# Corrective Action Response
# Documentation of Standards Verification

**Date of Incident:** Multiple. Identified February 15, 2022.

**Date of Corrective Action:** February 15, 2022 – April 11, 2022

**Description of Corrective Action(s) Taken:**

1. Previous SOPs were viewed to see if validating standards before being put into use was always a requirement. According to LOG-16 Standards, Controls, and Reagents section 3.1.3 and 3.1.3.1, even when the SOP was updated in January of 2021, the requirement remained the same.
   "3.1.3 All drug reference materials shall be verified before being put into use. If acceptable verification is not achieved the reference material may not be used in casework.
   3.1.3.1 Proof of verification shall be maintained with the date of verification and the reference material number."
2. All standards and/or reagents used in 2021 were identified.
3. The standard verification log was modified and implemented.
4. All identified standards and/or reagents were logged using the new standard verification log, LAB-LOG-40.
5. One designated individual will be verifying all incoming standards for the time being.

**Laboratory Number(s) (if applicable):** Multiple cases were affected by this documentation error, yet the outcome of the cases should not have been impacted. In order to report a drug at the time, SOP CS-19 GC/MS Drug Identification section 7.1.5 states that a match from both the total ion chromatogram from the mass spectroscopy and the retention time from gas chromatography were required. Instead of verifying the standard prior to analysis, it was verified at the time of analysis with no separate documentation.

"7.1.5 A drug is qualitatively identified if:
7.1.5.1 The mass spectrum of the unknown matches the spectral pattern found in the MS library with a minimum quality match of 50%; and
7.1.5.2 The retention time of the unknown matches the retention time of the Reference Material within ± 2%, or 0.2 minutes, whichever is greater.
7.1.5.2.1 Reference Materials should be run on the GC/MS within one week of the sample in order to be used as a viable comparison, so long as instrument parameters have not been altered."

Three groups of standard and/or reagents were identified. The first group is comprised of 12 standards and reagents used in casework in which no documentation was recorded. The

second group is comprised of standards used to make a standard mixture in which each standard was not verified first. The third group is comprised of standards and reagents that were properly recorded. Proper documentation was recorded for the first two groups. No action was necessary for the third group. See attached spreadsheet prepared by A. Tijerina.

I. Standards used in casework in which no documentation was recorded, including no original printout and not logged in the book.

| | | |
|---|---|---|
| R-19-035 | S-19-065 | S-21-019 |
| R-21-009 | S-19-076 | S-21-027 |
| S-17-036 | S-20-009 | S-21-029 |
| S-19-061 | S-21-016 | S-21-033 |

II. Standards in a CS Mix which were not individually verified before making the CS Mix.

| | | |
|---|---|---|
| S-19-008 | S-19-033 | S-21-008 |
| S-19-022 | S-19-058 | S-21-009 |
| S-19-023 | S-20-003 | S-21-013 |
| S-19-024 | S-20-047 | |

III. Standards that were properly recorded.

| | | |
|---|---|---|
| R-17-049 | S-18-013 | S-20-018 |
| R-18-062 | S-19-007 | S-20-019 |
| R-19-012 | S-19-010 | S-20-020 |
| R-19-019 | S-19-040 | S-20-030 |
| R-19-027 | S-19-043 | S-21-010 |
| R-19-029 | S-19-059 | S-21-012 |
| R-20-008 | S-19-073 | S-21-014 |
| R-20-043 | S-20-006 | S-21-017 |
| R-21-003 | S-20-008 | S-21-020 |
| R-21-004 | S-20-010 | S-21-034 |
| R-21-028 | S-20-016 | |
| S-18-006 | S-20-017 | |

**Comment(s):** This form was used in the interim while our Standard Operating Procedures (SOPs) are being revised. Under the proposed SOPs going forward, this would be considered an incident, and an incident form completed.

**Date of Resolution:** April 11, 2022

SD — 05/18/22
Applicable Analyst / Discipline — Date

Seized Drugs — 5/18/22
Applicable Analyst / Discipline — Date

18 May 2022
Lab Quality Manager — Date

18 May 22
Laboratory Director — Date