



TENNESSEE BUREAU OF INVESTIGATION

Forensic Services Division

Quality Assurance Manual

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3.0 Terms and Definitions

ANAB: ANSI National Accreditation Board (American National Standards Institute National Accreditation Board). A testing laboratory accreditation body offering accreditation for forensic laboratories. Any crime laboratory may participate to demonstrate its management, technical operations and overall quality management system meet ISO 17025 requirements and ANAB Supplemental Requirements.

Accreditation: A process by which an authoritative body, such as ANAB, gives formal recognition an entity is competent to carry out specific tasks.

Administrative Documentation: All case-related documentation for testing/calibration services not considered examination records. Examples of these may include:

- request for examination forms and attachments;
- records of conversations (Phone Log); and
- any original or facsimile correspondence related to the case.

Administrative Error: A clerical error such as a typographical error in a report or in the making of an internal proficiency test.

Administrative Personnel: Staff who provide administrative/clerical support.

Administrative Review: A procedure used to check case documentation is complete and the TBI Official Report complies with TBI Laboratory policy.

Administrative Reviewer: A Regional/Unit Supervisor or designee who conducts an administrative review.

Administrative Services Assistant: Provides support to the Assistant Director of Forensic Services, prepares monthly turnaround memos, monthly reports, statistical reports, backlog reports, turnaround comparison charts and directs calls into the laboratory to the appropriate unit. Also referred to as clerical support.

Amended Report: A report issued to make a change to a previously issued report. The amended report must indicate the date of the report it amends.

Analytical/Interpretative Error: An error in the examination process producing an incorrect result or conclusion.

Annual: Once per calendar year.

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Approved Test Provider: A proficiency test provider who has complied with the test manufacturing guidelines established by the ANAB.

Assessment: Term used by accrediting bodies for the external audit process.

Assessor: A person who conducts external assessments.

Assistant Director of Forensic Services: A member of executive management who provides necessary authority to coordinate the quality assurance activities within the Forensic Services Division. Also referred to as Laboratory System Director.

Association: A relationship concluded to exist between individuals and/or objects based upon testing.

Audit: An internal review conducted to compare the various aspects of the TBI Laboratory's quality system with performance criteria.

Audit Program Coordinator: An individual in the Quality Assurance Unit, usually the Quality Assurance Manager, who manages the internal audit program.

Audit Team Leader: An experienced auditor who is assigned the responsibility of leading a team of auditors to conduct an audit.

Auditor: A person who conducts internal audits. In the TBI, all auditors must successfully complete the ANAB or ASCLD/LAB-International Auditor Training course, an internal training course, or a training course related to the Federal Bureau of Investigation Quality Assurance Standards and be a current TBI employee.

Breath Alcohol Measuring Instrument: An instrument to measure the concentration of alcohol (ethanol or broader class of compounds based on legal requirement) in an exhaled sample of human breath.

Breath Calibration Certificate (Calibration Record): A complete calibration certificate consists of both the certification worksheet(s) and the certification form. The certification form will be made available to the agency where the instrument resides on the iResults program after it has been reviewed. Another copy will be retained with the certification worksheet(s) at the TBI Laboratory where the Breath Alcohol Scientist is assigned.

Calibration: The adjusting or standardizing of any instrument and/or equipment to ensure agreement with a reference standard or working standard of known value. The TBI Crime lab recognizes calibration services, as defined by ANAB, are restricted to the

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Breath Alcohol Unit or services provided by an accredited vendor. Any reference to calibration internally by testing units shall be a calibration check.

Case Documentation: All administrative and examination documentation for a given case, including notes, TBI Official Report, chain of custody, and any other related information in LIMS. This may also include data retained on instruments. This may also be referred to as a “case file” or “test report”.

Casework: TBI Laboratory activities concerning the examination of evidence and/or crime scenes. This may also include calibration activities carried out by the Breath Alcohol Unit.

Certified Reference Material: Reference material accompanied by a certificate, one or more of whose property values are certified by a procedure, which establishes its traceability to an accurate realization of the units in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

Check Standard: A stable in-house standard re-measured periodically to determine if a measurement process is within acceptable limits.

Competency Test: A test used to evaluate an individual’s ability to conduct examinations in a forensic discipline or sub-discipline prior to performing supervised casework during the training period or prior to performing independent casework.

Competent: Possessing the requisite knowledge, skills, and abilities to perform a job.

Contract: A binding agreement between the laboratory and the customer.

Control: A sample analyzed in parallel with test samples designed to demonstrate a procedure worked correctly. For some disciplines, it may be appropriate for this to be performed prior to casework. Refer to UOM’s for further guidance.

Controlled Document: A document issued and distributed in a traceable manner.

Convenience Seal: A seal (e.g. a stapled bag, a box with its lid applied) used for internal purposes only to maintain the integrity of the evidence while in the process of examination. This type of seal does not require initials. May not be used for long-term storage or destruction purposes.

Corrective Action: Action to eliminate the cause of nonconformity or other undesirable



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situation. This is documented on a Corrective Action Request.

Court Official: An individual such as a prosecutor or defense attorney who observes and completes a Court Testimony Evaluation.

Court Testimony Evaluation: A form used by a court official to document the evaluation of a TBI Laboratory employee's testimony.

Coverage Factor: A number larger than one by which a combined standard measurement uncertainty is multiplied to obtain the expanded measurement uncertainty.

Coverage Probability: The probability the set of true quantity values of the measurand is contained within a specific coverage interval.

Crime Laboratory Regional Supervisor: A member of executive management who provides necessary authority to coordinate the quality assurance activities within their specific laboratory. This individual is also responsible for the day-to-day operations of the laboratory and fulfills the requirements set forth by ANAB as the Laboratory Director for each individual laboratory within the TBI system. Also referred to as Laboratory Director.

Crime Scene: An area, object or person, from which evidence is identified, documented, collected, and/or interpreted; excluding said activities routinely occurring within the TBI Laboratory units.

Crime Scene Personnel: TBI forensic scientists who perform the identification, documentation, collection, and/or interpretation of material at a location outside of the TBI Laboratory.

Custody: The care and control of an item implying responsibility.

Customer: Law enforcement agencies and/or District Attorneys who submit evidence to a TBI Crime Laboratory for testing, request assistance from the VCRT or require calibration service.

Deviation: An authorized variance from a documented policy, practice, or procedure. The deviation is documented on the Protocol Departure Form.

Digital Evidence: Information of probative value stored or transmitted in binary form.

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Director: The highest ranking manager within an individual laboratory.

Discipline: A major area of casework for which a laboratory may seek accreditation.

Document: Information in any medium including, but not limited to: paper copy, computer disk, video tape, electronic file, or photograph.

Document Control: The process of ensuring controlled documents prescribing quality-affecting activities or specifying quality requirements, including revisions, are reviewed for adequacy, approved for release by authorized personnel, and distributed for use to the personnel performing the prescribed activities.

Documentation: Materials providing information or evidence of activities. This may include policies and procedures, work instructions, and records.

Drug Evidence: Illegal substances, drug paraphernalia, and/or prescription or nonprescription drugs.

Ensur: Software program used by TBI Crime Laboratory for document control.

Environmental Conditions: Any characteristic of the facilities that could reasonably be expected to impact quality of the TBI Laboratory's work product.

Equipment: As it applies to this document, equipment is to include instruments, reagents, consumables and reference material.

Evidence: An item submitted for examination(s).

Examination: Analysis of an item or comparison of items. The term examination is equivalent to the term "test" as used in this manual.

Examiner: An employee who is qualified by the TBI Crime Laboratory as having successfully completed a documented training program, including a competency test, in a particular forensic discipline(s) or sub-discipline(s). They conduct, or are responsible for, examinations within their discipline(s) or sub-discipline(s). They also generate a TBI Official Report conveying the results of those examinations and testify to those results in court.

Examination Documentation: Documents supporting the results and/or conclusions presented in the TBI Official Report. These documents are considered to be, but not limited to records of original observations and test results, derived data printouts,



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photographs, and diagrams.

Executive Management: The Assistant Director for Forensic Services and Crime Laboratory Regional Supervisors.

Exhibit Number: An alphanumeric designator assigned to an item submitted to the TBI Laboratory Evidence Receiving Unit. In limited situations, the exhibit number may be a numeric designator only.

Expanded Uncertainty: Uncertainty resulting from multiplying the combined standard uncertainty by the coverage factor.

External Proficiency Test: A test provided to the TBI Laboratory by an external source.

Forensic Scientist: Under supervision, performs professional forensic science laboratory work of routine through average difficulty and/or calibration services, performs related work as required within a particular discipline or sub-discipline, is responsible for court testimony on any work performed and may be assigned to a Violent Crime Scene Response Team (VCRT). This may be a Special Agent Forensic Scientist or a contract employee working as a Forensic Scientist.

Forensic Scientist Supervisor: This term refers to the unit chief or any person serving as an acting unit chief for a discipline or sub-discipline. They are responsible for court testimony on any work performed and may be assigned to a Violent Crime Scene Response Team (VCRT).

Forensic Technician: An employee who is qualified by the TBI Laboratory and who may work under the direction of a supervisor or an examiner/Forensic Scientist in conducting examinations or tasks within a particular discipline or sub-discipline, may be responsible for the receiving, distribution and security of evidence, is responsible for court testimony on any work performed.

Forensic Technician Supervisor: This term refers to the unit chief or any person serving as an acting unit chief for the evidence receiving unit, is responsible for court testimony on any work performed.

Good Laboratory Practice: Operating practices and procedures for promoting quality and ensuring the integrity of the work product.

Individual Characteristic Database: A computerized searchable collection of features, generated from individual characteristic database samples of known origin from which

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individual characteristic information originates (e.g., reference blood or biological specimens, fingerprints of known individuals, electronic fingerprint records, test fired ammunition).

Instructions: Detailed documents of how to perform a specific task.

Interested Party: Person or group having an interest in the performance or success of an organization.

Internal Proficiency Test: A proficiency test prepared by TBI Laboratory personnel.

iResults: External reporting module of the LIMS.

Key Managerial Personnel: Personnel designated as top management and additional personnel who do not have laboratory-wide authority but are 'key' to the laboratory providing testing/calibration services.

Laboratory Activities: Activities for testing and calibration performed by TBI-FSD Laboratories in accordance with the Scope of Accreditation.

Laboratory Case File: An official file containing TBI Laboratory administrative and examination documents and TBI Official Reports/calibration certificates. This includes electronic documentation found in LIMS. This may also be referred to as the TBI Laboratory file or TBI Laboratory folder.

Laboratory Case Number: A unique, computer-generated number assigned to a TBI Laboratory case. This nine-digit number indicates the year, the laboratory within the TBI Crime Lab system and sequential case submission for examination processed throughout a given year.

Laboratory Director: See Crime Laboratory Regional Supervisor.

Laboratory System Director: See Assistant Director of Forensic Services.

Laboratory Information Management System (LIMS): The TBI Laboratory's electronic evidence, testing, and reporting control system. For internal laboratory use, it is the JusticeTrax LIMS Plus, externally this is the JusticeTrax iResults reporting module.

Long Term Storage: Storage used for evidence pending analysis, waiting for return, or where the examination process has been temporarily halted or delayed.

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Management system: The quality, administrative and technical systems governing the operations of a laboratory.

May: A term used when an element of the quality system is optional or discretionary.

Measurand: Particular quantity subject to measurement.

Measurement Assurance: Practices put in place to monitor a testing or calibration process and to ensure the calibration status of equipment, reference standards or reference materials used in a measurement process.

Measurement of Uncertainty: A non-negative parameter associated with the result of a measurement characterizing the dispersion of the values that could reasonably be attributed to the measurand.

Media: Objects on which electronic data can be stored.

Method: The course of action or technique followed in conducting a specific analysis or comparison leading to an analytical result.

Must: A term used when an element of the quality system is required.

NIST: National Institute of Standards and Technology. A metrology institute who provides primary standards based on SI units of measurement.

Nonconformity: A finding with documented requirements usually identified during an audit or assessment.

Notes: The documentation of procedures, standards, controls, instruments used, observations made, results of tests performed, charts, graphs, photos, and other documents generated which are used to support the examiner's conclusions.

Objective: A measurable, definable accomplishment that furthers the goals of the organization.

Performance Check: A verification that the equipment, instrument, or process is working as expected. Analysis of a control may be used as a performance check.

Policy: A directive that embraces the general goals and acceptable practices of the TBI Laboratory and/or procedures of the units.

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Practicable: A term used when an element of the quality system is expected to be followed if possible.

Practices: In this manual, a term used to describe division-level quality affecting actions used by the TBI Laboratory.

Preventive Action: Action to eliminate the cause of a potential nonconformity or other undesirable situation.

Primary Standard: A standard designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quality.

Procedure: In this manual, a term used to describe unit-level processes. May also be referred to as a protocol.

Proficiency Test: A test used to evaluate the continuing capability of examiners and technicians and the performance of the TBI Laboratory. The expected results of the test are unknown to those individuals taking the test.

Proper Seal: An initialed seal that prevents loss, cross-transfer, or contamination to ensure unauthorized access of the evidence will result in obvious damage or alteration to the seal.

Qualified: A term used to identify personnel who successfully complete a unit's training program, pass a competency test and participate in the TBI Laboratory Proficiency Testing Program.

Quality Assurance: Those planned or systematic actions necessary to provide sufficient confidence the TBI Laboratory's work product or service will satisfy given requirements for quality.

Quality Assurance Manager: Responsible for preparing, updating, implementing and maintaining the Quality Assurance Manual as well as internal audit programs, proficiency testing program, and the Forensic Services Division Safety Program.

Quality Control: Internal activities or activities conducted according to externally established standards used to monitor the quality of analytical data and to ensure it satisfies specified criteria.

Quality Documentation: Documents or records pertaining to the quality system such as

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audit reports, corrective actions requests, deviation requests, and testimony evaluations.

Quality System: The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities contributing to quality, directly or indirectly. This term is equivalent to “management system” as used in ISO 17025.

Reagent: A substance used because of its chemical or biological activity. In the TBI Laboratory, a reagent can also be a substance used in a chemical reaction to detect, measure, examine, or produce other substances.

Record: A document providing evidence of a condition, work performed, activities conducted, and/or quality for archival purposes.

Rejection: As it applies to technical records; Action taken by the verifier or reviewer when conclusions, opinions and/or interpretations are not supported by the data, observations and/or calculations generated during analysis. Unit SOPs may use terms other than rejection when describing a disagreement between the analyst and the verifier and/or reviewer and actions taken to resolve the disagreement.

Remediation: Steps taken to correct a discrepancy or deficiency not due to a severe or systemic issue. Severe or systemic issues may result in a corrective action request.

Request: The act or instance of a customer asking for the examination of evidence by the TBI Laboratory.

Root Cause Analysis: An investigation into the fundamental reason for a condition affecting quality system objectives. Actions taken as a result of the determined root cause should minimize or prevent the condition, and/or similar conditions, from reoccurring.

Sample Selection: A practice of selecting items to test, or portions of items to test, based on training, experience and competence. In sample selection, there is no assumption about homogeneity.

Sampling: A process or procedure whereby a part of a substance, material or item is taken to provide testing of a representative sample of the whole.

Sampling Plan: A statistically valid approach to determine the number of sub-items that must be tested in order to make an inference about the whole population.

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Sampling Procedure: A defined procedure used to collect a sample or samples from the larger whole, to ensure the value obtained in the analysis is representative of the whole.

Secondary Standard: A measurement standard established through calibration with respect to a primary standard for a quantity of the same kind. The quantity value may be assigned by a ratio procedure. This may also be referred to as an Intermediate Standard.

Secured Area: Locked or otherwise limited access space under TBI Laboratory control with access restricted to personnel authorized by the Assistant Director or designee.

Shall: A term used when an element of the quality system is required.

Should: A term used when an element of the quality system is expected to be followed if possible.

SI Units: The International System of Units consisting of seven base units that have been adopted by the General Conference on Weights and Measures.

Standard Operating Procedure (SOP): A document specifying the steps, methods, equipment, and materials necessary to perform a task properly. SOPs are written to provide instruction and standardization for activities affecting quality.

Subcontractor: A non-TBI entity that conducts examinations or performs a service for the TBI Laboratory within the scope of the TBI Laboratory's accreditation.

Sub-Discipline: A specific type of analysis within an accredited discipline of forensic science.

Supplemental Report: A report addressing additional testing of item(s) of evidence or testing of additional item(s) by the same examiner or section. The supplemental report must indicate the date of the report it supplements.

Technical Documentation: All supporting materials considered examination records/documentation. Examples of these may include chromatograms, worksheets, case notes, electronic data, calibration certificates and the *TBI Official Report*.

Technical Leader: An employee who is accountable for the technical operations of the laboratory and who is authorized to stop or suspend laboratory operations.

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Technical Management: The Quality Manager, Technical Leaders and case working Unit Supervisors of the TBI Laboratory.

Technical Records: Data, observations and/or calculations generated during laboratory activities. Technical records are used to support the final conclusions, opinions and/or interpretations of the analyst. Technical records include all quality related information associated with any conducted analysis.

Technical Review: Review of notes, data and other supporting documents that form the basis for a scientific conclusion. This review consists of determining whether the appropriate examinations have been performed, the conclusions are consistent with the documented data, and are within the scope of the discipline or sub-discipline. Also, the periodic review of testimony to ensure the validity of opinions and interpretations.

Technical Reviewer: A person who is qualified in a specific discipline or sub-discipline that conducts a technical review in the discipline or sub-discipline. For the purpose of the Serology/DNA Unit, this is defined by the Federal Bureau of Investigation Quality Assurance Standards. See this document if further clarification is needed.

TBI Crime Laboratory: The units of the TBI Forensic Services Division responsible for evidence receiving, inventorying, and examination/calibration services.

TBI Official Report: The official document that presents case-related information, including any examination results, to a customer regarding TBI Laboratory activity.

Tender: The laboratory's response to the customer regarding their request. This may include an automated notification.

Testing: Determination of one or more characteristics of a test item, according to a procedure.

Test Record: Administrative records and technical records generated or received by a laboratory pertaining to testing/calibration performed, which may be stored in one or more locations.

Top Management: Person or group of people who direct and control an organization at the highest level.

Traceability: Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties.

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Uncertainty: A non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Uncontrolled Document: A document not distributed in a traceable manner.

Validation: The process of performing a set of experiments to establish the fitness for use of a technique, procedure, instrument, or modification thereof.

Verification: The rendering of an unbiased, independent evaluation, and subsequent opinion of the actual evidence items performed by a qualified examiner, other than the "primary examiner".

Will: A term used when an element of the quality system is required.

Working Standard: Used routinely to calibrate or check material measures, measuring instruments, or reference materials.

Work Sheet: A standard form that when completed may contain pertinent case information such as results, descriptions, instrument operating parameters, lot numbers, etc. for ease of record keeping.