



**Quality Division Use Only**

Quality Tracking #:	<input type="text" value="2018-054"/>	Classification:	<input type="text" value="Corrective Action"/>
Non-Conformance Level:	<input type="text" value="Class II"/>	Section:	<input type="text" value="Biology/DNA"/>
Date of Discovery:	<input type="text" value="07/02/18"/>	Date of Incident:	<input type="text" value="06/29/18"/>

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2017-23452 2017-23821 2017-23706 2017-23824 2017-23338 2017-23708 2017-23707 2017-23823 2017-23705 2016-00510 2015-05070 2015-01273 2014-15697 2014-18794 2015-09674 2015-09657 2015-09475 2015-11276 2016-06061 2015-17307 2016-10619 2015-13417 2018-01441 2018-01421 2017-17005 2018-01444 2018-00546 2018-05004 2017-06982 2017-07637	158782017 161979917 161398617 162094617 155786617 160948017 158858017 160984317 161106217 004345716 035225015 010103715 089844714 113793314 079062515 065705415 084708415 103833215 111429615 161974715 065664416 098563515 008736218 010557818 108533717 011030418 002204818 039324418 044748517 047832917

**Description of Non-conformance:**

Two contract employees were hired by the Forensic Biology laboratory in January and February 2018, respectively. Both contract employees had access to the laboratory's SOPs and all necessary worksheets because Qualtrax (the laboratory's electronic document control software) does not require login access in order to utilize controlled documents. However, it was later discovered that the contract employees' Qualtrax accounts had not been enabled and therefore neither had been notified via email regarding required tests/acknowledgements nor completed the required tests/acknowledgements. Both accounts were activated on June 29, 2018.

**Actions Taken:**

The first contract employee was authorized to perform technical reviews on March 28, 2018. A revision of the DNA SOP was published on March 29, 2018, but the contract employee did not complete the SOP acknowledgement. The contract employee performed 27 technical reviews between March 30, 2018 and May 23, 2018. These case files were reviewed and it was determined that they were not impacted by the DNA SOP updates. The contract employee did not technically review any cases between May 24, 2018 and July 8, 2018. A revised version of the Quality Manual was effective on July 5, 2018. The contract employee technically reviewed 3 cases on July 9, 2018 but did not complete the Quality Manual acknowledgement until July 11, 2018. These case files were reviewed and it was determined that they were not impacted by the Quality Manual updates. Both of her first and second quarter literature reviews were completed on August 11, 2018. The second contract employee completed all of her outstanding tests/acknowledgements prior to performing any technical reviews. Both of her first and second quarter literature reviews were completed on August 10, 2018.



**Summary of Root Cause Analysis:**

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

The contract employees were not treated as typical employees because they are both non-traditional re-hires. The contract employees were hired with the sole purpose of performing technical reviews and they are the Forensic Biology laboratory's only two contract employees. Both contract employees are former full-time employees and therefore the Biology Manager categorized them as "re-hires" rather than "new hires". Subsequently, these "re-hires" were not subjected to the typical onboarding processes, part of which would be to contact the Quality Division and request that their Qualtrax accounts be enabled. As further evidence of this the Manager's On-Boarding Checklist workflow (which is initiated when new employees are hired) was also not initiated for either contract employee. However, a workflow has been initiated for all other Forensic Biology employees who have been hired since November 2017. The Forensic Biology Manager has committed to initiating the Manager's On-Boarding Checklist workflow for all future contract employees in instances when one is not initiated by Human Resources. Additionally, neither employee keeps a traditional work schedule. The first contract employee comes on-site to perform technical reviews but her schedule is sporadic and includes evening hours and weekends. The second contract employee resides in another country and will not be coming on-site in order to perform technical reviews.

**Additional Information/Follow-Up:**

N/A

Section Manager: Courtney Head

Date: 10/12/18

Division Director: Amy Castillo

Date: 10/15/18

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

Technical Leader: Robin Guidry

Date: 10/11/2018

CODIS Administrator: Jennifer Clay

Date: 10/12/2018



**Houston Forensic Science Center**  
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**Quality Director:** Lori Wilson

**Date Closed:** 10/15/18