NATIONAL EMERGENCY AUDIT ADDENDUM

FOR THE

FBI QUALITY ASSURANCE STANDARDS

FOR

FORENSIC DNA TESTING

AND

DNA DATABASING LABORATORIES

IN ACCORDANCE WITH

THE QUALITY ASSURANCE STANDARDS

FOR

FORENSIC DNA TESTING LABORATORIES

AND

DNA DATABASING LABORATORIES

EFFECTIVE 07/01/2020

An Audit of: _____

Address of Laboratory: _____

Dates of Audit: _____

Date Range of National, State and/or Local Emergency Declaration: _____

NATIONAL EMERGENCY QAS AUDIT ADDENDUM

INTRODUCTION

As a result of the "national emergency" declared by the President in response to the coronavirus (COVID-19) pandemic (https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/) and other state/local emergency declarations, NDIS participating laboratories may be suspending or reducing operations in the coming weeks. Consequently, through no negligence or inaction on their part, laboratories and their personnel may miss scheduled audits, proficiency due dates, or other required actions and be unable to comply with the required time frames in the Quality Assurance Standards.

While not abdicating the responsibility to ensure the quality of the data contributed to the National DNA Index System, the Federal Bureau of Investigation is providing special relief relating to the FBI Director's Quality Assurance Standards for Forensic DNA Testing and DNA Databasing Laboratories (QAS) for NDIS Participating Laboratories, and Private Laboratories under contract to NDIS Participating Laboratories, in response to the COVID-19 pandemic.

The FBI expects all laboratories to make their best efforts to comply with the QAS; however, laboratories, who through no fault or inaction on their part and as a result of the COVID-19 pandemic, are unable to comply with certain time sensitive QAS requirements, will be eligible for this special relief. This Addendum provides guidance for maintaining quality when strict adherence to the standards as a result of the national emergency is not feasible and includes alternative compliance strategies and/or documentation needed to demonstrate a laboratory's best efforts to comply with the standards.

Instructions to Audit Team

This Addendum will be completed for any laboratory that had operations impacted by the national emergency declaration or state or local emergency declarations in response to the coronavirus (COVID-19) pandemic of 2020, that resulted in a laboratory suspending or reducing operations and therefore through no negligence or inaction on their part, were unable to comply with the time sensitive requirements of the QAS. This Addendum will supplement the 2020 Audit Document used with an audit scope containing time impacted by the national emergency and will be retained with the laboratory's Audit Documentation.

If a laboratory does not meet a standard in the 2020 Audit Document, but complies with the National Emergency Addendum version of the standard, then the corresponding standard in the 2020 Audit Document will be marked "N/A" (if available) or "Yes" with a comment to refer to the National Emergency Addendum. If applicable, a standard in the 2020 Audit Document that requires compliance with all substandards may be also marked yes if compliance with the National Emergency Addendum version of the standard is demonstrated. Any findings noted in this addendum will be marked "No" in the 2020 Audit Document and in the National Emergency Addendum and will be detailed and summarized by the auditor in Appendix A of the 2020 Audit Document.

As in the 2020 Audit Document, the rating system for assessing the laboratory with respect to each standard contains the choices of "Yes," "No" or "Not Applicable (N/A)." To supplement the QAS Guidance Document, guidance sections follow standards, as appropriate, and serve to clarify the interpretation necessary for compliance. A comment section is also provided following the guidance areas, affording auditors the opportunity to reference information that may have value in the audit process (such as listing the reason for a "No" or "N/A"). 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.

Standard 1. Scope

This NATIONAL EMERGENCY AUDIT ADDENDUM will be completed for audits to the FBI Director's Quality Assurance Standards for Forensic DNA Testing (FOR) and DNA Databasing (DB) Laboratories for internal and external audits that include the scope of time of the national emergency declared by the President in response to the coronavirus (COVID-19) pandemic of 2020. This document will be used to capture the assessment of laboratories that required the special relief provided by the FBI in response to the National Emergency of 2020.

Standard 2. Definitions

As used in this Audit Document Addendum, the following terms shall have the meanings specified:

National Emergency is the documented time period from March 1, 2020 until TBD, or an equivalent time as defined by a documented state or local emergency declaration, that results in suspension or reduction of laboratory operations and therefore through no negligence or inaction on their part prohibits a laboratory from complying with the required time frames contained in these standards.

Full-time employee will include individuals that maintain employment status with the agency, even if placed in a furloughed, non-reporting, limited reporting, or part-time status as a result of a suspension or reduction of laboratory operations during the national emergency, but would otherwise be considered a full-time employee.

Standard 3. Quality Assurance Program

		Yes	No	N/A
3.1	Does the laboratory have, follow, and maintain a documented quality system:	☐	☐	☐
	b. Is the quality system equivalent to or more stringent than what is required by these Standards?	☐	☐	☐
3.3	Does the laboratory perform an annual review of its DNA quality system <u>each calendar year or the calendar year plus 3 months if needed due to the national emergency</u>?	☐	☐	☐
	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?	☐	☐	☐

DB 3.4	Except for the exemption allowed for the annual review during the calendar year of the national emergency, does the laboratory annually review sample processing records determined by the technical leader to be a representative sample of the samples tested?	☐	☐	☐
	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?	☐	☐	☐
FOR 3.4	Except for the exemption allowed for the annual review during the calendar year of the national emergency, 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?	☐	☐	☐

Guidance

The laboratory must review their own more stringent requirements and document any deviations to time specific requirements within the laboratory's procedures. Deviations must be documented and authorized by technical leader.

Additionally, for standards that require the lab to "have and follow" a written procedure, the lab must evaluate any time frames contained in those procedures and document any deviations necessary for continued compliance during the time of the national emergency.

For a laboratory with operations affected by the national emergency, if necessary, an additional three months may be used to complete the annual review. An annual review performed during this extension into the next calendar year must be documented as fulfilling the requirement for the prior calendar year and may not be used to fulfill the annual review for both calendar years.

For a laboratory with operations affected by the national emergency, the annual review of sample processing records or of case files will be exempt for the calendar year of the national emergency.

Comment

Standard 4. Organization and Management

		Yes	No	N/A
4.1	Does the laboratory have:	☐	☐	
	4.1.4 At least two full-time employees who are qualified DNA analysts?	☐	☐	
	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 and, if applicable, notify the FBI as soon as practicable?	☐	☐	☐

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

Guidance

For the duration of the national emergency, employees who are working reduced hours, are not required to report, or are furloughed but would otherwise be considered a full-time employee will count towards the full-time employee requirements. If the laboratory continues to process samples for entry into NDIS with a reduced staff, they must continue to comply with the applicable standards (e.g., a second analyst available for technical review).

For an NDIS participating laboratory, the contingency plan for how the laboratory will proceed if no one is qualified to fill the technical leader vacancy or in the event the number of qualified analysts falls below two full-time employees who are qualified analysts requires the notification of the NDIS Custodian and State CODIS Administrator as required by the *NDIS Operational Procedures Manual*. In the event of the vacancy occurring during the national emergency and the notification deadlines cannot be met, the laboratory must notify the FBI as soon as practicable. Refer to Appendix B for the Contingency Plan Notification Form.

Comment

Standard 5. Personnel

		Yes	No	N/A
5.2	Is the technical leader a full-time employee of the laboratory or multi-laboratory system?	☐	☐	
5.2.3	If the technical leader was appointed on or after July 1, 2020, 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 with an additional 3 months, if needed, as a result of the national emergency?	☐	☐	☐
5.2.4	Has the technical leader successfully completed the FBI-sponsored auditor training within one year of appointment or within an additional 3 months?	☐	☐	☐
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, with the exception of semi-annual visits missed as a result of the national emergency?	☐	☐	☐
5.2.7	Has a newly appointed technical leader documented a review of the following within one year of appointment with an additional 3 months, if needed, as a result of the national emergency?	☐	☐	☐
	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
5.3.3	Has the CODIS administrator or casework CODIS administrator successfully completed the following training requirements?	☐	☐	☐

a. FBI sponsored CODIS software training within six months of appointment or within an additional 3 months, if not previously completed such training? ☐ ☐ ☐

b. FBI DNA auditor training within one year of appointment or within an additional 3 months, if not previously completed such training? ☐ ☐ ☐

Guidance

For the duration of the national emergency, employees who are working reduced hours, are not required to report, or are furloughed but would otherwise be considered a full-time employee will count towards the full-time employee requirements.

If the one year since appointment passes during the national emergency, the technical leader will be granted an additional 3 months of time to complete the FBI-sponsored auditor training and to complete the documented reviews of the validation studies and analytical procedures currently used by the laboratory and educational qualifications and training records of currently qualified analysts and technical reviewers.

If a semi-annual visit is missed as a result of the national emergency, the technical leader must ensure at least one on-site visit of each laboratory is scheduled for the calendar year of the national emergency declaration. The technical leader must remain accessible to the laboratory to provide on-site, telephonic, or electronic consultation as needed.

If the one year since appointment passes during the national emergency, the CODIS administrator or casework CODIS administrator will be granted an additional 3 months of time to complete the FBI auditor training.

If the six months since appointment passes during the national emergency, the CODIS administrator or casework CODIS administrator will be granted an additional 3 months of time to complete the FBI sponsored CODIS software training.

Comment

Standard 6. Training

		Yes	No	N/A
NOTE:	*Forensic Standard 6.12.1/Database Standard 6.10.1 will also be completed for any individual on extended leave for a period that takes them out of the proficiency test cycle <u>with the exception of proficiency tests missed as a result of the national emergency</u>.*			
DB 6.10.1	Did the individual successfully complete competency testing prior to his/her return to participation in database analyses?	☐	☐	☐
	a. Did the competency testing include a practical component?	☐	☐	☐
FOR 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?	☐	☐	☐

Guidance

At the discretion of the technical leader, absences up to three months as a result of the national emergency will not require competency testing prior to return to participation in casework or databasing analyses. With the exception of proficiency tests missed as a result of the national emergency, the **Forensic Standard 6.12.1/Database Standard 6.10.1** requirement will apply to individuals who have been on extended leave for a period that takes them out of the proficiency test cycle. The technical leader will determine if an individual requires training or retraining prior to competency testing.

The laboratory should evaluate any time frames contained in their written procedures and document any deviations necessary as a result of the national emergency.

Comment

Standard 8. Validation

		Yes	No	N/A
DB 8.6.1	Was the expert system subject to recertification in accordance with NDIS operational procedures, with the exception of quarters missed due to the national emergency?	☐	☐	☐

Guidance

A laboratory unable to complete a quarterly recertification in accordance with the laboratory's program as a result of the national emergency must document the exception for missed quarters and complete a recertification as soon as practicable when normal laboratory operations resume.

Comment

Standard 10. Equipment Calibration and Maintenance

		Yes	No	N/A
10.3.2	Are the following critical equipment or instruments performance-checked at least annually or within 3 months of the end of the calendar year of the national emergency:	☐	☐	
	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?	☐	☐	☐

Guidance

The laboratory must evaluate any time frames contained in their program for conducting performance checks and/or scheduled maintenance and document any deviations necessary to ensure continued compliance during the time of the national emergency.

A laboratory unable to complete an annual performance check in accordance with the laboratory's program as a result of the national emergency, must document the exception and complete the performance check within 3 months of the end of the calendar year. An annual performance check completed during this extension into the next calendar year must be documented as fulfilling the requirement for the prior calendar year and may not be used to fulfill the annual performance check for both calendar years.

Comment

Standard 13. Proficiency Testing

		Yes	No	N/A
13.1	Except for the exemptions allowed for tests unable to be completed due to the national emergency, 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, plus an additional 6 months if needed due to the national emergency?	☐	☐	
	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, plus an additional 6 months if needed due to the national emergency?	☐	☐	
13.1.2	Are analysts proficiency tested in each typing test kit at least once per calendar year, plus an additional 6 months if needed due to the national emergency?	☐	☐	

	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, plus an additional 6 months if needed due to the national emergency?	☐	☐	☐
13.1.3	Are individuals that perform analytical procedures on forensic samples or database, known, or casework reference samples proficiency tested on at least one method in each methodology at least once per calendar year, plus an additional 6 months if needed due to the national emergency?	☐	☐	
NOTE:	*Standard 13.1.5 and the substandards 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, plus an additional 6 months if needed due to the national emergency?	☐	☐	☐
	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, plus an additional 6 months if needed due to the national emergency?	☐	☐	☐
	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, plus an additional 6 months if needed due to the national emergency?	☐	☐	☐
13.1.6	Have newly qualified individuals undergone semi-annual external proficiency testing within eight months of the date of their authorization, or as soon as practicable if delayed by the national emergency?	☐	☐	☐
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 or during the national emergency document any deviations from the date used?	☐	☐	

Guidance

If the laboratory is unable to complete an assigned test or to assign a proficiency test to meet the requirements of semi-annual as a result of the national emergency, the laboratory must document the attempt to comply with the semi-annual requirements and issue the next proficiency test within eight months of the missed proficiency test in accordance with the requirements of semi-annual. Tests that have been initiated must be completed to a point to allow for an internal evaluation of the test results even if the test is unable to be submitted by the manufacturer's deadline.

If an analyst, technician, or technical reviewer misses a proficiency test due to the national emergency needed to comply with the annual requirements for proficiency testing (e.g., technology, test kit), the laboratory should document the missed requirement(s) and ensure a test in the first six months of the following calendar year addresses the missed requirement(s).

With the exception of proficiency tests missed as a result of the national emergency, the **Forensic Standard 6.12.1/Database Standard 6.10.1** requirement will apply to individuals who have been on extended leave for a period that takes them out of the proficiency test cycle. The technical leader will determine if an individual requires training or retraining prior to competency testing.

A newly qualified individual shall undergo external proficiency testing within eight months of their qualification date unless the national emergency prevents the laboratory from meeting this time frame and then must enter the proficiency test cycle as soon as practicable.

During the national emergency, the date the laboratory consistently uses as the date performed may be impacted (e.g., the due date extended or received date delayed) and therefore the lab should document any changes to dates that may impact their proficiency testing schedule.

Comment

Standard 15. Audits

		Yes	No	N/A
15.1	Has the laboratory been audited annually in accordance with the Quality Assurance Standards for DNA Databasing Laboratories?	☐	☐	☐

	a. Have the annual audits occurred every calendar year at least six months and no more than 18 months apart or did the laboratory document if the time between audits was outside of these time frames as a result of the national emergency?	☐	☐	☐
15.2	Has an external audit been conducted at least once every two years?	☐	☐	☐
NOTE:	*Auditor(s) and their applicable qualifications will be documented in Appendix C.*			
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 or as soon as practicable with documented notification to the NDIS Custodian?	☐	☐	☐

Guidance

In accordance with Standard 15.1, the required annual audit shall, at a minimum, occur once every calendar year and shall be at least 6 months but no more than 18 months apart. The laboratory must document if the national emergency prevents the laboratory from complying with these time frames.

Standard 15.2 requires that an external audit be performed at least once every two years and is based on federal statute. If the national emergency prevents a laboratory from complying with the external audit requirement (e.g., travel restrictions, external auditor availability), Standard 15.2 will be considered a noncompliance and the laboratory must contact the NDIS Custodian with a remediation plan.

To comply with Standard 15.5.2, it is incumbent on the NDIS participating laboratory to document for each external audit, the date that the external Audit Document was received from the auditor(s) and the date that the laboratory sent the external audit documentation and laboratory responses to the FBI. The laboratory response may include a notification to the NDIS Custodian if the laboratory needed to request an extension of time for sending the required audit documentation.

Comments

Standard 16. Professional Development

		Yes	No	N/A
16.1.1	Does the technical leader, CODIS administrator, and each analyst and technical reviewer stay abreast of topics relevant to the field of forensic DNA analysis and have 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 or four hours for the calendar year of the documented national emergency?	☐	☐	
16.1.2	With the exception of the calendar year of the documented national emergency, 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?	☐	☐	

		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?	☐	☐	

Guidance

A laboratory unable to document the annual review of scientific literature in accordance with the laboratory's program, must document the exception for the calendar year is a result of the national emergency.

The laboratory must document if the annual monitoring of the testimony of laboratory personnel in accordance with their program is impacted by the national emergency.

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 or DNA Databasing Laboratories, as applicable, and the accreditation requirements of federal law?	☐	☐	☐
	Does the procedure to perform an on-site visit include:			
17.4.2	An annual on-site visit if the NDIS participating laboratory's outsourcing agreement extends beyond one year with an additional 3 months for on-site visits missed as a result of the national emergency?	☐	☐	☐
	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 or did the lab document if the time between on-site visits was outside of these time frames as a result of the national emergency?	☐	☐	☐

Guidance

The allowances as a result of the national emergency also apply to vendor laboratories as needed and the National Emergency Addendum must be retained with the vendor laboratory audit documentation.

Forensic Standard 17.4.2 is applicable when an outsourcing agreement has been extended (e.g., extensions, renewals or re-award) and the technical specifications (e.g., technology, platform and typing amplification test kit) used to generate the DNA data have not changed. If the national emergency prevents an annual on-site visit from being conducted, an on-site visit must be conducted as soon as practicable.

Comments