Quality Division Use Only

Quality Tracking #:	2018-IA-14	**Classification:**	Corrective Action
Non-Conformance Level:	Class II	**Section:**	Seized Drugs
Date of Discovery:	01/31/18	**Date of Incident:**	01/31/18

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2017-09192	057704017

Description of Non-conformance:

The Quality Division conducted an internal audit of the Controlled Substances section in January 2018. A nonconformance was noted during the review of Reagent QC and Drug Standard Usage Logs. A portion of evidence encountered in case work was retained as reference material for reagent QC testing purposes. Removal of this reference material was not fully documented in the case record nor in the chain of custody. This lack of documentation violates Quality Manual section 5.6.3.2.1 which requires reference collections of data or items/materials encountered in casework that are maintained for identification, comparison, or interpretation purposes (for example, mass spectral libraries, drug samples, bullets, cartridges, DNA profiles, frequency databases) to be fully documented, uniquely identified, and properly controlled.

Actions Taken:

A portion of marihuana from a case tagged for destruction was retained by the Controlled Substance section for use as a reference material when performing QC checks of prepared Duquenois reagent. An Examination Sheet was used to document verification of the sample as marihuana but this was not documented as part of the case record. On February 15, 2018, the remaining portion of marihuana was assigned a unique drug standard identification number (420A), weighed and verified by microscopic examination, chemical screening, and GC/MS. A memo was issued by the section manager on March 8, 2018, to document these actions. All documentation has been included in the case record. On July 5, 2018, the sectional SOP was revised to include more detail on properly documenting casework samples to be used as drug standards so that it is clear to all staff members.

Summary of Root Cause Analysis:

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

The procedure for removing marihuana from casework for use as in-house reference material is infrequently used. This was the first time the analyst had performed this task and she was not aware that the Drug Standard Quality Control Procedure was applicable. Although the sectional SOP refers to this type of reference material as an in-house sample, it was not clear that it included samples collected from casework. On July 5, 2018, the sectional SOP was revised to include more detail on properly documenting casework samples to be used as drug standards so that it is clear to all staff members.

Additional Information/Follow-Up:

The analyst consulted the section manager for guidance on obtaining marihuana for use as a reference material for Quality Control (QC) reagent checks since this type of material is not commercially available. The case related to this nonconformance was set for destruction but was received by the laboratory because the plant material needed to be dried. The manager authorized the analyst to take a portion of the plant material from this case as reference material. The analyst assumed that, because this sample would only be used for QC checks, all she needed to do was test the plant material. She did not consider this material to be a "drug standard". Drug standards are typically commercially purchased and used for in-house reference libraries for instrumental characterization. However, casework samples can be used as drug standards if properly characterized. This laboratory does not typically use instrumental characterization to identify marihuana. Therefore, the analyst performed the same non-instrumental testing methods used in casework to identify the substance. Per the SOP, drug standards must be characterized with an instrumental technique. When this nonconformance was discovered during the internal audit, the analyst responsible for maintaining the drug standards retested the sample under the specified criteria outlined in the SOP.

Section Manager: James Miller **Date:** 07/06/18

Division Director: Amy Castillo **Date:** 07/06/18

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

Technical Leader: N/A **Date:**

CODIS Administrator: N/A **Date:**

Quality Director: Lori Wilson **Date Closed:** 07/06/18