Testing Quality Assurance Manual

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1 QUALITY MANAGEMENT SYSTEM 5
1.1 POLICY 5
1.2 DEFINITIONS 5
1.3 QUALITY POLICY STATEMENT 6
1.4 QUALITY ASSURANCE PROGRAM 7
1.5 QUALITY SYSTEM RECORDS 9
2 DOCUMENT CONTROL 11
2.1 POLICY 11
2.2 DEFINITIONS 11
2.3 PROCEDURE 11
2.4 REVISIONS TO PROCEDURES AND TECHNICAL DOCUMENTS 14
3 INTERNAL AUDITS AND MANAGEMENT REVIEWS 17
3.1 POLICY 17
3.2 DEFINITIONS 17
3.3 PROCEDURES 17
3.4 DOCUMENTATION 19
4 CONTROL OF NONCONFORMING WORK 20
4.1 POLICY 20
4.2 DEFINITIONS 20
4.3 PROCEDURE 21
4.4 PREVENTATIVE ACTION 26
5 PERSONNEL QUALIFICATIONS AND TRAINING 27
5.1 POLICY 27
5.2 DEFINITIONS 27
5.3 QUALIFICATIONS OF PERSONNEL 28
5.4 TRAINING 28
5.5 COMPETENCY TESTING AND AUTHORIZATIONS 32
5.6 JOB PERFORMANCE 32
5.7 PROFESSIONAL DEVELOPMENT PROGRAM 34
6 EQUIPMENT MAINTENANCE 37
6.1 POLICY 37
6.2 DEFINITIONS 37
6.3 CALIBRATION OF EQUIPMENT 37
6.4 BALANCES 39
6.5 CENTRIFUGES 39
6.6 DILUTERS 40
6.7 EVAPORATORS 40
6.8 HEATING BLOCKS, SAND BATHS, INCUBATORS, OVENS 41

6.9 HYDROGEN GENERATORS 42
6.10 NITROGEN GENERATORS 42
6.11 pH METERS 42
6.12 PIPETTES 43
6.13 VOLUMETRIC FLASKS AND PIPETTES 44
6.14 REFRIGERATORS AND FREEZERS 44
6.15 THERMOMETERS 45
6.16 TRACEABILITY 46
7 PURCHASING SERVICES AND SUPPLIES 47
7.1 POLICY 47
7.2 PROCEDURE 47
8 REAGENTS AND CONSUMABLE SUPPLIES 51
8.1 POLICY 51
8.2 REAGENTS 51
8.3 CONSUMABLE SUPPLIES 53
9 REFERENCE MATERIALS 54
9.1 POLICY 54
9.2 DEFINITIONS 54
9.3 PURCHASE 54
9.4 LABELING AND STORAGE 55
9.5 VERIFICATION 55
9.6 RECORDS 55
9.7 REFERENCE COLLECTIONS 56
9.8 REFERENCES 57
10 ASSURING THE QUALITY OF TEST RESULTS 58
10.1 POLICY 58
10.2 PROFICIENCY TESTING 58
10.3 TECHNICAL PROCEDURES AND METHODS 58
10.4 SAMPLING PROCEDURE 61
10.5 ENVIRONMENTAL CONDITIONS 62
10.6 DEVIATION FROM POLICY OR PROCEDURE 63
10.7 RESOLUTION OF ISSUES CONCERNING TECHNICAL PROCEDURES 63
10.8 SUBCONTRACTORS 63
10.9 QUALITY CONTROL 64
10.10 UNCERTAINTY OF MEASUREMENT 65
11 PROFICIENCY TESTING 67
11.1 POLICY 67
11.2 DEFINITIONS 67

11.3 FREQUENCY 68
11.4 APPROVED TEST PROVIDERS 68
11.5 GENERAL 69
11.6 ASSIGNMENT AND SCHEDULING 70
11.7 TESTING PROTOCOL 70
11.8 REVIEW OF PERFORMANCE 71
11.9 REFERENCES 73
12 RECORDS, REVIEWS AND REPORTS 74
12.1 POLICY 74
12.2 DEFINITIONS 74
12.3 TESTING DOCUMENTATION 75
12.4 REVIEW OF RECORDS 78
12.5 FOCUSED REVIEW 82
12.6 TOXICOLOGY TEST REPORTS 83
12.7 SUPPLEMENTAL TEST REPORTS 86
12.8 AMENDED TEST REPORTS 86
12.9 RESOLUTION OF TECHNICAL DIFFERENCES OF OPINION 87
13 TRACEABILITY AND QUALITY CONTROL 88
13.1 POLICY 88
13.2 TRACEABILITY AND QUALITY CONTROL OF REAGENTS 88
13.3 VALIDATION/VERIFICATION OF EQUIPMENT AND INSTRUMENTATION 89
13.4 ELECTRONIC DATA AND COMPUTER SOFTWARE 92
13.5 TRACEABILITY OF MEASUREMENT STANDARDS 93
LIST OF CHANGES 96

1 QUALITY MANAGEMENT SYSTEM

1.1 POLICY

The Washington State Patrol (WSP) Toxicology Laboratory Division (TLD) has developed and maintains a quality management system (QMS) appropriate to the testing work performed by the Laboratory. The Laboratory will document its policies, programs, procedures and instructions to the extent necessary to assure the quality of the test results. Use of the following terms indicate the relevant information is to be addressed in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule and specify.

The system's documentation will be communicated to, understood by, available to, and implemented by the appropriate personnel. The QMS policies, procedures and objectives are defined in this Quality Assurance Manual.

Forensic Scientists, and other technical personnel, are directed to seek guidance from TLD Management for specific topics not addressed in this or other related documents.

1.2 DEFINITIONS

1.2.1 Annual: Annual in this manual refers to the calendar year unless otherwise specified.

1.2.2 Analysts: Also referred to as Forensic Scientists. Laboratory personnel assigned to perform testing work in the laboratory, including the issuing of test reports, as authorized.

1.2.3 Appointing Authority: Person with direct authority to authorize qualified personnel to perform specific aspects of testing work, and remove/reinstate personnel or systems from performing testing; the TLD Commander/State Toxicologist.

1.2.4 Forensic Laboratory Services Bureau (FLSB): WSP bureau that includes the TLD, Crime Laboratory Division and Impaired Driving Section. The FLSB is overseen by the FLSB Director.

1.2.5 Laboratory Manager: The individual having overall operational responsibility of the testing laboratory.

1.2.6 Quality: Adherence to generally recognized standards of good laboratory practice.

1.2.7 Quality Assurance (QA): Those processes and systematic actions necessary to provide confidence that the laboratory's work product and services will satisfy given requirements for quality.

1.2.8 Quality Assurance (QA) Manager: The individual with oversight of the QA Program for the TLD.

1.2.9 Quality Assurance (QA) Manual: A collection of the TLD's quality management system policies and objectives for its testing functions, and how these policies, procedures and objectives will be implemented.

1.2.10 Quality Assurance Program: A planned system of activities describing requirements for forensic analyses and reporting, the purpose of which is to provide confidence that the work product and services provided by the TLD are scientifically sound and valid.

1.2.11 Quality Assurance Records: Records, logs, worksheets and electronic files that provide documented support of conformity to the QMS. These records include, but are not limited to, method and equipment validation documents, equipment verification records, reagent and chemical logs, training records, proficiency and competency test records, courtroom testimony monitoring records and audit records.

1.2.12 Quality Control (QC): Internal activities or activities conducted according to established standards used by the TLD to consistently ensure accurate analytical results.

1.2.13 Quality Management System (QMS): The total organizational structure, responsibilities, policies, procedures, and resources for implementing quality management. This includes all activities which contribute to quality, directly or indirectly.

1.2.14 Supervisors: Individuals with overall technical responsibility of personnel performing testing in the laboratory. Also known as the Forensic Scientist Supervisors (FS-5).

1.2.15 Technical Procedures/Training Procedures: Scientific methodologies used in forensic analyses. Written procedures will be prepared for routine tests performed by the TLD. The procedures used may be those developed and validated in–house or by an outside laboratory and the foundational training program required for all qualified forensic scientists, prior to assuming forensic analysis.

1.2.16 Testing: Testing functions performed by the TLD (testing of biological or aqueous specimens for the presence of alcohol and/or other drugs), unless otherwise specified.

1.2.17 TLD Management: Includes the TLD Commander/State Toxicologist, Laboratory Manager, QA Manager, Supervisors and Administrative Services Manager. Members of TLD Management are responsible for those tasks related to the Laboratory's management system, as described in this QA Manual.

1.2.18 TLD Commander: The individual who oversees the TLD. Also known as the State Toxicologist and Appointing Authority.

1.3 QUALITY POLICY STATEMENT

TLD Management, and all personnel, will operate the testing laboratory according to a documented quality management system. The purpose of the quality management

system is to provide a framework for producing quality service at all levels of the organization. TLD Management is committed to good professional practice and setting a high standard for the quality of its forensic toxicology testing services. TLD Management is also committed to the continuous improvement of the quality management system by monitoring its effectiveness through, amongst other things: meeting the training needs of personnel, successful proficiency testing, periodic audits and management system reviews, effective corrective and preventive actions and communication with its customers and staff to identify improvement measures.

All Laboratory personnel are required to familiarize themselves with this quality assurance manual and to implement the policies and procedures contained herein as well as those contained in technical documents, forms and other instructions when conducting testing in the Laboratory. Personnel are also required to familiarize themselves with the *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel*, reinforcing the Laboratory's overall commitment to good professional practice. By doing so, and by contributing to the objective of continual improvement of the management system, personnel will help to achieve the Laboratory's standard of service as stated below and affirmed by TLD Management signatories.

Laboratory Standard of Service

The TLD will provide professional, conscientious service to its customers by adherence to: consensus standards for laboratory competence which include the ISO/IEC 17025:2017 *General Requirements for the Competence of Testing and Calibration Laboratories* and ANAB ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125) and American Board of Forensic Toxicology (ABFT) requirements, its own quality management system, and to the laws of the State of Washington. High standards of service will be maintained through diligent attention to all details of testing work performed by the Laboratory, and the TLD will strive to set the standard for this work against which similar programs will be judged.

TLD Commander/State Toxicologist

TLD Quality Assurance Manager

TLD Laboratory Manager

Elizabeth Gough
Acting TLD Commander

1.4 QUALITY ASSURANCE PROGRAM

The Laboratory's QA program includes all technical and supporting procedures and quality records, which TLD Management uses to oversee and review the effectiveness of the program. This ensures that the Laboratory adheres to those policies and procedures described in this Quality Assurance Manual.

1.4.1 Laboratory Quality Management

TLD Management is responsible for ensuring that the policies and procedures adopted by the Laboratory are implemented and integrated into its daily operations. The QA Manager is also responsible for overseeing, monitoring and ensuring compliance to the QMS.

The main duties of the QA Manager include, but are not limited to:

- Overall responsibility for the Laboratory's QA program, including all audits and reviews
- Works to maintain and improve the Laboratory's QA program
- Maintaining QMS documents and records
- Monitors criteria compliance for respective accrediting bodies
- Evaluation of compliance to the Laboratory's training programs, ensuring uniform quality of education and training
- Ensure uniform methodology implementation and use within the Laboratory
- Ensure that procedures and training manuals for the discipline accurately reflect established standards and comply with accreditation requirements
- Review for adherence to procedure and approval of new methodology, technologies and equipment validations
- Evaluate new analytical procedures, equipment or technologies, oversee their validation and assist with implementation
- Administers and coordinates the Laboratory's proficiency testing program. This includes documentation and response to ANAB and ABFT regarding proficiency performance
- Oversight and review of root cause analysis and corrective actions for nonconformities and inconsistencies in testing work

The supporting duties of other members of TLD Management include, but are not limited to:

- Ensures compliance to the QMS by all technical and support personnel
- Coordinating the training and development of each Forensic Scientist from basic development through continuing education
- Monitors the development and implementation of the technical and training manuals
- Review of manuscripts for publications
- Review of research projects

1.4.2 All Technical and Support Staff

It is the role of all technical and support staff to follow technical and laboratory supporting procedures, including the documentation required by the QA Program, and to seek to produce the highest quality work in the most efficient manner possible. This commitment helps the Laboratory meet the needs of the customer and to demonstrate to the citizens of Washington that the TLD are good stewards of the resources given us.

1.4.3 Division Documents

The list below represents the documentation upon which the QMS is built. The Testing Quality Assurance Manual has over-riding authority over all operations and technical manuals. The WSP Regulation Manual has over-riding authority over all TLD Manuals.

WSP REGULATION MANUAL

TLD Testing Quality Assurance Manual

- TLD Operations Manual
- TLD Standard Operating Procedures and Policies
- TLD Training Modules/Manuals
- TLD Safety Plan

1.5 QUALITY SYSTEM RECORDS

The Laboratory will document those procedures for the access to, and filing, storage, retention and disposal of its quality system records. Quality system records are any logs, worksheets, electronic files or databases that provide documented support of conformity to the QMS.

1.5.1 These records include, but are not limited to:

- Method and equipment validation documents
- Instrument and equipment maintenance and verification records
- Reagent and chemical logs
- Training records
- Proficiency test records
- Competency test completion records
- Courtroom testimony monitoring records
- Audit records

These records are maintained by Laboratory staff, as described below.

1.5.2 Records filed, stored and retained by the QA Manager or designee

- Training completion records
- Proficiency test answer sheets
- Method validation approvals
- Corrective action and preventive action records
- Policy and procedure manual document review and approval forms
- Audit records and reports
- Management system review records
- Official electronic controlled documents/forms
- Equipment validation, performance verification and maintenance records
- Testing files and records, and any associated examination or administrative documentation according to retention schedules
- Chemical and reagent logs and worksheets

- Standards preparation records and verification logs

1.5.3 Records filed, stored and retained by TLD Management or designee

- Equipment Inventory
- Building maintenance and security records and logs (where applicable)
- Key control records
- Visitor logs
- Laboratory safety inspection reports

NOTE: FLSB or building-wide records may be stored and retained by FLSB or Crime Laboratory Division personnel (e.g., maintenance, security, key control or visitor logs)

1.5.4 Records Maintained in Bureau-Wide Databases

Other records (e.g., library/journal collections) may be maintained in FLSB computer systems or databases.

All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage, deterioration or loss.

Quality system records for the current calendar year and, as space allows, quality system records from previous years, are stored within the main Laboratory. Quality system records that the main Laboratory area cannot accommodate will be transferred to the on-site shared records storage room. The shared records storage room is within the limited-access, secured areas of the facility, and is used by the TLD and the Crime Laboratory Division.

Quality system records are transferred from the main Laboratory or shared records storage room to the State Records Center for secured, long-term storage (*see Operations Manual section 3.2*).

Records stored electronically shall be stored as to prevent unauthorized access or amendment, and will be routinely backed up to prevent loss.

1.5.5 Archive and Retention of Quality System Records

Retention and disposal of quality management system records will follow the WSP Archive Record Retention Schedule or for a period of five years or one accreditation cycle, whichever is longer. A current copy of the Archive Record Retention Schedule may be found on SharePoint.

2 DOCUMENT CONTROL

2.1 POLICY

The Laboratory shall control Management System documents to ensure that only the current, approved documents are being utilized. The procedures for the creation, revision and distribution of controlled documents are described below. The official versions of all TLD documents are accessible to personnel via the FLSB Portal (SharePoint), and all WSP manuals, documents and forms are controlled and distributed by the agency.

2.2 DEFINITIONS

2.2.1 Document: Information in any medium including, but not limited to, paper copy, electronic file, audio or videotape, photograph.

2.2.2 Document Control: The process for ensuring that controlled documents, including revisions, are reviewed, approved and issued by authorized personnel, and distributed to personnel performing the prescribed activities.

2.2.3 Controlled Document: A document distributed to personnel in a controlled manner. Examples of controlled documents include manuals, procedures, policies and forms.

2.2.4 Document Review and Approval Form (DRA): Form used for proposal of new controlled documents and all proposed modifications to controlled documents. Includes documentation of reviews and approval of the documents.

2.2.5 Records: Documents, logs, worksheets and electronic files that provide support of conformity to the QMS, maintained at the laboratory.

2.2.6 Uncontrolled Copy: A copy of a controlled document provided for informational purposes only. Examples include copies provided to external inspectors, copies required for legal discovery, and any printed copies of controlled documents.

2.2.7 Issuing Authority (ies): Personnel authorized to approve controlled documents. The Laboratory's issuing authorities are authorized members of TLD Management.

2.2.8 Master Document File: An electronic file maintained by the QA Manager and available to all TLD personnel, via the FLSB Portal, which contains the current revision status of any controlled document.

2.3 PROCEDURE

2.3.1 Controlled Document Format

Each controlled document will have the following format requirements:

2.3.1.1 A header on each page containing, at a minimum:

- Washington State Patrol Toxicology Laboratory Division
- Document title, including type of manual where applicable

2.3.1.2 A footer on each page containing, at a minimum:

- Page _ of _ (if more than 1 page)
- A statement indicating that “Printed Copies are Uncontrolled”
- The unique document identification
- Revision number and effective (issue) date
- Approved by/Issuing authority (ies)

2.3.1.3 Controlled forms used in the Laboratory do not require “Printed Copies are Uncontrolled” in the footer, as they are templates used for entering data or information.

2.3.1.4 The revision number indicates the total number of times the document has been revised since adoption of original document.

2.3.1.5 All controlled documents will have a history record maintained by the QA Manager, indicating the date of inception of the document and any subsequent revisions. The history record may be incorporated into a document (e.g., manual, test method/procedure) or as a separate document. The history record will include the following:

- A brief revision summary (why the revision was made)
- The section(s) revised
- Date revision approved
- Author of revision or reviewer of document and issuing authority

The Document Review and Approval (DRA) form fulfills the requirements for original documents and subsequent revisions listed above.

2.3.2 Preparation of Controlled Documents

2.3.2.1 Documents should be prepared by personnel with adequate knowledge of the subject and the detail of the document should be commensurate with the complexity of the activity and the background of the intended user of the document. The proposed document must include sufficient information to ensure that the activity conforms to quality specifications and/or expectations.

2.3.2.2 Laboratory-specific policies and procedures cannot supersede the Washington Administrative Code (WAC)/Revised Code of Washington (RCW), the WSP Regulation Manual, or the Division’s Testing Quality Manual.

2.3.2.3 The preparer of the new or revised document is responsible for:

- Preparing the document in the proper format
- Acquiring copies of listed references

- Addressing or resolving comments from reviewers
- Assuring that there are no conflicts with other TLD manuals, WSP regulations and/or the WAC/RCW
- Submitting for review and approvals using the DRA form

2.3.3 Review of Controlled Documents

2.3.3.1 A technical and quality review of each new or revised controlled document is required prior to approval. Technical review is for accuracy and clarity. The reviewer(s) must have adequate technical expertise in the discipline to evaluate the document.

2.3.3.2 The quality review is to ensure that the document conforms to accreditation and quality standards, and is typically performed by the QA Manager or designee. TLD Management may also perform reviews of controlled administrative documents.

2.3.4 Approval/Issue of Controlled Documents

2.3.4.1 Prior to issuance, controlled documents will be approved through the chain of command with final approval by authorized personnel. Once approved, the QA Manager or designee will post the official documents on the FLSB Portal. TLD personnel will be notified by the QA Manager or designee via e-mail, and the notification will include the effective date. Administrative access to the official electronic controlled documents will be restricted to prohibit unauthorized changes.

2.3.4.2 The Laboratory Manager and QA Manager are authorized by the TLD Commander/State Toxicologist to approve/issue TLD controlled documents. The TLD Commander/State Toxicologist has overall authority to approve/issue TLD documents.

2.3.5 Archiving Controlled Documents

2.3.5.1 Obsolete documents will be maintained in designated archive folders within the appropriate sections of the FLSB Portal (e.g., manuals, forms) and will be labeled as “Archived” with the archive date included. If a watermark cannot be imposed on the document, it will be otherwise clearly identified as obsolete (e.g., insert a text box with “Archived” and the date, insert “Archived” into the name of the posted document).

2.3.5.2 Obsolete documents shall be promptly removed from all points of issue or use, or otherwise assured against unintended use. Obsolete documents retained for either legal or knowledge preservation purposes shall be suitably marked.

2.3.6 Annual Review of Controlled Documents

2.3.6.1 All controlled manuals, documents and forms will be reviewed annually and revised as needed to ensure they reflect the current policies, practices, and technology. Document revisions are subject to the same review, approval, documentation and issuance requirements of the original document as described in section 2.3 above. Review of new

documents, or documents revised within the last calendar year, is documented in the relevant DRA record.

2.3.6.2 TLD Management and/or designees will conduct this review of all administrative documents and technical and training manuals, procedures and forms. This review is documented in writing (e.g., e-mail, spreadsheet), from the reviewer to the QA Manager.

2.3.6.3 The TLD Commander/State Toxicologist will also review the documentation of annual review and will authorize, in writing, the continued use of those documents not scheduled for revision as a result of annual review.

2.3.7 Official Controlled Documents

2.3.7.1 All official controlled documents are made available for use by laboratory personnel via the FLSB Portal (SharePoint), to which all TLD employees will have access. Employees shall only use current versions of approved documents. Any copies of documents from this site represent unofficial copies.

2.3.7.2 The QA Manager or designee will maintain all official controlled documents, including archived versions, on the FLSB Portal. The QA Manager will maintain the documents on the FLSB Portal (master document file); those administrative, quality or technical documents (internal and external documents) that govern the operations of the Laboratory. The master file must include the document identifier such as the version or revision number.

2.4 REVISIONS TO PROCEDURES AND TECHNICAL DOCUMENTS

2.4.1 Recommendations for additions, deletions or modifications to technical and training documents will be made through the QA Manager, or through the Laboratory Manager if administrative/operational in nature.

NOTE: Minor edits for typographical errors or administrative changes may be made/approved by a member of TLD Management.

2.4.2 For revisions of technical documents, the QA Manager or designee (i.e. the preparer) will be responsible to ensure that the recommended changes represent the accepted body of scientific knowledge, both internal and external to the Laboratory.

2.4.3 For administrative/operational changes to documents, personnel submitting proposed revisions are responsible to ensure that the recommended changes represent the objectives of the TLD and are not in conflict with the WSP Regulation Manual or the WAC/RCW. The QA Manager will be responsible for ensuring that there are no conflicts between recommended changes and the QMS.

2.4.4 A DRA with the suggested document changes must be submitted to the QA Manager for distribution and review by TLD Management. The following information must be provided:

- The document title, unique document identification and current revision number
- Reference to the specific section of the document to be modified, or the proposed new document or section
- A statement briefly describing the need for the procedure modification or incorporation of a new procedure

2.4.5 Proposed changes must be submitted, with the DRA, as an edited version of the current document. Changes to the document or procedure will be clearly identified, with deleted portions in strikeout text and additions highlighted in yellow (or otherwise marked clearly to indicate changes).

2.4.6 After review, the QA Manager will submit the written recommendation(s) to the TLD Commander for review and final approval (in DRA form). The TLD Commander or designee will make a decision within 30 days to approve/adopt, return or table the recommended document revision or additions.

2.4.7 Amendment of documents, pending the electronic re-issue of the revised controlled document, is allowed, provided the change(s) is clearly communicated to all personnel.

2.4.7.1 If circumstances dictate that an immediate revision is necessary, the revision may be communicated by e-mail or IOC, to allow for immediate implementation prior to actual manual changes. A watermark may be added to the affected document to clearly state the change. The Issuing Authority in these cases will be any member of TLD Management.

2.4.7.2 The communication will include the title/identification of the document, the effective date of the revision and the specific language being modified (added or removed). The communication will be posted alongside the affected document on the FLSB Portal and, wherever possible, a hyperlink will tie the communication directly to the revised document.

2.4.7.3 The affected document will be amended through the document revision process as soon as practicable from the time of the immediate implementation of the change (*see 2.4.4 and 2.4.5*).

2.4.8 Approved/Adopted

2.4.8.1 After approval, the revised document will be posted on the FLSB Portal and TLD personnel will be notified by the QA Manager or designee via e-mail. The notification will include the effective date of the revision.

2.4.8.2 Once a document is adopted, it is the responsibility of TLD Management to ensure it is implemented. If applicable, a Directive Control, Receipt and Compliance, or other sign-off sheet will be circulated for signatures of affected staff, and retained by the QA Manager.

2.4.9 Returned

Any DRAs submitted to the QA Manager that need to be returned will be accompanied by a written explanation and/or suggestion for modification.

2.4.10 Tabled

Any DRAs submitted to the QA Manager that need to be tabled will be accompanied by a written explanation along with the estimated date for reconsideration, if applicable.

3 INTERNAL AUDITS AND MANAGEMENT REVIEWS

3.1 POLICY

An internal audit of the Laboratory will be performed annually to verify that operations are in compliance with established TLD policies and procedures, ISO/IEC 17025 requirements (and any ANAB supplemental requirements) and ABFT checklist items, and applicable WSP policies, rules and regulations. A Management System Review of the Laboratory's management system and testing activities will also be conducted annually.

3.2 DEFINITIONS

3.2.1 Audit Cycle: The period of time between on-site audits by the accrediting body. An audit cycle will generally be a period of four years for full reassessment and two years for surveillance assessments.

3.2.2 Internal Audit: A review conducted by TLD or FLSB personnel to compare the various aspects of the Laboratory's performance against stated requirements, standards, policies and procedures.

3.2.3 External Audit: A review conducted by personnel from outside the TLD which compares the various aspects of the laboratory's performance against stated requirements, standards, policies and procedures.

3.2.4 Finding: A result from an audit that is not in conformance with accreditation criteria, TLD policies and procedures, or applicable WSP regulations.

3.2.5 Observation: A result from an audit that indicates a potential for nonconformity.

3.2.6 Focused Review: A review of an individual's testing work or a laboratory process, as requested by a member of TLD Management.

3.2.7 Management System Review (MSR): An annual review by TLD Management of the Laboratory's management and quality systems and testing activities to ensure continuing suitability and effectiveness. The finding of this review will be used as a tool to introduce necessary changes or improvements by management.

3.3 PROCEDURES

3.3.1 Audits will involve an on-site inspection of the Laboratory (including witnessing of testing work), and will address all elements of the quality system. The QA Manager will plan, organize and direct the audits and has oversight of findings, CARs and follow-up.

3.3.2 Audits will be conducted by qualified personnel who are, wherever resources permit, independent of the activity to be audited. Auditors may come from the TLD, FLSB or outside the Bureau.

3.3.3 Should audit findings cast doubt on the effectiveness of operations, or on the correctness or validity of the Laboratory's test results, corrective actions shall be

initiated.

3.3.3.1 If investigation indicates that test results may have been significantly affected, the Laboratory shall notify customers in writing. Policies and procedures regarding nonconforming work (*see Chapter 4*), internal audits, and job performance (if applicable, *see section 5.6*) will be followed.

3.3.3.2 Additional audits, such as a focused review or external audits may be requested by a member of TLD Management at any time to address specific concerns.

3.3.3.3 TLD Management will ensure that any corrective actions that arise from internal audit or MSR findings are implemented within an appropriate and agreed upon timeline and will evaluate the effectiveness of the corrective actions taken.

3.3.4 Elements of the Management System Review (MSR)

NOTE: Many elements of the MSR are continuously reviewed/discussed as part of supervisor and/or management meetings, with meeting minutes supplemental to the formal MSR report(s).

3.3.4.1 The annual MSR will address the following points:

- Internal and external issues relevant to the laboratory
- Review of status/actions from the previous MSR
- The suitability of policies and procedures
- Reports (written or verbal) from managerial and supervisory personnel
- A review of internal audits
- Corrective and preventive actions taken in the last year
- A review of external audits/assessments
- Proficiency test program results and any findings
- Client feedback
- Quality system complaints
- Recommendations for improvement and effectiveness of implemented improvements
- Other relevant factors such as quality control activities (ensuring validity of results), resources, and personnel training

3.3.4.2 The overall quality goals and fulfillment of objectives, as outlined in the quality policy statement, will also be reviewed. TLD Management will consider the results of the MSR when developing goals, objectives, and action plans for the coming year.

3.3.4.3 An evaluation of risks and opportunities related to the Laboratory's testing activities will be discussed to identify the potential impacts of any risks, including those to the health and safety of laboratory personnel.

3.3.4.4 The list of those drugs identified in the Laboratory's testing, and those test methods used (posted on the WSP Forensic Laboratory Services website) will

be reviewed during the MSR. The list will also be reviewed/updated, as needed, based on customer requests/comments or changes/additions to the Laboratory's test battery.

3.3.4.5 Any nonconforming work and resulting action(s), as well as results of Supervisory Case Review, will be discussed. TLD Management will determine whether any follow-up is needed in response to the review (e.g., additional training, reporting criteria or procedures).

3.3.5 Complaints

3.3.5.1 A review of handling of complaints by the laboratory will be included in the MSR. This review will ensure that:

- The laboratory has a documented process to receive, evaluate and make decisions on complaints
- A description of the handling process for complaints is available upon request
- The process of handling complaints is tracked, from receipt, through investigation and any actions taken in response
- Appropriate action is taken in response to complaints
- Communication to the complainant acknowledging receipt of the complaint, progress on the investigation/response and the outcome
- Where possible, person(s) included in complaints involving technical performance/personnel should not be involved in handling the investigation/ response to the complaint
- Complaints involving administrative or clerical errors may be resolved by the person(s) making the errors

3.4 DOCUMENTATION

3.4.1 A summary report for the internal audit (outlining the area of activity audited, any findings or observations and corrective actions) or the MSR will be prepared by the QA Manager and submitted to the TLD Commander.

3.4.2 Documentation of the outcome of the MSR will include the effectiveness of the management system and its processes, improvement of laboratory activities to demonstrate fulfillment of ISO/IEC 17025 requirements, acquisition of future resources and implementation of any changes required.

3.4.3 The MSR, internal audit reports and any corrective actions associated with findings will be documented by the QA Manager, submitted as required to accrediting agency(ies), and retained for a minimum of four years.

4 CONTROL OF NONCONFORMING WORK

The Laboratory will implement policies and procedures for the evaluation and investigation of testing work that is identified as not in conformance with the Laboratory's policies, procedures and other requirements. Personnel responsibilities, actions taken and documentation of the corrections or corrective action/preventive action process are described below.

4.1 POLICY

This policy applies to technical, quality and administrative aspects of the Management System within which nonconformity or opportunities for improvement may exist (e.g., in analyses, proficiency tests, reports, documentation, testimony).

Should Laboratory personnel identify a nonconformity, or potential source(s) of nonconformity, he/she will notify a member of TLD Management. Nonconformities will be documented, and nonconformities that require a corrective action plan will be investigated using root cause analysis.

Should the identified nonconformity cast doubt on the Laboratory's overall ability to maintain compliance with its policies and procedures, or other requirements (*ISO/IEC 17025:2017 and ANAB ISO/IEC 17025:2017 – Forensic Testing and Calibration Laboratories Accreditation Requirements (AR 3125, ABFT)*, an audit(s) shall be initiated of the relevant areas of testing work. Those policies and procedures found in sections 3.3 and 3.4 of this manual shall be followed.

4.2 DEFINITIONS

4.2.1 Appointing Authority: Person with authority to authorize personnel to perform testing work and approve test methods for use in the Laboratory. The Appointing Authority must authorize reinstatement of personnel or test methods, should the personnel/test method have been removed from testing work as part of either correction or the formal corrective action process; the TLD Commander/State Toxicologist.

4.2.2 Corrections: Actions taken to address and resolve a nonconformity that has occurred.

4.2.3 Corrective Action Process: The process followed in response to a nonconformity that requires a corrective action plan. It shall include:

- Cessation of work affected by the nonconformity
- Notification of appropriate authorities
- Evaluation of significance
- Assignment of corrective action responsibilities
- Preparation of corrective action plan (where applicable)

- Root cause analysis
- Selection, implementation and documentation of appropriate corrective action(s)
- Preparation of corrective action report (where applicable)
- Authorization to resume work
- Periodic assessment of plan effectiveness (where applicable)
- Evaluation of risks and opportunities in relation to the nonconformity

4.2.4 Corrective Action Report (CAR): A formal report (e.g., IOC) by the Supervisor or appropriate authority detailing the following:

- A description of the incident (what is the nature of the nonconformity?)
- A root cause analysis, including any chain of events leading to or causing the nonconformance
- The corrective action plan
- Any specific assessment of plan effectiveness including periodic evaluation and person designated responsibility for evaluation (where applicable)
- Risks and Opportunities that are identified as a result of the nonconformity

4.2.5 Nonconformity of Work: Non-fulfillment of a work requirement; any aspect of the Management System that does not agree with established laboratory, technical or quality system procedures or requirements. Identification of nonconformities may occur through the following:

- Internal or external inquiries or complaints
- Quality control processes
- Instrument calibration
- Observations of testing personnel
- Supervisor observations
- Technical and administrative review of reports and documentation
- Indications of inadequate peer review
- Management reviews
- Internal or external audits

4.2.6 Preventive Action: Actions that are taken to address potential sources of nonconformity that have been identified.

4.2.7 Root Cause Analysis: A process of fact finding used to evaluate all aspects of the occurrence to identify the basis of the nonconformity; a tool designed to help identify what, how, and why an event occurred, or the underlying factors leading up to the nonconformity.

4.3 PROCEDURE

The procedures followed when addressing nonconforming work are described below, including the corrective action process, if warranted in response to the identified nonconformity.

4.3.1 Nonconforming Work Procedures

4.3.1.1 Notification of Appropriate Authority

Personnel identifying any nonconformity or potential source(s) of nonconformity in testing work will notify a member of TLD Management, generally his/her Supervisor. The Supervisor will notify other members of TLD Management, as appropriate. Notification will include all details necessary to fully evaluate the significance of the nonconformity.

Laboratory personnel identifying improvement opportunities which may prevent nonconformity are also directed to notify his/her Supervisor or other member of TLD Management.

4.3.1.2 Evaluation of Significance

When nonconforming work is identified an evaluation of its significance, and acceptability of the affected work, will be initiated. The evaluation will include identification of the policy or procedure that has not been met and whether this has impacted testing work. If work has been affected, it must be determined whether or not work needs to be stopped or recalled (e.g., test method, personnel).

The evaluation process will be used to determine the appropriate course of action to address the nonconformity. Dictated by the severity of the nonconformity, response may range from corrections (implemented immediately) to initiation of the formal corrective action process. The evaluation, investigation and any corrections implemented will be documented.

Instances of nonconformity that do not result in the corrective action process will be documented in a report of nonconforming work (IOC), retained by the QA Manager, and in relevant testing files or case records, or on the Supervisory Case Review Checklist, retained in the case file. Initiation of the formal corrective action process, in response to a severe nonconformity, is described in 4.3.2, and will be documented in a corrective action report (CAR).

4.3.1.2.1 Where the nature or cause of the nonconformity does not, to any significant degree, affect the fundamental reliability of the laboratory work product or the integrity of the Management System, response/correction will be handled at the supervisory level by counseling and documentation, where appropriate. Recurring instances of nonconforming work by a single individual, test method or process may result in a more severe response.

4.3.1.2.2 Nonconformities are considered severe if the nature or cause of the nonconformity directly affects, raises immediate concern and has a fundamental, substantive impact on the work product of the laboratory and/or the integrity of the Management System.

If warranted, for the most severe nonconformities, response will include immediate removal of the personnel and/or method and/or Laboratory from testing work by the Appointing Authority. If the nonconformity is a

result of, or related to, a laboratory-wide or system-wide deficiency, the Appointing Authority will ensure the entire Laboratory discontinues testing work in the affected area until the nonconformity is addressed and resolved. The customer(s) will be notified and work recalled, when necessary. The occurrence will be reported to the accrediting agency(ies) within the agency's designated time frame, and/or included in the annual audit report (however named).

4.3.1.3 Where appropriate, the customer will be notified and, where necessary, an amended laboratory report will be issued. Those corrections implemented to resolve the identified nonconformity will be documented in the case record.

4.3.1.4 If testing personnel, instrumentation or a test method have been removed from testing work in response to the nonconformity, additional actions may be taken (e.g., instrument/method verification, proficiency testing of personnel) before the personnel, instrument or test method are authorized/reinstated for testing work. Personnel or test methods removed from testing work by the Appointing Authority may only be authorized to perform/return to testing work by the Appointing Authority (see 4.2.1).

4.3.1.5 If evaluation indicates that the problem could recur, or that compliance of operations with the Laboratory's policies and procedures is in doubt, the corrective action process will be implemented.

4.3.2 Corrective Action Process

4.3.2.1 Assignment of Corrective Action Responsibilities

4.3.2.1.1 The Appointing Authority will determine whether the issue may be handled locally or will require involvement of other personnel. The person having immediate supervisory authority will move forward with the corrective action process by implementing a Corrective Action Plan (see below).

4.3.2.1.2 The Appointing Authority will have final authority to determine the appropriate course of corrective action to eliminate and/or correct the problem and prevent recurrence. Corrective actions shall be appropriate for the magnitude and risk of the problem.

4.3.2.1.3 Depending upon the severity of the nonconformity, a course of corrective action may include focused review (see 12.5), an external investigation conducted by the WSP Office of Professional Standards (OPS), or an external audit conducted by an appropriate entity.

4.3.2.1.4 For less severe nonconformities, the immediate Supervisor will handle the corrective action process, generally with counseling. Documentation will be maintained with the Supervisor in the individual's supervisory desk file. If technical in nature, the nonconformity may also be documented in the appropriate testing files and/or records.

4.3.2.2 Corrective Action Plan

A corrective action plan will be prepared in response to those nonconformities described in 4.3.1.2.1. The personnel assigned supervisory authority will prepare a Corrective Action Plan, which will be forwarded to the QA Manager and Appointing Authority for approval. Once the corrective action plan is approved, it should be implemented immediately and all necessary corrective actions taken within the expected time frame for completion.

4.3.2.2.1 A Corrective Action Plan should consider the following:

- The root cause of nonconformity
- Recall and review of prior testing work to ensure correct analysis
- Consideration if the analyst, laboratory or entire system is to be removed from testing work and a plan describing timeframe to return analyst, laboratory or system to calibration work.
- A Job Performance Improvement Plan (JPIP) if needed, limited to no more than 90 days in length
- A description of how the work is to be reassigned until the nonconformity is corrected
- Identification of any training, equipment, protocol modification, or testing work reanalysis needed to correct the problem. A reasonable timeline for completion should be established.
- Any steps needed to inform external customers of the extent of the problem and recommendations for appropriate resolution

4.3.2.2.2 Difficulties with an employee's individual work performance will generally be addressed by the employee's Supervisor with assistance from other members of TLD Management, as needed. The actions taken to correct the problem should be focused on the professional development of the employee, which normally includes remedial training and other assistance in effort to help the employee overcome the problem.

4.3.2.3 Root Cause Analysis

4.3.2.3.1 Root cause analysis may include an evaluation of procedures, documents and records, staff training, consumable supplies, equipment, customer requests and requirements, test items, reagents and controls. While conducting a root cause investigation, the supervisory authority may consult with all necessary personnel, inside and outside of the laboratory, to determine the basis of the nonconformity.

4.3.2.3.2 Nonconforming work may be a systemic error rather than employee error, or a combination of both. The root cause analysis may provide a platform for process improvement, and may help guide value-additive changes in policy and procedure.

4.3.2.3.3 If, at the conclusion of the investigation, the root cause cannot be determined, it will be documented that the root cause of the nonconformity could not be identified.

4.3.2.4 Notification of Clients

When nonconformities occur that impact testing work, it may be necessary to notify the customer of the facts surrounding the event. Where necessary, an amended laboratory report will be prepared as soon as possible, and provided to the submitting agency and/or customer (client notification). The technical and/or administrative measures taken to resolve the discrepancy will be documented in the case record.

4.3.2.5 Corrective Action Report (CAR)

All changes implemented as a result of the corrective action process will be documented. Following completion of the corrective action plan, the person assigned supervisory authority will submit a written summary of the action(s) taken and the CAR, including all the elements listed above in the definition, to the QA Manager for review before submitting to the Appointing Authority.

The CAR and all supporting documentation will be retained by the QA Manager for a minimum of four years.

4.3.2.6 Responsibility for Authorizing Resumption of Work

In cases where an analyst has been removed from testing work, or when required by a corrective action plan, a follow-up proficiency test may be issued by the QA Manager, following successful completion of the corrective action plan. Anytime a process or instrument is removed from work as a result of a nonconformity, it may not be returned to use in casework until authorized by the Appointing Authority, Laboratory Manager or QA Manager. Personnel removed from testing work by the Appointing Authority may only be authorized to resume testing work by the Appointing Authority.

4.3.2.6.1 The QA Manager may direct follow-up action(s) to confirm the effectiveness of the corrective action plan, if applicable. This may include review of testing work and audits of the laboratory.

4.3.2.6.2 The QA Manager will maintain records of significant nonconformities, proposed improvements and proposed preventative actions for at least four years.

4.3.2.6.3 When corrective actions require revision of current Laboratory policies and procedures, the process for amending/revising controlled documents described in 2.4 will be followed. The QA Manager is responsible for coordinating these changes and notifications.

4.3.2.7 Evaluation of Implemented Corrective Action

The results of implementation of the corrective action plan will be evaluated and monitored to ensure their effectiveness, where applicable.

4.3.2.7.1 A review of performance (employee, laboratory, system) will be conducted following completion of the corrective action report.

4.3.2.7.2 Reviews will be conducted by the assigned supervisory authority, within the time frames described in the CAR, with a summary report provided to the QA Manager and Appointing Authority.

4.3.2.7.3 If the nature of the nonconformity, and resulting corrective action plan, does not dictate that future monitoring is needed (beyond scheduled annual reviews, audits, etc.), this will be noted in the CAR.

4.3.2.7.4 If, upon conclusion of the corrective action process, opportunities for changes to the management system and potential risks are identified, these will be evaluated by TLD Management. Any changes implemented as a result of the nonconformity/corrective action will be documented in the nonconformance/corrective action record or MSR summary.

4.4 PREVENTATIVE ACTION

The Laboratory employs procedures for identifying opportunities for improvement and for the identification, implementation and monitoring of preventive actions, with the goal of eliminating potential sources of nonconformity or its reoccurrence. All personnel are encouraged to identify improvements and preventive actions, as an opportunity to enhance the quality of the Laboratory's testing work.

4.4.1 Proposals for improvement or preventive actions will be brought to the attention of TLD Management, preferable in writing (e-mail, IOC). TLD Management will evaluate the suggestion(s) and determine if an action plan is needed.

4.4.2 Improvements and preventive actions will be documented in a preventive action plan may include one or more of the following:

- Research regarding policies and procedures in other toxicological testing laboratories or jurisdictions
- Consultation with clients to ascertain the extent of their needs
- Consultation with laboratory technical personnel to obtain developmental suggestions
- Validation of technical methods according to Laboratory procedures
- Monitoring of effectiveness with Laboratory personnel and clients of the toxicological testing services

4.4.3 Procedures for preventive actions shall include the initiation of such actions and include the use of measureable controls to ensure their effectiveness.

5 PERSONNEL QUALIFICATIONS AND TRAINING

The Laboratory will ensure that personnel performing specific aspects of testing work shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills. The Laboratory shall use only those personnel employed by the Laboratory (to include permanent or project positions assigned to the laboratory). Personnel must be competent, trained and supervised by competent staff to ensure that their work conforms to the Laboratory's quality program.

The Laboratory will have a documented training program to include new employee training, training in a new area, retraining and continuing education for maintaining skills and expertise in the field of forensic toxicology. TLD Management is responsible for ensuring that proper training occurs for all Laboratory personnel, and each employee will share in the responsibility of maintaining his/her functional area expertise.

5.1 POLICY

5.1.1 The Laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

5.1.2 Training records will be sufficiently detailed to provide evidence that employees have been properly trained and that their ability to perform specific responsibilities associated with each category of testing has been evaluated.

5.2 DEFINITIONS

5.2.1 Competency Test: The final examination provided to a trainee at the end of training modules or at the end of the training plan for a specific area or procedure. The competency test may be written, oral and/or practical. The competency test results are evaluated by the assigned trainer, Supervisor, and/or the QA Manager.

5.2.2 In-Training Plan (TP): Documents the essential duties and responsibilities for the trainee and includes the timeline and requirements for completion of the plan.

5.2.3 Position Description Form (PDF): The PDF shall be completed for all Laboratory personnel and is retained in the employee's supervisory desk file and updated as necessary.

5.2.4 Testing Work: Analytical work performed by a Forensic Scientist, in the discipline of Toxicology, and categories of human performance and post-mortem testing.

5.2.5 Trainee: A trainee is any employee of the Laboratory who is training in a new discipline, procedure or job classification. Trainees can be permanent, probationary, or trial service.

5.2.6 Trainer/Instructor: Trainers/Instructors interact with the trainee to teach one or more aspects of a technical procedure or administrative topic. Trainers/Instructors have

the responsibility for ensuring the trainee successfully completes his/her training tasks.

5.2.7 Training Module: Outlines the necessary requirements to become competent in a specific procedure and may include information on theory and principles, reading assignments, and practical exercises.

5.3 QUALIFICATIONS OF PERSONNEL

The Laboratory must ensure that all employees' qualifications are verified and documented. The Laboratory Manager has the overall responsibility to demonstrate the qualifications and competence of all Laboratory personnel.

5.3.1 Educational Background

5.3.1.1 Minimum educational and/or other requirements for Laboratory technical positions are found in the respective position description forms.

5.3.1.2 Verification of educational requirements for personnel is under the purview of the Washington State Department of Personnel (DOP) and WSP Human Resource Division (HRD).

5.3.1.3 The WSP HRD will ensure that college transcripts of all employees are reviewed at the time of employment. Official transcripts will be maintained in the employee's file at WSP HRD.

5.4 TRAINING

New employees will receive training in order to become qualified and competent in their assigned area(s) of responsibility, and tenured employees must build upon their current knowledge and abilities in order to meet the challenges of the constantly evolving discipline of toxicology.

5.4.1 Training Goals

Training needs of an employee may be identified through individualized training plans and goals (e.g. quarterly Performance Development Plans (PDP) for new Forensic Scientists), TLD strategic plans, TLD Management requests and needs of the customers.

5.4.1.1 Training goals include, but are not limited to:

- Basic competency in area(s) of responsibility
- Maintenance of acquired skills and abilities
- Instruction in new and improved techniques and/or methods
- Instruction in the use of new instrumentation and/or equipment
- Acquiring and maintaining professional accreditation or certification
- Meeting agency requirements for mandatory training and policy awareness

5.4.1.2 Training goals/needs are also addressed in *5.4.2 Training Plans* and *5.7.1 Continuing Professional Development and Maintaining Competency.*

5.4.1.3 Training goals may also be discussed in Laboratory meetings and/or during the annual Management System Review.

5.4.2 Training Plans

Training plans will be developed and maintained for each new and permanent employee. Supervisors will work with each employee to develop his/her training plan, which serves as the basis for the employee's professional development program. When developing the training plan, the Supervisor must consider the needs of the individual employee, the Laboratory and the Laboratory's customers.

5.4.2.1 Training plans will have clearly defined, measureable goals (*see 5.4.1*), whereby progress and successful completion of specific aspects of training are established. Measureable goals may include, but are not limited to, examinations, certifications and/or competency tests.

5.4.2.2 Training plans shall include the review and application of ethical practices in forensic sciences, a general knowledge of forensic science, specifically in the toxicology discipline, and those criminal and civil law procedures that may apply to the testing work (if applicable).

5.4.2.3 For new employees, an In-Training Plan (ITP) may be utilized by the employee's Supervisor. The ITP may be developed by Supervisors, WSP HRD, the Laboratory Manager or the TLD Commander and includes a description of the essential duties and responsibilities of the position, a timeline for the trial service period, and the requirements for successful completion of the ITP. The Supervisor and employee will meet periodically to discuss/evaluate the ITP throughout his/her training.

5.4.2.4 Employees' ongoing training plan may be included as part of the annual performance evaluation. The plan should be updated at least annually, or as often as needed throughout the year. The Supervisor or employee may request a review or update to the training plan.

5.4.2.5 Supervisors will take an active role in the training of their employees and ensure training is documented appropriately.

5.4.3 Training Documents

The Laboratory enlists several document resources for training purposes, including Laboratory manuals, policies, training modules, technical procedures and other references. Technical procedures (i.e. standard operating procedures, "SOPs") contain the approved test methods, instrument parameters and criteria for acceptance of the results.

5.4.3.1 Training modules are developed by the Supervisors, Forensic Technical Leads and/or other technical personnel. The modules include technical procedures and may include procedures for other aspects of the testing work, such as documentation, review of documentation and report writing.

5.4.3.2 Training modules may be controlled or uncontrolled documents, and may be updated as frequently as needed, as new information and/or techniques become available.

5.4.3.3 Laboratory manuals, policies, technical procedures and SOPs used in employee training are updated, as warranted, to reflect changes implemented in the Laboratory. Trainees are instructed on how to locate the official, approved versions of these, and all controlled documents, on the FLSB portal.

5.4.4 Trainer/Trainee Method

The Laboratory employs the trainer/trainee method as a valuable component in training of new employees or those employees in a new job classification. This method ensures that specific training goals are achieved and provides means of evaluation and feedback for the trainee and trainer/instructor, ultimately gauging the overall effectiveness of the training program.

5.4.4.1 Trainer/instructor Selection

The trainer/instructor will be selected by the Supervisor, based on their overall knowledge and experience. The trainer/instructor should possess a thorough understanding of WSP and TLD policies and procedures, a strong working knowledge of the chemistry and instrumentation implemented in the Laboratory, and awareness of the specific standards, requirements and expectations of work performed in a forensic toxicology laboratory. Any permanent member of Laboratory's technical personnel may be considered as a trainer/instructor, provided they exhibit those qualifications listed above, and the role is often filled by Forensic Scientists and Forensic Technical Leads (FS 4).

5.4.5 Training Program

5.4.5.1 Policy

Prior to receiving authorization to perform testing work in the toxicology laboratory, trainees will successfully complete the established training, certifications and competency tests, and must be appropriately supervised throughout this process. This training will provide personnel with the knowledge, skills and abilities needed to perform testing work.

5.4.5.2 Procedure

The following guidelines are provided to ensure the effective implementation, and the employee's successful completion, of the Laboratory's training program:

5.4.5.2.1 The Supervisor and employee develop the employee's training plan, as described in 5.4.2.

5.4.5.2.2 The Supervisor assigns a trainer/instructor to the employee. Note that different trainer/instructors may be assigned for specific phases of the employee's training, and the trainer/instructor may be the Supervisor.

5.4.5.2.3 The trainee will work with the assigned trainer/instructor(s) to successfully complete the developed training program. Completion of the required training elements will be documented by both the trainee and the trainer/instructor.

5.4.5.2.4 During the training period, training evaluations will be completed and documented by the trainer/instructor (may be documented on PDP). The results of these evaluations will be discussed with both the trainee and the trainee's Supervisor. At the conclusion of the training period, the effectiveness of the training program shall be evaluated and documented (e.g., questionnaire completed by the employee, interview).

5.4.5.2.5 Upon successful completion of the prescribed training plan by the trainee, the Supervisor will submit a request (e.g., email, IOC) to the QA Manager, indicating training has been completed and the trainee is ready to receive the competency test. The QA Manager or designee will administer the competency test, either directly, or indirectly, through the Supervisor.

5.4.5.2.6 The trainee will submit the results of the competency test, and all examination records associated with the testing, to the Supervisor for review and evaluation. The QA Manager will also review the employee's performance on the competency test.

5.4.5.2.7 If the trainee does not successfully complete the competency test, the Supervisor will work with the employee to determine a course of action which may include additional training prior to administration of another competency test.

5.4.5.2.8 If the trainee has successfully completed the competency test, the QA Manager will submit an IOC to the TLD Commander/State Toxicologist, recommending that the analyst be authorized to perform toxicology testing work.

5.4.5.3 Training Program Records

All records related to the training of an employee will be maintained by the trainee and/or Supervisor, and will be retained for four years or one accreditation cycle, or in accordance with agency/division records retention policies.

NOTE: A Forensic Scientist may receive individual authorizations to perform specific test methods through the method certification process. The scientist may perform evidential analysis using those test methods for which they have received authorization. However, scientists may not assume the work of a primary analyst (e.g., issue/authorization of test reports with results from any testing performed by the laboratory or subcontractors) until this training program has been completed and he/she has been authorized by the TLD Commander/State Toxicologist to perform toxicology casework testing (*see 5.5.2 and 5.5.3*).

5.5 COMPETENCY TESTING AND AUTHORIZATIONS

TLD Management will ensure the competence of personnel authorized to perform specific tests, use equipment and instrumentation, evaluate results, and sign/author test reports.

5.5.1 All analysts, regardless of academic qualifications or past work experience, shall satisfactorily complete a competency test prior to assuming testing work.

5.5.1.1 Competency tests include individual certification tests for particular test method(s) and general competencies covering the scope of a specific discipline or category (ies) of testing.

5.5.1.2 The competency test will include, but is not limited to:

- Examination of unknown samples, covering the spectrum of the analyst's expected testing work
- Evaluation of the analyst's ability to select and perform proper testing methods
- A written test report to evaluate the analyst's ability to properly convey results
- A written or oral examination to assess the analyst's knowledge of human performance and post-mortem toxicology, or the specific task being performed

5.5.2 Analysts shall receive written authorization from the TLD Commander/State Toxicologist to perform a particular test method(s) prior to using that test method(s) in testing work. Authorization will include use of sampling (if applicable) and any equipment, instrumentation, software, etc. associated with performance of that test method.

NOTE: A single written authorization may cover a single test method, several methods of the same type, or all testing work in a particular discipline or category of testing.

5.5.3 Analysts shall receive written authorization from the TLD Commander/State Toxicologist to perform toxicology casework testing. This authorization includes reporting of results of the test (LIMS entry), issue (authorize) test reports and provide opinions and interpretations of information contained in the test reports.

5.6 JOB PERFORMANCE

5.6.1 Documenting Job Performance

Supervisors will document the work performance of each employee they supervise and maintain those records in a supervisory desk file. Annual performance evaluations are required, and are documented using the PDP form.

5.6.1.1 Supervisory desk files include the PDP form, used in the annual performance evaluation, and may include other positive and/or negative supporting documents, counseling, work directives, evaluations, or records relating to an employee's job performance throughout a performance period.

5.6.1.2 Supervisory desk files are required to be purged each year following an annual evaluation. Employee training records will be maintained separately and shall not be purged (*see 5.4.5.3*).

5.6.1.3 Employees will have access to and be made aware of the contents of the supervisory desk file (*see the respective Collective Bargaining Agreement*).

5.6.2 Re-Training

Re-training in a given discipline will be required when:

- An employee has not maintained competency or proficiency in a discipline in which he/she was previously qualified
- An employee was previously qualified in a discipline, but within another laboratory system
- A procedure or training manual has been significantly revised
- Re-training is directed by a corrective action request (CAR), corrective action plan, job performance improvement plan (JPIP) and/or remedial training

5.6.3 Job Performance Improvement Plans, Corrective Action Plans and Remedial Training

Discrepancies and complaints regarding the work of an employee will be investigated, and it will be determined whether further action is needed. Remedial training, a Job Performance Improvement Plan (JPIP), or a corrective action plan may be required due to discrepancies or issues discovered during any of the quality review processes employed by the Laboratory, or by internal or external complaints received.

5.6.3.1 If a discrepancy in an employee's testing work has been identified, the employee may be removed from such work, pending evaluation of the significance of the discrepancy. If the discrepancy is determined to be the result of nonconforming work, procedures in *Chapter 4 Nonconforming Work* will be followed.

5.6.3.2 If evaluation has determined that remedial training is needed, the Supervisor and the employee, with input from other members of TLD Management, will design a JPIP or corrective action plan with clearly defined goals and time lines. The time frame for the completed JPIP should be no more than 90 days, and the progress of the plan will be measured at frequent intervals and fully documented in the employee's supervisory desk file.

5.6.3.3 If the employee removed from testing work successfully completes their JPIP or corrective action plan, the Supervisor will forward a recommendation for the employee to resume work to the QA Manager, who will review and forward the recommendation to the Appointing Authority for final approval.

5.6.3.4 If the employee cannot successfully achieve competency after the required training, the Supervisor will consult with the Laboratory Manager and QA Manager to recommend a course of action to the Appointing Authority. Any course of action will be taken with due regard given to the needs of both the employee and the Laboratory.

5.7 PROFESSIONAL DEVELOPMENT PROGRAM

TLD management is committed to the continuing professional development and ongoing competency of all employees. The Laboratory's professional development program encourages employees to participate in their professional development, as this is vital to the overall quality of the Laboratory's programs and services.

5.7.1 Continuing Professional Development and Ongoing Competency

5.7.1.1 TLD Management will use Laboratory meetings, and other means of communication (e.g., e-mail, newsletters, annual evaluations) with employees, to identify and evaluate ideas for improvement, training needs and opportunities, in support of the professional development program.

5.7.1.2 Training and continuing education opportunities are available through online programs or seminars and partnerships with local agencies (e.g., medical examiners, WSP Drug Recognition Expert program). The TLD will also provide in-service training opportunities for the purpose of exchanging technical information on techniques, legal challenges, policy changes and/or research developments.

5.7.1.3 Attendance at conferences and workshops sponsored by professional forensic organizations, or membership in those organizations, is an effective way for personnel to establish and maintain contact with others in the fields of toxicology and analytical chemistry.

5.7.1.4 Other sources of training and information include:

- Laboratory personnel experienced in a variety of forensic analyses and processes
- Laboratory-sponsored training courses utilizing visiting experts
- WSP sponsored training
- Agencies and institutions such as the Washington Criminal Justice Training Commission
- Journals of professional forensic science organizations and other scientific literature
- Instrument applications or maintenance/troubleshooting training provided by the manufacturer
- Robert F. Borkenstein Course on Alcohol and Highway Safety
- Robert F. Borkenstein Course on the Effects of Drugs on Human Performance and Behavior

5.7.2 Request for Training/Completion of Training

If an employee has interest in attending external training, the employee will submit a Training/Travel Request (TTR). The completed forms will be routed through the chain of command for approval, with out-of-state training events requiring final approval by the Bureau Chief or designee. The TTR may be created and forwarded as a hard copy or electronic document.

5.7.2.1 All education and training requests should be approved or denied within thirty (30) calendar days from the submission of a properly completed request. If a

request is denied, the person denying the request will provide a reason for the denial to the employee (*consult current Collective Bargaining Agreement*).

5.7.2.2 An employee must report the completion of their approved training event on a TTR for any training requiring chain of command approval. If a certificate of completion is provided for the training, a copy will be attached to the form. If a certificate of completion is not provided, the form will be forwarded to the Supervisor for signature to verify completion of training.

5.7.2.3 The employee will retain the original TTR, and the Supervisor will retain a copy. If a certificate of completion is provided, the Supervisor will retain a copy of the certificate.

5.7.2.4 The employee may request that the training be entered into his/her official record of training by forwarding the completed TTR, signed by the Supervisor or accompanied by a certificate of completion, to the Bureau's e-train coordinator.

5.7.3 Laboratory Library

The Laboratory will have access to a library containing current books, journals, and other references related to the field of forensic toxicology (e.g., analytical chemistry, chemical analysis, pharmacology).

5.7.3.1 Forensic Scientists are responsible for taking time to read periodicals, journals, articles, books, and other relevant literature in order to keep current with information and developments in the field.

5.7.3.2 The Laboratory maintains a list of the contents of the FLSB libraries, often distributes by email the tables of contents of various journals, magazines and publications, and is a resource for obtaining specific journal articles and other references upon request.

5.7.3.3 References may also be posted on the FLSB Portal (e.g., presentations or publications from SOFT or AAFS meetings, newsletters, published news articles, journal articles, studies).

5.7.4 Courtroom Testimony Training

TLD Management will ensure that testimony training is provided to employees whose job descriptions include providing courtroom testimony in support of the Laboratory's testing work (*see also Chapter 5 of the TLD Operations Manual*).

5.7.4.1 Training will include, but is not limited to:

- Basic courtroom procedures
- Appropriate interaction with attorneys and judges
- Presentation of education, qualifications and experience
- Addressing chain of custody for submitted evidence
- Discussion/interpretation of test results and other information contained in the test report or case record
- Mock trial

5.7.4.2 This training may be provided internally by the Laboratory and/or by an external source. Training will be documented, with documentation retained in the employees' training records.

6 EQUIPMENT MAINTENANCE

6.1 POLICY

The Laboratory shall implement policies and procedures for the calibration, maintenance, traceability and maintenance of records for equipment used in the performance of testing work.

6.1.1 The Laboratory shall be furnished with all sampling, measurement and test equipment needed to ensure the correctness and quality of the testing performed. All equipment employed in testing activities is utilized within the permanent Laboratory.

6.1.2 Equipment will be uniquely identified by its manufacturer serial number. In addition, an internal identification may be assigned for purposes of internal documentation.

6.1.3 Equipment will be operated by authorized Laboratory personnel, and current instructions for the use and maintenance of the equipment (e.g., maintenance checklists, maintenance procedures, manufacturer user manuals) will be readily available.

6.1.4 Equipment will be stored, transported and handled in a manner as to ensure its proper function and protect it from contamination or deterioration, according to manufacturer and/or service provider recommendations. Should the performance of equipment be in question due to possible improper storage, transport or handling, performance verification will be performed and documented (*see 13.3.5*).

6.2 DEFINITIONS

6.2.1 Equipment: Equipment refers to those devices used during the course of testing that support the test result or measurement and that may or may not affect the outcome. In general, equipment is distinct from the instrumentation used to conduct a test on evidence.

6.2.2 Maintenance: Those activities associated with the proper handling and operation of equipment that help to ensure its continued suitability for use. Maintenance may include a repair or, as more frequently encountered, an ongoing process of preventative care done at a defined interval.

6.2.3 Calibration: Operation that, under specified conditions, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication (VIM 2008).

6.3 CALIBRATION OF EQUIPMENT

Analytical equipment requiring calibration (e.g., diluters, analytical balances, pipettes, volumetric flasks, thermometers), having a significant effect on the accuracy or validity of the result of the test or sampling procedures, will be calibrated prior to

being implemented in the laboratory. Calibration status will be checked after removal of the equipment from service and following service or other substantial maintenance.

6.3.1 Equipment used for testing and calibration (hardware and software), will be safeguarded from adjustments that may cause the test and/or calibration results to be invalid.

6.3.1.1 It is the policy of the Laboratory that Laboratory personnel will not perform any adjustments to the hardware or software of equipment. Personnel operating equipment must be trained appropriately and authorized.

6.3.1.2 Access to the internal hardware and/or software of balances, diluters, pipettes and thermometers is prevented by the use of physical barriers such as covers or plates. Annual calibration/verification and the use of intermediate checks of equipment are performed to ensure compliance.

NOTE: User-approved maintenance of positive displacement pipettes includes removal of the outer sheath for cleaning. If necessary, the inner sheath/shaft may also be removed for cleaning. Performance verification must be done following removal of the inner sheath/shaft.

6.3.2 External calibration of equipment will only be conducted by an approved calibration provider.

6.3.3 Approved calibration providers will be evaluated for the competence and traceability of their calibrations.

6.3.4 Accreditation to ISO/IEC 17025 is considered evidence of the competency and traceability of a calibration provider's services; however, the scope of the calibration services must be appropriate to the equipment undergoing calibration.

6.3.5 Up-to-date certificates and scopes of accreditation will be maintained for all approved calibration providers.

6.3.6 Equipment requiring calibration will have a documented calibration schedule.

6.3.7 Should it be determined that intermediate checks of the calibration status of equipment is necessary, this will be documented (*see 10.9.4*). Intermediate checks (e.g., pipette performance verification, diluter certification), of equipment will be conducted according to written procedures. When an internal check fails to meet a standard of acceptability, the equipment shall be transferred to an external calibration provider for service.

6.3.8 Equipment requiring calibration shall be labeled, coded or otherwise identified to indicate calibration status, including the date of the last calibration/ verification and the date (or other criteria) when recalibration/verification is due.

6.3.9 Calibration/recalibration documentation and calibration certifications will be maintained on file at the laboratory.

6.4 BALANCES

6.4.1 Calibration will be performed on an annual basis for any analytical or top-loading balances by an approved calibration service provider.

6.4.2 Maintenance of balances will include the following:

6.4.2.1 Keep the weighing stage clean and dry

6.4.2.2 Isolate the balance from vibration and air currents

6.4.2.3 Ensure the balance is level

6.4.3 Intermediate checks on balance accuracy will be made quarterly by the QA Manager or designee.

6.4.3.1 Analytical balances will be checked using ASTM Class-1 mass standards.

NOTE: Analytical balance checks performed prior to preparation of a stock solution from weighed reference material fulfill this quarterly requirement.

6.4.3.2 Top-loading balances will be checked using NIST Class F mass standards (or better).

6.4.3.3 Tolerances will be based on manufacturer specifications or internal acceptability ranges (listed on the Quarterly Balance Calibration Check Worksheet, BALCHWS). If tolerances are not met for an intermediate check, internal re-calibration functions for the balance may be employed or an approved calibration service provider may perform re-calibration.

6.4.4 Records of annual calibration, intermediate checks and of repairs will be retained in the Balance Calibration log.

6.4.5 ASTM Class-1 mass reference standards will be certified at least every 3 years by an approved service provider that can establish traceability to SI Units.

6.5 CENTRIFUGES

6.5.1 Calibration of laboratory centrifuges is not required. There are no critical speeds associated with any procedure and as such all references to centrifugal force, force of gravity or revolutions per minute (rpm) that appear in laboratory procedures are merely offered as recommendations. Additionally, any timeframes for the use of centrifuges in a particular procedure may be lengthened or shortened as needed to obtain the results

sought (separation of liquid layers, concentration of solids dispersed in liquids, etc.)

6.5.2 Maintenance of centrifuges will include the following.

6.5.2.1 Keeping the centrifuge clean and dry.

6.5.2.2 Using the centrifuge with the rotor properly balanced

6.5.2.3 Operating the centrifuge on a level surface

6.5.3 Intermediate checks on centrifuge performance are not required.

6.5.4 Any records of centrifuge repair will be maintained in the Miscellaneous Equipment log.

6.6 DILUTERS

6.6.1 External calibration of diluters (a.k.a. diluter-dispensers) will be performed annually, by an approved calibration service provider. Intermediate checks (diluter certification) will be performed by laboratory staff every 90 days or three months, whichever is longer, according to the *Procedure for Gravimetric Certification of Hamilton Microlab® Series Diluter-Dispensers (PQ12700).* If the diluter is not returned to service immediately following calibration or certification, the next diluter certification will be performed at 90 days or three months, whichever is longer, from the date the diluter was placed in service.

6.6.2 Additional intermediate checks on diluter performance (beyond 90-day/three month schedule) may be performed if diluter performance is in question.

6.6.3 User-approved diluter maintenance is described in the *Procedure for the Maintenance of Hamilton Microlab® Diluter-Dispensers (PThd12506)*. Internal maintenance and repair of diluters will only be performed by an approved external service provider.

6.6.4 Records of diluter certification are maintained in the Diluter Certification log and records of maintenance/repairs will be maintained in the Diluter Maintenance log.

6.7 EVAPORATORS

6.7.1 Calibration of evaporator temperatures is not required unless intermediate checks or normal operational use identify complete failure of the heating system requiring repair.

6.7.2 Maintenance of evaporators will include the following

6.7.2.1 Maintaining proper volume of water in the heated space of the evaporator.

6.7.2.2 Periodic replacement of water and use of anti-algae additives in the water.

6.7.2.3 Keeping the outside of the evaporator clean.

6.7.3 Intermediate checks of evaporator temperature will be conducted annually by the QA Manager or designee.

6.7.3.1 The temperature of the evaporator heated space will be measured using a NIST traceable thermometer.

6.7.3.2 The evaporator water will be heated to 40° C and the temperature verified to be within ± 4° C.

6.7.3.3 If the temperature is outside of tolerance, the evaporator will be taken out of service pending repair.

6.7.4 Records of evaporator maintenance, intermediate temperature checks and repairs will be maintained in the Miscellaneous Equipment log.

6.8 HEATING BLOCKS, SAND BATHS, INCUBATORS, OVENS

6.8.1 Calibration of heating sources is not required. There are no critical temperatures associated with any procedure and as such all references to temperatures employed for periods of incubation appearing in laboratory procedures are merely offered as recommendations. Heating sources may have integrated thermometers or supplemental thermometers.

6.8.1.1 Temperatures of heating implements will be recorded at time of use, documented on the worklist or other batch paperwork.

6.8.2 Maintenance of heating sources will include the following

6.8.2.1 Equipment will be kept clean.

6.8.2.2 Equipment faults will be identified and the equipment removed from service until repair.

6.8.2.3 Any supplemental thermometers used to estimate temperature will be maintained in good working order and replaced if damaged or found to be outside of tolerance by intermediate checks.

6.8.3 Intermediate checks of heating source temperature and supplemental thermometers will be conducted annually by the QA Manager or designee.

6.8.3.1 The temperature of the heating source will be measured using a NIST traceable thermometer.

6.8.3.2 The heating source will be set to the desired temperature and it, or supplemental thermometer, will be measured to within ± 4°C.

6.8.3.3 If the temperature is outside of tolerance, the heating source will be taken out of service pending repair. If measured using a non-integral thermometer, the thermometer will be replaced.

6.8.4 Records of intermediate temperature checks, repairs and supplemental thermometer replacement will be maintained in the Miscellaneous Equipment log.

6.9 HYDROGEN GENERATORS

6.9.1 Maintenance of hydrogen generators will include the following as needed. This maintenance, or more extensive preventive maintenance, may be performed by an approved service provider.

6.9.1.1 Add deionized water (DI H_2O).

6.9.1.2 Change moisture filter.

6.9.1.3 Replace deionizer bag/cartridge according to manufacturer recommendations.

a. Records of hydrogen generator maintenance and repairs will be maintained in the Hydrogen Generator Maintenance log.

6.10 NITROGEN GENERATORS

6.10.1 Maintenance of nitrogen generators will include the following. This maintenance, or more extensive preventive maintenance, may be performed by an approved service provider.

6.10.1.1 Replacement of pre-filters, as needed.

6.10.1.2 Replacement of any additional downstream filters according to particular instrument manufacturer recommendations.

a. Records of nitrogen generator maintenance and repairs will be maintained in the Miscellaneous Equipment log.

6.11 pH METERS

6.11.1 Calibration of pH meters will be done prior to use, and recorded on the pH Meter Maintenance Checklist. Specific calibration procedures will depend on the individual meter. Acceptability of calibration will depend upon tolerances defined for each meter but in general pH measurements should be within ± 0.1 units of the reference buffer.

6.11.2 Maintenance of pH meters will include the following.

6.11.2.1 pH probes will be rinsed with deionized water between each use.

6.11.2.2 Contact of pH probe with protein-containing samples and biological samples will be minimized.

6.11.2.3 pH probes will be stored according to manufacturer recommendations.

6.11.2.4 pH probes will be cleaned or the reference solution replaced every three months, following manufacturer instructions

6.11.2.5 Reference buffers will be used which bracket the pH range being measured.

6.11.2.6 Reference buffers will not be used past manufacturer expiration

dates.

6.11.2.7 Reference buffers will be dispensed into separate containers for measurement and never placed back into the source container.

6.11.3 Intermediate checks are not required for pH meters. Once calibration has been performed the pH meter is suitable for use for the remainder of the business day.

6.11.4 Records of maintenance and repairs will be noted in the pH Meter Equipment log.

6.11.5 For most measurements of pH, the use of indicating pH paper is a suitable substitute for a pH meter.

6.12 PIPETTES

6.12.1 Calibration of pipettes will be performed annually, by an approved calibration service provider. Pipettes refer to fixed volume, adjustable volume and multi-channel pipettes which employ disposable pipette tips (see 6.13 for volumetric pipettes). Calibration service may be more frequent if normal operational use identifies the need.

6.12.2 Maintenance of pipettes will include the following.

6.12.2.1 Pipettes will be kept clean and stored in an upright position.

6.12.2.2 Pipettes will be disinfected prior to being sent out for calibration.

6.12.3 Intermediate checks (performance verification) will be performed by an external provider, six months from the date of calibration. If the pipette is not returned to service immediately following calibration, the performance verification will be performed at six months from the date the pipette was placed in service.

NOTE: The pipette calibration/verification schedule permits completion of the performance verification within two weeks of the scheduled six-month due date.

6.12.4 New pipettes received by the Laboratory will be sent to the external calibration provider for performance verification prior to being put into use, and on an intermediate basis if performance is suspect.

6.12.5 Repeater-type pipettes do not require annual calibration. Performance verification is performed every six months by the Laboratory (*see NOTE in 6.12.3*).

6.12.6 Pipettes used for transfer only (not calibrated to deliver) do not require performance verification or calibration, and must be clearly labeled to indicate that they are not calibrated equipment.

6.12.7 Records of pipette calibration, performance verification, parts replacement and repair will be maintained in the Pipette Calibration log.

6.13 VOLUMETRIC FLASKS AND PIPETTES

6.13.1 Calibrated, serialized volumetric flasks will be used in preparation of stock or working standards (for use in preparing quantitative calibrators or positive controls). Calibrated, serialized volumetric pipettes may also be used in preparation of stock or working standards (e.g., ethanol calibrators).

6.13.1.1 Serialized volumetric flasks and pipettes will be calibrated by an external calibration provider prior to use. Once calibrated, the flask/pipette does not require periodic calibration checks.

6.13.1.2 Calibration is valid for a period of 10 years, unless otherwise specified by the calibration provider. Should the calibration status of a piece of glassware be suspect, it will be removed from use and calibrated by the external calibration provider.

6.13.1.3 Serialized volumetric glassware will be maintained and stored as to protect its integrity.

6.13.1.4 Records of volumetric glassware calibration will be maintained in the Glassware Calibration log.

6.14 REFRIGERATORS AND FREEZERS

6.14.1 Refrigerators and freezer cooling systems do not require calibration, but their proper operation will be monitored on a continual basis through the use of temperature logs.

6.14.2 Refrigerator and freezer maintenance will include the following

6.14.2.1 Temperatures will be monitored and recorded every business day.

6.14.2.2 Door seals will be kept clean and replaced if leaking or damaged.

6.14.2.3 Freezers will be defrosted as needed to prevent excessive build-up of ice.

6.14.2.4 Refrigerators should maintain average temperatures between 2 and 8°C. Freezers should maintain average temperatures between-20 and -5°C. Individual extreme temperature deviations (and, if necessary, associated follow up), should be noted in the temperature log.

NOTE: Laboratory refrigerators/freezers are opened often in the course of performing work (e.g., PEC/scientists retrieving evidence, scientists accessing the standards/blank blood refrigerators). As such, the average temperature is used as a gauge of performance for refrigerators and freezers.

6.14.3 If temperatures are noted to be just outside acceptable ranges then the thermostat may be adjusted to meet tolerances. If temperature control completely fails then all evidence, reference standards, quality control samples, drug standards or other temperature-sensitive materials are to be immediately re-located to a properly functioning refrigerator or freezer, where

possible. The malfunctioning equipment is to be tagged as out of service and a repair request begun.

6.14.3.1 Where an alternate refrigerator/freezer is not immediately available for relocation of temperature-sensitive materials, access to the affected refrigerator/ freezer will be limited, to minimize the temperature variation until repairs are made or a secondary location can be found. If it is determined the temporary storage conditions have impacted the contents of the refrigerator/freezer, this will be documented in the temperature monitoring records.

6.14.4 Records of thermostat adjustment, repairs and archived temperature logs are to be maintained in the Refrigerator/Freezer Temperature log. Records for temperature tracking using TempGenius™ are stored in, and accessible through, the manufacturer's data logging platform (see 6.15.2).

6.15 THERMOMETERS

6.15.1 Thermometers used to check critical temperatures in the laboratory will be NIST traceable or will have their measurement accuracy verified against NIST traceable thermometers.

6.15.2 Thermometers may be of the digital type or of the graduated tube, liquid expansion type. The wireless temperature monitoring platform TempGenius™ may be used for automated tracking of refrigerator/freezer temperatures. Alternative thermometers for non-critical temperature measurement may be used, such as bi-metal thermometers used in heating blocks.

6.15.3 Measurement accuracy will be verified at least annually for all thermometers used to check critical temperatures in one of the following ways.

6.15.3.1 Comparison to a NIST traceable, calibrated reference thermometer with comparative temperature tolerance of ± 2°C.

6.15.3.2 Certification by an approved calibration service provider.

6.15.4 Any thermometer found to be outside of measurement tolerance will be re-calibrated or replaced.

6.15.5 NIST traceability is good for two years from the date of purchase of a thermometer. Any certificate of calibration or traceability that accompanies a thermometer purchase should be retained.

NOTE: Certificates of calibration for thermometer/hygrometers may specify that NIST traceability for the thermometer is good for two years from the purchase date and NIST traceability for the hygrometer is good for one year from the purchase date. In this instance, the thermometer and hygrometer components will both be calibrated at one year from the purchase date and annually, thereafter.

6.15.6 Records of NIST traceability, certification by approved calibration service provider, intermediate temperature checks, annual temperature verification and repairs will be maintained in the Thermometer log.

6.16 TRACEABILITY

6.16.1 Analytical measuring equipment will be chosen that can show traceability to the International System of Units (SI) through an unbroken chain of comparisons to reference standards or primary standards.

6.16.2 Traceability to SI units is satisfied provided that the calibration provider is accredited to ISO/IEC 17025 and their scope of accreditation is relevant to the equipment being calibrated.

7 PURCHASING SERVICES AND SUPPLIES

7.1 POLICY

Services and supplies that affect the quality of testing work will be selected and purchased at a quality appropriate for the testing. The Laboratory shall maintain specifications for supplies and materials that affect the quality of the work within the standard operating procedures or other technical protocols.

7.1.1 The Laboratory shall ensure that standards, controls and reagents used in technical procedures are inspected or otherwise verified as complying with any defined standard specifications or requirements and verified prior to use, where applicable.

7.1.2 The Laboratory shall evaluate all suppliers of materials and services that have been determined to directly affect the quality of the testing work. A current list of evaluated and approved suppliers (Approved Vendor List) is maintained by the QA Manager or designee (*see 7.2.6*).

7.2 PROCEDURE

7.2.1 Purchasing of Supplies

Only Laboratory-approved vendors will be used for the purchase of supplies and reagents that affect the quality of the testing work (*see 7.2.6*). Vendors of other supplies, reagents and consumable materials, not affecting the quality of the testing work) do not require evaluation. The specifications for these materials may be found in the purchasing documents, described in the test method, or in the manufacturer item description (e.g., HPLC-grade solvents).

7.2.1.1 The Administrative Services Manager or designee oversees the purchasing process, including assignment of purchase order numbers (or equivalent), payment to the vendor(s) and maintenance of associated records (e.g., order tracking spreadsheet, invoice filing system).

Technical personnel are responsible for verifying that items entered in the electronic order tracking spreadsheet meet all specifications found in this quality manual or relevant SOPs. For those supplies and reagents that affect the quality of the testing work, only those suppliers listed on the Approved Vendors list will be used. Specifications of purchased items are also verified at time of receipt (see 7.2.2).

7.2.1.2 Orders will be approved by a member of TLD Management prior to being placed by the Administrative Services Manager or designee, documented by adding his/her initials to the order tracking spreadsheet.

7.2.1.3 The spreadsheet will include the following for each item:

- Date added and initials of the person adding the item
- Vendor from which the item is purchased
- Description of the item (e.g., purity, grade, pack size) and item count

- Item/order number
- Initials of person approving the order
- Purchase order number
- Date the order was placed

When possible, an order confirmation list, including item numbers and specifications, will be printed for orders submitted electronically.

7.2.2 Receipt of Supplies

Upon receipt, supplies and reagents will be checked or verified to ensure they are appropriate for their intended use.

7.2.2.1 Personnel receiving the supplies or reagents will check the packing slip against both the purchase request and those items received. If any discrepancies are identified, the supplies or material will not be placed in use until the problem is resolved. Discrepancies in the order will be recorded on the order documents. In addition, if the resolution includes returning the item, this will be noted on the shipping documents.

7.2.2.2 The person receiving the materials will indicate the following on the packing slip:

- The date received and his/her initials
- A check-mark by the items received to indicate the appropriate item and quantity were shipped
- Any discrepancies will be noted

7.2.2.3 The packing slip or receipt will be attached to the order document. Both will be retained at the Laboratory, by the Administrative Services Manager or designee, for a minimum of one year.

7.2.2.4 Purchased reagents or materials that affect the quality of the testing work will be verified or undergo reliability testing prior to release for use (*see 5.2 Reagents*).

7.2.2.5 If an item or product that has been put in use is found to be defective (e.g., not the expected quality) the following shall occur:

- The Supervisor will assess the product/item for suitability
- If the product/item has or may damage instrumentation or a process, then the Supervisor will immediately contact the QA Manager or designee who will alert all possible users
- A Supervisor will assess the damage and contact the responsible company for replacement of the product/item and/or possible reimbursement for damages
- Review of any testing work that may have been affected will be conducted (*see Chapter 4: Control of Nonconforming Work*)

7.2.2.6 Laboratory personnel will inform their immediate supervisor of any problem with a product/item or services received from any vendor.

7.2.3 Procurement of Equipment

Equipment will be selected and purchased on the basis of its appropriateness for specific functions, initial cost, ongoing support costs, and the availability of funds for equipment purchases and maintenance. Equipment may be procured directly by the Laboratory, or through the FLSB or WSP procurement and supply section.

7.2.4 Storage of Reagents and Laboratory Consumable Supplies

At a minimum, reagents and laboratory consumable supplies should be stored according to manufacturer/vendor recommendations. Material Safety Data Sheets (MSDS) or Safety Data Sheets (SDS) shall be readily available to all personnel.

7.2.5 Procurement of Services

Vendors selected to provide calibration, maintenance, repair, or other services will be evaluated prior to providing those services to the Laboratory. This evaluation may be conducted by the Laboratory, through the FLSB or WSP, or both. If it is determined that the service(s) have a direct effect on the testing work, this evaluation will be documented through the vendor approval process.

7.2.6 Vendor Evaluation

The Laboratory shall maintain a list of approved suppliers of reagents, supplies and services that affect the quality of testing. This list is maintained by the QA Manager or designee, is reviewed annually, and is posted on the FLSB Portal.

7.2.6.1 Suppliers of those items described above will be approved through the vendor evaluation process, with the evaluation and approval documented on the Vendor Evaluation and Approval form. The vendor evaluation may be based on the following criteria:

- The vendor currently meets ISO standards of accreditation or accreditation from another national accrediting organization
- Ability of the vendor to provide service/product in necessary time frame
- Ability of the vendor to provide service/product at acceptable cost
- Quality of product/service provided by the vendor as related to requirements in documented Laboratory policies and procedures
- Ability of the vendor to provide technical support when necessary
- Ability of the vendor to provide adequate instruction on use of service/product
- Ability of the vendor to provide adequate documentation of quality of service/product
- Ability to provide product traceability and uncertainty information, where applicable

7.2.6.2 The Vendor Evaluation and Approval form will include a description of those services or supplies/materials the vendor is approved to provide.

7.2.6.3 The Vendor Evaluation and Approval form, and supporting information/documentation (e.g., certificates of accreditation, certificates of analysis, product descriptions) will be prepared by, or submitted to, the QA Manager for review. This information may be in hard copy or electronic form.

7.2.6.4 The QA Manager, Laboratory Manager or TLD Commander/State Toxicologist has the authority to approve suppliers of those products/services that affect the quality of testing.

7.2.7 Transfer and Disposal of Equipment and Supplies

Transfer and/or disposal of items obtained by the Laboratory must comply with all applicable laws and administrative rules (see the WSP Regulation Manual). Supervisors or designee will ensure that the current agency policy on disposal of equipment is followed.

7.2.7.1 Equipment, including computer equipment and peripherals, that has been replaced or been placed permanently not in use will be disposed of or sent to the appropriate location as soon as practicable. Such equipment should not be retained or stored at the Laboratory, unless deemed necessary by TLD Management.

8 REAGENTS AND CONSUMABLE SUPPLIES

8.1 POLICY

This procedure describes the receipt, preparation, verification, labeling and documentation associated with reagents and consumable supplies used by the Laboratory. Deviations from these guidelines must be approved by a member of TLD Management and the approval documented.

8.2 REAGENTS

8.2.1 A reagent is broadly defined as a chemical, dilution of a chemical or combination of chemicals that is employed by the laboratory as specified in a technical procedure.

NOTE: Reagent is *not* synonymous with reference standards or reference materials which are used directly to (or in prepared standards that) calibrate, provide qualitative identification or verify quantitative accuracy (*see Chapter 9 Reference Materials*).

8.2.2 Critical reagents

Critical reagents are those materials determined to have a direct effect on the quality of testing performed by the Laboratory. For testing work, the 200 proof ethanol used to produce calibrators for blood ethanol/volatiles analysis is considered a critical reagent.

8.2.3 Examples of reagents may include any of the following:

8.2.3.1 A dry chemical such as the salt sodium chloride

8.2.3.2 A liquid chemical such as the solvent ethyl acetate

8.2.3.3 A liquid chemical prepared from either a dry or liquid chemical such as a buffer or dilute acid; for example sodium phosphate buffer or 0.1 M acetic acid.

8.2.3.4 A pre-diluted or pre-mixed chemical specified for use on a particular piece of equipment or by the manufacturer of a particular testing system; for example a labeled antibody or antigen complex used for immunoassay testing.

8.2.4 Receipt of reagents will include verification of the identity, quantity and, where applicable, the grade or purity of the order.

8.2.4.1 The person receiving the reagent will indicate the following on the packing slip; the date received, a check-mark by the items received to indicate the appropriate item and quantity were shipped, and receiver's initials or signature to indicate approval.

8.2.4.2 Receipt records will be maintained by the Administrative Services Manager.

8.2.5 If a reagent has been defined as critical then it may only be obtained from approved suppliers. An approved vendor list will contain information on critical supplies and services obtained from pre-approved sources.

8.2.6 Reagents will be handled, transported and stored with consideration of the hazards associated with the reagent and any manufacturer recommendations.

8.2.7 Verification of reagents or checking the reliability of reagents will occur through the normal testing process unless specified otherwise. If a reagent has been defined as a critical supply then the verification or reliability testing will occur before it is employed for evidence testing.

8.2.7.1 Acceptability of a reagent will be demonstrated through the attainment of acceptable results in routine casework whether they are proper qualitative identification of a known analyte or quantitative accuracy of a positive QC sample(s).

8.2.7.2 If verification or reliability checks do not support the reagent's use, then the reagent will be removed from service and any necessary retesting will be conducted.

8.2.7.3 If data/printouts or reports of analysis are generated in the process of verification, these will be filed in the Reagent Preparation log.

8.2.8 The reagent container will be labeled as follows or the information will be recorded in a log that is referenced to the specific reagent. For those reagents prepared at the laboratory, preparation/traceability information will be recorded in the Reagent Preparation log.

8.2.8.1 The identity.

8.2.8.2 Date of receipt, date of preparation or lot number.

8.2.8.3 The following will be recorded where applicable.

- Date the reagent container was opened (if original container)
- Initials of the person opening the container
- Initials of the person who prepared the reagent
- Raw material lot numbers used in reagents prepared in the laboratory
- The date the reagent was verified or the reliability was checked
- The initials of the person performing verification
- The expiration date
- Verification data, if performed

8.2.9 When reagents are transferred to secondary containers, the identity, date of preparation or lot number, initials of the person transferring and expiration date will be recorded on the container. For pure solvents transferred directly from supplier stock to a secondary container (e.g., oxford dispenser), labeling of the container with the solvent identity is sufficient.

8.2.10 Reagents prepared by the Laboratory may be stored at room temperature and used for up to 2 years after the preparation date, unless specified otherwise. This timeframe may be shortened based upon reagent performance.

8.2.11 Unless specified otherwise, pure solvents do not have an associated expiration date.

8.2.12 Reagents that are prepared in the laboratory will be done so following good laboratory and safety practices.

8.3 CONSUMABLE SUPPLIES

8.3.1 A consumable supply is any material other than a reagent which is purchased for laboratory use. It is not equipment or instrumentation but may be a component of either. For example, a GC injector inlet liner is used on the instrument as a consumable.

8.3.2 Consumable supplies should be selected through careful consideration of level of quality and performance and cost.

8.3.3 Any consumable supply that has been defined as critical will be purchased exclusively from an approved vendor as described on an approved vendor list.

8.3.4 As with reagents, receipt of consumable supply orders will be checked to verify that the quantity and type received is correct (*see 8.2.4.1 above*), with receipt records maintained by the Administrative Services Manager.

9 REFERENCE MATERIALS

9.1 POLICY

This procedure describes the purchase, handling and documentation related to reference materials used in the Laboratory. The term “reference material”, as it applies to toxicology testing, is synonymous with a drug, drug metabolite, toxin, or any other substance which is the focus of toxicological identification, calibration, value assignment or quality assurance. Deviations from these policies must be approved by a member of TLD Management and the approval recorded in the receipt records or other location, where appropriate.

9.2 DEFINITIONS

9.2.1 Certified Reference Material (CRM): Reference material, accompanied by documentation issued by an authoritative body and referring to valid procedures used to obtain a specified property value with uncertainty and traceability. [9.8.1]

9.2.2 Reference Material (RM): Material, sufficiently homogenous and stable regarding one or more properties, used in calibration, in assignment of a value to another material, or in quality assurance. [9.8.1]

9.3 PURCHASE

9.3.1 RMs are considered critical supplies and will be purchased only from suppliers who have been evaluated and approved as vendors of critical supplies. An approved RM supplier will have a Vendor Evaluation and Approval on file with the QA Manager.

9.3.2 Approval of an RM provider is based on adherence to ISO 17025 or ISO 17034 requirements, accreditation to other recognized and appropriate requirements, sole-source justification, ability to provide traceability to SI units, or a combination of these.

9.3.3 A RM may be obtained from a non-approved supplier if that supplier is the sole source of the RM; such as the case with a patented or proprietary compound.

9.3.4 RMs shall be traceable to SI units of measurement or CRMs. Internal reference materials shall be checked/verified, where practicable. If the CRM is changed in a way that alters the traceable measurement value (e.g., a measured volume is used in preparation of a standard solution), the equipment used must be evaluated for purposes of measurement traceability.

9.3.5 Wherever possible, the highest quality and highest purity RMs, appropriate to their intended use, will be purchased by the Laboratory. Lower purity reference materials may be employed but all necessary steps must be taken to compensate for sub-optimal purity (examples: factor purity into calculations, examine the effect, if any, of impurities on testing).

9.3.6 Upon receipt of RMs, the purchasing documents will be inspected to verify the following:

9.3.6.1 The identity.

9.3.6.2 The supplier is currently listed as an approved vendor of RM. (*see exception in 9.3.3*)

9.3.6.3 The RM is of the correct type, purity or grade as specified in the original order documentation.

9.3.6.4 The quantity received is correct.

9.3.6.5 The person receiving the material will indicate the following on the packing slip; the date received, a check-mark by the items received to indicate the appropriate material and quantity were shipped, and receiver's initials or signature to indicate approval.

9.3.7 Copies of any certificates of analysis (COAs), traceability or property value uncertainty will be retained and filed appropriately.

9.4 LABELING AND STORAGE

9.4.1 RMs will be labeled with, at a minimum, the identity and date of receipt.

9.4.2 RMs will be stored securely, to maintain their integrity, and according to any manufacturer recommended storage conditions, and applicable laws. RMs are used, and stored, within the permanent laboratory.

9.4.3 Powdered RMs will be stored at room temperature unless otherwise specified. Liquid RMs may be stored frozen or under refrigeration, as recommended by the manufacturer.

9.5 VERIFICATION

9.5.1 RMs obtained from approved suppliers do not require verification as long as a COA (however named) is available to document purity analysis and the method(s) of identification. The COA may describe the traceability, purity, certification testing, manufacture, quality, shelf life, lot number, production run or other information that supports the use of the material in the laboratory.

9.5.2 When RMs are obtained from a non-approved supplier, the identity and purity of the material will be examined prior to use.

9.5.2.1 Acceptable means of RM testing include gas chromatography, high performance liquid chromatography, mass spectrometry or other measurements of physical constants.

9.6 RECORDS

9.6.1 COAs (however named) will be retained for each RM received. If a RM purchase is a resupply of a previously purchased lot number for that

material, then duplicate certificates do not need to be retained.

9.6.2 Records of any RM verification will be retained with the COAs. The verification records will identify the person performing the verification and the date of verification.

9.6.3 Purchasing documents will be maintained by office administrative staff.

9.7 REFERENCE COLLECTIONS

Mass spectra reference collections used in compound identification/confirmation will be documented, uniquely identified and controlled as to prevent unauthorized changes.

9.7.1 The Laboratory utilizes mass spectra libraries obtained from traceable sources (e.g., NIST, AAFS), for purposes of identification and/or confirmation of target compounds in unknown samples.

9.7.1.1 External libraries are purchased/sourced from, and controlled by, the owner agency, and cannot be edited by Laboratory personnel. As updated versions of current libraries or libraries from new sources become available, TLD Management will evaluate the need for/cost of the update or purchase of the new library (ies).

9.7.1.2 Mass spectra printed for inclusion with instrumental data/reports of analysis will include the name of the library, which serves as the library's unique identifier.

9.7.2 Mass spectra reference collections or libraries created by the Laboratory will be fully documented and traceable. This is accomplished through the use of CRMs with traceability to SI units of measurement. Traceability documentation will be maintained by the QA Manager or designee.

9.7.2.1 CRMs for uncommon or emerging drugs may not be readily available. If RMs are not traceable to SI units, the source will be documented and records will include a certificate of analysis for the RM used and, whenever possible, a second reference should be included for identification (e.g., mass spectra from published journal article, reference book – *see 9.7.3*).

9.7.2.2 Creation and editing of Laboratory-developed reference collections or libraries will be controlled. The QA Manager or designee will monitor the issue, editing (addition of compound spectra) and traceability of internal reference collections.

9.7.3 Reference data from published reference books, textbooks or scientific journals may also be used for purposes of identification. Examples include:

- Clarke's Analysis of Drugs and Poisons
- Instrumental Data for Drug Analysis
- Clarke's Isolation and Identification of Drugs
- CRC Handbook of Chemistry and Physics

9.7.3.1 When a journal article is used for reference, the full journal article, or selections from a journal article with full citation, will be included with the instrumental data and maintained in the case record.

9.7.3.2 When pages from a reference book or textbook are used, copies of the relevant pages will be included with the instrumental data and maintained in the case record. The title, edition/revision, author, publisher/editor and page numbers shall be clearly indicated.

9.8 REFERENCES

9.8.1 International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM), 3rd ed. BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML, International Organization for Standardization (ISO), 2006.

10 ASSURING THE QUALITY OF TEST RESULTS

10.1 POLICY

The Laboratory is committed to providing the best quality service available to the customer. Key components to providing this level of service is implementation of a documented proficiency testing program, and the use of certified reference materials, validated test methods, quality controls, technical and administrative reviews and other quality assurance practices.

10.2 PROFICIENCY TESTING

The Laboratory's Proficiency Testing Program, directed by the QA Manager, serves to ensure the quality of work and fitness-for-purpose of the test methods. The Program shall be in compliance with ANAB and ABFT requirements and proficiency test providers approved/recommended by ANAB and/or ABFT will be used where available. The Proficiency Testing Program is outlined in Chapter 11.

10.3 TECHNICAL PROCEDURES AND METHODS

The Laboratory will use appropriate technical procedures and methods that have been scientifically validated and/or accepted for use in the field of forensic science, are fit-for-purpose for the testing performed, and meet the needs of the customer(s). This includes methods and procedures for the handling, transport, storage and preparation of testing items, the operation of all relevant equipment and an estimate of the measurement uncertainty where appropriate.

10.3.1 Definitions

10.3.1.1 Laboratory Developed Methods: Methods developed in house as standard methods for a specific laboratory purpose.

10.3.1.2 Methods: Any technical procedure detailing the use of reagents, equipment and/or instrumentation for scientific analyses; synonymous with "procedure".

10.3.1.3 New Methods: Scientifically validated and/or forensically adopted methods that have not previously been implemented in the Laboratory.

10.3.1.4 Non-Standard Methods: A scientifically validated method or procedure that is not routinely applied or used for forensic analysis.

10.3.1.5 New Method Validation: Validation of a standard method, non-standard method, standard method used outside of its intended scope or a laboratory-developed method which is to be adopted by the Laboratory as a new method.

10.3.1.6 Performance Verification: The act of confirming that a method or instrument that has been scientifically validated and adopted for forensic analysis continues to conform to the specifications for which it is intended.

10.3.1.7 Validation: A process used by the scientific community for acquiring the necessary information to assess equipment/instrumentation, a technique or an experimental procedure to determine if the equipment, technique or procedure consistently provides the expected result(s).

10.3.2 Where applicable, standard methods published in international, national or regional will be used.

10.3.3 Published methods, standard methods (national/international standards, manufacturer-developed), laboratory-developed methods or non-standard methods used by the Laboratory will be appropriate for the intended use and validated. The test method(s) used will be communicated to the customer on the test report.

10.3.4 All methods and procedures will be documented and readily available for review by Laboratory personnel. Any deviation from a standard technical procedure or method will require that the details of the modification, as well as the justification and authorization, be documented in the testing record.

10.3.5 Developing Analytical Methods and Procedures

Analytical methods and procedures must be based upon sound scientific principles, and be as effective and efficient as possible. Those procedures and/or principles used should be generally accepted in the field of analytical chemistry and/or forensic toxicology.

Introduction of laboratory-developed test methods to the Laboratory will be planned, and assigned to qualified personnel equipped with adequate resources. The plan will be updated, as necessary, and TLD Management will ensure there is effective communication (verbal or written) amongst all personnel involved.

Laboratory personnel wishing to introduce a new method, or modify an existing one, shall seek initial approval for development through their Supervisor. When the proposal is at the draft stage, it shall be presented to the QA Manager. Authorization to perform method development work is authorized by the TLD Commander/State Toxicologist.

10.3.5.1 When developing a technical procedure, the following should be considered:

- Compatibility with the Laboratory's current technical and administrative procedures
- Ability to efficiently provide data in a timely manner
- Accuracy, precision, reliability, speed, and cost
- Compatibility with available equipment and facilities
- Materials, equipment, reagents and standards required

10.3.5.2 The development of the technical procedure must be as well documented as possible. Documentation may include specific literature articles, texts, reviews, and data compilations. A list of references may be included in technical procedures or training manual. Where applicable, the procedure should include:

- Definition of terms
- Scope of the analysis conducted
- Standards for notes, interpretation of results and reporting
- Minimum testing requirements
- Equipment/instrument specifications required
- Equipment/instrument operation, maintenance and verification procedures
- QA and/or QC statement(s)

Technical procedures should include provisions for quality control and quality assurance, which may include acceptance/reporting criteria, use of negative/positive controls, and known samples.

These procedures must be understood, supported and accepted by those personnel using them in performing testing work. TLD Management will communicate the development and implementation plan and progress to all personnel.

Where applicable, procedures will include verbiage to ensure safe handling, transport, storage, use and planned maintenance of measuring equipment (i.e. diluters, pipettes) to ensure proper functioning and in order to prevent contamination or deterioration (*see chapter 6 – Equipment Maintenance*).

10.3.6 Method Validation

The Laboratory will validate or verify all new test methods prior to implementation. Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

10.3.6.1 The extent of validation for a test method will be as to meet the needs of the given application. Personnel will be given adequate resources to perform the validation.

10.3.6.2 Method validation work will be performed by qualified personnel authorized by the TLD Commander/State Toxicologist. Those performing validation work may include Forensic Scientists (including those in training), and technical or QA personnel, under the direction of the QA Manager, Laboratory Manager and/or TLD Commander/State Toxicologist

10.3.6.3 Results of validation studies will be documented and archived. Validation data, the test procedure, controls and/or reference materials used, a statement indicating whether the method is fit for the intended use, and documentation of approving authority will be included.

The guidelines below will be used to introduce new methods or modify existing methods. Contemporary scientific working group guidelines should also be considered in this process.

10.3.6.4 Procedure

The proper validation of a new method requires an understanding of its theoretical basis. Such knowledge provides a means of assessing the selectivity and limitations of the method and predicting possible sources of error. The validation process should address the baseline characteristics of precision, accuracy, selectivity and sensitivity of the method (*see 10.3.5.1*).

10.3.6.4.1 Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the laboratory (as in the case of laboratory-developed methods, standard methods used outside their intended scope or where significant modifications are made to previously validated methods). Validation will be sufficient to ensure the reliability of the method against any documented performance expectations.

10.3.6.4.2 The method must be tested using known samples. If a new method is intended to supersede an existing one or if it parallels an existing one, then the two may be compared on split samples, where practicable.

10.3.6.4.3 If the analysis provides quantitative data, the validation should include investigation of the range, accuracy and precision of the method relative to its intended use and the needs of the customer (*see Validation Procedure for Confirmatory Methods*). Uncertainty of measurement will also be evaluated, where applicable.

10.3.6.4.4 Upon completion of method validation, all documentation will be sent to the QA Manager for review. The QA Manager and TLD Commander/State Toxicologist will decide if the method has been sufficiently validated and is fit-for-purpose. The TLD Commander/State Toxicologist will indicate approval of the test method and written procedure by signing the DRA form, as part of the controlled document approval process.

10.3.6.5 Detailed protocols for method validation are found in the Validation Procedure for Confirmatory Methods and the Validation Procedure for Qualitative Methods and may include use of reference standards/materials, accuracy/precision studies, reproducibility, selectivity, sensitivity/linearity studies and literature or journal references, as appropriate.

10.4 SAMPLING PROCEDURE

10.4.1 The Laboratory employs policies and procedures for sampling from specimens submitted as evidence for testing. For purposes of toxicological testing of biological samples, the sampling procedure is described as follows:

10.4.1.1 For fluid samples such as whole blood, serum, plasma, urine, cavity fluid or vitreous humor, a sample of the submitted volume is removed for purposes of performing a test. Sample volume is documented in the SOP and in the batch record.

10.4.1.1.1 The Forensic Scientist will examine the submitted container to verify that a homogenous fluid is present. If the fluid appears homogenous, the sample removed for testing is considered to be representative of the whole.

10.4.1.1.2 If a fluid does not appear homogenous, the Forensic Scientist will document this in the examination records (*see 10.4.1.2*).

10.4.1.2 Fluid, or semi-fluid samples such as spleen squeeze, gastric contents, blood clots or clotted whole blood, may not be considered homogenous without mechanical intervention. If homogenization or sonication is used, this will be documented in the examination records.

10.4.1.3 For tissue samples such as liver, kidney, brain or muscle, a sample of the submitted specimen is taken for purposes of homogenization. The area from which the sample is taken is at the discretion of the Forensic Scientist. This may be based on the type/condition of the specimen, and the number/type of tests that will be performed.

10.4.1.3.1 The test report will clearly communicate to the customer that testing was performed on a homogenate prepared from a sample of the submitted specimen (e.g., results reported are from homogenate prepared from a sample of the liver specimen, however noted). The preparation of the homogenate is documented in the examination records and this information is available to the customer upon request.

10.4.1.3.2 Should the customer request a deviation from the Laboratory's sampling procedure (e.g., specifiy areas of a tissue, or the entire tissue, to be homogenized/tested), this will be documented, in the relevant examination records pertaining to that case.

10.5 ENVIRONMENTAL CONDITIONS

10.5.1 Toxicological testing is performed within the permanent Laboratory, under secured, controlled laboratory conditions. The Forensic Scientist has the authority to halt work, and notify a Supervisor, if at any time he/she determines that environmental conditions, or other factors, may affect the quality of the work.

10.5.2 Should a test method specify environmental conditions essential to producing accurate results, those conditions will be verified by the Forensic Scientist at the time the test is performed, and documented in the examination records (e.g., worklist, worksheet).

10.6 DEVIATION FROM POLICY OR PROCEDURE

Deviations are changes/variations from those written policies and procedures found in the Testing Quality Manual, Operations Manual, relevant technical documents, and other specific policies and procedures.

10.6.1 Any deviations from official policies, rules or procedures must be technically justified, approved in writing by TLD Management as appropriate, and documented in the testing record.

10.7 RESOLUTION OF ISSUES CONCERNING TECHNICAL PROCEDURES

Technical problems will be resolved by the analyst and the Supervisor where possible, and documented appropriately.

Complex technical problems not resolvable by the Supervisor will be referred to the Laboratory or QA Manager. The TLD Commander/State Toxicologist with input from the Laboratory or QA Manager, may direct cessation of work if a technical procedure being utilized exhibits problems that cannot be resolved. Should nonconforming work be identified, the Corrective Action process will be followed (*see Chapter 4 – Control of Nonconforming Work*).

10.8 SUBCONTRACTORS

Only approved subcontracted laboratories may perform testing on evidence submitted to the Laboratory, unless otherwise specified by the customer (*see 10.8.1.4*).

10.8.1 Approved Subcontractors

10.8.1.1 External laboratories regularly used to perform subcontracted testing work will be evaluated by TLD Management to ensure compliance with the Laboratory's standards of quality assurance and good laboratory practice. The Laboratory assumes responsibility to the customer for any work performed by an approved subcontracted laboratory (*see 10.8.1.4*).

10.8.1.2 Subcontractor evaluation and approval will be documented using the Subcontractor Questionnaire – Evaluation and Approval Form. The prospective subcontracting laboratory will complete the questionnaire and provide documented evidence of their quality program.

10.8.1.3 The subcontractor is only approved to perform the specified tests, or scope of testing, indicated on the form. Once approved, the subcontracted laboratory will be evaluated annually to ensure they continue to meet those standards on which the original evaluation/approval was based.

10.8.1.4 When specialized testing is requested by the customer (e.g. hair analysis, anabolic steroids testing, clinical testing), this may necessitate services of an external laboratory that has not been previously approved.

10.8.1.4.1 The external laboratory will be evaluated by a member of TLD Management, for limited approval to perform the specific test(s). This approval will be documented in the case file, and any information on which the limited approval is based will be included.

10.8.2 Customer-Selected Subcontractors

10.8.2.1 Should the customer stipulate that a specific subcontracted laboratory (not approved by the Laboratory) be used, the customer assumes responsibility for the subcontractor's work.

10.8.2.1.1 When test items are sent directly from the customer to the subcontracted laboratory for analysis, that testing is performed under contract between the customer and the subcontractor.

10.8.2.2 Requests by the defense counsel/defendant for independent analysis of a test item(s) after issuance of the test report are considered a contract between the defense/defendant and the independent laboratory. The Laboratory may facilitate shipment of the test item to the independent laboratory, but assumes no responsibility for the analyses performed.

10.9 QUALITY CONTROL

Quality control policies and procedures will be implemented to monitor the performance of the Laboratory's materials, methods and test procedures.

10.9.1 The Laboratory employs the use of certified reference materials for preparation of standard solutions used in testing work (*see Chapter 9 – Reference Materials*).

10.9.2 The Laboratory's test methods employ appropriate standards and controls, as described in the relevant SOPs (*see also Quality Assurance Principles*). The traceability of these materials is documented in the testing and quality assurance records.

10.9.3 Quality control data is recorded and monitored continuously to evaluate the ongoing validity of those test methods used regularly in the Laboratory.

10.9.3.1 Positive quality control values are submitted to the QA Manager or designee for review. Graphical and statistical analyses are used to track and evaluate the performance of testing materials and test methods.

10.9.3.2 Quality control results and any deviations for each testing batch are recorded in the batch file. Actions taken due to individual quality control failures are documented, and will be included with each report of analysis for that batch.

10.9.3.3 When the monitoring of quality control results indicate that there may be a problem with materials, test methods, equipment or

instrumentation, further action will be initiated. This may include an evaluation of test method performance, instrument maintenance records and standard solution preparation, and will be documented in the quality control records (i.e. tracking spreadsheet). After evaluation, the results will continue to be monitored for an appropriate time frame to ensure that any actions taken have adequately addressed the problem.

10.9.4 Intermediate Checks

10.9.4.1 If it is determined that intermediate checks of equipment, instrumentation or standard materials are necessary, these policies and procedures will be documented in the relevant technical procedure, maintenance plan or maintenance checklist.

10.9.4.2 Intermediate checks may be implemented based on, but not limited to, the following factors:

- Frequency of use of the equipment/instrumentation
- Sensitivity, precision and/or accuracy required of the instrumentation
- Contribution of the equipment/instrumentation/standard materials to uncertainty of measurement
- Equipment calibration schedule
- Actions taken in response to findings from audits, assessments and quality control review
- Manufacturer recommendations

10.9.4.3 Intermediate checks will be documented, with documentation maintained in the case record (e.g., equipment/instrument logs, standards preparation file).

10.10 UNCERTAINTY OF MEASUREMENT

Factors which contribute to the total uncertainty of measurement, and the extent of their contribution to this uncertainty, vary amongst the types of tests (or calibrations) performed. The Laboratory shall consider these factors when developing test methods and procedures, in determining qualifications of personnel, when developing the training program(s), and in the selection and calibration of the equipment used.

10.10.1 The Laboratory shall implement procedures for estimating uncertainty of measurement of its test methods, where applicable. These procedures, including those for reporting of uncertainty of measurement, shall be in compliance with accreditation requirements *(see Estimation and Reporting of Measurement Uncertainty (PQ12706)*.

10.10.1.1 For some test methods, this estimation may include a rigorous, metrologically-based, statistically valid calculation of uncertainty of measurement.

10.10.1.1.1 The evaluation of the instrument used in performance of a test method must be included in the estimation of measurement

uncertainty for that test method.

10.10.1.1.2 In these cases the Laboratory shall attempt to identify all the components of uncertainty and make a reasonable estimation. Reasonable estimation shall be based on knowledge of the performance of the method and measurement scope and shall make use of, for example, previous experience and validation data.

10.10.1.1.3 Records of evaluation of uncertainty of measurement will be maintained at the Laboratory.

10.10.1.1.4 The Laboratory shall ensure that the method of reporting results does not give a wrong impression of the uncertainty of measurement associated with those results.

10.10.1.1.5 The procedure for estimating uncertainty of measurement shall include the process of rounding the expanded uncertainty.

10.10.1.1.6 The coverage probability of the expanded uncertainty shall be a minimum of 95.45% (often referred to as approximately 95%).

10.10.2 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account, using appropriate methods of analysis. Evaluation shall include the following elements:

- Statement defining the measurand
- Statement of how traceability is established for the measurement
- The equipment (e.g., measuring devices or instruments used)
- All uncertainty components considered
- All uncertainty components of significance and how they were evaluated
- Data used to estimate repeatability and/or reproducibility
- All calculations performed
- The combined standard uncertainty, the coverage factor, the coverage probability and the resulting expanded uncertainty
- The schedule to review and/or recalculate the measurement uncertainty

10.10.3 Reporting (*see also 12.6.4*)

At a minimum, the Laboratory shall report the estimated uncertainty when it impacts evaluation of a specification limit (stated by case law, statute or legal requirement, external to the Laboratory). Reporting of test results and the associated expanded uncertainty are described in *Estimation and Reporting of Measurement Uncertainty (PQ12706)*.

11 PROFICIENCY TESTING

11.1 POLICY

The Laboratory will implement a Proficiency Testing Program, in compliance with ANAB and ABFT accreditation requirements.

11.1.1 The QA Manager is responsible for, and will oversee, the Proficiency Testing Program, including the assignment of proficiencies to personnel, submission of results, maintenance of records, and personnel notification of proficiency test performance. Deviations from the following guidelines must be approved by the TLD Commander/State Toxicologist or the QA Manager and the approval recorded in the proficiency test record.

11.1.2 The objectives of the proficiency testing program are to:

- Demonstrate the current competence of Forensic Scientists
- Demonstrate the current competence of the Laboratory
- Ensure that quality work is being performed and maintained
- Identify areas where additional training or resources would be beneficial
- Verify the validity of technical procedures

11.2 DEFINITIONS

11.2.1 Approved test provider: An external proficiency test (PT) provider that has been evaluated and found to comply with the standards of an accrediting body (ANAB, ABFT) or found to meet the proficiency test needs of the laboratory.

11.2.2 Assigned value: The value attributed to a particular property of a proficiency test item.

11.2.3 Blind proficiency test: The analyst is not aware that they are performing a proficiency test.

11.2.4 External proficiency test: A test provided by a source external to the laboratory.

11.2.5 Internal proficiency test: A test supplied by the testing laboratory.

11.2.6 Open proficiency test: The analyst is aware of the nature of the proficiency test.

11.2.7 Proficiency test: An internal or external test that is provided to evaluate the capability of analysts, technical support personnel and the overall quality performance of a laboratory.

11.2.8 Proficiency test item: Sample, product, artifact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing. Proficiency test material/sample may include whole

blood, urine, lyophilized matrix (serum, urine) obtained from an external proficiency test provider, or prepared internally.

11.2.9 Proficiency testing provider: Organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme.

11.3 FREQUENCY

11.3.1 Each Forensic Scientist shall successfully complete at least one (internal or external) proficiency test per calendar year in the forensic discipline of toxicology.

11.3.1.1 Each Forensic Scientist shall successfully complete at least one externally provided whole blood ethanol proficiency test and one drug proficiency test (whole blood, serum, urine) per calendar year.

11.3.2 Each Forensic Scientist shall successfully complete at least one proficiency test within each accreditation cycle, in each category of testing (as appears on the Laboratory's Scope of Accreditation (however named by the accrediting body).

11.3.2.1 The Laboratory provides services in two categories under the toxicology discipline: human performance forensic toxicology and post-mortem forensic toxicology. The laboratory uses the same test methods for both categories of testing.

11.3.3 Annually, the Laboratory shall successfully complete at least one external proficiency test in the toxicology discipline, obtained from an ANAB and/or ABFT approved test provider, when an approved provider is available.

11.3.4 External proficiency test providers will typically provide a delivery schedule for the year's testing cycle. The schedule may be used to ensure that assignments of proficiency tests are designed to meet those requirements listed above. The QA Manager maintains a schedule for assignment of proficiency tests.

11.4 APPROVED TEST PROVIDERS

11.4.1 The following proficiency test providers are approved by the Laboratory.

11.4.1.1 Collaborative Testing Services (CTS)

- 564 – Blood alcohol analysis
- 5661 – Blood drug analysis
- 5662 – Blood cannabinoids analysis

11.4.1.2 College of American Pathologists (CAP)

- AL1 – AACC/CAP Alcohol/Ethylene Glycol/Volatiles
- FTC – Whole Blood Forensic Toxicology
- T – Serum Toxicology
- DFC – Drug Facilitated Crimes (urine)

- LN14 – Serum Ethanol Calibration Verification/Linearity

  NOTE: ABFT accreditation requirements include participation in the CAP AL1, FTC, T and DFC proficiency test surveys.

11.5 GENERAL

11.5.1 External proficiency tests will only be obtained from suppliers who have been approved by the QA Manager or State Toxicologist.

11.5.2 Internal proficiency tests will only be produced by the QA Manager or designee. The preparation of internally-produced proficiency tests will be documented and retained in the proficiency test record, and is determined by the QA Manager.

11.5.3 Proficiency test items will be retained by the Laboratory until a summary report is received and any corrective actions satisfactorily completed.

11.5.4 Proficiency test results will be retained according to the record retention schedule and for at least the duration of a single accreditation cycle.

11.5.5 Completed proficiency test records will include:

- Proficiency test unique identifier
- How tests were obtained or created
- Written instructions for completion
- Identity of person taking the test
- Testing data (and notes, if applicable)
- Dates of analysis and completion
- Due date and submission date
- Proficiency results (answer sheet(s))
- Proficiency test evaluation form
- Any discrepancies noted
- Analyst feedback communication
- Details of corrective actions taken (when necessary)

11.5.6 When possible, proficiency testing will be conducted in a manner that is consistent with standard testing methods used in the laboratory. If the test provider instructions conflict with laboratory practice, the test provider instructions are authoritative. For example, standard laboratory practice may include volatile testing but this is unnecessary if stated in test provider instructions or if test material is lyophilized.

11.5.7 Proficiency test samples (e.g., blood, lyophilized urine or serum) will be handled by analysts in a similar manner to those samples routinely received by the Laboratory.

11.5.8 Proficiency tests should not be subject to policies adopted by the Laboratory for efficiency or expediency of casework. All parts of a proficiency test

provided by an approved test provider should be examined as completely as the Laboratory's procedures allow.

11.5.9 External proficiency tests will be of the open variety. Internal proficiency tests may be open or blind.

11.6 ASSIGNMENT AND SCHEDULING

11.6.1 The QA Manager or designee will coordinate the ordering, receipt and assignment of proficiency tests, based on a schedule that ensures the Laboratory, and all personnel, meet requirements for proficiency testing frequency.

11.6.2 The QA Manager or designee will provide copies of PT paperwork to the analyst including directions on the handling or preparation of the PT item and the reporting paperwork.

11.6.3 Once in receipt of their assigned test, the analyst will make every effort to complete testing and submit results in advance of the deadline for submission of test results. This will allow for review of the results and assignment of supplemental testing where appropriate.

11.6.4 If the PT cannot be completed by the deadline, the reason will be documented in the PT file and follow-up testing of the PT item may be conducted after the deadline has elapsed. The production of an acceptable PT result after the assigned value has been reported by the PT provider is not considered a successful completion of a PT.

11.7 TESTING PROTOCOL

11.7.1 Analysts will conduct those tests appropriate to the nature of the proficiency test and may take it to account any case scenario or history included by the PT provider.

11.7.2 Any special instructions for testing, such as storage conditions or timetables for PT item stability, shall be followed by the analyst.

11.7.3 Generally, the PT will be completed using current laboratory test methods. Where a test method is not available but suitable reference materials are, a test method may be developed and utilized for the PT. The decision to report the PT results from a novel test method rests with the QA Manager.

11.7.4 The analyst will report quantitative results in accordance with any specific laboratory reporting guidelines concerning rounding, truncation or significant figures.

11.7.5 When the PT provider requests quantitative results in units different that those reported by the laboratory, the analyst will convert their results to the requested units (after applying reporting criteria for the specific test method – e.g., truncation, significant figures).

11.7.6 Normal procedures for testing batch review and technical/administrative review of final results form, will apply prior to submission of results to the

QA Manager or designee.

11.7.7 The analyst will submit all data and reporting paperwork to the QA Manager or designee upon completion of the PT.

11.7.8 The QA Manager or designee will review the PT records for completion before authorizing release of PT results to the PT provider.

11.8 REVIEW OF PERFORMANCE

11.8.1 The PT provider will publish a report of the results for an individual PT cycle. That report may indicate the statistical evaluation of all participant results with a separate evaluation of the analyst's results.

11.8.2 The assigned value for a PT item, unless otherwise specified by the PT provider, will be assumed to be the participant mean/average (PM), and the standard deviation for the proficiency assessment (SDPA) will be assumed to be the standard deviation of the participant results. Unless otherwise specified, it is assumed that participant results have been examined for outlier data which have then been removed.

11.8.3 Evaluation Criteria

11.8.3.1 The analyst's proficiency results will be evaluated against the PT provider's PM and SDPA. If it meets the evaluation criteria of the PT provider, the provider will indicate the result is acceptable.

11.8.3.2 The analyst's results will also be evaluated against the Laboratory's internal criteria[1]:

- No false positive results
- Ethanol/mixed volatiles results are within ±2 SD of the PM or ±10% of the weighed-in target
- Drug results are within ±2 SD of the PM or ±20% of the weighed-in target

11.8.3.2.1 The percent difference used above, also known as bias, is calculated according to the following equation; where $D_{\%}$ is the percent bias; x is the analyst's result; and X is the assigned value:

$$D_{\%} = \frac{(x - X)}{X} \times 100$$

11.8.3.3 The QA Manager will evaluate the results in terms of standards of accuracy in 11.8.3.2, and/or with the use of one or more performance statistics, such as a *z*-score.

11.8.3.3.1 A *z*-score (also known as the normal deviate), describes the extent to which a point deviates from a mean or specification point in units of SD.

[1]American Board of Forensic Toxicology (ABFT) Forensic Toxicology Laboratory Accreditation Checklist, E-17 (4/2021).

The *z* score is calculated according to the following equation, where *x* is the analyst's result, *X* is the PM, and σ is the SDPA:

$$z = \frac{x - X}{\hat{\sigma}}$$

Satisfactory performance is indicated when $|z| \leq 2$.

11.8.3.4 Results of internal proficiency tests will be evaluated using criteria in 11.8.3.2. The QA Manager may also use performance statistics in the evaluation. The method of calculation for the mean result and standard deviation will be documented, as determined by the QA Manager, based on the specimen type and volume, number of tests performed, and other factors.

11.8.4 Satisfactory Proficiency Results

If the test results are satisfactory, the QA Manager will complete documentation of the satisfactory result in the records. Notification of satisfactory completion will be issued to the analyst and the Supervisor in writing. The analyst and their Supervisor will document their review of the analyst's performance by initialing and dating the written notification. The notification receives a final review by the TLD Commander/State Toxicologist, documented by initialing and dating the written notification.

11.8.5 Proficiency Test Discrepancies

11.8.5.1 If there is a discrepancy between the analyst's test results and the provider's results, the QA Manager will immediately notify the analyst who performed the test and their Supervisor. The QA Manager and the Supervisor will determine a course of action.

11.8.5.2 The Corrective Action Form – Proficiency Results will be completed, documenting the investigation of the root cause of the discrepancy, any follow-up testing or other corrective action performed, and, if applicable, action(s) taken to prevent the occurrence of future discrepancies.

11.8.5.3 If an analyst's performance on a proficiency test requires further development to meet quality standards, the QA Manager will work with the Supervisor and the analyst on a plan of action which may include removal of the analyst from work and participation in remedial training. The QA Manager will prepare a report to the TLD Commander/State Toxicologist, outlining the issues and the actions taken.

11.8.5.4 The proficiency test records will contain a record of the discrepancy and any associated corrective action documentation. The QA Manager will retain the PT records for the Laboratory.

11.8.5.5 Report of Inconsistencies to the accrediting agencies

Refer to the current ANAB accreditation manual and ABFT accreditation

checklist for detailed protocols on notifying accrediting agencies of the occurrence of PT discrepancies.

11.8.6 Proficiency Testing and Job Performance

Any problems identified from the review of a proficiency test, if reflective of difficulties with an analyst's individual work performance, will be addressed by the Supervisor and documented in the supervisory desk file. The Supervisor may enlist input and assistance other members of TLD Management or other personnel, as necessary.

11.9 REFERENCES

11.9.1 EURACHEM, Selection use and interpretation of proficiency testing (PT) schemes, 2nd. Ed. 2011

11.9.2 Eurolab, Technical report No. 1/2007 Measurement uncertainty revisited: Alternative approaches to uncertainty evaluation, March 2007

11.9.3 ISO 13528:2005, Statistical methods for use in proficiency testing by interlaboratory comparisons

11.9.4 ISO/IEC 17042:2010, Conformity assessment – General requirements for proficiency testing

11.9.5 M. Thompson, S.L.R. Ellison and R. Wood, The international harmonized protocol for the proficiency testing of analytical chemistry laboratories, Pure Appl. Chem. 78(1): 145-196 (2006).

12 RECORDS, REVIEWS AND REPORTS

12.1 POLICY

All technical and administrative records created and/or maintained by the Laboratory will be identifiable, accessible to authorized personnel and properly stored to prevent damage or loss. Electronic documentation will be backed-up and should be protected to prevent unauthorized access to or amendment of these records. Examination records, test reports and other technical or administrative content of case files will be reviewed prior to release of test reports to the customers.

12.2 DEFINITIONS

12.2.1 Administrative Record: Records (electronic or hardcopy) that do not constitute data or information resulting from testing. May include case related conversations, test item receipts, chain of custody records, request for analysis forms, incident reports, correspondence or other pertinent information.

12.2.2 Administrative Review: A review of case records for consistency with laboratory policy and for editorial correctness.

12.2.3 Analyst: An individual who conducts and/or directs the analysis of forensic casework samples, interprets data, reaches conclusions, and issues test reports concerning conclusions.

12.2.4 Batch File: A batch file contains technical documentation pertaining to a particular test conducted by an analyst in the Laboratory. This may include, but is not limited to:

- Sequence table, batch worklist or equivalent
- Chromatograms and/or reports of analysis
- Traceability information (for standards, positive controls, blank matrices)
- Documentation of review by peer or supervisor

12.2.5 Batch Record: A batch record is a collection of all the administrative and technical documentation pertaining to a particular test conducted by an analyst in the Laboratory. This may include, but is not limited to:

- Electronically stored data
- Instrument maintenance and/or verification documentation
- Reagent and standard quality control documentation

Information in the batch record may be in the batch file or in other locations in the Laboratory which are designated as extensions of the batch file.

12.2.6 Case File: A case file contains both administrative and technical documentation pertaining to a particular case for which testing was conducted by an analyst in the Laboratory. This includes, but is not limited to:

- Toxicology Test Report
- Administrative Records (e.g., Laboratory Request for Analysis, correspondence and communication logs, incident reports)
- Examination Records (e.g., reports of analysis, spectral data, documentation of review)

12.2.7 Case Records: Administrative records, examination records, and any other applicable technical records (electronic or hardcopy), generated or received by the laboratory pertaining to a particular case, which may be stored in one or more locations. This may include, but is not limited to:

- The batch file/record
- Chain of custody records
- Traceability documentation (e.g., receipt records and certificates of analysis for reference materials used in testing)

Information in the case record may be in the case file or in other locations in the Laboratory which are designated extensions of the case file.

12.2.8 Examination/Analysis: A test. A procedure used by an analyst to obtain information from evidence in order to reach conclusions concerning the nature of evidence received by the laboratory.

12.2.9 Examination Records/Documentation: Documentation (hardcopy or electronic) of procedures followed, tests conducted, standards and controls used, diagrams, printouts, photos, observations and results of testing and examinations.

12.2.10 Supervisor Review: A general review of testing records by a supervisor to maintain oversight of Laboratory operations.

12.2.11 Technical Records: Accumulations of data and information which result from carrying out tests and which indicate whether specified quality or process parameters are achieved. May include forms, contracts, worksheets, work books, check sheets, work notes, control graphs, external and internal test reports, customers' notes, papers and feedback.

12.2.12 Technical Review: Review of all examination records and test reports to ensure the validity of scientific results and conclusions.

12.2.13 Toxicology Test Report: Final presentation of results of testing conducted in the Laboratory.

12.3 TESTING DOCUMENTATION

12.3.1 Administrative Records

Administrative records related to a specific case shall bear the unique identifier in order to be placed back into its source file if it becomes separated. Multi-paged administrative documentation that is bound together shall have the unique identifier on at least the first page.

12.3.2 Technical Records

12.3.2.1 The Laboratory shall retain technical records (e.g., original observations, derived data, calibration records, staff records, issued/authorized test reports), according to the documented retention schedule (at least five years or one accreditation cycle).

12.3.2.1.1 Technical records for the current calendar year are stored within the main Laboratory. As space allows, technical records from previous years will also be stored within the main Laboratory.

12.3.2.1.2 Technical records that the main Laboratory area cannot accommodate will be transferred to the on-site shared records storage room. The shared records storage room is within the limited-access, secured areas of the facility, and is used by the TLD and the FLSB Crime Laboratory Division.

12.3.2.1.3 Technical records are transferred from the main Laboratory or shared records storage room to the State Records Center for secured, long-term storage (*see Operations Manual section 13.2*).

12.3.2.2 Technical records will contain sufficient information to perform an audit trail, facilitate identification of those factors affecting uncertainty of measurement, and to enable the test to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling of the evidence item, performance of each test and checking of results.

12.3.2.3 Technical records shall bear some unique identifier.

12.3.2.3.1 For a batch file, this is generally the instrument data file folder name or data analysis batch name, which relates the examination records to the instrument, analyst, type of testing, and date the testing was performed.

12.3.2.3.2 For a case file, this is the ST# assigned by the Laboratory, which identifies all examination records pertaining to a particular case. NOTE: The unique identifier may be represented as ST XX-XXXXX or without the ST prefix, as XX-XXXXX.

12.3.2.4 Records will include the identity of personnel responsible for the performance of each function, and the review and issue of results.

12.3.3 General Documentation Requirements

12.3.3.1 Handwritten documentation will be recorded using permanent ink.

12.3.3.2 Nothing in the testing documentation may be erased or obliterated. Changes, additions, or any other form of alteration must be initialed and dated by the person making the alteration. Overwrites should be struck-through, rewritten, and initialed/dated (*see NOTE in 12.3.3.15*).

12.3.3.3 For records that are duplicated in electronic format, such as for public disclosure or legal discovery purposes, corrected originals will be copied to, but will not replace, the electronic duplicates. Amended reports will be duplicated in electronic format and will be added to the electronically duplicated records of the original report.

12.3.3.4 Dates must be recorded in the documentation to indicate when analysis of the test item(s) began and when testing was completed. It shall be clear from the documentation when specific tests were performed.

12.3.3.5 Abbreviations are acceptable if they are readily comprehensible to a reviewer. A key will be available to the reviewer for those abbreviations that may be specific to the Laboratory.

12.3.3.6 The Laboratory's unique identifier and the analyst's handwritten initials shall be on each page of the examination records.

NOTE: The handwritten addition of the batch file or case/evidence unique identifier requires the initials of the analyst only.

12.3.3.7 When examination records are prepared by an individual other than the analyst who interprets the findings and issues/authorizes the test report and/or testifies concerning the records, the handwritten initials (or secure electronic equivalent of initials or signature) of that individual shall be on those pages of the examination records representing his/her work.

12.3.3.8 When examination records are printed/recorded on both sides of a page, each side will be considered a separate page, and must contain the unique identifier and the analyst's initials

12.3.3.9 When data from multiple cases is recorded on a single printout, the unique identifier for each case for which data was generated shall be recorded on the printout (e.g., worklist).

12.3.3.10 Examination records created in electronic format (e.g., instrumental data) are retained/backed up in electronic form, and are printed prior to review (see 12.1.2.2). Review of the testing batch is documented on the hard copy data, and hard copies are considered the official examination records. Testing batch records are considered complete after testing batch review is completed.

12.3.3.11 Any changes made to the hard copy examination records after review are documented within the printed record. Any changes made to electronic data files are tracked and documented in the printed record.

12.3.3.12 Testing documentation includes but is not limited to the following:

- Results of testing (e.g., instrument chromatograms and data reports)
- Records of data and calculations
- Handwritten or machine-generated worksheets

- Identity and source of any standards or references used

12.3.3.13 When instrumentation is used, the specific instrument used must be noted in the batch file. If the Laboratory has only one instrument for a specific test or procedure, that instrument's identification may be documented in the Laboratory's equipment list. If the Laboratory has multiple instruments of the same make/model, the unique identifier of the instrument used must be recorded in the batch file.

12.3.3.14 The instrument operating parameters for the test method used shall be recorded. If parameters are not included in the written test procedure or other designated location, they will be printed and added to the batch file prior to review.

12.3.3.15 Any handwritten observations, calculations, or other information recorded in the examination record must be attributable to the author, with the addition of his/her initials and the date the notation was made.

NOTE: Handwritten abbreviations on the cover of the case file folder are not considered part of the examination record and do not require the analyst's initials/date.

12.3.3.16 Documentation to support the results shall be manner in the absence of the analyst, another competent analyst or Supervisor could evaluate what was done and interpret the data.

12.3.3.17 Documentation of the batch review is discussed in 12.4.2.1.

12.4 REVIEW OF RECORDS

12.4.1 Policy

The Laboratory will ensure that reports are accurate and supported by the technical documentation, and that established policies and procedures are being followed. All laboratory test reports and associated documentation will be subject to technical and administrative reviews. Administrative reviews may be independent of technical reviews or may be conducted concurrently.

12.4.2 Procedures

Review of technical records by the testing analyst, and subsequent review by a peer or supervisor, provides a verification that Laboratory procedures were followed and results are valid. Personnel performing testing batch review must meet competency requirements described in 5.1 and be authorized by the Laboratory Manager or TLD Commander/State Toxicologist.

12.4.2.1 Testing Batch Review

12.4.2.1.1 Analysts will conduct a thorough review of their testing work, prior to submission for batch review by a peer or supervisor. The analyst will sign

or initial each page of the batch file, documenting their review of the batch against those criteria described in the relevant SOP and Laboratory policies and procedures.

The review includes, but is not limited to, the following:

- A report of analysis is included for each member of the testing batch. Note: Injections included to equilibrate or rinse an HPLC column may appear in the worklist/sequence, but are acquired under a different method, and a report of analysis is not required.
- The batch unique identifier appears on each page of the batch record (data file folder name – for example, YYMMDDRR, where RR is the analyst's initials). Note: Batch identifier is unique to the instrument used (e.g., instrument X and instrument Y may each have a batch ID 10506RR).
- Calibration curve, retention time and qualifier ion ratio criteria are acceptable
- Calibrator and quality control results are acceptable
- Reportable case results meet all applicable criteria

12.4.2.1.2 Any discrepancies/deviations shall be noted by the analyst.

12.4.2.1.3 The reviewer (peer or supervisor) will review the batch as described above. Any deviations from the SOP or other relevant policies and procedures must be approved by a supervisor or manager. The reviewer will document their review by the following:

- Initial/date the first page of the sequence/worklist
- Initial/date the first page of the calibration/curve report or printed data analysis method (however named)
- Initial/date each calibration curve, if printed individually
- If calplot (ChemStation) or a calibration report (MassHunter) is used to print calibration curves, only the first page of a multi-page curve printout will be initialed/dated
- Initial/date the calibration update report (for calplot only)
- Initial/date the first page of each report of analysis (e.g., blanks, calibrators, controls, case samples)
- Sign/date the bottom of the worklist
- Sign/date the bottom of the QC Tracking form (if applicable)

Note: For blood ethanol/volatiles test batches, the reviewer will only initial/date the first page of the sequence and calibration/curve report, then sign and date the InfoPath form and worklist. For EMIT screening test batches, the reviewer will only initial/date the calibration report and reports of analysis for quality control samples (negative and positive), then sign and date the worklist.

12.4.2.2 Analyst Review of Test Report and Case File

The analyst will ensure their handwritten initials are on each page of each

instrument data report the examination records and all contents of the case file meet those documentation requirements in 12.3.3.

The issuing/authorizing analyst will document their review of all relevant pages of examination records (including those generated by another person) and the test report signing and dating the test report (*see 12.6.8 – Issue of Test Reports*).

12.4.2.3 Technical Review of Test Report and Examination Records

Technical review will be conducted on all test reports and examination records prior to release to the customer. Examination records shall be considered completed prior to technical review.

12.4.2.3.1 Technical review will only be performed by personnel authorized by the Laboratory Manager or TLD Commander/State Toxicologist, based on his/her knowledge and experience in forensic toxicology testing.

12.4.2.3.2 Technical review shall not be conducted by the author(s) or co-author(s) of the examination records or test report under review.

12.4.2.3.3 The technical review shall include, but is not limited to, verification of the following:

- The appropriate test procedures, and applicable policies and procedures, were followed
- The results on the test report are accurate and appropriate test data and any supporting documentation is included
- Criteria for acceptance described in the relevant test procedure has been met
- Any deviations from established procedures were recorded in the record with adequate justification/foundation for the deviation and approval
- Standards and controls used were appropriate and traceability information documented
- Any strikeouts are noted with the analyst's initials and date, and no obliterations are present (*see NOTE in 12.3.3.15*)

12.4.2.3.4 Should the reviewer identify discrepancies, or determine that additional testing is needed in the process of technical review, the case file will be returned to the analyst. The reviewer will communicate to the analyst those necessary change(s) or the additional test(s) requested.

12.4.2.3.5 The reviewer will document his/her technical review by signing/dating the test report and initialing/dating the first page of each report of analysis in the case file (also documenting administrative review – 12.4.2.4.3).

12.4.2.4 Administrative Review of Test Report and Case File

An administrative review of the case file, and test report, will be conducted by authorized personnel, prior to the release of written reports (including amended

reports) to the customer. Examination records shall be considered completed prior to administrative review.

12.4.2.4.1 The administrative review shall be conducted by someone other than the author(s) or co-author(s) of the test report and will verify the following:

- The test report is checked for spelling and grammatical accuracy.
- Submitting agency case information (e.g., case number, address) on the test report corresponds to the information on the Laboratory Request for Analysis.
- The external chain of custody has been documented.
- Reports of analysis (however named) and related documentation (e.g., chromatograms, mass spectral data, traceability information) for each test performed, including documentation of technical review.
- Data reports and related documentation support results recorded on the test report, and are technically accurate.
- The Laboratory's unique identification number (ST XX-XXXXX or XX-XXXXX) assigned to the case, appears on administrative documentation (see 12.3.1) and all pages examination records.
- Appropriate testing has been performed based on the type of case submission and any supporting information described on the Laboratory Request for Analysis.
- All testing performed conforms to the Laboratory's documented policies and procedures.
- The file contains other documents as appropriate, such as external test reports, correspondence, letters, and communication logs.
- The final report includes all key information, and is an accurate reflection of the specific testing performed, the results obtained, the dates of each test, and the correct testing analyst is indicated.
- The analyst (author) has signed and dated the test report.

12.4.2.4.2 Should the reviewer identify discrepancies in the process of administrative review, the case file will be returned to the analyst. The reviewer will communicate the necessary change(s) to the analyst.

12.4.2.4.3 The reviewer will document his/her administrative review by signing and dating the test report and initialing/dating the first page of each report of analysis in the case file (also documenting technical review – 12.4.2.3.5).

12.4.2.5 Supervisory Review

Supervisory case reviews will be carried out on a sample of completed case records to monitor the effectiveness of the technical/administrative review process. This may occur at any time after the release/distribution of the test report, and is in addition to the technical and administrative review performed on all test reports and case files prior to release.

12.4.2.5.1 The scope of the supervisor review is the same as is listed for technical (12.4.2.3) and administrative (12.4.2.4) review, and those items listed on

the Supervisory Case Review Checklist.

12.4.2.5.2 Supervisory review will only be performed by personnel authorized by the Laboratory Manager or TLD Commander/State Toxicologist.

12.4.2.5.3 The total number and selection of case records subject to supervisory review each year will be based on the Laboratory's caseload, workflow and additional factors, as determined by TLD Management.

12.4.2.5.4 The selection will encompass all types of case submissions and work from all analysts issuing test reports.

12.4.2.5.5 The review will be documented on the Supervisory Case Review Checklist, which is maintained in the case file.

12.4.2.5.6 Should the reviewer identify a discrepancy in the process of supervisory review, TLD Management will determine if customer notification and/or issuance of an amended report are warranted. The identified discrepancy, and any action(s) taken, will be documented on the Supervisory Case Review Checklist. If additional documentation is needed, this will be included in the case file or the case record. Wherever possible, corrections/corrective actions that arise as a result of supervisory review will be completed within 30 days.

12.4.2.5.7 The Laboratory Manager will maintain a summary of those cases that received supervisory review. The summary will include the name of the person performing the supervisory review, date of review, case identifier, case submission type, name of issuing analyst and information on any discrepancies identified and action(s) taken.

12.5 FOCUSED REVIEW

When internal quality processes uncover serious or repeated errors in testing work, or there is a complaint alleging misconduct or incompetence, TLD may initiate a focused testing work review. If a root cause analysis has been completed, TLD Management will review the analysis as part of their deliberation as to the necessity of a focused casework review.

12.5.1 Review of Affected Testing Work

The focused testing work review will be conducted by a Supervisor or panel selected by TLD Management. The reviewing Supervisor will prepare a report summarizing the findings and forward the report to the QA Manager who will review and discuss the report with the TLD Commander/State Toxicologist.

12.5.2 Notifications

If the test report reflecting results obtained from the testing work in question has been released prior to the commencement of the focused testing work review, TLD Management will notify the customer as soon as practical but not later than 30 days after the review begins. The notification will include the fact that a review or audit is

being conducted and will identify all testing work under review.

12.5.3 Removal from and Reinstatement to Testing Work

The analyst who is under review will be removed from testing work by the Appointing Authority until the matter is resolved. In addition to the fact finding, technical review, re-examination of work, or other action taken by TLD Management, an amended test report may be issued to the customer, with copies sent to the prosecuting attorney's office, where necessary. Reinstatement to testing work must be authorized by the Appointing Authority.

12.6 TOXICOLOGY TEST REPORTS

12.6.1 After completion of testing, the analyst will generate a report of the test results. This report is titled "Toxicology Test Report for ST XX-XXXXX."

12.6.2 The test report shall include all information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the test method.

12.6.3 The results of each test carried out by the Laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods. The test method may specify limits of quantitation, units of measurement and number of significant figures.

12.6.4 The test report will include the following information:

- A title (e.g., Toxicology Test Report for ST# XX-XXXXX)
- The name and address of the Laboratory (where testing was performed)
- Unique identification of the test report (unique report barcode generated in LIMS), on each page
- A clear identification of the end of the test report (page x of total pages)
- The name and address of the customer
- Date the test items were received by the Laboratory
- Identification of the procedure/method used in testing
- Identification and description of the item(s) being tested
- Date(s) the testing was performed
- Test results, including units of measurement
- Where required, the expanded measurement uncertainty of the test results, including a coverage probability of minimum 95.45% (also referred to as approximately 95%)
- The name, function, and signature (or equivalent) of the person authorizing (issuing) the test report
- Date the report was issued
- Where relevant, a statement to the effect that the results relate only to the items tested, and that the report shall not be reproduced except in full, without the written approval of the Laboratory

12.6.4.1 The following information, where applicable and necessary for interpretation of results, or required by agreement with the customer, will be contained in the

case record:

- Deviations from, additions to or exclusions from the test method used, or information on the specific conditions of the test (e.g. environmental conditions)
- Statement of compliance or non-compliance with requirements and/or specifications
- Additional information required by the specific test method or customer(s)

12.6.4.2 If the test report includes results of testing performed tissue homogenate, the case record will contain the following, where necessary for interpretation of those results:

- Date the sample was taken/homogenate prepared
- Identification of the specimen sampled
- Description of the sample (e.g., 1.23 g sample taken from submitted liver)
- Reference to the sampling procedures used
- Any other applicable information, including deviations from the sampling procedures

12.6.4.3 In the event that testing is performed, but no definitive conclusion can be reached (i.e. no results are reported), the test report will communicate to the customer the reason(s) why this occurred.

12.6.4.3.1 For example, sample screening indicates the presence of an opiate compound(s), and opiates confirmation testing is performed. The condition/quality of the sample prevents reporting of results, as the chromatography does not meet the test method's acceptability criteria. The test report will indicate that the testing was performed, and a comment will be added to inform the customer that a result was not reported due to the condition/quality of the sample.

12.6.4.4 If requested by the customer(s), the results may be reported in simplified manner, provided that any applicable information in 12.6.4 above, not included in the test report, is readily available at the Laboratory.

12.6.5 In certain circumstances, a case may be adjudicated prior to completion of testing, or the submitting agency may request that testing be halted or not performed. The Laboratory may issue a test report indicating that testing was incomplete or not performed.

12.6.5.1 This is at the discretion of TLD Management and is determined on a case-by case basis. If a test report is issued, it will be clearly stated that testing is incomplete or no testing was performed. Those items listed in 12.6.4 will be included on the test report, as applicable.

12.6.6 In the event that a test report is not generated for evidence received by the Laboratory, the reason will be documented in the case record. Examples of circumstances where a test report is not generated include the following:

- The Laboratory receives a court order for expungement prior to completion of testing

and issuance of a test report

- The submitting agency contacts the Laboratory and requests that no testing be performed or, if testing has begun, that testing is halted and no record of test results is generated
- Evidence is mistakenly sent to the Laboratory and the Laboratory is contacted by the submitting agency with a request to perform no testing and return the evidence to the agency

12.6.7 Results from Subcontractors

12.6.7.1 When testing is performed by an approved subcontracted laboratory, the subcontractor must provide a report of results for this testing (this may be electronic or hard copy). The report is considered an administrative record, and is subject to technical and administrative review (12.4.2.3 and 12.4.2.4).

12.6.7.2 The written report of results from the subcontracted laboratory shall have enough information that the Laboratory, and customer, can clearly understand the identity of the test item submitted for analysis and the results, including units of measurement. If not included in the written report of results, the test method(s) used and uncertainty shall be part of the subcontracted laboratory's examination records and available upon request.

12.6.7.3 Results of testing performed by a subcontractor shall be clearly identified on the Laboratory's final report. The final report will indicate those tests performed by the subcontracted laboratory and reference the written report of results from the subcontractor. A copy of the subcontractor's report will be provided to the customer.

12.6.8 Issue of Test Reports

12.6.8.1 Prior to issue, the analyst will review the contents of the case file and the test report for content and correctness (*see 12.4.2.2*). The test report is considered issued once the analyst signs and dates the bottom of the printed test report. The analyst will mark the test report as "draft complete" in LIMS before submitting for review.

12.6.8.2 Once issued, the test report is included in the case file and the case file is sent for technical and administrative review of the test report.

12.6.9 Release of Test Reports

12.6.9.1 After technical and administrative review, the reviewer will sign and date the bottom of the test report and mark the test report as "admin reviewed" in LIMS, indicating the test report is ready for distribution to the customer.

12.6.9.2 Test reports are marked as "distributed" in LIMS (this may be performed by technical or administrative personnel), when released.

12.6.9.3 The customer may receive test reports via mail or e-mail, or the report may be

posted to a secured server provided by the customer. If test reports are submitted via electronic means, provisions will be made to protect the integrity and confidentiality of the information, and the test reports must meet those criteria in 12.6 above.

12.7 SUPPLEMENTAL TEST REPORTS

12.7.1 If additional testing is performed on evidence related to a case where a final report has been issued and released, this will be considered supplemental testing, and a supplemental test report will be issued.

12.7.1.1 Supplemental testing may be performed when, after issue of the final report, the customer requests additional testing on evidence originally submitted to the Laboratory or submits new evidence items for testing.

12.7.2 The supplemental test report will be titled "Supplemental Test Report for ST# XX-XXXXX" and will contain that information in 12.6.4. The report will be uniquely identified by the report barcode generated in LIMS (original report barcode with appropriate suffix).

12.7.3 The supplemental test report will reference the initial test report through the ST # and related report barcode generated in LIMS.

12.8 AMENDED TEST REPORTS

12.8.1 Once the final test report has been issued, amendments shall only be made in the form of a new document; an amended report.

12.8.1.1 The amended test report will be titled "Amended Toxicology Test Report for ST# XX-XXXXX and will contain that information in 12.6.4. The report will be uniquely identified by the report barcode generated in LIMS (original report barcode with appropriate suffix).

12.8.1.2 The amended test report will reference the initial test report through the ST# and the related report barcode generated in LIMS.

12.8.1.3 Should the Laboratory receive a notice of amended results (however named) from a subcontractor, an amended test report will be issued, and those items in 12.6.6 will apply.

12.8.2 Procedure

12.8.2.1 If it is determined that the necessary amendment constitutes nonconformity, follow the procedures in *Chapter 4 - Control of Nonconforming Work*, in addition to those listed here.

- If it is determined that the amendment is the result of nonconformity, the issue(s) must be addressed to the satisfaction of the TLD Commander/State Toxicologist and/or QA Manager, with their review and approval documented in writing. NOTE: This may be documented as part of the non-conformity/corrective action.
- The customer will be notified, in advance, that an amended test report will be

issued and the nature of the amendment.
- The issued amended test report will be subject to technical and administrative review prior to release.

12.9 RESOLUTION OF TECHNICAL DIFFERENCES OF OPINION

12.9.1 Disagreements may sometimes arise between the analyst and reviewer during the technical or administrative review process. Every effort will be made to resolve these issues at that level. Reviewers may request changes in reports, further work to clarify issues, or further work to complete the testing work. If there are unresolved differences during the review, the following process will be used:

- The reviewer and the analyst will bring the issue to the attention of the QA Manager, Laboratory Manager or Appointing Authority, who will act as a mediator.
- If not resolved, the mediator will review the issues and make a recommendation to the Appointing Authority (unless mediator is Appointing Authority).
- Recommendations may include re-analysis, issuance of an administrative report, or other suitable action.
- The decision of the Appointing Authority concerning the resolution of the testing work shall be binding.
- The resolution will be concluded prior to the release and distribution of the report.

13 TRACEABILITY AND QUALITY CONTROL

13.1 POLICY

The Laboratory will take into account those factors that contribute to the accuracy and reliability of testing performed. The Laboratory will ensure that personnel are qualified and properly trained, that testing/analytical procedures and instrumentation are validated, that the selected equipment is calibrated/verified, and that reagents and materials are traceable, with their performance verified, as applicable.

Personnel qualifications and training is outlined in Chapter 5, validation of test methods is described in section 10.3.6, uncertainty of measurement is outlined in 10.10, and equipment maintenance is detailed in Chapter 6.

13.2 TRACEABILITY AND QUALITY CONTROL OF REAGENTS

13.2.1 Policy

Traceability will be established for the individual measurement (test) results (not for laboratories, methods or personnel), or in the case of blood ethanol/volatiles testing, the mean calculation. Traceability should establish an unbroken chain of comparisons for the measurement results back to national or international measurement standards such as NIST and will allow for comparability between different analytical instruments and methods.

13.2.2 Testing batch records will include the lot numbers of those reagents, materials and standard solutions used in testing.

13.2.2.1 For laboratory-prepared reagents used in sample preparation (e.g. dilute acids, bases, buffer solutions), the internal lot number or the preparation date and preparing analyst information will be recorded in the batch. Original preparation information is recorded in the Reagent Preparation Log *(see 8.2 Reagents)*.

13.2.2.2 If the test method utilizes liquid chromatography, the preparation date and preparing analyst information for the mobile phase used (e.g., 0.1% formic acid) will be recorded. Original preparation information is recorded in the Mobile Phase Log.

13.2.3 In-house preparation of standard solutions for use in spiking calibrators and controls is documented as described in the Standard Solution Preparation procedure.

13.2.4 Certified reference materials or standard reference materials used without further dilution will have their manufacturer-assigned lot numbers and expiration dates recorded in the testing batch record.

13.2.5 Temperatures associated with the test method (e.g., derivatization, evaporation) will be recorded in the testing batch record.

13.2.6 Certificates of Analysis (COAs)

The Laboratory will retain Certificates of Analysis (COAs) for those certified reference materials or standard reference materials used in testing. The COAs include the manufacturer lot number and expiration date, value assigned to the material, uncertainty of measurement information and a description of the traceability of the material's concentration to SI units of measurement.

13.3 VALIDATION/VERIFICATION OF EQUIPMENT AND INSTRUMENTATION

13.3.1 Policy

Laboratory instrumentation must be validated prior to being placed into service. Instrumentation used for existing applications and methods must have performance verified before initial use. Validation/verification is performed in order to demonstrate that the instrumentation is capable of achieving the Laboratory's and the manufacturer's specifications for the test(s) (*see 10.3.6*).

13.3.1.1 Equipment/instruments will only be operated by authorized personnel, and will have regular maintenance and performance verifications to ensure continued performance. Maintenance, calibration and verification procedures will be documented and maintained in an equipment/instrument maintenance and/or verification logbook. The Laboratory will maintain a list of persons authorized to operate the equipment/instrumentation.

13.3.2 Testing batch records will include the unique identifier (e.g., internal assigned ID, serial number) of equipment and instrumentation used in testing.

13.3.3 Definitions

13.3.3.1 Performance Verification: Performance verification is a set of operations to determine if a piece of equipment or instrumentation is working correctly within manufacturer's specifications or the Laboratory's specified parameters.

13.3.3.2 Traceability: The property of a measurement result whereby it can be related to standard references, usually national or international, through an unbroken chain of comparisons.

13.3.4 Procedure

All analytical equipment/instruments and any associated software will have records that are maintained in an equipment/instrument maintenance and/or verification logbook. This logbook will be kept in the Laboratory, and in close proximity to the equipment/instrument, whenever possible. Retired logbooks will be retained for at least one accreditation cycle. An electronic logbook is an acceptable alternative to a written log.

13.3.4.1 Where applicable, the following information should be kept in the Equipment/Instrument logbook:

- The equipment/instrument identity: type, manufacturer, model, serial

number or unique name and current location
- The original equipment paperwork provided with instrument installation, wherever possible
- The maintenance plan and/or procedure and records of maintenance performed
- Date of maintenance, initials of the person doing the maintenance and activity conducted
- Performance verification procedures
- Documentation of performance verification
- Scheduled calibration (if required) including dates, results, reports and certificates
- Any documentation related to damage, malfunction, modification or repair to the equipment/instrumentation

13.3.4.2 Each instrument will be uniquely identified and the identifier will be used in all documentation, including any reports or hard copy instrument data.

13.3.4.3 Where applicable, other equipment/instrument documentation to be maintained includes:

- The Manufacturer's maintenance and operating manuals or reference to their location
- Internal validation procedure, data and documentation

13.3.5 Equipment/Instrument Maintenance

Maintenance procedures will include a maintenance plan that indicates the frequency and type of maintenance to be performed (i.e., annual, as needed, by manufacturer, etc.) and any scheduled manufacturer maintenance contract information (if applicable).

For equipment, calibration check intervals will be defined by the laboratory. The maintenance plan will be located in the technical procedures and/or the maintenance logbook.

13.3.6 Equipment/Instrument Performance Verification

The Laboratory will ensure that all equipment/instrumentation, either newly purchased or existing, are properly validated or have their performance verified prior to use. The process will be as extensive as is necessary to meet the needs of the given application. All validation/verification studies will be performed by qualified personnel with adequate resources to perform the study.

13.3.6.1 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.

13.3.6.2 Performance verification will be documented in the equipment/instrument maintenance logbook. Verification protocols are described in the *Procedure for Instrument Maintenance and*

Performance Verification and include verification requirements (e.g., frequency of verification and tolerances, acceptance criteria) and specific verification protocols, including the use of any reference standards. When possible, all verification will be completed with traceable reference standards or materials.

13.3.6.3 If equipment goes outside the direct control of the laboratory (e.g., sent for maintenance, repair or calibration), the function/condition of the equipment, or the calibration status of the equipment will be verified before the equipment is returned to service.

NOTE: For pipettes, thermometers, thermometer/hygrometers and barometers sent to the calibration provider for calibration in packaging that secures the equipment and prevents any damage during shipping, calibration status is verified by reviewing the as-found and as-left results on the calibration certificate and inspecting the physical condition of the equipment upon receipt. For diluter-pipetters, a performance verification is performed prior to being returned to service (aliquots of calibrators/controls analyzed by HSCC).

13.3.6.4 If a performance verification is performed, the minimum information that will be recorded in the equipment/instrument maintenance logbook will include the following:

- The instrument unique identifier or name, model and serial number
- The verification date
- Initials of the person performing the verification
- The type of verification performed (post-maintenance, scheduled, etc.)
- If the instrument passed or failed performance verification
- Identification of reference material used, where applicable
- Any comments regarding the performance check

13.3.6.5 Equipment/instrumentation that does not meet performance specifications shall be taken out of service. The instrument will be clearly labeled or marked as being “Out of Service” until it has been repaired or evaluated, and shown by calibration or performance verification to perform within specifications. In addition, the removal of the instrument from service should be documented in the equipment/instrument log and should indicate why the instrument was removed from service. The date the instrument is placed back in service should also be indicated in these logs.

13.3.6.6 If the nature of the malfunction is such that the accuracy of previous reported test results are suspect, the situation shall be immediately brought to the attention of the Supervisor and the QA Manager. The QA Manager will determine if corrective actions is needed (see Chapter 4).

13.3.7 Equipment Calibration

Calibration policies and procedures for specific types of equipment are

described in Chapter 6, individual standard operating procedures, and maintenance checklists/logbooks.

13.3.7.1 When external calibration services are used, traceability of measurement will be assured by the use of services that can demonstrate competence, measurement capability and traceability.

13.3.7.2 The calibration certificates issued by these services will contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

13.3.8 Responsibilities

13.3.8.1 Forensic Scientists are responsible for:

- Performing assigned instrument verification and maintenance and documenting all necessary information concerning verification and maintenance activities in the instrument logbooks
- Ensuring that the equipment in use has been properly calibrated or verified prior to use

13.3.8.2 Laboratory Manager/Supervisors are responsible for:

- Ensuring that calibration/verification and maintenance procedures are in place for each instrument determined to require verification and maintenance
- Monitoring compliance with calibration/verification and maintenance procedures through periodic spot checks
- Addressing problems concerning verification according to TLD Policy
- Ensuring that all users are authorized prior to instrument use
- Ensuring that required calibration/verification and maintenance as outlined in the written procedures are carried out, and according to schedule
- Periodic review of all calibration/verification and maintenance records and activities

13.3.8.3 The QA Manager is responsible for:

- Monitoring compliance with calibration/verification and maintenance procedures
- Conducting an annual review and update of this policy

13.3.8.4 The TLD Commander/State Toxicologist is responsible for:

- Monitoring all instrument calibration/verification and maintenance activities through review of annual audit reports and other communications through Laboratory personnel.

13.4 ELECTRONIC DATA AND COMPUTER SOFTWARE

13.4.1 The Laboratory employs procedures to protect the integrity of electronic

quality and technical records, including the entry/collection, processing, storage, back-up, protection and transmission of the data/records.

13.4.1.1 The Laboratory's evidence tracking system (Laboratory Information Management System - LIMS) holds all case information and test results related to a specific submission for analysis. This system is accessible to Laboratory and support (e.g., information technology) personnel, through use of a secured PIN.

13.4.1.2 Instrumental data is collected and stored on the computer system specific to that instrument. All data from instrument computer systems is also stored on the WSP network for security and accessibility purposes, and is backed-up regularly.

13.4.1.3 Instrumental data may be processed at the instrument where acquired, or from another computer station with access to the network. Use of local computer systems, or those on the WSP network, ensures security in the transmission of testing data.

13.4.1.4 Any calculations and transfers of data will be appropriately verified. For policies and procedures, this is documented on the DRA form. For test results, this is performed at time of testing batch review or the technical/administrative review of the test report and case record, and is documented with the signature and date of the reviewer.

13.4.1.5 Transmission of results (test reports) via electronic means or disclosure of information will be done according the Laboratory procedures (*see 12.6.8.3 and Operations Manual 4.2 and 4.4*).

13.4.2 Computer systems and automated equipment used in testing work will be maintained under the appropriate environmental and operating conditions to ensure proper function and the integrity of the test results.

13.4.3 Computer software developed or modified for use in testing work will be documented and validated. Software used to perform calculations or statistical analysis of testing data will be validated, with systematic checks performed, as appropriate.

13.4.4 Electronic quality records, current and archived, are maintained on the secured WSP server and are backed-up regularly.

13.5 TRACEABILITY OF MEASUREMENT STANDARDS

13.5.1 Policy

All equipment/instrumentation used in the laboratory, having a significant effect on the measurement result and their associated uncertainties of measurement, will be traceable to national and/or international standards of measurement. This is demonstrated through the use of a measurement standard. The TLD will safely handle, transport and store these measurement standards in order to prevent contamination or deterioration and in order to protect their integrity.

13.5.2 Definitions

13.5.2.1 National/International Standard: A standard recognized by national or international agreement to serve as the basis for assigning values to other standards of the quantity concerned. The standards which generally apply are the metric system of measures expressed in SI units, the units of the International System of Units (SI).

13.5.2.2 National Institute of Standards and technology (NIST): This federal agency, also known as NIST, is located within the U.S. Department of Commerce and represents the final authority for metrology in the United States. Ideally, all measurement results should be documented and shown to be traceable to NIST.

13.5.2.3 Reference Material Producer: An organization or firm which manufactures and provides certified reference materials for the purpose of ensuring traceability and estimated uncertainty. The producer shall be responsible for assigning a reference value to the material along with any available uncertainty.

13.5.2.4 Certified Reference Material (CRM): A material or substance, accompanied by a certificate, one or more of whose property values are certified by a procedure that establishes traceability to an accurate realization of the unit in which the property values are expressed. Each certified value is accompanied by an uncertainty. An example of such a CRM would be a NIST traceable thermometer.

13.5.3 Procedure

13.5.3.1 Reference standards or materials (e.g., ASTM weights) used to check accuracy of equipment or instrumentation shall not be used for other purposes.

13.5.3.1.1 Mass reference standards will be stored appropriately to protect their integrity, in the case provided by the manufacturer, kept clean and dry.

13.5.3.1.2 Should mishandling of standards bring their accuracy into question, they shall be taken out of service and recalibrated.

13.5.3.2 Adjustments and/or calibration of reference standards shall only be conducted by approved, external calibration service providers, and will be documented.

13.5.3.2.1 Wherever possible, vendors used for calibration or recertification of these standards shall be certified or accredited by ISO or other international/national accrediting bodies.

13.5.3.2.2 Traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability, by means

of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement.

13.5.3.2.3 Following service, maintenance and recalibration, the certification/documentation provided by the service provider will be maintained in the Laboratory.

13.5.3.2.4 The calibration certificates issued by the service provider shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

13.5.3.2.5 When traceability of measurements cannot be made in or is not relevant to SI units, then reference materials will establish traceability by one of the following:

- The use of a certified reference material from a supplier
- The use of specified methods, published standards
- Participation in inter-laboratory comparisons

13.5.3.2.6 Documentation of this traceability to SI units or CRMs and the recalibration/recertification information shall be maintained at the laboratory.

LIST OF CHANGES

Revision Date	Procedure	Change	Page Number
7/8/13	Original	Document approved by the State Toxicologist. See DRA dated 07/08/13. Effective date 07/08/13.	All
6/1/15	7/8/13	Added chapters 2 – Document Control, 3 – Internal Audits and Management Reviews, 4 – Control of Nonconforming Work, 5 – Personnel Qualifications and Training, and 10 – Assuring the Quality of Test Results.	11-35, 56-65
6/1/15	7/8/13	The following chapters were removed, and some issued as stand-alone documents: Quality Assurance Guidelines, Blank Blood Certification, Standard Solution Preparation, Validation Procedure for Confirmatory Methods, Procedure for the Gravimetric Certification of Hamilton Microlab 500A Series Diluter Dispensers, Procedure for the Gravimetric Calibration of Adjustable Air-Displacement Pipettes, and the procedure for the Gravimetric Performance Verification of Adjustable Air-Displacement Pipettes.	All
6/1/15	7/8/13	Edits to all existing chapters for content and/or formatting. See DRA dated 3/31/15 for detailed changes.	All
7/10/17	6/1/15	Edits to chapters 4 to revise nonconforming work/corrective action procedures, edited chapter 6 to update calibration schedules for diluters, pipettes and thermometer/ hygrometers and updated list of approved proficiency test providers and tests in 11.4. Other minor edits throughout. See DRA dated 1/10/17 for detailed changes.	20-27, 38-46, 69-70
10/13/21	7/10/17	Updated references for ISO/IEC 17025 to 2017 revision, and ASCLD/LAB references to ANAB throughout. Revised elements of MSR in 3.3.4. Added calibration for volumetric flasks and volumetric pipettes used for prep of quantitative standards in 6.13. Added use of TempGenius™ for refrigerator/freezers in 6.14 and 6.15. Revised list of PT provider tests in 11.4. See DRA with marked revision for all changes.	All Chapters