Incident / Corrective Action Plan Form
Root Case Nonconformance

Incident/Corrective Action Number: 2023-03

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 ISO/IEC 17025:2017 - Section 8.7.1 – Corrective Actions (Root Cause Analysis)

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 root cause analysis. The form used to document the corrective action only contained sections that documented incident date, incident type, incident description, proposed corrective action, timeframe for corrective action, and a comment section. There was not a section to delineate the root cause analysis of the nonconformance. As a result, analysis of an observed non-conformance may not have discovered the root cause(s) of the issue in order to identify appropriate solutions and to prevent similar events from happening again.

Root Cause Analysis:
In the 2022 ANAB Surveillance Document review of the Brazoria County Sheriff's Office Crime Laboratory, a conforming with comment was noted. The comment was as follows – the forensic service provider would benefit from having a delineated section in their Corrective Action forms that specifically addresses the Root Cause Analysis. Laboratory management took this comment with due diligence and held several meetings to outline a reworking of the corrective action process and forms. However, as the Laboratory was dealing with other issues that arose throughout the year, the reworking of the process and forms never materialized. Issues that hindered the fulfillment of

this obligation included self-disclosure filings with the Texas Forensic Science Commission that were pertinent to the continued operations of the Laboratory, an overhaul of the Seized Drug standard operating procedures, a total reworking of the Laboratory's Safety manual, and staffing levels that prevented full investment into all areas needing direct attention of management. As preparation increased during late spring/early summer for the upcoming on-site ANAB assessment inspection in August, attention again turned to the reworking of the process and forms; however, time simply expired before the process was addressed.

Level of Non-Conformity: I

Level of Non-Conformity Determination and its Impact on Casework:
This nonconformity deals with how the corrective action process 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-19-04-A) and a Corrective Action Response (LOG-19-04-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