

# TENNESSEE BUREAU OF INVESTIGATION

## Forensic Services Division



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### Quality Assurance Manual

### Process Requirements-Monitoring the Validity of Results

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## 7 Process Requirements

### 7.7 Ensuring the Validity of Results

**7.7.1** In an effort to maintain the highest level of quality in the performance of laboratory activities for our customers, the TBI-FSD quality system has a program for monitoring the validity of results obtained by laboratory personnel. Monitoring activities will be the responsibility of the Unit Supervisor/Technical Leader and the Quality Assurance Manager.

Monitoring activities will utilize the following measures to ensure the validity of results:

#### 7.7.1.1 Quality control (QC) checks

Quality control checks vary by unit and test/calibration activity. Therefore, each unit has quality control procedures outlined in the unit's SOPs. Defined acceptance criteria have been established for all quality effecting examination/calibration activities. Units address necessary measures for unacceptable QC checks. Quality control measures may include, but are not limited to the following:

- Routine use of certified reference materials and/or secondary reference materials;
- Functional and intermediate checks of equipment;
- Use of appropriate standards;
- Correlation of results for different characteristics of an item of evidence;
- Use of positive and negative controls contemporaneously with test samples. Appropriate controls and standards shall be specified in the appropriate testing/calibration methods and the result of each quality control activity shall be recorded in the case file.

#### 7.7.1.2 Verification of test results by other authorized personnel

The procedures for verification will include the following:

- Verifications shall be conducted by an individual who is competent in the forensic discipline or sub-discipline being verified;
- Verification shall be documented to include identity of verifier, date verified, and the result of the verification;
- There shall be a plan of action to deal with situations where the verification does not agree with the original test result; and
- Resolutions of any discrepancies shall be recorded.

Applicable Unit SOPs will outline the procedure and requirements for blind verifications.

#### 7.7.1.3 Review of results by authorized personnel

TBI-FSD management recognizes the important role of the review process in the quality system. The following outlines the requirements for technical and administrative reviews.

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##### 7.7.1.4 Technical reviews

All results issued by TBI laboratory personnel will be technically reviewed. Procedures for conducting technical reviews include the following requirements:

1. Technical reviews of examination/calibration documentation and *TBI Official Report* or the *Certification Worksheet* and the *Certificate of Instrument Accuracy* will be conducted on all case records;
2. Technical reviewers must be qualified in the forensic discipline or sub-discipline being reviewed. Qualification is measured by the successful completion of a relevant competency test;
3. The examiner who conducted the analysis and issued the reports cannot conduct their own technical review;
4. The technical review shall include a review of all examination/calibration records and the associated results, as applicable, to ensure conformance with technical procedures and laboratory policies. The technical review shall ensure the data supports the results and conclusions in the test report, associations are properly qualified in the report, and the test report contains all required information;
5. Technical approval of the case file will be indicated by changing the milestone in the LIMS from 'Draft' status to 'Technical Review' status. The 'Technical Review' milestone indicates agreement between the examining analyst and the technical reviewer. The technical reviewer may be held to the same accountability as the examining analyst;
6. The laboratory shall follow a Conflict Resolution Policy to address any discrepancies that are found during the technical review. All discrepancies identified that are of a quality nature must be documented in the case file.

Additional requirements for technical reviews may be outlined in Unit SOPs.

**7.7.1.4.1** Requests for examination withdrawn by customers or cases found to be closed/disposed within the judicial system prior to analysis:

- Require a *TBI Official Report* stating the reason why no analysis was performed (e.g. 'Request for examination was withdrawn by (name/agency)'). Documentation supporting 'no examination' will be retained in the case file.
- Evidence does not need to be itemized. Reports should state items of evidence were not verified.
- Technical review is not required since analysis was not performed. However, an administrative review is required and may be conducted by any TBI Forensics Division employee other than the author of the report. The reviewer will set both the technical review and administrative review milestones in LIMS.
- If analysis was completed or partially completed prior to notice to withdraw request for examination, then the case will need to follow the typical review process designated by Lab QAM policy 7.7.1.4 and Unit SOPs. Unit SOPs should also address at what point analysis can be stopped and how partial results should be reported.

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#### **7.7.1.5 Testifying as technical reviewer or verifier**

TBI-FSD recognizes there may be instances when an analyst is not available to testify. When this occurs, management will request to have the technical reviewer/verifier be allowed to testify to the report as they are already listed in the case folder and have knowledge of the case. See policy 7.8 regarding the issuing of a supplemental report by technical reviewer.

#### **7.7.1.6 Administrative review**

An administrative review will be conducted prior to the release of the *TBI Official Report*. Administrative reviews shall be conducted by someone other than the author(s) of the test report. The administrative review shall include a review of the test report for spelling and grammatical accuracy, a review of all administrative and examination records to ensure the records are uniquely identified according to TBI policy and/or procedure, and a review of the test report to ensure all key information is included. The administrative reviewer will ensure the chain of custody is complete and accurate and ensure evidence has been returned to evidence receiving, where applicable. The administrative review shall be documented under milestones in the LIMS.

Additional requirements for administrative review may be outlined in Unit SOPs.

#### **7.7.1.7 Courtroom testimony monitoring**

Annually, TBI Laboratory personnel will receive testimony evaluations from relevant court officials. These evaluations will be reviewed with the appropriate Unit Supervisor. These evaluations are utilized to ensure our customers are receiving quality services when analysts are testifying. Should an analyst receive an unsatisfactory testimony evaluation, the Unit Supervisor will investigate the relevant circumstances. Measures will be taken to rectify issues and minimize their reoccurrence.

Within an accreditation cycle, each analyst should be monitored by the Unit Supervisor, Technical Leader or another analyst competent in the discipline and receive a Technical Testimony Evaluation. Should an analyst receive an unsatisfactory technical testimony evaluation, the Unit Supervisor, Technical Leader, Quality Assurance Manager and/or the Crime Lab Regional Administrator will initiate Root Cause Analysis procedures. Documented corrective action(s) will be implemented as necessary to remediate and prevent reoccurrence of the nonconformity.

Courtroom testimony monitoring will be maintained in personnel training records.

Additional requirements may be outlined in Unit SOPs.

#### **7.7.2 Monitoring of Laboratory Activities**

Performance of each laboratory within the TBI Laboratory System is monitored by laboratory management. Monitoring activities include:

- a) participation in external proficiency testing programs;

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- b) interlaboratory comparisons between the three labs of the TBI Laboratory System may take place as needed to ensure the validity of results.

**7.7.2.1** TBI Laboratory ensures the following proficiency testing requirements are met, where available:

- a) at least one external proficiency test will be administered for each discipline in which accreditation services are provided;
- b) each Regional laboratory under the TBI Laboratory scope of accreditation shall successfully complete, per calendar year, at least one external proficiency test for each discipline in which accreditation services are provided. Proficiency test provider is authorized to release results to ANAB.

**7.7.3** TBI-FSD will utilize the data available from monitoring activities for evaluating the effectiveness of the quality system. When necessary, management will address issues and take appropriate actions to prevent incorrect results from being reported.

**7.7.3.1** If issues arise from the monitoring program, the following steps may be implemented:

- Replicate tests/calibrations using the same or different methods;
- Retesting/recalibrations of retained items;
- Use of acceptable alternative instrumentation.

**7.7.3.2** Discrepancies between the results obtained by TBI analysts and the proficiency test provider may occur. In the event a discrepancy has been identified, an investigation shall be opened to discover the source of the discrepancy. Types of discrepancies that may exist include:

- The test was presented poorly;
- The test sample was inadequate or improperly manufactured;
- The report contained typographical errors;
- The report contained non-technical errors;
- The examiner/forensic technician utilized inappropriate or inadequate analytical procedures;
- The examiner erred in interpreting the analytical data thereby creating inaccurate or inappropriate conclusions;

**7.7.3.3** Recommended remediation will be based on the outcome of the proficiency test outlier investigation. Remediation may include the following:

- A review of the technical procedures utilized by the laboratory unit may be conducted and changes made if needed;
- A review of the examiner's cases/calibrations may be conducted going back to the last successfully completed proficiency test;
- A referee laboratory may conduct a reanalysis of the proficiency test;

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- The examiner/forensic technician involved should be issued and successfully pass a new externally prepared proficiency test. This test should be prepared using samples similar to those utilized in the initial proficiency test;
- The individual may be subject to disciplinary action up to and including termination.

**7.7.3.4** The Quality Assurance Manager and Unit Technical Leaders will conduct checks of monitoring activities in each Regional Laboratory. Quarterly Technical Reviews, as outlined in Standard 8, will be issued to the AD-FSD and the appropriate CLRA.

**7.7.4** All personnel will successfully complete at least one internal/external proficiency test per calendar year in each discipline on the scope of accreditation in which the individual conducts testing.

**7.7.4.1** Forensic Biology examiners performing DNA analysis will comply with the proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories.

**7.7.5** Performance monitoring of laboratory personnel shall include the following requirements:

- a) proficiency test results will not be known or readily available during the testing period;
- b) appropriate Unit SOP(s) shall be followed when participating in proficiency testing programs and the full range of testing will be covered if possible;
- c) criteria will be established prior to all other monitoring activities. Criteria for determining successful completion of proficiency tests shall be established in Unit SOPs;
- d) proficiency testing records will be retained permanently by the TBI Laboratory. Technical records will also be retained with the analysts training documents. Analyst will generate a report in the LIMS;
- e) calibration: proficiency test will be conducted on a breath alcohol measuring instrument previously calibrated using an approved method by the person taking the proficiency test;
- f) if an analyst obtains an unexpected result, the QAM will initiate a Root Cause Analysis. ANAB will be notified within 30 days of notification.

**7.7.6** The Quality Assurance Manager of the TBI Laboratory shall maintain proficiency testing records. These records will be retained indefinitely. Records will ensure:

- a) each Laboratory in the TBI Laboratory System conducts proficiency testing in each discipline in their Scope of Accreditation per calendar year and, each analyst involved in testing/calibration activities will participate in at least one proficiency test per calendar year;
- b) a representative sample of the types of tests within each discipline on the scope of accreditation are included in the monitoring plan.

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**7.7.7** The TBI laboratory's Quality Assurance Manager will oversee the proficiency testing program and ensure:

- a) proficiency test providers are accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the APLAC MRA or IAAC MLR and has the applicable proficiency test(s) on its scope of accreditation; or
- b) if an approved test provider is not available for a particular discipline or sub-discipline, approval from ANAB for alternative means by which the laboratory's performance can be assessed. In the event an internally created proficiency test is administered, the quality of the test will be evaluated before being issued;
- c) all tests are submitted to the proficiency test provider on or before the due date

**7.7.8** The Quality Assurance Manager will maintain the following records for monitoring activities:

- a) the test identifier, discipline tested and the identity of the person taking the test;
- b) how samples were obtained or created;
- c) the expected results;
- d) the Regional Laboratory where the test was taken;
- e) date of analysis and date submitted to proficiency test provider;
- f) evaluation of the results and actions taken for questionable results;
- g) feedback provided to the analyst including discrepancies, if applicable.

**7.7.8.1** When available, the proficiency test provider's summary report will be retained with the test records maintained by the QAM and made available to the analyst.