# Incident / Corrective Action Plan Form
## Internal Audit Nonconformance

**Incident/Corrective Action Number:** 2023-05

**Date of Discovery:** August 8, 2023

**Incident Date(s):** May 30, 2023

**Section:** Seized Drugs

**Reported By:** Quality Manger/Laboratory Director

**Classification:** Corrective Action

**Incident Type: Other** - Nonconformance with Guidance Document ISO/IEC 17025:2017 – Section 8.8.2 - Internal Audits (Implementation of Corrective Action without Undue Delay)

**Description of Non-Conformity:**
At the closing meeting of the 2023 ANAB on-site assessment of the Brazoria County Sheriff's Office Crime Laboratory, a nonconformance was noted that dealt with Guidance Document ISO/IEC 17025:2017 - Section 8.8.2 – Internal Audits. Specifically, the Internal audits performed for the 2022 and 2023 Laboratory accreditation cycle identified multiple nonconformance's. These nonconformance's were documented within the 2022 and 2023 Laboratory Internal audits but were not taken any further than documentation. These nonconformance's should have been addressed with undue delay once the issues were identified in the Laboratory's Internal audit.

**Root Cause Analysis:**
Guidance document ISO/IEC 17025:2017 section 8.8.2, subsection "d" speaks to implementing appropriate correction and corrective actions without undue delay once an audit is concluded. Although Laboratory management understood the gravity of each nonconformance identified in the Internal audit, no prompt action was taken to remedy the nonconformance's. This ultimately means that there was a lack of sufficient understanding of the Internal audit process by management. Management assumed that simply identifying the nonconformance's in the audit completed the task without connecting the dots to realize that additional steps needed to be taken to mitigate the nonconformance's identified.

**Level of Non-Conformity:** II

**Level of Non-Conformity Determination and its Impact on Casework:**
This nonconformity deals with how the issues identified by the 2022 and 2023 Internal audits were interpreted by management. Misinterpretation of the duties required by management once the Internal audits were completed allowed the nonconformance's to linger on the books without resolution. Several of the nonconformance's identified were clerical in nature while others are procedural and traceable back to the analyst's understanding of relevant standard operating procedures, safety protocols, and ethical obligations. Although the non-action by management to address the finding of the Internal audit is one attribute, this cannot be separated from the severe nature of several of the nonconformance's identified. The nonconformance's run the gamut from one-time occurrences without any direct effect on casework to random occurrences with direct effect on casework. Therefore, this nonconformity will be graded a level II.

**Preventive Action(s):**
Not applicable

**Proposed Corrective Action(s):**
1. Rereading ISO/IEC 17025:2017 Guidance document and the ANAB supplemental document AR-3125:2023 by management with concentration on the corrective action process and auditing requirements.

2. Additionally, the BCCL Laboratory Operations Guide - LOG 12.04 (Internal Audits) will be modified to reflect the new approach to fulfilling all obligations of the internal audit including resolving any nonconformance(s) identified by the audit.

3. Finally, all nonconformances documented in 2023 Laboratory Internal Audit will be reviewed. For those nonconformances rising to the level of a corrective action, the nonconformances will be documented using the approved Laboratory corrective action forms.

**Timeframe for Corrective Action(s):**
Sixty days from August 8, 2023

Lab Quality Manager

30 Nov. 2023
Date

Laboratory Director

06 Oct 2023

Date