Deviation from Documented Procedures for Signatures Acknowledging Revisions to the Toxicology Section Operations Guide (TOX)

Dates of Deviation: TBD

Type of Deviation: Signature Requirements for TOX-01-00 (General Toxicology SOP)

Describe the Deviation:
The Crime Laboratory normally uses a digital document management system (PowerDMS) to acknowledge the reinstatement/revision of the Toxicology Section Operations Guide (TOX) 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 the reinstatement/revision to the Toxicology Section Operations Guide (TOX). The revision to TOX-01-00 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 Swayze Evidence Technician	10.19.23 Date
Gabi Odd Seized Drug Analyst	10/17/23 Date
Kayla M. Baylor Analyst	10/17/2023 Date
Melina Henry Analyst	10/17/2023 Date
Derek Sedlacek Laboratory Director	17 Oct 2023 Date
Ann Watson 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

General Toxicology SOP

1. Safety
   - 1.1 The safety procedures in the Brazoria County Crime Laboratory Safety Manual (SAF-01-01) will be followed in the toxicology section.
   - 1.2 All biological samples shall be treated with universal precautions. Appropriate personal protective equipment will be utilized when analyzing biological samples. Safety Data Sheets (SDS) shall exist as a hard copy or in electronic format for all laboratory personnel to review.

2. Evidence
   - 2.1 Storage of Evidence
     - 2.1.1 Toxicology evidence is stored in refrigerators in the Brazoria County Crime Laboratory.
     - 2.1.2 The refrigerator/freezer temperatures shall be monitored weekly. Loss of refrigeration requires immediate action to arrange repair and to preserve refrigerator contents.
     - 2.1.3 Non-fatality toxicology cases should be moved to room temperature storage 6 months after analysis is complete.
   - 2.2 Evidence Handling
     - 2.2.1 Toxicology personnel shall maintain the integrity of the evidence at all times while in their custody. Evidence shall be protected from loss and contamination.
     - 2.2.2 Evidence transfers in the toxicology section shall be documented electronically as part of the chain of custody and should include any relevant comments pertaining to evidence processing. Relevant comments shall be made for each analysis. If needed, evidence transfers shall be documented on a paper chain of custody using the appropriate BCCL Chain of Custody Form.
     - 2.2.3 Insufficient sample volume shall require a consumption order or court order in order for the Brazoria County Crime Laboratory to proceed with analysis. This applies to instances where the evidence consists of one blood tube containing less than 4 mL and when the evidence consists of two or more tubes of blood, all of which must be opened to complete analysis.
       - 2.2.3.1 A request to consume will be communicated to the submitting agency by email or in a report.
       - 2.2.3.2 When a consumption order is received, the defense shall have an opportunity to timely object within 5 business days before moving forward with analysis.
     - 2.2.4 The laboratory will reserve one unopened tube for additional testing by an outside laboratory if more than one tube has been collected. If only one tube is received, laboratory management will determine the amount to reserve on a case by case basis.

2.3 Specimen Condition

2.3.1 If a blood specimen can be aliquoted without the need for homogenization, the specimen shall be deemed acceptable for analysis. If a specimen requires homogenization prior to analysis, this shall be documented on the report.

2.3.2 Blood tubes selected for analysis should be based on multiple factors such as sample volume, biological fluid type, and collection date or time.

2.3.2.1 Case samples that have multiple items containing different colored top blood tubes, preference will be given in the following order based on top color: gray>lavender>pink>tan>royal blue>red. Any other color top tubes shall require consultation with the laboratory manager or designee.

3. Analytical Requests

3.1 Based on the type of offense the workflow will be as follows:

3.1.1 DWI/DUID

Blood specimens-alcohol analysis, if ethanol is <0.100 g/100 mL → Drug Screen, if positive → Confirmation

3.1.2 Fatalities

Blood Specimens-alcohol analysis → Drug Screen, if positive → Confirmation

3.2 Deviations from the standard operation procedure (SOP) affecting an analytical batch or analysis of a case are documented in the Deviation Form (LOG-18-02-X). Deviations shall be approved by the lab manager or designee and included in the case file or batch file.

4. Instruments and Equipment

4.1 Pipettes

4.1.1 Refer to the appropriate user manuals for proper handling and use.

4.1.2 Calibration

4.1.2.1 Each pipette shall be externally calibrated and certified by an external vendor annually and prior to being place in service.

4.1.3 Performance Verifications and Maintenance

4.1.3.1 Pipette performance verifications shall be performed quarterly and following maintenance, cleaning, or return of pipettes after external calibration.

4.1.3.2 Pipette verifications shall be recorded on Pipette Monitoring and Maintenance Form (LAB-INS-01).

4.1.4 Performance Verification Procedure

4.1.4.1 See SOP on Instrument Performance and Maintenance (LOG-15-07) section on Mechanical Pipettes.

4.2 Balances

4.2.1 Refer to the appropriate user manuals for proper handling and use.

4.2.2 Performance Verification Check

4.2.2.1 See SOP on Instrument Performance and Maintenance (LOG-15-07) section on Balances.

4.3 Refrigerators and Freezers

4.3.1 Refrigerators and freezers should remain clean and organized.

4.3.2 The temperatures of refrigerators shall be monitored weekly. Refrigerators for biological specimens shall have a constant temperature approximately 0°C to 8°C. Freezers shall have an approximate temperature of less than -20°C.

4.3.3 Loss of refrigeration requires immediate action to arrange repair and to preserve refrigerator contents.

4.3.4 If a refrigerator or freezer stops functioning and exceeds the acceptable temperature range, evidence will be moved to another functioning refrigerator or freezer and the transfer shall be documented.

4.4 Headspace GC-FID

4.4.1 Refer to the appropriate operating manual and guides for proper handling, use, and troubleshooting.

4.4.2 Preventative Maintenance (PM)

4.4.2.1 Preventative maintenance shall be performed annually by an external vendor.

4.4.2.2 Preventative maintenance should include but not limited to

4.4.2.2.1 Inlet maintenance (e.g., replace liner)
4.4.2.2.2 Replace split vent trap cartridge filter
4.4.2.2.3 Clean and inspect split vent tube
4.4.2.2.4 Replace jets and ignitor, if needed
4.4.2.2.5 Zero all pressure sensors
4.4.2.2.6 Perform inlet pressure decay test
4.4.2.2.7 Check cabling
4.4.2.2.8 Vacuum/remove dust

4.4.3 Verification

4.4.3.1 If maintenance, repair, or changes in data acquisition significantly affects retention times of ethanol (e.g., installing new GC column), the mean retention time of calibrators included in the verification shall be used to establish the new retention time of ethanol.

4.4.3.2 As part of the verification following annual preventative maintenance, the calibrator data should be used to update the retention time for ethanol in the method.

5. Batch File

5.1 A batch file shall be created by the casework analyst.

5.2 Batch files shall include:

5.2.1 Appropriate Batch Review Checklist
5.2.2 Appropriate Batch Information Sheet
5.2.3 Sequence
5.2.4 Calibration/Controls
5.2.5 Data
5.2.6 Appropriate Worksheet summarizing the data

5.3 Batch files should include when appropriate:

5.3.1 Method
5.3.2 Any corrective action documentation

6. Case File

6.1 A case file shall be generated upon submission of evidence to the BCCL.
6.2 Examination Documentation
6.2.1 Data relevant to the case

7. Reporting
7.1 Report Content
7.1.1 The following shall be included in the laboratory report, if available
7.1.1.1 Name, address, and contact information of the laboratory where analytical testing was performed
7.1.1.2 Agency name and case number of the specimen submitter
7.1.1.3 Subject's name
7.1.1.4 List of specimens
7.1.1.5 Received date
7.1.1.6 Date lab report issued
7.1.1.7 Laboratory results
7.1.1.8 Name of the person responsible for the report
7.1.1.9 Page numbers and case number on each page
7.1.1.10 Instrumentation method used
7.1.2 The following shall be included on the submission form or documented elsewhere in the case record, if known
7.1.2.1 Subject's sex
7.1.2.2 Subject's date of birth
7.1.2.3 Specimen container type(s)
7.1.2.4 Date and time of specimen collection
7.1.3 If the condition of the specimen(s) was unsuitable for analysis and/or may have compromised the results of the testing, this will be noted in the report.
7.1.4 If low specimen amount precluded any or all testing, it will be noted.
7.1.5 A list of analytes covered in analysis shall be made available to the customer on the laboratory website.

7.2 Reporting Laboratory Results
7.2.1 Results should be none detected, positive (qualitative or quantitative), or inconclusive.
7.2.1.1 Positive qualitative results
7.2.1.1.1 Qualitative toxicology results shall be reported as positive with no numerical value.
7.2.1.2 Positive quantitative results
7.2.1.2.1 Quantitative toxicology results shall include both the amount and units of measurement for each analyte meeting the laboratory's requirements along with an estimated uncertainty of measurement. It is acceptable to report analytical results as "greater than" or "less than".
7.2.1.3 Inconclusive results
7.2.1.3.1 Inconclusive toxicology results are results that do not meet criteria for reporting or were unsuitable due to analytical

interferences or condition of the sample and shall be marked as such (e.g., coeluting peaks, consistency of sample).

7.2.1.3.2 Inconclusive results shall be reported as follows:

7.2.1.3.2.1 If the sample is unsuitable for analysis, the report shall state "Sample unsuitable for analysis" or an equivalent statement.

7.2.1.3.2.2 If there is insufficient sample, the report shall state "Insufficient sample for analysis" or an equivalent statement.

7.2.1.3.2.3 Additional information can be provided if deemed necessary.

7.2.2 Dilutions

7.2.2.1 Water is used as a diluent for alcohol analysis.

7.2.2.2 Dilution factors used shall be validated.

7.2.2.3 The dilution factor used shall be incorporated before truncating the original result to the appropriate decimal place.

7.2.2.3.1 Ethanol analysis for liquid samples: Reported result is truncated to two decimal places if the concentration is <10 and to one decimal place if the concentration is ≥10.

8. Amended Reports

8.1 Modifications to an original report shall be documented. See Laboratory Reports SOP (LOG-21-08) section 3.4.3 for detailed requirements.

9. Technical and Administrative Review

9.1 Following completion of a casework batch, a batch file shall be created by the casework analyst conducting the analysis. The casework analyst shall then enter case-related information into the Laboratory Information Management System (LIMS). This will result in a laboratory report.

9.2 The batch file and laboratory reports shall be initially reviewed by the casework analyst and afterwards technically reviewed by another qualified individual using the appropriate Batch Review Checklist. Upon successful completion of the batch and technical review, each case shall then be administratively reviewed by a qualified individual.

9.3 Any errors found during technical or administrative review shall be addressed before proceeding to the task in the review process. If an error is found during administrative review of a case file, the error shall be corrected, and the case file technically (if applicable) and administratively reviewed once more.

9.4 Calculations regarding case sample data (e.g., dilution, averaging of multiple valid results) shall be checked during the batch and technical review.

9.5 If the batch file is printed, the casework analyst shall scan and store the documentation in the proper digital location following successful batch file administrative review. If the batch file exists digitally, it shall be moved to the proper digital location. Printed or digital case-specific documentation shall then be uploaded to the LIMS system and store in the proper digital location.

9.5.1 If the entire batch fails, documentation of the reason for failure shall be included in the batch file. If part of the batch fails, documentation of the

reason for the failure shall be included in the batch file and case data shall be uploaded to LIMS.

9.5.2 Submission Form

10. Administrative Review Checklist
    10.1 The following items constitute a case file administrative review.
        10.1.1 Data
            10.1.1.1 All comments and/or strikethroughs, if any, initialed
            10.1.1.2 All pages have correct unique lab case number
        10.1.2 LIMS
            10.1.2.1 Review chain of custody for consistency with documentation and date of analysis
        10.1.3 Report
            10.1.3.1 Appropriate identifiers (i.e., name, date of birth, agency case number) and lab case number consistent with submission information
            10.1.3.2 All items received listed
            10.1.3.3 Review results are consistent with examination documentation
            10.1.3.4 Review all items listed and descriptions are consistent with documentation
            10.1.3.5 Statement included for each item untested or requiring additional analysis
            10.1.3.6 Any comments/discrepancies are clear and consistent with documentation
            10.1.3.7 Reviewed for clerical errors

11. Estimation of Uncertainty of Measurement (UM)
    11.1 The UM is calculated for quantitative methods to ensure the reported quantitative results can be interpreted within the context of accuracy and precision of the analytical methods.
    11.2 Calculating and Reporting of UM
        11.2.1 For ethanol analysis, the confidence level use is 99.73%, k=3.
        11.2.2 The expanded uncertainty is rounded to two significant figures, which shall be used to calculate the UM value associated with a quantitative test result.
        11.2.3 The reported expanded uncertainty values are located in the UM packets.
        11.2.4 UM is reported in the same units and decimal places as the test results.
            11.2.4.1 For ethanol analysis, reported UM is rounded to three decimal places for blood alcohol samples with the exception of diluted samples (e.g., liquid samples), which will follow the decimal place of the reported test result after incorporation of the dilution factor.
        11.2.5 Reported UM is calculated using the following formula:
            Reported UM = ± (Reported Concentration x UM%)
        11.2.6 The uncertainty of measurement shall be evaluated annually.
        11.2.7 The Uncertainty of Measurement Packets shall be stored in proper digital location and on the laboratory website.
    11.3 Uncertainty Components

11.3.1 Measurement reproducibility accounts for the control with the largest percent relative standard deviation (%RSD) or pooled %RSD based on historical control data.

11.3.2 Certified reference material (CRM) uncertainty accounts for the CRM used as a calibrator with the largest reported uncertainty.

11.3.3 Duplicates (ethanol analysis only) accounts for the maximum allowed difference between analytically obtained values of duplicate case samples.

11.3.4 Pipettes use the highest %RSD reported from external calibration certificates and verification checks across all pipettes within the volume range used.

12. Opinions and Testimony

12.1 This section describes the acceptable extent of the contents of expert opinions and testimony provided by a toxicologist. ANSI/ASB Best Practice Recommendation 037, First Edition 2019: Guidelines for Opinions and Testimony in Forensic Toxicology was used to establish the requirements in this section

12.2 This section is intended for written and oral expert toxicological opinions regarding interpretation of analytical toxicology findings.

12.3 Written and Oral Opinions

12.3.1 Written expert toxicological opinions regarding the interpretation of analytical toxicology findings should not be part of the basic analytical toxicology report. A separate expert report or other communication format (e.g., email) should be used to convey such opinions.

12.3.2 Written expert toxicological opinions should include a comment that states that the opinions may be subject to change based upon new information that becomes available (e.g., case history, additional analytical testing, new research findings and publications, etc.)

12.3.3 An expert toxicological opinion, whether written or oral, should:

12.3.3.1 be expressed in a clear, coherent manner;

12.3.3.2 be based on established scientific principles and foundations;

12.3.3.3 be based on the totality of information available, including case history, observations, circumstances, and other relevant information, and not based solely on analytical results;

12.3.3.4 include information on case specific documents and records reviewed;

12.3.3.5 have references that support the opinion;

12.3.3.5.1 References should be provided either in the expert report or made available upon request

12.3.3.6 clearly state any assumptions made; and

12.3.3.7 clearly state any known limitations to the opinion.

12.4 Appropriate Opinions and Testimony by a Toxicologist

12.4.1 Through testimony and offering an expert toxicological opinion, it is generally appropriate for a toxicologist to:

12.4.1.1 discuss a laboratory report and any analytical work that supports that report. Applicable limitations should be addressed.

12.4.1.2 qualify a reported concentration in the context of a given case as a subtherapeutic, therapeutic, toxic or lethal when that statement can

be backed by appropriate references, databases and/or relevant information.

12.4.1.3 address the pharmacokinetics/toxicokinetics, as well as the pharmacodynamics/toxicodynamics of drugs or other chemicals.

12.4.1.4 discuss the toxicological impact of the presence, absence and/or stability of drugs or other chemicals.

12.4.1.5 address impairment for the average individual to the extent that effects are consistent with documented pharmacodynamic and toxicodynamic properties of the substance and within the context of a given case.

12.4.1.6 perform or discuss toxicological calculations that are generally accepted in the field and can be supported by research and references, provided appropriate limitations are cited. For example, ethanol back extrapolation calculations may be performed.

12.5 Inappropriate Opinions and Testimony by a Toxicologist

12.5.1 The following are considered to generally be inappropriate opinions and/or testimony for a toxicologist to offer, as they currently lack consensus within the scientific community or are generally beyond the scope of the toxicologist's expertise.

12.5.1.1 A toxicologist should not opine as to the absolute cause of death of an individual. This does not preclude a toxicologist from addressing the toxicological impact of any substances found in the toxicological analysis of specimens from the case.

12.5.1.2 A toxicologist should not address behavioral intent based solely upon a drug concentration.

12.5.1.3 A toxicologist should not opine as to a specific individual's degree of impairment based solely on a quantitative result.

12.5.1.4 A toxicologist should not imply impairment of an individual based on analytical findings from urine, hair or other matrices unless supported by the literature.

12.5.1.5 A toxicologist should not opine as to the absolute cause of an accident.

12.5.1.6 A toxicologist should not perform extrapolation calculations for drugs other than ethanol.

12.5.1.7 A toxicologist should not calculate the dose of a drug based on a postmortem drug concentration in blood.

12.5.1.8 A toxicologist should not calculate the dose of a drug (with the exception of ethanol) through body burden calculations.

12.5.1.9 A toxicologist should not opine as to the effects of a drug or combination of drugs on a specific individual without context of a given case. This does not preclude a toxicologist from addressing general effects of drugs at varying concentrations (Section 12.4).

12.5.1.10 A toxicologist should not use words such as "scientific certainty" or "reasonable degree of scientific certainty", unless required by jurisdictional regulation.

13. References

13.1 Guidelines for Opinions and Testimony in Forensic Toxicology, ANSI/ASB Best Practice Recommendation 037, First Edition 2019.

13.2 Standard Practices for Measurement Traceability in Forensic Toxicology, ANSI/ASB Standard 017, First Edition 2018.