



Calibration Quality Manual

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**Washington State Patrol
Toxicology Laboratory Division**

2203 Airport Way South, Suite 360
Seattle, WA 98134-2927
(206) 262-6100

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INTRODUCTION

This manual describes the Quality Assurance (QA) program of the Washington State Patrol (WSP) Toxicology Laboratory Division (TLD) as it relates to its breath alcohol calibration functions, and provides personnel with a description of the Division's policies for maintaining an effective QA program. Written procedures for implementing the policies are described herein.

Within the WSP Forensic Laboratory Services Bureau (FLSB), the TLD and the Breath Test Program (BTP) of the Impaired Driving Section (IDS) are responsible for functions related to breath alcohol calibration. The TLD prepares and certifies two types of simulator solutions: the Quality Assurance Procedure (QAP) solutions and the External Standard solution (ESS). These solutions are then used by the BTP, where the QAP solutions are used to set and confirm the calibration of the evidentiary breath test instruments, and the ESS is used to verify the accuracy and proper working order of the Datamaster instrument as part of a field evidential breath test.

This QA program applies to all breath test calibration functions within the TLD, and the policies and procedures are binding on all personnel, and shall be followed. This manual covers all work done by responsible personnel, to include but not be limited to work done within the TLD, in addition to duties outside the laboratory, whether in court, training venues, or anywhere else the duties of responsible personnel might be employed. Any adjustments or deviations from the policies and procedures detailed in this manual must be approved by TLD Management, and appropriately documented.

The official version of this manual is the electronic version as it appears on the FLSB SharePoint site (FLSB Portal). Any controlled TLD or agency documents referenced in this manual refer to the current official versions posted on SharePoint.

1 QUALITY MANAGEMENT SYSTEM

1.1 POLICY

The TLD will establish, implement and maintain a quality management system (QMS) appropriate to the scope of its calibration activities. The TLD will document its policies, programs, procedures and instructions to the extent necessary to assure the quality of the calibration results. 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 Manual.

1.2 DEFINITIONS

1.2.1 Annual

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

1.2.2 Calibration

For the purposes of this manual, any and all breath alcohol functions of the TLD (namely the production and certification of reference materials), unless otherwise specified.

1.2.3 Quality

Adherence to generally recognized standards of good laboratory practice.

1.2.4 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.

1.2.5 Quality Assurance Manager

The designated individual with oversight of the QA Program for the TLD.

1.2.6 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.

1.2.7 Quality Assurance Records

Records, logs, worksheets and electronic files that provide documented support of conformity to the quality management system. 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.

1.2.8 Quality Control (QC)

Internal activities or activities conducted according to externally established standards used by the TLD to consistently ensure accurate analytical results.

1.2.9 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.

1.2.10 Quality Manual

A collection of the TLD's quality management system policies and objectives for its breath alcohol calibration functions, and how these policies and objectives will be implemented.

1.2.11 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. This foundational training program is required for all qualified forensic scientists, prior to assuming forensic analysis.

1.2.12 Forensic Laboratory Services Bureau (FLSB) Director

The Director with ultimate responsibility and authority over the FLSB, which is comprised of the Toxicology Laboratory Division, the Impaired Driving Section and Breath Test Program, the Crime Laboratory Division, and the Standards and Accountability Section. This is the Laboratory Director for the Bureau's breath alcohol calibration functions.

1.2.13 Toxicology Laboratory Division (TLD) Management

Includes the TLD Commander/State Toxicologist, Laboratory Manager, QA Manager and Supervisors; also referred to as Top Management and Key Management.

1.2.14 TLD-Commander/State Toxicologist

The Commander who oversees the TLD, also known as the Appointing Authority.

1.2.15 Laboratory Manager

Individual having overall operational responsibility of the laboratory performing breath alcohol calibration functions.

1.2.16 Supervisors

Individuals with overall technical responsibility of personnel performing breath alcohol calibration functions. Also known as the Forensic Scientist Supervisors (FS-5).

1.2.17 Appointing Authority

Individual with authority to authorize qualified personnel to perform technical procedures, and remove/reinstate personnel or systems from performing calibration functions. For the TLD, the Appointing Authority is the TLD Commander or designee.

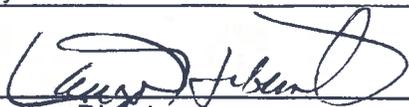
1.3 QUALITY POLICY STATEMENT

The management and personnel of the TLD will operate its breath alcohol calibration functions according to a documented quality management system, the purpose of which is to provide a framework for producing quality service at all levels of the organization. Management is committed to demonstrating compliance with the International standard for competence of testing and calibration laboratories (ISO/IEC 17025:2005) and the specific standards for the toxicology discipline in the category of breath alcohol reference materials (ASCLD/LAB-*International* 2007 Supplemental Requirements). Management is committed to good professional practice and setting a high standard for the quality of its breath alcohol calibration services. Management is committed to continually improving 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.

TLD personnel are required to familiarize themselves with the quality manual and to implement the policies and procedures contained in that manual as well as those contained in technical documents, forms and other instructions when conducting their breath alcohol calibration functions. By doing so and by contributing to the objective of continual improvement of the management system, personnel will help to achieve the TLD's standard of service as stated below and affirmed by the Laboratory Director and the following Top Management representatives, as signatories; TLD Commander, Laboratory Manager and Quality Assurance Manager.

Laboratory Standard of Service

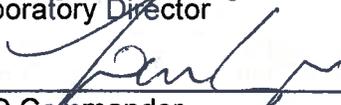
The TLD will provide professional, conscientious service to its customers by adherence to: consensus standards for laboratory competence, its own quality management system, and to the laws of the State of Washington. High standards of service will be maintained through diligent attention to all details of its breath alcohol calibration activities. The TLD will strive to set the standard for this work against which similar programs will be judged and will work toward the following objectives: comprehensive review of reference material records prior to shipment; maintenance of reference material supply levels to rapidly meet customer needs; and expediting the process whereby the laboratory identifies, corrects and documents nonconforming work.



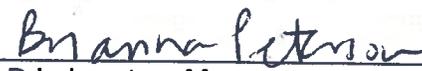
Laboratory Director



TLD Quality Assurance Manager



TLD Commander



TLD Laboratory Manager

1.4 QUALITY ASSURANCE PROGRAM

The TLD 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 TLD adheres to the Calibration Quality Manual policies and procedures and conforms to the ISO standards and any supplemental requirements.

1.4.1 Division Quality Management

TLD Management are responsible for ensuring that the policies and procedures adopted by the TLD are implemented and integrated into the daily operations of the laboratory. 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:

- Responsibility for the overall QA program of the TLD, including all audits and reviews
- Works to maintain and improve the QA program of the TLD
- Maintains QMS documents and records
- Monitors ISO criteria compliance
- Evaluates compliance to the TLD training programs, ensuring uniform quality of education and training
- Ensures uniform methodology implementation and use within the laboratory
- Ensures that procedures and training manuals for the discipline accurately reflect established standards and comply with accreditation requirements
- Performs reviews for adherence to procedure and approval of new methodology, technologies and equipment validations
- Evaluates new analytical procedures, equipment or technologies and oversee their validation and assist with implementation
- Administers and coordinates the TLD's proficiency testing program. This includes documentation and response to the Proficiency Review Committee (PRC)
- Organizes and schedules QA meetings
- Oversees and reviews of root cause analysis and corrective actions for nonconformities and inconsistencies in all calibration work

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

- Coordinates the training and development of each Forensic Scientist from basic development to continuing education

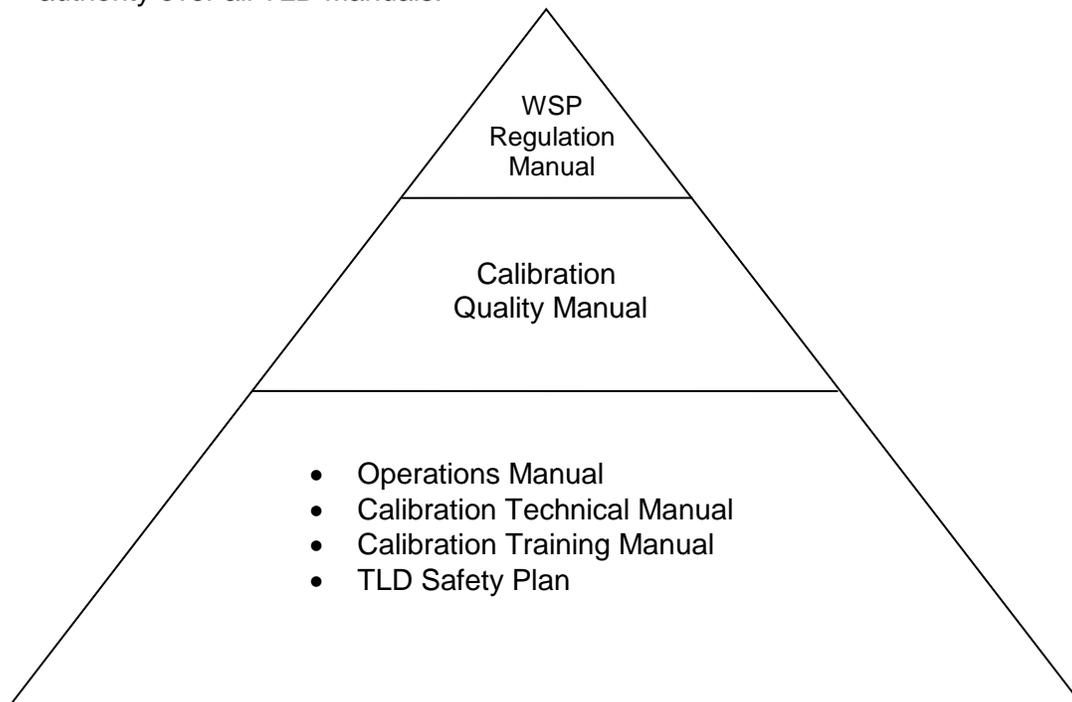
- Evaluates the ongoing effectiveness of, and ensuring compliance with, the technical and training manuals
- Identifies nonconforming work and documents the follow-up investigation and corrective/preventative actions
- Performs annual review of TLD documents (manuals, policies, procedures)
- Participates in the annual Management System Review
- Reviews manuscripts for publications
- Reviews 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 TLD 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 pyramid below represents the documentation upon which the QMS is built. The Calibration Quality Manual has over-riding authority over all operations and technical manuals in the calibration laboratory. The WSP Regulation Manual has over-riding authority over all TLD Manuals.



1.5 QUALITY SYSTEM RECORDS: ACCESS, FILING, STORAGE, RETENTION AND DISPOSAL

Quality system records are any logs, worksheets, electronic files or databases that provide documented support of conformity to the QMS. 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
- Chemical inventory records
- Audit records

These records are maintained by TLD staff. Filing, storage and retention of these records are as described below.

1.5.1 Records Filed, Stored and Retained by the TLD QA Manager or designee

- Training completion records
- Proficiency test answer sheets
- Method validation approvals
- Corrective actions
- Records on deviations from procedure
- Policy and Procedure manual document review and approval forms
- Audit records and reports
- Laboratory safety inspection reports
- Official electronic controlled documents/forms
- Equipment validation, performance verification and maintenance records
- Calibration files and records, and any associated examination or administrative documentation according to retention schedules
- Chemical and reagent logs and worksheets (where applicable)
- Standards inventory records and verification logs
- Key control records
- Equipment Inventory
- Building maintenance and security records and logs (where applicable)
- Visitor logs

1.5.2 Records Maintained in Bureau-Wide Databases

- Bureau Library Collection
- WSP BTP Discovery Material Website (WebDMS)
- Simulator Solution Information Management System (SIMS)

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.

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

1.5.3 Archive and Retention of Quality System Records

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

2 DOCUMENT CONTROL POLICY AND PROCEDURES

2.1 POLICY

All Management System documents used within the TLD are controlled to ensure that only current, up-to-date documents are being utilized. All official TLD documents will be made available to TLD staff via the FLSB Portal (SharePoint). The following procedure provides instructions concerning the creation, revision and distribution of these controlled documents. All WSP agency manuals, documents and forms are controlled and distributed by the agency.

Amendment of documents by hand pending the electronic re-issue of the revised controlled document is not allowed. Instead, changes may be relayed to laboratory personnel by e-mail or interoffice communication (IOC) to allow for immediate implementation prior to actual manual changes. Immediate changes may be issued by the TLD Commander, the Laboratory Manager, or the QA Manager.

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 released by authorized personnel, and distributed to personnel performing the prescribed activities.

2.2.3 Controlled Document

A document that is distributed to personnel in a controlled manner and ensures the recipients receive subsequent revisions and replace previous controlled copies. Examples of controlled documents include manuals and forms.

2.2.4 Document Review and Approval Form (DRA)

Document Review and Approval Form, used for new documents and all proposed modifications to controlled 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 or copies required for legal discovery.

2.2.7 Issuing Authority

Personnel that are authorized to approve the posting of controlled documents on the FLSB Portal. The issuing authority for FLSB-wide controlled documents is the FLSB Director. For Division-wide documents, it is the TLD Commander or TLD Management.

2.2.8 Master Document File

An electronic file maintained by the QA Manager and available to all TLD employees 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:

A header on each page containing, at a minimum:

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

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 date

Forms do not require the “Printed Copies are Uncontrolled” statement, as they are intended to serve as a template for entering data or information. No modifications to forms are allowed without going through the document revision process.

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

All controlled documents will have a history table indicating when the document was originally adopted and any revisions that have occurred since date of adoption. The table will include the following:

- A brief revision summary (why the revision was made)
- The section(s) revised (or reference to corresponding DRA)
- Revision effective date (or date of document review)

- Author of revision or reviewer of document and issuing authority
- Record of annual review

This history table for each document will be maintained by the QA Manager. The history table may be within the document itself, as with Division manuals, where the history table is the final page(s) of the document (also called List of Changes).

2.3.2 Controlled Document Preparation

Documents should be prepared by personnel with adequate expertise in the subject. 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 document must include enough detail and specificity to ensure that the activity conforms to quality specifications and/or expectations. The State Toxicologist is legally responsible for technical procedures for the TLD and its programs as authorized by statute (RCW 46.61.506).

Laboratory-specific policies and procedures cannot supersede the Washington Administrative Code/Revised Code of Washington, the WSP Regulation Manual, or the Division's Quality Manual.

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

- Preparing the document in the proper format
- Acquiring copies of listed references, where applicable
- Addressing or resolving comments from reviewers
- Assuring that there are no conflicts with other TLD manuals, WSP regulations and/or the Washington Administrative Code/Revised Code of Washington
- Submitting for review and approvals using the DRA form

2.3.3 Controlled Document Review

Each new or revised controlled document is required to have a technical and a quality review 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.

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

2.3.4 Controlled Document Approval

Each controlled document issued will be approved through the chain of command with final approval by the TLD Commander or designee.

2.3.5 Controlled Document Issuing

After the documents are approved, the document will be issued through the QA Manager or designee and posted on the FLSB Portal.

All personnel will have access to official electronic documents. However, administrative access to the official electronic controlled documents will be restricted to prohibit unauthorized changes. Only those personnel with Issuing Authority can authorize change.

2.3.6 Archiving Controlled Documents

Obsolete documents will be archived in the “Archived” section of the FLSB Portal. The document will be given a watermark labeled “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).

Employees shall only use current versions of approved documents.

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.

2.3.7 Annual Review of Controlled Documents

Controlled documents will be annually reviewed and revised if needed to ensure they reflect the current policies, practices, and technology. The revised documents are subject to the same review, approval, documentation and issuance requirements of the original document as stated above.

TLD Management will conduct this review for their respective technical and training manuals. TLD Management may also review administrative manuals. Documentation of this review will be by an IOC from the reviewer to the QA Manager, who will record the review on the document history table.

2.3.8 Official Controlled Documents

The official controlled documents to be used by personnel are those posted on the FLSB Portal (SharePoint). All TLD employees will have access to this site. Any copies of documents from this site represent unofficial copies and will be designated as such. The QA Manager or designee will maintain the official controlled documents and archived versions of all controlled documents on the FLSB Portal.

2.4 REVISIONS TO PROCEDURES, TRAINING AND TECHNICAL DOCUMENTS

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

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

For administrative/operational changes to documents, TLD personnel putting forward proposed revisions for consideration must ensure that the recommended changes represent the objectives of the Bureau/Division and are not in conflict with the WSP Regulation Manual or the Washington Administrative Code/Revised Code of Washington. The QA Manager will be responsible for ensuring that there are no conflicts between recommended changes and the existing management system.

Recommended changes must be submitted on the DRA form to the QA Manager for distribution and review by management. The following information must be provided:

- The document name and 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

Proposed changes must be submitted as an edited version tracking all changes made to the current document or procedure as follows:

- Deleted portions will have a strikeout
- Additions will be highlighted in yellow

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

When circumstances require an immediate revision to a document, the revision may be communicated by e-mail or IOC. The Issuing Authority in these cases will be the TLD Commander, the Laboratory Manager or the QA Manager. The communication will include specific information of the following: the document being revised, 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. Wherever possible, a hyperlink will tie the communication directly to the revised document.

2.4.1 Approved/Adopted

The approved 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.

Once a document is adopted, it will be the responsibility of TLD Management to ensure it is implemented. If applicable, a Directive Control, Receipt and Compliance sheet will be circulated to affected staff.

2.4.2 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.

2.4.3 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 CONTROL OF NONCONFORMING WORK

3.1 POLICY

In the event that any TLD personnel becomes aware of a nonconformity, or identifies potential sources of nonconformity for which preventative action is warranted, they shall notify the appropriate Supervisor. The Supervisor will notify the QA Manager, Laboratory Manager and/or the TLD Commander, as appropriate. If TLD personnel identify improvement opportunities which may prevent nonconformity, they are also directed to notify the appropriate Supervisor. 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, or care and preservation of calibration items).

The Supervisor shall ensure that significant nonconformities are documented. Level I nonconformities will be investigated using root cause analysis as directed by the QA Manager or designee, and appropriate corrective action taken. Level II nonconformities will be documented and the documentation will identify the nonconformity and the corrective actions taken in response.

3.2 DEFINITIONS

3.2.1 Corrective Action

Actions that are taken to address and resolve a nonconformity that has occurred.

3.2.2 Corrective Action Process

The process followed when addressing a nonconformity. 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)
- 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)

3.2.3 Corrective Action Report (CAR)

A formal report by the Supervisor or appropriate authority detailing the following:

- A description of the incident (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 the person responsible for evaluation

3.2.4 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.

3.2.5 Preventative Action

Actions that are taken to address potential sources of nonconformity that have been identified.

3.2.6 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.

3.3 PROCEDURE

In dealing with a nonconformity, the Corrective Action process can be broken down into the following steps:

3.3.1 Cessation of Work

The affected work process will be halted upon the identification of nonconformity. The duration will be based upon specifics of the work and the impact of halting the work on the overall management system.

Identification of nonconformities may occur through any of the following:

- internal or external inquiries or complaints
- quality control
- instrument calibration
- staff observations
- supervisor observations
- technical and administrative review of reports and documentation
- indications of inadequate peer review
- management reviews
- internal or external audits

3.3.2 Notification of Appropriate Authority

The person identifying the nonconformity will inform their Supervisor who in turn will notify the QA Manager/Appointing Authority. Notification will include all details necessary to fully evaluate the significance of the nonconformity.

3.3.3 Evaluation of the Significance of Nonconforming Work

If the evaluation of the significant nonconforming work indicates that the problem could recur, or that there is doubt about the compliance of the laboratory's operations with policies and procedures, the corrective action process will proceed.

Nonconformity may occur at several levels, some more serious than others. For the purposes of TLD calibration functions, two levels are distinguished:

- Level I Nonconformity - 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. These nonconformities would result in a finding by an accreditation assessor and will be reported to the accrediting agency within 30 calendar days of determining that the nonconformity has occurred. They will also be reported in the annual audit report. Level I nonconformities will result in immediate removal of the personnel/method/laboratory from calibration related work by the Appointing Authority. If the nonconformity is determined to be related to a laboratory wide or system wide deficiency, then the Appointing Authority will ensure the entire laboratory will discontinue work in that area until the nonconformity is addressed and resolved. The customer(s) will be notified and work recalled, when necessary.
- Level II Nonconformity - 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. These can generally be handled at the supervisory level by counseling and documentation, where appropriate. Repeated Level II violations by a single individual and/or laboratory may result in the incident being elevated to a Level I response.

3.3.4 Assignment of Corrective Action Process

Upon identification of any Level I nonconformity, the person having supervisory authority will notify the QA Manager/Appointing Authority. A determination will be made by the QA Manager/Appointing Authority whether the issue may be handled locally or if it will require involvement of other personnel. The QA Manager will assign the person having immediate supervisory authority to move forward with the corrective action process by implementing a Corrective Action Plan (see below).

The QA Manager/Appointing Authority will have final authority to determine the appropriate course of corrective action to eliminate and/or correct the problem and prevent reoccurrence. Corrective actions shall be appropriate for the magnitude and risk of the problem. Depending upon the severity of the nonconformity, a course of corrective action may include focused calibration work review (see *Chapter 9.9*), an external investigation conducted by the WSP Office of Professional Standards (OPS), or an external audit conducted by an appropriate entity.

Level II nonconformities are typically handled by the immediate Supervisor, generally with counseling. They should be documented by the Supervisor and the corrective action process implemented as needed. 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 calibration files and/or records. Repeated level II nonconformities, when documented appropriately, may become justification for raising the issue to a Level I.

3.3.5 Corrective Action Plan

For all Level I nonconformities, a corrective action plan will be prepared. When assigned, the person with 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. If the corrective action plan continues more than a month, then monthly reports should be issued by the Supervisor to the QA Manager /Appointing Authority.

A Corrective Action Plan should consider the following:

- The root cause of nonconformity
- Recall and review of prior calibration work to ensure correct analysis
- Consideration if the analyst, laboratory or entire system is to be removed from calibration 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 calibration 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

Difficulties with an employee's individual work performance will normally be addressed by the employee's Supervisor with assistance and input from other appropriate individuals if necessary. 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 designed to help the employee overcome the problem.

3.3.6 Root Cause Analysis

When a Level I nonconformity has been identified, the corrective action plan will include a root cause analysis to identify the source of the nonconformity. The QA Manager may direct other TLD personnel to conduct the root cause analysis investigation. Root cause analysis may include an evaluation of procedures, documents and records, staff training, consumable supplies, equipment, customer requests and requirements, calibration 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.

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.

3.3.7 Notification of Clients

When Level I nonconformities occur 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 calibration files or records should contain documentation of the technical and/or administrative measures taken to resolve the discrepancy.

3.3.8 Corrective Action Report (CAR)

Following completion of the corrective action plan, the Supervisor will submit a written summary of the action 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.

A review of the employee's performance, laboratory performance, or system performance will be conducted after completion of the corrective action report for all Level I nonconformities. If deemed necessary, reviews will be conducted at pre-determined intervals, from the time of completion of the report, to assess plan effectiveness, and a report will be issued by the Supervisor to the QA Manager and Appointing Authority.

The CAR and all supporting documentation will be retained by the QA Manager for a minimum of one accreditation cycle.

3.3.9 Responsibility for Authorizing Resumption of Work

In cases where an analyst has been removed from calibration 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 someone, some process, or some instrument is removed from work as a result of a Level I nonconformity, they/it may not return to calibration work until authorized by the Appointing Authority.

The QA Manager may also direct appropriate follow-up action to confirm the effectiveness of the corrective action plan. This may involve review of calibration work and audits of the laboratory.

The QA Manager will maintain records of significant nonconformities, proposed improvements and proposed preventative actions for at least one accreditation cycle and in accordance with WSP retention schedules.

Changes to laboratory policies and procedures resulting from corrective actions will be documented in the appropriate Quality, Operations and/or Technical Manuals. Depending upon the impact of these corrective actions, the changes may be relayed to

laboratory employees by e-mail or IOC to allow for immediate implementation prior to actual manual changes. The QA Manager will be responsible for coordinating these changes and notifications.

3.4 PREVENTATIVE ACTION

Preventative actions are designed to eliminate the cause of a potential nonconformity or its reoccurrence. Implementation of a preventative action may include one or more of the following:

- Research regarding policies and procedures in other calibration laboratories or jurisdictions
- Consultation with clients to ascertain the extent of their needs
- Consultation with TLD personnel to obtain developmental suggestions
- Validation of technical methods following the Method Validation section of the TLD Quality Manual
- Monitoring of effectiveness with TLD personnel and clients of the calibration services

TLD personnel are encouraged to identify preventative actions as opportunities to improve quality and correct potential sources of nonconformity before they arise.

These proposals may be brought to the attention of the Supervisor, Laboratory Manager and/or QA Manager preferably through written correspondence such as e-mail or IOC. The Supervisor, Laboratory Manager and/or QA Manager shall evaluate the suggestion. If a preventative action is implemented, it shall be monitored for effectiveness.

4 INTERNAL AUDITS AND MANAGEMENT REVIEWS

4.1 POLICY

The Laboratory will be audited annually to verify that operations are in compliance with established policies and procedures, ISO requirements, any supplemental requirements, and applicable WSP policies, rules and regulations. Internal audits will be documented, and documentation will be retained for at least one cycle of accreditation.

In addition to the annual internal audit, an annual Management System Review of the TLD Management system's operations for the previous year will be conducted. Calibration activities will be reviewed to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.

The Laboratory will submit an annual accreditation audit report (however named) to the accrediting agency by the laboratory's accreditation anniversary date.

When audit findings cast doubt on the effectiveness of operations, or on the correctness or validity of the laboratory's calibration results, the TLD shall initiate corrective actions. Where necessary, the TLD shall notify customers in writing if investigations show that the laboratory results may have been significantly affected. Policies and procedures regarding nonconforming work (see Chapter 3), internal audits, and job performance (see section 7.5) will be followed.

Additional audits, such as a focused review or external audits may be requested by the QA Manager or TLD Commander at any time to address specific concerns.

4.2 DEFINITIONS

4.2.1 Audit Cycle

The period of time between on-site audits by the accrediting body. An audit cycle will generally be a period of five (5) years.

4.2.2 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.

4.2.3 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.

4.2.4 Finding

A result from an audit that is not in conformance with accreditation criteria, TLD policies and procedures, or applicable WSP regulations. Findings that indicate a Level I nonconformity must be followed up with a Corrective Action Report (CAR).

4.2.5 Observation

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

4.2.6 Focused Review

A review of an individual's calibration work or a laboratory process requested by the Supervisor, Laboratory Manager, QA Manager and/or the TLD Commander.

4.2.7 Management System Review (MSR)

An annual review by TLD Management of the Laboratory's management and quality systems and calibration 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.

4.3 PROCEDURES

A review of the management system and internal audits will be conducted at least annually to ensure the continued suitability and effectiveness of the quality system and laboratory operations.

Audits will include an on-site inspection of the laboratory and will address all elements of the quality system, including the calibration activities. The QA Manager will plan, organize and direct the audits. The QA Manager has oversight of findings, CARs and follow-up.

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, FLSP or outside the Bureau.

4.3.1 The Eleven Elements of the Management System Review (MSR)

The annual Management System Review will address the following points:

- The suitability of policies and procedures
- Reports from managerial and supervisory personnel
- A review of internal audits
- Corrective and preventive actions taken in the last year
- A review of external audits
- Proficiency test program results and any findings
- Changes in the volume and type of work
- Client feedback
- Quality system complaints

- Recommendations for improvement
- Other relevant factors such as quality control activities, resources, and personnel training

The overall quality goals and objectives, as outlined in the quality policy statement, will also be reviewed. The results of the Management System Review will be considered by TLD Management for planning purposes. Items from the management review considered for planning purposes will have goals, objectives, and action plans.

A summary report outlining findings and observations of an internal audit or a Management System Review will be prepared by the QA Manager for the TLD Commander.

The Management System Review, internal audit reports and any corrective actions associated with findings will be documented by the QA Manager and retained for at least one accreditation cycle.

The QA Manager, Laboratory Manager, and Supervisors will ensure that corrective actions are implemented within an appropriate and agreed upon timeline.

5 PURCHASING SERVICES AND SUPPLIES

5.1 POLICY

The TLD is responsible for the acquisition, custody and disposal of all equipment and supplies within their control. State equipment and property will not be used for personal purposes. The procedures outlined below are designed to guide personnel through the acquisition process, conforming to all applicable laws, policies and administrative rules.

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.

Supplies and services that affect the quality of calibration work shall 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 protocols of the procedural manuals.

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

The Laboratory shall evaluate all suppliers of critical consumables, supplies and services, ensuring that specific requirements and standards of quality are met. One indication that these standards are met is if they are an ISO certified supplier. A list of evaluated and suitable approved suppliers/vendors of critical supplies and services shall be maintained by the QA Manager or designee, along with their record of compliance with established specifications.

5.2 PROCEDURE

5.2.1 Purchasing Equipment, Services and Supplies

Only TLD approved vendors will be used for the purchase of critical supplies and services.

An order will be placed with a supplier only after the Laboratory Manager or designee has authorized the order in writing or by e-mail. Prior to placing an order, it will be assigned a purchase order number or other approved means of payment to be provided to the vendor if needed. A system shall be used for monitoring supply orders.

The Laboratory Manager and/or Office Manager will designate:

- Person(s) responsible for placing orders
- Person(s) responsible for receiving orders and verifying that they are complete and correct (this may be all TLD personnel)
- Person(s) responsible for tracking orders from time of placement through preparation of payment vouchers

5.2.2 Receiving Equipment, Services and Supplies

Upon receipt, supplies, reagents or services will be checked or verified as complying with the purchase request. This can be done by checking the packing slip against the purchase request and against what was actually received to ensure all are in agreement. If the shipping documents or labels do not match, the supplies or material will not be placed into service until the problem is resolved. Any 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.

The person receiving the material should 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
- Receiver's initials to indicate review and approval

The packing slip or receipt will be attached to the order document. Both will be retained for a minimum of one year in the laboratory for future reference.

Where appropriate, purchased critical supplies will not be placed into service until they have been verified per procedures in the technical manual.

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 calibration work that may have been affected will be conducted (*see Chapter 3: Control of Nonconforming Work*)

TLD personnel have the responsibility to inform their immediate supervisor of a problem with product/item or services received from any vendor.

5.2.3 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) shall be readily available to all personnel.

5.2.4 Vendor Evaluation

The TLD shall maintain a list of approved suppliers of critical reagents, supplies and services that affect the quality of testing. This list is maintained electronically by the QA Manager or designee, and available on the FLSB Portal. The purchaser shall evaluate

new suppliers of reagents, supplies and services and provide this information to the QA Manager or designee. The vendor evaluation may be based on the following criteria:

- The vendor currently meets ISO 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 procedures of the Technical, Operations or Quality Manual
- 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
- Service or description of supplies/materials the vendor is approved to provide

A Vendor Evaluation and Approval, copies of national accreditation documents and/or a memo covering these points for each vendor should be prepared by the purchaser and forwarded to the QA Manager or designee. This information may be transmitted electronically.

5.2.5 Transfer and Disposal of Equipment and Supplies

Transfer and/or disposal of items obtained under these guidelines 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.

Equipment, including computer equipment and peripherals, that has been replaced will be either disposed of or sent to the appropriate location as soon as practicable. Such equipment should not be retained or stored at the laboratory. Exceptions to this policy must be approved by the Laboratory Manager. Requests for exception will clearly address the following:

- The reasons for retaining the equipment
- The intended future use of the equipment
- Cost of returning equipment to operation in the future
- Current value of the equipment
- The location where the equipment will be stored and the cost of storage, if applicable
- A cost/benefit analysis of retaining the equipment

6 TRACEABILITY AND QUALITY CONTROL

Many factors contribute to the accuracy and reliability of the calibration functions performed by the TLD, including:

- The training and qualifications of personnel
- Technical/analytical methods
- Reagents and supplies
- Selection, verification and maintenance of equipment

The TLD will take into account these and other factors and will ensure that the personnel are properly qualified and trained; that procedures are validated; that reagents and supplies are traceable and/or verified for performance; and that equipment is calibrated and/or verified. All procedures, reagents, supplies and equipment/instrumentation will be controlled.

6.1 TRACEABILITY AND QUALITY CONTROL OF REAGENTS

6.1.1 Policy

All commercially and laboratory prepared reagents, as well as chemicals used to prepare reagents, used for calibration work within the TLD will be of sufficient quality to assure the integrity of the results. Reagents should be checked to ensure their reliability and that the quality will equal or exceed that necessary for the type of testing or use designated in the Calibration Technical Manual. Procedures for, and the frequency of reagent checks, will be specified in corresponding laboratory procedures.

Reagents prepared in the laboratory shall be labeled with the identity of the reagent, the preparer's initials, the date of preparation, and the expiration date. Records of reagent preparation shall be maintained, including that its reliability was verified prior to use, where applicable.

6.2 VALIDATION OF EQUIPMENT AND INSTRUMENTATION

6.2.1 Policy

Instrumentation to be used must be validated prior to being placed in service in the TLD. Instrumentation to be used for existing applications and methods must have performance verified before initial use. The purpose is to establish that it is capable of achieving the Division's and the manufacturer's specifications for the test.

All instruments and major equipment will be uniquely identified. Equipment/instruments 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. In addition, equipment/instruments will only be operated by authorized personnel, for official breath alcohol calibration work, as determined by the Appointing Authority. The Laboratory will maintain a list of persons authorized to operate the equipment/instrumentation.

6.2.2 Definitions

6.2.2.1 Calibration

The process by which standards having known reference values are introduced into an instrument. The instrument is then adjusted or programmed (either by software, hardware, electronics, etc.) to report the known reference value.

6.2.2.2 Performance Verification

A set of operations to determine if a piece of equipment or instrumentation is working correctly within manufacturer's specifications or TLD's specified parameters.

6.2.2.3 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.

6.2.3 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. The laboratory will maintain retired logbooks for at least one accreditation cycle. An electronic logbook is an acceptable alternative to a written log.

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 damage, malfunction, modification or repair to the equipment/instrumentation

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

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
- List of authorized instrument users. A copy will be submitted to the Laboratory Manager.

6.2.4 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). Calibration check intervals will not be less stringent than that recommended by the manufacturer. The maintenance plan will be located in the technical manuals and/or the maintenance logbook.

6.2.5 Equipment/Instrument Performance Verification

The Laboratory will ensure that all equipment/instrumentation, either newly purchased or existing, that has been significantly modified such that the change(s) affects the outcome of the test, is properly validated or has performance verified prior to use. The process will be as extensive as is necessary to meet the needs of the given application or field of application. All validation/verification studies will be performed by qualified personnel with adequate resources to perform the study.

Performance verification procedures will be documented in the equipment/instrument and/or verification logbook. Verification procedures will include verification requirements (e.g. frequency of verification and tolerances, acceptance criteria) and specific step-by-step verification protocols, including the use of any reference standards. When possible, all verification will be completed with traceable reference standards or materials.

The minimum information that will be recorded in the equipment/instrument and/or verification 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 (internal diagnostic, comparison to a reference standard, etc)
- If the instrument passed or failed performance verification
- Identification of reference material used, where applicable
- Any comments regarding the performance check

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.

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 inform the TLD Commander, and corrective action shall be performed. The laboratory will follow the corrective action process for nonconformities (see *Chapter 3*).

6.2.6 Equipment Calibration

Analytical equipment requiring calibration (e.g. diluters, analytical balances, thermometers, thermometer/hygrometers) will be calibrated prior to being implemented in the laboratory.

Calibration status will be checked after any unexpected shutdown or removal of the equipment from service and following service or other substantial maintenance.

Equipment calibration will be described in the technical manuals and/or maintenance logbook.

Equipment requiring calibration will have a documented calibration schedule, including the frequency of calibration required, the status of calibration and the next calibration due date. Calibration/recalibration documentation and calibration certifications will be maintained on file at the laboratory.

Whenever practicable, all equipment requiring calibration will be labeled or identified to indicate the status of calibration. This should include the date when last calibrated and the date when recalibration is due.

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. 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. External calibration services will be ISO accredited.

6.2.7 Responsibilities:

Forensic Scientists are responsible for:

- Performing assigned instrument verification and maintenance and will document 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 using for breath alcohol calibration functions

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 in their discipline
- Monitoring compliance with calibration/verification and maintenance procedures through periodic spot checks
- Addressing problems concerning verification according to TLD Policy;
- Ensuring external calibration companies are ISO compliant
- 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

The QA Manager is responsible for:

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

The TLD Commander is responsible for:

- Monitoring all instrument calibration/verification and maintenance activities through review of annual audit reports and other communications through laboratory employees

6.3 TRACEABILITY OF MEASUREMENT STANDARDS

6.3.1 Policy

All calibration equipment/instruments 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 will be done 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.

6.3.2 Definitions

6.3.2.1 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.

6.3.2.2 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.

6.3.2.3 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.

6.3.2.4 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.

6.3.2.5 Calibration Equipment

Any measuring equipment used as part of the laboratory's breath alcohol calibration functions, according to a procedure.

6.3.3 Procedure

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

Adjustments and/or calibration of reference materials shall only be conducted by approved, external calibration service providers. All calibrations and adjustments to these materials will be documented.

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

Following service, maintenance and recalibration by such vendors, the certification or documentation provided by them will be maintained in the laboratory.

If mishandling of standards brings accuracy into question, the standards shall be taken out of service and recalibrated.

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

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

6.4 OTHER DIVISION REFERENCE DATABASES

6.4.1 Policy

The FLSB maintains databases for the cataloging, storing and retrieval of quality and technical information. Access to these databases will be limited to FLSB personnel and other authorized personnel such as FLSB Information Technology (IT) staff. Administration and changes to these databases will be by designated individuals only. The TLD Commander, or IT Division Management will designate an individual(s) for the management and administration of Division specific databases.

These databases include but are not limited to:

- Simulator Solution Information Management System (SIMS)
- WSP BTP Discovery Materials Website (WebDMS)

6.5 UNCERTAINTY OF MEASUREMENT

6.5.1 Policy

The TLD will have procedures for estimating the uncertainty of measurement where required. The procedure will attempt to identify all components of uncertainty and make a reasonable estimation to ensure that the form of reporting the result takes into consideration any applicable measurement uncertainty.

6.5.2 Definitions

6.5.2.1 Accuracy

The proximity of a measured value to a reference value.

6.5.2.2 Bias

The difference between a measurement result and the true reference value of the property being measured. The bias can be absolute or relative. The bias quantifies the accuracy of the measurement.

6.5.2.3 Coefficient of Variation (CV)

The relative standard deviation expressed as a percentage of the mean.

6.5.2.4 Combined Uncertainty

The estimate of measurement uncertainty that includes the contribution from all components significantly influencing a measurement result.

6.5.2.5 Measurement Uncertainty

The property associated with a measurement result that characterizes the dispersion of the values that could reasonably be attributed to the true value being measured.

6.5.2.6 Precision

The ability of a technique to perform a measurement in a reproducible manner. Precision is quantified by the standard deviation.

6.5.2.7 Significant Figures

Those digits between and including the least and most significant digits in a number. The leftmost nonzero number is the most significant. The rightmost nonzero number is the least significant digit. If a decimal point is in the number, the rightmost digit is the least significant even if it is a zero.

6.5.3 Procedure

Uncertainty of measurement is a parameter associated with a measured result that characterizes the possible range of values that could be attributed to the result or method. In other words, the measurement uncertainty is used to indicate the degree of variability that can be expected for that particular measurement or method.

Measurement uncertainty takes into consideration all potential variables that contribute to the measured result. Sources contributing to the uncertainty may include, but are not limited to, the reference standards or materials used, the procedure or equipment used, the environmental conditions, the properties or condition of the item being tested and the analyst performing the test. Components that may contribute to the measured uncertainty should be taken into consideration when estimating the measurement uncertainty.

For the breath alcohol calibration functions performed by the TLD, the Calibration Technical Manual details the procedures for estimating measurement uncertainty and how it should be applied when reporting specific results.

6.5.4 Reporting Uncertainty of Measurement

When uncertainty of measurement is required, the calibration record(s) must contain the uncertainty of measurement or a reference to it. When this uncertainty of measurement is of significance to the requestor, the range of values and the uncertainty will be reported. As described in *Chapter 7 of the Calibration Technical Manual*, the uncertainty of measurement will appear on the Test Report as the expanded uncertainty, using a coverage factor of $k=2$, which is equivalent to a 95.45% (often referred to as approximately 95%) confidence level.

7 PERSONNEL QUALIFICATIONS AND TRAINING

7.1 SCOPE

The TLD will ensure that personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

A Position Description Form (PDF) shall be completed for all Division personnel below the level of TLD Commander. The PDF shall be retained in the employee's supervisory desk file and shall be updated as necessary.

The TLD 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.

All analysts, regardless of academic qualifications or past work experience, shall satisfactorily complete a competency test prior to assuming calibration work in the laboratory.

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. Training records will be sufficiently detailed to provide evidence that employees have been properly trained and that their ability to perform the task of their specific discipline has been assessed.

Various types of training opportunities are available for TLD personnel including in-state and out-of-state workshops and seminars, professional meetings and conferences, on-line/webinar trainings, laboratory specific training, reading literature, networking with other experts and through state resources. Continuing education opportunities are also available through local universities and community colleges. In addition, the TLD will periodically provide in-service training opportunities for the purpose of exchanging technical information on techniques, legal challenges, policy and procedure changes and/or research developments.

Training needs of an employee may be identified through individualized training plans and goals (e.g. quarterly Performance Development Plans for new forensic scientists), TLD strategic plans and performance measures, management requests and needs of the client agency. Requests for training shall be processed through the chain of command. Each employee will share in the responsibility of maintaining and continuing his/her functional area expertise.

7.2 DEFINITIONS

7.2.1 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 and Supervisor.

7.2.2 Calibration Work

Analytical work performed by a forensic scientist, relating to breath alcohol calibration functions.

7.2.3 Trainee

Any employee of the TLD who is training in a new discipline, procedure or job classification. Trainees can be permanent, probationary, or trial service.

7.2.4 Trainer/Instructor

Interacts 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.

7.2.5 Training Manual

Outlines the necessary requirements to become competent in a specific discipline or procedure. It may include modules or sections on theory and principles, reading assignments, and practical exercises. The manual is designed to provide the trainee with a sufficient understanding and skill level to satisfactorily conduct independent breath alcohol calibration work.

7.3 QUALIFICATIONS OF PERSONNEL

All personnel assigned to the TLD must be competent, trained and supervised by competent staff to ensure that they conduct work according to the quality program of the TLD. It is the responsibility of the Laboratory Manager to demonstrate the competence of all personnel.

7.3.1 Educational Background

Minimum educational and/or other requirements for TLD technical positions are found in the Operations Manual. Verification of educational requirements for personnel is under the purview of the WSP Human Resource Division (HRD). Whenever possible, the Laboratory Manager should ensure that college transcripts of all employees are reviewed at the time of employment and maintained at the Laboratory or in the employees' HRD files.

7.4 TRAINING

7.4.1 Training Goals

New employees must become qualified to perform competently in their assigned area of responsibility, and tenured employees must maintain and build upon their current knowledge and abilities. Training goals include:

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

7.4.2 Trainer/Trainee Method

The TLD employs the trainer/trainee method as one component in teaching for technical area training and training in a new job classification. This method has proven invaluable to ensure that the TLD training goals are met and that a feedback mechanism is in place.

7.4.3 Training Plans

Training plans will be developed for each new employee (e.g. In-Training Plan) and permanent employee. The training plan for permanent employees is normally accomplished as part of their annual performance evaluation but may also be included as part of the Division's strategic plan and/or performance measures. In developing the training plan, the Supervisor must take into consideration the needs of the individual employee, the discipline, the TLD and the customer agencies.

Training plans will have clearly defined goals or outcomes which are measurable in order to document progress and successful completion of the training module.

Training plans should be reviewed and/or updated annually (e.g. during the employee's performance evaluation) and may be adjusted as needed throughout the year.

7.4.4 Training Manuals

Training manuals provide the guidelines and instructions for the basic technical procedures used in breath alcohol calibration functions. The goal of the training manual is to provide employees with an understanding of theory and principles, application, methodology, technical limitations, and equipment involved in the area. The technical procedures or training manuals will contain the approved methods, the scientific references and resources, and the requirements for successfully completing a training program.

These training manuals will be used to develop training plans for employees, and will also be used as a guide when designing job performance improvement plans or re-training needs.

The training manuals are developed by the section Supervisors and/or competent laboratory personnel. The training manuals shall be reviewed annually by TLD Management and updated as necessary. In addition to the basic technical procedures employed in the discipline, the training manual may address other areas such as documentation, quality assurance program, ethics, safety and report writing.

7.4.5 Training Program

7.4.5.1 Policy

Prior to being authorized to perform calibration work, trainees will successfully complete the established training modules and competency tests for that discipline.

7.4.5.2 Procedure

The following steps will be taken to ensure successful completion of the training program:

- **Assign Trainer(s)/Instructor(s):** The trainee will work under the direction of a trainer/instructor, who is assigned by the Supervisor or Laboratory Manager. The primary considerations for trainer/instructor selection will be laboratory needs and the qualifications of the trainer/instructor.
- **Develop Training Program:** The Supervisor will develop a comprehensive training program for each new employee. Modified training programs will require approval from the Laboratory Manager or QA Manager. Training programs may also be developed for journey-level employees as required.
- **Complete Training Program:** The trainee will work with the assigned trainer/instructor to successfully complete the developed training program. Completion of the required training elements will be documented by both the trainee and the trainer/instructor.
- **Training Evaluations:** During the period of training, training evaluations will be completed and documented by the trainer/instructor. The results of these evaluations will be discussed with both the trainee and the Supervisor of the trainee. At the end of the training period, the effectiveness of the training actions shall be evaluated. Effectiveness may be assessed through the successful completion of competency and proficiency tests, discussions between the trainee and supervisor, or performance in mock trials and/or expert testimony.
- **Final Competency Test:** The Supervisor/Instructor will be responsible for administering a final competency test. The final competency test must be successfully completed by the trainee prior to the start of calibration work. The results will be maintained as part of the training record.

- Approval for Calibration Work: The trainee must demonstrate the successful completion of the training program by passing examinations and/or competency tests that are part of the training program. Upon successful completion of either training modules or the final training program, an IOC will be submitted to the TLD Commander for final approval before the trainee can begin work in that defined area. The analyst will be authorized to perform work in only those areas in which he/she was approved.
- Training Records: Training records of the trainee will be retained by the trainee and/or Supervisor.

7.4.6 Trainer/instructor

7.4.6.1 Abilities and Expectations

The trainer/instructor will be selected by the Supervisor and/or Laboratory Manager and should demonstrate a thorough understanding of the TLD breath alcohol calibration program's policies and procedures, and have appropriate experience performing calibration work.

7.5 JOB PERFORMANCE

7.5.1 Documenting Job Performance

Supervisors will document the work performance of each employee they supervise and maintain those records in a supervisory desk file. Supervisory desk files may contain positive and/or negative supporting documents, counseling, work directives, evaluations, or records relating to an employee's job performance throughout the performance period. Supervisory desk files are maintained according to WSP policy, found in the regulation manual.

Employees will have access to and be made aware of the contents of the supervisory desk file (*see the Collective Bargaining Agreement*). Regular performance appraisals are required and will be completed for each employee.

7.5.2 Re-Training

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

- Employees were once qualified in the discipline but have not maintained the required competency or proficiency in that discipline
- Employees were previously qualified at another laboratory system (non-WSP) in the particular discipline
- A discipline's procedure or training manual has been significantly revised
- Directed by a corrective action request (CAR), corrective action plan, job performance improvement plan (JPIP) and/or remedial training
- As required by administrative rule

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

Remedial training, a JPIP, or a corrective action plan may be required due to problems discovered during any of the quality review processes utilized by the TLD, or by complaints received from inside/outside the Division. Problems and complaints will be investigated and a determination made as to the need for further corrective action.

If a discrepancy in calibration work has been determined, the employee will be removed from such work until further assessment is completed. If remedial training is needed, the Supervisor and the employee, with input from TLD management, will design a JPIP or corrective action plan with clearly defined goals and time lines. The time limit for the JPIP should be 90 days or less. The progress of this plan will be measured at frequent intervals and thoroughly documented in the employee's supervisory desk file.

If the employee removed from calibration work successfully completes their JPIP or corrective action plan, the Supervisor will forward a recommendation for the employee to resume work to the Appointing Authority for final approval.

If the employee cannot assimilate the required training and achieve competency, the Supervisor will consult with the Laboratory Manager and/or 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 agency.

7.6 PROFESSIONAL DEVELOPMENT PROGRAM

7.6.1 Training Resources

Available training resources include:

- TLD personnel experienced in a variety of forensic analyses and processes
- TLD sponsored forensic training courses utilizing visiting experts
- WSP sponsored training
- Agencies and institutions such as the Washington Criminal Justice Training Commission
- Professional forensic science organizations such as the American Academy of Forensic Sciences, the Society of Forensic Toxicologists, and the International Association of Chemical Testing
- Journals of professional forensic science organizations and other scientific literature

7.6.2 Continuing Professional Development and Maintaining Competency

TLD Management and employees will normally meet as needed to discuss and evaluate scientific advancement, process improvement, solving technical problems, and identification of relevant training needs and opportunities. All of these goals support the continuing professional development and maintenance of competency of

individual employees which in turn support the overall competency of the Division's programs.

Attendance at conferences and workshops sponsored by professional forensic organizations will be encouraged by the TLD, and is an effective way for personnel to stay current in their field. Such venues provide a significant source of continuing education that directly supports their professional development and maintenance of competency. Serving as members or officers of these organizations facilitates employees staying in contact with their peers across the nation, a process vital to scientific advancement.

7.6.3 Request for Training/Completion of Training

For training held outside the laboratory, the employee must submit a Training/Travel Request along with a Training Request Checklist, and any other documentation required by the agency. The completed forms will be routed through the chain of command for approval. All education and training requests should be approved or disapproved 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.

An employee should report the completion of their approved training event on a Training/Travel Request form for any training requiring management approval as discussed above, and will forward to the Supervisor for approval/signature. If a certificate of completion is provided for the training, a copy will be attached. The completed form should be routed to the Supervisor who will keep a record of completed training.

7.6.4 Laboratory Library

The laboratory will have access to a library containing current books, journals, and reference materials for each discipline. Each analyst is responsible for taking time to read periodicals, journals, articles, books, laboratory memorandums and other relevant literature in order to keep current with information and developments in their respective disciplines. A list of the contents in each library is maintained by the FLSB Librarian. The FLSB Librarian distributes by e-mail the table of contents of various journals, magazines and publications. The FLSB Librarian is a resource for obtaining journal articles and other needed reference material and should be contacted when necessary. These may also be found on FLSB Portal.

7.6.5 Courtroom Testimony Training

TLD Management is responsible for ensuring that testimony training is provided to employees who testify in court. Topics such as chain of custody, calibration work results and interpretation of calibration results should be discussed during the training. This training can be given internally by a TLD employee or by an external source.

8 ASSURING THE QUALITY OF CALIBRATION RESULTS

8.1 POLICY

The TLD is committed to providing the best quality service available to the customer. A key component to providing high quality service is through a documented proficiency testing program, in addition to standards, controls, and other conventional quality assurance practices.

The TLD may use, but is not limited to the following for monitoring the validity of testing performed:

- Certified reference materials
- Positive and negative controls
- Replicate testing
- Repeat testing (re-examination)
- A documented proficiency testing program
- Technical and administrative reviews

Preparation and certification of calibration items (namely simulator solutions) is performed within the permanent TLD location, under controlled laboratory conditions, in a designated area. This area is free from sources of drastic temperature, humidity or air circulation changes, and the environmental conditions are evaluated by the forensic scientist prior to solution preparation. The scientist has the authority to halt calibration work, and notify a Supervisor, if at any time he/she determines that environmental conditions, or other factors, may affect the work.

8.2 PROFICIENCY TESTING

The objectives of the proficiency testing program are to:

- Demonstrate the current competence of the analyst
- Demonstrate the current competence of the laboratory
- Ensure that quality work is being maintained
- Identify areas where additional training or resources would be beneficial
- Verify the validity of technical procedures

8.2.1 Definitions

8.2.1.1 ASCLD/LAB

The American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB). An organization that offers accreditation under the ASCLD/LAB-*International* program, which is based on the ISO 17025 standards and the ASCLD/LAB-*International* Supplemental Requirements.

8.2.1.2 Approved Proficiency Test Provider

An individual, organization or company which has applied for and obtained approval from ASCLD/LAB to prepare and provide proficiency tests to participating forensic laboratories in the forensic disciplines for which the provider has been approved.

8.2.1.3 Proficiency Test

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

8.2.1.4 Proficiency Review Committee (PRC)

A committee of individuals appointed by the Board of ASCLD/LAB, because of their experience and expertise, to provide oversight for ASCLD/LAB in the proficiency testing program for specific forensic disciplines.

8.2.1.5 Proficiency Test Evaluation Form

The form used to provide comments on a laboratory's or an individual's proficiency test.

8.2.2 Procedure

The TLD proficiency program will be directed by the QA Manager and shall be in compliance with the ASCLD/LAB Proficiency Review Program. ASCLD/LAB approved proficiency test providers will be used where available. Before ordering proficiency tests, the QA Manager will confer with the Laboratory Manager and Supervisors to determine the numbers and types of tests needed.

Each analyst within the TLD will successfully complete at least one internal or external proficiency test per year in the area(s) in which they perform calibration work. Further, the laboratory must complete at least one external proficiency test for each area in which it provides accredited services.

8.2.3 Proficiency Test Samples

Proficiency test samples will be handled in the same manner as routine calibration work until the QA Manager determines that all proficiency test requirements have been satisfied and the sample is no longer needed for that purpose. The sample may then be kept as a training sample, or it may be destroyed as determined by the Supervisor or QA Manager.

8.2.4 Proficiency Testing Process

Proficiency tests must be completed and the results submitted to the test provider within the timeframe imposed by the provider. This requirement is essential to the

overall success of the TLD Proficiency Testing Program; therefore it is the responsibility of the analyst assigned the test to ensure that this requirement is met.

The test must also be completed in a similar manner as calibration work. The proficiency test results will undergo a technical review and an administrative review before results are sent back to the test provider. The technical review will be documented on the copy of the answer sheet by the reviewer's initials and date.

The proficiency will be assigned to the analyst in a timely manner. The analyst must perform the testing so that there is sufficient time to accomplish appropriate reviews for the test results to be sent to the test provider by the due date.

The intent of the proficiency testing program is to identify individual technical issues and also systemic issues. Therefore, if a technical reviewer disagrees with the conclusions reached by an analyst, then it is incumbent upon the reviewer to bring the problem to the attention of the analyst and his/her Supervisor. The procedure used to resolve technical review conflicts in calibration work, as outlined in Section 9.8 below, will be followed.

The QA Manager will keep records regarding how the test samples are obtained or prepared, as well as completion dates and results of the testing. As tests are received, the QA Manager or designee will assign the tests to the analysts, providing each analyst with enough advance notice for completion prior to deadlines. The analyst will document and report to their Supervisor and the QA Manager if a proficiency cannot be completed by the deadline.

It is the responsibility of the QA Manager to ensure that proficiency results are completed and returned to the test provider. Copies of the answer sheets signed with the assigned analyst's signature and other necessary paperwork for the proficiency test will be sent to the QA Manager.

When the results of the proficiency tests are received from the provider, the QA Manager or designee will review the analyst's and the provider's results. The analyst's results, supporting documentation, and the provider's results will be reviewed for technical accuracy based on availability of the test answers.

Proficiency test records will be maintained at the Laboratory for at least one full accreditation cycle, and shall include all data and notes supporting the conclusions. Proficiency test records may include:

- Proficiency test unique identifier
- How tests were obtained or created
- Written instructions for completion
- Identity of person taking the test
- Due date and completion date
- Copy of the proficiency answer sheet(s)
- Copy of the proficiency test evaluation form
- Any discrepancies noted
- Details of corrective actions taken (when necessary)

8.2.5 Satisfactory Proficiency Test 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, their Supervisor, and the TLD Commander will document their review of the analyst's performance by initialing and dating the written notification.

8.2.6 Proficiency Test Discrepancies

If there is a discrepancy between the analyst's test results and the provider's results, the QA Manager will immediately notify the Laboratory Manager or Supervisor, as applicable, and the analyst who performed the test. The QA Manager and the Appointing Authority will determine a course of action, if necessary, and coordinate that process with the PRC.

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 calibration work and remedial training. The QA Manager will prepare a report to the TLD Commander outlining the issues and the actions taken.

The proficiency test records will contain a record of the discrepancy between the analyst's test results and those of the test provider. The QA Manager will retain complete records for the Division.

8.2.7 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 from the TLD management, and other appropriate individuals. (See *Chapter 3 - Control of Nonconforming Work*; and *section 7.5 - Job Performance*).

8.3 TECHNICAL PROCEDURES AND METHODS

8.3.1 Policy

The TLD will use appropriate technical procedures and methods that have been scientifically validated and/or accepted for use in the field of forensic science. This includes methods and procedures for the handling, transport, storage and preparation of testing and calibration items, the operation of all relevant equipment and an estimate of the measurement uncertainty where appropriate.

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 calibration records.

8.3.2 Definitions

8.3.2.1 Laboratory Developed Methods

Methods developed in house as standard methods for a specific laboratory purpose.

8.3.2.2 Methods

Any technical procedure detailing the use of reagents, equipment and/or instrumentation for scientific analyses; synonymous with “procedure.”

8.3.2.3 New Methods

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

8.3.2.4 Non-Standard Methods

A scientifically validated method or procedure that is not routinely applied or used for forensic analysis.

8.3.2.5 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 TLD as a new method.

8.3.2.6 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.

8.3.2.7 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).

8.3.3 Developing Analytical Methods and Procedures

Technical procedures must be based upon sound scientific principles. Every procedure and/or principle used should be generally accepted in the relevant scientific field.

Technical procedures must be as effective and efficient as possible. The following should be considered when developing a technical procedure or when considering it for inclusion in a manual:

- Compatibility with other laboratory technical and administrative procedures
- Ability to quickly provide data
- Accuracy, precision, reliability, speed, and cost
- Compatibility with available equipment and facilities
- Materials, equipment, reagents and standards required

Technical procedures must be as well documented as possible. Documentation may include specific literature articles, texts, reviews, and data compilations. A reference list may be included in either the technical procedures or the training manuals. 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. This may include guidelines for acceptance criteria, negative/positive controls, knowns, and calibrations, and how they should be reported.

Although a technical procedure may have gained general acceptance within the relevant forensic science community, it must also be understood, supported and accepted by those who must employ that technical procedure. Supervisors will communicate the development and implementation plan and progress to all personnel.

Where applicable, procedural manuals will include verbiage to ensure safe handling, transport, storage, use and planned maintenance of measuring equipment (i.e., diluters, pipettes, etc.) to ensure proper functioning and in order to prevent contamination or deterioration.

8.3.4 Method Validation

The TLD will ensure that new methods or existing methods that are significantly modified, such that the change(s) affects the outcome of the test, are sufficiently validated prior to use.

The validation will be as extensive as is necessary to meet the needs of the given application or field of application. All validation studies will be performed with the aid of, or under the direction of, the QA Manager, Laboratory Manager and/or TLD Commander by qualified personnel with adequate resources to perform the validation. Results of the validation will be documented and archived. Documentation should include the data, the procedure and controls or standards used, a statement as to whether the method is fit for the intended use, and documentation of approving authority.

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

8.3.5 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.

Validation determines the conditions under which results can be obtained reliably and determines the limitations of the method.

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). The TLD will ensure that all methods will be validated internally prior to implementation in the laboratory. Validation will be sufficient to ensure the reliability of the method against any documented performance expectations.

The Laboratory will perform method validation for all laboratory-developed methods, standard methods which have been modified or that will be used outside of their originally intended scope and for non-standard methods. The validation will be completed before these types of methods are employed. For standard methods, the laboratory will confirm that it can properly execute the method before it is implemented. If the standard method changes, the laboratory will either confirm it can properly operate the method or, depending on the severity of the change, it may require validation prior to implementation.

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 should be compared on split samples.

If the analysis provides quantitative data, the validation should include an estimate of accuracy and precision.

Prior to beginning validation, a validation plan will be prepared by the analyst involved and the Supervisor, and submitted to the QA Manager for approval. Effective communication amongst all personnel involved, including other analysts in the section and TLD management, will be accomplished through verbal or written communications.

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.

Upon completion of method validation, all documentation will be sent to the QA Manager for review. The QA Manager and TLD Commander will decide if the method

has been sufficiently validated and if it should be included in the Calibration Technical Manual or other official procedural manuals. The procedure should be formatted in preparation for inclusion in a procedural or technical manual, following the document control process as outlined in Chapter 2 above.

8.3.6 Method Validation may include:

- **Reference standards:** The samples used for validation should be representative of the type of standards routinely used for controls and calibration samples routinely analyzed using the technique or procedure.
- **Accuracy/Precision Studies:** The results must demonstrate that the Laboratory is measuring the quantity of standard tested within a reasonable variability according to the manufacturer's specifications or within the variability of the technique being used. An estimate of the uncertainty of measurement will be determined, where required.
- **Reproducibility:** The method must be reproducible by another individual using the original test documentation.
- **Selectivity:** The method should be able to differentiate between the analyte being examined and other components that may be expected to be present.
- **Sensitivity or Linearity Studies:** The procedure must be sufficiently sensitive and bracket the expected or anticipated linearity detection limits of the method or instrument should be evaluated.
- **Literature research:** Review of publications, academic materials, safety procedures, protocols and manufacturer's specifications, etc. involving the technique or procedure being validated.
- **Technical review:** Validation data will be submitted to the QA Manager and/or designee for technical review. The TLD Commander performs final review prior to method approval.

8.3.7 Performance Verification of methods may include:

- **Reference standards:** The samples used for verification should be representative of the type of standards routinely used for controls and specimens routinely analyzed using the technique or procedure.
- **Accuracy/Precision Studies:** Verify that instrument or procedure is within previously established manufacturers or procedure specifications.

8.4 DEVIATION FROM POLICY OR PROCEDURE

Deviations from the Calibration Quality Manual, Operations Manual, Calibration Technical Manual and other specific TLD policies and procedures may occasionally be justified.

8.4.1 Definitions

8.4.1.1 Deviation

A change or variation in a policy or procedure.

8.4.2 Policy

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

8.5 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, 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. The Corrective Action process will be followed.

9 CALIBRATION RECORDS, REVIEWS, AND REPORTS

9.1 POLICY

Calibration records (i.e., all administrative and technical documentation related to breath alcohol calibration) 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. Calibration documentation will also contain sufficient information to facilitate identification of factors affecting uncertainty of measurement and to enable the test or calibration to be repeated under conditions as close as possible to the original. Records will include the identity of personnel responsible for the performance of each function, and the reviewing and issuing of results.

9.2 DEFINITIONS

9.2.1 Administrative Documentation

Documentation either received or generated by the laboratory. Administrative documentation includes records such as reagent receipts, certificates of analysis, simulator solution receipts (packing slips), and other pertinent information.

9.2.2 Technical Documentation

Usually generated by the laboratory and includes reference to procedures followed, tests conducted, standards and controls used, printouts, results of tests, technical reviews, etc.

9.2.3 Calibration File

A calibration file contains both administrative and technical documentation pertaining to a breath alcohol calibration function that is performed by the laboratory. This typically refers to either an ESS or QAP Batch File, and may include, but is not limited to:

- Affidavits
- Chromatograms
- Test report

9.2.4 Calibration Record

A calibration record is a collection of all the administrative and technical documentation pertaining to a breath alcohol calibration function that is performed by the laboratory. This typically refers to a Batch Record, and 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 calibration record may be in the calibration file or in other locations in the laboratory which are designated as extensions of the calibration file.

9.2.5 Test Report

Final presentation of results produced through the certification of simulator solutions.

9.3 REVIEW OF REQUESTS

9.3.1 Policy

The TLD will ensure that the customer's requirements, including procedures to be used, are adequately defined, documented and understood; that the laboratory has the capability and resources to meet the requirements and that the appropriate procedure is selected and capable of meeting the customer's request.

9.3.2 Procedure

Requests for calibration services may be in the form of written or verbal communication. Requests for simulator solution preparation will be submitted using the Solution Request & Packing Slip.

9.4 CALIBRATION DOCUMENTATION

9.4.1 Administrative Documentation

Administrative documentation should bear some unique identifier in order to be placed back into its source file if it becomes separated. If the administrative documentation is a packet of material that is fastened together, the unique identifier need only be on the first page.

9.4.2 Technical Documentation

Each page of the technical documentation should have the following:

- Analyst's original handwritten signature or initials
- The date of the testing/procedure
- Unique calibration number or other unique identifier
- Machine generated dates and calibration numbers are acceptable

9.4.3 General Calibration Documentation Requirements

Handwritten documentation will be recorded using permanent ink.

Nothing in the calibration 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.

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 or certificates will be duplicated in electronic format and will be added to the electronically duplicated records of the original report or certificate.

Dates must be recorded in the documentation to indicate when work was performed.

Abbreviations are acceptable if they are readily comprehensible to a reviewer or if a key is available.

Calibration documentation includes but is not limited to the following:

- Results of testing (e.g. chromatograms and other instrumental printouts)
- Records of data and calculations
- Handwritten or machine-generated worksheets and observations
- Identity and source of any standards or references used

When instrumentation is used, the specific instrument used must be noted in the calibration record. 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 calibration record.

Observations, data and calculations must be recorded at the time they are made, and must be identified to the specific analysis or test.

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

Documentation of the technical review is discussed below.

9.5 CALIBRATION REVIEW

9.5.1 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 reports and associated calibration documentation will be subject to technical and administrative reviews.

9.5.2 Definitions

9.5.2.1 Administrative Review

Final review for non-technical matters of the calibration file and final report prior to release of the report to the customer.

9.5.2.2 Supervisor Review

A general review of calibration records by a Supervisor to maintain oversight of laboratory operations.

9.5.2.3 Technical Review

A review of the calibration documents and the report to ensure that proper technical procedures were used and documented, and that the analytical data support the conclusions in the report.

9.5.3 Procedure

Review of calibration information by the analyst, and other personnel, provides a verification of procedures and results.

9.5.3.1 Analyst Review

Analysts will conduct a thorough review of their own work prior to a technical review. This review is done after all analyses for that request are complete and the report has been printed, where applicable. This review is a complete review of the calibration file consisting of all elements of the technical and administrative reviews. Analyst reviews should include, but are not limited to, the following:

- Examination of the documentation for transcription errors
- Examination of the documentation for appropriate references to work done in the laboratory, amended reports, calibration numbers, and analyst's initials/signature
- Verification that each page of the calibration file has the required identifying information, and that corrections are documented with initials/date
- Verification that calibration documentation is complete

9.5.3.2 Technical Review

Technical review will be conducted on all reports before release. This is to ensure that the calibration documentation supports the conclusions stated in the report, and that it is free of omissions and errors.

Technical review should be conducted by individuals who have been authorized by the Appointing Authority.

The technical reviewer should consider the following points:

- The procedures conducted were appropriate to satisfy the request made by the customer. Communications and phone notes should be present, if applicable.
- The documentation supports the results stated in the report.
- All relevant calibration information is included.
- All procedures, data, and results are documented.

- Established procedures were used and test parameters were appropriate for the examination. Any deviations from established procedures were recorded in the calibration record with adequate justification/foundation for the deviation.
- Appropriate standards and controls were used when necessary and documented.
- All strikeouts or insertions were noted with the analyst's initials and date. No obliterations are present.
- All pages of the technical documentation are labeled with the calibration number/unique identifier, dates, and analyst's handwritten initials.
- For proficiency tests, the answer sheet has been fully completed and is free of errors.

Excessive errors or insufficient documentation to support the results are brought to the attention of the analyst and the Supervisor. Even with technical review, the final responsibility for the scientific findings in the report rests with the analyst.

An approved review checklist may be used to facilitate the review process and retained in the calibration file as administrative documentation.

The analyst must address all the observations and recommended corrections of the technical reviewer. If, during the review process, there are concerns regarding technical or quality issues including those listed below, the calibration file must be turned over to the Supervisor and/or QA Manager (see *Chapter 3 - Control of Non-conforming Work*). The Supervisor and/or QA Manager will evaluate the concerns, and if appropriate, notify the TLD Commander.

- The calibration documentation does not support the results
- The calibration documentation is not clear in content, intent, or purpose
- The calibration documentation contains procedural errors
- The calibration documentation exhibit s numerous errors
- The calibration documentation contains inappropriate strikeouts, obliterations or overwrites or cut-and-paste errors
- If issues or discrepancies cannot be successfully resolved, or if, after communicating issues and discrepancies to the analyst, requests for corrections have been ignored

The technical review process is vital to the continued success of the TLD. Review is a normal job function of all analysts qualified to perform that function, and will therefore be subject to documentation and evaluation by supervisors. The reviewer is equally responsible for the quality of the final report and will be held accountable.

Errors discovered after the review process may be addressed by corrective actions and will involve both the originating analyst and the reviewer.

Technical reviews will be documented with the reviewer's signature/initials and date on the final report. The presence of the reviewer's initials indicates that the

calibration file is complete and the documentation found within the file clearly supports the final results.

9.5.3.3 Administrative Review

An administrative review will be conducted on the calibration file prior to the release of written reports, including amended reports and proficiency test answer sheets. The administrative review is designed to ensure that:

- The report or answer sheets being released correctly and completely reflect the results
- The report or answer sheets being released do not contain misspelled words or grammatical errors
- Values and computations are recorded correctly
- Calibration documentation is initialed and dated, where applicable
- A technical peer review has been completed and is documented on the report or answer sheet
- Proficiency tests contain a clean copy of the answer sheet (to be sent to the proficiency provider, unless submitted electronically) as well as a second copy of the answer sheet with initials and documentation of peer review, to remain with the file

The administrative reviewer does not have to be technically proficient in the functional area, but may not be the analyst. The administrative reviewer may be the same individual performing the technical review. The administrative review is documented in the calibration file if separate from the technical peer review.

9.5.3.4 Supervisor Review

A supervisor review is a general review of calibration records by a Supervisor to maintain oversight of laboratory operations. The review is to confirm that laboratory policies are being followed and reported results are accurate. The supervisory review does not necessarily include a full administrative review or technical review. A Supervisor review should be done on at least 10% of all calibration work. This review can be done after distribution of the report. Completed Supervisor reviews will be documented in the calibration file by date and the Supervisor's initials.

9.6 CALIBRATION TEST REPORT

9.6.1 After completion of review, authorized personnel will issue the calibration test report.

9.6.1.1 The calibration test report will include the following information:

- A title (e.g., External Standard Solution Test Report)
- The name and address of the Laboratory (where testing is performed)
- Unique identification of the test report (simulator solution batch number)
- The name and address of the customer

- Identification of the procedure/method used in testing
- Identification and description of the items being tested
- Date(s) the testing was performed
- Test results, including units of measurement
- 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 the test report
- 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

9.7 AMENDED RECORDS AND REPORTS AFTER ISSUANCE OF REPORT

9.7.1 Amended Worksheets/Records

Amendments to worksheets/records will be struck-through, rewritten, and initialed/dated.

If the complete batch file has been uploaded to the public records site (WebDMS), the original will be clearly marked to indicate a correction was made (this may be done by adding a watermark across the document). The corrected worksheet/record will be uploaded, preceding the marked original.

9.7.2 Amended Reports

Once the report has been issued, amendments shall only be made in the form of a new document; an amended report. The amended report must reference the original report; this is done through the unique identifier (the solution batch number and the date the original report was issued).

9.6.2.1 Procedure

If it is determined that the necessary amendment constitutes a nonconformity, follow the procedures in *Chapter 3 - Control of Nonconforming Work*.

- The handwritten correction is made to the original report, with the initial and date of the analyst or Supervisor making the correction.
- If the reason for the amendment is clerical in nature, only the Supervisor's approval is required. The Supervisor will document his/her review and approval by initialing and dating the hand-amended report.
- If it is determined that the amendment is the result of a nonconformity, the issue(s) must be addressed to the satisfaction of the TLD Commander and/or QA Manager, with their review and approval documented in writing. Note: This may be documented as part of the nonconformity/corrective action.
- The original report will be clearly marked to indicate a correction was made (this may be done by adding a watermark across the document). The re-issued, amended report, followed by the marked hand-amended report, and the marked original report (in that order) will be uploaded to the appropriate file on WebDMS.

9.8 RESOLUTION OF TECHNICAL DIFFERENCES OF OPINION

Possible Level I nonconformities (see *Chapter 3*), or recurring Level II nonconformities discovered during technical reviews are to be brought to the attention of the QA Manager by the Supervisor as soon as possible. The corrective action process will be followed.

Disagreements may sometimes arise between the analyst and reviewer during the technical review process. Every effort will be made to resolve these issues at that level. Technical reviewers may request changes in reports, further work to clarify issues, or further work to complete the calibration 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 who will act as a mediator.
- If not resolved, the QA Manager will review the issues and make a recommendation to the 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 calibration work shall be binding.
- The resolution will be concluded prior to the release and distribution of the report.

9.9 FOCUSED CALIBRATION WORK REVIEW

When internal quality processes uncover serious errors in calibration work, or there is a complaint alleging misconduct or incompetence, the Appointing Authority may initiate a focused calibration work review. If a root cause analysis has been completed, the Appointing Authority will review the analysis and its recommendations and any other input from the QA Manager as part of their deliberation as to the necessity of a focused casework review.

9.9.1 Review of Affected calibration work

The focused calibration work review will be conducted by an appropriate Supervisor or panel chosen by the Appointing Authority. 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 Appointing Authority.

9.9.2 Notifications

The notification must be made 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 calibration work under review.

If the report had been released and distributed prior to the commencement of the focused calibration work review, the Appointing Authority will notify the customer as soon as practical but not later than 30 days after the review begins.

9.9.3 Removal from and reinstatement to calibration work

The analyst who is under review will be removed from calibration work by the Appointing Authority until the matter is resolved, as required by *Chapter 3 - Control of Nonconforming Work*. In addition to the fact finding, technical review, re-examination of work, or other action taken by TLD Management, amended test reports may be issued to the customer, with copies sent to the prosecuting attorney's office, where necessary. Reinstatement to calibration work will also be by the Appointing Authority.

10 RESEARCH PROJECTS, PUBLICATIONS AND PRESENTATIONS

10.1 POLICY FOR RESEARCH PROJECTS

All research projects employing the use of laboratory resources will be reviewed and approved by the Laboratory Manager and/or the QA Manager prior to the initiation of the project. This includes research projects for the investigation of new methodology or technology, uncertainty of measurement studies, or additional studies on currently used methods.

10.2 PROCEDURE FOR RESEARCH PROJECTS

Prior to beginning any research study, a research plan, including experimental design, will be prepared by the analyst and submitted up the chain of command to the Laboratory Manager or designee for approval. The selection of the appropriate type of equipment, standards, controls, and reagents should be part of the plan, as well as a budget estimate. As the research progresses, the plan will be updated as necessary. Effective communication amongst all personnel involved, including other analysts in the section and TLD Management, will be accomplished through verbal or written communications.

Where applicable, the research plan shall follow the same criteria as those listed in section 8.3 for developmental or non-standard method validation.

10.3 POLICY FOR MANUSCRIPTS AND PRESENTATIONS

The analyst must submit presentations of original research or manuscripts prepared for publication to the TLD Management for review prior to submission of the manuscript to the journal or prior to the presentation. This policy applies specifically to situations where the TLD is mentioned in manuscripts for publication or presentations, when the author is a representative of the TLD, or when the research or preparation for the presentation occurred on duty time. It is the responsibility of the Laboratory Manager to ensure all presentations from the laboratory have been approved. Final approval will come from the QA Manager or the Appointing Authority.

10.4 PROCEDURE FOR MANUSCRIPTS AND PRESENTATIONS

The final draft of the manuscript should be submitted to TLD Management for review via the analyst's Supervisor approximately 14 days prior to the time the manuscript is sent to the journal.

The final draft of the presentation should be submitted to TLD management for review via the analyst's Supervisor approximately 5 working days prior to the scheduled presentation.

Preferably, two individuals will be selected to review the manuscript/presentation.

The review of the final draft of the manuscript/presentation will focus on the following topics:

- Accuracy of the conclusions. The data in the manuscript/presentation should support the conclusions.

- Proofing of mathematics, spelling, grammar and punctuation

Feedback will be presented directly to the author within 7 days from receipt of the manuscript, or in 2-3 working days from receipt of the presentation. The author must address the reviewer's comments and any differences of opinion will be resolved by consensus.

Presentations previously reviewed and approved do not have to be reviewed again when presented in a different venue or do not differ significantly in content.

LIST OF CHANGES

Since Revision 1 (05/11/09)

Revision Date	Procedure	Change	Page Number
06/13/11	Overall format	Reformatted header & footer. Adopted new pagination for revisions to individual chapters. Included Chapter 11, List of Changes, to track chapter revisions. Total page count now appears in footer of Chapter 11	All
06/01/13	Overall content	Removed wording related to work performed by the WSP Breath Test Program (BTP). Wording that describes action taken when amending documents and reports added to section 9.6. Management system/organizational structure updated.	All
10/07/14	Introduction Chapter 1, 2	Added wording to Introduction to note than any references to TLD controlled documents in this manual refer to the current, official versions posted on SharePoint. Revised definition of TLD Management in 1.1.14 and added to the list of TLD Management supporting duties in 1.3.1. Revised history table contents in 2.3.1 and marking of archived documents in 2.3.6.	4, 6-9, 13-15
10/07/14	Chapter 4, 6, 8, 9	Added wording to 4.1 to describe the submission of an annual accreditation report and to 6.5.4 for description of expanded uncertainty. Added description of laboratory/environmental conditions for calibration work to 8.1 and listed required items for calibration test reports in 9.6. Replaced "Laboratory Management" with "TLD Management," and other minor edits throughout.	24, 38, 47, 61-62
10/07/14	Chapter 7	Revised wording in 7.4.3 pertaining to employee training plans and in 7.4.5.2 for evaluation of effectiveness of training. Removed bullet point list from 7.4.6.1.	39-46
10/07/14	Overall format	Changed numbering format for entire document (page x of y), implemented revision number in footer and reformatted cover page to include the document ID, revision number, effective date, approval date and approval by State Toxicologist.	All