis initiated:

Laboratory:

Signed by: _____
(Name and Signature of Person Completing Form)

Date: _____

Appendix C – Audit Team Self-Verification for QAS Audits

To be completed by each auditor/audit team member who will be conducting a QAS audit and/or completing the QAS Audit Document.
For external audits, return to the laboratory prior to the scheduled audit date.
For internal audits, maintain in the laboratory's files.

Name: Click here to enter name.
Employer: Click here to enter employer.
Title or Position: Click here to enter title or position.

Qualifications:

A. Completed FBI DNA Auditor Course: ☐Yes ☐No
   If yes: *(Required for all external auditors)*
   Year (If multiple, list at least the most recent.): Click here to enter year of completion.

B. Current or Previously Qualified DNA Analyst: ☐Yes ☐No
   If yes:
   1. Was the qualification as a Casework and/or Database Analyst?
      Enter the qualifying laboratory(ies).
      (If multiple, list at least the most recent for each applicable category.)
      ☐ Casework: Click here to enter qualifying laboratory.
      ☐ Database: Click here to enter qualifying laboratory.
   2. Technologies Currently or Previously Qualified In (e.g., STR, mtDNA):
      Click here to list technologies.
   3. Platforms Currently or Previously Qualified In (e.g., Gel based, CE):
      Click here to list platforms.

I verify that:

The information contained above is correct; and
I have read the *Instructions to Audit Team* contained in the applicable Audit Document; and
For External Audits, I understand the requirements of Standard 15.2 and
I have no conflicts of interest with the laboratory being audited.

Signed By _____ **Date** _____

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

During the External Audit of Click here to enter Laboratory

Dates of Audit: Click here to enter start date. to Click here to enter end date.

To be completed by the audit team. In accordance with Standards 15.2.1 and 15.2.1.1, this form shall be used to document the evaluation and approval of analysts, technical reviewers, casework CODIS administrators and technical leaders during an external audit. **Such personnel shall be assessed in accordance with the applicable Quality Assurance Standards for Forensic DNA Testing Laboratories (QAS)[1] in effect at the time of their hire/appointment or qualification[2].** Analysts, technical reviewers, casework CODIS administrators and technical leaders who have previously undergone two successive external audit reviews in his/her current role and those reviews have been captured in the corresponding external audit documents do not need to be continuously captured in Appendix D.

Section 1 is for documenting personnel who are receiving the **first** external audit approval of their education, experience, and the initial training qualifications in this external audit.
Section 2 is for documenting personnel who are receiving the **second successive** external audit approval of their education, experience, and the initial training qualifications in this external audit.
Section 3 is for documenting personnel whose **additional training** in new technologies, typing test kits, and/or platforms is receiving external audit approval in this external audit.

Section 1. The following personnel have been evaluated and approved for the first time as meeting the education, experience, and initial training qualifications required under QAS Standard 5.1:

Analysts/Technical Reviewers[3]	Casework CODIS Administrator	Technical Leader

[1] Applicable Quality Assurance Standards for Forensic DNA Testing Laboratories may include those that took effect in 2004, 2009 2011, and 2019.
[2] As defined by the laboratory in accordance with Standard 4.2.
[3] For individuals whose initial training qualification in the laboratory is for Technical Review only (i.e., is not currently or previously qualified as an analyst in the laboratory for which they are performing technical reviews), indicate these individuals as "TR only" in the table.

Section 2. The following personnel have been previously evaluated once in their current role and are receiving the second successive external audit approval of their education, experience, and initial training qualifications required under QAS Standard 5.1:

Analysts/Technical Reviewers[3]	Casework CODIS Administrator	Technical Leader

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Section 3. The training of Analyst(s)/Technical Reviewer(s) in additional technologies, typing test kits, platforms, and interpretation software for the following personnel have been evaluated and are receiving external audit approval required under QAS Standards 6.5 through 6.6: [please include the technology, typing test kit, or platform]

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**. Modified procedure evaluations and software testing reviewed during the audit will also be listed below.

Validations reviewed during an external audit but not approved in their entirety may be listed in this Appendix with a notation of the study(ies) requiring additional review and approval in order for the validation to be approved.

To be completed by the external audit team:

Were new developmental and/or internal validations evaluated during this audit?

Yes ☐ No ☐

List of validations approved during this audit:

List of modified procedure evaluations reviewed during this audit:

List of software testing reviewed during this audit: