Deviation from Documented Procedures for Signatures Acknowledging Revisions to the Laboratory Operations Guide

Dates of Deviation: TBD

Type of Deviation: Signature Requirements for LOG-19-06 (Quality Action Plan)

Describe the Deviation:
The Crime Laboratory normally uses a digital document management system (PowerDMS) to acknowledge the revision of the Laboratory Operations Guide by Laboratory staff. Due to Laboratory Director not having access to this system, this deviation will be used to record the signatures of the Laboratory staff. The Quality Manager is on leave and cannot acknowledge revisions to the Laboratory Operations Guide. The revision to LOG-19-06 will go into effect once all staff have signed this deviation to exclude the Quality Manager. The Quality Manager shall acknowledge the revision on their return from leave. Once all signatures have been recorded, this deviation shall be digitized and included within the controlled document files.

LOG-17-04 Document Management
"4.6 All laboratory personnel shall be responsible for:
4.6.1 Reading and acknowledging the existence of new/revised policies and procedures"

BCCL Quality Manual 8.3.2 Document Issuance and Maintenance
"8.3.2.4 CHANGES TO ELECTRONICALLY STORED DOCUMENTS… Staff shall be notified when revised and updated documents become available…. Personnel shall be responsible for verifying that they are using and following current policies…."

Reason for Deviation: Due to leave on the part of the Quality Manager, access to the digital document management system has been disrupted until their return.

Laboratory Number(s) (if applicable): Not applicable.

Evidence Technician	Date: 9.21.2023
Analyst	Date: 9/21/2023
Analyst	Date: 9/21/23
Analyst	Date: 9/22/23
Laboratory Director	Date: 21 Sept 2023
Quality Assurance Manager	Date: 20 Nov. 2023

Approval Date: November 30, 2021
Effective Date: November 30, 2021

Issuing Authority: Upper Management
Authorized for Distribution by Laboratory Director

Quality Action Plan

1.0 Scope

1.1 This document addresses the process for assessing potential Laboratory nonconformances or problems, deficiencies, and/or work product of an unacceptable quality, and shall address initiating, implementing, and checking the effectiveness of corrective actions or quality improvements.

1.1.1 The purpose of corrective action is to bring about continuous improvement; immediate resolution of incorrect results; remediation of its effect(s) on similar work, if appropriate; and minimize recurrence.

2.0 Responsibility

2.1 Due to the limited staff of Brazoria County Crime Laboratory, more than one of the functional responsibilities below may at times be held by one individual.

2.1.1 Laboratory Director is responsible for:

- Assisting in the assessment of the significance and root cause of a nonconformance or problem and notification of customers, if warranted
- Reviewing and approving proposed quality action plans and corrective actions
- Implementing and/or assisting in the implementation of corrective action procedures
- Ensuring that corrective actions are implemented within a reasonable timeframe
- Determining the final resolution of each nonconformance or problem
- Periodically monitoring the effectiveness of corrective action and recording observations as part of the annual Management Review

2.1.2 Quality Manager is responsible for:

- Investigating and documenting each nonconformance or problem, including performing a root cause analysis, assessing the significance of a nonconformance or problem with respect to related casework and, if warranted, notifying customers
- Developing quality action plans and proposing corrective action plans, as necessary, to address a nonconformance or problem and to prevent recurrence
- Documenting remedial actions and subsequent evaluations of analyst competency

2.1.3 Analyst is responsible for:

- Identifying and reporting nonconformances or problems to the Quality Manager and/or Laboratory Director
- Cooperating in the investigation and resolution of each nonconformance or problem, including evidence reexamination and remedial training, as required

3.0 Practice

3.1 Investigation

3.1.1 When a nonconformance or problem is suspected, the Quality Manager and/or Laboratory Director shall be notified immediately or as soon as practicable, and a corrective action plan be implemented.

3.1.1.1 The Quality Manager shall use the Corrective Action Plan (CAP) Form (LOG-19-XX-A) to document the nonconformance or problem, including but not limited to the date of occurrence, classification, description of the nonconformance or problem, the root cause analysis, the significance of the issue, its impact on casework, if any, and to propose the necessary corrective action.

3.1.1.1.1 Classification is broken down into incident and corrective action. An incident is classified as a nonconformance which is an initial occurrence and does not affect work product. A corrective action is a nonconformance in which corrective action is needed and may or may not affect work product.

3.1.1.1.1.1 If classified as a corrective action, the significance or level of non-conformity will be determined. The levels are as follows:

I. A nonconformance in which an initial occurrence is repeated. Work product is not affected.

II. A nonconformance in which corrective action is needed. Work product may have been affected.

III. A nonconformance in which corrective action is needed in regards to a serial issue. Work product was affected.

3.1.1.2 The Quality Manager shall use the Corrective Action Response (CAR) Form (LOG-19-XX-B) to document the corrective action, including the description of the corrective action(s) taken, date of resolution of the corrective action, and to evaluate the effectiveness of the resolution of the action.

3.2 Root Cause Analysis

3.2.1 The Quality Manager or designee shall examine all documents and records associated with the nonconformance or problem to determine the significance with respect to related casework and to identify specific root causes of the nonconformance or problem. Cause determination is important to detect and correct systemic problems. The Cause and Effect Map (LOG-19-00-C) may be utilized to determine the policy and/or procedure that could have resulted in the need for a corrective action.

3.2.2 The Laboratory Director may suspend casework for analytical testing until he/she is assured the nonconformance or problem has been resolved and future occurrences shall be avoided. Suspension of casework and an audit of related cases may be required if the nonconformance or problem is related to:

- An analyst's casework or proficiency testing;
- A particular method, instrument, or reagent; or
- Environmental factors.

3.3 Corrective Action

3.3.1 The Quality Manager or designee investigating the root cause shall propose a corrective action plan to address the nonconformance or problem and to prevent its recurrence. Both interim and long-term resolutions shall be reviewed to ensure both immediate containment and permanent resolution of the nonconformance or problem.

3.3.2 The Quality Manager shall submit the corrective action plan to the Laboratory Director for review and approval. If the corrective action plan is not approved by the Laboratory Director, then the Quality Manager shall amend the plan and resubmit it until a satisfactory proposal is achieved.

3.3.3 Final resolution of the nonconformance or problem shall be determined by the Laboratory Director.

3.4 Customer Notification

3.4.1 Notification may be issued to the relevant customers, the Texas Forensic Science Commission, and ANAB, as appropriate. Depending on the nature and extent of the nonconformance or problem, the customer may be notified in writing.

3.4.1.1 Significant nonconformances or problems shall trigger the notification of all customers and/or accreditation bodies. Significant nonconformances include, but are not limited to, gross negligence or criminal acts committed by employees or recurring/critical failures.

3.4.1.1.1 Notifications shall be disclosed within 30 calendar days of the occurrence. If the event or nonconformity is identified more than 30 days after the occurrence, it shall be disclosed as soon as possible.

3.4.1.2 If reexamination is necessary and a Laboratory report has already been issued, then an amended or supplemental report shall be issued which identifies the affected samples, results, and opinions.

3.4.1.3 If no Laboratory report has yet been issued, then it is not necessary to notify the customer of additional work or technical issues, so long as they are fully resolved prior to reporting.

3.5 Corrective Action Completion

3.5.1 Corrective action shall be completed in an appropriate timeframe, based on an assessment of the significance and/or root cause of the nonconformance or problem.

3.5.1.1 If corrective action cannot be completed within a reasonable timeframe, then additional steps to remediate the deficiency shall be determined and documented using the corrective action response (CAR) form.

3.5.1.2 New timeframes for completion and/or a new follow-up plan may be necessary to verify compliance and/or satisfactory correction.

3.5.2 All corrective actions shall be documented with sufficient detail to ensure that the nature of the nonconformance or problem and the resolution are described.

3.5.3 Effectiveness of corrective action(s) taken shall be reviewed at a later date.

4.0 Records

4.1 Corrective Action Plan (CAP) form

4.2 Corrective Action Response (CAR) form

Date	Section	Previous	Changed to	Reason	By whom
01.14.19	2.1.3	Identifying and reporting nonconformances or problems to the technical leader and Laboratory management	Identifying and reporting nonconformances or problems to the Quality Manager and/or Laboratory Director	Altered to coincide with current laboratory procedures	HB/PVD
11.30.21	Footer	Approval Date: January 28, 2019 Issuing Authority: Upper Management Effective Date: January 28, 2019 Authorized for Distribution by Paul Van Dorn	Approval Date: November 30, 2021 Issuing Authority: Upper Management Effective Date: November 30, 2021 Authorized for Distribution by Laboratory Director	Altered to coincide with current laboratory staffing	AW/DS
06.26.23	Body		3.4.1.1.1 Notifications shall be disclosed within 30 calendar days of the occurrence. If the event or nonconformity is identified more than 30 days after the occurrence, it shall be disclosed as soon as possible.	Altered to coincide with current accreditation guidelines: shared files are no longer kept on the P Drive	AW/DS
	Footer	THIS DOCUMENT IS CONSIDERED UNCONTROLLED IF PRINTED OR NOT VIWED ON THE "P:\Controlled Documents" FOLDER	Uncontrolled when printed.		
08.22.23	3.1.1.1	The Quality Manager shall use the Corrective Action Plan (CAP) Form (LOG-19-01-A) to document the nonconformance or problem, including the date of occurrence, area(s) of impact, and individual(s) involved, and to propose the necessary corrective	The Quality Manager shall use the Corrective Action Plan (CAP) Form (LOG-19-XX-A) to document the nonconformance or problem, including but not limited to the date(s) of occurrence, area(s) of impact, classification,	Added to coincide with form changes and current accreditation guidelines.	AW/DS

		action.	significance of nonconformance or problem, root cause analysis, and to propose the necessary corrective action.		
	3.1.1.1.1		Classification is broken down into incident and corrective action. An incident is classified as a nonconformance which is an initial occurrence and does not affect work product. A corrective action is a nonconformance in which corrective action is needed and may or may not affect work product.		
	3.1.1.1.1.1		If classified as a corrective action, the level of non-conformity will be selected. The levels are as follows: I. A nonconformance in which an initial occurrence is repeated. Work product is not affected. II. A nonconformance in which corrective action is needed. Work product may have been affected. III. A nonconformance in which corrective action is needed in regards to a serial issue. Work product was affected.		
	3.1.1.2	The Quality Manager shall use the Corrective Action Response (CAR) Form	The Quality Manager shall use the Corrective Action Response (CAR)		

		(LOG-19-00-B) to document the corrective action, including the timeframe for completion, and evaluate the resolution of the incident.	Form (LOG-19-XX-B) to document the corrective action, including the timeframe for completion, and evaluate the resolution of the incident.		
	3.5.3		Effectiveness of corrective action(s) taken shall be reviewed at a later date.		
09.19.2023	3.1.1.1	The Quality Manager shall use the Corrective Action Plan (CAP) Form (LOG-19-XX-A) to document the nonconformance or problem, including but not limited to the date(s) of occurrence, area(s) of impact, classification, significance of nonconformance or problem, root cause analysis, and to propose the necessary corrective action.	The Quality Manager shall use the Corrective Action Plan (CAP) Form (LOG-19-XX-A) to document the nonconformance or problem, including but not limited to the date of occurrence, classification, description of the nonconformance or problem, the root cause analysis, the significance of the issue, its impact on casework, if any, and to propose the necessary corrective action.	Added to coincide with form changes and current accreditation guidelines.	DS
	3.1.1.1.1.1	If classified as a corrective action, the level of non-conformity will be selected. The levels are as follows:	If classified as a corrective action, the significance or level of non-conformity will be determined. The levels are as follows:		
	3.1.1.2	The Quality Manager shall use the Corrective Action Response (CAR) Form (LOG-19-XX-B) to document the corrective action, including the	The Quality Manager shall use the Corrective Action Response (CAR) Form (LOG-19-XX-B) to document the corrective action,		

		timeframe for completion, and evaluate the resolution of the incident.	including the description of the corrective action(s) taken, date of resolution of the corrective action, and to evaluate the effectiveness of the resolution of the action.		