



Quality Division Use Only

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|------------------------|---------------------------------------|-------------------|---|
| Quality Tracking #: | <input type="text" value="2020-058"/> | Classification: | <input type="text" value="Incident"/> |
| Non-Conformance Level: | <input type="text" value="N/A"/> | Section: | <input type="text" value="Seized Drugs"/> |
| Date of Discovery: | <input type="text" value="07/16/20"/> | Date of Incident: | <input type="text" value="07/27/20"/> |

| Forensic Case Number(s), if applicable: | Agency Case Number(s), if applicable: |
|---|---------------------------------------|
| 2019-19242 | 155593619 |
| 2019-20682 | 170189419 |
| 2020-04570 | 042896520 |
| 2020-05413 | 052397320 |

Description of Non-conformance:

Statistical sampling was completed on four Seized Drugs cases and while the reports included a statement documenting that statistical sampling was used, the reports did not include a statement about confidence levels or inference regarding the population as required by the Quality Manual section 7.8.5.d.

Additional Information/Follow-Up:

On February 11, 2019 HFSC transitioned and incorporated into their quality management system the 2017 revision of ISO/IEC 17025 standard and the associated accrediting body requirements. In this new revision, cases using statistical sampling are now required to report the confidence level and the corresponding inference regarding the population. Previous to this revision, this information was only required to be part of the sampling plan and procedure. This change in reporting requirement was noted during the 2020 surveillance assessment. A query was conducted on all cases completed since February 2019 and four cases were identified that used the statistical sampling method but did not include the required confidence level and population inference in the report.



Actions Taken:

The statistical sampling report footnote was updated on July 23, 2020 to include a confidence level and population inference and now reads as: "Reported results of analysis for item(s) XX included hypergeometric statistical sampling in which (number of sampled items) exhibits were randomly selected and individually identified by the listed test methods. This statistically based sampling plan gives a 95% level of confidence that at least 90% of the population contains the reported substance."

The footnote update was discussed at a section meeting on September 4, 2020 with all of the staff members. The Seized Drugs SOP was updated on September 7, 2020 to require confidence levels and corresponding inference regarding the sampled population to be noted on reports. The reports for the cases involved were amended to update the footer with the aforementioned statistical sampling footnote.

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

Section Manager: James Miller

Date: 09/28/20

Division Director: Amy Castillo

Date: 09/29/20

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

Technical Leader: N/A

Date: N/A

CODIS Administrator: N/A

Date: N/A

Quality Director: Erika Ziemak

Date Closed: 09/29/20