

NOTICE ON QAS RELIEF IN RESPONSE TO NATIONAL EMERGENCY

April 23, 2020

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 (hereinafter referred to as "laboratories"), in response to the COVID-19 pandemic.

After consultation with the Scientific Working Group on DNA Analysis Methods (SWGDM), time sensitive requirements in the 2011 and 2020 QAS were identified for which compliance may be jeopardized as laboratories respond to federal guidelines for social distancing during the national emergency. National Emergency is defined as the documented time period beginning March 1, 2020 until TBD, or a time period 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.

The FBI expects all laboratories to make their best efforts to comply with the QAS and to continue to document your efforts to do so. 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. Depending on the standard at issue, the special relief offered to laboratories will include the following:

- (1) Additional guidance on specified QAS requirements;
- (2) Extension of time to satisfy certain annual QAS requirements; or
- (3) Exemption for certain QAS requirements for the calendar year 2020, with appropriate documentation of efforts to comply.

Questions or notifications relating to your laboratory's compliance with the 2011 and 2020 QAS should be directed to the NDIS Custodian at ndis@fbi.gov.

Both the 2011 QAS and the QAS scheduled to take effect on July 1, 2020 will be impacted by the COVID-19 pandemic. Specific information on the special relief for both the 2011 QAS and the 2020 QAS are contained in the following pages.

Additional Guidance on Specified QAS Requirements:

2011 Standard(s)	2020 Standard(s)	Additional Guidance
Databasing and Forensic QAS 3.1(b)	Databasing and Forensic QAS 3.1(b)	This is a caution to review your laboratory's procedures. If your quality system has more stringent requirements than the FBI Director's QAS and that includes more stringent time requirements, the laboratory shall document any deviations from the more stringent time requirements. Documentation shall be maintained and available for audits and accreditation inspections.
Databasing and Forensic QAS 4.1.4 and 5.2.4.1	Databasing and Forensic QAS 4.1.4, 4.1.6 and 5.2	Additional guidance for the definition of full-time employee applicable during this National Emergency period: Full-time employee will include individuals that maintain employment status with the agency, even if placed in a furloughed, non-reporting, or limited reporting 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.
Databasing and Forensic QAS 6.1.5 Databasing and Forensic QAS 9.7 Databasing and Forensic QAS 10.2 and 10.3 Databasing QAS 12.1 and 12.6 Forensic QAS 12.6	Databasing QAS 6.10 and Forensic QAS 6.12 Databasing and Forensic QAS 9.12.1 Databasing and Forensic QAS 10.2	Laboratories should review their internal procedures, particularly those relating to standards requiring the laboratory to "have and follow written procedures" to ensure that they do not impose additional time sensitive requirements. If the laboratories internal written procedures include additional time requirements, the laboratory shall document any deviations from such requirements during the National Emergency period. For purposes of these alternative mechanisms during the National Emergency, deviations shall be documented and authorized by the technical leader.
	Databasing QAS 6.10.1 and Forensic QAS 6.12.1	At the discretion of the technical leader, absences of three months or less as a result of the National Emergency shall not be considered to implicate the requirement for competency testing.
Databasing and Forensic QAS 13.1.3	Databasing and Forensic QAS 13.3	Laboratories shall document their attempts to comply with their established dates for proficiency testing and any deviations (e.g.,

		due date extended, received date delayed) in the proficiency testing dates as a result of the National Emergency that impact their proficiency testing schedule.
Databasing and Forensic QAS 15.1	Databasing and Forensic QAS 15.1	Laboratories shall document their attempts to comply with the time frames in the standards and any deviations to those time frames resulting from the National Emergency. A laboratory's documented inability to comply with the time requirement that the audit be at least 6 months and no more than 18 months apart as a result of the National Emergency shall not be considered a noncompliance.
Databasing and Forensic QAS 15.2	Databasing and Forensic QAS 15.2	Laboratories shall document their attempts to comply with the time frames in the standards and any deviations to those time frames resulting from the National Emergency. Laboratories that are unable to comply with the biannual external audit requirement as a result of the National Emergency (e.g., ongoing travel restrictions, scheduling conflicts) shall notify the NDIS Custodian as soon as they are aware of the anticipated noncompliance.

Extension of QAS Time Frames:

Laboratories are strongly encouraged to attempt to comply with the time frames contained in the QAS, when possible. Laboratories shall document their attempt to comply with the time frames in those standards and any deviations to the QAS time frames as a result of the National Emergency. As a result of the National Emergency, time frames contained in the following Standards may be extended for the periods noted below for a maximum of an additional three-month period into 2021. Laboratories with appropriate documentation of the above shall be considered to be in compliance with these QAS Standards.

2011 QAS	2020 QAS	Extension Period
Databasing and Forensic QAS 3.3	Databasing and Forensic QAS 3.3	3 months
	Databasing and Forensic QAS 4.1.6	As soon as practicable
	Databasing and Forensic QAS 5.2.3	3 months
Databasing and Forensic QAS 5.2.2	Databasing and Forensic QAS 5.2.4	3 months
Databasing and Forensic QAS 5.2.4.1.1		As soon as practicable
	Databasing and Forensic QAS 5.2.7	3 months
Databasing and Forensic QAS 5.3.3	Databasing and Forensic QAS 5.3.3	3 months
Databasing and Forensic QAS 9.1		3 months
Databasing and Forensic QAS 10.2.1	Databasing and Forensic QAS 10.3.2	3 months
Databasing and Forensic QAS 13.1.2	Databasing and Forensic QAS 13.1.6	As soon as practicable
Databasing and Forensic QAS 15.5.1	Databasing and Forensic QAS 15.5.2	As soon as practicable
Databasing QAS 17.4.3.3 and Forensic QAS 17.7.2.1	Databasing and Forensic QAS 17.4.2	3 months

Exemption from QAS Time Frames:

Laboratories are strongly encouraged to attempt to comply with the time frames contained in the QAS, when possible. Laboratories shall document their attempt to comply with the time frames in those standards and any deviations to the QAS time frames as a result of the National Emergency.

As a result of the National Emergency, laboratories with the appropriate documentation may be exempt from the specified time frame. Please take note of specific additional guidance for these exemptions. Laboratories with appropriate documentation of the above shall be considered to be in compliance with these QAS Standards:

2011 QAS	2020 QAS	Exemption
	Databasing and Forensic QAS 3.4	Laboratories being audited in accordance with the 2020 QAS Audit Document shall be exempt from this new requirement for calendar year 2020.
Databasing and Forensic QAS 5.1.3.1	Databasing and Forensic QAS 16.1.1	Laboratories shall be exempt from half of the requirements as a result of the National Emergency and shall be required to demonstrate compliance with a minimum of 4 cumulative hours for calendar year 2020.
Databasing and Forensic QAS 5.1.3.2	Databasing and Forensic QAS 16.1.2	Laboratories shall be exempt from the requirement for the annual review of scientific literature for calendar year 2020.
Databasing and Forensic QAS 5.2.4	Databasing and Forensic 5.2.6	Laboratories shall document their attempts to comply with this requirement. A technical leader who was able to conduct a site visit to a laboratory in their multi-laboratory system during the first half (January – June) of calendar year 2020 shall not be exempt from this requirement for that laboratory. A technical leader who was unable to conduct a site visit to a laboratory in their multi-laboratory system during the first half of calendar year 2020 as a result of the National Emergency shall be exempt from the semi-annual requirement of this Standard but shall be required to conduct a site visit during the second half (July – December) of calendar year 2020 and the performance of one site visit shall be deemed to be in compliance with this Standard. Laboratories shall be responsible to maintain and have available appropriate documentation of their attempts to comply with this Standard.

	Databasing 8.6.1	Laboratories shall document their attempts to comply with this requirement and laboratories presenting appropriate documentation shall be considered to be in compliance with this Standard if they are unable to conduct recertifications in each quarter of calendar year 2020 that is impacted as a result of the National Emergency.
Databasing and Forensic QAS 9.5.5 and Rapid DNA Addendum 9.5.5.1		Laboratories shall be exempt from the requirement for the annual check against a NIST standard or standard traceable to a NIST standard for calendar year 2020.
Databasing QAS 10.2.2.1 and Rapid DNA Addendum 10.2.2		Laboratories shall document their attempts to comply with this requirement and laboratories presenting appropriate documentation shall be considered to be in compliance with this Standard if they are unable to conduct recertifications in each quarter of calendar year 2020 that is impacted as a result of the National Emergency.
Databasing and Forensic QAS 12.7	Databasing and Forensic QAS 16.2	Laboratories shall document their attempts to comply with this requirement and laboratories presenting appropriate documentation shall be considered to be in compliance with this Standard.
Databasing and Forensic QAS 13.1 and 13.1.1	Databasing and Forensic QAS 13.1, 13.1.1, and 13.1.1.1	Laboratories shall document their attempts to comply with this requirement. Analysts, technical reviewers, technicians and other personnel designated by the technical leader who were able to complete and submit their external proficiency tests during the first half (January – June) of calendar year 2020 shall not be exempt from this requirement. Analysts, technical reviewers, technicians and other personnel designated by the technical leader who were unable to complete and submit their external proficiency tests during the first half of calendar year 2020 as a result of the National Emergency shall be required to complete and submit one external proficiency test for the second half (July – December) of calendar year 2020 and such completion and submission of that one external proficiency test shall be deemed to be in compliance with this Standard. Laboratories shall be responsible to maintain and have

		<p>available appropriate documentation of their attempts to comply with this Standard.</p> <p>The dates used for determining the compliance with semiannual may be impacted by the National Emergency (e.g., due date extended, received date delayed) and deviations shall be documented as instructed above.</p> <p>If an analyst, technician, or technical reviewer misses a proficiency test needed to comply with the requirement to proficiency test to the full extent in which he/she participates in casework or database analysis (e.g., platform, test kit) as in the 2011 QAS or needed to comply with the annual requirements for proficiency testing (e.g., technology, test kit) as in the 2020 QAS as a result of the National Emergency, the laboratory shall document the missed requirement(s) and ensure a test in the first six months of the following calendar year addresses the missed requirement(s).</p> <p>Laboratories unable to proficiency test each individual who is qualified in both manual and automated methods in each method in the calendar year of the National Emergency shall be exempt from this requirement for calendar year 2020. For laboratories audited under the 2011 QAS in calendar year 2020 that are unable to complete and submit two external proficiency tests as a result of the National Emergency, and having the appropriate documentation, shall be exempt from the requirements of Standard 13.1.1.</p> <p>Laboratories unable to proficiency test on the interpretation of data generated by a Rapid DNA instrument within calendar year 2020 as a result of the National Emergency shall document their efforts to comply and ensure the required proficiency test is conducted within the first six months of the following calendar year. Laboratories having appropriate documentation of the above shall be exempt from the</p>
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		requirements of Standard 13.1.1.1 for modified Rapid DNA analysis for calendar year 2020.
Databasing and Forensic QAS 16.2		Laboratories being audited during calendar year 2020 under the 2011 QAS shall be exempt from the requirements of Standard 16.2.