



Quality Division Use Only

Quality Tracking #:	2022-043	Classification:	Incident
Risk Level:	N/A	Section:	Seized Drugs
Date of Discovery:	06/03/22	Date of Incident:	04/20/20

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
N/A	N/A

Description of Non-conformance:

The Seized Drugs section used a more stringent acceptable range for their balance performance checks than what was required per their procedure.

Additional Information/Follow-Up:

The uncertainty of measurement (UM) for weight determinations is evaluated on an annual basis for all types of balances used in the Seized Drugs section. As part of this evaluation, the acceptable weight range for each balance and corresponding check weight is determined from these UM studies. The purpose of this acceptable weight range is to determine when a balance needs troubleshooting or needs to be taken out of service as part of the required monthly and/or weekly routine balance checks.

In 2015, the acceptable weight range values determined from the expanded UM values for the analytical and top-loading balances were 0.0005 g and 0.06 g respectively.

In 2016, the expanded UM for the analytical and top-loading balances decreased in value from the previous years which would have resulted in a decrease in the acceptable weight range values based on the wording in the SOP at that time. The SOP and the Balance Performance Check worksheet were revised to denote that the acceptable weight range values would be obtained from the historical expanded UM values. In this SOP revision the expanded UM values for 2014 and 2015 were larger than the 2016 calculated values, therefore, the word "largest" was also incorporated in both documents.

In 2017, an additional bulky balance was placed into service in the Seized Drugs section and was included in the annual evaluation of uncertainty of measurement. The expanded uncertainty values for the analytical, top-loading, and bulky balances were 0.0005 g, 0.06 g, and 0.002 kg, respectively. The corresponding acceptable weight range values adopted in the section were 0.0005 g, 0.06 g and 0.002 kg.

From 2017 through 2019, the expanded UM values and acceptable weight range values for the three balance types remained the same (0.0005 g, 0.06 g, and 0.002 kg).

In November 2019, the balances used in the Seized Drugs section were transferred from the previous facility at 1200 Travis to the new facility at 500 Jefferson. Prior to conducting casework analysis at 500 Jefferson, an



evaluation of the uncertainty of measurement was conducted on all balance types. The expanded UM values for the three balance types remained the same at 0.0005 g, 0.06 g, and 0.002 kg, therefore, the acceptable weight range values remained the same as well.

In 2020, the expanded UM for the analytical and top-loading balances increased in value (0.0006 g and 0.07 g) from the historical data while the value for the bulky balances remained 0.002 kg. Per the 2016 SOP requirement, the acceptable weight range in 2020 for both the analytical and top-loading balances should have been increased to include the new larger historic values, however, this modification was overlooked by the section. The section continued to use 0.0005 g and 0.06 g as the acceptable range values which actually provided a more stringent acceptable range than using the 0.0006 g and 0.07 g values would have provided.

In 2021, the expanded UM for the analytical and top-loading balances decreased back to the 0.0005 g and 0.06 g values, and the section continued to use these same values for the acceptable weight ranges.

In 2022, the expanded UM for the analytical and top-loading balances again increased in value (0.0006 g and 0.08 g). This increase was noted by the section, and the process of determining the acceptable range was reconsidered. While the SOP requirement to use the largest historical expanded UM to determine the acceptable range was intended to account for increases in variability over time, this approach is not an appropriate indicator for possible decreases in precision of the balances. In other words, if the acceptable weight ranges are allowed to increase, this could mask decreases in precision. It was decided that a more appropriate approach in determining the acceptable weight range values for all balance types would be to use the values for expanded UM obtained from the initial UM evaluation at the current facility performed in November 2019.

All performance checks conducted on the analytical and top-loading balances after moving to the 500 Jefferson facility (November 2019 through 2022) used the historical expanded UM values of 0.0005 g and 0.06 g, rather than the largest values. Therefore, neither the acceptable range values in the SOP nor for the performance check worksheet were updated as specified in the SOP.

The variation in the expanded UM values used from November 2019 through 2022 did not result in a technical impact because the values actually used for this period allowed for a more stringent acceptable range.

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:

The Seized Drugs SOP clause 6.7.6.5.2 was rephrased to clarify that the acceptable weight range for each balance type will be determined from the values for expanded UM obtained from the initial UM evaluation at the current facility.

The Balance Performance Check worksheet was re-named to the Expanded Balance Check Worksheet and modified to include the rephrasing of the determination of the acceptable weight range values.

The Seized Drugs SOP clause 6.7.6.5.2 and the Expanded Balance Check worksheet were discussed with the section at the November 17, 2023, meeting and both documents were issued with these changes on December 4, 2023.

Section Manager: James Miller

Date: 12/28/23

Division Director: Amy Castillo

Date: 01/05/24

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: Jackeline Moral

Date Closed: 01/05/24