Guidance for NDIS Participating Laboratories’ Request for Approval for A Virtual External QAS Audit

In Compliance with the 2020 Quality Assurance Standards (QAS)

August 2020

Pursuant to the 2020 Quality Assurance Standards for DNA Databasing and Forensic DNA Testing Laboratories (QAS), an audit is defined as “an on-site inspection used to evaluate, confirm and/or determine the extent to which specified requirements are fulfilled.” Thus, the external QAS audit required by Standard 15.2 implies a physical on-site inspection of the laboratory being audited by the auditors from a second agency.

The on-site requirement will require at least one member of the audit team to visit the laboratory to determine compliance with QAS. As long as there is a documented on-site inspection to evaluate, confirm and/or determine the extent to which the laboratory is in compliance with the QAS by one or more members of the audit team, then there is compliance with the definition of an audit. The review of a laboratory’s documentation as part of the audit process, electronically or on-site, must be conducted in accordance with the laboratory’s procedures for the confidentiality of reports, case files, DNA records and DNA databases (QAS 11.3) and by an individual who has successfully completed the FBI’s DNA auditor training course (QAS definition of auditor). The QAS also requires, for external audits, that at least one auditor be or have been an analyst previously qualified in the laboratory’s current DNA technologies and platforms (QAS 15.2 & 15.3). For practical purposes, the on-site inspection to evaluate, confirm and/or determine the extent to which the laboratory is in compliance with the QAS should be conducted by the auditor who is or has been previously qualified in the laboratory’s current DNA technologies and platforms.

During the next year, however, as social distancing, travel and quarantine restrictions remain in place, through no fault of nor any inaction on the part of NDIS participating laboratories, it may be challenging to schedule an on-site external QAS audit due to limited auditor availability. The Federal Bureau of Investigation’s (FBI) Notice on QAS Relief in Response to National Emergency (April 23, 2020) contains additional guidance for Standard 15.2 that requires notification of the NDIS Custodian in the event of possible noncompliance with the external QAS audit requirements. Upon notification, the FBI’s NDIS Custodian may authorize a virtual external QAS audit for compliance with the Standard 15.2 external QAS audit requirements. A virtual external QAS audit is an external QAS audit conducted by one or more qualified auditor(s) from a second agency(ies) who are not physically on-site at the laboratory being audited pursuant to documented FBI approval and in accordance with this guidance.
## Guidance for Virtual External QAS Audit

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<th>Responsible Party(ies)</th>
<th>Action</th>
<th>Comment</th>
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<td><strong>Step 1:</strong> Laboratory</td>
<td>Laboratory requests approval from the NDIS Custodian for a virtual external QAS audit.</td>
<td>In a written communication to the NDIS Custodian, the Laboratory requests approval for a virtual external QAS audit and documents the reason(s) necessitating a virtual external QAS audit. For example: “Our originally scheduled external QAS audit was cancelled due to the COVID-19 pandemic because the selected auditors would be required by their agencies to quarantine after travel. We are now nearing the end of our external QAS audit window and are requesting a virtual audit to stay in compliance with the requires time frame.” The NDIS Custodian will respond, in writing, to the request.</td>
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<td><strong>Step 2:</strong> Laboratory, Accrediting/Auditing External Agency</td>
<td>Confirm that proposed QAS auditors are qualified to conduct the external QAS audit.</td>
<td>See QAS definition of auditor (individual who has successfully completed the FBI’s DNA auditor training course); Standard 15.2 further requires that at least one auditor shall be or have been an analyst previously qualified in the laboratory’s current DNA technologies and platforms.</td>
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<td><strong>Step 3:</strong> Laboratory, Auditor/Audit Team (Accrediting/Auditing Agency)</td>
<td>Prepare a plan, in conjunction with the qualified auditors (accrediting/auditing agency), for the review of documentation, facility and instrument/reagent reviews, interviews, etc.</td>
<td>The virtual external QAS audit plan should address, at a minimum: - Listing of all documentation to be reviewed electronically (i.e., laboratory’s procedures and quality assurance manuals, case files, corrective action, etc.); - How the facility and equipment standards will be evaluated; - How security will be maintained for case file reviews; - How interviews will be conducted; - Dedicated time for performing the virtual external QAS audit to ensure that laboratory staff is on-</td>
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The QAS auditors will be provided with access to the following (the information must be current at the time of the audit):

- List of laboratory personnel at each facility at the time of the audit and their education, experience, training/competency test records, proficiency test records, continuing education records and testimony monitoring records, as applicable;
- List of all QAS-defined critical equipment, instruments, and reagents at each laboratory facility and associated maintenance, quality, and performance check records, as applicable;
- List of validations, including summaries and supporting documentation, as applicable; and
- Facility security and evidence/sample controls, including sample inventory or evidence tracking system, as applicable.

### Step 4: Laboratory, Auditor/Audit Team

Schedule time for the virtual external QAS audit interviews and virtual facility walk through to ensure dedicated staff attention.

Request virtual tour of the laboratory facilities, noting the location and placement of equipment and instruments to determine compliance with the QAS. Ensure dedicated time for the auditor(s) and on-site laboratory staff. A QAS emergency line (571) 359-0866 will be available for real time responses to QA questions during a virtual external audit.

### Step 5: Auditor/Audit Team

In completing the virtual external QAS audit, indicate on the Audit Document it was a virtual external audit. For example:

- Dates of Audit: September 10-14, 2020
- (VIRTUAL EXTERNAL QAS AUDIT)
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<th><strong>Step 6: Auditor/Audit Team</strong></th>
<th><strong>QAS audit under “Dates of audit” and reference date of NDIS Custodian approval for the virtual external QAS audit.</strong></th>
<th><strong>approved by NDIS Custodian August 16, 2020</strong></th>
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<td><strong>In the event of a “Finding,” include sufficient detail and documentation in the Audit Document(s) to ensure that laboratory can propose appropriate corrective action for review.</strong></td>
<td><strong>Include NDIS Custodian approval for the virtual external QAS audit in the audit documentation.</strong></td>
<td><strong>Documentation may reference the mode of observation for virtual audit. For example: “Standard 6.1.3 is marked “No” because the laboratory does not maintain amplified DNA product in a room separate from PCR-setup areas. The PCR-setup areas reviewed during the virtual laboratory tour (date) showed refrigerators labeled “Post-amp DNA product storage.” Interviews with analysts at the lab facility confirmed that the refrigerators are for storing amplified DNA product and located in the PCR-setup area.”</strong></td>
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