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

Dates of Deviation: TBD

Type of Deviation: Signature Requirements for LOG-12-05 (Internal Audits)

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-12-05 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.

Summer S Wargo — Evidence Technician — 10.6.23 — Date

Seth Dodd — Analyst — 10/6/23 — Date

Melissa Henry — Analyst — 10/6/2023 — Date

Kayla M. Bayer — Analyst — 10/6/2023 — Date

Laboratory Director — 06 Oct 2023 — Date

Quality Assurance Manager — 20 Nov. 2023 — Date

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

Issuing Authority: Upper Management
Authorized for Distribution by Laboratory Director

Internal Audits

1.0 Scope

1.1 To verify that Laboratory operations are in compliance with internal policies, procedures, and accreditation criteria, an internal audit of the Brazoria County Crime Laboratory shall be conducted on an annual basis.

2.0 Responsibility

2.1 Due to the limited staff of BCCL, more than one of the functional responsibilities below may be held by one individual.

2.1.1 Quality Manager is responsible for:

- Preparing and publishing an audit schedule
- Coordinating and conducting an annual internal audit
- Documenting the findings of the annual internal audit
- Conducting and documenting other inspections of the Laboratory
- Documenting the internal audit summary report
- Preparing Laboratory responses to findings of the internal audit, resolving issues, and developing corrective action plans/ responses, if applicable

2.1.2 Auditor is responsible for:

- Assisting with the execution of audits
- Reviewing documentation and resources with regards to applicable criteria
- Direct observation of relevant testing and/or personnel
- Preparing reports of findings and observations

2.1.3 Laboratory Director is responsible for:

- Reviewing and approving the findings of the annual internal audit
- Reviewing and approving Laboratory responses to findings of the internal audit and any corrective action plans/responses, if applicable
- Providing final resolution to issues
- Coordinating the ANAB annual surveillance visit for the Laboratory

3.0 Practice

3.1 Audit

3.1.1 To determine compliance with Laboratory policy as well as accreditation criteria, prior to the audit, auditors shall devise a plan on what should be assessed. At a minimum, the plan should include the following:

- The previous internal audit

- Quality assurance records, including the most current Quality Manual
- The proficiency testing program and associated records
- Laboratory safety and security measures
- Evidence handling procedures
- Evidence storage
- A selection of completed cases from each analyst in each discipline for which case work is conducted
- Direct observation of relevant testing and/or personnel
- Compliance with ISO/IEC 17025 and ANAB Criteria

3.2 Any noted compliance issues with documented procedures shall cite the specific criteria or procedure violated; objective evidence of the violation; where the violation affected casework; and case number(s).

3.3 Documentation

3.3.1 Documentation may include an audit checklist, recommendation letter, and/or case review letter, depending on the nature of the audit.

3.3.2 Internal audit summary reports shall be prepared and distributed to concerned parties.

4.0 Records

4.1 Internal audit summary report

4.2 Response(s) to internal audit summary report

Date	Section	Previous	Changed to	Reason	By whom
11.06.17	Body	Will	Shall	Altered to coincide with current laboratory terminology	HB/PVD
11.06.17	1.1	The Brazoria County Crime Laboratory will be audited annually.	To verify that Laboratory operations are in compliance with internal policies, procedures, and accreditation criteria, an internal audit of the Brazoria County Crime Laboratory shall be conducted at least annually, and before the annual surveillance activity by ANAB.	Altered to coincide with current laboratory terminology	HB/PVD
11.06.17	2.1.1	Laboratory Director is responsible for: • Facilitating and coordinating an annual internal audit, management system review, and ASCLD/LAB surveillance visit for the laboratory • Preparing and publishing a schedule for the annual audit of the laboratory to take place during the last quarter of the calendar year • Documenting the audit summary report and submitting the Annual Report to ASCLD/LAB • Providing final resolution to issues	Quality Manager is responsible for: • Preparing and publishing an audit schedule • Coordinating and conducting an annual internal audit • Documenting the findings of the annual internal audit • Conducting and documenting other inspections of the laboratory • Documenting the internal audit summary report • Preparing laboratory responses to findings, resolving issues, and developing corrective action plans/responses, if applicable	Altered to coincide with current laboratory procedures	HB/PVD
11.06.17	2.1.2	Auditor/Inspector is responsible for: • Assisting with the execution of audits • Reviewing documentation and facility with reference to applicable standards • Interviewing personnel • Preparing reports of findings and observations	Auditor is responsible for: • Assisting with the execution of audits • Reviewing documentation and resources with regards to applicable criteria • Direct observation of relevant testing and/or personnel • Preparing reports of findings and observations	Altered to coincide with current laboratory procedures	HB/PVD
11.06.17	2.1.3	Quality Manager is responsible for: • Conducting and documenting an annual internal audit • Conducting other inspections of the laboratory • Preparing laboratory responses to findings, resolving issues, and developing action plans to both internal and external audit reports	Laboratory Director is responsible for: • Reviewing and approving the findings of the annual internal audit • Reviewing and approving laboratory responses to findings and corrective action plans/responses, if applicable • Providing final resolution to issues • Coordinating the ANAB annual surveillance visit for the Laboratory	Altered to coincide with current laboratory procedures	HB/PVD
11.06.17	3.1.1	Auditors may audit the following, to include, but not limited to:	To determine compliance with laboratory policy as well as accreditation criteria, auditors shall assess the following (to include, but	Altered to coincide with current laboratory	HB/PVD

			not limited to):	procedures	
11.06.17	3.1.1.1 3.1.1.2 3.1.1.3 3.1.1.4 3.1.1.5 3.1.1.6	A minimum of three case folders from each analyst in each discipline for which case work is conducted to determine compliance with laboratory standard operating procedures. Quality assurance records, including the most recent Quality Manual Laboratory safety and security measures Evidence handling procedures Evidence storage Compliance with ASCLD/LAB ISO/IEC 17025:2005 and ASCLD/LAB Supplemental Requirements (2011)	• A selection of completed cases from each analyst in each discipline for which case work is conducted • Quality assurance records, including the most current Quality Manual • Laboratory safety and security measures • Evidence handling procedures • Direct observation of relevant testing and/or personnel • Evidence storage • Compliance with ISO/IEC 17025 and ANAB Criteria	Altered formatting and to coincide with current laboratory procedures	HB/PVD
11.06.17	3.1.1	N/A	• The proficiency testing program and associated records • Direct observation of relevant testing and/or personnel	Added to coincide with current laboratory procedures	HB/PVD
11.06.17	3.2	Any noted compliance issues with documented procedures will cite the specific criteria violated; objective evidence of the violation; where the violation affected casework and case number.	Any noted compliance issues with documented procedures shall cite the specific criteria or procedure violated; objective evidence of the violation; where the violation affected casework; and case number(s).	Altered to coincide with current laboratory procedures	HB/PVD
11.06.17	3.3.1 3.3.2	Documentation may include the ASCLD/LAB ISO Field Assessment Guide for Testing Laboratories, the ASCLD/LAB ISO Electronic Conformance File for Testing Laboratories, an internal checklist, recommendation letter, and/or case review letter, depending on the nature of the audit. Final audit reports shall be prepared and distributed to concerned parties.	Documentation may include an audit checklist, recommendation letter, and/or case review letter, depending on the nature of the audit. Internal audit summary reports shall be prepared and distributed to concerned parties	Altered to coincide with current laboratory procedures	HB/PVD
11.06.17	4.1 4.2	Final audit reports Responses to the final audit report	Internal audit summary report Response(s) to internal audit summary report	Altered to coincide with current laboratory procedures	HB/PVD
11.30.21	Footer	Approval Date: November 6, 2017 Issuing Authority: Upper Management Effective Date: November 6, 2017 Authorized for Distribution by Paul	Approval Date: November 30, 2021 Issuing Authority: Upper Management Effective Date: November 30, 2021 Authorized for Distribution by	Altered to coincide with current laboratory	AW/DS

		Van Dorn	Laboratory Director	staffing	
08.08.23	1.1 3.1.1	To verify that Laboratory operations are in compliance with internal policies, procedures, and accreditation criteria, an internal audit of the Brazoria County Crime Laboratory shall be conducted at least annually, and before the annual surveillance activity by ANAB. To determine compliance with Laboratory policy as well as accreditation criteria, auditors shall assess the following (to include, but not limited to): •Quality assurance records, including the most current Quality Manual •The proficiency testing program and associated records •Laboratory safety and security measures •Evidence handling procedures •Evidence storage •A selection of completed cases from each analyst in each discipline for which case work is conducted •Direct observation of relevant testing and/or personnel •Compliance with ISO/IEC 17025 and ANAB Criteria	To verify that Laboratory operations are in compliance with internal policies, procedures, and accreditation criteria, an internal audit of the Brazoria County Crime Laboratory shall be conducted on an annual basis. To determine compliance with Laboratory policy as well as accreditation criteria, prior to the audit, auditors shall devise a plan on what should be assessed. At a minimum, the plan should include the following: •The previous internal audit •Quality assurance records, including the most current Quality Manual •The proficiency testing program and associated records •Laboratory safety and security measures •Evidence handling procedures •Evidence storage •A selection of completed cases from each analyst in each discipline for which case work is conducted •Direct observation of relevant testing and/or personnel •Compliance with ISO/IEC 17025 and ANAB Criteria	Altered to coincide with accreditation standards.	AW/DS
08.08.23	Footer	THIS DOCUMENT IS CONSIDERED UNCONTROLLED IF PRINTED OR NOT VIEWED ON THE "P:\Controlled Documents" FOLDER	Uncontrolled when printed.	Shared files are no longer kept on the P Drive.	AW/DS
10/02/2023	2.1.1	Quality Manager is responsible for: • Preparing and publishing an audit schedule • Coordinating and conducting an annual internal audit • Documenting the findings of the annual internal audit • Conducting and documenting other inspections of the Laboratory • Documenting the internal audit summary report • Preparing Laboratory responses to findings, resolving issues, and developing corrective action	Quality Manager is responsible for: • Preparing and publishing an audit schedule • Coordinating and conducting an annual internal audit • Documenting the findings of the annual internal audit • Conducting and documenting other inspections of the Laboratory • Documenting the internal audit summary report • Preparing Laboratory responses to findings of the internal audit, resolving issues, and developing corrective action		DS

			plans/ responses, if applicable.		
	2.1.3	Laboratory Director is responsible for: • Reviewing and approving the findings of the annual internal audit • Reviewing and approving Laboratory responses to findings and corrective action plans/responses, if applicable • Providing final resolution to issues • Coordinating the ANAB annual surveillance visit for the Laboratory	Laboratory Director is responsible for: • Reviewing and approving the findings of the annual internal audit • Reviewing and approving Laboratory responses to findings of the internal audit and any corrective action plans/responses, if applicable • Providing final resolution to issues • Coordinating the ANAB annual surveillance visit for the Laboratory		