Deviation from Documented Procedures for Signatures Acknowledging Revisions to the Laboratory Toxicology Forms Section (LAB-TOX)

Dates of Deviation: TBD

Type of Deviation: Signature Requirements for LAB-TOX-11-00 (Validation_BAC)

Describe the Deviation:

The Crime Laboratory normally uses a digital document management system (PowerDMS) to acknowledge additions to the Laboratory Toxicology Forms Section (LAB-TOX) by Laboratory staff. The Laboratory Director is on leave and cannot acknowledge the newest addition to the Laboratory Toxicology Forms Section. LAB-TOX-11-00 Validation _BAC will go into effect once all staff have signed in PowerDMS to exclude the Laboratory Director, who 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: The Laboratory Director is on leave and had previously approved the validation packet, which can be viewed by his signature on the original validation packets for both instruments BAC-1 and BAC-2. However, the template had not been added to the standard operating procedures at that time. A document identifier and the appropriate headers and footers were added to the template and uploaded to PowerDMS.

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

Analyst

Moline Henry

Analyst

Quality Assurance Manager

Laboratory Director

11/21/2023 Date

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Date

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Date

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

Issuing Authority: Upper Management Authorized for Distribution by Laboratory Director