1 SCOPE OF DOCUMENT

1.1 GENERAL

This Quality Manual gives the general requirements for the day to day clerical and scientific operation of the Brazoria County Sheriff's Office Crime Laboratory. It also provides standards of behavior regarding ethical and managerial matters.

1.2 TESTING ACTIVITIES

This manual applies to all aspects of testing conducted by the Laboratory and its employees, including all methods, sampling, and reporting.

1.3 SAFETY

This manual is not intended to address safety matters. Please see the Laboratory Safety SOPs for any safety issue or concern.

2 NORMATIVE REFERENCES

- ISO/IEC 9000:2015, Quality Management Systems – Fundamentals and Vocabulary
- ISO/IEC 30:2015, Reference Materials – Selected Terms and Definitions
- ISO/IEC 17000, Conformity Assessment – Vocabulary and General Principles
- ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories
- ANAB AR 3125, ISO/IEC 17025:2017 Forensic Science Testing and Calibration Laboratories Accreditation Requirements
- ANAB PR 3077, Minimum Requirements for Assessment Activities
- ANAB GD 3050, Program Applications for Forensic Science Testing Laboratories
- ANAB PR 3095, Proficiency Testing and Review Program
- ANAB PR 1018, Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status
- *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel*
- ILAC P8 – ILAC Mutual Recognition Arrangement: Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies
- ILAC P9 – ILAC Policy for Participation in Proficiency Testing Activities
- ILAC P10 – ILAC Policy on the Traceability of Measurement Results
- ILAC G19 – Modules in a Forensic Science Process
- The Code of Professional Conduct of the Southwestern Association of Forensic Scientists
- International Vocabulary of Metrology – Basic and general concepts and associated terms (VIM)
- The most current published versions of ANAB policies regarding the estimation of uncertainty of measurement, measurement traceability, and sampling/sampling plans/sample selection

3 TERMS AND DEFINITIONS

The definitions given in ISO/IEC 9000, ISO/IEC 17000, VIM, and ANAB AR 3125 apply.

4 GENERAL REQUIREMENTS

4.1 IMPARTIALITY

4.1.1 LABORATORY ACTIVITIES

Activities within the Laboratory shall be undertaken impartially and structured and managed so as to safeguard impartiality. All employees shall abide by and adhere to the principals espoused in the BCCL "Ethical Oath" (Laboratory Ethics SOP).

4.1.2 LABORATORY COMMITMENT

Laboratory management shall be committed to impartiality and shall perform their management duties in keeping with ISO/IEC 17025 and AR 3125.

4.1.3 UNDUE INFLUENCES

The Laboratory shall strive to ensure that there are no influences on the professional judgment and impartiality of personnel, including any undue internal and/or external commercial, financial, or other pressures and influences that may adversely affect the quality of their work. Laboratory personnel shall report any perceived undue pressures or influences to the Laboratory Director, and/or the Brazoria County Sheriff or his Chief Deputy, and/or to the Texas Forensic Science Commission.

4.1.3.1 ANAB GUIDING PRINCIPLES

4.1.3.1a GENERAL

The Laboratory is committed to good professional practice. The Laboratory uses the *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel* as a framework for describing professional and ethical responsibilities for the Laboratory and its staff.

4.1.3.1b REVIEW OF ANAB GUIDING PRINCIPLES

To ensure that the *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel* are familiar to all employees, the Laboratory Director shall ensure that this document is reviewed annually by all Laboratory personnel. A record of this review shall be maintained through one cycle of accreditation or four years, whichever is longer.

4.1.3.1c ENFORCEMENT OF ANAB GUIDING PRINCIPLES

Actions or behavior of employees that are contrary to the *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel* shall not be tolerated and appropriate actions shall be taken when necessary.

4.1.4 RISKS TO IMPARTIALITY

The Laboratory shall identify risks to its impartiality in the form of conflict of interest, bias, and other forms of undue influence on an on-going basis. This shall include those that arise from evidence handling, the Laboratory's relationship with its customers, or from the relationships between Laboratory personnel.

4.1.5 ELIMINATION OR MINIMIZATION OF RISK

Any potential risks to impartiality that are identified by the Laboratory shall be addressed through Laboratory policies and procedures.

4.2 CONFIDENTIALITY

4.2.1 PROTECTION OF CONFIDENTIAL INFORMATION

Laboratory management shall strive to keep information obtained from casework confidential to ensure that investigations are not compromised and that the public trust is not eroded. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

4.2.2 RELEASE OF LABORATORY CASE INFORMATION

Laboratory case information shall only be released to the submitting agency, appropriate judicial official(s), or anyone designated by the submitting agency or appropriate judicial official(s) as authorized to receive the information. Court orders and other legitimate information requests shall be honored in accordance with the requirements found in the Release of Laboratory Records and Information SOP.

Any request for employees to release or prepare case documents or information other than the Laboratory Report shall be approved by the Laboratory Director, or his/her designee. No case file documents containing results may be released to any entity outside of the Laboratory unless the information and/or data has been technically reviewed and/or administratively reviewed by appropriate Laboratory personnel.

4.2.3 CUSTOMER INFORMATION

Information about the customer obtained by the Laboratory from sources other than the customer shall be kept confidential. The source of this information shall be kept confidential by the Laboratory and shall not be shared with the customer, unless agreed by the source.

4.2.4 SECURITY OF LABORATORY INFORMATION

All case information in the Laboratory shall be treated as confidential. Case identities, Laboratory findings and other confidential information shall not be discussed with any unauthorized person(s), including family members. Copies of reports or information from submitted cases, current or otherwise, shall not be provided to anyone except those approved by current Laboratory policy. All other requests for case information should be referred to the Laboratory Director, as appropriate.

- Case files shall be secured either within the Laboratory or under controlled access within Brazoria County facilities. Their contents shall be protected from unauthorized personnel.

- Material from Laboratory cases or from case files shall not be removed from the Laboratory, except for official Laboratory business. Original analytical documentation shall not be removed from the custody of the Laboratory except as the result of a court order, or as needed for courtroom or other judicial proceedings.

COMPUTER SECURITY

The Laboratory shall ensure the integrity and confidentiality of data entry or collection, data storage, data transmission and data processing events taking place within the Laboratory. The following policies have been implemented to safeguard all computer functions:

All computers containing confidential information shall be kept within the confines of the Laboratory or in another secure location, such as a server room. Only Laboratory employees shall operate computers located within the Laboratory facility. Only information needed for Laboratory purposes shall be sought. Exceptions to this policy include use of computers by:

- Brazoria County Information Systems (IS) employees
- Authorized assessment or other investigation teams
- Service representatives for the Laboratory Information Management System (LIMS)
- Service representatives performing maintenance or repair on instruments/equipment that are connected to computers.

The LIMS shall be protected by the use of passwords and PIN numbers unique to individual Laboratory personnel. The Brazoria County Information Systems (IS) Department shall be responsible for the security and maintenance of the servers as well as the maintenance of computer systems within the control of the Laboratory. Refer to the Laboratory Information Management System SOP for more information.

Archived case information contained on external hard drives, tapes, or other electronic media shall be kept within the Laboratory facility and/or kept securely by the Brazoria County Information Systems (IS) Department. Program changes to Laboratory computer systems shall not be made unless approved by the Laboratory Director.

5 STRUCTURAL REQUIREMENTS

5.1 LABORATORY ENTITY

The Brazoria County Sheriff's Office Crime Laboratory (BCCL) is a part of the Brazoria County Sheriff's Office (BCSO) and provides testing of evidentiary materials to aid in the investigation of criminal offenses (see Laboratory Designation, Location, and Functions SOP). All Laboratory employees are sworn by the Sheriff of Brazoria County to support the laws and regulations of the State of Texas and of the United States of America. The Laboratory is currently accredited by ANAB and the Texas Forensic Science Commission, and provides analysis in Seized Drugs.

5.2 KEY & TOP MANAGEMENT

Due to the small number of employees in the Laboratory, the management structure is minimal. The Laboratory Director is the only individual designated as "key management personnel" or "top management personnel". Refer also to the Laboratory Organizational Chart.

5.2.1 LABORATORY DIRECTOR

The Laboratory Director is charged with the executive and administrative responsibilities of the Laboratory. He/she shall maintain administrative control and govern Laboratory activities either directly or through appointed designees. The Laboratory Director shall oversee the technical operation of the Laboratory to ensure that practices conform to internal policy as well as to accreditation criteria, and to ensure the provision of resources needed to achieve the required quality of Laboratory operations.

The Laboratory Director may delegate training assignments to staff that are competent and proficient in each discipline. The Laboratory Director shall also serve as the Quality Manager for the Laboratory in the absence of personnel designated as such. The Laboratory Director may delegate responsibilities relating to these positions to other Laboratory staff at his/her discretion.

The Laboratory Director shall be responsible for ensuring that subordinates follow established quality procedures and practices. He/she shall supervise the following tasks:

- Monitoring of Laboratory practices to verify continuing compliance with policies and procedures related to quality
- Solicitation and evaluation of customer feedback
- Evaluation of instrument calibration and maintenance records
- Monitoring the reliability of reagents
- Validation of new technical procedures
- Investigation of technical problems, proposal of remedial actions, and verification of their implementation
- Administration of proficiency testing, evaluation of results, and updating of individual competency and proficiency test records

The Laboratory Director may choose to temporarily appoint a staff member to take responsibility of the Laboratory at any time if he or she is unable to fulfill the duties of Laboratory

management. In this situation, verbal or electronic notification may be sufficient.

If, for any reason, the Laboratory Director is unable to fulfill the duties of Laboratory management due to an unforeseen circumstance or event, and/or is away from the Laboratory for an extended period of time, then the Chief Deputy Sheriff may appoint an interim Director.

5.2.2 QUALITY MANAGER

The Quality Manager shall have the responsibility and authority to ensure that the management system is implemented and followed at all times. The acting Quality Manager shall have direct access to those who make decisions regarding Laboratory policy or resources. This access shall be provided through the Laboratory and/or BCSO chain of command.

The Quality Manager's duties include:

- Approval of new quality procedures and modifications to existing procedures
- Approval of modifications to analytical protocols used for casework
- Approval of corrective actions proposed and/or taken regarding analytical or interpretive problems detected by the QA/QC process
- Periodical review adequacy of case file and testimony monitoring processes
- Maintaining and updating the Quality Manual
- Selecting and training internal auditors
- Scheduling and coordinating management system audits
- Evaluating results from management system audits
- Maintaining records of management system audits
- Submitting audit reports and maintaining communication with accrediting entities
- Maintaining training records of Laboratory personnel
- Maintaining proficiency, competency and testimony monitoring records of Laboratory personnel
- Recommending training to improve the quality of Laboratory staff
- Proposing corrections and improvements to the management system

5.3 LABORATORY ORGANIZATION

The Laboratory performs services in the disciplines of Seized Drugs. Job descriptions for Laboratory personnel and the Management System SOP further outline the Laboratory Organization. Moreover, the Laboratory's place in its parent organization is described in the "Parent Organization Influence" section of this manual (5.5a).

5.4 LABORATORY RESPONSIBILITIES

It is the responsibility of the Brazoria County Sheriff's Office Crime Laboratory to perform all aspects of testing in a manner that conforms to the latest versions of the ISO/IEC 17025 document criteria and to the ANAB AR 3125 supplemental document. Moreover, it is the responsibility of the Laboratory to perform all aspects of testing in a manner that satisfies the needs of its customers - the law enforcement community and citizens in Brazoria County, Texas. The law enforcement community served by the Laboratory includes all police agencies

doing business in Brazoria County; Court systems; prosecutors and defense attorneys; probation departments; and County jails and State jail systems found in Brazoria County.

5.4.1 USE OF ANAB ACCREDITATION SYMBOLS

When a reference to accreditation is made in any Laboratory documents, reports, or other means of communication by use of an accreditation symbol, business name, or business acronym, the Laboratory shall ensure:

- Use is only by the legal entity accredited and as named on the certificate of accreditation;
- The accreditation symbol or statement used is specific to the ANAB Forensic Science Testing Laboratories Accreditation Program;
- Non-accredited testing is clearly identified as such;
- No misleading or unauthorized representation of accreditation status;
- No implication that the accreditation body accepts responsibility for test results; and
- No implication that a process, system, or person is approved by the accreditation body.

In addition, Laboratory reports shall ensure the following:

- No reference of accreditation shall be made within Laboratory reports that include testing done that is not included in the scope of accreditation; and
- Opinions or interpretations included in Laboratory reports that are based on test results for which accreditation is held, but are outside the scope of accreditation, shall be clearly identified as such.

5.4.2 AUTHORITY OF STATUTES, REGULATIONS, OR OTHER LEGAL

The Laboratory shall perform all testing in a manner that follows the laws pertaining to forensic laboratory accreditation mandated by the State of Texas. In the event of a nonconformity, refer to the Quality Action Plan SOP.

5.5 SCOPE OF MANAGEMENT SYSTEM

All authorized work undertaken by Laboratory employees shall be performed in accordance with the management system. The management system applies to forensic operations performed at the permanent Laboratory facility located at 3602 CR 45, Angleton, TX 77515.

5.5a PARENT ORGANIZATION INFLUENCE

The Laboratory Organizational Chart shows the relationship of key personnel within the BCSO and the employees that oversee the Laboratory. If a member of the parent organization requests or instructs Laboratory personnel to deviate from policy, approval shall be sought and received from the Laboratory Director or his/her designee, prior to any work being performed. The results issued by the Laboratory shall be supported by data generated in the Laboratory and shall not be biased or influenced by others. Any Laboratory personnel encountering situations or conditions that may cause undue pressure, conflict of interest, or that may adversely affect the quality of their work shall notify the Laboratory Director and/or the Quality

Manager.

Key agency and county personnel that are not Laboratory personnel but may influence testing are:

- **Administrative Captain:** This individual is the direct supervisor of the Laboratory Director. The Captain may make decisions that could affect the daily operations of the Laboratory.
- **Chief Deputy Sheriff:** This individual is the direct supervisor of the Administrative Captain. The Chief may make decisions that could affect the daily operations of the Laboratory and is the person that maintains the Laboratory budget.
- **Sheriff of Brazoria County:** The Sheriff is the elected official in charge of the county-wide law enforcement agency known as the Brazoria County Sheriff's Office. All employees who work for the Brazoria County Sheriff's Office, including those employed in the Laboratory, are employed at the will of the Sheriff. The Sheriff may make decisions which affect the daily operations of the laboratory.
- **Members of the Brazoria County Commissioner's Court:** These elected individuals oversee all departments within Brazoria County. They approve the BCSO budget and approve personnel matters and expenditures in Brazoria County.
- **Brazoria County District Attorney:** This elected official may facilitate the prioritization of casework in the Laboratory by submitting work lists of cases pending court proceedings.

5.5b PERSONNEL AUTHORITY & INTERRELATIONSHIPS

Seized Drugs: As of January 2023, there are only two Laboratory staff members licensed by the Texas Forensic Science Commission to practice Seized Drug analyses.

Toxicology: As of June 2023, there are only two Laboratory staff members licensed by the Texas Forensic Science Commission to practice Toxicology - Blood Alcohol/Drug analyses.

In addition to following approved procedures for the analysis of samples and subsequent work, it is the responsibility of Laboratory employees in each discipline of testing to identify, evaluate, isolate, and control the testing of samples and/or the release of analytical results that may be impacted by nonconformance, deficiencies that do not meet quality standards, or actions that increase measurement uncertainty.

The interrelationships of Laboratory employees that manage, perform, or verify analytical work may be varied. In addition to being co-workers, analytical staff may serve as supervisors and subordinates, technical or administrative reviewers, verifiers, trainers and trainees, and other workers within a discipline.

5.5c LABORATORY PROCEDURES

Each forensic discipline (or section) within the Laboratory shall have a technical procedures manual that is part of the management system. Testing procedures shall be documented to the extent necessary to ensure consistent application and the quality of results. The outline of the

structure of the documentation used in the management system is described in the "Management System Documentation" section of this manual (8.2).

5.6 AUTHORITY & RESOURCES OF PERSONNEL

All Laboratory policies, procedures, quality issues, and personnel issues shall be under the authority of the Laboratory Director. The Laboratory Director shall ensure that all personnel possess the authority and resources needed to carry out their respective duties, including the implementation, maintenance and improvement of the management system. Because of unforeseen circumstances or necessity, Laboratory personnel may temporarily deviate from documented policies or procedures as a result of changes in technology, availability of materials, or issues beyond the control of the Laboratory (Deviation from Documented Procedures SOP).

Additionally, the Laboratory Director has the authority to make and enforce decisions regarding Laboratory operations. This includes the authority to take disciplinary action against any Laboratory employee for violation of any lawful order, rule or policy for any neglect, failure, or refusal on the part of the employee to comply with such orders or regulations. Additionally, if the Laboratory Director experiences a situation where there is a conflict of interest, undue pressure, or that the best interest of the Laboratory is being compromised or undermined, the Laboratory Director has the option of reporting the situation to the Texas Forensic Science Commission, the Brazoria County Sheriff, and/or the Brazoria County District Attorney's Office. Moreover, the Laboratory Director may require an employee of the Laboratory to participate in either a training or proficiency program at any time.

Corrective or preventive actions may be initiated by any Laboratory personnel to either prevent or minimize a departure from the management system and documented policies and procedures. (Quality Action Plan: Corrective Action Request Form)

5.7 EMPLOYEE AWARENESS OF MANAGEMENT SYSTEM

The Laboratory Director shall ensure that all personnel are aware of the relevance and importance of their roles and how they contribute to the achievement of the objectives of the management system. This awareness shall be accomplished through correspondence, personnel assessments, career development, training, and/or audits of work. Moreover, employees shall be kept aware of changes to and given access to appropriate management system documents.

The Laboratory shall maintain documentation of pertinent correspondence, personnel assessments, career development, training, and/or audits for all current Laboratory employees.

5.7a COMMUNICATION PROCESSES

The Laboratory Director shall ensure that appropriate communication processes are established within the Laboratory and that communication takes place regarding the effectiveness of the management system. All employees of the Laboratory shall read and comprehend the Quality Manual and other management system documents. Communication regarding the Quality Manual and other management system documents shall be encouraged

at any time and may be accomplished verbally, in writing, or through electronic means.

If personnel have concerns about the actions of coworkers or others that could affect the quality or integrity of the lab, then they should bring the concerns to the immediate attention of the Laboratory Director, whether the concerns are of a technical nature or otherwise.

The Laboratory Director shall communicate to all Laboratory employees the importance of meeting customer requirements as well as statutory and regulatory requirements. Results of customer surveys, problems with meeting customer requirements, and any new or significantly different statutory or regulatory policies may be communicated to employees via electronic notifications, staff meetings, and/or in writing.

5.7b INTEGRITY OF MANAGEMENT SYSTEM

The Laboratory Director shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented by reviewing all documents and procedures relevant to the change(s). The Laboratory Director shall ensure all Laboratory employees are informed of the change(s) via electronic notifications, staff meetings, and/or in writing. Laboratory employees shall be provided with electronic or hard copies of pertinent management documents.

Staff members shall be encouraged to make suggestions for changes to the management system; however, changes to any document or any other component in the management system shall be implemented only with the approval of the Laboratory Director or designee.

6 RESOURCE REQUIREMENTS

6.1 GENERAL

The Brazoria County Sheriff's Office, of which the Laboratory is part, shall maintain the Laboratory facility. Systems and equipment within the Laboratory shall be monitored by qualified staff. Maintenance shall be performed by Laboratory staff and/or service contract vendors. Refer also to the Laboratory Physical Plant-Space and Design.

6.2 PERSONNEL

6.2.1 COMPETENCY OF PERSONNEL

Personnel performing specific tasks within the Laboratory shall act impartially, be competent and work in accordance with the management system.

6.2.2 TECHNICAL PERSONNEL QUALIFICATIONS

Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required. Technical personnel who are in training shall be supervised appropriately and all training shall be documented.

6.2.2.1 MINIMUM EDUCATION

Employees who operate scientific equipment, perform tests, evaluate/interpret results, and issue test reports (Laboratory Director and Forensic Scientists) shall be considered technical personnel. All technical personnel of the Laboratory shall meet the minimum qualifications required to establish and maintain forensic analyst licensure in the State of Texas.

6.2.2.1.1 TESTING PERSONNEL

Forensic Scientists shall establish and maintain forensic analyst licensure in the State of Texas in which he/she performs testing, makes interpretations, or conducts technical review.

6.2.2.2 TRAINING PROGRAM

This Quality Manual shall serve as a guide to assist in the training of employees who are new, untrained, or in need of remedial training. With respect to the education, training, and skills of Laboratory personnel, staff members shall be encouraged to establish training goals for the development of the individual, each analysis section, and the Laboratory as a whole.

The Laboratory training program shall identify training needs and provide training for personnel, and the effectiveness of training actions taken shall be evaluated. Past work experience and training may be substituted for portions of the training program to the extent that it has been demonstrated to be relevant and sufficient.

TRAINING RECORDS

The Laboratory shall maintain files which include training information for each employee. The Quality Manager and employee shall periodically review this file and ensure that it is updated. All or part of this file may be stored electronically. For technical personnel, this file should contain:

- The employee's training objectives
- A list of formal training (seminars and courses) received
- The employee's education record
- The employee's competency and proficiency test record (to be updated at the end of the calendar year)
- Other information related to training and qualifications (e.g., copies of certificates, papers or presentations authored, etc.) at the discretion of the employee

6.2.2.2a KNOWLEDGE, SKILLS, AND ABILITIES

The Laboratory shall have a documented training program that shall be used to train technical personnel in the knowledge, skills, and abilities needed to perform testing.

TRAINING OF NEW PERSONNEL

The Laboratory Director shall ensure the training of each new employee, and may assign personnel to train the employee as needed.

All new employees shall undergo an initial orientation and safety training. Training checklist(s) shall be maintained by the Laboratory.

New employees shall understand security policies prior to being issued keys.

Support staff shall be trained according to their position and shall demonstrate understanding of procedures prior to handling evidence or case files.

TRAINING IN FORENSIC DISCIPLINES

Each section of the Laboratory shall maintain a documented training program specific to the analysis in that discipline.

Technical personnel shall undergo training and competency testing/evaluation sufficient to acquire and demonstrate an understanding of the principles, use and limitations of the equipment, and procedures used in each forensic discipline in which they perform casework. Refer also to the "Competency Testing" section of this manual (6.2.3). The specific content and length of the initial training period should naturally be a function of the individual's prior educational background and experience, as well as the complexity of the assigned tasks. Projects assigned to technical personnel in training may vary, depending on the current operational needs of the Laboratory.

Work done by technical personnel while in training shall be documented and reviewed by the designated trainer(s) and/or Laboratory Director. The designated trainer(s) and/or Laboratory Director shall evaluate the progress of training by assessing the trainee's knowledge, understanding, and skill in conducting and/or describing the procedures or process. Moreover, the trainee's analytical and interpretive competence shall be demonstrated through practice, analysis, competency, and proficiency testing exercises.

6.2.2.2b GENERAL KNOWLEDGE

The documented Laboratory training program shall incorporate a general knowledge of forensic science

6.2.2.2c ETHICAL PRACTICES

The documented Laboratory training program shall incorporate the application of ethical practices in forensic science. For more information, refer to the Laboratory Ethics SOP.

6.2.2.2d LAW & EXPERT TESTIMONY

The documented Laboratory training program shall incorporate the review of applicable criminal and civil law procedures, and expert testimony. Effective testimony is an essential component of professional competence in forensic science. In order to prepare Laboratory employees for court appearances, the Laboratory training program shall include training in the presentation of evidence in court. An individual's readiness for testimony should be assessed prior to court testimony by performance in mock court situations.

Technical personnel should be able to demonstrate:

- Familiarity with literature related to the forensic discipline employed
- Experience and training in the forensic discipline employed
- An understanding of the scientific principles underlying the procedures used in the Laboratory
- Knowledge of Laboratory management system policies and procedures
- The ability to explain the analysis procedure to a lay audience
- The ability to advise and assist attorneys in presentation of forensic evidence
- A professional appearance and demeanor

6.2.2.2e RETRAINING

The documented Laboratory training program shall include procedures for remedial training. Remedial training should be structured to upgrade individual knowledge and skills that are identified as deficient. Remedial training may be required when an employee repeatedly fails at completing a task, produces substandard work, commits safety violations, violates other Laboratory policy, shows difficulty understanding certain concepts, or when their performance needs improvement. Specific examples of instances requiring retraining would be when an employee shows a deficiency in any technical area, has unsatisfactory performance on a proficiency test, or demonstrates a lack of understanding of Laboratory procedures.

The Laboratory shall be able to demonstrate their affirmative effort at rehabilitating the employee. Verbal correction is usually the first step. If this does not correct the deficiency, then a written warning should be issued. All written material should state the nature of the deficiency with enough detail to convey to the reader the scope of the problem. Documentation should include what action shall be taken if the problem is not corrected.

The Laboratory Director shall determine when and if remedial training is necessary. If the Laboratory Director deems that an employee needs remedial training, he/she shall oversee the

training, which may involve a variety of training methods, including skill exercises, planned lectures, discussion sessions, and directed self-study. The method used and the duration of the remedial training should be dictated both by the extent of training required and individual performance.

Successful completion of remedial training shall be determined by an appropriate assessment of the material covered. The assessment should cover all areas previously identified as deficient and may include a written or on-the-job evaluation, proficiency test, or competency test. Performance standards for remedial training should be the same as for the original training.

6.2.2.2f MAINTENANCE OF SKILLS

Employees shall complete the minimum continuing forensic education hours per 2-year licensing cycle per the Texas Forensic Science Commission to maintain licensure in their forensic discipline, as well as improve their general knowledge, expertise, and skills. This may be accomplished by attending training classes, seminars, technical meetings, conferences, or professional meetings.

The following factors should be considered by the Laboratory Director regarding an employee's request for training:

- The employee's need for training
- The extent to which the employee's knowledge, skills, or performance are likely to be improved by the training
- The ability of the employee to pass the training on to others
- The length of time and degree to which the Laboratory may benefit from the employee's improved knowledge, skill, or performance
- Training opportunities previously afforded the employee by the Laboratory
- The employee's own interest in and efforts to improve their work
- The employee's ability to meet the established prerequisites for attending the training class

Requests for attendance at training classes, seminars, technical meetings, conferences, and professional meetings should be made to the Laboratory Director as far in advance as possible to permit preparation of the Laboratory budget and to adequately allocate funds.

6.2.2.2g PERFORMANCE CRITERIA

The documented Laboratory training program shall include criteria for acceptable performance.

6.2.3 COMPETENCY TESTING

The Laboratory shall ensure that technical personnel have the competence to perform the Laboratory testing for which they are responsible and shall evaluate the significance of deviations. At a minimum, this shall be accomplished through in-house training, competency testing, proficiency testing, and technical personnel authorizations. Moreover, analysts employed by the Laboratory shall acquire and maintain a Forensic Analyst License

encompassing each discipline in which he or she performs testing, makes interpretations, or conducts technical review.

6.2.3.1 REQUIREMENTS FOR TESTING

All technical personnel, regardless of academic qualifications or past work experience, shall satisfactorily complete a competency test/evaluation with a 70% or higher in each category of testing after completion of basic training and prior to being assigned independent casework.

For all technical personnel, a competency test shall include, at a minimum:

- Analysis of sufficient unknown samples to cover the anticipated spectrum of assigned tasks and evaluate the analyst's ability to perform proper testing methods;
- A written report or oral evaluation to demonstrate the analyst's ability to properly convey results and/or conclusions and the significance of those results/conclusions; and
- A written or oral examination to assess the analyst's knowledge of the discipline, category of testing, or task being performed.

6.2.3.2 REQUIREMENTS FOR TECHNICAL REVIEW

The competency requirements as specified in 6.2.3.1 shall also be met by all personnel prior to conducting technical review of results or testimony.

6.2.4 TECHNICAL ROLES & RESPONSIBILITIES

The roles and responsibilities of Laboratory personnel regarding the management system shall be defined by their job title. Moreover, the roles and responsibilities of the Laboratory Director shall be covered in section 5.2.1 of this manual.

Technical Staff (Forensic Scientists)

Technical staff shall be responsible for conducting and documenting the following quality verification checks:

- Routine calibration checks of equipment (GC-MS's, GC-FID's, EMIT, etc.). Certain equipment may be checked by support staff (refrigerators, freezers, balance, etc.) if appropriate training has been provided.
- Routine verification checks of all reagents and materials used for analysis.

In addition, each technical staff member shall be responsible for:

- Understanding and following established procedures and interpretation of casework, including the use of proper controls
- Immediately bringing possible analytical or interpretation problems to the attention of Laboratory management, including suggestions for corrective action
- Actively seeking new knowledge and remaining current with appropriate literature
- Participating in technical or administrative review, competency testing, proficiency testing and remedial training as assigned

- Testing that satisfies the requirements of ISO/IEC 17025, AR 3125, and all other pertinent documents which comprise the management system of the Laboratory

Support Staff (Lab Evidence Technician)
Support staff shall support the management system of the Laboratory and be responsible for the following:

- Understanding and following established procedures
- Participating in quality verification checks, maintenance procedures, and record keeping as assigned
- Being committed to fulfilling the requirements of ISO/IEC 17025, AR 3125, and all other pertinent documents which comprise the Laboratory management system

Additional employee responsibilities may be found in "Job descriptions".

6.2.5 PERSONNEL RECORDS

6.2.5a COMPETENCY TESTING

The competency test records for all technical personnel shall contain a report of the trainee's conclusions or other indication of performance, and the signature or initials and comments (if any) of the technical reviewer. The file may also contain all analytical data (notes, sequence logs, etc.) generated in the analysis. In any situation where the results of the test are not satisfactory, the file shall also include documentation of the corrective action(s) taken.

6.2.5b JOB DESCRIPTIONS

The Laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in testing. Job descriptions for all Laboratory personnel shall be kept with the Brazoria County Human Resources Department.

6.2.5c TRAINING

At the conclusion of initial training, a record or log of each individual trainee's competency test shall be placed in his/her training file. Following any remedial, supplemental, or other forms of training, a record or log of the training shall also be placed in the training file.

6.2.5d SUPERVISION

The Laboratory Director is the direct supervisor of all Laboratory personnel.

6.2.5e AUTHORIZATION

The Laboratory Director shall authorize specific personnel to perform tasks. Records of the relevant authorizations, competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contract personnel, shall be maintained by the Quality Manager and shall include the date on which authorization and/or competence is confirmed.

6.2.5f PERSONNEL MONITORING

The Laboratory Director shall monitor the analytical work in each forensic discipline. The

Laboratory Director may delegate monitoring tasks to staff that are competent in each discipline.

6.2.6 AUTHORIZED TASKS

In addition to the requirements specified in 6.2.3.2, personnel authorizations shall address personnel who perform particular types of sampling and testing, perform method validation or verification, issue test reports, perform technical review of test reports and related records, give opinions and interpretations, and operate particular types of equipment, as applicable.

6.3 FACILITIES & ENVIRONMENTAL CONDITIONS

6.3.1 LABORATORY FACILITIES

The environmental conditions at the Laboratory shall facilitate the correct performance of the tests. The Laboratory shall ensure that factors such as, but not limited to, energy sources, lighting and other environmental conditions do not invalidate test results or adversely affect the required quality of any measurement.

Measures shall be taken to ensure good housekeeping in the Laboratory. Special procedures shall be enacted where necessary.

6.3.2 SPECIFYING REQUIREMENTS

The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be specified in the Laboratory Physical Plant – Space and Design SOP.

6.3.3 MONITORING OF CONDITIONS

The Laboratory shall monitor, control, and record environmental conditions that may affect the quality of results. Testing shall be halted when the environmental conditions jeopardize the results.

6.3.4 LABORATORY ACCESS POLICY & PROCEDURE

6.3.4a CONTROLLABLE ACCESS

Access to the testing areas of the Laboratory is controllable and limited. Only Laboratory employees (key holders) shall have access to Laboratory testing areas and/or evidence storage areas; visitors shall not have unrestricted access to the testing areas of the Laboratory. The Laboratory is a completely controlled-access facility, with all exterior doors secured against access by unauthorized personnel. The roll-up door in the processing bay may be opened to receive large items into the Laboratory. When this door is open, a Laboratory employee shall be present in the processing bay until the door is secured. All other exterior doors to the Laboratory shall remain locked at all times.

ENTRANCE AND EXIT POINTS

All entrance/exit points of the Laboratory shall have security control at all times. Building security (video cameras, access to the building other than through the Laboratory, perimeter security, etc.) is the responsibility of the Brazoria County Sheriff's Office.

INTRUSION ALARM

The Laboratory is monitored during vacant hours by an intrusion alarm. Each employee shall be given an alarm user number and each employee should select his/her own alarm access code, which may be used to arm and disarm the system. Employees shall not give out their access codes to any other person, including other Laboratory employees. The first employee to arrive at the Laboratory in the morning shall disarm the system, and the last employee to leave for the day shall arm the system. When an employee leaves employment with the Laboratory, that user number shall be deleted.

LOCK SYSTEM

Internal areas that require additional limited/controlled access shall have a lock system.

ACCOUNTABILITY OF KEYS

The accountability of all keys used in the Laboratory shall be documented and distribution shall be limited to those individuals designated access by the Laboratory Director. Laboratory keys shall be assigned by the Laboratory Director, and shall be issued to all Laboratory employees with access granted as appropriate to their duties. Keys may be electronic or standard keys, but each key shall be signed for by the employee. Records of keys shall be maintained by the Laboratory Director or his/her designee. Laboratory keys shall not be duplicated. Each Laboratory employee shall safeguard his/her Laboratory keys against loss or unauthorized use. Lost or misplaced keys shall be reported to the Laboratory Director immediately upon discovery. All Laboratory keys shall be returned to the Laboratory Director upon termination of employment.

SPECIAL JOB CREWS

All special jobs, regardless of size, shall require the advance approval of the Laboratory Director.

Special work crews, such as construction or building alteration crews, may be engaged for after-hours or weekend jobs. During the job, one or more Laboratory staff, or Laboratory Director designated Brazoria County Sheriff's Office personnel, shall be in constant attendance to oversee the work. Large jobs may require the movement of property, the suspension of particular services and/or temporary alterations in procedures.

VISITOR LOG

All visitors who enter the Laboratory area shall be escorted by a Laboratory employee and sign the Laboratory visitation log.

LABORATORY TOURS

Tours of the Laboratory for the general public shall be discouraged, and shall require approval from the Laboratory Director. Tours for others or for those individuals whose work relates to a Crime Laboratory function may be permitted with prior approval, as long as precautions are taken to ensure the integrity of the evidence and equipment.

6.3.4b EVIDENCE STORAGE AREAS

Evidence storage areas shall be secured to prevent theft or interference and there is limited, controlled access. The storage conditions for all evidence shall prevent loss, deterioration or contamination and maintain the integrity and identity of the evidence. This applies both before and after analysis has been performed.

6.3.4c SEPARATION OF TESTING AREAS

There shall be effective separation between neighboring areas of testing. Measures shall be taken to prevent cross-contamination. In the event that any area need be used for more than one purpose, the area shall be effectively cleaned between uses.

6.3.4.1 ACCESS TO LABORATORY

To ensure the security of the facility, the Laboratory has adopted the security procedures outlined above in sections 6.3.4a – 6.3.4c.

6.3.5 UNCONTROLLED FACILITIES

The Laboratory does not operate in multiple locations or perform testing at sites outside its permanent control.

6.4 EQUIPMENT

6.4.1 AVAILABILITY OF EQUIPMENT

The Laboratory shall furnish all equipment and other items necessary for testing. This refers to instruments, software, measurement standards, reference materials, reagents, consumables and other equipment that is relevant to the quality of analytical results, as appropriate. Authorizations and instructions shall not be required for generic laboratory equipment such as vortexes, sonicators, vacuum pumps, water baths etc., or for equipment that is common in everyday use such as computers, thermometers, hot plates, etc.

6.4.2 EQUIPMENT OUTSIDE LABORATORY CONTROL

Under normal circumstances, the Laboratory shall not use equipment outside its permanent control. If the Laboratory requires the use of equipment outside of its permanent control, it shall ensure that the requirements of ISO/IEC 17025 and AR 3125 are met.

6.4.3 PROCEDURES FOR HANDLING OF EQUIPMENT

The Laboratory shall have procedures for the safe handling, transport, storage, use and planned maintenance of measuring equipment, including weight sets and mechanical pipettes, to ensure proper functioning and in order to prevent contamination, damage or deterioration. Procedures for the calibration, performance verification, and maintenance of Laboratory instruments/equipment shall be specified in the individual forensic discipline procedure manuals.

6.4.3.1 REAGENT LABELING

Labels on commercial reagent bottles shall identify the reagent, any applicable hazards, and the concentration, when appropriate.

Reagents made within the Laboratory shall be labeled with, at a minimum, the identity of the reagent, the date of preparation, the preparer's initials and, as applicable, storage requirements, any applicable hazards, and components/concentration. Exceptions to this policy may be solutions that are made, used once, and then discarded. For very small bottles or vials, it shall be understood that there may not be room for the appropriate hazard labels.

The Laboratory shall have procedures for routinely checking the reliability of reagents used in testing. Refer to the Standards, Controls, and Reagents SOP for more information.

6.4.3.2 REFERENCE COLLECTIONS

Reference collections of data or items and materials encountered in casework which the Laboratory maintains for identification, comparison, or interpretation purposes (for example, mass spectra, drug samples, etc.) shall be documented, uniquely identified and properly controlled by the Laboratory.

Commercial libraries of mass spectra in electronic form that were acquired from external sources for use with the Laboratory's analytical instrumentation meet these requirements, as do published reference collections and reputable scientific literature.

6.4.4 EQUIPMENT OPERATION

Equipment shall be operated by authorized personnel and verified prior to use in casework. Prior to being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the specification requirements of the Laboratory and complies with the relevant standard specifications. Equipment shall also be checked after being moved, or if a major repair is performed. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate Laboratory personnel.

To verify that the refrigerators and freezers continue to function at the optimum temperature, the temperature shall be monitored by Laboratory staff. Temperature checks shall generally be performed on a weekly basis and the results entered into the appropriate log stored near the unit. These records shall be maintained by the Laboratory and archived as needed. Deviations from the expected temperature tolerances on the log indicate that maintenance or repair of the equipment may be needed. These deviations should be reported to the Quality Manager and/or Laboratory Director. Any unit that fails to maintain consistent appropriate temperature shall be taken out of service.

6.4.4.1 RETURNED EQUIPMENT

If equipment leaves the direct control of the Laboratory for any reason, including maintenance or recalibration, a performance verification check shall be done prior to the returned equipment being put back into service in the lab.

6.4.4.2 EQUIPMENT MAINTENANCE

Computers and other automated equipment shall be maintained to ensure proper functioning and protected from adverse operating conditions in order to maintain the integrity of test data.

6.4.5 EQUIPMENT CAPABILITY

Equipment used for measuring, testing, and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests concerned.

6.4.6 REQUIREMENTS FOR EQUIPMENT

Calibration programs have been established for equipment used for measurements that have a significant effect on Laboratory results. Refer to the “Metrological Traceability” section of this manual (6.5) for more information on calibration programs.

6.4.7 CALIBRATION PROGRAM

The Laboratory calibration program shall be reviewed and modified as necessary in order to maintain confidence in the status of calibration of Laboratory equipment. Changes to the calibration program of Laboratory equipment shall not be made unless approved by the Laboratory Director.

6.4.7.1 CALIBRATION CHECKS

Procedures to check calibration of equipment and measurement devices shall be established and followed. The following, at a minimum, shall be defined:

- A list of the equipment requiring calibration
- Specified requirements for the calibration
- The frequency of calibration checks

Policies related to discipline-specific equipment may be found in the individual forensic discipline procedure manuals.

6.4.8 CALIBRATION STATUS

Whenever practicable, all equipment under the control of the Laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due. Equipment that is calibrated with each use is an exception to this policy and does not have to be labeled or identified as to the calibration status.

6.4.9 OUT OF SERVICE

Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. The problem shall be recorded in the appropriate log, and Laboratory management should be notified. The equipment shall be isolated to prevent its use or clearly labeled or marked as being out of service.

Any equipment that has been taken out of service should be isolated and repaired, and quality verification procedures shall be performed to ensure that it is working properly. A test or calibration shall show correct performance prior to any instrument or equipment being returned to service.

The Laboratory shall examine the effect of the defect or departure from specified limits on previous tests and shall institute the control of "Nonconforming Work" procedure in this manual (7.10), as appropriate.

6.4.10 INTERMEDIATE CHECKS

When intermediate checks are needed to maintain confidence in the calibration status or stability of equipment, reference standards, and reference materials, these checks shall be carried out according to a defined procedure which shall define the frequency of the intermediate checks. These procedures may be found in the individual forensic discipline procedure manuals.

6.4.11 SAFEGUARDING FROM ADJUSTMENTS

Test and calibration equipment shall only be accessed and/or operated by authorized personnel in order to safeguard against adjustments which could invalidate the test results.

6.4.12 EQUIPMENT RECORDS

Records shall be maintained of each item of equipment significant to the tests performed (see Equipment List). The records shall include at least the following:

- The identity of the item of equipment (designated lot number, serial number, unique name, county equipment number, etc.);
- The manufacturer's name, type identification, and serial number or other unique identification;
- Checks that equipment complies with the specification (see the "Requirements for Equipment" section above, 6.4.6);
- The current location, where appropriate;
- Dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
- Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity (see Master Inventory);
- The maintenance plan, where appropriate, and maintenance carried out to date;
- Any damage, malfunction, modification or repair to the equipment
- Manufacturer's instructions, if available, or reference to their location;

6.5 METROLOGICAL TRACEABILITY

6.5.1 GENERAL

Discipline-specific procedures regarding measurement traceability shall be located in the individual forensic discipline procedure manuals, and shall conform to the most current published version of the appropriate ANAB policy regarding measurement traceability.

All weighing equipment that is in use shall be examined at least once per year, and the calibration of this equipment shall be adjusted at that time, if needed. At the time of service or shortly thereafter, the Quality Manager or designee shall evaluate the calibration reports to determine if any tests may have been adversely affected by the status of the equipment. If so,

then the corrective action procedure shall be implemented.

To ensure the reliability of the weighing equipment between service visits, weighing equipment shall be checked at least quarterly with reference standards and compared to the tolerances on the log sheet for that balance. Any balance that cannot meet tolerance requirements shall be taken out of service.

All mechanical pipettes that are in use shall be examined at least once per year, and the calibration of this equipment shall be adjusted at that time, if needed. At the time of service or shortly thereafter, the Quality Manager or designee shall evaluate the reports for each pipette to determine if any tests could have been adversely affected by the status of the pipette. If so, then the corrective action procedure shall be implemented.

Any calibration certificates or reports provided to the Laboratory by outside vendors shall be maintained by the Quality Manager.

6.5.1.1 REQUIREMENTS OF SUPPLIERS

All equipment used for tests that has a significant effect on the accuracy, quality, or total uncertainty of the result of the sampling or test (including balances, weight sets, pipettes, and equipment used for measuring environmental conditions) shall be calibrated prior to being put into service, and verified annually by a qualified outside vendor that is either accredited to ISO/IEC 17025 or is a National Metrology Institute that is a signatory to the BIPM.

6.5.1.2 PROOF OF COMPETENCE

In the event a vendor who meets the requirements of section (6.5.1.1) is unavailable, the Laboratory shall confirm competence, measurement capability and traceability to the International System of Units (SI) for the calibration service provider. All confirmation records shall be maintained by the Laboratory and shall be available for review.

6.5.1.3 IN–HOUSE CALIBRATION

The Laboratory does not perform in-house calibrations on metrological equipment, reference standards, and/or reference materials.

6.5.1.4 ALTERATIONS TO REFERENCE MATERIALS

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

6.5.2 TRACEABILITY TO SI UNITS

Any measurements reported by the Laboratory shall be traceable to the International System of Units (SI), and vendors who calibrate equipment used to measure reported quantities shall be able to demonstrate competence, measurement capability and traceability to the International System of Units (SI). The calibration certificates issued by these vendors shall contain the measurement results, including the measurement uncertainty and/or a statement of which specification that the measurements have been compared.

All reference standards that are in use shall be calibrated by a body that provides traceability as described in this section. Such reference standards of measurement held by the Laboratory shall be used for calibration or verification of calibration only and for no other purpose.

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials.

6.5.3 TRACEABILITY TO SI UNITS NOT POSSIBLE

In the event metrological traceability to the SI units is not technically possible, the Laboratory shall demonstrate metrological traceability to an appropriate reference, such as certified values of certified reference materials provided by a competent producer; or results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.6 EXTERNALLY PROVIDED PRODUCTS & SERVICES

6.6.1 SUITABILITY OF PRODUCTS & SERVICES

The Laboratory shall only use products, supplies, and services that are suitable for testing activities. These may include reference standards and reference materials, and suppliers of calibration services of equipment and reference standards used to establish and/or maintain measurement traceability. Refer to the Purchasing of Consumables SOP for more information.

6.6.2 PROCEDURE

6.6.2a PURCHASING POLICY

Care shall be taken in the selection and purchasing of supplies and materials that affect the quality of the tests conducted by the Laboratory. The Laboratory Director and/or personnel performing analyses in the Laboratory shall be responsible for the appropriate selection of adequate materials and supplies that are used in each discipline, including any supplies and/or materials that affect the quality of the tests. Once the suitability of an item has been determined, the analyst or Laboratory Director shall request that the item be purchased. All purchase requisitions shall be signed or initialed by the Laboratory Director or his/her designee, indicating approval for the purchase as well as the suitability of the item for its intended purpose.

6.6.2a.1 PURCHASING DOCUMENTS

Purchase requisitions for items affecting the quality of Laboratory tests shall contain information describing the services and supplies to be ordered. The Laboratory Director, or his/her designee, shall review and approve these requisitions for technical content prior to issuance to the Brazoria County Purchasing Department. Purchase requests shall be maintained by the Laboratory and the Brazoria County Purchasing Department.

6.6.2b EVALUATION CRITERIA

The Laboratory shall evaluate the suppliers of products and services used for testing through technical data review of casework and evaluations of Proficiency Testing. Unsuitable products

or services shall not be utilized.

6.6.2c INSPECTION OF SUPPLIES

All supplies and materials that affect the quality of the tests shall be inspected or otherwise verified to comply with the standard specifications or requirements defined in the test method or other document. When the item is received into the Laboratory, the person receiving or unpacking the item(s) shall confirm that the supplies are received in satisfactory condition. If there is an indication that the item(s) fails to meet established Laboratory standards or is not of sufficient quality for use in casework, then the item(s) shall be discarded or marked for another use in the Laboratory, as deemed appropriate.

Individual forensic discipline procedure manuals shall include any procedures necessary for checking the supplies or materials that affect the quality of the tests for use in casework. Records of the verifications or checks performed on supplies or materials that affect the quality of the tests shall be maintained by the Laboratory.

6.6.2d RECORDS OF EVALUATION

Records of any actions arising from evaluations, performance monitoring and re-evaluations of supplies and/or suppliers shall be maintained by the Quality Manager.

6.6.3 COMMUNICATION OF REQUIREMENTS

The Laboratory shall communicate to its external providers, by written or verbal means, the requirements for products or services which may affect testing.

7 PROCESS REQUIREMENTS

7.1 REVIEW OF REQUESTS, TENDERS & CONTRACTS

7.1.1 CUSTOMER SERVICE AGREEMENT

The Laboratory customer service agreement allows the Laboratory to choose methods which are appropriate for testing. Laboratory submission forms shall notify the customers of the Laboratory's general testing capabilities.

7.1.2 COOPERATION WITH CUSTOMERS

The Laboratory shall cooperate with customers or their representatives in clarifying the customer's needs and in monitoring Laboratory performance in relation to testing. This may be accomplished by different means, including questions upon evidence submittal, phone conversations, or other follow-up methods or surveys. Moreover, the Laboratory shall cooperate with customers or their representatives in the preparation, packaging, and dispatch of test items needed by the customer for verification purposes, which may include the dispatching of test items at the request of the District Attorney's Office or other legal representatives.

7.1.2.1 AMENDED CONTRACT

If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

7.1.3 RECORDS OF REQUESTS & CONTRACTS

Customer service agreements shall be maintained by the Laboratory. Moreover, The Laboratory shall retain all records generated as a result of testing, as well as reports, reviews, and any pertinent communication with the customer.

7.2 SELECTION, VERIFICATION & VALIDATION OF METHODS

7.2.1 SELECTION & VERIFICATION OF METHODS

7.2.1.1 GENERAL

The Laboratory shall use appropriate methods and procedures for all tests within its scope. These include sampling, handling, transport, storage and preparation of items to be tested, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test data, as needed.

7.2.1.1.1 ASSOCIATED DATA INTERPRETATION

All associated data interpretation shall be considered part of a validated method. When changes are made, then section 7.2.2.2 shall apply.

7.2.1.1.2 EVALUATION OF UNKNOWNS FOR COMPARISON

Criteria for the evaluation of mass spectrometry fragments and ratios in unknowns shall be found in the forensic discipline-specific SOPs.

7.2.1.2 METHOD AVAILABILITY

All instructions, standards, manuals and reference data relevant to the work of the Laboratory

shall be kept up to date and shall be made readily available to personnel. Refer also to the "Control of Management System Documents" (8.3) section of this manual.

Protocols for each analytical method routinely used in casework shall be maintained for each forensic discipline of the Laboratory. These protocols shall specify the requirements for the supplies and materials that affect the quality of the tests, as appropriate, and shall include the reference materials and controls required for each procedure.

Instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing, where the absence of such instructions could jeopardize the results of the tests, shall be available as a hard copy or through electronic means.

7.2.1.3 METHOD APPLICATION

Personnel within the Laboratory shall use the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

7.2.1.4 METHOD SELECTION

The Laboratory shall use test methods, including methods for sampling, which are appropriate for the tests it undertakes. These methods may be from external sources, such as appropriate published methods from international, regional or national standards, reputable technical organizations, or relevant scientific texts or journals. Laboratory-developed methods or methods adopted by the Laboratory may also be used if they are appropriate for the intended use and if they are validated.

7.2.1.5 METHOD VERIFICATION

Methods that are widely used and generally accepted by scientifically qualified entities shall be considered valid. Methods that have been demonstrated to be reliable through sufficient testing by the developer shall also be considered to be valid; however, any method that has not been validated or any method that is new to this Laboratory shall be subjected to internal validation and/or evaluation to ensure its reliability as it is applied in-house. The reliability of the method shall be demonstrated against any documented performance characteristics of that method, and the Laboratory shall maintain records of this performance verification for future reference. Significant changes made to analytical methods shall necessitate the revalidation of the method and shall not be made without prior approval of the Laboratory Director or his/her designee.

7.2.1.6 METHOD DEVELOPMENT

The introduction of test methods developed by the Laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. Test methods shall not be used on case work until they are properly validated. Any plans concerning the new method or the implementation of the new method shall be updated as development proceeds and the Laboratory shall ensure that all affected personnel are notified, as appropriate. Modification of any manual shall not be done without the consent of the Laboratory Director.

7.2.1.7 METHOD DEVIATIONS

Laboratory procedure manuals cannot be relied upon to cover every possible aspect of casework. It is recognized that every case and every exhibit has the potential to be unique. Therefore, deviations from protocol may occasionally be justified and allowable in those circumstances requiring alternative actions. However, these deviations require prior approval from the Laboratory Director and deviations from test methods shall occur only if the deviation has been documented and technically justified. Any deviation from standard procedure shall not be open ended and shall be limited to the procedures and timeframe specified by the Laboratory Director.

7.2.2 VALIDATION OF METHODS

7.2.2.1 NON–STANDARD METHODS

When it is necessary to use methods not covered by standard methods, these shall be validated appropriately prior to use in casework.

7.2.2.1.1 DATA INTERPRETATION & LIMITATIONS

Protocols for the validation of each analytical method routinely used in casework shall specify the requirements and guidelines for interpretation and reporting of analytical results, identify limitations of the method, and, where appropriate, identify references on which the procedures are based. The extent of the validation shall depend on the complexity of the method and whether or not it has been previously validated. Modification to a validated method requires evaluation to confirm that changes do not have an adverse effect on the method's performance, based on consideration of the specific parameter(s) likely to be affected by the changes.

7.2.2.2 METHOD CHANGES

Laboratory methods shall be periodically updated or expanded to improve quality of service. This may be accomplished by adopting new or improved methods from other laboratories or from literature, developing new methods internally, or improving the methods currently used in the Laboratory. The Laboratory shall record the procedure used for the validation, the results obtained, and a statement as to whether the method is fit for the intended use, in accordance with the Validation SOP.

7.2.2.3 RELEVANCE OF VALIDATION DATA

When the analytical method produces quantitative results, validation shall also evaluate, as appropriate, the acceptable range and accuracy of the values obtained with respect to uncertainty of results, detection limits, selectivity of the method, linearity, limit of reproducibility, and possible interferences.

7.2.2.4 VALIDATION PROCEDURE

Only validated methods shall be used to analyze case samples in order to ensure the quality of casework. New or modified technical procedures shall not be employed for casework until they have been subjected to sufficient testing to ensure their reliability. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application and shall:

- Include data interpretation using the method;
- Establish the data required to report a test result, opinion, or interpretation;
- Identify limitations of the method, reported results, opinions, and interpretations;
- Identify needs for additional validation of currently validated methods; and
- Include an evaluation with acceptance criteria to determine if the method is fit-for-purpose prior to starting a method validation.

All validation records shall be maintained by the Laboratory, and shall be available for review.

7.3 SAMPLING

7.3.1 POLICY

Laboratory procedures regarding sampling shall be located in the individual forensic discipline procedure manuals.

7.3.2 SAMPLING PLAN

The sampling plan shall provide guidelines for the selection of sample(s), the preparation of sample(s) to be used for testing, and provide instruction regarding the course of action to take if one or more selected items demonstrate a lack of homogeneity.

7.3.2.1 STATISTICAL SAMPLING

When used, a statistical sampling plan shall make use of probability and provide an interpretation with a minimum confidence level of 95%.

7.3.3 RECORDS

Analytical records for sampling shall include the sampling plan used, when the sampling occurred, the identification of the sampler, environmental conditions (if relevant), diagrams or other equivalent means to identify the sampling location as necessary, the equipment used, and, if appropriate, the statistics the sampling plan is based upon.

Deviations, additions, or exclusions from the documented sampling plan shall be:

- Recorded in detail with the appropriate sampling data;
- Included in all documents containing test results; and
- Communicated to the appropriate personnel.

7.4 HANDLING OF TEST OR CALIBRATION ITEMS

7.4.1 POLICY

Laboratory policy and procedures for the identification and handling of test items shall be defined in order to protect the integrity of the items and to protect the interests of the Laboratory and the customer. Refer to the Evidence Control SOP for more information.

7.4.1.1 PROCEDURES

7.4.1.1a ITEMS ENCOMPASSED

Laboratory procedures shall address all evidence accepted and stored in the Laboratory, not

only those items tested.

7.4.1.1b STORAGE, PACKAGING, AND SEALING

7.4.1.1b.1 PROTECTION OF EVIDENCE INTEGRITY

The Laboratory shall ensure that evidence accepted and stored in the Laboratory is properly sealed. A package is "properly sealed" only if its contents cannot readily escape and only if “entering the package results in obvious damage/alteration of the package or seal” that is “sufficient to compromise the integrity of the evidence”. All packages shall be heat sealed or sealed with evidence tape, and the tape used to seal the package or the heat seal shall be signed or initialed to document the person sealing the evidence. Manufactured evidence bags having adhesive seals shall be accepted, provided that the seal is initialed. If the container bearing the seal is a box, then the bottom seam of the box shall also be sealed with evidence tape and initialed or signed.

Evidence is sometimes submitted to the Laboratory without a proper seal. If possible, the seal should be remedied by the submitting agency at the time of submission. If this is not possible, then the Laboratory shall ensure that the evidence is stored under proper seal. This may be accomplished by either placing a seal across the area that is not properly sealed and then initialing and dating it, or by putting the evidence item into another container and properly sealing the secondary container. Although it is the policy of the Laboratory that all evidence submitted shall be sealed when it is submitted, exceptions to this policy may occur for items too large to place in sealable containers.

7.4.1.1b.2 RE-SEALING EVIDENCE AFTER ANALYSIS

Evidence shall be re-sealed as soon as practicable after testing is completed.

7.4.1.1c SECURING EVIDENCE

Evidence should only be in the custody of Laboratory staff for the time necessary to complete analysis, technical review, or other necessary functions. Evidence in the process of analysis shall remain in the custody of technical personnel and be protected from loss, cross-transfer, contamination or deleterious change. Evidence analysis is normally performed on a bench top in one of the Laboratory work areas. If the analyst needs to leave the room for a short period of time, it is not necessary to pack up the evidence; however, unsealed/sealed evidence shall not be left unattended unless the evidence is secured in its storage area. Other necessary functions include meeting with prosecutors or defense attorneys to demonstrate or discuss evidence pre-trial. Under normal circumstances, the analyst should not have evidence in their possession longer than the length of a normal work day. Deviations from this policy shall only be granted by the Laboratory Director.

Evidence that is not in the process of analysis shall be maintained in a secured, limited-access storage area under proper seal. In general, evidence that is not in the process of analysis shall be stored in the evidence vault or secured in the appropriate biological evidence freezers/refrigerators.

Evidence shall be retained by the Laboratory until it is forwarded to another Laboratory for

analysis, picked up by the submitting agency, turned over to the prosecuting official, or destroyed. If not retained by the Laboratory, evidence should be returned to the submitting agency in person or by another appropriately secure means which provides a return receipt. Evidence may be submitted for destruction only, but shall be clearly marked as such upon submission. All evidence shall be destroyed according to the Evidence Destruction SOP. In most instances, evidence submitted for analysis shall be destroyed only upon receipt of one of the following:

- Court order;
- Authorization letter from submitting agency; or
- Authorization letter from the office of the prosecuting official.

7.4.1.1d TRACKING CHAIN OF CUSTODY

All internal evidence transfers within the Laboratory shall be recorded. This chain of custody record may be in the LIMS, in the case folder, or a combination of both.

7.4.1.1d.1 ITEMS ENCOMPASSED

All evidence accepted and stored in the Laboratory, not only those items tested, shall have documented chain of custody records.

7.4.1.1d.2 CREATED ITEMS

Created items within the Laboratory, such as containers used for storage of items of evidence or sub-samples for bulk items of evidence, shall have documented chain of custody records.

7.4.1.1e CHAIN OF CUSTODY IDENTIFICATION

The Laboratory shall maintain a written and/or electronic chain of custody record with all necessary data which provides for complete identification and tracking of all evidence.

7.4.1.1e.1 RECEIVING OR TRANSFERRING

Each person shall acknowledge by signature, initials, or secure electronic equivalent, at the time of transfer, when they take possession of evidence or transfer evidence to a storage location or agency representative.

7.4.1.1e.2 ITEM(S) BEING TRANSFERRED

For transfers to and from Laboratory custody, chain of custody documentation shall include the date, the number of items and/or a description of the evidence or packaging, and the written or electronic signature of each person making the transfer.

For evidence transfers within the Laboratory, chain of custody documentation shall include the date, the Laboratory number, the number of items and/or a description of the evidence or packaging, the location(s) receiving or transferring the items, and the initials of the person(s) making the transfer by using a password or pin number in the LIMS.

7.4.1.1e.3 ORDER OF TRANSFERS

Chain of custody records for evidence transfers, written or electronic, shall be in chronological

order by date.

7.4.1.1f ITEM DISPOSITION

Disposition of items received by the Laboratory shall be provided to the customer upon request. The Laboratory shall not dispose of items of evidence without proper authorization from the customer.

7.4.1.1g ITEM PRESERVATION

Items of evidence received by the Laboratory shall be preserved for future testing in accordance with the Evidence Control SOP. In the event that evidence cannot be preserved for future testing, the customer shall be notified.

7.4.2 IDENTIFICATION OF TEST ITEMS

Analysts shall review and inventory the submitted evidence (test items) and accompanying documentation. All evidence received or analyzed in the Laboratory shall be marked with the LIMS-generated Laboratory number and exhibit number, which may be contained on a barcode label. When it is not advisable, not possible, or not necessary to mark an item directly, then the container in which it is placed shall be marked. The Laboratory number, exhibit number, and any other identifier shall remain on the item (or on the container) throughout the life of the item in the Laboratory so as to ensure that items cannot be confused physically or when referred to in records or other documents.

7.4.2.1 ITEMS ENCOMPASSED

The Laboratory policy for identifying evidence shall address all evidence accepted and stored in the Laboratory, not only those items tested.

7.4.2.2 SUBDIVISION OF EVIDENCE

The Laboratory policy for identifying evidence shall, when appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the Laboratory. When evidence is subdivided due to an excess quantity of evidence or a bulk case, the sub-items shall be tracked through a documented chain of custody record to the same extent that original items of evidence are tracked.

If evidence is subdivided due to sampling or testing (itemization) procedures, the sub-items shall inherit the documented chain of custody record of the original item of evidence that was submitted to the Laboratory.

If the sub-items are separated from the original item of evidence that was submitted to the Laboratory, then an independent chain of custody record shall be created to track the sub-items and documented to the same extent that original items of evidence are tracked.

7.4.3 ABNORMALITIES IN TEST ITEMS

Upon receipt of the evidence item, or as soon as possible afterward, abnormalities or departures from normal or specified conditions, as described in the test method, shall be recorded. When there is doubt as to the suitability of an item for testing, or when an item does

not conform to the description provided, the Laboratory shall document this in the case file and, if necessary, shall consult the customer for further instructions prior to proceeding. All relevant communication shall be recorded.

7.4.4 PRESERVATION OF EVIDENCE

All evidence under the control of the Laboratory shall be properly handled, protected, and stored in a way that minimizes the possibility of loss, contamination, or deleterious change. Evidence shall be stored in a secure location under proper seal. All Laboratory employees have a responsibility to follow the procedures designated in this manual and any other Laboratory policy to protect the integrity of evidence.

Evidence shall not be removed from the Laboratory except for legitimate purposes such as transportation to court, transfer to another laboratory, or return to the submitting agency. In each of these cases, proper documentation of chain of custody shall be maintained.

7.5 TECHNICAL RECORDS

7.5.1 REQUIREMENTS FOR TECHNICAL RECORDS

The Laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report issued. These technical records shall be permanently maintained by the Laboratory, either in hard copy or electronic format, or both.

The records for each test shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the test, performance of each test, and checking of results.

When instrumental analyses are conducted, operating parameters shall be recorded and stored electronically.

7.5.1.1 CONTENT OF TECHNICAL RECORDS

Completed case records shall contain all information received or generated – including technical and administrative documentation – that may be needed for review, testimony, or response to a discovery request for that particular case. This may include the chain of custody, a record of all relevant correspondence, analytical data, the laboratory report, sampling information, derived data and sufficient information to establish an audit trail, calibration records, diagrams, photos, worksheets, printouts, spectra, charts, or other data or records used by technical personnel to support their conclusions. Documentation of administrative and technical review and the formal written report(s) shall also be in the case record. Notes, faxes or telephone messages written for the purpose of notifying technical personnel of possible trials (stand-by notes or docket order) shall not be considered administrative documentation and shall not be required to be retained.

To assist with case record management and tracking of caseload distribution, the Laboratory shall use the LIMS, JusticeTrax. The procedures outlined in the Case Documentation and Records SOP shall be followed.

A unique Laboratory number is assigned to each case for which evidence has been submitted. Information for each case is entered into the LIMS upon submission to the Laboratory. New case file folders shall be created for each Laboratory number and the folder is then normally placed into the appropriate section of the "to be worked" files in numerical order by Laboratory number.

When analysis is complete, case file folders should be placed into the "worked" files, in numerical order by Laboratory number. All reports shall be placed into the Laboratory case file folders upon their completion and review. Case files shall be organized in a manner to:

- Ensure efficient, timely flow of evidence, casework and reports;
- Facilitate inquiries and review of work in progress by ensuring files on open cases are readily accessible and accounted for; and
- Provide information to management on the status of current cases.

Case files may be archived after execution of a court destruction order or other authorization of destruction. Disposal of original Laboratory reports and case notes shall be authorized by court order (as in expungement). Disposal of these documents shall be done in a manner that guarantees the confidentiality of the information. Confidential documents may be torn or shredded and placed in Laboratory trash receptacles. Reports and/or notes shall never be disposed of outside of the Laboratory, unless escorted and shredded by a Laboratory employee. Refer to the Archiving of Laboratory Case Files SOP for more information.

7.5.1.1.1 IDENTIFICATION OF TECHNICAL RECORDS

All technical records generated by the Laboratory for a specific case shall be identified with the Laboratory number.

- The unique Laboratory case identifier and the analyst's handwritten initials (or secure electronic equivalent of initials or signature) shall be on each page of technical records. Pages may be copied for filing in multiple places without the necessity of placing original identifiers on each copy.
- When data from multiple cases is recorded on a single printout, the Laboratory number for each case for which data was generated shall be appropriately recorded on the printout. The printout may be kept in a single file and referenced in all files for which data was generated.

If the technical record consists of multiple pages, page numbers shall be recorded on the analyst's worksheet so that the total number of pages is reflected.

- Page numbers that are automatically generated by instruments are not relevant and shall not be considered in the numbering scheme. Instrument or other computer print-outs shall be numbered and/or included in the total number of pages recorded on the worksheet.

When technical records are recorded on both sides of a page, each side shall be treated as a separate page (labeled with Laboratory number and initials) and included in the page count).

7.5.1.1.2 RECORDING OF TECHNICAL RECORDS

Observations, data, and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

The technical record of any case is the foundation for testimony for that case. Therefore, the case notes taken during evidence analysis are crucial to the needs of the Laboratory customer. The functions of note taking shall be to support the conclusions in the Laboratory report, to permit internal review of the work product, to allow re-evaluation of the data by outside scientific observers, and to provide a foundation for the introduction of the work product into court. Notes on the initial testing of evidence items should describe the item, noting the method of sealing/packaging, sampling, the item's condition, and/or the presence of unusual features. Tablet logos, etc. should be described, diagrammed and/or photographed prior to sampling, as appropriate, at the discretion of the analyst working the case. Abbreviated or simplified notes may be taken for a case or evidence item that is only being inventoried and not analyzed. Analytical notes shall be recorded on appropriate case note forms or worksheets. If original notes are recopied by hand, the copy shall be clearly marked “rewritten”, “copy of original”, or other similar phrase. The original shall be retained in the case file.

7.5.1.1.3 RECORDING OF DATES

Technical records shall reflect when testing was performed. Differing dates may be recorded throughout the testing to indicate when certain aspects of analysis were performed. Analysis start dates shall be indicated on the analyst’s Worksheet(s). Analysis end dates shall be indicated by the Draft Complete date in the LIMS. Should technical review require further analysis, the new Draft Complete date shall reflect the analysis end date.

7.5.1.2 ABBREVIATIONS

An approved list of abbreviations specific to the Laboratory shall be kept electronically and revisions shall be approved by the Laboratory Director (see Approved Abbreviations SOP). It should be noted that all forms or tenses of a term do not have to be specified on the abbreviations list. Abbreviations on the list are not necessarily case sensitive but may be context sensitive. Moreover, the list of abbreviations may not be comprehensive of all abbreviations used at all times.

7.5.1.3 REPRODUCIBILITY OF TECHNICAL RECORDS

The data in the case record shall be sufficient to support all conclusions and opinions stated in the report, and sufficiently detailed enough so that another competent scientist may evaluate what was done and interpret the data without assistance from the original reporter of results.

7.5.1.4 PERMANENT NATURE OF RECORDS

Technical records shall be of a permanent nature. All handwritten notes, drawings and/or diagrams shall be made in ink.

7.5.1.5 REJECTION OF TECHNICAL RECORDS

If an observation, data, or a test result is rejected, the reason, the identity of the individual(s) taking the action, and the date shall be recorded in the technical record.

7.5.2 AMENDMENTS TO TECHNICAL RECORDS

In the case of technical records, either hardcopies or electronic, the Laboratory shall take measures to avoid loss of original data and to document changes to original data. These changes shall include those made as a result of verification or technical review.

Amendments or corrections shall be indicated by a single strike and shall be signed or initialed by the analyst responsible for the change. Interlineations (inserted notes) shall also be initialed. If the amendment is done on a date other than the recorded date of analysis, then the date of the change shall also be required with the initials. Otherwise, it is understood that the change was made at the time of the original documentation. White-out solution shall not be used on any part of the technical record or report.

If a copy of a technical record is generated as a result of an alteration, then both the original and amended copy shall be retained. The date of alteration, an indication of the altered aspect(s), and the personnel responsible shall also be documented.

7.6 EVALUATION OF MEASUREMENT UNCERTAINTY

7.6.1 COMPONENTS

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

7.6.1.1 PROCEDURE

Procedures regarding the estimation of uncertainty of measurement shall conform to the most current published version of the appropriate ANAB policy regarding the estimation of uncertainty of measurement**.**

At a minimum, the procedures shall:

- Require the specific equipment used for a test result to have been included in the estimation of uncertainty of measurement for that test method;
- Include the process of rounding the expanded uncertainty of measurement value;
- Require the coverage probability of the expanded uncertainty of measurement value to be at least approximately 95%; and
- Specify the schedule to review and/or recalculate the uncertainty of measurement.

7.6.2 POLICY

For reported measurements (excluding ranges), the Laboratory shall attempt to identify all of the components of uncertainty and make a reasonable estimation of the uncertainty of the measurement. The reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data. The Laboratory shall report the uncertainty of measurements in a clear and concise manner.

7.6.2.1 QUANTITATIVE RESULTS

The Laboratory shall have a procedure regarding the estimation of uncertainty of measurement of all quantitative results and shall apply it appropriately. An item descriptor that includes a number is not considered a result and does not require estimation of uncertainty of measurement.

7.6.3 RECORDS

All estimation of uncertainty of measurement records shall be maintained by the Laboratory Director, and shall be available for review.

The records shall include:

- A statement defining the measurand;
- A statement of how traceability is established for the measurement;
- The equipment used;
- All of the components considered;
- The components of significance and how they were evaluated;
- Data used to estimate repeatability, intermediate precision, and/or reproducibility;
- All calculations performed; and
- The combined standard uncertainty, the coverage factor, probability, and the resulting expanded uncertainty.

7.7 ENSURING THE VALIDITY OF RESULTS

7.7.1 QUALITY MONITORING POLICY

Laboratory technical procedures shall describe the appropriate and specific measures required to ensure the validity of results. These measures may include:

- The use of blanks and controls
- The use of internal standards
- The use of certified reference materials
- Comparison to widely accepted or validated spectral databases
- Replicate analyses or analyses done by two alternative methods
- Verification of findings
- The use of the uncertainty of measurement
- Review of records kept for balances and pipettes
- Recording of data, where appropriate, in such a way that trends may be detectable

The Laboratory also employs the following quality verification measures as an overall means of monitoring the quality of its work product:

- Technical and administrative review of Laboratory findings prior to their release
- Proficiency testing of all technical personnel
- Testimony monitoring of all technical personnel
- Yearly audits

Records shall be maintained to show that all appropriate measures have been taken. Appropriate reference materials and controls shall be specified in the methods and their use recorded in the case file.

7.7.1.1 INDEPENDENT CHECKS

When verification of a test result is carried out, it shall be conducted by an individual having expertise gained through training and casework experience in the category of testing, and a record of the review shall be made and agreed to, by whom, and when the check was performed. This verification shall be recorded in the technical record. Moreover, any discrepancies with the original findings shall be discussed with the Laboratory Director or his/her designee. Failure to resolve discrepancies may necessitate contracting the services of another accredited laboratory or other tertiary checks.

7.7.1.2 TECHNICAL REVIEW POLICY

Specific procedures regarding the technical review of records, test reports, and testimony shall be specified in the Lab Operation Guide.

7.7.1.2.1 COMPETENCY OF TECHNICAL REVIEWERS

Technical reviews shall be conducted by individuals who have demonstrated competency in the category of testing being reviewed, and who have been authorized by the Laboratory Director based on expertise gained through training and casework experience. Technical review may be performed by an individual outside of the Laboratory; however, the reviewer should have knowledge of Laboratory's technical procedures and be approved by the customer and the Laboratory Director.

7.7.1.2.2 AUTHOR CANNOT CONDUCT REVIEW

Reviews shall not be conducted by the author of the technical records or test report under review.

7.7.1.2.3 CASES SUBJECT TO TECHNICAL REVIEW

Every case in which an analysis is reported shall be peer reviewed for technical accuracy prior to reporting the results.

7.7.1.2.4 TESTIMONY MONITORING

<u>INITIAL ASSESSMENT</u>

When an employee testifies in court for the first time, their performance shall be evaluated by qualified Laboratory personnel through direct observation and the evaluation shall be documented. The purpose of this assessment is to evaluate the individual's speaking skills in giving testimony and his/her ability to present fair, impartial, and comprehensive testimony within the rules of the court. Other areas that should be covered in the assessment include appearance, poise, performance under direct or cross-examination, the ability to present evidence in an understandable manner to a lay jury, the overall effectiveness of the presentation, and whether the testimony is consistent with the work documented in the case record. The evaluation results shall be reviewed with the analyst following the testimony.

YEARLY MONITORING

Subsequent to this initial assessment, testimony should be monitored by qualified personnel at least once per year. Methods used for testimony monitoring may include: direct observation, video, transcript, or audio review, or a telephone interview of an appropriate official. Each of these methods shall involve the use of the testimony evaluation form provided by the Laboratory, and include any positive comments or information concerning any area needing improvement. Monitoring of testimony may be more frequent if the analyst is relatively inexperienced in the subject of the testimony or if there is an indication that remedial action is needed. In this situation, the Laboratory Director or his/her designee should evaluate the performance of the analyst through direct observation and document the evaluation.

When testimony review indicates a possible deficiency in the testimony, the Quality Manager or his/her designee shall evaluate and implement the proper course of action to resolve the deficiency. This may involve remedial action, including additional training, mock court exercises or other corrective counseling. If an individual does not testify within the calendar year, then no monitoring of testimony may be performed. In this case, the employee shall sign a memo stating that they did not testify (in any discipline) for that calendar year. Refer to the Court Testimony Monitoring SOP for more information.

Records of testimony monitoring shall be retained through one cycle of accreditation or four years, whichever is longer. The Quality Manager shall maintain the testimony monitoring records.

7.7.1.2.5 TECHNICAL REVIEW RECORDS

Documentation of technical review shall be recorded by the reviewer in the case file, and shall include the reviewer's initials or electronic signature, type of review, and date reviewed. Use of a password or pin number in the LIMS shall be considered an electronic signature and acceptable documentation of technical review.

In the event that records are technically reviewed by qualified personnel outside of the Laboratory, this review shall be noted on the appropriate worksheet. Since these technical reviewers may not have access to the LIMS, other Laboratory personnel may be listed as reviewers in the LIMS; however, the true technical review documentation shall be maintained in the case file.

7.7.1.2.6 REQUIREMENTS FOR TECHNICAL REVIEW

At a minimum, the technical review shall include a review of all data, test results, and the test report to ensure:

- The testing addressed the submitting agency's request;
- Results and/or conclusions drawn are supported by the documentation (notes, charts, etc.) and are scientifically appropriate;
- The test results included on forwarding forms are correct; and
- The test report is accurate and contains all required information.

7.7.1.2.7 SCOPE OF TECHNICAL REVIEW

Laboratory procedures for technical review shall ensure conformance with proper technical procedures (test methods) and applicable Laboratory policies and procedures by:

- Verifying that the conclusions of technical personnel are reasonable and within the constraints of validated scientific knowledge; and
- Monitoring case results for clarity, quality, and adherence to Laboratory standards.

7.7.1.2.8 FEEDBACK FROM TECHNICAL REVIEW

Cases that are found by any reviewer to be deficient shall be returned to the original analyst. Simple errors may be indicated with a brief note. More serious or complex deficiencies may require a conference between the reviewer and the original analyst. All technical personnel shall be expected to exhibit courtesy and cooperation toward reviewers. If a disagreement arises between the original analyst and the reviewer, the dispute may be resolved by additional technical review, or with consultation with peers up to and including the Laboratory Director, whose decision shall be final.

7.7.2 PROFICIENCY TESTING

The Laboratory shall participate in proficiency testing in order to monitor the performance of individual technical personnel, as well as the Laboratory as a whole. Proficiency tests provide a mechanism for critical self-review and a means by which others, such as ANAB, may evaluate Laboratory performance on an on-going basis.

7.7.2.1 EXTERNAL PROFICIENCY TESTS

The Laboratory shall complete at least one external proficiency test in each forensic discipline each year. The Laboratory Director shall authorize the release of the test results to ANAB.

7.7.3 DATA MONITORING

Quality verification data shall be analyzed, used to control and, if applicable, improve the laboratory's activities. When outside of pre-defined criteria, action shall be taken to correct problems and to prevent incorrect results from being reported. If there is an indication that any Laboratory findings do not conform to Laboratory policy, then the policy for the control of nonconforming testing work in this manual shall immediately be followed, including the implementation of the corrective action procedure, if warranted.

7.7.4 PERFORMANCE MONITORING

All technical personnel, either performing casework or solely reviewing and authorizing results, shall complete one proficiency test during each four year accreditation cycle for each discipline in which he or she performs casework or conducts technical review. A schedule shall be maintained by the Quality Manager to ensure that the proficiency testing is being performed.

Moreover, all fully trained technical personnel shall successfully complete at least one proficiency test annually for each assigned discipline. If an individual fails to complete proficiency testing in any discipline, he/she should not resume casework in that discipline until proficiency testing is completed and documented as satisfactory by the Laboratory Director. The proficiency program and files shall be maintained by the Quality Manager, and he/she shall oversee the assignment of all proficiency tests.

7.7.5 PROFICIENCY TEST POLICY

7.7.5a RESULTS

Proficiency tests may be “internal” (i.e., samples prepared in-house and/or results not reported to an external body) or “external” (i.e., samples acquired from and results reported to an independent outside source). Samples may be retained from previously completed external tests and re-issued to other technical personnel as unknowns in subsequent internal tests. In any case, the “correct results” shall be unknown to both the individual being tested and technical reviewer until after the tests are completed and the results are reported.

Proficiency tests may be “open” (i.e., the fact the samples are part of a test is known to the individual being tested) or “blind” (i.e., the individual being tested is unaware the samples are a test). Because technical personnel routinely confer with submitting agencies and laboratories about their cases, a true “blind test” in casework may be difficult to construct in practice. However, re-analysis of randomly selected casework by other technical personnel may serve the same purpose.

7.7.5b METHODS USED

Proficiency tests shall be conducted using the current approved procedures being applied on casework samples in order to evaluate the normal analysis protocol of the Laboratory. Work shall be done independently by technical personnel, supported by notes, photographs, or other documentation, and summarized in a written form as required for casework. Prior to reporting the proficiency test results, the work shall receive the same level of technical review required for casework.

Internal, external, open, and blind proficiency testing may be employed by the Laboratory to monitor routine evidence testing abilities, the reliability of new methodology, employees who have demonstrated a need for remedial training in an area of evidence testing, or the abilities of employees working with new types of evidence.

7.7.5c RECORD RETENTION

The proficiency test files, maintained by the Quality Manager, shall be retained through one cycle of accreditation or four years, whichever is longer. A record or log of the completion of

each individual's proficiency tests shall be maintained by the Quality Manager, and retained indefinitely.

7.7.5d COMPLETION CRITERIA

The Laboratory shall establish criteria for the successful completion of proficiency tests. The Laboratory Director or his/her designee shall review all test materials and compare results to information supplied by the test provider to determine if test performance is satisfactory.

7.7.5e QUALITY ASSURANCE

The Laboratory shall ensure the quality of proficiency tests by applying appropriate and validated methodology to testing activities.

7.7.6 PROFICIENCY TEST PLAN

The Laboratory proficiency test plan shall ensure that personnel participate in the required proficiency testing per each accreditation cycle, and that the proficiency tests are representative of the test samples encountered and methods used in each discipline.

7.7.7 COMPLIANCE TO ANAB POLICY

7.7.7a REQUIREMENTS OF TEST PROVIDERS

The Laboratory subscribes to external proficiency tests from an outside vendor accredited to ISO/IEC 17043. ANAB approved test providers shall be used where available.

7.7.7b APPROVAL OF TEST PROVIDER

If there is not an approved test provider available, then the Laboratory shall locate and gain approval from ANAB for the use of a source of an external test in that discipline.

7.7.7c SUBMISSION OF RESULTS

The Laboratory Director or his/her designee shall ensure that test results are returned to the vendor within the applicable deadlines in each of the forensic disciplines.

7.7.8 PROFICIENCY TESTING RECORDS

The Laboratory shall maintain records of proficiency testing and the documentation of the proficiency testing program shall include, at a minimum:

- The discipline tested;
- How samples were obtained or created;
- The expected proficiency test results
- Identity of the person taking the test;
- Date of analysis and completion;
- All technical records and the results and conclusions obtained;
- Evaluation of test results, including any discrepancies noted;
- Documentation of technical review;
- Records of submission to external test provider; and
- Feedback provided to the participants.

In any situation where the results of the test are not satisfactory, the file shall also include documentation of corrective action taken. For external tests, the file also contains the report of the test provider regarding that particular test. Deficiencies in proficiency tests may be recorded in administrative files and/or personnel records, as appropriate.

7.7.8.1 EVALUATION & FEEDBACK

Proficiency tests shall be evaluated and the individual who was tested shall be provided written feedback in a timely fashion by the Laboratory Director or his/her designee as to whether or not the performance is satisfactory. When proficiency tests indicate a possible deficiency in the training or abilities of a Laboratory employee, the Laboratory Director, his/her designee, and/or Quality Manager shall evaluate the proper course of action, to include the policy for the control of "Nonconforming Work" in this manual (section 7.10), or "Corrective Action" (section 8.7), if warranted.

7.7.9 ADMINISTRATIVE REVIEW POLICY

After completion of a case and prior to issuing the results to the submitting agency, all case files shall be administratively reviewed, including an assessment of the completed report. The purpose of the administrative review shall be to verify that:

- The report is sufficiently detailed, clear, and concise; and
- The information in the report is accurate and free of errors.

Administrative reviews shall be conducted by someone other than the author(s) of the report. Administrative reviews shall be performed following technical reviews; however, administrative reviews may be conducted by any authorized Laboratory employee. Documentation of the administrative review shall be recorded by the reviewer in the case record, and shall include the reviewer's initials or electronic signature, type of review, and date reviewed. Use of a password or pin number in the LIMS shall be considered an electronic signature and acceptable documentation of administrative review.

Location of Review Documentation

Technical and administrative reviews for casework in all disciplines shall be documented in LIMS.

7.7.9.1 REQUIREMENTS

At a minimum, the administrative review shall include:

- A review of the test report for spelling and grammatical accuracy;
- A review of all administrative and technical records to ensure that the records are uniquely identified according to Laboratory policy and/or procedure; and
- A review of the test report to ensure that all key information is included.

7.8 REPORTING OF RESULTS

7.8.1 GENERAL

7.8.1.1 REVIEW

All findings and results shall be technically and administratively reviewed by qualified Laboratory personnel prior to release, and the review shall be documented in the case file.

7.8.1.1.1 AUTHORIZER OF RESULTS

The analyst authorizing the report shall review the technical record and document the review in the case file.

7.8.1.2 POLICY

Laboratory results shall be reported accurately, clearly, unambiguously and objectively, and as agreed to by each customer in the customer service agreement.

7.8.1.2.1 FORMAT OF REPORTS

Results of testing shall be provided to the customer in a written report or through electronic access. Each section of the Laboratory may elect to have a different reporting format, as necessary; however, this format shall be designed to accommodate each type of test carried out and to minimize the possibility of misunderstanding or misuse. Refer to the Laboratory Reports SOP for more information.

7.8.1.2.2 ITEMS REPORTED

Specific procedures regarding the reporting of results for all testing performed shall be specified in the individual forensic discipline procedure manuals.

7.8.1.2.2a PROCEDURE

Laboratory reports shall be issued for all completed cases. If no confirmatory instrumental analysis is performed, or if only partial analytical work in the form of presumptive or screening testing is performed on an item of evidence, then normally the item shall be reported as “not analyzed”, or similar phrase.

7.8.1.2.2b LACK OF CONCLUSIONS

If no definitive conclusions may be reached, the report shall clearly communicate the reason(s).

7.8.1.3 SIMPLIFIED REPORTS

The Laboratory customer service agreement allows the Laboratory to issue simplified reports. The Laboratory shall ensure that the case record contains all of the relevant information required by ISO/IEC 17025 and AR 3125. Any information which is not reported to the customer shall be readily available in the Laboratory as part of the case record.

Laboratory management shall maintain written documentation of this customer agreement.

7.8.2 COMMON REQUIREMENTS FOR REPORTS (TEST & SAMPLING)

7.8.2.1 CONTENT OF TEST REPORTS

Each test report shall include at least the following information unless the Laboratory has valid reasons for not doing so:

a) The title of the report;
b) The name and address of the Laboratory and the customer (submitting agency);
c) The unique Laboratory number;
d) The name of the subject;
e) Identification of the confirmatory testing methodology or confirmatory analytical techniques used;
f) An unambiguous identification of the item(s) tested;
g) The date of receipt of the test item(s) (submission date);
h) The date the report was printed (issue date);
i) The date of offense or incident (for drug evidence);
j) The date of specimen (for biological evidence);
k) The test results with, where appropriate, the units of measurement;
l) Reference to the sampling plan and procedures used where relevant;
m) The signature of the person authorizing the test report; and
n) A statement regarding uncertainty of measurement, if applicable.

The following shall be identified in the case record:

- Data with the unique Laboratory number on each page, and the total number of pages;
- A description of the condition of the item(s) tested and the date(s) of performance of the test;
- Identification of preliminary or screening methodology or preliminary or screening analytical techniques used; and
- The start and end dates of analysis.

7.8.2.2 DATA FROM CUSTOMERS

Data provided by a customer that may have an affect the validity of results shall be clearly identified in the report and/or case file (i.e. if the customer advises the Laboratory that analysis is not necessary).

7.8.3 SPECIFIC REQUIREMENTS FOR TEST REPORTS

7.8.3.1 REGARDING INTERPRETATIONS

In addition to the requirements listed in section 7.8.2, case records shall, where necessary for the interpretation of the test results, include the following:

a) Deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;
b) Where appropriate and needed, opinions and interpretations (see the “Opinions and Interpretations” section of this manual, 7.8.5); and
c) Additional information which may be required by specific methods, customers or groups of customers
d) The measurement uncertainty value in the format y ± U, presented in the same units and to the same number of decimal places as that of the measurand

Specific procedures for reporting the estimation of uncertainty of measurement shall be specified in the individual forensic discipline procedure manuals.

7.8.3.1.1 EXCEPTIONS TO REPORTING UNCERTAINTY

If a regulatory body or legal requirement prohibits the reporting of measurement uncertainty, the Laboratory shall have objective evidence of such.

7.8.3.2 REGARDING SAMPLING

In addition to the requirements listed in 7.8.2 and 7.8.3.1, all Laboratory test reports that include results of sampling shall meet the requirements listed in section 7.8.4.

7.8.4 REPORTING SAMPLING – SPECIFIC REQUIREMENTS

Case records containing the results of sampling shall include the following, where necessary, for the interpretation of test results:

- The date of sampling;
- Unambiguous identification of the substance, material or product sampled;
- The location of sampling;
- A reference to the sampling plan and procedures used;
- Details of any environmental conditions during sampling that may affect the interpretation of the test results; and
- Any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

7.8.4.1 REPORTS CONTAINING SAMPLING

Laboratory reports containing the results of sampling shall include a reference to the sampling plan and procedures used, including the confidence level and inference to population.

7.8.5 REPORTING OPINIONS & INTERPRETATIONS

7.8.5.1 AUTHORIZATION

Only personnel authorized for the expression of opinions and interpretations shall release the respective statement. The basis upon which the opinions and interpretations have been made shall be documented.

7.8.5.2 IDENTIFICATION

The Laboratory shall clearly identify opinions and interpretations expressed in a test report.

7.8.5.3 COMMUNICATION WITH CUSTOMER

Any opinions and interpretations directly communicated by dialogue with the customer shall be documented in the case file.

7.8.6 AMENDMENTS TO TEST REPORTS

An “Amended Report” shall normally be issued if additional information is to be reported, such as an additional evidence item, or additional analysis of a previously reported item.

7.8.6.1 CONTENT OF AMENDED TEST REPORTS

When an issued report is amended or supplemented, the Laboratory shall uniquely identify the report, state why the report was revised or corrected, and clearly indicate the new and/or corrected information.

If analysis is not needed for the amended report to be issued, then a technical review is not required; however, an administrative review shall be performed. Distribution of these reports shall follow normal report issue procedures.

7.8.6.2 REQUIREMENTS FOR REPORTING

Material amendments to a test report after issue shall be made only in the form of a further document, which includes the statement "Amended Report" and a reference to the original report. Such amendments shall meet all the requirements of ISO/IEC 17025 and AR 3125.

7.8.6.3 IDENTIFICATION OF AMENDED TEST REPORTS

If an error is noted in a final report and it has not been distributed outside of the Laboratory, all copies shall be collected and destroyed. A correct report shall then be issued.

If the report has been distributed outside of the Laboratory, another report entitled "AMENDED REPORT", or similar wording shall be issued.

7.9 COMPLAINTS

7.9.1 POLICY

Formal complaints or concerns regarding quality or other aspects of the management system shall be brought to the attention of Laboratory management, in writing. Complaints shall be investigated by Laboratory management to determine necessary changes and/or to improve quality of Laboratory services. Customers shall be notified in writing if the complaint or concern warrants a documented response.

7.9.2 HANDLING OF COMPLAINTS

Laboratory management shall be available to receive complaints during normal business hours (Monday through Friday, between 8:00 am and 5:00 pm). The Laboratory's process for handling complaints shall be available to any interested party upon request.

7.9.3 PROCEDURE

The Laboratory shall handle all formal complaints according to the Complaints SOP.

7.9.4 LABORATORY RESPONSIBILITY

Laboratory management shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 COMMUNICATION

Laboratory management shall acknowledge receipt of all complaints, and shall provide progress reports to the appropriate parties, as needed.

The Laboratory shall maintain records of complaints and any action taken to resolve complaints.

7.9.6 IMPARTIALITY REGARDING COMPLAINTS

Investigation of the complaint shall be conducted, reviewed, and approved by individual(s) not involved in the Laboratory activities pertaining to the complaint.

7.9.7 COMPLAINT RESOLUTION

The Laboratory Director shall document the final resolution of complaints, and shall provide a timely response to the complainant.

7.10 NONCONFORMING WORK

7.10.1 POLICY REGARDING NONCONFORMING WORK

The following procedures in sections 7.10.1a – 7.10.1f shall be implemented when there is an indication that any aspect of analytical testing or results do not conform to Laboratory policy.

7.10.1a IDENTIFICATION OF NONCONFORMING WORK

It is the responsibility of every Laboratory employee to identify possible situations where the analytical testing or results may not conform to Laboratory policy. All Laboratory employees who manage, perform, or verify analytical work shall immediately inform Laboratory management if a situation arises that could adversely affect the required quality of the analysis or increase the measurement uncertainty of cases yet to be reported.

7.10.1b EVALUATION OF RISK

The Laboratory shall select and implement response(s) to nonconforming work. Refer to the Quality Action Plan SOP for more information.

7.10.1c EVALUATION OF NONCONFORMING WORK

If applicable, the Laboratory Director, or his or her designee, shall immediately investigate any indication of nonconforming work or results and make a determination about whether the problem is of an individual nature or is systemic to the Laboratory operation (methodology / reagents / instrumentation, etc.). The evaluation of the nonconformance shall include an investigation of the possible impact (if any) on past casework.

7.10.1d IMMEDIATE ACTION

Once nonconforming work has been evaluated, corrective action should begin immediately, if appropriate, including any decision about the acceptability of the nonconforming work. Corrective action may include the issuing of corrected reports, if necessary.

7.10.1e CUSTOMER NOTIFICATION

If the evaluation of nonconforming work reveals an impact on past casework, then the customer shall be notified via an “Amended Report” or otherwise.

7.10.1f RESUMING CASEWORK

Once casework has been halted as a result of nonconforming work, only the Laboratory

Director, or his/her designee, shall authorize the resumption of casework by the individual or the discipline affected.

7.10.2 RETENTION POLICY FOR NONCONFORMING WORK

Records of nonconforming work and related actions shall be retained through one cycle of accreditation or four years, whichever is longer.

7.10.3 MANDATORY CORRECTIVE ACTION

Where the evaluation indicates that the nonconforming work could recur or indicates that there is doubt about the compliance of Laboratory operations with its own policies and procedures, corrective action procedures shall be implemented.

7.11 CONTROL OF DATA & INFORMATION MANAGEMENT

7.11.1 ACCESS OF DATA

The Laboratory shall provide personnel access to all data and information needed to perform Laboratory activities.

7.11.2 DATA ON EQUIPMENT

Software for computers or other automated equipment that is used in the acquisition, processing, recording, reporting, storage or retrieval of test data shall be suitable for the intended use and tested or validated to verify performance prior to use in casework. The Laboratory Director shall approve all changes to laboratory software or other automated equipment in the management system.

7.11.3 DATA PROTECTION

The Laboratory shall ensure the protection of the integrity and confidentiality of data by limiting access to the data, limiting access to areas within the Laboratory where data is stored, and using password encrypted software for its LIMS.

The Brazoria County Information Systems (I.S.) Department performs daily data backups of the LIMS. Refer to the Laboratory Information Management System SOP for more information.

7.11.4 DATA ON EXTERNAL SERVERS

The Brazoria County Information Systems (I.S.) Department shall ensure that the security and maintenance of the computer server(s) on which the LIMS software is installed complies with all applicable requirements of ISO/IEC 17025 and AR 3125.

7.11.5 LITERATURE RESOURCES

Laboratory personnel shall have access to instruction manuals and other reference data related to the LIMS, as available.

7.11.6 CALCULATIONS & DATA TRANSFERS

Manual calculations and appropriate data transfers shall be checked during technical review.

7.11.6.1 CHECKS OF CALCULATIONS & DATA TRANSFERS

The case file shall indicate the check and who performed the check. This check shall not be conducted by the person who performed the calculation or data transfer.

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 OPTIONS

8.1.1 GENERAL

The Laboratory management system is designed to comply with ISO/IEC 17025 and AR 3125.

8.1.2 OPTION A

As a minimum, the Laboratory management system shall address the following:

- Management system documentation (see 8.2);
- Control of management system documents (see 8.3);
- Control of records (see 8.4);
- Actions to address risks and opportunities (see 8.5);
- Improvement (see 8.6);
- Corrective actions (see 8.7);
- Internal audits (see 8.8); and
- Management reviews (see 8.9).

8.2 MANAGEMENT SYSTEM DOCUMENTATION (OPTION A)

For the fulfilment of the purposes of this document, the Laboratory shall establish quality policies and objectives, and ensure their acknowledgement and implementation at all levels of the organization.

8.2.1 MANAGEMENT POLICY & OBJECTIVES

The following is the Laboratory quality policy statement:

> **The Brazoria County Sheriff's Office Crime Laboratory and its management are committed to an ongoing program of services in the forensic discipline of Seized Drugs that meet or exceed the needs of its customers and that meet or exceed the minimum requirements of ISO/IEC 17025 and AR 3125.**
>
> **The BCCL management is committed to good professional practice, satisfying the needs of its customers, compliance with established standards, and the continuous improvement of its management system. In addition to following established laboratory quality objectives and procedures, all employees shall strive to improve the quality of operations of the Laboratory.**

The mission/objective of the Laboratory is as follows:

> **The mission of the Brazoria County Sheriff's Office Crime Laboratory is to provide meaningful, timely, unbiased, and accurate forensic services to its customers.**

The Laboratory standard of service is as follows:

The Brazoria County Sheriff's Office Crime Laboratory serves its customers by analyzing Seized Drugs evidence that may be of interest in judicial proceedings.

Seized Drugs
Identification of controlled substances and/or dangerous drugs

By submitting evidence to the Laboratory for forensic evaluation or analysis, customers are agreeing to the Laboratory standard of service. The submitting agencies are also authorizing the Laboratory to select the appropriate method for testing and to make other technical decisions regarding the evidence.

By accepting evidence into the Laboratory, the Laboratory is not agreeing to test all of the items submitted using the entire capabilities of the Laboratory. BCCL policies exist to expedite the sampling and processing of cases, and the Forensic Scientists in the Laboratory shall make the final determination of which samples shall be tested, and to what extent, as well as which methods of testing shall be used. If deviations from standard methods occur, they shall be technically justified, reviewed and approved prior to being implemented in casework.

8.2.1.1 CONFORMANCE IN WRITING

The following words (to include forms of the same word) used in ISO/IEC 17025 and AR 3125 require addressing the requirement in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, and specify.

8.2.2 SCOPE OF POLICY & OBJECTIVES

The Laboratory policies and objectives address the competence, impartiality, judgment or operational integrity of its employees.

8.2.3 COMMITMENT TO MANAGEMENT SYSTEM

Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. Evidence of this may be found in the implementation of procedures, solicitation of employee input, feedback from Laboratory customers, staff meetings, annual review of manuals and procedures, audits and audit follow-up, investigation of complaints concerning the management system, and/or an annual review of the management system.

8.2.4 FULFILLMENT OF MANAGEMENT SYSTEM REQUIREMENTS

The management system shall contain and/or reference in this manual all Laboratory documents and records related to the fulfilment of the requirements of ISO/IEC 17025 and AR 3125.

8.2.5 ACCESS TO PERSONNEL

The management system shall be communicated to and available to all Laboratory personnel for review and application in their respective duties. Implementation of the management system is the responsibility of all Laboratory personnel.

8.3 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS (OPTION A)

8.3.1 GENERAL

The Laboratory shall establish procedures to control all documents that comprise the management system. Documents, not including case files, that specify requirements or prescribe tasks that affect the quality of Laboratory testing shall be controlled to ensure that they are adequate, approved for use, and that only the current version of those documents are in use. Refer also to the Document Management SOP.

8.3.2 DOCUMENT ISSUANCE AND MAINTENANCE

8.3.2.1 APPROVAL BY LABORATORY DIRECTOR

All documents intended for use by Laboratory personnel as part of the management system shall be reviewed and approved by the Laboratory Director prior to being issued. All current versions of issued documents shall be found on the Laboratory network in the "Controlled Documents" folder.

8.3.2.2 DOCUMENT REVIEW

All manuals and appendices comprising the management system that were generated by the Laboratory shall be reviewed. Job Descriptions and forms that were generated by the Laboratory shall be reviewed at least once every cycle of accreditation to ensure the continuing suitability of the content and to comply with applicable requirements.

Management system documents generated outside of the Laboratory should be replaced with current versions as they become available. At a minimum, these documents shall be reviewed at least once every cycle of accreditation to ensure that they are still applicable to Laboratory operations.

8.3.2.3 DOCUMENT REVISION

Revisions to management system documents prepared by the Laboratory shall be subject to the same review, approval, documentation, and issuance requirements as the original documents unless specifically designated otherwise by the Laboratory Director. Also, revisions to instrumentation manuals or externally produced management system documents shall be subject to the same review and approval as the original. Changes to policies, practices, procedures, and training program manuals shall be described in the revision history portion of the document. In addition, all meaningful and substantive changes made to manuals shall be communicated to appropriate personnel when the new version is issued.

If necessary, the Laboratory Director may make changes to a management system document by issuing a memorandum which clearly communicates the additional policy or change in policy, the effective date, and the scope of the policy. This memorandum shall be shared with all staff members affected by the change. As soon as practical, but no later than the completion

of the next annual document review, any changes shall be incorporated into the next version of the document.

8.3.2.4 CHANGES TO ELECTRONICALLY STORED DOCUMENTS

The official version of controlled documents shall be found as a word file in the password protected Crime Laboratory "Controlled Documents" folder, and shall be viewed from all laboratory networked computers as a non-editable .pdf file located in the "Current SOPs" folder. Only Laboratory management shall have access to the "Controlled Documents" folder. Staff shall be notified when revised and updated documents become available. All controlled management system documents shall have the statement of being uncontrolled when printed or similar wording in the footer. Personnel shall be responsible for verifying that they are using and following current policies. The Laboratory shall not make changes to the interactive or electronically published instrument manuals or other documents generated outside of the Laboratory, except to replace the documents with new versions as needed.

8.3.2.5 AVAILABILITY OF CURRENT VERSIONS

Current versions of appropriate documents shall be available at all locations where operations essential to the effective functioning of the Laboratory are performed. Authorized editions of appropriate documents shall be readily available to all Laboratory personnel as a non-editable .pdf file located in the "Current SOPs" folder.

8.3.2.6 IDENTIFICATION OF DOCUMENTS

Management system documents generated by the Laboratory shall be uniquely identified. Such identification shall include the title of the document, "Brazoria County Sheriff's Office Crime Laboratory" or "BCCL", and a version number. In addition, all management system documents shall include the issuing authority (the Laboratory Director or Laboratory management), and the pages shall be numbered in the format of "Page _ of _".

8.3.2.7 REMOVAL OF OBSOLETE VERSIONS

Documents that are invalid, obsolete, or otherwise unsuitable shall be considered "Archives". Archived documents may be kept for compliance with court orders, and should be kept available on the Laboratory computer network or backed up to external electronic media. Any hard copies of these documents shall be clearly marked "Archived".

8.4 CONTROL OF RECORDS (OPTION A)

8.4.1 GENERAL

The Laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of management system records. These shall include reports from internal audits and management reviews, as well as records of corrective and preventive actions. All records shall be uniquely identified, stored by year or other appropriate grouping in binders or in electronic format, maintained within the Laboratory, and accessible as needed. Refer also to the Case Documentation and Records SOP.

8.4.2 GENERAL POLICIES

8.4.2.1 RECORD IDENTIFICATION

Records received or generated by the Laboratory for a specific case shall be identified with the Laboratory number. Multi-paged records which are bound together in some manner may be identified by the Laboratory number on the front page.

8.4.2.2 STORAGE OF RECORDS

All records shall be legible and stored in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. All records shall be labeled appropriately, and may be in any media, such as hard copy or electronic.

8.4.2.3 RECORD SECURITY & PROTECTION

Records shall be held secure and in confidence. Records stored on the Laboratory network and other servers shall be backed up on a daily basis. The Brazoria County Information Systems (I.S.) Department shall be responsible for the backup of these devices. Electronic data from individual, computer-driven, analytical instrumentation shall be backed up on external hard drives at the completion of each batch.

8.4.2.4 RECORD RETENTION

Retention times of records shall be established in a way that satisfies applicable legal requirements. Records of internal audits and management system reviews shall be retained through one cycle of accreditation or four years, whichever is longer. Purchasing documents shall be retained by the Brazoria County Purchasing Department and kept according to Brazoria County Policy.

8.5 ACTIONS TO ADDRESS RISKS & OPPORTUNITIES (OPTION A)

8.5.1 POLICY TO ADDRESS RISKS

Laboratory policies and procedures outlined both in this document and in management system documents serve to minimize potential failures and improve overall quality.

8.5.1.1 HEALTH AND SAFETY RISKS

Laboratory policies and procedures outlined in the Safety Manual SOPs serve to minimize potential health and safety risks.

8.5.2 PROCEDURE TO ADDRESS RISKS

Specific procedures for minimizing potential nonconformances and/or failures shall be found in the management system documents related to the activity(s). The effectiveness of these procedures at managing Laboratory activities shall be evaluated as part of the Management Review (see section 8.9).

8.5.3 SUITABILITY OF ACTIONS TO ADDRESS RISKS

Laboratory management shall select and implement actions or policies which best promote quality of service.

8.6 IMPROVEMENT (OPTION A)

8.6.1 GENERAL

The Laboratory shall continually seek to improve the effectiveness of its management system through the use of the quality policy and objectives, audit results, analysis of data, corrective and preventive actions, and management review.

All Laboratory employees have the responsibility and authority to identify and report opportunities for improvements to the management system. Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

Once an opportunity for improvement is identified, it shall be immediately reported to Laboratory management, preferably in writing. If improvements are identified as part of the internal auditing process, then the audit packet shall be considered sufficient in this regard. The Laboratory Director shall then evaluate the opportunity and determine whether it is suitable for implementation, any repercussions it would create, and how it may affect the other aspects of the management system. If it is determined that it is suitable for implementation, then the policy shall be initiated. The implementation plan should include who is affected by the policy (the scope), and who is responsible for compliance, as appropriate. These controls, as well as other aspects of the management system, shall ensure that the policy is effective.

8.6.2 CUSTOMER FEEDBACK

The Laboratory shall seek feedback, both positive and negative, from its customers through the use of a customer satisfaction survey. This feedback may be used and analyzed to improve the management system, testing activities, and customer service. A record of completed surveys shall be retained through one cycle of accreditation to show compliance with this policy.

8.7 CORRECTIVE ACTIONS (OPTION A)

8.7.1 GENERAL POLICY

The Laboratory procedure for corrective action shall cover nonconforming work or deviations from Laboratory policy that could affect the quality of testing or results. Any nonconformance or problem that may potentially affect the quality of Laboratory results shall warrant possible implementation of the corrective action procedure.

8.7.1a SELECTION OF CORRECTIVE ACTION

When a nonconformity occurs, Laboratory management shall identify potential corrective actions, and shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

8.7.1b CAUSE ANALYSIS

The Laboratory procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem and likelihood of recurrence. Refer to the Quality Action Plan SOP.

8.7.1c CORRECTIVE ACTION PROCEDURE

The Laboratory procedure for corrective action shall be implemented when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified. Laboratory management shall be responsible for the implementation of the corrective action procedure.

8.7.1d MONITORING OF CORRECTIVE ACTIONS

The Laboratory shall monitor the results to ensure that the corrective actions taken have been effective. At a minimum, the effectiveness of corrective actions shall be considered during annual management reviews. Refer also to the “Management Reviews” section of this manual, 8.9.

When a serious issue is identified due to a nonconformity or departure, then the Laboratory may require that the appropriate areas of testing be audited in accordance with section 8.8.

8.7.1e UPDATES TO RISKS & OPPORTUNITIES

Laboratory management shall evaluate the impact of corrective actions on Laboratory activities and shall recommend changes to the management system, as needed.

8.7.1f IMPLEMENTING CHANGES

Laboratory management shall implement any required changes to the management system resulting from corrective action investigations.

8.7.1g TIMEFRAME FOR CORRECTIVE ACTION

Laboratory management shall establish a reasonable timeframe for the completion of any corrective action resulting from corrective action investigations.

8.7.2 EXTENT OF CORRECTIVE ACTION

The specific combination of corrective action shall be determined by the magnitude and type of error involved. Any significant discrepancy determined to be the result of an analytical or interpretive problem shall prohibit the individual(s) involved from further testing of case evidence until the cause of the problem is identified and corrected. Prior to resuming casework, the individual(s) responsible for the discrepancy should satisfactorily complete an additional set of proficiency samples. In no instance shall an analyst who has been removed from casework be allowed to resume casework in the affected discipline until the Laboratory Director has been assured the error has been corrected and future occurrences shall be avoided.

Significant discrepancies found to be the result of a systemic error (equipment, materials, or environment) require implementation of corrective action and the immediate suspension of all casework using that procedure until the problem is completely resolved. This may require a review of related casework since the last proficiency test successfully completed by the Laboratory. Once the cause of the problem has been identified, all technical personnel shall be made aware of any corrective action taken to minimize the recurrence of the discrepancy.

ANAB shall be notified if any analysis is discontinued, according to their policy requiring updates which affect the accreditation scope of the Laboratory.

8.7.3 RECORDS OF CORRECTIVE ACTION

The Laboratory shall maintain documentation of all corrective actions, their implementation, cause(s), and any resulting changes to the management system. Corrected reports shall be issued, as necessary.

8.8 INTERNAL AUDITS (OPTION A)

8.8.1 GENERAL POLICY

The Laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits in order to verify that Laboratory operations continue to comply with the requirements of the management system, ISO/IEC 17025, and AR 3125.

8.8.1.1 INTERNAL AUDIT SCHEDULE

Internal audits shall be conducted at least annually.

8.8.2 INTERNAL AUDIT REQUIREMENTS

8.8.2a INTERNAL AUDIT PLAN

It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule, or as additional audits are needed. The Quality Manager shall serve as the audit team leader, or may appoint one. The Quality Manager may divide the responsibilities of the audit among other appointed staff members in accordance with their expertise and experience. Training should be provided to internal auditors prior to every yearly audit on topics such as the audit process, audit requirements, and audit effectiveness.

8.8.2b EXTENT OF INTERNAL AUDITS

The extent of internal audits may vary, depending on evaluation of nonconformities or management system changes. Refer to the Internal Audits SOP for more information.

8.8.2b.1 ELEMENTS OF INTERNAL AUDITS

Internal audits shall address all elements of the management system, including direct observation of a sampling of testing within each discipline. Internal audits should also take into consideration the results of previous audits.

8.8.2c INTERNAL AUDIT REPORTS

Following audit activities, an internal audit report shall be reviewed and approved for distribution by Laboratory management.

8.8.2d INTERNAL AUDIT FINDINGS

When audit findings cast doubt on the effectiveness of Laboratory operations or on the correctness or quality of Laboratory testing or results, Laboratory management shall take timely corrective action, and shall notify customers in writing if investigations show that the Laboratory results may have been inaccurate.

8.8.2e INTERNAL AUDIT RECORDS

The area of activity audited, the audit findings, and corrective actions that arise from them shall be recorded. Records of internal audits shall be retained through one cycle of accreditation or four years, whichever is longer.

8.9 MANAGEMENT REVIEWS (OPTION A)

8.9.1 GENERAL POLICY

In accordance with a predetermined schedule and procedure, the Laboratory Director shall periodically conduct a review of the management system and testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.

Results from management reviews shall be used to influence Laboratory planning and should consider the goals, objectives and action plans for the coming year, as well as long term strategic planning goals.

8.9.1.1 MANAGEMENT REVIEW SCHEDULE

Management reviews shall be conducted at least.

8.9.2 EXTENT OF MANAGEMENT REVIEW

Management reviews shall take account of:

- The suitability of policies and procedures
- The outcome of recent internal audits and management reviews
- Corrective actions and their effectiveness
- The results of proficiency tests
- Adequacy of resources, including changes in volume and type of work
- Assessments by external bodies
- Customer feedback and/or complaints
- Recommendations for improvement and effectiveness of implemented improvements
- Changes to the management system
- Fulfillment of the Laboratory quality policy statement, objectives, and standard of service
- Results of risk identification;
- Other relevant factors, such as quality verification activities, resources, and staff training

8.9.3 MANAGEMENT REVIEW FINDINGS

Findings from management reviews and the actions that arise from them shall be recorded and shall encompass:

- Overall effectiveness of the management system and related processes
- Improvement of Laboratory test methods in relation to criteria within this document;
- Resource provision, acquisition, etc.
- Changes to the management system, including recommendations for improvement

Date	Section	Previous	Changed to	Reason	By whom
07.30.19	7.7.1.2	Specific procedures regarding the technical review of records, test reports, and testimony shall be specified in the individual forensic discipline procedure manuals.	Specific procedures regarding the technical review of records, test reports, and testimony shall be specified in the Lab Operation Guide.	Altered to coincide with current laboratory procedures	HB/PVD
08.08.19	7.8.6.2	Material amendments to a test report after issue shall be made only in the form of a further document, which includes the statement "Amended Report", or one of the other formats listed in this section…	Material amendments to a test report after issue shall be made only in the form of a further document, which includes the statement "Amended Report" and a reference to the original report…	Altered to coincide with current laboratory procedures	HB/PVD
07.30.19	7.8.6.3	If the report has been distributed outside of the Laboratory, another report entitled "AMENDED REPORT", or similar wording shall be issued. If a supplemental report is to be issued, and an error is found on the original report, then the supplemental report shall be titled "SUPPLEMENTAL REPORT", or similar wording.	If the report has been distributed outside of the Laboratory, another report entitled "AMENDED REPORT", or similar wording shall be issued.	Altered to coincide with current laboratory procedures	HB/PVD
07.14.20	5.5b	Seized Drugs: In addition to the Laboratory Director, the Laboratory employs three Chemists who are competent, trained, and proficient in Seized Drugs testing. Toxicology: In addition to the Laboratory Director, the Laboratory employs two Chemists who are competent, trained, and proficient in Blood Alcohol analysis and one Chemist who is competent, trained, and proficient in Blood Drug analysis.	Seized Drugs: As of August 2020, there are only two Laboratory staff members licensed by the Texas Forensic Science Commission to practice Seized Drug analyses. Toxicology: As of August 2020, there are only two Laboratory staff members licensed by the Texas Forensic Science Commission to practice Toxicology - Blood Alcohol/Drug analyses.	Changed to reflect current staffing.	PVD
08.17.21	7.7.3	Quality verification data shall be analyzed and, when outside of pre-defined criteria, action shall be taken to correct problems and to prevent incorrect results from being reported. If there is an	Quality verification data shall be analyzed, used to control and, if applicable, improve the laboratory's activities. When outside of pre-defined criteria, action shall be taken to correct problems and to	Altered to meet ISO 17025:2017 7.7.3	AW

		indication that any Laboratory findings do not conform to Laboratory policy, then the policy for the control of nonconforming testing work in this manual shall immediately be followed, including the implementation of the corrective action procedure, if warranted.	prevent incorrect results from being reported. If there is an indication that any Laboratory findings do not conform to Laboratory policy, then the policy for the control of nonconforming testing work in this manual shall immediately be followed, including the implementation of the corrective action procedure, if warranted.		
08.16.21	6.2.3.1	Shall satisfactorily complete a competency test/evaluation in each category of testing after completion	Shall satisfactorily complete a competency test/evaluation with a 70% or higher in each category of testing after completion	Altered to meet AR 3125 6.2.2.2	AW
08.16.21	8.2.1	Elucidation of Drug/Alcohol content in blood	Identification of drugs in blood and quantification of ethanol	Altered for clarification	AW
06.14.22	Footer	Issuing Authority: Quality Assurance Manager Authorized for Distribution by All Laboratory Personnel **THIS DOCUMENT IS CONSIDERED UNCONTROLLED IF PRINTED OR NOT VIEWED ON THE "P:\Quality Assurance" FOLDER**	Issuing Authority: Upper Management Authorized for Distribution by Laboratory Director. Uncontrolled when printed.	Altered to coincide with current laboratory procedures. Shared files are no longer kept on the P Drive.	AW/DS
06.14.22	7.7.9	…Administrative reviews shall generally be performed at the same time as peer review by the technical reviewer; however, administrative reviews may be conducted by any Laboratory employee other than the author of the report… …Technical and administrative reviews for casework in all disciplines shall be documented on the appropriate worksheet(s) and in the LIMS.	…Administrative reviews shall be performed following technical reviews; however, administrative reviews may be conducted by any authorized Laboratory employee… …Technical and administrative reviews for casework in all disciplines shall be documented in LIMS.	Altered to allow all authorized laboratory personnel to administratively review casework, as well as begin the process of going paperless.	AW/DS

08.09.23	4.2.4	…All current case files shall be secured within the Laboratory and their contents shall be protected from unauthorized personnel. Archived case files shall be stored under controlled access within the Sheriff's Office facilities located outside of the Laboratory premises. The LIMS shall be protected by the use of passwords and PIN numbers unique to individual Laboratory personnel. In addition, full versions of the LIMS software shall only be installed on the computers within the Laboratory facility and on the computer server(s) which are located inside a secure area within the BCSO. The Brazoria County Information Systems (IS) Department shall be responsible for the security and maintenance of the servers as well as the maintenance of computer systems within the control of the Laboratory. Refer to the Laboratory Information Management System SOP for more information.	…Case files shall be secured either within the Laboratory or under controlled access within Brazoria County facilities. Their contents shall be protected from unauthorized personnel. The LIMS shall be protected by the use of passwords and PIN numbers unique to individual Laboratory personnel. The Brazoria County Information Systems (IS) Department shall be responsible for the security and maintenance of the servers as well as the maintenance of computer systems within the control of the Laboratory. Refer to the Laboratory Information Management System SOP for more information.	Altered to coincide with current laboratory practices and scope of accreditation.	AW/DS
	5.1	The Brazoria County Sheriff's Office Crime Laboratory (BCCL) is a part of the Brazoria County Sheriff's Office (BCSO) and provides testing of evidentiary materials to aid in the investigation of criminal offenses (see Laboratory Designation, Location, and Functions SOP). All Laboratory employees are sworn by the Sheriff of Brazoria County to support the laws and regulations of the State of Texas and of the United States of America. The Laboratory is currently accredited by ANAB and the	The Brazoria County Sheriff's Office Crime Laboratory (BCCL) is a part of the Brazoria County Sheriff's Office (BCSO) and provides testing of evidentiary materials to aid in the investigation of criminal offenses (see Laboratory Designation, Location, and Functions SOP). All Laboratory employees are sworn by the Sheriff of Brazoria County to support the laws and regulations of the State of Texas and of the United States of America. The Laboratory is currently accredited by ANAB and the		

		Texas Forensic Science Commission, and provides analysis in Seized Drugs and Toxicology.	Texas Forensic Science Commission, and provides analysis in Seized Drugs.		
	5.2.1	…The Laboratory Director shall supervise the analytical work in each forensic discipline and be competent and proficient in the methods and procedures used in each discipline. Additionally, the Laboratory Director may delegate training assignments to staff that are competent and proficient in each discipline. The Laboratory Director shall also serve as the Quality Manager for the Laboratory in the absence of personnel designated as such. The Laboratory Director may delegate responsibilities relating to these positions to other Laboratory staff at his/her discretion.	…The Laboratory Director may delegate training assignments to staff that are competent and proficient in each discipline. The Laboratory Director shall also serve as the Quality Manager for the Laboratory in the absence of personnel designated as such. The Laboratory Director may delegate responsibilities relating to these positions to other Laboratory staff at his/her discretion.		
	5.3	The Laboratory performs services in the disciplines of forensic Toxicology and Seized Drugs. The discipline of forensic Toxicology is limited to Blood Alcohol analysis and Blood Drug analysis. Job descriptions for Laboratory personnel and the Management System SOP further outline the Laboratory Organization. Moreover, the Laboratory's place in its parent organization is described in the "Parent Organization Influence" section of this manual (5.5a).	The Laboratory performs services in the disciplines of Seized Drugs. Job descriptions for Laboratory personnel and the Management System SOP further outline the Laboratory Organization. Moreover, the Laboratory's place in its parent organization is described in the "Parent Organization Influence" section of this manual (5.5a).		
	5.4.2	The Laboratory shall perform all testing in a manner that follows the laws pertaining to forensic laboratory accreditation mandated by the State of Texas.	The Laboratory shall perform all testing in a manner that follows the laws pertaining to forensic laboratory accreditation mandated by the State of Texas. In the event of a nonconformity, refer to the Quality Action Plan SOP.		

	5.5.a		Administrative Captain: This individual is the direct supervisor of the Laboratory Director. The Captain may make decisions that could affect the daily operations of the Laboratory.		
		Chief Deputy Sheriff: This individual is the direct supervisor of the Laboratory Director. The Chief may make decisions that could affect the daily operations of the Laboratory and is the person that maintains the Laboratory budget.	Chief Deputy Sheriff: This individual is the direct supervisor of the Administrative Captain. The Chief may make decisions that could affect the daily operations of the Laboratory and is the person that maintains the Laboratory budget.		
	5.5b	Seized Drugs: As of August 2020, there are only two Laboratory staff members licensed by the Texas Forensic Science Commission to practice Seized Drug analyses.	Seized Drugs: As of January 2023, there are only two Laboratory staff members licensed by the Texas Forensic Science Commission to practice Seized Drug analyses.		
		Toxicology: As of August 2020, there are only two Laboratory staff members licensed by the Texas Forensic Science Commission to practice Toxicology - Blood Alcohol/Drug analyses.	Toxicology: As of June 2023, there are only two Laboratory staff members licensed by the Texas Forensic Science Commission to practice Toxicology - Blood Alcohol/Drug analyses.		
	5.5c	Each forensic discipline (or section) within the Laboratory shall have a technical procedures manual that is part of the management system (Seized Drugs and Toxicology). Testing procedures shall be documented to the extent necessary to ensure consistent application and the quality of results. The outline of the structure of the documentation used in the management system is described in the "Management System Documentation" section of this manual (8.2).	Each forensic discipline (or section) within the Laboratory shall have a technical procedures manual that is part of the management system. Testing procedures shall be documented to the extent necessary to ensure consistent application and the quality of results. The outline of the structure of the documentation used in the management system is described in the "Management System Documentation" section of this manual (8.2).		

	6.2.2.1.1	TESTING PERSONNEL (SEIZED DRUGS SECTION) Forensic Scientists assigned to the Seized Drugs section of the Laboratory shall establish and maintain forensic analyst licensure in the State of Texas as a Seized Drugs analyst.	TESTING PERSONNEL Forensic Scientists shall establish and maintain forensic analyst licensure in the State of Texas in which he/she performs testing, makes interpretations, or conducts technical review.		
	6.2.2.1.2	TESTING PERSONNEL (TOXICOLOGY SECTION) Forensic Scientists assigned to the Toxicology (Blood Alcohol and Blood Drug Confirmation) section of the Laboratory shall establish and maintain forensic analyst licensure in the State of Texas as a Toxicology analyst.			
	6.2.2.2f	Employees shall complete a minimum of twenty-four continuing forensic education hours per 2-year licensing cycle to maintain licensure in their forensic discipline, as well as improve their general knowledge, expertise, and skills. This may be accomplished by attending training classes, seminars, technical meetings, conferences, or professional meetings.	Employees shall complete the minimum continuing forensic education hours per 2-year licensing cycle per the Texas Forensic Science Commission to maintain licensure in their forensic discipline, as well as improve their general knowledge, expertise, and skills. This may be accomplished by attending training classes, seminars, technical meetings, conferences, or professional meetings.		
	6.5.3		TRACEABAILITY TO SI UNITS NOT POSSIBLE In the event metrological traceability to the SI units is not technically possible, the Laboratory shall demonstrate metrological traceability to an appropriate reference, such as certified values of certified reference materials provided by a competent producer; or results of reference measurement procedures, specified methods or consensus standards that are clearly described and		

			accepted as providing measurement results fit for their intended use and ensured by suitable comparison.		
	7.1.2.1		AMENDED CONTRACT If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.		
	7.7.4	… Moreover, all fully trained technical personnel should successfully complete at least one proficiency test annually for each assigned discipline. If an individual fails to complete proficiency testing in any discipline, he/she should not resume casework in that discipline until proficiency testing is completed and documented as satisfactory by the Laboratory Director. The proficiency program and files shall be maintained by the Quality Manager, and he/she shall oversee the assignment of all proficiency tests.	…Moreover, all fully trained technical personnel shall successfully complete at least one proficiency test annually for each assigned discipline. If an individual fails to complete proficiency testing in any discipline, he/she should not resume casework in that discipline until proficiency testing is completed and documented as satisfactory by the Laboratory Director. The proficiency program and files shall be maintained by the Quality Manager, and he/she shall oversee the assignment of all proficiency tests.		
	8.2.1	… The Brazoria County Sheriff's Office Crime Laboratory and its management are committed to an ongoing program of services in the forensic disciplines of Seized Drugs and Toxicology that meet or exceed the needs of its customers and that meet or exceed the minimum requirements of ISO/IEC 17025 and AR 3125… The Brazoria County Sheriff's Office Crime Laboratory serves its customers by analyzing Seized Drugs or Toxicology evidence that may be of interest in judicial proceedings…	… The Brazoria County Sheriff's Office Crime Laboratory and its management are committed to an ongoing program of services in the forensic discipline of Seized Drugs that meet or exceed the needs of its customers and that meet or exceed the minimum requirements of ISO/IEC 17025 and AR 3125… The Brazoria County Sheriff's Office Crime Laboratory serves its customers by analyzing Seized Drugs evidence that may be of interest in judicial proceedings…		

		Toxicology Identification of drugs in blood and quantification of ethanol			
	8.3.2.2	All manuals and appendices comprising the management system that were generated by the Laboratory shall be reviewed once a year. Job Descriptions and forms that were generated by the Laboratory shall be reviewed at least once every cycle of accreditation to ensure the continuing suitability of the content and to comply with applicable requirements.	All manuals and appendices comprising the management system that were generated by the Laboratory shall be reviewed. Job Descriptions and forms that were generated by the Laboratory shall be reviewed at least once every cycle of accreditation to ensure the continuing suitability of the content and to comply with applicable requirements.		
	8.3.2.4	…All controlled management system documents shall have the statement “THIS DOCUMENT IS CONSIDERED UNCONTROLLED IF PRINTED OR NOT VIEWED ON THE “P:\Controlled Documents” folder” or similar wording in the footer. Personnel shall be responsible for verifying that they are using and following current policies...	…All controlled management system documents shall have a statement of being uncontrolled when printed or similar wording in the footer. Personnel shall be responsible for verifying that they are using and following current policies…		
	8.8.1.1	Internal audits shall be conducted at least annually and prior to the initial assessment of each accreditation cycle.	Internal audits shall be conducted at least annually.		
	8.8.2a	…Audits shall be conducted by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Training should be provided to internal auditors prior to every yearly audit on topics such as the audit process, audit requirements, and audit effectiveness.	…Training should be provided to internal auditors prior to every yearly audit on topics such as the audit process, audit requirements, and audit effectiveness.		
	8.9.1.1	Management reviews shall be conducted at least annually and prior to the initial	Management reviews shall be conducted at least annually.		

		assessment of each accreditation cycle.			