## Quality Division Use Only

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| **Quality Tracking #:** | 2022-052 | **Classification:** | Incident |
| **Non-Conformance Level:** | N/A | **Section:** | Biology/DNA |
| **Date of Discovery:** | 08/15/22 | **Date of Incident:** | 08/15/22 |

| Forensic Case Number(s), if applicable: | Agency Case Number(s), if applicable: |
|---|---|
| 2016-20852 121286704 2010-17022 2010-17472 2010-21048 2011-00445 2011-16562 2012-13391 2012-19144 2013-15526 2015-01435 2015-03615 2015-09880 13-28430 2014-18046 | 124649616 121286704 113282309 120288410 130661110 049624810 068776004 073739409 108611612 041372413 010557815 022524515 090059915 125377413 107100914 |

**Description of Non-conformance:**

Cases were authored or technically reviewed by analysts whose two-year authorization window for the reinterpretation of legacy data had lapsed. Authorization to reinterpret legacy data is limited to two years by DNA General SOP clause 4.9.1.2.

**Additional Information/Follow-Up:**

According to the DNA General SOP section 4.9.1.2, if an analyst has not been proficiency tested using a legacy test kit within the last two calendar years, the technical leader must document and approve the completion of the analyst's review of the associated validation data and the standard operating procedures associated with the legacy test kit. An analyst's review is documented as a successfully completed Qualtrax test documenting their review of the associated validation data and/or SOPs along with an authorization memo signed (which signifies review and approval) by the technical leader and the Quality Division, as required by Quality Manual 6.2.5e.
After review of reinterpretation of legacy data authorization memos, the technical reviewer and reporting analyst of case 2016-20852 discovered that they did not have the appropriate memos for the reinterpretation of Identifier Plus data.

The reporting analyst of case 2016-20852 had successfully completed the Qualtrax test documenting her review of the associated validation data and/or SOPs for the legacy Identifiler Plus amplification kit previously used by HFSC. In addition, she had signed her authorization memo as well as the technical leader, but the memo was missing the required signature of a member of the Quality Division and the forensic biology manager since it is the section's practice to also document the manager's approval of all authorization memos. Once this issue was discovered the forensic biology manager was able to locate the partially signed authorization memo in her email inbox.

**The technical reviewer's previous two-year authorization window had already expired when she performed the technical review of case 2016-20852. Therefore, although she had previously reviewed the associated validation data and/or SOPs for the legacy Identifiler Plus amplification kit previously used by HFSC, it had been more than two years since her review.**

**The technical leader queried cases completed within the timeframe since the reporting analyst and the technical reviewer's authorization had expired and reviewed those cases to determine if reinterpretation of legacy data had occurred. Fourteen additional cases were identified for the reporting analyst and no additional cases were identified for the technical reviewer.**

**Additionally, the technical leader reviewed all previous authorization memos for the reinterpretation of legacy data and identified three additional issues.**

**In addition to not having the previously discussed authorization memo, the reporting analyst had completed the Qualtrax test for another legacy amplification kit but did not have a signed authorization memo approving her to perform reinterpretations. A review of casework confirmed no reinterpretations using that legacy amplification kit had occurred.**

**In addition to not having the previously discussed authorization memo, the technical reviewer's authorization memo for another legacy amplification kit had also expired, however a review of casework confirmed that no reinterpretations using that legacy amplification kit had occurred. The technical leader also identified that the CODIS administrator's two-year window for reinterpretation of another legacy amplification kit had expired. Again, a review of casework confirmed that no reinterpretations had occurred.**

**While none of these three issues were a direct violation of the DNA General SOP, they were evidence the previous system of authorizing analysts for the reinterpretation of legacy data and monitoring where analysts are in their two-year window of authorization was no longer effective.**

**Summary of Root Cause Analysis:**
**Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.**

**N/A**

| Actions Taken: |
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| **Since at the time the technical review occurred for case 2016-20852 the technical reviewer's review of the associated validation data and/or SOPs for the legacy Identifiler Plus amplification kit previously used by HFSC had surpassed two years, a second technical review occurred after the authorization was granted to ensure the integrity of the technical review.**<br><br>**The technical leader does not recommend further action for the additional fourteen cases identified for the reporting analyst as she determined there to be minimal technical risk since at the time the reinterpretation was performed the reporting analyst had successfully completed the Qualtrax test, and the authorization memo was in the signature process and had already been reviewed and approved by the technical leader.**<br><br>**As part of this nonconformance and subsequent query of potential cases involving reinterpretation, it was also noted that there was a possibility that the technical reviewer performed administrative reviews of cases with Identifiler Plus data generated by the outsourcing laboratory Strand Analytical Laboratories in cases involved in Quality Corrective Action 2018-IA-09. If this review occurred, it has been determined to be administrative in nature and reinterpretation (as defined by the FBI Quality Assurance Standards) did not occur, therefore any cases that could fall under these criteria are not affected.**<br><br>**The technical leader, CODIS administrator, DNA interpretation supervisor, quality specialists, and reinterpretation analysts met to create a plan to improve the system of tracking authorizations of reinterpretation of legacy kits. Starting in September 2022, the technical leader will be releasing reinterpretation tests in Qualtrax to all analysts that will require authorization to reinterpret any legacy data every two years with the expectation of improving the tracking of required re-authorizations. Additionally, the authorization memos will be uploaded to Qualtrax as controlled documents to enable the expiration feature. All authorization memos for reinterpretation of legacy data will have the same expiration date and will expire to the assistant technical leader. The assistant technical leader will be responsible for following up with the appropriate analysts to ensure they complete the appropriate test(s) in Qualtrax, drafting the authorization memos, and sending the authorization memos out for review, approval, and signatures.**<br><br>**In addition, it was recommended for analysts to be vigilant and always confirm in Qualtrax that they have the appropriate authorization memo when re-interpreting legacy data.** |

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| | Courtney Head | | 09/01/22 |
| **Section Manager:** | | **Date:** | |
| **Division Director:** | Amy Castillo | **Date:** | 09/02/22 |

**Incidents or Corrective Actions that involve the Biology/DNA section are reviewed by the Technical Leader and CODIS Administrator.**

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| **Technical Leader:** | Cheron Maxwell | **Date:** | 09/01/2022 |
| **CODIS Administrator:** | Jennifer Clay | **Date:** | 09/01/2022 |

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| **Quality Director:** | Erika Ziemak | **Date Closed:** | 09/08/22 |