Incident / Corrective Action Plan Form
Effectiveness of Corrective Action

Incident/Corrective Action Number: 2023-04

Date of Discovery: August 8, 2023

Incident Date(s): Multiple throughout 2022 and 2023

Section: Applicable to all sections of the Laboratory

Reported By: Quality Manager/Laboratory Director

Classification: Corrective Action

Incident Type: Other - Nonconformance with Guidance Document Section ISO/IEC 17025:2017 – Section 8.7.1 – Corrective Actions (Effectiveness of Corrective Action)

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 8.7.1 - Corrective Actions. Specifically, the corrective action process in effect at the time did not adequately address the effectiveness of a corrective action implementation. The form used to document the corrective action only contained sections that documented incident date, date of corrective action, description of the corrective action(s) taken, laboratory cases affected, date of resolution, and a comment section. There was not a section to evaluate whether the corrective action(s) taken were successful or if additional actions were needed. As a result, a nonconformance documented through that corrective action process may not have highlighted if the actions taken to remedy the nonconformance had been satisfactory.

Root Cause Analysis:
Guidance document ISO/IEC 17025:2017 section 8.7.1, subsection "d" speaks to reviewing the effectiveness of any corrective action taken. Laboratory management took this comment to mean that the nonconformance addressed through the corrective action process only needed to document and describe the steps taken to resolve the nonconformance. As long as the nonconformance was resolved and the steps taken towards that resolution were documented, laboratory management deemed this sufficient. Essentially, laboratory management did not fully appreciate section 8.7.1, subsection "d"

of the guidance document and therefore did not apply the principle outlined in section 8.7.1, subsection "d" to its full extent.

Level of Non-Conformity: I

Level of Non-Conformity Determination and its Impact on Casework:
This nonconformity deals with how the corrective action response was documented during the Laboratory's accreditation yearly cycle. Because this nonconformance speaks to only the corrective action process, there was no impact on casework.

Preventive Action(s):
Not applicable

Proposed Corrective Action(s):

1. The corrective action process will be changed to better characterize a nonconformance. BCCL Laboratory Operations Guide - LOG 19.05 (Quality Action Plan) will be modified to reflect the new approach to identifying and reporting a nonconformance. The corrective action process will be divided into two parts – a corrective action plan (documents the nonconformance, its root cause, extent of its effect on casework, proposed remedies, and a time frame for correction) and a corrective action response (documents the corrective action(s) taken and the effectiveness of the corrective action(s)).

2. Additionally, new forms will be created to document the nonconformance, a Corrective Action Plan (LOG-19-03-A) and a Corrective Action Response (LOG-19-03-B).

3. Finally, all nonconformances documented through the corrective action process in 2022 and 2023 will be reviewed. For those nonconformances rising to the level of a corrective action, the nonconformances will be amended using the new forms to better highlight the root cause analysis, the impact on casework, and the effectiveness of the process.

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

Lab Quality Manager — Date: 20 Nov. 2023

Laboratory Director — Date: 06 Oct 2023

Approval Date: September 25, 2023
Effective Date: October 2, 2023

Issuing Authority: Upper Management
Authorized for Distribution by Laboratory Director