

Washington State Patrol

BREATH TEST PROGRAM

Quality and Operations Manual

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Forensic Laboratory Services Bureau
Impaired Driving Section
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1 INTRODUCTION

Within the WSP Forensic Laboratory Services Bureau (FLSB), the Breath Test Program (BTP) of the Impaired Driving Section (IDS) is responsible for breath alcohol calibration functions for evidential breath test instruments in the state of Washington.

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

The purpose of this manual is to provide the responsible personnel with written policies and procedures that will:

- Maintain an effective Quality Assurance program,
- Promote an efficient and effective operation,
- Assist personnel in performing assigned duties and tasks, and
- Ensure that the work product and services of the program are fit-for-purpose and of the highest quality possible.

This manual covers all work done by responsible personnel, to include but not be limited to work done within the BTP, in addition to duties outside the laboratory, whether in court, training venues, or anywhere else the duties of responsible personnel might be employed. The policies and procedures are binding on all personnel of the BTP, and shall be followed.

The official version of this manual is the electronic version as it appears on the Forensic Laboratory Services Bureau (FLSB) SharePoint site. Any alterations or deviations from the policies and procedures detailed in this manual must be approved by the IDS Commander, and appropriately documented.

1.1 MISSION STATEMENT

The BTP will provide forensic breath alcohol calibration services and training for Washington's criminal justice agencies. The BTP is committed to providing the highest quality forensic services which ultimately enhances public safety for the citizens of Washington.

1.2 GOALS AND OBJECTIVES

The goals and objectives of the BTP will be reviewed continually and are based upon the needs of the Criminal Justice System and the needs of the agencies served by the program.

1.3 LEGAL DIRECTION

The BTP is a publicly funded, legal entity that is responsible for its legislatively mandated actions. The BTP provides scientific and technical assistance for prosecuting attorneys and statewide criminal justice agencies as mandated by Revised Code of Washington (RCW) 46.61.506 and the Washington Administrative Code (WAC) 448-15 and 448-16.

1.4 DEFINITIONS

1.4.1 Breath Test Program (BTP)

A program within the IDS that calibrates and verifies the accuracy and proper working order of the evidentiary breath test instruments throughout Washington State.

1.4.2 Forensic Investigations Council (FIC)

An oversight group, appointed by the Governor, whose purpose it is to oversee the FLSB and, in consultation with the Chief of the Washington State Patrol or the chief's designee, control the operation and establish policies of the FLSB.

1.4.3 Forensic Laboratory Services Bureau (FLSB)

A bureau within the WSP that includes the Toxicology Laboratory Division (TLD), the Impaired Driving Section (IDS), and the Crime Laboratory Division (CLD).

1.4.4 Impaired Driving Section (IDS)

A section within the FLSB that includes the Breath Test Program (BTP), among other statewide programs. For the purposes of this manual, IDS shall refer to those functions that pertain to its breath alcohol calibration functions, namely the calibration and verification of evidentiary breath test instruments, unless otherwise noted. Within the IDS, the breath alcohol calibration functions are performed by the BTP.

1.4.5 Policy

A guiding principle, operating practice, or plan of action by which the BTP operates. Policies influence, direct and determine the decisions and actions of the BTP and employees.

1.4.6 Procedure

A defined and established method for implementing a policy or carrying out a process.

1.4.7 Toxicology Laboratory Division (TLD) Quality Assurance

Includes the TLD Quality Assurance Manager, the TLD Commander/State Toxicologist, and the TLD Technical Lead or designee.

1.5 SERVICES AND FUNCTIONS

The BTP will provide breath alcohol calibration services for all statewide criminal justice services. This will include the calibration, verification, maintenance and operation of the breath test instruments used throughout Washington State. In addition, services will be provided regarding training, expert court testimony, legal discovery, supplies and equipment, and data analysis.

The primary operational functions within the programs include:

1.5.1 Breath Test Instrument Calibration and Verification

Certified Breath Test Technicians will support the breath test instruments within their geographical region of responsibility and perform the required calibration and verification procedures (Quality Assurance

Procedure; QAP) on each instrument. The Breath Test Technicians ensure the accuracy, precision and proper working order of the instruments in addition to maintaining documentation of these procedures.

1.5.2 Breath Test Instrument Maintenance

Certified Breath Test Technicians will ensure the repair and maintenance of the breath test instruments and associated equipment as necessary. Documentation of these events will be maintained.

1.5.3 Expert Court Testimony

Certified Breath Test Technicians within the BTP will provide expert testimony regarding their responsibilities, results and/or records for courts and other legal proceedings throughout the state.

1.5.4 Records Custodian, Discovery and Public Records Requests

Qualified BTP personnel will be considered custodians of the records for breath alcohol calibration related documents. Trained BTP personnel will respond to, and provide documents for, requests pertaining to official breath alcohol calibration documents (e.g., *subpoena duces tecum*, public records requests).

1.5.5 Training

Certified Breath Test Technicians provide statewide initial or basic and refresher BAC training to WSP troopers and other allied agency law enforcement personnel. Qualified BTP personnel provide breath test instrument familiarization training to Washington's criminal justice personnel, such as judges, prosecutors and defense attorneys.

1.6 ORGANIZATION AND MANAGEMENT STRUCTURE

The BTP is a program of the Impaired Driving Section (IDS) which is a part of the Forensic Laboratory Services Bureau (FLSB) of the Washington State Patrol (WSP) (*see Appendix B*). The BTP Headquarters is located at its primary laboratory in Seattle. The BTP has satellite laboratory facilities located at sites throughout the state where breath test technicians conduct their areas of responsibility.

Top management for the BTP consists of the FLSB Bureau Director, the IDS Commander, the State Toxicologist, and the TLD Quality Assurance Manager. The Bureau Director is responsible for all Bureau operations and management. The IDS Commander is responsible to ensure that all policies, rules, procedures, directives, goals and guidelines are written in a clear manner, are consistent with department policy, State and Federal Law, and are made available to all BTP personnel. The State Toxicologist is legally responsible for technical procedures as authorized by statute (RCW 46.61.506). TLD QA oversees the QA program, handling audits and proficiency testing. The TLD QA Manager functions as the Quality Assurance Manager for the BTP.

Key management positions consist of top management and Breath Test Program Supervisors, who all have key roles in the BTP operations and quality oversight of the BTP work.

Examples of documents containing policies, rules, procedures and guidelines include:

- WSP Regulation Manual
- Collective Bargaining Agreements
- BTP Quality and Operations Manual
- BTP Technical Manual
- BTP Training Manual
- WSP Safety and Wellness Manual

The IDS Commander and BTP Supervisors (sergeants), hereinafter referred to as BTP management, have the responsibility to ensure that policies, rules, procedures, directives, goals and guidelines are understood and practiced by all employees.

When a supervisor or manager is unavailable, a person will be designated as the acting supervisor or manager. If no one is available or has been designated to take this responsibility, the next level up in the chain of command will be responsible.

1.7 PERSONNEL RESPONSIBILITIES

1.7.1 Forensic Laboratory Services Bureau Director

The Washington State Patrol's Forensic Laboratory Services Bureau (FLSB) Director is responsible for all Bureau operations and management. The position also functions as the Laboratory Director of the Breath Test Program in the Impaired Driving Section.

1.7.2 TLD Commander/State Toxicologist

This position is responsible for managing and approving all operational, technical, policy and fiscal aspects of the TLD, and reports to the FLSB Director.

The State Toxicologist:

- Promulgates revisions to the Washington Administrative Code (WAC)
- Approves analytical methods and instrumentation
- Authorizes technicians to perform calibration work
- Provides expert court testimony where required

1.7.3 Impaired Driving Section (IDS) Commander

The IDS Commander has the primary responsibility for the daily operation of the IDS and BTP, and is responsible for supervising and monitoring the compliance with policies and procedures for all personnel within the IDS/BTP. This position reports to the FLSB Director.

The IDS Commander:

- Will be a commissioned officer having the RCW rank of Lieutenant
- Directly supervises the BTP supervisors
- Prepares and is responsible for the BTP budget
- Works with supervisors to develop and implement program policy and practice
- Gives direction to the BTP's QA Program
- Directs the technical peer review program
- Ensures the effective application of the BTP's QA Program
- Assists the QA Manager with the annual review of the quality management system
- Authorizes, monitors and tracks training and professional development requests
- Oversees grant management
- Monitors compliance with accreditation and audit criteria
- May act as final arbiter in technical matters not resolved at the supervisory level

1.7.4 Quality Assurance (QA) Manager

The designated individual with oversight of the BTP QA Program. The QA Manager implements and maintains the QA Program, and monitors the quality of the work product and the personnel of the BTP. This position is within the TLD and reports to the TLD Commander/State Toxicologist.

The QA Manager:

- Works to maintain and improve the quality program of the BTP
- Oversees the proficiency testing program
- Assists with the training (and retraining) program for the BTP
- Directs annual technical and quality audits of each laboratory
- Assists with maintenance and revisions of technical and training manuals for the BTP
- Organizes and schedules QA meetings
- Makes recommendations to the IDS Commander regarding issues of nonconformity
- Provides expert court testimony where required

1.7.5 Technical Leader/Calibration Activities Supervisor

The IDS Commander will appoint a Technical Leader/Breath Test Program Supervisor to provide quality assurance program support through technical oversight.

The Technical Leader/Calibration Activities Supervisor:

- Assists the QA Manager in maintaining the laboratory's quality processes and ensuring operational compliance with all accreditation and legal standards and requirements
- Is designated as part of technical management
- Has responsibility for uniform methodology implementation and use in all laboratories and responsibility for evaluating all methods used
- Has the responsibility to oversee standard training for new employees, and re-training of existing employees as needed in conjunction with the employee's supervisor
- Has the responsibility to see that quality practices are utilized in all scientific equipment maintenance, and ensures appropriate quality control is implemented within the discipline
- Evaluates new analytical procedures, equipment or technologies and oversees their validation and assists with implementation
- Ensures methodologies are in compliance with health and safety requirements
- Assists in resolving disagreements between technicians and technical reviewers, resolving other technical issues, and assists Standards and Accountability with root cause analysis involving technical nonconformities
- Has the responsibility to recommend the termination of testing through the chain of command in the event of a technical problem with a technical procedure, instrumentation or equipment.

1.7.6 Breath Test Program (BTP) Supervisor

The BTP Supervisor has primary responsibility for the supervision of breath test technicians, and reports to the IDS Commander.

The BTP Supervisor:

- Will be a commissioned officer having the RCW rank of Sergeant
- Directly supervises the breath test technicians
- May be appointed as BTP technical management
- Ensures the breath test technicians are complying with program policies and procedures

- Ensures the personnel under their supervision receive appropriate training
- Under the direction of the QA Manager, coordinates the proficiency testing program
- Organizes and conducts periodic meetings of subordinates
- Observes subordinates periodically as they testify in court
- Observes subordinates periodically as they teach classes
- Attends functional area meetings and visits all assigned laboratories
- Assists the QA Manager with the annual review of the quality management system
- Provides expert court testimony where required

1.7.7 Breath Test Technician

This position is assigned to one of the field locations where there is geographical responsibility for the BTP, and reports to the BTP Supervisor.

The Breath Test Technician:

- Is a commissioned trooper or a forensic scientist
- Are qualified Operators and Instructors
- Performs calibration and certification procedures on evidential breath test and preliminary breath test (PBT) instruments
- Performs repairs and maintenance on evidential breath test instruments
- Trains local police officers to be qualified Operators of the evidential breath test and PBT instruments
- Generates and maintains records and other documentation regarding the evidential breath test instruments and training responsibilities
- Performs technical review of calibration work, as authorized by the IDS Commander
- Authorizes/issues Calibration Certificates, as authorized by the IDS Commander
- Generates reports and summary statistics of program activities and DUI enforcement
- Provides expert court testimony where required

1.7.8 Administrative Staff

Perform a wide variety of routine clerical duties in support of office and BTP operations.

1.8 COMMUNICATIONS

1.8.1 Policy

BTP Management will establish a proper flow of communication internally throughout the BTP, and externally with its customers. Management will ensure that within each calibration laboratory all employees are well informed, and employees at each level have input into the system. Management will also ensure there is clear and frequent communication between the TLD and BTP sections of the Bureau. In addition, management will ensure that communication with relevant customers is effective and responsive to their needs.

BTP employees will follow the chain of command for all internal written communications as required by the WSP Regulation Manual. The chain of command, in ascending order, will normally be the employee's Supervisor, the IDS Commander, the FLSB Director, Assistant Chief and Chief of the Washington State Patrol.

1.8.2 Procedures

Examples of various forms of communication to be used by the BTP include:

- Agency meetings
- Manager meetings
- Supervisor meetings
- Section meetings
- Conference calls
- Written direction from Bureau or Section Headquarters for review by all members
- Interoffice Communication (IOC) or e-mail

Examples of external communication are as follows:

- Personal contact by telephone, e-mail, letter, or in person
- Attendance at meetings of local law enforcement, attorneys, traffic safety groups, and other customer and/or community groups
- Customer newsletters
- Training provided to law enforcement, attorneys, traffic safety groups, and other customer and/or community groups
- Membership and participation in WSP or State committees
- Customer surveys

Every employee has the responsibility to safeguard all confidential information obtained in his or her official capacity from unauthorized distribution. In addition, employees will not access or disclose any confidential information except where legally authorized.

1.8.3 Customer Feedback

Customer feedback, both positive and negative, will be solicited. Efforts will be made to include command staff, line officers, allied law enforcement agencies, attorneys, and any other members of the criminal justice system who have an interest in the BTP's breath alcohol calibration functions. This may be accomplished through any of a number of methods:

- a periodic statewide customer survey
- a local focus group conducted
- questionnaires submitted randomly to a limited numbers of customers
- other direct interaction, both formal and informal, with specific customers.

The objective is to gather information to provide insight into the wants and needs of the customer agencies and how we can improve service.

The decision to submit a statewide customer survey will be made jointly by the IDS and the FLSB Director. BTP staff are responsible for documenting use of any other methods to collect feedback along with the feedback itself from their own service area.

BTP staff shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the BTP's performance in relation to the work performed, provided that the BTP appropriately ensures confidentiality to other customers.

Customer feedback will be reviewed and addressed at the annual management review where any issues will be identified and addressed. Laboratory-specific issues will be addressed by the Supervisors, with responses to the impacted agency, the IDS Commander and the FLSB Director.

1.9 COMPLAINTS

1.9.1 Policy

A complaint is an allegation of conduct or omission that is contrary to state statute, Washington Administrative Code, Civil Service Rules, WSP Agency rules and regulations, and the Program/Bureau policies and procedures. They may include an allegation of conduct or omission that could amount to misconduct, exercise of poor judgment, or failure to meet established standards. A complaint may be made against an individual, a laboratory, a procedure or the Program/Bureau.

Complaints regarding program personnel, policies or procedures may come from internal or external (e.g., officers, prosecutors, defense attorneys, the public) sources. Complaints could be written or communicated orally. Personnel that become aware of a complaint either from an internal or external source have the responsibility to communicate the complaint either to their management staff or up through the chain of command. Should a complaint involve personnel, it shall not be handled by personnel included in that complaint. Management has the responsibility to ensure that complaints are resolved appropriately, using one of the three procedures outlined below.

1.9.2 Procedure

1. Non-Quality System complaints follow the WSP Agency Complaint Procedures (see WSP Regulation Manual). Investigation and resolution of the complaint may follow several courses of action depending upon the severity of the allegation.
2. Complaints regarding any aspect of calibration that do not conform to quality policies and/or procedures shall be directed through the chain of command (see chapter on nonconforming work).
3. Any complaints regarding other areas of the employee's responsibility shall be directed to that employee's immediate supervisor.

Management may respond directly to the complainant and attempt to resolve the issue by discussing existing policies. As necessary, corrective or preventative actions may be initiated as a response.

Any changes or revisions to controlled documents resulting from complaints will follow the Document Control and Document Revision policy and procedure section of the of this manual.

1.10 UNDUE INFLUENCE ON ANALYSIS

1.10.1 BTP Policy

BTP management will strive to ensure there is no influence on the professional judgments of employees, including any undue internal and external commercial, financial or other pressures and influences that may adversely affect the quality of their work. Personnel shall not engage in activities that may diminish confidence in the laboratory's competence, impartiality, judgment, or operational integrity. All conflict of interest concerns and situations that could cause undue pressure that adversely affect the quality of the work shall be brought to the attention of management.

Managers have the responsibility and authority to receive and take action on employee concerns within their section. Serious instances of undue influence on analytical findings or conflict of interest will be reported to immediate supervisors and escalated through the chain of command.

1.11 EXTERNAL DIVISIONS, AGENCIES AND ENTITIES

The BTP interacts on a regular basis with external divisions, agencies and other entities, in relation to its breath alcohol calibration activities. Any requests, suggestions and/or directives given by any of these interest groups must be approved by the IDS Commander before being implemented.

The following summarizes the roles of several of these interest groups:

1.11.1 Forensic Investigations Council

The Forensic Investigations Council (FIC) is an oversight group, appointed by the Governor, whose purpose it is to oversee the operations and budget of the FLSB and, in consultation with the Chief of the Washington State Patrol or designee, assists the FLSB in devising policies to promote the most efficient use of laboratory services (RCW 43.43.670, 43.88.030). The FIC meets on a regular basis, during which the FLSB Director, the Crime Lab Division Commander, the Toxicology Division Commander and the IDS Commander or designees provides policy, operational and budgetary updates.

1.11.2 Field Operations Bureau

The Field Operations Bureau (FOB) is headed by a WSP Assistant Chief, who reports directly to the Chief and commands eight districts each commanded by a captain). Back-up Breath Test Technicians are assigned to, and are supervised within, the FOB.

1.11.3 Allied Law Enforcement Agencies

Allied agencies include Sheriff and Police Departments throughout the state, which are overseen by the Washington Association of Sheriff and Police Chiefs (WASPC). Certified Breath Test Operators assigned to these agencies use calibrated evidentiary breath test instruments maintained by the BTP.

1.11.4 Office of the Attorney General

An assistant attorney general (AG) is assigned to the WSP and assists with tort claims, lawsuits and discovery requests. Changes to the RCW and WAC, pertaining to breath alcohol calibration activities, are reviewed by the AG.

1.11.5 Prosecuting Attorneys

The BTP provides expert testimony services to prosecuting attorneys throughout the state. The Washington Association of Prosecuting Attorneys is one oversight group.

1.11.6 Councils, Commissions and Committees

Examples include the Washington Traffic Safety Commissions (WTSC) and the Washington Impaired Driving Advisory Council (WIDAC). Such groups interact with the BTP/FLSB to support their own goals and objectives of reducing the incidence of impaired driving collisions within the State of Washington.

2 QUALITY MANAGEMENT SYSTEM

2.1 POLICY

The BTP will establish, implement and maintain a Quality Management System (QMS) appropriate to the scope of its calibration activities. The BTP shall document its policies, programs, procedures and instructions to the extent necessary to assure the quality of the calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel. The Program's QMS policies, procedures and objectives are defined in this Quality and Operations Manual. Use of the following terms indicate the relevant information is to be addressed in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule and specify.

2.2 DEFINITIONS

2.2.1 Annual

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

2.2.2 ANAB

ANSI-ASQ National Accreditation Board (ANAB) is an organization that accredits forensic science calibration laboratories to ISO/IEC 17025 standards and the ANAB ISO/IEC 17025 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements.

2.2.3 Calibration

For the purposes of this manual, any and all breath alcohol functions of the BTP (namely the calibration of breath alcohol measuring instruments), unless otherwise specified.

2.2.4 Quality

The adherence to generally recognized standards of good laboratory practice.

2.2.5 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.

2.2.6 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 BTP are scientifically sound and valid.

2.2.7 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.

2.2.8 Quality Control (QC)

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

2.2.9 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.

2.2.10 Quality and Operations Manual

A collection of the BTP's quality management system and operational policies and objectives for its breath alcohol calibration functions and description of their implementation.

2.2.11 Supervisors

Individuals with overall technical responsibility of personnel performing breath alcohol calibration functions. For the BTP, this is the BTP Supervisor (Sergeant).

2.2.12 Technical Procedures/Training Procedures

Scientific methodologies used in forensic analyses and the calibration of evidentiary breath test instruments. Written procedures will be prepared for routine tests and calibrations performed in the BTP Laboratories. The procedures used may be those developed and validated in-house or by an outside laboratory and the foundational training program required for all qualified breath test technicians prior to assuming forensic analysis.

2.3 QUALITY POLICY STATEMENT

The management and personnel of the BTP 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: 2017) and the ANAB ISO/IEC 17025: 2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125) for forensic science organizations providing calibration services for breath alcohol measuring instruments. 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. The BTP embraces and supports Agency ethics and the principles presented in the ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel, which includes statements addressing Professionalism, Competency and Proficiency, and Clear Communications, and ensuring appropriate actions are taken when necessary. Chapter 8 of the WSP Regulation Manual covers rules of conduct and a code of ethics. Breath test personnel will annually review the most current, published version of the Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel. This annual review will be documented.

BTP personnel are required to familiarize themselves with the Quality and Operations 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 BTP's standard of service as stated below and affirmed by Management signatories.

BTP Standard of Service

The BTP 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 BTP will strive to set the standard for this work against which similar programs will be judged and will work toward the quality assurance objectives listed below in 2.4.

FLSB Director

TLD QA Manager

IDS Commander

2.4 QUALITY ASSURANCE OBJECTIVES

The overall quality assurance objectives for the Breath Test Program are:

2.4.1 SERVICE

To provide quality service to Washington's Criminal Justice System by using procedures that are valid, accurate, reliable and sufficient for the intended purpose and by meeting customer, statutory and regulatory requirements.

2.4.2 STANDARDIZATION

To bring uniformity to our technical policies and procedures with the intent of producing high quality work that satisfies the customer requirements for service and meets the accrediting body's standards.

2.4.3 TRAINING AND EDUCATION

- To provide training to breath test technicians
- To provide training to BTP personnel in the quality management system,
- To provide growth opportunities for BTP personnel,

- To facilitate involvement of our personnel at the national and international level,
- To provide continuing education to our customers regarding BTP services, policies and procedures.

2.4.4 ACCREDITATION

To maintain in both field and laboratory environments, quality, excellence and reliability by conforming to International Organization for Standardization (ISO) International standards and maintaining accreditation requirements.

2.4.5 REVIEW

To proactively review and monitor the Quality Management System to identify potential nonconforming work.

2.4.6 AUDITS

Assess and document quality assurance activities through an audit process to demonstrate conformance to accreditation standards and maintain trust in the work product.

2.4.7 SURVEY AND COMMUNICATION

- To facilitate and enhance communication within the organization.
- To conduct surveys and maintain open communication with both internal and external customers.
- To review and analyze customer requirements and satisfaction with the BTP services.
- To communicate to all BTP personnel the importance of meeting customer requirements as well as statutory and regulatory requirements.

To meet quality assurance objectives, the staff of the Breath Test Program will:

- Utilize established technical procedures in calibration work that are reliable, reproducible, accepted in the forensic science community and adequate for the intended purpose.
- Participate in a proficiency testing program to monitor the routine performances of the technicians.
- Provide sufficient training to all staff. Technicians will successfully complete a competency or qualifying test before the assignment of calibration work. Continuing education and professional career development training will be available to all staff as necessary to provide the best possible work product. Training will include topics on Quality Assurance and Quality Control.
- Conduct regular court testimony monitoring of staff members.
- Have an employee performance evaluation program in which the tasks, responsibilities, safety and career development needs of the employee are reviewed each year.
- Have a system of technical and administrative review of calibration certificates.
- Undergo an annual (within the calendar year) quality assurance audit. This audit will be the responsibility of the QA Manager. The quality assurance audits ensure that the BTP stated policies and procedures are being followed.

- Have an annual (once per calendar year) management system review to include a review of the quality assurance program and discuss this review at scheduled management meetings. Information from these meetings will be communicated to all BTP staff by BTP Management. This review will generally be conducted in the last quarter of the year.

2.5 QUALITY ASSURANCE PROGRAM

The BTP Quality Assurance program includes all technical and supporting procedures and quality records. Management uses these procedures and records to oversee and review the effectiveness of the QA program. This ensures that the BTP is adhering to the Quality and Operations Manual policies and procedures and conforms to the ISO standards and any supplemental accreditation requirements.

2.6 BTP QUALITY MANAGEMENT

The FLSB Director, IDS Commander, QA Manager, and Supervisors are responsible for ensuring that the policies and procedures adopted by the BTP 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, related to breath alcohol calibration functions, include, but are not limited to:

- Responsibility for the overall QA program of the BTP, including all audits and reviews.
- Working to maintain and improve the QA program of the BTP
- Maintaining QMS documents and records
- Monitoring accreditation criteria compliance
- Evaluation of statewide compliance to the BTP training programs to ensure uniform quality of education and training in all calibration laboratories
- Ensuring uniform methodology implementation and use in all calibration laboratories within the program
- Ensuring that procedures and training manuals for the discipline accurately reflect established standards and comply with accreditation requirements
- Reviewing for adherence to procedures and approval of new methodology, technologies and equipment validations
- Evaluating new analytical procedures, equipment or technologies and overseeing their validation and implementation
- Administering and coordinating the BTP's proficiency testing program. This includes documentation and response to ANAB regarding proficiency test performance.
- Organizing and scheduling QA meetings
- Oversight and review of root cause analysis and corrective actions for nonconformities and inconsistencies in all calibration work

In addition to assisting the QA Manager with the aforementioned duties, the supporting duties of other management include, but are not limited to:

- Coordinating the training and development of each breath test technician from basic development to continuing education.
- Monitoring the development and implementation of the technical and training manuals

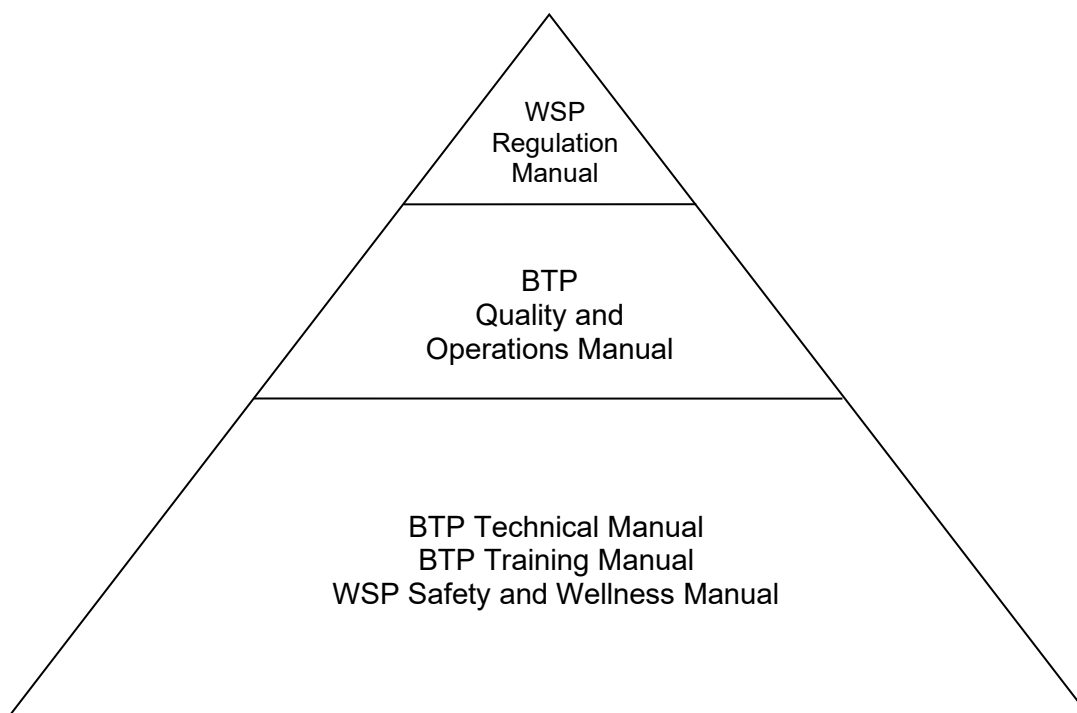
- Reviewing of manuscripts for publications
- Reviewing of research projects

2.6.1 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 produce the highest quality work in the most efficient manner possible. This commitment helps the BTP meet the needs of the customer and demonstrate to the citizens of Washington that the BTP are good stewards of the resources given us.

2.6.2 Program Documents

The pyramid below represents the documentation upon which the QMS is built. The BTP Quality and Operations Manual has overriding authority over all BTP manuals. The WSP Regulation Manual has over-riding authority over all BTP Manuals.



2.7 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
- Equipment repair and verification records
- Standard reference solutions and chemical records
- Training records

- Proficiency test records
- Competency test completion records
- Courtroom testimony monitoring records
- Audit records

These records are maintained by the BTP. Filing, storage and retention of these records are as described below. There may be overlap between records held at BTP headquarters and the individual laboratories and many records are stored electronically.

2.7.1 Records Filed, Stored and Retained at BTP Headquarters by the 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
- Key control records where applicable
- Equipment validation, performance verification and maintenance records will be maintained at the laboratory in close proximity to the equipment (on-site)
- Calibration files and records, and any associated examination or administrative documentation according to retention schedules
- Reference standard solution inventory records
- Equipment inventory

2.7.2 Records Filed, Stored and Retained at Individual BTP Laboratories

- Chemical and reagent logs and worksheets (where applicable)
- Key control records where applicable
- Building maintenance and security records and logs (where applicable)
- Visitor logs

2.7.3 Records Maintained in Bureau-Wide Databases

- Laboratory Library Collection
- Breath Test Records database

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.

2.7.4 Retention of Quality System Records

Retention and disposal of quality records will follow the state and Agency Record Retention Schedules or for a period of one accreditation cycle, whichever is longer.

3 DOCUMENT CONTROL POLICY AND PROCEDURES

3.1 POLICY

All Quality Management System documents used within the BTP are controlled to ensure that only current, up-to-date documents are being utilized. All official BTP documents will be made available to staff via the FLSB SharePoint. The following procedures provide instructions concerning the management, creation, revision, distribution, retention and destruction 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, memorandum, or interoffice communication (IOC) to allow for immediate implementation prior to actual manual changes. Immediate changes may be issued by the IDS Commander or the QA Manager.

3.2 DEFINITIONS

3.2.1 Document

A document is information in any medium including, but not limited to, paper copy, electronic file, audio or videotape, photograph.

3.2.2 Document Control

The process for ensuring that controlled documents, including revisions, are reviewed, approved and released by authorized personnel (see Issuing Authority), and distributed to personnel performing the prescribed activities.

3.2.3 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.

3.2.4 Document Review and Approval form (DRA)

A form used for all proposed modifications to controlled documents.

3.2.5 Records

Documents, logs, worksheets and electronic files that provide support of conformity to the Quality Management System. They may be held in the individual laboratories or at headquarters.

3.2.6 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.

3.2.7 Controlled Document Issuing Authority

Personnel that are authorized to approve the posting of controlled documents on the FLSB SharePoint. The issuing authority for FLSB wide controlled documents is the Bureau Director. For BTP documents, it is the IDS Commander.

3.2.8 Master Document File

An electronic file maintained by the QA Manager and available to all BTP employees via the FLSB SharePoint which contains the current revision status of any controlled document.

3.3 PROCEDURE

3.3.1 Controlled Document Format

Each controlled document will have the following format requirements:

A header on each page containing, at a minimum:

- Washington State Patrol Breath Test Program
- 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 “All Printed Copies are Uncontrolled”
- The unique document identification
- Revision number and effective date

Forms do not require the “All Printed Copies are Uncontrolled” statement, as they are intended to serve as a template for entering data or information. No modifications to form templates 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
- Date revision approved
- 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.

3.3.2 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 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 Program'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
- Addressing or resolving comments from reviewers
- Assuring that there are no conflicts with other BTP manuals, WSP regulations and/or the Washington Administrative Code/Revised Code of Washington
- Submitting for review and approval using the Document Review and Approval Form.

3.3.3 Controlled Document Review

Each new or revised controlled document is required to have a technical and 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. BTP management may also perform reviews of controlled administrative documents. Minor typographical and grammatical errors and formatting changes in manuals and forms do not require a DRA. These types of errors will be brought to the attention of authorized BTP personnel for correction.

3.3.4 Controlled Document Approval

Each controlled document issued will be approved through the chain of command with final approval by the IDS Commander, or the State Toxicologist, where applicable.

3.3.5 Controlled Document Issuing

After the documents are approved, the document will be issued through the IDS Commander or designee and posted on the FLSB SharePoint.

All personnel will have access to controlled documents posted on FLSB SharePoint. Any copies of documents from this site represent unofficial copies and will be designated as such. Administrative access to the official electronic controlled documents will be restricted to prohibit unauthorized changes. Only authorized changes can occur.

3.3.6 Archiving Controlled Documents

Obsolete documents will be archived in the “Archived Manuals” section of the FLSB SharePoint. The document will be given a watermark labeled “Archived” with the archive date included. The IDS Commander or designee will maintain the official controlled documents and archived versions of all controlled documents on FLSB SharePoint.

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.

3.3.7 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.

The IDS Commander, QA Manager and/or Supervisors will conduct this review. 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.

3.4 REVISIONS TO PROCEDURES, TRAINING AND TECHNICAL DOCUMENTS

Recommendations for additions, deletions or modifications to technical and training documents will be made through the IDS Commander.

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 Program.

For administrative/operational changes to documents, BTP personnel putting forward proposed revisions for consideration must ensure that the recommended changes represent the objectives of the Bureau 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 Document Review and Approval form (DRA) 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
- “Track changes” can be used as an alternative

The QA Manager will submit the written recommendation(s) to the IDS Commander, or State Toxicologist, where applicable, 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.

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 IDS Commander or the QA Manager. The communication will include specific information regarding 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 SharePoint. Wherever possible, a hyperlink will tie the communication directly to the revised document.

3.4.1 Approved/Adopted

The approved document will be posted on the FLSB SharePoint and BTP personnel will be notified by BTP Management or the QA Manager/designee via e-mail. The notification will include the effective date.

The affected individuals will be required to acknowledge they have reviewed the approved document via CITE. Supervisors will be responsible for tracking the acknowledgements which will be subject to the audit process. Once a document is adopted, it will be the responsibility of management to ensure it is implemented.

3.4.2 Returned

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

3.4.3 Tabled

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

3.5 RETENTION AND STORAGE OF DOCUMENTATION

3.5.1 Retention Time of Documentation

All documentation addressed in this policy is to be retained in accordance with the WSP agency and Impaired Driving Section Records Retention Schedules.

3.5.2 Storage of Documentation

All documentation covered by this chapter will be stored in a manner that is readily retrievable and protected from damage, deterioration or loss. Back-ups of documentation stored electronically will be accomplished and stored in such a manner to allow efficient access and security from unauthorized access to or amendment of these records.

All calibration documentation will be maintained under the control of the BTP until they are archived. BTP Headquarters will maintain at least the most recent five years of calibration documentation. Calibration documentation older than five years may be sent to the State Records Center for secure long term storage.

3.5.3 Web Based Access to Documentation

The FLSB maintains a WebDMS web based system (<http://breathtest.wsp.wa.gov/>) where calibration records generated and maintained with the program are made available.

3.5.4 Expungement and Destruction of Documentation

On receipt of a court order for expungement, the IDS Commander should be contacted. BTP personnel will make any appropriate contacts with the WSP Risk Management Division and/or the Attorney General's Office who will provide guidance to the laboratory for compliance with the order.

Documentation will be destroyed in accordance with the WSP Records Retention Schedule.

3.6 APPROVED EVIDENTIAL BREATH TEST INSTRUMENT SOFTWARE

The State Toxicologist shall approve software which allows the evidential breath test instrument to meet the strict accuracy and precision standards of the Quality Assurance Procedure (QAP) and perform evidentiary breath tests in compliance with the standards required by statute and the WAC.

The software employed within the evidential breath test instrument will be those versions currently approved for use by the State Toxicologist. A list of those versions of software currently approved for use can be obtained from the BTP Headquarters or on the BTP Master Document List. Documentation for the approved software is also available on the WebDMS web site.

3.7 DISCLOSURE AND RELEASE OF INFORMATION

3.7.1 Policy

The BTP is required by law to disclose documentation and information when it is requested by the media, attorneys, insurance companies, the public, or other parties designated by the Public Records Act.

3.7.2 Release of Results

The release of results through Calibration Certificates will only be authorized after completion of any mandatory reviews of technical and administrative content. Instrument Calibration Certificates will be issued by personnel who have been authorized by the IDS Commander to review and authorize/issue certificates. Copies of Calibration Certificates may be maintained for each instrument in the satellite laboratory from which the instrument is based. Original Calibration Certificates will be maintained in either hard copy or electronic format in the Breath Test Program Headquarters.

Material amendments to Calibration Certificates will be made only in the form of a further document. The amended document will have a completed Calibration Certificate Amended Document Record form approved by a member of BTP Management attached to it. The amended document will be titled as follows:

Washington State Patrol Draeger Alcotest 9510 Amended Calibration Certificate.

3.7.3 Procedure for Public Disclosure

Public disclosure requests will be handled according to procedures established by WSP (see WSP Regulation Manual and WSP Public Disclosure Manual).

Any request for information under Public Disclosure will be directed to the appropriate public records coordinator within the BTP. Routine discovery requests or other requests for specific information can be provided directly to the requesting party by the responsible personnel handling the request.

Court orders for discovery of documentation, records and other related breath alcohol calibration materials will typically be fulfilled by routing discovery documents through the prosecuting attorney, unless specifically ordered otherwise by the court or authorized by the prosecuting attorney.

Parties requesting information or documentation from the BTP may also be directed to the WebDMS web site (<http://breathtest.wsp.wa.gov/>). Most relevant materials will be found there.

The prosecuting attorney and/or defense counsel may request a pre-trial conference with a technician to discuss findings in a particular case. Technicians should participate in trial preparation with attorneys, whether in face-to-face meetings or by teleconference. To comply with policies governing release of information, technicians must notify prosecuting attorneys of pending interviews with defense counsel. The prosecuting attorney may request to be present for any interviews.

4 NONCONFORMING WORK AND CORRECTIVE ACTIONS

4.1 POLICY

In the event that any BTP 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 and the IDS Commander. If BTP personnel identify improvement opportunities which may prevent nonconformity, they are directed to notify the appropriate Supervisor. This policy applies to technical, quality and administrative aspects of the Quality Management System within which nonconformity or opportunities for improvement may exist (e.g. in calibrations, proficiency tests, reports, documentation, testimony, or care and preservation of calibration items).

The Supervisor shall ensure that nonconformities are documented. When a nonconformity has been identified, an evaluation of the significance of the nonconforming work will be made by BTP Management or the QA Manager. The level of nonconformity will be assessed and addressed accordingly.

4.2 DEFINITIONS

4.2.1 Corrective Action

The overall actions taken and plan or process used to address a nonconformity and to eliminate the cause of a detected nonconformity or other undesirable situation. The level of significance of the nonconformity will determine the appropriate action.

The corrective action shall start with an investigation to determine the root cause(s) of the problem.

4.2.2 Correction

Immediate action taken to eliminate a detected nonconformity (a correction can be made in conjunction with a corrective action)

4.2.3 Corrective Action Process

The process to follow when addressing 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)

4.2.4 Corrective Action Plan (CAP)

A formal statement by the supervisor or designated authority prepared, detailing the following:

- Description of the incident (what is the nature of the nonconformity?) Root cause analysis (including the chain of events leading to or causing the nonconformity)
- The immediate corrective actions taken (how was the problem handled?)
- Preventive action to avoid future occurrences
- A timeline for completion of the corrective and preventive actions
- A recommended schedule for follow-up to determine the effectiveness of the preventive measures to be taken (if required)

4.2.5 Corrective Action Report (CAR)

A summary report in IOC format, prepared by the supervisor or designated authority upon the conclusion of a corrective action (if required). The report should include any further needed actions or recommendations.

4.2.6 Nonconformity of Work

Non-fulfillment of a work requirement; any aspect of the Quality Management System that does not agree with established laboratory, technical or quality system procedures or requirements.

4.2.7 Preventative Action

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

4.2.8 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 non-conformity.

4.3 PROCEDURE

The Corrective Action procedure is a step-wise process as outlined below:

4.3.1 Identification

While not an exhaustive list, 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 calibration files
- indications of inadequate technical review
- calibration certification checking
- management reviews
- internal or external audits

4.3.2 Notification

When a potential nonconformity has been identified, the Supervisor and QA Manager will be notified. The Supervisor or designee will begin documenting the nonconformity using the Nonconformance Review/Corrective Action Plan form. A nonconformity as described in an internal or external audit report, a letter of inquiry from ANAB, or a Court Testimony Performance Evaluation may also be acceptable forms of notification sufficient to initiate the corrective action process. If the potential nonconformity is confirmed, the IDS Commander will then be notified.

Substantive nonconformance will require disclosure to ANAB within thirty days of determining that nonconformance has occurred and that it was substantive. In consultation with all involved parties, the disclosure report will be prepared and submitted by the QA Manager.

4.3.3 Root Cause Analysis

This is a process of fact finding used to evaluate all aspects of the incident, including the policy or procedure involved, to identify the basis of the nonconformity. This process is a tool designed to help identify what, how, and why an event occurred, or the underlying factors leading up to a work error. There can be more than one cause for a nonconformity. Whenever a discrepancy or nonconformity occurs, the cause(s) should be determined if possible. The QA Manager may direct members of the FLSB other than a supervisor to conduct the root cause analysis investigation.

The investigation may include an evaluation of procedures, staff skills and training, consumable supplies, equipment and instruments, calibration status, customer requests and requirements, samples, reagents and controls. The investigator shall consult with all necessary personnel, beginning with the technician involved, to determine the basis of the nonconformity as completely as possible.

Nonconforming work may be a systemic error rather than an 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.

Refer to Appendix A for root cause analysis guidelines and procedures.

4.3.4 Evaluation of the Significance of Nonconforming Work

Nonconformities occur in a continuum of significance and severity. Because of this, they must be evaluated for their significance and a decision made regarding the appropriate corrective action for the nonconforming work. This evaluation is the joint responsibility of the supervisor(s), the QA Manager, and the IDS Commander and is documented using the Nonconformance Review/Corrective Action Plan form.

The evaluation of the significance level of the nonconforming work must consider:

- The severity of the nonconformance
- The possibilities and implications of the nonconforming work recurring
- If there is/was laboratory compliance with its own policies and procedures
- The suitability of those laboratory policies and procedures

For instances where the nonconforming work is determined to be nonsubstantive, the correction or immediate action taken may be sufficient, and no (or limited) further action would be necessary. However, the supervisor(s), QA Manager or IDS Commander may decide to implement a corrective action plan at any time.

In instances where the nonconforming work is deemed to be substantive, the corrective action process, described below, will be implemented. If a corrective action is required, the QA Manager will prepare the CAP or designate another person, such as a supervisor, to prepare the plan.

If warranted, for the most severe nonconformities, an instrument, the method, equipment or a Laboratory (or combination thereof) may be removed from calibration work by the IDS Commander. The IDS Commander has the authority to suspend the authorization of personnel to perform calibration work, and authorization to resume calibration work must be granted by the IDS Commander.

If the nonconformity is a result of, or related to, a laboratory-wide or system-wide deficiency, the IDS Commander will ensure the entire Laboratory discontinues calibration work in the affected area until the nonconformity is addressed and resolved.

4.3.5 Corrective Action Plan and Implementation

The Corrective Action Plan will be completed by the designated individual.

The individual preparing the Corrective Action Plan will identify potential corrective and preventive actions. They must select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem. The plans should also consider how the work is to be reassigned until the nonconformity is corrected. It should identify any training, equipment, protocol modification, or calibration work reanalysis needed to correct the problem.

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

The Corrective Action Plan is documented using the Nonconformance Review/Corrective Action Plan form, and must be approved by the QA Manager and/or the IDS Commander. Once the corrective action plan has been approved, the corrective action plan will be implemented.

4.3.6 Timeline

As part of the corrective action plan, a reasonable timeline for completion will be included. If the planned actions call for interim reviews prior to completion, these shall be scheduled and included in the timeline. The approved CAP should state who will prepare the final corrective action report (most often the author of the plan).

4.3.7 Corrective Action Report (CAR)

Following the completion of the corrective action plan, the designated person will submit through the chain of command to the IDS Commander a corrective action report in the form of an IOC, detailing the success or failure of the corrective action taken. Notifications will be given to involved parties. All CARs require approval by the IDS Commander and the QA Manager.

4.3.8 Follow-up

In order to ensure continued compliance and that the corrective actions have been effective, monitoring of the employee's performance, laboratory performance, or system performance will be conducted. The QA Manager may state on the corrective action plan that follow-up is unnecessary if it is thought that it does not serve a useful purpose.

In all other cases, the QA Manager will 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 area of activity or section or laboratory. An IOC or other written documentation, describing the follow-up activities and results, will be prepared for inclusion in the corrective action documentation file.

Internal auditors will review corrective actions taken during the Annual Internal Quality Audit, and will look for reoccurrences of problems or documentation demonstrating that there has been no reoccurrence.

4.3.9 Notification of Customers

When substantive nonconformities occur it may be necessary to notify the customer of the facts surrounding the event. Where necessary, an amended calibration certificate will be prepared as soon as possible, and provided to the customer (client notification). The calibration files or records will contain documentation of the technical and/or administrative measures taken to resolve the nonconformity.

4.3.10 Reporting Requirements and Responsibilities

ANAB requires that a summary of nonconforming work events, the actions taken, and a summary of any other substantive corrective actions completed, or in process, since the last on-site visit be included in the BTP annual internal audit and report. QA will prepare these summaries as part of the annual report to ANAB.

In addition, the laboratory must disclose to ANAB all substantive occurrences of noncompliance within thirty days of determining that the noncompliance has occurred. (See ANAB Accreditation Manual for Forensic Service Providers current guidelines for reporting.) The disclosure report will be prepared and submitted by QA.

Records of Corrective Actions will be retained for at least one accreditation cycle, or four years, and in accordance with the agency retention schedule.

4.3.11 Responsibility for Authorizing Resumption of Work

In cases where a technician has been removed from calibration work, or when required by a corrective action plan, a follow-up competency test may be issued by the QA Manager following successful completion of the corrective action plan. If an individual, process, or instrument is removed from work, they/it may not return to casework until authorized by the IDS Commander.

4.4 PREVENTATIVE ACTION

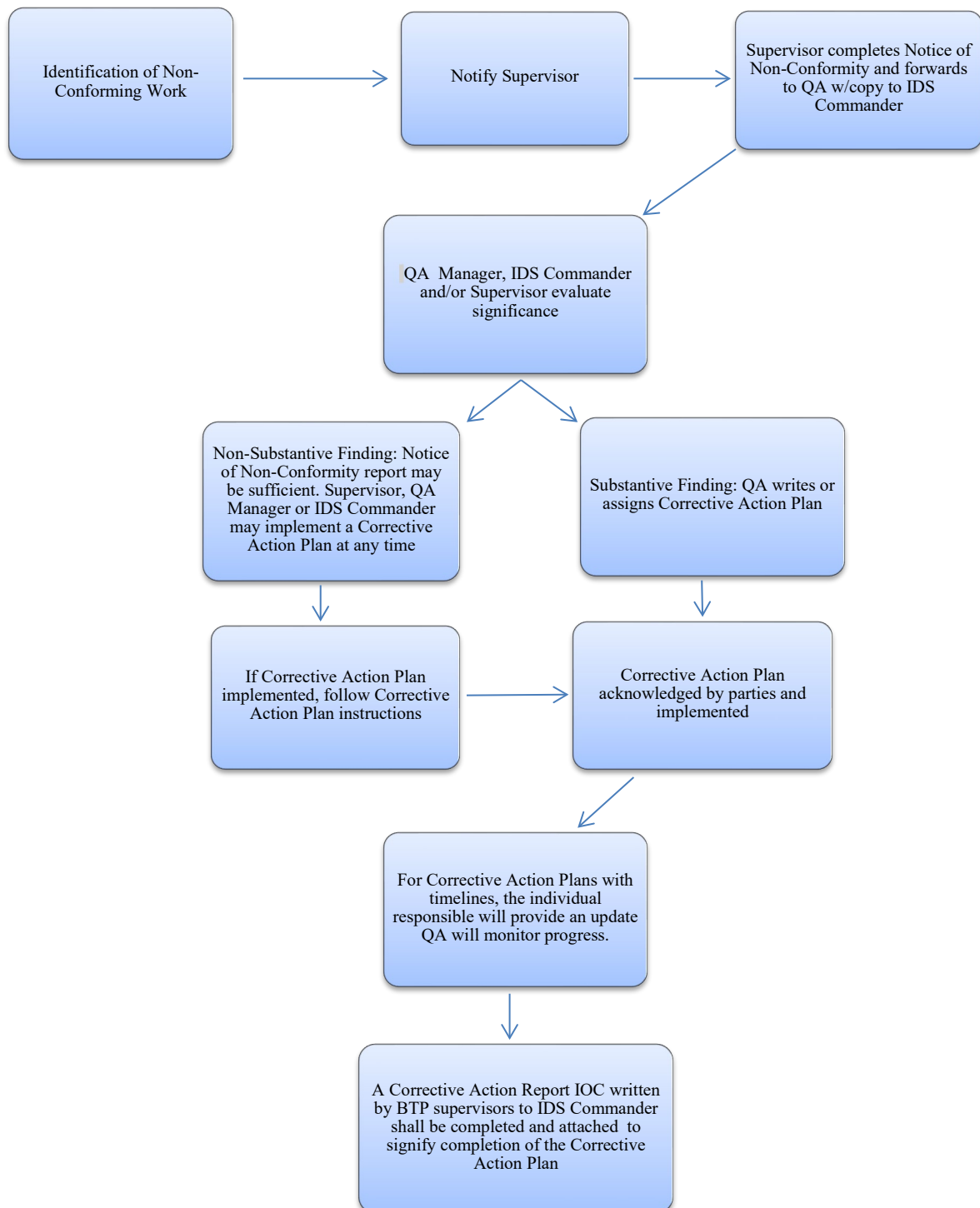
Preventive actions are designed to eliminate the cause of a potential nonconformity and prevent occurrence. Identification of needed improvements, either technical or concerning the management system, evaluation and implementation of a preventive action may include one or more of the following:

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

BTP 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, IDS Commander and/or QA Manager preferably through written correspondence such as e-mail or IOC. The IDS Commander and/or QA Manager shall evaluate the suggestion. If a preventative action is implemented, it shall be monitored for effectiveness.

Corrective Action Flow Chart



5 INTERNAL AUDITS AND MANAGEMENT REVIEWS

5.1 POLICY

All laboratories will be audited annually to verify that operations are in compliance with established policies and procedures, all accreditation 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 BTP management and quality 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.

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

5.2 DEFINITIONS

5.2.1 Audit (or Assessment) Cycle

An audit cycle is the period of time between on-site assessments by the accrediting body, and will generally be a period of four (4) years.

5.2.2 Internal Audit

A review conducted by BTP or FLSB personnel to compare the various aspects of the laboratory's performance against stated requirements, standards, policies and procedures.

5.2.3 External Assessment

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

5.2.4 Nonconformance

A nonconformance (finding) is a result from an audit that is not in conformance with accreditation criteria, BTP policies and procedures, or applicable WSP regulations. Substantive nonconformities must be followed up with a Corrective Action Plan (CAP).

5.2.5 Management System Review (MSR)

A Management System Review is an annual review by the BTP top management of the program's management and quality systems, and calibration activities to ensure continuing suitability and effectiveness.

5.3 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. The results of this review will be used as a tool to introduce necessary changes or improvements by management.

Internal audits will include on-site inspections of laboratory facilities. These audits will address all elements of the quality system, including direct observation of the calibration activities. The QA Manager will plan, organize and direct the audits and management system review. QA has oversight of findings of nonconformance, CAPs, 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 FLSB or outside the Bureau.

5.3.1 Elements of the Management System Review (MSR)

The annual management system review will address the following points:

- The suitability of policies and procedures
- A review of internal audits
- Corrective and preventive actions taken in the last year
- A review of external assessments
- Changes in the volume and type of work
- Client and personnel feedback
- Quality system complaints
- Effectiveness of implemented improvements
- Fulfillment of objectives
- Status of actions from previous management reviews
- Changes in the volume and type of work or in the range of laboratory activities
- Adequacy of resources
- Results of risk identification
- Outcomes of the assurance of the validity of results
- Other relevant factors such as quality control activities, proficiency testing, resources, and personnel training

The results of the MSR will be considered by BTP Management for planning purposes. Items from the management review considered for planning purposes will have goals, objectives, and action plans. The objectives will be measurable, definable accomplishments which further the goals.

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

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

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

6 ACQUIRING SERVICES, EQUIPMENT AND SUPPLIES

6.1 POLICY

The BTP acquires equipment and supplies allowing them to perform its responsibilities. The BTP is responsible for the acquisition, custody and disposal of all equipment and supplies within their control, and should only acquire those necessary to fulfill their mission. All purchasing, ordering and payment procedures will comply with WSP Budget and Fiscal Services (BFS) requirements.

Supplies and services that affect the quality of calibration work shall be selected and purchased at a quality appropriate for the testing. Only BTP approved vendors will be used for supplies and services that affect the quality of calibration work.

Reference standards, reference materials, and calibrations of equipment/reference standards used to establish and/or maintain measurement traceability are critical as they affect the quality of the calibration work. Where applicable, the BTP shall maintain specifications for supplies and materials that affect the quality of their work within the protocols of their procedural manuals.

Documentation shall be kept that demonstrates the receipt of supplies to include the ordering and acquisition dates, and the receiver. Each laboratory shall ensure that reference standards and materials, 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 BTP shall evaluate all suppliers of materials (reagents and supplies) and services affecting the quality of tests ensuring that specific requirements and standards of quality are met. One indication that these standards are met is if they are an ISO-accredited supplier. A list of evaluated and suitable approved suppliers shall be maintained by the BTP, along with their record of compliance with established specifications.

For the purposes of this section, equipment means all physical items used by employees to conduct the official business of the BTP including, but not limited to, communications equipment, computers, scientific instrumentation, office machines, vehicles, tools, and other issued equipment or materials.

Equipment will be selected on the basis of its appropriateness for specific functions, initial cost, ongoing support costs, and the availability of funds for equipment purchases and maintenance.

All equipment will be kept secure from damage, misuse, misappropriation, and theft. All equipment must be maintained in proper working condition. Equipment needing repair outside the scope of the technical manual and/or maintenance plans, or systemic problems, must be brought to the attention of the supervisor who will inform the IDS Commander of the need to obtain and authorize repairs.

6.2 PROCEDURE

6.2.1 Purchasing Supplies and Services

An order will be placed with a supplier only after the IDS Commander, supervisor, or designee have authorized the order in writing or by email. 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 IDS Commander will designate:

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

6.2.2 Receiving Supplies and Services

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 approval

The packing slip or receipt will be attached to the order document. Both will be retained according to agency retention schedules.

Where appropriate, purchased 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, and 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*)

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

6.2.3 Storage of Reagents and Laboratory Consumable Supplies

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

6.2.4 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 IDS Commander. Requests for exception will clearly address the following:

- The reasons for retaining the equipment
- The intended future use of the equipment
- The cost of putting the equipment back into operation in the future
- The 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

6.2.5 Vendor Evaluation

The BTP shall maintain a list of approved suppliers of reagents, supplies and services that affect the quality of testing. This list is maintained electronically by the IDS Commander, QA Manager or designee, and is available on the FLSB SharePoint along with their record of compliance with established specifications. New suppliers of reagents, supplies and services will be evaluated under direction of the QA Manager, based on the following criteria:

If available, suppliers of external calibration services for reference standards requiring calibration, and equipment where the calibration of the equipment has a significant effect on the accuracy or validity of the calibration, shall be either:

- A National Metrology Institute that is a signatory to the International Bureau of Weights and Measures (BIPM) - CIPM Mutual Recognition Arrangement with the calibration to be performed listed in Appendix C of the BIPM key comparison database (KCDB), or
- A service supplier accredited to ISO/IEC 17025: 2017 by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement, with the calibration to be performed listed in a scope of accreditation.

In addition, the vendor evaluation may be based on the following criteria:

- The vendor is accredited to other relevant ISO standards by a 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, or Quality and Operations 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 vendor is approved to provide

A Vendor Evaluation and Approval form, copies of national accreditation documents and/or a memo covering these points for each vendor will be prepared and forwarded to the QA Manager, who will then submit to the IDS Commander for subsequent final approval. This information may be transmitted electronically.

7 TRACEABILITY AND QUALITY CONTROL

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

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

The BTP 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, supplies and equipment/instrumentation will be controlled.

7.1 TRACEABILITY AND QUALITY CONTROL OF STANDARDS AND REFERENCE MATERIALS

7.1.1 Policy

Reference standards and materials used in the equipment calibration method shall be traceable with appropriate measurement uncertainties. Purchased chemical containers must be dated and initialed when received and when first opened.

7.1.2 Definitions

7.1.2.1 External Standard

The reference standard attached to the instrument and used to provide a known alcohol vapor concentration to verify the accuracy and proper working order of the instrument as part of a field evidentiary breath test. This is a dry gas external standard consisting of an ethanol/nitrogen mixture.

7.1.2.2 Quality Assurance Procedure (QAP)

A testing procedure for evidentiary breath test instruments in which known traceable reference materials are used to set and confirm the adjustment and establish quantitative estimates for bias and precision. Several other performance measures are also evaluated in order to ensure the proper working order and evidential suitability of the instrument.

7.1.2.3 Reference Material

An item, material or substance which may be encountered in calibration work which are maintained for identification, comparison or interpretation purposes.

7.1.2.4 Reference Standard

A sample acquired or prepared that has known properties (e.g., concentration, chemical composition) for the purpose of calibrating equipment, verifying performance and/or for use as a control in experiments.

7.1.2.5 Reagent

A substance used because of its known chemical or biological activity.

7.1.3 Simulator Solutions

Alcohol certified reference materials (ethanol solutions, QAP solutions) are purchased from an approved vendor. The vendor provides a certificate of analysis (COA) with the assigned (analytical) concentration and statement of metrological traceability. These solutions are then distributed to, and used by, the BTP where the QAP solutions are tested concurrent with the QAP and used to set and confirm the adjustment of the evidentiary breath test instruments.

All solutions used in the QAP will be in labeled bottles with the name of the solution, date of preparation, date of expiration, lot or batch number, and any special storage requirements.

If a certified reference material is changed in a way that alters the traceable measurement value, then the equipment used to alter the certified reference material shall be evaluated for applicability of measurement traceability accreditation requirements.

7.1.4 QAP Acetone and Ethyl Alcohol

During the QAP, acetone is added to a simulator solution to ensure the instrument's recognition of the interfering substance. Also during the QAP, a mouth alcohol/invalid sample test is performed using a substance containing ethyl alcohol (i.e., mouthwash). The acetone and mouth alcohol/invalid sample needed to complete these verifications are not used directly in the calibration itself, are not reagents used for calibration, are not critical and need not be traceable to NIST. The acetone and mouth alcohol/invalid sample containers will be labeled with the identity and contents to assure it contains acetone (for interfering substance) and ethyl alcohol (for invalid sample test), and is fit for purpose. Mouth alcohol (e.g., mouthwash) is purchased commercially, and the manufacturer label is appropriate identification.

Receipt of acetone is recorded in the acetone tracking sheet. Acetone is stored at ambient conditions, and containers should be dated and initialed when first opened. The date opened and initials of the person first opening the container serve as the lot number.

7.2 EQUIPMENT AND INSTRUMENTATION

7.2.1 Policy

Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Before being placed into service for use, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. Equipment/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 Program's and the manufacturer's specifications for the test.

All instruments and major equipment will be uniquely identified. Equipment/evidential instruments will have regular maintenance and performance verifications to ensure continued performance. All analytical equipment/evidential instruments and any associated software will have records that are maintained in an equipment/instrument record. The record will include maintenance, calibration and verification procedures. In addition, equipment/evidential instruments will only be operated by authorized personnel, for official breath alcohol calibration

work, and as determined by the IDS Commander. The BTP will maintain documentation of persons authorized to operate the equipment/evidential instrumentation.

Due care and caution should be used while moving, storing and transporting breath test instruments from field locations to and from the labs. This includes securing all instruments in locked spaces when lab personnel are not present. This will prevent damage and maintain the integrity of the instruments and all information contained therein.

7.2.2 Definitions

7.2.2.1 Adjustment

A set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of the quantity to be measured. For the BTP, the process by which reference standards having known 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. Adjustment normally precedes the calibration.

7.2.2.2 Calibration

Process where each of four QAP solutions of known value is tested to ensure that their values satisfy the requirements for precision and accuracy (previously known as linearity check). The process compares the "indications" of the measurement standard on the equipment to the reference value of the QAP solution. This allows the laboratory to determine if the performance of the equipment being calibrated meets the required specifications. A calibration is not an adjustment or verification of calibration.

7.2.2.3 Performance Verification

Performance verification is a set of operations to determine if a piece of equipment or instrumentation is working correctly within manufacturer's specifications or BTP's specified parameters, or to determine if a validated method is fit for purpose and performing as expected. Performance verifications for evidential breath test instruments are performed with the QAP. Performance verifications for equipment, such as multimeters, digital reference thermometer and barometers, are normally performed externally by appropriate approved vendors.

7.2.2.4 Traceability

The property of a measurement result whereby it can be related to reference standards, usually national and/or international, through an unbroken chain of comparisons.

7.2.2.5 Validation

Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled and is fit for purpose.

7.2.3 Procedure

Equipment will have regular maintenance, adjustment/calibration (if required) and performance verifications to ensure continued performance. The equipment/instrument records will be maintained at BTP Headquarters with electronic copies available on WebDMS. Copies may also be available in each laboratory. BTP Headquarters will maintain retired records for at least one accreditation cycle. An electronic record is an acceptable alternative to a written log.

Where applicable, the following information shall be kept as part of the equipment/instrument records:

- The equipment/instrument identity: type, manufacturer, model, serial number or unique name and current location
- The manufacturer's instructions, if available, or reference to their location
- The maintenance plan and/or procedure and records of maintenance performed
- Date of maintenance, the person doing the maintenance, and activity conducted
- Performance verification procedures
- Documentation of performance verification
- Frequency of checks for verifications and calibration status.
- Scheduled calibration (if required) including dates, results, reports and certificates
- Any damage, malfunction, modification or repair to the equipment/instrumentation

The unique identifier for each instrument will be used in all documentation, including any reports or hard copy instrument data.

Maintenance/verification records will be kept with the instrument if the instrument is transferred to another laboratory.

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 IDS Commander.

7.2.4 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 record.

Calibration of equipment shall only be conducted by approved calibration service providers.

7.2.5 Equipment/Instrument Performance Verification

Each laboratory will ensure that all equipment/instrumentation, either newly purchased or existing, that is significantly modified such that the change(s) affects the outcome of the test, are properly validated or have their performance verified prior to use. The process will be as extensive as is necessary to meet the needs of the given application 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 record. 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 record will include the following:

- The instrument unique identifier or name, model and serial number
- The verification date
- 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 IDS Commander, and corrective action shall be performed. The laboratory will follow the corrective action process for non-conformities (see *Chapter 3*).

7.2.6 Equipment Calibration

Analytical equipment requiring calibration (e.g., NIST traceable thermometers, barometers) will be calibrated prior to being implemented in the laboratory.

Adjustments and/or calibration of equipment shall only be conducted by approved, external calibration service providers.

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 record.

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. Any change in the calibration schedule that lengthens the time between calibrations must include a documented reason for the extension based on an evaluation of the risk of the extended period and objective evidence. Calibration/recalibration documentation and calibration certifications will be maintained on file at the local 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.

7.2.7 Methods Used on Equipment

The laboratory will ensure that all methods used on analytical equipment, either newly purchased, or existing equipment that is significantly modified such that the change(s) affects the outcome of the test, or are to be used for new analytical applications, are properly validated prior to being placed in service for the BTP. Refer to the section on Method Validation for more details.

A laboratory may adopt a validated method which has been published as a standard or purchased from a qualified vendor (e.g., a complete measuring system to be used for a specific application). In both these cases, basic validation work has already been carried out. However, the laboratory must confirm its ability to apply the method. This verification requires that some experimental work be completed in order to demonstrate that the method works in the BTP.

Equipment/instrument method validations must be approved by the State Toxicologist prior to implementation. All equipment method validations will be performed by qualified personnel with adequate resources to perform the validation. Upon completion, documentation of the validation will be retained in the laboratory. The IDS Commander will prepare an IOC directed to the State Toxicologist, and QA Manager, as appropriate, advising them that the equipment method has been validated and is ready for use in calibration work. By signing and acknowledging the IOC, the State Toxicologist authorizes the placing of the equipment into service.

7.2.8 Responsibilities:

Technicians are responsible for:

- Performing assigned instrument verification and maintenance and will document all necessary information concerning verification and maintenance activities in the instrument records
- Ensuring that the equipment in use has been properly calibrated or verified prior to using for breath alcohol calibration functions
- Providing training opportunities to ensure users are authorized prior to instrument use
- IDS Commander/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 BTP Policy

- Ensuring external calibration companies are ISO compliant
- Ensuring that required calibration/verification and maintenance as outlined in the written procedures are carried out, and according to schedule
- Periodic review of 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 IDS Commander is responsible for:

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

7.3 TRACEABILITY OF MEASUREMENT STANDARDS

7.3.1 Policy

All calibration equipment/instruments used in the laboratories, 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 BTP will safely handle, transport and store these measurement standards in order to prevent contamination or deterioration and in order to protect their integrity.

7.3.2 Definitions

7.3.2.1 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.

7.3.2.2 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.

7.3.2.3 Certified Reference Material (CRM)

Certified Reference Materials (CRMs) are controls or standards used to check the quality and metrological traceability of products, to validate analytical measurement methods, or for the calibration of instruments. An example of such a CRM would be a NIST traceable thermometer or QAP solutions used in calibration.

7.3.2.4 Calibration Equipment

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

7.3.2.5 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.

7.3.3 Procedure

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

Vendors used for calibration or recertification of these standards shall be certified or accredited to ISO or other international/national standards.

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 by BTP Headquarters or the QA Manager.

7.4 OTHER DIVISION REFERENCE DATABASES

7.4.1 Policy

The FLSB maintains databases for the cataloging, storing and retrieval of quality and technical information. Access to these databases will be limited to BTP and 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 IDS Commander will designate an individual(s) for the management and administration of Program specific databases which include, but are not limited to the Breath Test Records Database.

7.5 MEASUREMENT UNCERTAINTY

7.5.1 Policy

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

7.5.2 Definitions

7.5.2.1 Accuracy

The proximity of a measured value to a reference value.

7.5.2.2 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.

7.5.2.3 Coefficient of Variation (CV)

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

7.5.2.4 Combined Uncertainty

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

7.5.2.5 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.

7.5.2.6 Precision

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

7.5.2.7 Significant Figures

Significant figures are 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.

7.5.3 Procedure

Measurement uncertainty 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 the 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/technician 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 BTP, the BTP Technical Manual details the procedures describing how measurement uncertainty is estimated and how it should be applied when reporting specific results.

The following are considered part of the procedure:

- a) the requirement that the specific measuring device or instrument used for a reported calibration result be included in or evaluated against the estimation of measurement uncertainty for that calibration method;
- b) limiting the rounded expanded uncertainty to at most two significant digits, unless there is a documented rationale for reporting additional significant digits, and that the rounded expanded uncertainty is reported to the same level of significance as the measurement result;
- c) the coverage probability of the expanded uncertainty is a minimum of 95.45% (often referred to as approximately 95%); and
- d) a review and/or recalculation of the estimation of measurement uncertainty is made upon completing the calibration certificate according to the breath test instrument calibration schedule.

The following records for each estimation of measurement uncertainty are retained by the BTP Program:

- a) statement defining the measurand;
- b) statement of how traceability is established for the measurement;
- c) the equipment or instrument(s) used;
- d) all uncertainty components that were considered;
- e) all uncertainty components of significance and how they were evaluated;
- f) data used to estimate repeatability, intermediate precision, and/or reproducibility;
- g) all calculations performed; and
- h) the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty (found on each calibration certificate).

The measurement uncertainty will be reviewed annually to verify it continues to be fit-for-purpose. Should changes be made to the method (e.g., reference materials, instrumentation, equipment or quality control procedures), the uncertainty budget will be re-evaluated and updated accordingly. Records of review and re-evaluation will be maintained by the QA Manager.

7.5.4 Reporting Measurement Uncertainty

When measurement uncertainty is required, the calibration record(s) must contain the measurement uncertainty or a reference to it. When this measurement uncertainty is of significance to the requestor, the range of values and the uncertainty will be reported with a stated confidence level.

8 PERSONNEL QUALIFICATIONS AND TRAINING

8.1 SCOPE

BTP management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. The BTP 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 non-commissioned BTP personnel. The PDF shall be retained in the employee's supervisory file and shall be updated as necessary.

The BTP 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 technicians, 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.

BTP Management will ensure that proper training occurs for all BTP personnel. In addition, each employee will share in the responsibility of maintaining his/her functional area expertise.

Various types of training opportunities are available for BTP personnel, including in-state and out-of-state workshops and seminars, professional meetings and conferences, 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 BTP will periodically provide in-service training opportunities for the purpose of exchanging technical information on techniques, legal challenges, policy changes and/or research developments.

Training needs of an employee may be identified through individualized training plans and goals, strategic plans, management requests and needs of the client agency. Requests for training shall be processed through the chain of command.

8.2 DEFINITIONS

8.2.1 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(s) shall include practical examination(s) that cover all aspects of calibration work performed, including issuing a calibration certificate, technical review and providing testimony. The competency test results are evaluated by the assigned trainer and supervisor.

8.2.2 Calibration Work

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

8.2.3 Trainee

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

8.2.4 Trainer/instructor

Trainers/Instructors interact with the trainee to teach one or more aspects of a technical procedure or administrative topic. Trainers/Instructors have the responsibility for ensuring the trainee successfully completes his/her training tasks. See the Trainer/Instructor Qualifications section below.

8.2.5 Training Manual

A 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.

8.3 QUALIFICATIONS OF PERSONNEL

All personnel assigned to the BTP must be competent, trained and supervised by competent staff to ensure that they conduct work according to the quality program of the BTP. It is the responsibility of the IDS Commander to demonstrate the competence of all personnel. There must be documented evidence of the training and qualifications for all personnel.

8.3.1 Educational Background

Minimum educational and/or other requirements for BTP personnel, including the IDS Commander, technical management and those performing specific calibration-related tasks, are found in *Appendix C*). Verification of educational requirements for personnel is under the purview of the Washington State Department of Personnel (DOP) and WSP Human Resource Division (HRD).

8.4 TRAINING

8.4.1 Training Goals

Forensic science demands highly skilled professionals. New employees must become qualified to perform competently in their assigned area of responsibility, and tenured employees must build upon their current knowledge and abilities in order to meet the challenges of a constantly evolving science. 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

8.4.2 Trainer/Trainee Method

The BTP 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 BTP training goals are met and that a feedback mechanism is in place.

8.4.3 Training Plans

Training plans will be developed for each new and permanent employee. The training plan for permanent employees is normally accomplished as part of their annual performance evaluation. Supervisors will work with each employee to develop a training plan, the plan forming the basis for the employee's professional development program. In developing the training plan, the supervisor must take into consideration the needs of the individual employee, the discipline, the BTP and the customer agencies.

Training plans will have clearly defined goals which are measurable in order to document progress and successful completion of the training module. Measurement tools will normally include but are not limited to scored examinations and/or competency tests.

Training plans should be updated annually during the employee's performance evaluation and may be adjusted as needed throughout the year. Supervisors must be actively involved in the employees' training, including documenting training events and training performance in the employee's supervisory file.

8.4.4 Training Manual

The training manual provides 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. Training shall include:

- The knowledge, skills and abilities needed to perform calibration work
- General knowledge of forensic science
- The application of ethical practices in forensic science
- Applicable criminal and civil law
- Procedures and practical training in courtroom presentation to the extent necessary based on job function
- Provisions for retraining
- Provisions for maintenance of skills and experience
- Criteria for acceptable performance needed to complete the training

The training manual will be used to develop training plans for employees, and will also be used as a guide when designing job performance improvement plans.

The training manual is developed by the section Supervisors and/or competent laboratory personnel, with input from BTP management. The State Toxicologist approves the final training manual. The training manual shall be reviewed annually by the Supervisors and/or QA Manager and updated as more current information and techniques become available. 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.

8.4.5 Training Program

8.4.5.1 Policy

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

8.4.5.2 Procedure

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

- **Assign Trainer/Instructor:** The trainee will work under the direction of a trainer/instructor, who is assigned by the Supervisor or IDS Commander. 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 IDS Commander. 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. BTP Management will be notified of successful completion of the training program
- **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 and documented. One example may be to provide a questionnaire to the trainee
- **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 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 through the chain of command to the IDS Commander for final authorization before the trainee can begin work in that defined area. The technician will be authorized to perform work, including technical review of calibration records and certificates, in only those areas in which he/she was authorized by the IDS Commander.
- **Training Records:** Training records of the trainee will be retained by the trainee and/or Supervisor

8.4.6 Trainer/instructor Qualifications

8.4.6.1 Abilities and Expectations

The trainer/instructor will be selected by the Supervisor and/or IDS Commander and should be able to demonstrate the following abilities:

- Have a thorough understanding of WSP structure, policies, and procedures, as well as the structure, policies, and procedures of the BTP
- Has experience or has demonstrated an ability to instruct others successfully
- Have an understanding and working knowledge of the current procedures, requirements, and expectations for the given discipline
- Be willing to standardize their instruction and training based on the training manual for the given discipline
- Be able to offer constructive criticism and positive reinforcement that is crucial to the trainee's learning process
- Be flexible and able to accommodate for differences in trainee learning styles
- Interact routinely, frequently, and one-on-one with the trainees to assess their understanding and mastery of the new discipline
- Record the trainees' progress with evaluations per BTP requirements
- Should possess those personal qualities that motivate the trainees and enable them to reach their maximum potential
- Have demonstrated good organizational, verbal and written skills
- Have management commitment to provide a quality training experience that does not allow the trainer to be pressured to rush the training process

8.5 JOB PERFORMANCE

8.5.1 Documenting Job Performance

Supervisors will document the work performance of each employee they supervise and maintain those records in an electronic supervisory file. The supervisory file 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. Training records will be maintained separately.

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

8.5.2 Re-Training

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

- Employees who were once qualified in the discipline but have not maintained the required competency or proficiency in that discipline

- Employees who 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

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

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

If a significant 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 BTP 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 document book.

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 IDS Commander 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.

Should the issue involve commissioned personnel the process established by their bargaining unit and contract will also be followed (*see the Collective Bargaining Agreements*).

8.6 PROFESSIONAL DEVELOPMENT PROGRAM

8.6.1 Training Resources

Available training resources include:

- Experienced BTP personnel
- BTP in-service training
- BTP 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

8.6.2 Continuing Professional Development and Maintaining Competency

All BTP personnel will strive to meet at least once annually to conduct BTP business aimed at scientific advancement, process improvement, solving technical problems, identification of relevant training needs and opportunities, and conducting in-service training. 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 FLSB's programs. FLSB management will support BTP meetings and endeavor to act on recommendations when possible.

The BTP will provide support to personnel who wish to pursue personal certification through a relevant professional organization.

Attendance at conferences and workshops sponsored by professional forensic organizations will be encouraged by the BTP, 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. The BTP will endeavor to send at least one technician to each of the annual conferences sponsored by the major professional forensic organizations with a level of financial support consistent with current resources.

8.6.3 Requests for Training

Refer to WSP Regulation Manual 10.12.020 TRAINING DIVISION for instructions on completing a Training/Travel Request (TTR, WSP Form 3000-320-016). The same form will be used for training requests for time only. The completed forms will be routed through the chain of command for approval. All education and training requests will 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.

Employees engaged in their planned training program in their laboratory generally do not need to submit Training/Travel Requests for the training modules in their program unless the above conditions apply.

8.6.4 Completion of Training

Refer to WSP Regulation Manual 10.12.020 TRAINING DIVISION for instructions on submitting a Report of Training using the TTR form. The completed form or certificate must be routed to the supervisor who will keep a record of completed training.

8.6.5 Laboratory Library

Each laboratory will have access to a library containing current books, journals, and reference materials for each discipline. Each technician 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 email 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 SharePoint.

8.6.6 Courtroom Testimony Training

BTP Management is responsible for ensuring that testimony training is provided to employees who testify in court. Topics such as presentation of evidence in court, chain of custody, calibration work results and interpretation of calibration results will be discussed during the training. This training can be given internally by a BTP or FLSB employee or by an external source. Documentation will be maintained for each individual with their regular training records.

9 ASSURING THE QUALITY OF CALIBRATION RESULTS

9.1 POLICY

The BTP is committed to providing the best quality service available to all members of the criminal justice system. 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 BTP may use, but is not limited to the following for monitoring the validity of tests and calibrations performed:

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

9.2 PROFICIENCY TESTING

The objectives of the proficiency testing program are to:

- Demonstrate the current competence of the technician
- 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

9.2.1 Definitions

9.2.1.1 Approved Proficiency Test Provider

An individual, organization or company that meets ANAB requirements to prepare and provide proficiency tests to participating forensic laboratories, in the forensic disciplines and scope for which the provider has been accredited.

9.2.1.2 Proficiency Test

A proficiency test is an internal or external test that is provided to evaluate the capability of technicians, technical support personnel and the quality performance of a laboratory.

9.2.2 Procedure

The BTP proficiency program will be directed by the QA Manager and shall be in compliance with ANAB requirements. ANAB approved proficiency test providers will be used where available. Before ordering proficiency tests, the supervisors may confer with QA and the IDS Commander to determine the numbers and types of tests needed. Proficiency tests should

primarily be in the same matrix as is used in calibration of the instruments (i.e. simulator solution). Proficiency tests in another matrix (i.e. gas cylinder) may be analyzed, in addition to tests in the same matrix as calibration.

Each technician within the BTP will successfully complete at least one internal or external proficiency test per year in the area(s) in which they perform calibration work. Further, each laboratory must annually complete at least one external proficiency test for each area in which it provides accredited services. Technicians will complete the proficiency test using a breath alcohol measuring instrument on which they have performed the job function being tested.

9.2.3 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.

For external proficiency tests, the BTP will use a proficiency test provider that is accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the APLAC MRA or IAAC MLA6 and has the applicable proficiency test(s) on its scope of accreditation. For internal proficiency tests samples, the BTP may use previously worked or older unworked commercially provided tests or external tests whose results were not submitted to the test provider by the due date. When a proficiency test sample is being used a second time for an internal proficiency, the technician performing the proficiency test must ensure the previously used test is in good condition and has not experienced severe environmental extremes. The BTP does not use internally created tests.

9.2.4 Proficiency Testing Process

Proficiency tests must be completed and the results submitted to the test provider within the timeframe imposed by the provider. The proficiency test will be assigned to the technician in a timely manner and completed 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. Because timeliness is essential to the overall success of the BTP Proficiency Testing Program, it is the responsibility of the technician assigned the test and the supervisors to ensure that this requirement is met.

The proficiency test will be completed in a similar manner as calibration work. The technician must perform the testing on the instrument for which they performed the QAP. The expected proficiency test results must not be known or readily available to the technician. The proficiency test results will be reviewed by a supervisor and QA before results are submitted to the test provider. The supervisor's review will be documented on the copy of the answer sheet with their initials and date.

The intent of the proficiency testing program is to identify individual technical issues and also systemic issues. If a supervisor identifies any issues with the results provided by a technician, it is incumbent upon the supervisor to bring the problem to the attention of the technician. The procedure used to resolve technical review conflicts in calibration work, as outlined in Section 9.2.7 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 supervisors will disperse the necessary tests to appropriate laboratories. The supervisors are responsible for assigning proficiency tests to their technicians as needed. The supervisors will ensure that appropriate proficiency test samples are obtained, assigned, and provided to each technician

with enough advance notice to allow completion and review prior to deadlines. The technician will document and report to their supervisor and the QA Manager if a proficiency cannot be completed by the deadline.

Copies of the answer sheets with the assigned technician's signature or unique identifier and other necessary paperwork for the proficiency test will be sent to the BTP supervisors. It is the responsibility of the supervisors to ensure that proficiency results are completed and returned to the test provider.

When the results of the proficiency tests are received from the provider, the QA Manager or designee will review the technician's and the provider's results. The technician'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 BTP Headquarters for at least one full accreditation cycle, a minimum of four years, and shall include all data and notes supporting the conclusions. Proficiency test records shall include:

- Proficiency test unique identifier
- How tests were obtained or created
- Discipline tested
- Written instructions for completion
- Identity of person taking the test and location where proficiency test was taken
- Due date and completion date
- Instrument printouts/reports
- Expected proficiency test results
- Copy of the proficiency test evaluation form
- An indication that the proficiency test provider results were compared and evaluated with the technician's reported results
- Any discrepancies noted
- Copy of the email and/or IOC that was sent to each technician providing feedback on their results as compared to the proficiency test provider results; and
- Details of corrective actions taken (when necessary)

9.2.5 Satisfactory Proficiency Test Results

Upon completion of the proficiency test, results will be submitted to the supervisor. When all technicians have submitted their results, the supervisor will review the technician responses and provide them to the QA Manager.

Once the proficiency test manufacturer issues a report of results for the proficiency test round (including individual test results from all participating laboratories), the QA Manager will provide the report to the supervisor. The supervisor will compare each individual technician's results to the test information on the proficiency test provider's report and the QA Manager will perform an independent verification of each technician's performance. The technician will receive feedback on his/her performance within two weeks of receipt of the provider's report.

Proficiency test criteria for acceptable results are as follows¹:

For consensus-based proficiency tests (e.g., Collaborative Testing Services 5681 Breath Alcohol Simulator Solution Analysis), technicians' results must be within $\pm 10\%$ or 2 SD of the consensus mean (whichever is greater).

For traceable reference material proficiency tests (e.g., Collaborative Testing Services 5691 Breath Alcohol Calibration Verification), technicians' results must be within $\pm 10\%$ or 0.005 g/210 L of the reported nominal quantity value (whichever is greater).

For internal tests (retests of proficiency test items previously analyzed), technicians' results must be within the criteria described above for consensus-based or reference material tests or within $\pm 5\%$ of the results from the technician performing the original analysis of the proficiency test item.

If the test results are satisfactory, the QA Manager will complete documentation of the satisfactory result in the records. Documentation of satisfactory completion will be issued to the technician by the supervisor. The supervisor will provide an email and/or IOC to each technician providing feedback on the technician's results

9.2.6 Proficiency Test Discrepancies

If there is a discrepancy between the technician's test results and the provider's results, the supervisor will request the technician perform retests of the proficiency test item(s), to be completed within two weeks of the retest assignment.

The QA Manager and the supervisor and/or IDS Commander will conduct a root cause analysis and determine a corrective action plan. The plan will include a timeline for implementation of corrective actions, and completion within 60 days. The corrective action plan may include removal of the technician from calibration work and remedial training. The supervisor will work with the QA Manager to prepare a report to the BTP Commander outlining the issues and the actions taken.

The proficiency test records will contain a record of the discrepancy between the technician's test results and those of the test provider. BTP Headquarters will retain complete records for the proficiency test program.

9.2.7 Proficiency Testing and Job Performance

Any problems identified from the review of a proficiency test, if reflective of difficulties with a technician's individual work performance, will be addressed by the supervisor and documented in the supervisory file. The supervisor may enlist input and assistance from BTP management, and other appropriate individuals. (See *Chapter 4.0 - Nonconforming Work and Corrective Actions*; and *Chapter 8.5 - Job Performance*).

9.3 TECHNICAL PROCEDURES AND METHODS

9.3.1 Policy

The BTP will use appropriate technical procedures and methods that have been selected and approved by the State Toxicologist, scientifically validated and/or accepted for use in the field of

¹ Derived from DRAFT (4/2022) *ASB 153 Standard Practices for Proficiency Testing for Forensic Toxicology Laboratories and Breath Alcohol Programs*.

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 BTP 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. Personnel participating in the development, modification, verification and validation of test methods must be authorized by the IDS Commander to perform this work.

9.3.2 Definitions

9.3.2.1 Laboratory Developed Methods

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

9.3.2.2 Method

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

9.3.2.3 Modified Method

Standard scientifically validated and forensically adopted methods that are used outside their intended scope, or have been amplified or modified.

9.3.2.4 Non-Standard Method

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

9.3.2.5 Performance Verification

Performance verification is a set of operations to determine if a piece of equipment or instrumentation is working correctly within manufacturer's specifications or BTP's specified parameters, or to determine if a validated method is fit for purpose and performing as expected; 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.

9.3.2.6 Validation

Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled and is fit for purpose.

9.3.3 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 new 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.

An additional criterion for the selection of a new technical procedure is general acceptance by those overseeing the breath alcohol calibration activities within the Program. Even though 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 the members of their detachments.

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

9.3.4 Method Validation

The BTP 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, and/or IDS Commander by qualified personnel with adequate resources to perform the validation. Results of the validation will be documented and archived. Documentation will 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.

9.3.5 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). Validation will be sufficient to ensure the reliability of the method against any documented performance expectations.

The BTP 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, prior to implementation in the laboratory. Such validations require an approved plan that:

- Establishes the required data
- Includes limitations of the method
- Specifies whether a currently validated method requires additional validation
- Includes direction for parameter evaluation and parameter acceptance criteria to determine if the method is fit-for-purpose prior to starting a method validation

Prior to implementation of a validated method that is new to the laboratory, the reliability of the method shall be demonstrated in-house against all documented performance characteristics of that method. 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 technician involved and the supervisor, and submitted to the QA Manager for review and approval. Effective communication among all personnel involved, including other technicians in the section and BTP 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 IDS Commander will decide if the method has been sufficiently validated and if it should be included in the Technical Manual or other official procedural manuals. Final approval of the method will come from the State Toxicologist. The method should be formatted in preparation for inclusion in a procedural or technical manual, following the document control process as outlined in Chapter 3.0 above.

9.3.6 Method Validation will include:

- **Reference standards and breath alcohol calibration samples:** 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 you are 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 measurement uncertainty 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:** Is the procedure sufficiently sensitive and does it bracket the expected or anticipated linearity? What are the detection limits of the method or instrument?
- **Literature research:** Review of publications, academic materials, safety procedures, protocols and manufacturer's specifications, etc. involving the technique or procedure being validated.
- **Technical review**

9.3.7 Performance Verification

Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use in the laboratory. A performance check tends to mimic an abbreviated validation and is meant to check the accuracy and reliability of equipment and methods.

Performance verifications must be completed for the following:

- Methods that have undergone validation and are to be implemented;
- Newly purchased equipment of similar make and model or operating on the same principles or basic technologies as other equipment already implemented and used in the BTP;
- Equipment transferred from one lab to another;
- Regular verification of equipment currently in use to ensure that the instrument/equipment continues to function to manufacturer's specifications and to in-house procedure specifications
- Previously validated methods (e.g., published standard methods) new to a laboratory;

Performance verification procedures:

- All verification results must be documented, maintained onsite, and will be subject to review during the annual internal audit.
- Verification must demonstrate that a representative set of reference materials has been carried through the process and yielded the expected results.
- The performance verification must have demonstrated in-house the reliability of the method against all documented performance characteristics of the method and shall be maintained for reference.
- 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 and precision studies to verify that the equipment or procedure is within previously established manufacturers or procedure. Specifications include estimates of measurement uncertainty for quantitative methods, as applicable.
- For equipment, a copy of the verification results and data must be kept in the equipment log for the life of the equipment.

Performance verification of equipment or a method that has already been validated involve:

- **Reference standards and breath alcohol calibration samples:** 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 and precision studies to verify that instrument or procedure is within previously established manufacturers or procedure specifications.
- Documentation that the equipment or method worked correctly within manufacturer's specifications or BTP specified parameters

9.4 DEVIATION FROM POLICY OR PROCEDURE

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

9.4.1 Definitions

9.4.1.1 Deviation

Deviation is a change or variation in a policy or procedure.

9.4.2 Policy

Any deviations from official BTP policy, rules or procedures must be approved in writing by the IDS Commander as appropriate. If calibration related deviation, the approval must be technically justified and documented in the calibration record, and approved by the State Toxicologist.

9.5 RESOLUTION OF ISSUES CONCERNING TECHNICAL PROCEDURES

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

Complex technical problems not resolvable by the Supervisor will be referred to the IDS Commander or QA Manager. The IDS Commander, with input from the supervisor 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.

10 CALIBRATION RECORDS, REVIEWS, AND REPORTS

10.1 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, deterioration or loss. Electronic documentation will be backed-up and shall 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.

10.2 DEFINITIONS

10.2.1 Administrative Documentation

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

10.2.2 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.

10.2.3 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 QAP File, and may include, but is not limited to:

- Calibration certificate
- Additional QAP documents (Review Form, Adjustment Record, software printout, As-Found test printout, if applicable)

10.2.4 Calibration Record

A calibration record is a collection of all the administrative and technical documentation, whether electronic or hard copy, pertaining to a breath alcohol calibration function that is performed by the laboratory. 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. This typically refers to an Instrument Record, and will include, but is not limited to:

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

10.2.5 Calibration Certificate

A technical record that is the final presentation of results produced through the Quality Assurance Procedure following technical/administrative review. The draft calibration certificate,

initially produced by the BTP technician, first undergoes technical/administrative review prior to being authorized/issued by an authorized BTP technician.

10.3 REVIEW OF REQUESTS

10.3.1 Policy

The BTP 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 customers' request.

10.3.2 Procedure

Requests for calibration services may be in the form of written or verbal communication. Requests for the QAP of instruments may be routine (e.g., scheduled and/or annual QAP) or ad hoc (e.g., customer request).

10.4 CALIBRATION DOCUMENTATION

10.4.1 Administrative Documentation

Administrative documentation shall 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.

10.4.2 Technical Documentation

Each page of the technical documentation shall have the following:

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

10.4.3 Calibration Certificate

Each calibration certificate shall include at least the following information:

- a title with "Calibration Certificate"
- the name and address of the laboratory where the calibration was carried out
- unique identification of the calibration certificate (combination of date of calibration, item calibrated and serial number; and if more than one calibration of the same item on the same day, also time); and on each page, as applicable, an identification in order to ensure that the page is recognized as a part of the calibration certificate, and a clear identification of the end of calibration certificate
- page number and total number of pages (a certificate is generally only a single page)
- a statement specifying that the calibration certificate shall not be reproduced except in full, without written approval of the WSP Breath Test Program

- the name and address of the customer
- identification of the breath test instrument and method used
- a description of, the condition of, and unambiguous identification of the item(s) calibrated
- the date(s) of performance of the calibration
- the calibration results with, where appropriate, the units of measurement
- the name(s), function(s) signature(s) or equivalent identification of person(s) performing the calibration and issuing the calibration certificate
- a statement to the effect that the results relate only to the items tested or calibrated
- the environmental conditions at facility where the calibrations were made that have an influence on the measurement results
- a statement that the measurements are traceable
- the measurement uncertainty as follows:
 - the uncertainty statement includes the measured quantity value (y), along with the associated expanded uncertainty (U), the coverage factor, and the coverage probability
 - the uncertainty statement is in the format of $y \pm U$ where the units of y and U are consistent
 - limits the rounded expanded uncertainty to at most two significant digits, unless the laboratory has a documented rationale for reporting additional significant digits
 - the rounded expanded uncertainty is reported to the same level of significance as the measurement result

10.4.4 Calibration (QAP) Files

Calibration files to be maintained include:

Quality Assurance Procedure (QAP) File – The BTP will prepare and maintain this file following the completion of an initial QAP. Once an instrument is transferred to a permanent training status, the QAP File will not be further maintained. The QAP File will include the following documents normally presented in this order:

- QAP Review Form – Draeger Alcotest 9510
- Calibration Certificate - Draeger Alcotest 9510
- Draeger Alcotest 9510 Calibration/Adjustment Record
- As Found printout (if applicable)
- Software verification printout (internal printer)
- Uncertainties Table

10.4.5 General Calibration Record Requirements

Calibration records to be maintained include:

Instrument Record - The BTP will prepare and maintain all original documentation related to a specific instrument. Each component of the Instrument Record may be maintained in a separate but designated place. The Instrument Record includes, but is not limited to, the following documents:

- QAP Printouts
- Instrument Status Report
- Simulator Thermometer Certification records
- Records of repairs and/or adjustments by Technicians
- Repair documentation provided by the manufacturer
- Breath Test Technician Affidavits (in accordance with CrRLJ 6.13)
- Copy of all relevant Simulator Solution Test Reports
- Dry gas change records

Calibration records to support a calibration certificate shall be such that another reviewer possessing the relevant knowledge, skills and abilities could evaluate what was done and interpret the data. A calibration certificate will be prepared for all calibrations that are completed. However, research activities, training exercises, and validation studies are examples of calibration work that may not require the preparation of a calibration certificate.

Handwritten documentation will be recorded using permanent ink.

Nothing in the calibration documentation may be erased or obliterated. Changes, additions, overwrites, or any other form of alteration must be initialed and dated by the person making the alteration. Whether hardcopy or electronic, any change made to completed calibration records shall identify the person making the change and when the change occurred. All versions of the calibration record will be maintained.

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

Observations, data and calculations must be recorded at the time they are made, and must be identified to the specific analysis or test. Dates must be recorded in the documentation to indicate when work was performed. If a full calibration or a QAP calibration level fails and is repeated, or if a new adjustment is performed, the date, reason, and the identity of who authorized this action shall be recorded as a Repair Record in Instrument Tracking.

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

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

Thermal paper generated by breath test instruments that could be affected by time or environmental conditions will be duplicated electronically (scanned or photocopied) and included in the calibration records following a check for accuracy and completeness.

Documentation of the technical and administrative review is discussed below.

10.5 CALIBRATION REVIEW

10.5.1 Policy

Each laboratory will ensure that calibration certificates are accurate and supported by the technical documentation, and that established policies and procedures are being followed. All calibration certificates and associated calibration documentation will be subject to technical and administrative reviews.

10.5.2 Definitions

10.5.2.1 Administrative Review

A review for non-technical matters of the calibration file and calibration certificate prior to release of the certificate to the customer.

10.5.2.2 Supervisory Review

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

10.5.2.3 Technical Review

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

10.5.2.4 Technician Review

A review of the calibration documents prepared by the technician prior to technical review.

10.5.3 Procedure

Review of calibration documentation by the technician and other personnel provides a quality check and verification of procedures and results.

10.5.3.1 Technician Review

Technicians will conduct a thorough review of their own work prior to a technical/administrative review. This review is done after all analyses are completed and the calibration certificate has been printed, where applicable. The technician has the primary responsibility to ensure that their certificate and calibration documentation are complete and of the highest quality. The final responsibility for the scientific findings in the certificate rests with the technician. The technician review is a complete review of the calibration file consisting of all the elements of the technical and administrative reviews. Such reviews include, but are not limited to:

- 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 technician'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

10.5.3.2 Technical/Administrative Review

Technical/administrative review will be the first review conducted on all calibration certificates and accompanying calibration documentation after the technician review and before the calibration certificate is issued and released. This is to ensure that the calibration documentation supports the conclusions stated in the certificate, and that it is free of omissions and errors. Personnel shall be authorized to conduct technical/administrative review by the IDS Commander based successful demonstration of competency, and expertise gained through training and work experience in the calibration of breath alcohol measuring instruments. The technical/administrative reviewer must not be the technician who completed the calibration work.

The technical/administrative reviewer shall evaluate the following :

- The procedures conducted were appropriate to satisfy the service provided
- Documentation supports the results stated in the certificate
- All relevant calibration information is included
- The certificate being released correctly and completely reflect the results
- All procedures, data, and results are documented
- Established procedures were used and test parameters were appropriate for the examination
- Any deviations from established procedures are recorded in the calibration record with adequate justification/foundation for the deviation
- The certificate does not contain misspelled words or grammatical errors
- Values and computations are recorded correctly
- Appropriate standards and controls were used when necessary and documented
- All strikeouts or insertions were noted with the technician's initials and date. No obliterations are present
- All pages of the calibration documentation are labeled with the calibration number/unique identifier, dates, and technician's handwritten initials

All changes made to technical records as a result of technical/administrative review will be tracked to include what changes were made, when, and by whom. This is done by saving all calibration draft certificates and technical records that show changes resulting from technical review, to include who made the changes by their initials and date.

An approved review checklist (Quality Assurance Procedure Review Form) will be used to facilitate the review process and retained in the calibration file as administrative documentation.

The technician must address all the observations and recommended corrections of the technical/administrative 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 3.0 Control of Non-conforming Work*). The Supervisor and/or QA Manager will evaluate the concerns, and if appropriate, notify the IDS Commander.

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

The technical/administrative review process is vital to the continued success of the BTP. Review is a normal job function of all technicians 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 or certificate and will be held accountable.

Errors discovered after the review process may be addressed by corrective actions and/or amended certificates that involve both the originating technician and the reviewer.

Technical /administrative reviews will be documented with the reviewer's signature/initials and date on the certificate and on the review form. 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.

10.5.3.3 Authorization/Issuing of Calibration Certificate

Only after a calibration certificate has been technically and administratively reviewed can it be authorized/issued (reported to the customer). The person authorizing the certificate will review the calibration certificate and calibration record prior to authorizing the certificate. The review will be documented on the review form and by their authorizer/issuer signature and date on the final certificate. All personnel who authorize/issue a certificate will meet appropriate educational requirements (baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science) and be authorized by the IDS Commander.

The calibration certificate is provided to the customer by posting on WebDMS by staff at IDS headquarters. If a customer requests an endorsed certificate, one can be produced by photocopying the certificate onto paper bearing the endorsement watermark. The watermarked certificate shall make clear that there is no implication that the accreditation body accepts responsibility for calibration results nor that a product, process, system or person is approved by the accreditation body.

10.5.3.4 Supervisory Review

A supervisory review may be conducted on the calibration file after the issue and release of calibration certificates, including amended certificates and proficiency test answer sheets, to maintain oversight of laboratory operations. The supervisory review is designed to ensure that:

- The certificate or proficiency test answer sheets are being released correctly and completely reflect the results
- The certificate or proficiency test 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, and is uniquely identified according to laboratory policy
- A technical/administrative review has been completed and is documented on the certificate or answer sheet
- Proficiency tests contain a clean copy of the answer sheet and has been fully completed and is free of errors (to be sent to the proficiency test provider)

The supervisory reviewer does not have to be technically proficient in BTP calibrations and can be personnel designated by a supervisor.

10.6 AMENDED RECORDS AND CERTIFICATES AFTER ISSUANCE OF CERTIFICATE

10.6.1 Amended Worksheets/Records (non-Certificates)

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

If the complete QAP 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.

10.6.2 Amended Certificates

Once the certificate has been issued, amendments shall only be made in the form of a new document; an amended certificate. The amended certificate must include the statement: "Amended Calibration Certificate, and the date of amendment. The amended certificate must be uniquely identified and reference the original certificate. This is done through the serial number of the instrument and the date of the QAP. The amended document will have a completed Calibration Certificate Amended Document Record form, approved by the QA Manager, attached to it.

10.6.2.1 Procedure

- The handwritten correction is made to the original certificate, with the initial and date of the Technician 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 their review and approval by initialing and dating the hand-amended certificate.
- If it is determined that the amendment is the result of a nonconformity, follow the procedures in Chapter 4 – Control of Nonconforming Work. These issues must be addressed to the satisfaction of the IDS 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 amended certificate, followed by the marked original certificate, and the Calibration Certificate Amended Document Record form will be added to the appropriate instrument record (in that order).

10.7 RESOLUTION OF TECHNICAL DIFFERENCES OF OPINION

Possible substantive non-conformities (*see Chapter 4.0*) or recurring non-conformities discovered during technical reviews are to be brought to the attention of the QA Manager through the chain of command as soon as possible. The corrective action process will be followed.

Disagreements may sometimes arise between the technician 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 calibration documentation, further work to clarify issues, or further work to complete the calibration work. If there are unresolved differences during the review, the supervisor will be consulted to resolve the differences.

10.8 FOCUSED CALIBRATION WORK REVIEW

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

10.8.1 Review of affected calibration work

The focused calibration work review will be conducted by an appropriate supervisor or panel chosen by the IDS Commander. 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 IDS Commander.

10.8.2 Notifications

The QA Manager or designee will notify ANAB within 30 days of the initiation of a focused casework review.

Disclosures to prosecuting attorneys and the judiciary will be in accordance with WSP Regulation Manual section 6.01.065.

10.8.3 Removal from and reinstatement to calibration work

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

11 COURTROOM TESTIMONY

Providing testimony in a legal context is one of the most important responsibilities for BTP personnel. Employees must approach this responsibility with sincerity, honesty and diligence. Testimony is a significant part of the employee's responsibility and will be subject to the same quality assurance standards as other aspects of their work.

BTP personnel will not be advocates for either side but rather advocates for the evidence and/or scientific work. Testifying in a court, telephonically or for a deposition will be limited to the policies, procedures, results, training and expertise of the employee. Most often requests for appearance will be through a subpoena. All legal subpoenas will be honored for appearance as directed, regardless of the party issuing the subpoena. Reasonable effort should be made to comply with requests for appearance regardless of whether a subpoena is received or not, as this is the legal culmination of the program responsibilities.

Subpoenas received that pose a scheduling conflict with the employee must be resolved. Resolution is generally done via conversations between the employee and the person issuing the subpoena.

11.1 COURT TESTIMONY MONITORING

The testimony of each breath test technician must be monitored and technically reviewed by their immediate supervisor or designee at least once during the year. Personnel performing technical review of testimony must be competent and authorized to perform this review. Documentation will be completed and maintained.

11.1.1 Employee Requirements

Ideally, prior to going to court to testify, it is the responsibility of the employee to inform their supervisor. This may be done by personal contact, phone or email.

11.1.2 Supervisor Requirements

If the employee's testimony was directly observed, the employee should be given feedback through their supervisor on the positive aspects of the testimony as well as the areas that need improvement. If court testimony was not directly observed, the supervisor may consult with an officer of the court who was present for feedback on the employee's participation. Alternatively, a transcript of the employee's testimony may be obtained for review. Information received in this manner will be shared with the employee. The technical content of the employee's testimony must be reviewed by personnel meeting competency requirements, as described in 8.2.1.

Written evaluations will be provided to employees and discussed and signed as soon as practical. Records of testimony monitoring shall be retained not less than one full accreditation cycle.

It is the responsibility of the supervisors to ensure that testimony of all technicians they supervise be evaluated and documented yearly, provided that they testified during that year.

11.1.3 Evaluation Criteria

Evaluation criteria may include:

- Communication Skills
 - Maintains eye contact with the judge or jury
 - Speech is clear, concise, and understandable
 - Posture is open and approachable
- Demeanor
 - Demeanor is polite, professional, and non-argumentative
- Objectivity
 - Answers questions directly
 - Does not speculate
 - Does not show any bias
 - Impartial and not an advocate
- Appearance
 - Demonstrates a clean and well-groomed appearance
 - Clothing is appropriate for a formal appearance in court
- Technical knowledge
 - Limits answers to area of expertise
 - Demonstrates knowledge of the subject matter
 - Is able to translate complex scientific principles into lay terms
 - Testimony is accurate, properly qualified and supported by the calibration record
- Other relevant comments

11.2 TESTIMONY REVIEW AND JOB PERFORMANCE

Any problems identified from the review of testimony will be addressed by the supervisor and documented in the employee's supervisory file. The Corrective Action process will be implemented as warranted.

The nature of any corrective actions taken should be consistent with the severity of the problem and aimed at the professional development of the employee. Any Job Performance Improvement (JPIP) plans should include remedial training, and progress must be measured at frequent intervals. Progress, as well as any continued problems, must be documented in the employee's supervisory desk file.

Employees experiencing significant problems in providing competent testimony based upon deficiencies in technical training, errors in calibration work, or other major difficulties shall be removed from calibration work until the matter is resolved.

12 RESEARCH PROJECTS, PUBLICATIONS AND PRESENTATIONS

12.1 POLICY FOR RESEARCH PROJECTS

All research projects employing the use of laboratory resources will be reviewed and approved by the IDS Commander 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.

12.2 PROCEDURE FOR RESEARCH PROJECTS

Prior to beginning any research study, a research plan, including experimental design, will be prepared by the technician and submitted up the chain of command to the IDS Commander, QA 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 technicians in the section and BTP management, will be accomplished through verbal or written communications.

Where applicable, the research plan shall follow the same criteria as those listed in Chapter 9.3 for developmental or non-standard method validation.

12.3 POLICY FOR MANUSCRIPTS AND PRESENTATIONS

All original research or presentations given to peers at conferences, professional meetings or for publication must receive a technical peer review and be approved through the chain of command to the IDS Commander prior to presentation or submission for publication. This policy applies specifically to situations where the BTP is mentioned in manuscripts for publication or presentations, when the author is a representative of the BTP, or when the research or preparation for the presentation occurred on duty time. It is the responsibility of the IDS Commander to ensure all presentations from their laboratory have been approved. Final approval will come from the QA Manager or the IDS Commander.

12.4 PROCEDURE FOR MANUSCRIPTS AND PRESENTATIONS

The final draft of the manuscript should be submitted to BTP management for review via the technician'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 BTP management for review via the technician's supervisor approximately 5 working days prior to the scheduled presentation.

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

- The review of the final draft of the manuscript/presentation will focus on the following topics: Accuracy of the data and conclusions. Does the data in the manuscript/presentation support the conclusions?
- Proofing of mathematics, spelling, grammar and punctuation

Feedback will be presented directly to the author in 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 to attorneys, law enforcement agencies and other personnel for training purposes must be technically reviewed and approved through the chain of command.

Informational presentations to the public (schools, Rotary, etc.) do not require technical review, but do require supervisor notification and approval.

PowerPoint presentations which have been approved in the past will be posted on the FLSB SharePoint for use by BTP personnel in preparing other similar presentations. 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.

13 LABORATORY SPACE AND SECURITY

The security of equipment, supplies, records and personnel are of high priority to the WSP. Effort will be made to ensure the security of all offices and facilities used by employees within the BTP. Security of facilities helps to enhance the credibility and confidence that can be placed in services provided by the BTP.

The BTP shall maintain secure facilities into which only authorized personnel are allowed access. The manner in which security is maintained, either by lock and key or security codes, shall be determined and ensured by section supervisors.

The safety and wellness of Laboratory personnel is also of high priority. The Laboratory will maintain a health and safety program, established to safeguard employees from service-related injury and health problems.

13.1 SPACE

In order for the personnel within the BTP to efficiently carry out their goals and objectives, adequate and proper space should be allocated for each laboratory activity and function.

Each employee should have enough working space to efficiently accomplish assigned tasks without the risk of mishandling or contaminating materials and/or equipment. All employee and general laboratory working areas should have sufficient storage space for proper storage and handling of individual and general laboratory supplies, equipment and tools. In addition to the space needed for technical work, there should be sufficient space for writing reports, reviewing documentation, working at the computer, filing cabinet storage, water supply, etc.

The laboratory will have space designated for the safekeeping of official records and reports as well as space for reference materials, books, and other documents necessary for carrying out the functions of the laboratory. In addition, proper and sufficient space will be provided for long-term storage of any volatile and hazardous materials.

The BTP will take measures to ensure good housekeeping in all laboratories.

13.2 SAFETY

In addition to implementing a health and safety program, the IDS Commander will designate personnel to serve as safety officer(s). The safety officer(s) will ensure compliance with chemical hygiene and workplace safety by providing current information, and monitoring the use of chemicals and other hazardous processes.

The safety officer(s) have delegated authority from the IDS Commander to carry out their duties. BTP Management has ultimate responsibility for the health and safety program and will draw upon the safety officer(s) and their designees for technical support and assistance.

13.3 SECURITY

Security at BTP facilities shall be ensured through a lock and key, proximity card or combination lock system that ensures only authorized personnel have access.

13.4 PROCEDURE

Each laboratory facility shall define their areas of accessibility and have guidelines that govern accessibility to those areas. Laboratories differ in design, consequently some areas may, out of necessity, be used for several purposes. The laboratory's security measures must account for multiuse areas and develop procedures to ensure proper security. In general, guidelines should consider the following types of areas:

- Public Area: An area such as a lobby, common hallway, conference room, or restroom which may be accessed by members of the public during business hours without escort.
- Work Area: An area designated for responsible employees to perform their assigned duties.

13.4.1 Securing the Laboratory

BTP Lab exterior doors will be kept secure when the lab is not occupied by authorized personnel.

13.4.2 Keys, Proximity Cards, and Combinations

Where applicable, supervisors will issue laboratory door and alarm keys or proximity cards, and combinations or codes to employees. Key and proximity card logs will be maintained in accordance with departmental regulations by appropriate personnel, and combinations will be changed as needed to ensure that only authorized individuals have laboratory access. Keys and proximity cards may not be duplicated or loaned, and combinations or codes may not be divulged to unauthorized personnel.

The supervisor or designee shall maintain an inventory of keys, proximity cards and combinations for the laboratory facilities. Audits of these inventories will be conducted each calendar year by each person responsible for maintaining each inventory and a copy of each verified inventory shall be provided to the IDS Commander.

Entrance/exit points and internal areas requiring additional limited/controlled access will have a separate lock system. Access to these areas will be restricted to certain employees, on a routine or limited basis, and such access will be determined and documented by the IDS Commander or designee.

13.4.3 Visitors

All visitors (non-departmental) to the laboratory will sign in and be escorted by authorized personnel while within secured work areas.

Approved, non-departmental janitorial personnel will not be required to sign in and will not require an escort. They will work only during normal business hours, and only in areas occupied by laboratory personnel.

13.5 INTERVIEWING EMPLOYEES

Interviews of employees by media, attorneys, or others as deemed appropriate, are allowed only insofar as the employee agrees to be interviewed and the interview process does not have a deleterious effect on the laboratory's efficiency and resources. Interviews will conform to the following standards:

- Interviews of employees will be prescheduled and conducted with minimum impact to employees' work assignments
- All interviews will be conducted in a courteous and professional manner
- A maximum of two hours will be allowed for any interview. If additional time is needed, a second interview may be scheduled or additional time may be arranged.
- Employees have the authority to stop or pause an interview for a rest break, or if they become uncomfortable for any other reason
- Employees may consult with their supervisor or IDS Commander at any time, and may opt to terminate an interview if appropriate
- The employee may request legal representation to be present.

13.6 SECURITY OF VOLATILE CHEMICALS

Responsibilities of employees within the BTP involve the use of volatile chemicals, including ethanol and acetone. Volatile chemicals will be stored within the secure offices or laboratories of the BTP, according to NFPA and manufacturer recommendations.

Program supervisors shall ensure that the security of volatiles and their documentation are maintained by all subordinates.

14 APPENDIX A: ROOT CAUSE ANALYSIS

Root cause analysis (RCA) is used to define, evaluate and systematically analyze a problem to determine the underlying factor(s) or reason(s) for the problem in order to focus on prevention and continued improvement of the system or process. It is important to realize that a root cause analysis is an event review, not a performance evaluation, and the purpose is learning, not punishment. Accordingly, personnel and disciplinary issues should be handled through a separate process from RCA.

14.1 JUST CULTURE

The BTP embraces a method of root cause analysis that creates a “just culture”. A “just culture”:

- Is a culture of learning
- Recognizes that competent professionals make mistakes, but holds individuals accountable for reckless behavior. Holding people accountable by punishing them for human error is not going to advance the culture of learning.
- Balances blame-free event reviews with the need for professionals to be personally accountable for adherence to reasonable standards of professional conduct
- Balances an open and honest reporting environment with a quality learning environment and culture
- Fosters learning that will embed knowledge (lessons-learned) that may help prevent similar problems from occurring in the future
- Fosters continuous improvement

Root cause analysis may be the most difficult part of establishing proper corrective actions following the reporting of a nonconformity. By becoming skillful at investigating and solving problems of nonconformity in their work, a laboratory will ultimately need to conduct fewer investigations. But if done inappropriately, a root cause analysis investigation may lead to the inadvertent blame of individuals instead of identifying where a work process has broken down. Such blame will be detrimental to encouraging participation in the root cause analysis process.

The purpose of an RCA is to find out what happened, why it happened, and determine what changes need to be made to mitigate the identified causes of the problem and reduce the likelihood of recurrence.

RCAs are conducted by the individual(s) assigned by QA as the investigator. RCAs may be performed by a team, Technical Lead, Supervisor, Lab Manager and/or other subject matter expert. The number of participants conducting the RCA may vary depending on the nature of the nonconformity.

14.2 PROCEDURE

Step 1: Identifying the Problem

The event, or nonconformance, should be clearly defined and analyzed for its causal factors.

This entails a detailed review of the event by the investigator. The analysis and review is conducted to identify problems – what went wrong, what is the problem? The investigation normally begins with the objective stating of the problem. The problem statement is a concise, complete, and accurate single sentence describing what the problem or nonconformity is. Examples include but are not limited to:

- the proficiency test was not passed;
- the calibration file is missing documentation;
- the wrong individual was identified;
- the sample was contaminated; and
- the results from a different case were reported.

The problem statement should objectively state what went wrong, not why, or how. A good problem statement will facilitate a more thorough examination of the problem.

One tactic in formulating a problem statement is to work backwards from the point of not meeting a known policy, procedure, goal or objective of the organization. When a determination of what objectives were impacted is completed, the problems affecting the objectives may be more discernable and the problem statement more readily drafted.

Collect and organize the facts surrounding the event to understand what happened. It is often helpful to create a detailed timeline of events pertaining to and leading up to the nonconformance. The investigator should consider reviewing equipment logbooks, instrument data, calibration files, procedures and policies, previous occurrences and any trends.

The investigator should interview personnel involved. It is important to get the perspective of people personally involved in the event since people naturally see and interpret things differently. Bring all parties involved in the problem in early so it fosters the non-punitive and problem solving nature of RCA investigations. Keep it transparent, focused, simple, and engaging. It may be helpful to provide a brief review of the process before starting the interview or discussion.

Step 2: Identify Root Causes

In this step, the investigator determines why something went wrong. The contributing factors, situations, circumstances or conditions that led to or increased the likelihood of the event are identified and analyzed. In this step, the investigator must be both focused and open-minded.

A thorough analysis of contributing factors leads to identification and understanding of the underlying process and system issues (root causes) of the event. Contributing factors are not necessarily the root causes. The investigator must examine the contributing factors to find the root causes. A timeline should be used whenever possible as the basis for identifying all contributing factors. When identifying contributing factors, be careful to avoid “hindsight bias.” Knowing the eventual outcome of a timeline can influence how the investigator views activities leading up to the event. The

investigator should consider only those factors that were actually present and known to those involved at the time, not what was only realized after-the-fact.

The investigator must determine if they've truly identified a root cause, versus a contributing factor which would require more digging. Ask the following questions for each potential root cause identified:

- Would the event have occurred if this cause had not been present?
- Will the problem recur if this cause is corrected or eliminated?

If the answer is NO, then the investigator has identified a root cause. If the answer to any question is YES, then the investigator may not have identified a true root cause and needs to ask more "why" questions. Continue asking these questions until you get to root causes. There may be multiple root causes.

The investigator should not make judgments about whether an individual did the right thing. This judgment is to be made by the supervisor and manager responsible for evaluating the employee's performance.

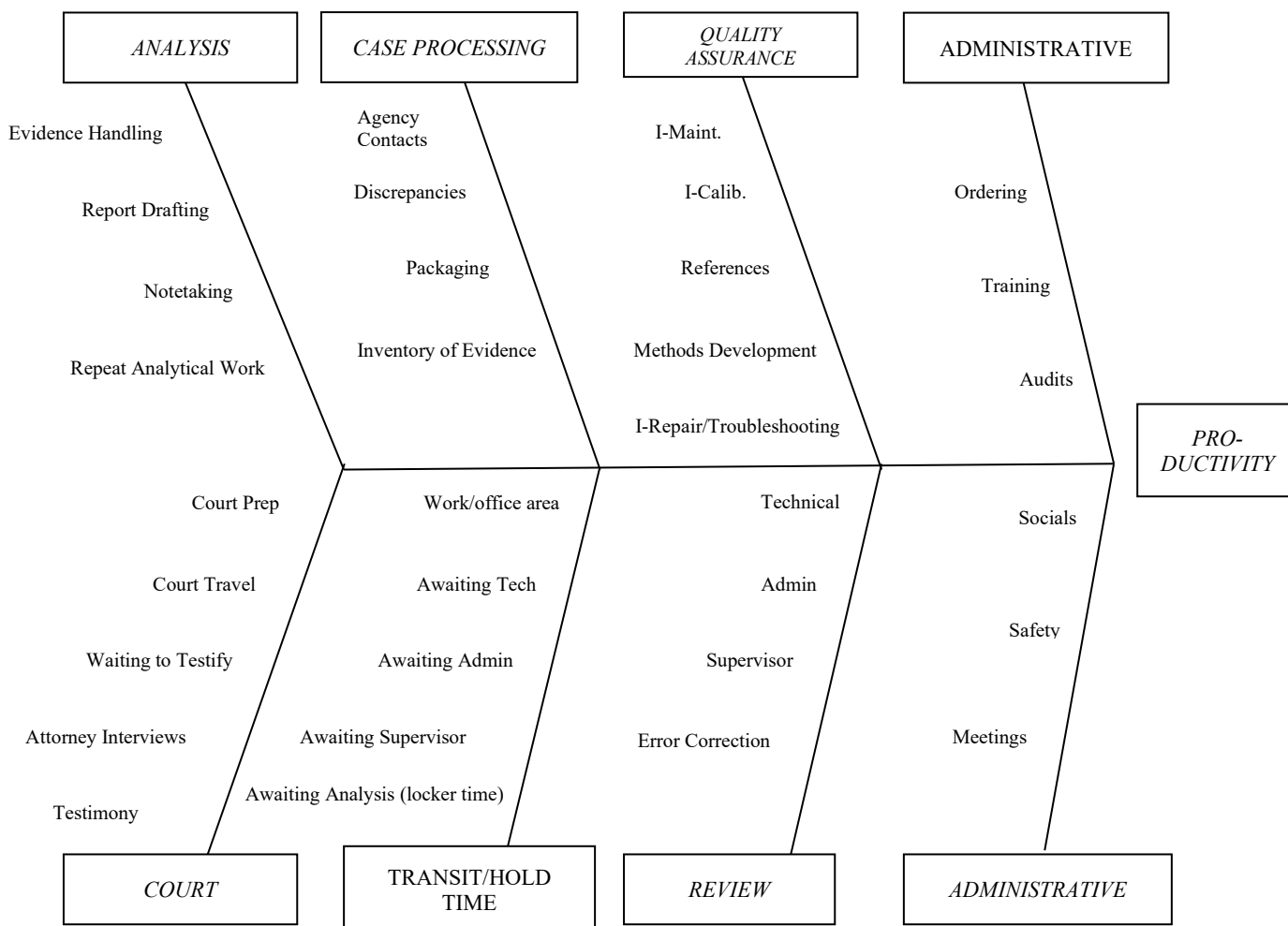
At least one of the RCA tools mentioned below must be used.

RCA Tools

There are various approaches to RCA and some may be more effective than others depending on the nonconformity. Brainstorming and creating a cause and effect diagram are two such tools to determine problem statements and root causes. Using a cause/effect diagram while brainstorming possible causes to a problem helps one to focus on the various possibilities. This "Cause Mapping" can be used as a visual technique for capturing the cause and effect relationships in order to lead one back to the root cause(s). First identify the effect (problem statement), then list all possible causes. Some useful categories of causes include:

- People (health, training/skills, time management, knowledge of policies and procedures, etc.)
- Materials and supplies (lack of correct/complete forms, lack of appropriate containers, improper packaging, etc.)
- Procedures/methods (incorrect order of steps, incorrect application of procedure, etc.)
- Environment (HVAC failure, freezer water pipe burst, etc.)
- Equipment/instruments (ran out of gas, CE shut down, etc.)

Below is an example of a cause and effect "fishbone" diagram (I = Instrument):



Another common RCA tool is “5 Whys”. Starting with the problem statement, the investigator asks “Why (did this process fail)?” repeatedly until the root cause is identified. This questioning process is continued until all the root causes are found. The “5 Why’s” process can also be used as part of a cause and effect diagram as discussed above. It is common to find the same root cause for two or more contributing factors. For example:

Problem statement: Analysis of an evidence item was not completed by the deadline.

1. Why? The instrument failed to complete the run.
2. Why? The instrument ran out of carrier gas.
3. Why? The tank of carrier gas emptied mid-run.
4. Why? More gas was not ordered.
5. Why? An employee forgot to order more gas.

Three basic types of root causes are:

1. Physical causes – Tangible, material items failed in some way (e.g., the GC stopped working).
2. Human causes – People did something wrong or did not do something that was needed.
Human causes typically lead to physical causes (e.g. the GC ran out of carrier gas).
3. Organizational causes – A system, process, or policy that people use to make decisions or do work, is faulty (e.g. the employee did not receive instruction on how to order more carrier gas).

Each root cause must be addressed in the corrective action plan.

Step 3: Develop a Corrective Action Plan (CAP)

The RCA is shared with the individual assigned the CAP by QA, which may or may not be the individual assigned the RCA. The CAP will include the result of the RCA, corrective/preventive actions, and a timeline to implement the plan and report results of the implementation. The investigator should make specific, prioritized recommendations for preventive actions that are intended to prevent occurrences of similar events. These recommendations will be made in writing and submitted to the individual assigned the corrective action plan if different from the investigator.

To create the CAP, prioritize the factors that contributed to the nonconformance, evaluating both their severity and the probability of recurrence. The CAP will describe corrective actions (including preventive) that respond to the prioritization and likelihood of repetition of the root causes. Choose actions that address each root cause. These actions will generally require creating a new procedure or making a change to a current process.

When developing corrective actions, consider questions such as:

- What safeguards are needed to prevent this root cause from happening again?
- What contributing factors might trigger this root cause to reoccur? How can we prevent this from happening?
- How could we change the way we do things to make sure that this root cause never happens?
- If an event like this happened again, how could we stop the accident trajectory (quickly catch and correct the problem) before its severity escalates?

Aim for corrective actions with a stronger or intermediate rating, based on the categories of actions below. Corrective actions that change the system and do not allow the errors to occur are the strongest.

Stronger Actions

- Change physical surroundings
- Testing of equipment before purchasing
- Engineering controls into system (forcing functions which force the user to complete an action)
- Simplify process and remove unnecessary steps
- Standardize equipment or process

Intermediate Actions

- Make software enhancements/modifications
- Eliminate or reduce distractions
- Create checklist or other cognitive aid
- Eliminate look alike and sound alike terms
- “Read back” to assure clear communication
- Enhance documentation/communication

Weaker Actions

- Double checks
- Warnings and labels
- New procedure/policy
- Training
- Additional study/analysis

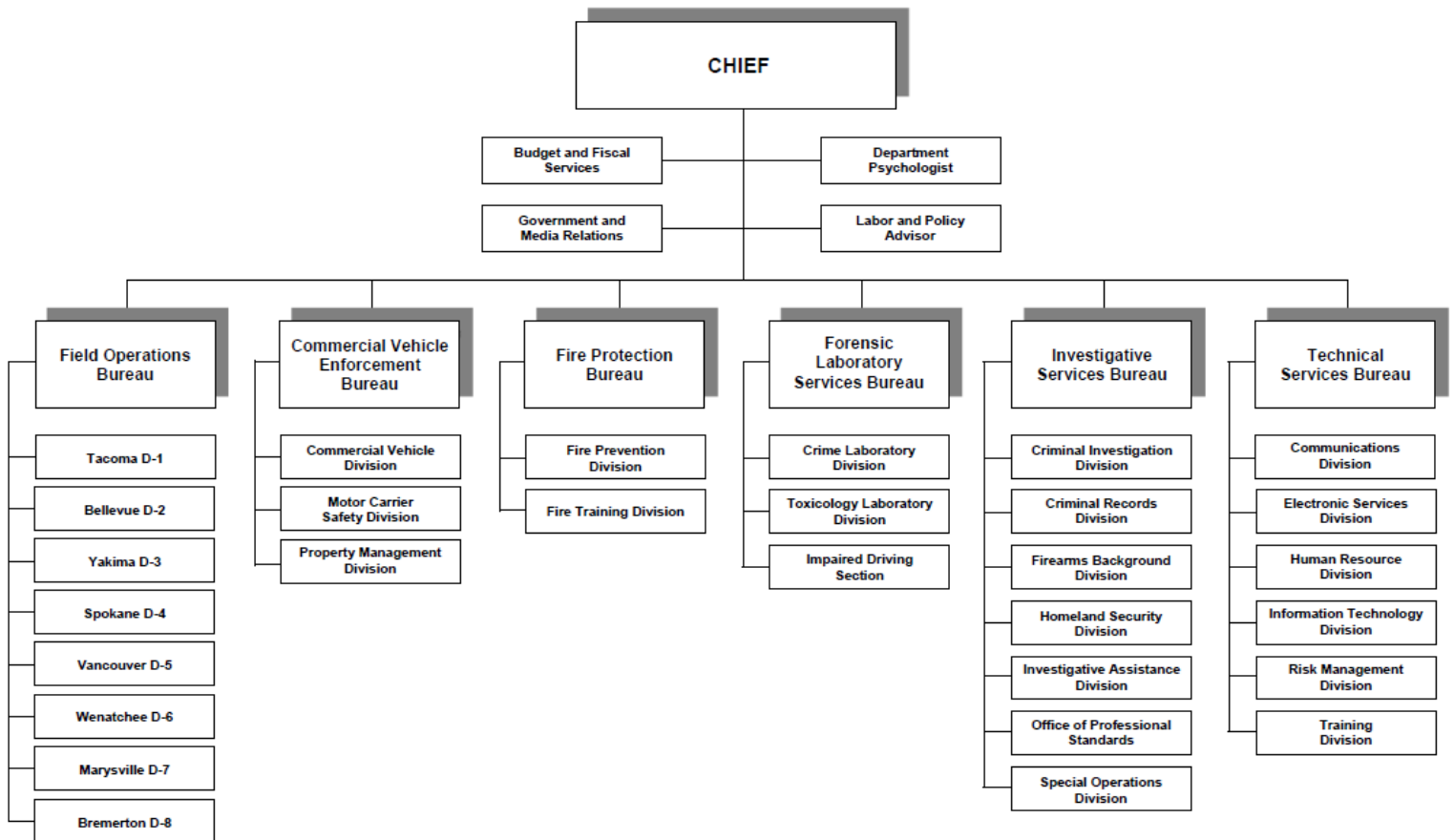
If a particular action cannot be accomplished due to current constraints (e.g. lack of resources), the person investigating or individual assigned the CAP should look for other ways of changing the process to prevent a similar event from occurring in the future. Doing nothing should not be an option.

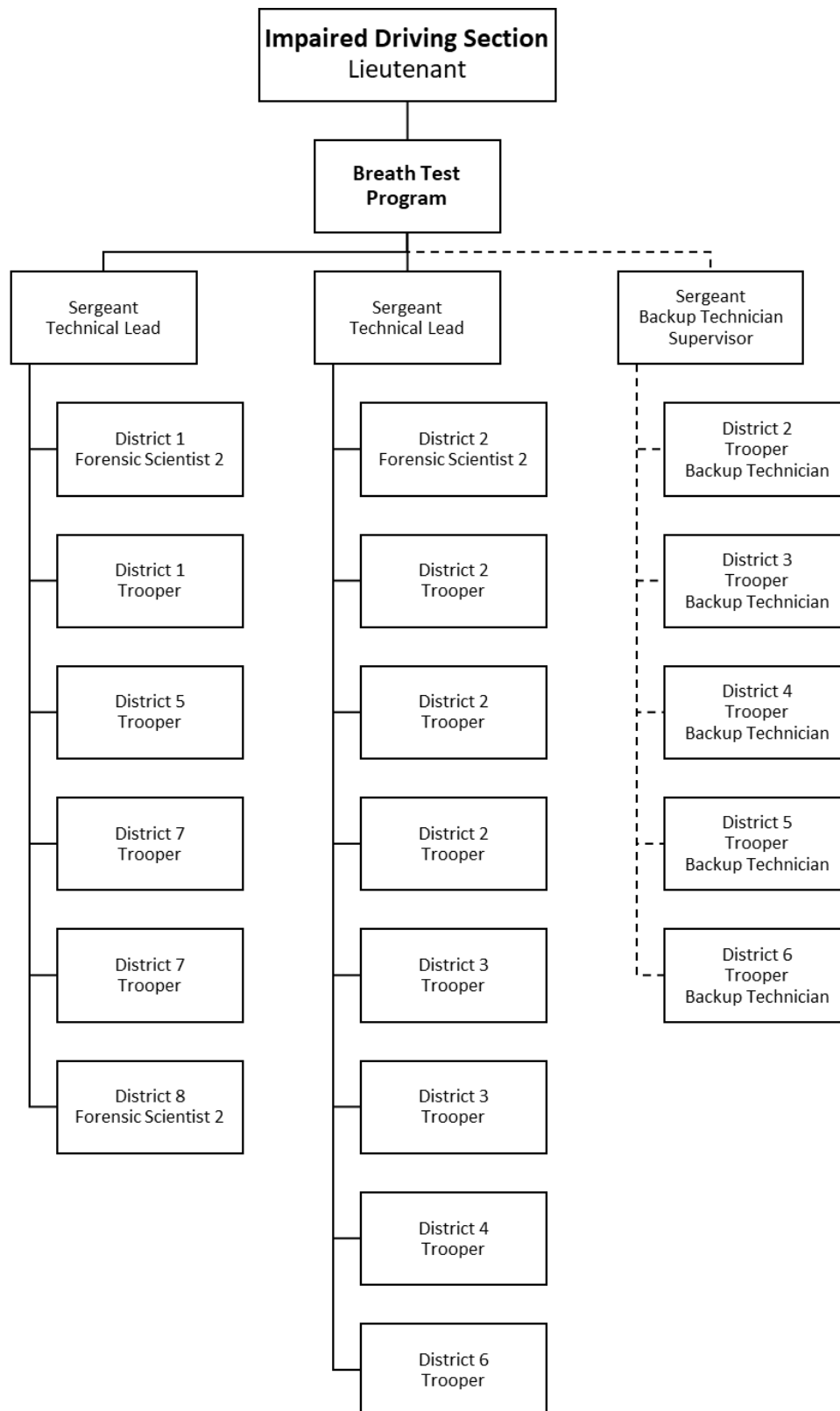
When developing corrective action plans, clearly state what is to be done, by whom, and when. Satisfactory implementation of the corrective action plan will be monitored so it is important to have clearly defined plans with timelines.

Step 4: Evaluation

Corrective actions will be monitored through annual internal audits or as detailed in the CAP. Was the CAP properly implemented and effective? This evaluation is summarized in the Corrective Action Report.

15 APPENDIX B: ORGANIZATIONAL CHARTS





16 APPENDIX C: MINIMUM JOB REQUIREMENTS

FORENSIC SCIENTIST

- Required: A baccalaureate or an advanced degree in a chemical, physical, biological or forensic science.

BREATH TEST TECHNICIAN

- Possess a high school diploma from a state sanctioned and recognized school, GED, or associates or higher from an accredited college
- Commissioned Trooper or Forensic Scientist
- Basic knowledge of math, statistics, chemistry, biology, physiology, and electronics
- Completion of evidential breath test instrument training program including Technician, Instructor, and External Standard Changer training.
- Desirable: Bachelor of Science degree in one of the natural sciences
- Desirable: Field experience with the Breath Test Program

BREATH TEST PROGRAM SUPERVISOR

- Possess a high school diploma from a state sanctioned and recognized school, GED, or associates or higher from an accredited college
- Commissioned officer having the RCW rank of Sergeant
- Completion of evidential breath test instrument training program including Technician, Instructor, and External Standard Changer training
- Desirable: Bachelor of Science degree in one of the natural sciences
- Desirable: Field experience with the Breath Test Program

IDS COMMANDER

- Possess a high school diploma from a state sanctioned and recognized school, GED, or associates or higher from an accredited college
- Is a commissioned officer and selected from the RCW Lieutenant's eligibility register, or
- Is currently an RCW Lieutenant with at least eight (8) years of commissioned experience, and is selected to perform lieutenant's duties; and
- Has demonstrated his/her capabilities through the selection process to perform in this capacity

- Desirable: Can effectively communicate orally and in writing; be able to speak to wide variety of audiences such as command staff, legislative committees, at Washington Impaired Driving Advisory Council meetings, and SAF.

17 APPENDIX D: QUALITY AND OPERATIONS MANUAL HISTORY

Section and Comments	Date Approved	Author/Reviewer
Original Manual	1/11/2018	Dearmore/Sharpe
References to the Standards and Accountability Section (SAS) and Laboratory Accreditation Manager (LAM) have been removed, replaced with QA. References for ASCLD/LAB have been changed to ANAB and references to ISO/IEC 17025:2005 were updated to ISO/IEC 17025:2017. References to the Datamaster breath testing instruments were removed. References to the issue of calibration certificates were changed to authorize/issue. Section 5.3.1: list of elements of the MSR was updated to meet requirements listed in ISO/IEC 17025:2017 and ANAB AR 3125 documents. Section 7.5.3: detailed procedure for measurement uncertainty was added (as described in directive dated 4/13/18) . Updated information on receipt, storage and lot number for acetone in section 7.1.4. Procedure for evaluation of proficiency test results was updated in Chapter 9 (incorporated information in IOC dated 5/28/20). Procedure to complete Repair Records in Instrument Tracking for instances where a QAP is stopped for any reason added to Chapter 10. Wording was added to section 11.1.2 to specify reviewers of the technical content of courtroom testimony must meet competency requirements described in 8.2.1. Section 13.2: designation and authority of the safety officer added. Education requirements for forensic scientists was updated in the appendix (edits described in directive dated 8/16/18). The IDS personnel chart was updated.	08/11/2020	Harbour/Black/Maier
2.1 Added language to address the following words in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify.	4/28/2022	Black Harbour Benante

3.7.2 Corrected text referencing Amended Certificate title 7.1.2.1 Removed reference to Operators who were certified to change the external standard. 9.2.2, 9.2.5, 9.2.6 Updated process for selection and review of proficiency tests 10.4.5 Included scenario for QAP level replicates repeated during calibration and recording this in the Repair Record. 11.1 Added that reviewers of technical testimony must be competent and authorized. Updated WSP Organizational Chart		
Edited section 4.3.2 to remove reference to the Notification of Nonconformance and specify use of the new form Nonconformance Review/Corrective Action Plan. Changes made to section 4.3.4 for use of the Nonconformance Review/Corrective Action Plan form and add specific information regarding the removal of work (personnel, instrument, method) and reinstatement to work by the IDS Commander. Specified use of the Nonconformance Review/Corrective Action Plan in section 4.3.5 and approval of the plan by the QA Manager and/or IDS Commander.	12/15/2023	Black Harbour Leonard