

## Incident / Corrective Action Plan Form Chemical Re-Verification

**Incident/Corrective Action Number:** 2024-03

**Date of Discovery:** March 21, 2024

**Incident Date(s):** 01/31/2024 - 03/21/2024

**Section:** Seized Drugs

**Reported By:** Laboratory Director

**Classification:** Corrective Action

**Incident Type:** Procedural

**Description of Non-Conformity:**

An analyst brought to the Laboratory Director's attention at the beginning of January that the Formaldehyde chemical was due to be reverified that month. A mental note was made but forgotten. The Laboratory Director, who also serves as the Seized Drugs section leader, failed to remember to re-verify the chemical, and the other analysts did not catch that the Formaldehyde being used was past the retest date.

LOG-16-08 Standards, Controls, and Reagents

*"3.3.3 Reagents, stock solutions, reference material dilutions and chemicals used in the Laboratory shall be re-verified when it has exceeded its shelf life according to the guidelines in 3.5.2. Each shall be determined to still be suitable for its intended purpose. Upon successful re-verification, any material past the manufacturer's expiration may only be used for research and training purposes. Material used in casework cannot be expired. If acceptable re-verification is not achieved, the reagent or solution may not be used.*

*3.3.4 Reagents used for presumptive testing shall be verified the first business day of each month using positive and negative control samples. A Reagent Verification Log Book shall be maintained. Reagents used for extraction shall be evaluated using appropriate analytical methodology."*

When the laboratory director went to reverify the Formaldehyde (C-23-0004), two other solutions not associated with seized drug analysis were found to be out of date. 1-Propanol (C-20-0040A) was expired, and 2-Propanol (C-19-0048) was past its reverification date.

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The same issue of using expired chemicals or chemicals which were past their reverification date was previously addressed and resolved in correction actions 2022-03 and 2022-04.

### **Root Cause Analysis:**

Due to the small nature of the laboratory, many responsibilities are shared between different laboratory personnel. The laboratory director has been mainly functioning as the lead seized drug analyst to assist with the backlog of casework while also maintaining his managerial obligations. One of the outcomes of the previously addressed related corrective actions included implementing a new spreadsheet, which has taken some getting used to. Having to go back and forth between the old and new inventory sheets has decreased the lead analyst's situational awareness. Until the caseload decreases to be able to be fully attentive to other aspects of analysis or additional personnel are added, the possibility of overlooking certain aspects continues.

### **Level of Non-Conformity: III**

### **Level of Non-Conformity Determination and its Impact on Casework:**

The Formaldehyde was tested in the monthly meth standard spot test in February and March. There was the expected color reaction in the standard and no color reaction in the blank. Because presumptive testing is a huge part of the identification scheme, the expired formaldehyde will have indirect implications on casework. However, the identification of the unknown does not solely rest on presumptive test results. Laboratory policy dictates that an acceptable presumptive test is combined with a positive confirmatory test in order to identify an unknown. Due to the perceived right answer when the marquis reagent (of which formaldehyde is a key component) was tested before casework samples, it does lessen the severity of the chemical being expired.

Both 1-Propanol and 2-Propanol are not used in casework for seized drugs analysis. 1-Propanol is a blood alcohol solvent but was never used. 2-Propanol is a blood drug solvent. Due to the laboratory not currently performing blood drug analysis, the solvent was only being used for cleaning purposes.

### **Preventive Action(s): N/A**

### **Proposed Corrective Action(s):**

1. Assign a designated analyst to go through the inventory spreadsheet once a month, identify everything that is expiring within roughly 31 days, and notify all laboratory personnel of what is about to expire and when.
2. Re-verify identified expired or past re-test date chemicals using GC/MS analysis.

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3. Order new stock solutions.
4. Dispose of expired materials.
5. The Seized Drugs section will begin having monthly meetings to discuss such things, such as what is about to expire.

**Timeframe for Corrective Action(s):**

Mayla M. Bayle / seized drugs 5/3/2024

Applicable Analyst / Discipline

Date

Gidi Ild Seized Drugs

05/03/24

Applicable Analyst / Discipline

Date

Allin Hunt

9 May 2024

Lab Quality Manager

Date

Derek Skrz

09 May 2024

Laboratory Director

Date