

TENNESSEE BUREAU OF INVESTIGATION

Forensic Services Division



Quality Assurance Manual Management System Requirements

8 Management System Requirements

8.1 General

The TBI-FSD is committed to maintaining a management system to meet the needs of its customers in the law enforcement community. The following criteria were established and are periodically evaluated to ensure the goals and objectives of the TBI- Forensic Services Division (FSD) management system are continually met.

8.1.1 The management system for the TBI- FSD was established in accordance with ISO 17025:2005 in 2014 and received accreditation status through ASCLD/LAB. January 01, 2018 the TBI-FSD management system transitioned to standards set forth in ISO 17025:2017 and ANAB AR3125.

8.1.2 As a minimum, the TBI-FSD management system will address management system documentation (section 8.2 below), control of management system documents (8.3), control of records (8.4), actions to address risks and opportunities (8.5), improvements (8.6), corrective actions (8.7), internal audits (8.8) and management reviews (8.9)

8.2 Management System Documentation

8.2.1 The TBI-FSD management system has policies and procedures in place to meet the requirements for the standards set forth in ISO 17025:2017 and ANAB AR3125. All policies and procedures generated to meet these standards are uniquely identified and controlled in the Ensur document control portal. Creation or revisions must be reviewed and authorized by top management before going into effect. Confirmation of acknowledgement by all necessary personnel is captured by Ensur before implementation.

8.2.1.1 Any accreditation requirement that is agreed, appointed, authorized, defined, instructed, planned or scheduled will be done so in writing.

8.2.2 The policies and procedures in use by the TBI-FSD address the competence, impartiality and consistent operation of the laboratory.

8.2.3 Commitment to the continued improvement of the management system documentation is demonstrated by the use of annual management reviews, periodic reviews of policies/procedures, and internal audits. TBI-FSD personnel of all levels within the division are encouraged to submit ideas for improvements to the system.

8.2.4 All procedures, records, and documentation needed for the application of accreditation requirements cited by our accrediting body, ANAB, are linked to the TBI-FSD management system.

8.2.5 Management system documents and related information are available to all TBI-FSD personnel through the Ensur portal, as it is applicable to their responsibilities. TBI-FSD personnel are responsible for understanding and practicing all policies and

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procedures set forth in this quality manual applicable to their responsibilities within the division.

8.3 Control of Management System Documents

8.3.1 TBI-FSD has policies in place to address the need for the control of records. Controlled records include all documents having an effect on laboratory activities. Policies are in place to address the identification, collection, organization, accessibility, filing, storage, maintenance, and disposal of quality records and technical records.

8.3.2 The use of Ensur document control system allows the management system to:

- Approve policies prior to issue;
- Periodically review and update policies;
- Document changes to policies;
- Restrict access to only current policies;
- Allow access to policies both within the Laboratory and in the field;
- Document training activities of personnel;
- Document non-conforming work occurrences;
- Document corrective and preventative actions;
- Allow open access to policies and procedures.

8.3.3 Official Forms listed in the Appendix folder of the Laboratory Quality Assurance Manual are not controlled. If Laboratory personnel use their own form(s), they must include all of the information contained in the Official Form(s).

8.4 Control of Records

8.4.1 All TBI Laboratory records will be legible and readily retrievable from storage in the appropriate TBI facility. Every effort will be made to ensure the integrity of records will be maintained.

If an original document is to be maintained electronically, the electronic record must be ensured as accurate prior to the destruction of the original document.

8.4.2 TBI-FSD records will be properly identified, stored, protected, backed-up, archived, retained and properly disposed. Access to these records is controlled and held secure and in confidence. Retention times will be determined by State of Tennessee or for one accreditation cycle, whichever is longer.

Blood alcohol reports will be held for a minimum of 5 years from the date the report was issued and then be destroyed (RDA34800-0000000905).

Drug analysis reports will be held for a minimum of 8 years from the date the report was issued and then be destroyed (RDA 34800-0000000900).



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Fingerprint cards (and other items involving criminal record checks and mug shots) will be maintained until the subject reaches 100 years of age (RDA 34800-0000001686).

Capital cases will be held indefinitely (RDA 34800-0000002307).

Non-capital cases are held for a minimum of 8 years from the date of the report was issued and then be destroyed. This requirement may be superseded by the statute of limitations (e.g. Class A felonies have a statute of limitations of 15 years) (RDA 34800-0000002406).

8.4.3 Electronic records on the LIMS are maintained and backed up by the TBI Information Systems Division (IS). Access to these records is controlled.

8.4.4 At the discretion of the Regional Supervisor, TBI case files may be taken home at the end of a work day. This may be for case review or court purposes. The following guidelines shall be followed to ensure case record security:

- Case files taken home for case file review must be able to be recreated should an accident occur. If information contained within the case file cannot be reprinted from computer files, copies of records/paperwork/worksheets/request forms etc. must be made prior to taking the files home and must be retained at the laboratory.
- Case files taken home must be returned to the laboratory the next day, if possible.
- Case files shall be taken directly home. Employees should not make any stops that would allow case files to leave their sight. They must be transported in such a way as to prevent the possibility of loss of any case file contents (i.e. closed container or box, briefcase, or bag with clasp closure).
- A list shall be compiled and remain at the laboratory as a record of all cases being taken home. Employees have the option of using photocopies or originals of examination or administrative documentation to serve as this list. This list does not have to be retained following the return of all case files to the laboratory. This excludes case files being taken home for court appearances.
- Retired or former TBI employees needing case files for court appearances may check files out as required. A record of this will be kept at each applicable laboratory until the case file is returned.

8.5 Actions to Address Risks and Opportunities

8.5.1 TBI-FSD will consider laboratory risks and opportunities with associated activities in order to give assurance to the management system that intended results are achieved, to enhance opportunities to achieve the purpose and objectives of the laboratory, to prevent, or reduce, undesired impacts and potential failure in lab activities and to achieve improvement.



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8.5.2 TBI-FSD management system's risk assessment and improvement program uses the results obtained during the annual internal audit, management review and quarterly technical system reviews to evaluate risks within the quality system and evaluate opportunities for improvement. When improvements are implemented or risks ascertained, the effectiveness of these activities will also be evaluated. All nonconforming work occurrences or protocol departures are subject to risk assessment to determine if risks to the quality system may exist.

8.5.3 Any actions taken to address risks and opportunities will be proportional to the impact on the validity of laboratory results.

8.6 Improvement

8.6.1 The TBI-FSD uses policies, objectives, audit results, data analysis, root cause analysis, corrective actions, preventive actions and management reviews to continuously improve the effectiveness of the quality system. The TBI-FSD will use a Deming's Wheel approach in this task. According to this approach, actions will be planned, implemented, carried out, and evaluated. Documentation of these evaluations and improvement activities shall be maintained by the Unit Supervisors, Crime Laboratory Regional Supervisor, the Quality Assurance Manager, or designee.

8.6.2 The TBI-FSD encourages feedback from its customers. Surveys will be solicited to customers seeking their feedback both positive and negative. Customers will be notified of survey opportunities either by email or by posting in the Crime Laboratory Evidence Receiving area. Feedback provided by customers will be used and analyzed to improve the management system, testing and calibration activities, and customer service.

8.7 Corrective Actions

8.7.1 When nonconforming work is identified, appropriate TBI Laboratory management will:

- a) Immediately take necessary action to control and correct the situation. The technical procedure, protocol, or instrument will be withdrawn from use, if necessary. The consequences encompassing the nonconformity will be addressed;
- b) Initiate the Root Cause Analysis (RCA) procedure to:
 - Review and analyze the nonconformity;
 - Determine the cause(s) of the nonconformity;
 - Determine the extent of the nonconformity and existence of other similar nonconformities or the potential for more nonconformities.
- c) Determine the actions to be implemented based on the outcome of the RCA;
- d) Periodically review the actions taken to address the nonconformity for their effectiveness;
- e) Evaluate the risks of reoccurrence;

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- f) Evaluate the need for changes to policy and procedure;
- g) Ensure actions are completed within a reasonable timeframe.

8.7.2 Actions taken to address nonconformities will be suitable to the magnitude and risk of the nonconformity.

8.7.3 All nonconforming work documentation will be retained for at least one accreditation cycle. Records will include:

- a) The nonconformity, cause(s), and actions taken;
- b) The results from periodic reviews.

8.7.4 Upon indication of a commercial laboratory's analytical deficiency, either by the outsourcing laboratory itself or by TBI personnel, a notation will be made in the affected case folder as to the problem. Any correspondence whether telephonic, electronic, or written, to try to determine the root cause of the problem, will be documented in the case folder. If applicable, an amended report authored by the outsourcing laboratory will be issued. All corrective action documentation provided by the outsourcing laboratory will be kept in the corrective action request folder maintained by the Quality Assurance Manager.

8.8 Internal Audits

8.8.1 The Quality Assurance Manager conducts internal audits, at least annually, to evaluate the effectiveness of the management system. The internal audit process ensures the management system:

- a) Conforms to the standards in ISO/IEC 17025, AR3125 and the policies and procedures set forth in the Quality Assurance Manual and Unit SOPs;
- b) Is effectively implemented and maintained.

8.8.2 Procedure for internal audits:

- a) At a minimum, internal audits will be conducted annually. The Quality Assurance Manager will plan and organizing audits as required or when requested by executive management.
 - Internal Auditors will be selected from TBI Laboratory personnel previously trained and approved by ASCLD/LAB or ANAB or trained and approved for internal audits by the Quality Assurance Manager. TBI Laboratory personnel in the Forensic Biology Unit may participate in QAS audits if they have successfully completed the FBI QAS training;
- b) The Quality Assurance Manager will submit an audit plan to the TBI-FSD AD and the appropriate CLRS. An example audit plan is included in the appendix section. The audit plan may include but is not limited to items such as review of case files, conducting interviews with the personnel,



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- reviewing instrumentation and calibration records, reviewing training manuals, reviewing court testimony, and reviewing other areas deemed appropriate or requested by executive management. Internal audits shall include direct observation of testing and calibration activities;
- c) The Quality Assurance Manager will issue an audit report to the TBI-FSD AD and the CLRSs. The report should include the date of the audit, laboratories/units audited, name of the auditor(s), nonconformity(s) identified, and any remedial action(s) required to resolve any nonconformity. The report will identify opportunities for improvement;
 - d) When an audit identifies nonconformity, the Quality Assurance Manager will address the nonconformity accordingly (see nonconforming work section). When necessary, the TBI Laboratory will notify agencies in writing if TBI Laboratory results have been affected. When corrective actions are required, the effectiveness of the corrective action will be verified by the Quality Assurance Manager and notification provided to the appropriate unit when nonconformities have been adequately remediated;
 - e) Internal audit documents will be maintained by the Quality Assurance Manager and will be retained for at least one ANAB accreditation cycle.

The TBI Audit Trail worksheet will be utilized to facilitate the internal audit process. The audit trail will act as supporting evidence of the management systems successful implementation or continued maintenance of the quality system.

8.9 Management Reviews

8.9.1 The TBI Laboratory's executive management, with assistance from the Quality Assurance Manager, will evaluate the quality system and examination activities to ensure their continued suitability and effectiveness. This management review will be used as the foundation for future development of TBI Laboratory goals and objectives, as well as any necessary changes or improvements to the quality system. Management reviews will be conducted at least annually.

8.9.2 Management reviews will be documented and the documentation will be retained by the Quality Assurance Manager for at least one accreditation cycle. Management reviews will assess:

- a) Relevant internal or external changes effecting the laboratory;
- b) Fulfilment of TBI Laboratory objectives;
- c) The suitability, adequacy, and completeness of policies, practices, and procedures;
- d) Any reports from technical management;
- e) The internal audit program;
- f) Any preventive, follow-up, and/or corrective actions;
- g) Any external assessments;
- h) Changes in the volume and type of work being performed in the TBI Laboratory;

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- i) Any feedback from agencies and TBI Laboratory personnel;
- j) Any complaints from agencies and TBI Laboratory personnel;
- k) Any recommendations for improvements;
- l) The adequacy of the organizational structure, staff training and resources to implement the TBI Laboratory quality system;
- m) Results of periodic risk assessment and opportunities for improvement;
- n) The proficiency test program;
- o) Assurance of the validity of results outcomes.

8.9.3 Management review outputs shall record all decisions and actions related to:

- a) The effectiveness of the management system;
- b) Improvements to laboratory activities;
- c) Needs concerning required resources;
- d) Any necessary changes identified.

8.10 Quarterly Technical System Reviews

Quarterly technical system reviews are conducted by the Quality Assurance Manager and the Laboratory's Technical Leaders. These reviews will ensure testing and calibration services in the three regional labs meet TBI-FSD quality and technical standards. When the internal audit falls within a quarter, it will serve as the technical system review for the quarter.

Documentation will include case files and training records reviewed, personnel observed, proficiency test results, and resolutions to any nonconforming work occurrences or other issues. Opportunities for improving the quality system will be assessed.

A quarterly technical system review report will be issued by the Quality Assurance Manager and submitted to the TBI-FSD AD, CLRSs and the unit supervisors.