Quality Manual

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ABOUT THIS DOCUMENT:

This document is reviewed at least annually by the Forensic Technical Director and Quality Manager, and changes are made as needed. Previous versions are retained on SharePoint for at least one full accreditation cycle. All analysts in the Forensic Chemistry Section acknowledge the existence of any updated version.

Table of Contents

1. Scope

This Quality Manual describes the management system for the Forensic Chemistry Section of Maine's Health and Environment Testing Laboratory (HETL). This manual provides guidance to meet the requirements of ISO/IEC 17025:2017. It describes the minimum requirements for all areas and how ISO standards are met.

Core Values

Our dedication to integrity, fairness, and service ensures that our customers are always provided with certificates of analysis and expert testimony that are informative, ethical, impartial, and scientifically valid.

Mission Statement

The mission of the Forensic Chemistry Section at HETL is to provide accurate, reliable, and timely analysis and subsequent testimony in the forensic disciplines of seized drugs and toxicology to the Criminal Justice Agencies of Maine.

Vision

Vision of the Forensic Chemistry Section at HETL is to be an exemplary model of a forensic science laboratory by leading with integrity and by continually striving for improvements and innovations.

Responsibilities

The FCS assists in the criminal justice process and serves as an investigative aid to the Criminal Justice System. The FCS provides professional expert testimony in courts of law and preserves the integrity of evidence.

- We serve Law Enforcement, Public Safety, and other Criminal Justice agencies throughout the State of Maine;
- We provide expert analysis of seized drugs, antemortem, and postmortem toxicology evidence, utilizing scientifically sound analytical techniques and technology;
- We acknowledge our customers as our highest priority and strive to meet their individual needs;

- We recognize the value of our employees and consider them the most important asset of the organization;
- We strive to project professionalism, teamwork, courtesy and competence to our customers and the citizens of the State of Maine.

2. Normative References

Reference List

- ISO/IEC 17025:2017 International Organization of Standardization/International Electrotechnical Commission – General Requirements for the Competence of Testing and Calibration Laboratories, 2017;
- ANSI National Accreditation Board (ANAB) AR3125 – Forensic Science Testing Laboratories Accreditation Requirements;
- ANAB GD3150 – Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel;
- ISO/IEC Guide 99 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM);
- ISO/IEC 17000, Conformity Assessment – Vocabulary and General Principles;
- Scientific Working Group for the Analysis of Seized Drug (SWGDRUG) Recommendations;
- ANAB PR1018 – Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status.

Cross-References

This manual is numerically aligned with the international standard ISO/IEC 17025:2017. It is expected that this will prove useful during accreditation audits and expediting the process.

3. Terms and Definitions

For the purposes of this manual, the terms and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 apply. The following terms and definitions apply:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at http://www.electropedia.org
- Shall – a requirement
- Should – a recommendation

ANAB® – ANSI National Accreditation Board is an accreditation program in which any crime laboratory may participate to demonstrate that its management, technical operations, and overall quality management system meet ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories and ANAB AR3125 Accreditation Requirements for Forensic Testing and Calibration Laboratories.

Accreditation – Formal recognition of a laboratory by an independent science-based organization that the laboratory is competent to perform specific tests.

Administrative Records – Records, electronic or hardcopy, such as case related conversations, evidence receipts, Certificates of Analysis, chain of custody records, description of evidence packaging and seals, incident reports, service requests (Contract for Laboratory Examination form), correspondence received/sent, subpoena, and other pertinent information.

Administrative Review – A procedure used to check case records and case reports for consistency with laboratory policy and for editorial correctness.

Analyst (see also *Chemist*) – An individual who conducts and/or directs the analysis of forensic casework samples, interprets data, reaches conclusions, and issues reports concerning conclusions.

Approved Test Provider – A proficiency test provider which has complied with the test manufacturing guidelines and requirements established by ANAB and has been recognized as an approved test provider by ANAB.

Association – A determination that a relationship exists between individual and/or objects.

Associate Director of Laboratory Services (see also *Chief of Laboratory Operations*) – The highest-ranking manager within an individual laboratory.

Audit – A systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled (ISO/EIC 17000:2004).

Batch and/or Case File – Administrative and technical records (i.e. control charts, sequences, etc.), whether electronic or hardcopy, such as case related conversations, test item (evidence) receipts, chain of custody records, description of evidence packaging and seals, incident reports, service

request documentation, correspondence received/sent, reports issued related to the examinations of evidence, and other pertinent information, generated or received by a laboratory pertaining to a particular case, which may be stored in one or more locations.

Casefile Review Report for Testimony – Issued when the information in the original report was reviewed by a second, certified Chemist who issues a new report detailing their own independent conclusions as to the results of the case for testimony purposes. Used when the original Chemist is not available for testimony and retesting of evidence was not performed.

Certificate of Analysis (CoA) – The official laboratory report that communicates the results, opinions and interpretations made during the analysis of evidence samples. Refers to both internally generated reports and external vendor reports.

Certified Reference Material (CRM) – Reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (ISO Guide 30:2015, modified).

Chain-of-Custody – A process that documents all transfers of evidence over which the Laboratory has control.

Chemist (see also *Analyst*) – An individual who conducts and/or directs the analysis of forensic casework samples (evidence), interprets data and reaches conclusions.

Chief of Laboratory Operations – See Associate Director of Laboratory Services.

Competent – Possessing the requisite knowledge, skills and abilities to perform a job or task.

Competency Test – The evaluation of a person's knowledge, skills, and/or ability to perform work.

Complaint – Expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected.

Contract – The agreement between the forensic service provider (laboratory) and the customer.

Control Sample – An analysis performed in parallel with unknown (case) samples and designed to demonstrate that a procedure worked correctly; a standard of comparison for verifying or checking the findings of a test or examination.

Controlled Document – A document issued and distributed in a trackable manner.

Controlled Substances (forensic science discipline) – A substance(s) or chemical(s), listed in appropriate drug schedules as being controlled by the State of Maine or the U.S. Government.

Corrective Action – A laboratory response to eliminate or reduce the likelihood of recurrent non-conforming work or unauthorized departures from established policies and procedures.

Critical Consumable, Supplies and Services – A consumable, supply or service which must meet one or more specifications to ensure the quality of the test result. In this context, "critical" means extremely significant, important, or potentially influencing the overall test result if the appropriate consumable, supply, or service does not meet specification.

Customer (Client) – An individual or organization that could or does receive a product or a service that is intended for or required by this person or organization. A customer can be internal or external to the forensic service provider. The laboratory acknowledges there may be multiple agencies with the authority to act as the customer for one case which includes, but is not limited to, the submitting agency.

Decision Rule – Rule that describes how measurement of uncertainty is accounted for when stating conformity with a specified requirement.

Deviation – An authorized variance from a documented policy, practice, or procedure. A deviation can be major or minor depending on the circumstances.

Director – See *Forensic Technical Director and Associate Director of Laboratory Services*.

Discipline – A major area of activity in forensic science.

Document Control – The process of ensuring that controlled documents prescribing quality-affecting activities or specifying quality requirements, including revisions, are reviewed for adequacy, approved

for release by authorized personnel, and distributed for use to the personnel performing the prescribed activities.

Evidence (Test Item) – Material, regardless of form, which is received by a laboratory for the purpose of testing. Evidence (test item) is generally relevant to a criminal investigation through examination by one or more of the laboratory's testing procedures.

Environmental Conditions – Any characteristic of a laboratory facility that could reasonably be expected to impact the quality of the laboratory's work product (e.g., lighting, heating, air conditioning, humidity, temperature, etc.).

Examination (Test) – The process(es) utilized by the laboratory analyst to glean information from evidence in order to reach conclusions concerning the nature of and/or associations related to evidence received by the laboratory.

Examination Documentation (see also *Notes*) – Includes reference to procedures followed, tests conducted, standards and controls used, diagrams, printouts, photographs, observations, and results of examinations.

External Accreditation Cycle – period of time between full on-site assessments performed by an external certified accreditation body (CAB). This cycle is determined and scheduled by the CAB and the length of time comprising a full cycle may vary.

External Proficiency Test – A test prepared and provided by a source external to the laboratory, laboratory system, or the laboratory's parent organization. External proficiency tests are from ANAB Approved Proficiency Test Providers.

Forensic Chemistry Section (FCS) – Laboratory which examines physical evidence in criminal matters and provides opinion testimony with respect to such physical evidence in a court of law.

Forensic Technical Director – Chemist III assigned to oversee the daily operations of the Forensic Chemistry Section within the HETL laboratory.

Impartiality – Presence of objectivity.

Interlaboratory Comparison – Organization, performance and evaluation of measurement or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. These comparisons are not submitted to the accrediting body for review. May also include proficiency tests provided by an external proficiency test provider that is not accredited to ISO 17034.

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

Internal Audit – An annual in-house audit that gauge's compliance with ISO/IEC 17025 and/or HETL FCS policies. Internal audits are conducted by FCS staff members.

Internal Proficiency Test – A proficiency test administered and reported internally.

Intralaboratory Comparison – Organization, performance and evaluation of measurements or tests on the same or similar items, within the same laboratory, in accordance with predetermined conditions.

Laboratory – Body that performs testing, calibration, or sampling activities that is subsequently used for testing or calibration.

Laboratory Case Number – A unique, laboratory generated identifier assigned to items of evidence submitted to the laboratory for examination.

Laboratory Support Personnel – Individuals who perform casework related duties within the laboratory at the direction of an analyst but do not handle evidentiary samples, and who do not issue reports nor render conclusions.

Limited Access – Access limited to personnel authorized by the Forensic Technical Director.

Management System – The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly.

Manager – A person with the responsibility for directing and controlling an organizational unit or program.

Media – Objects on which electronic data can be stored.

Member of Staff – A position which is under the control of the laboratory.

Measurement Uncertainty – A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measured quantity. Also known as uncertainty of measurement.

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

Nonconforming Work – Nonconforming work is the result of an act, mistake, and/or omission, and/or the violation of an approved procedure/process, that affects the accuracy, reliability, and/or integrity of the FCS's testing or CoAs.

Notes (see also *Technical Record* and *Examination Documentations*) – Records of procedures, standards, controls, and instruments used, observations made, results of tests performed, charts, graphs, photos, and other records generated which are used to support the analyst's conclusions.

Objective – A measurable, definable accomplishment which furthers the goals of the organization.

Open Proficiency Test – A proficiency test known to the participant as such.

Policy – A guiding principle, operating practice, or plan of action governing decisions made on behalf of an organization.

Practicable – If the laboratory can meet the requirement, it shall meet the requirement.

Preventative Action – An action intended to improve a process or eliminate the cause of a potential nonconformance. Preventive actions may be referred to as process improvements or continuous improvements.

Procedure (see also *Instructions*) – The manner in which an operation is performed; a set of directions for performing an examination or analysis - the actual parameters of the methods employed.

Proficiency Review Committee (PRC) – An ANAB committee whose role is to review reported testing results and supporting data and to evaluate the performance of accredited laboratories in proficiency tests.

Proficiency Test (PT) – An evaluation of the capability and performance of analysts, technical support personnel and the laboratory against pre-established criteria by means of interlaboratory comparison.

Proper Seal – A seal that prevents loss, cross-transfer, or contamination while ensuring that attempted entry into the container is detectable. A proper seal may include a heat seal, tape seal, or a lock. The initials or other identification of the person creating the seal shall be placed on the seal or across the seal onto the container when possible.

Quality Assurance (QA) – Those planned and systematic actions necessary to provide sufficient confidence that a laboratory's product or service will satisfy given requirements for quality.

Quality Control (QC) – Internal activities, or activities conducted according to externally established standards, used to monitor the quality of analytical data and to ensure that it satisfies specified criteria.

Quality Manager – An individual designated by top management who, irrespective of other responsibilities, has the defined authority and obligation to ensure that the quality requirements of the management system are implemented and maintained.

Reagent – A substance used because of its chemical or biological activity.

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

Re-Examination Report – At the request of the client or due to the inability of the original examiner to testify, a sample is re-analyzed in the same manner (protocol) as reported in the original report.

Reference Collection – Data or materials of known origin or property, which are maintained for identification, comparison, or interpretation purposes (e.g., mass spectra, drug samples, or laboratory developed databases).

Reference Material (RM) – Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process. Also referred to as Standard Reference Material (SRM).

Reference Material Producer (RMP) – Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference material it produces (ISO17034:2016).

Reference Standard – A measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location.

Request – The process utilized by a customer when seeking services from the forensic service provider.

Reprint Report – Reprint of the original case findings. The Reprint report may have a different Issue date and will have a different notarization date.

Revised Report – Issued when the information in the original report was not correct, when additional testing has been completed, or when the biographical information related to a case has changed or needs to be corrected.

Risk – Effect of uncertainty on objectives. Risk can also be viewed as the probability/threat of damage, injury, liability, loss, or any other negative occurrence that is caused by either external or internal vulnerabilities that may be avoided through pre-emptive action.

Sample – Portion drawn from a whole or population for the purpose of examination/testing, not necessarily representative of the whole.

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

Sampling – Taking a part of a substance, material, or product for testing in order to make an inference about, and report on the whole.

Sampling Method – The method used to collect a sample or samples from the larger whole, to ensure that the result obtained in the analysis is representative of the whole.

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

Scientist (see also *Chemist*) – A person who employs scientific methods in the examination of evidence in a forensic laboratory.

Secure Area – A locked space (for example, cabinet, vault, or room) with access restricted to personnel authorized by the laboratory director.

Sub-discipline (replaced by "Category of Testing") – A specific type of analysis within an accredited discipline of forensic science.

Supervisor – A person directly responsible for overseeing the work of an individual or an organizational unit.

Supplemental Report – See *Revised Report*.

Technical Record (see also *Notes*) – The documentation, whether electronic or hardcopy, of procedures followed, tests conducted, standards and controls used, diagrams, printouts, photographs, observations and results of testing and examinations.

Technical Review – Review of all records which form the basis for a scientific conclusion.

Technical Support Personnel – Individuals who perform casework related duties within the laboratory at the direction of an analyst but who do not issue reports related to conclusions reached.

Tender – The response to the customer request for services.

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

Toxicology (forensic science discipline) – Analysis of biological samples for the presence of alcohol, drugs and other potentially toxic materials.

Uncertainty of Measurement – An estimated value, within specified confidence limits, that depicts a value of variability that can be attributed to a quantitative value.

Validation – The process of performing a set of experiments which establish the efficacy and reliability of a technique or procedure or modification thereof. Validation is used to assess the ability of a procedure to produce reliable results, determine the conditions under which such results can be obtained and determine the limitations of the procedure. The type and extent of validation for use of a procedure are determined by appropriate personnel (Forensic Technical Director, Quality Manager, Unit Supervisor, Chemist certified by the DHHS in that discipline or a scientist who demonstrates specific expertise for that methodology).

Verification – Provision of objective evidence that a given item fulfils specified requirements.

4. General Requirements

4.1 Impartiality

4.1.1 Laboratory activities shall be undertaken impartially, and structured and managed to safeguard impartiality.

4.1.2 Laboratory management shall be committed to impartiality. If any staff member feels that an entity is attempting to or has exerted influence or pressure on them, that individual shall notify laboratory management.

4.1.3 The laboratory is responsible for the impartiality of its laboratory activities and does not allow commercial, financial, or other pressures to compromise impartiality. Policies and procedures to ensure that the management and personnel are free from any undue internal and external commercial, financial and influences that may affect the quality of their work are in place and reviewed by employees annually.

The management system will ensure impartiality in the following ways:

- The FCS has a code of ethics as part of the management's commitment to good professional practice (ANAB GD3150 – Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel);
- Each employee of the Maine Health and Environmental Testing Laboratory (including those in the Forensic Chemistry Section) is bound by the **Code of Ethics and Conduct for the Executive Branch of Maine State Government**. The code is posted on the State of Maine intranet and a hard copy is provided to each new employee during orientation;
- The FCS will participate in an annual ethics training program;
- The FCS code of ethics is reviewed annually by all personnel and a record of that review will be maintained;
- If a violation of the FCS code of ethics is identified, appropriate actions will be taken to rectify the violation;
- The laboratory will identify risks to its impartiality on an on-going basis. This includes risks that arise from its activities, or from its relationships, or from the relationships of its personnel. All laboratory employees are encouraged to bring impartiality concerns to the Forensic Technical Director. The impartiality risk review will occur during the annual management review.

4.1.3.1 Conflicts of Interest

When FCS personnel discover they know a victim or suspect (beyond a professional relationship) or could have a personal or vested interest in the outcome of the case, FCS management should be notified immediately. Appropriate actions shall be taken to ensure the impartiality of the laboratory is maintained. Personnel involved in dishonest activities are subject to a range of disciplinary actions, including dismissal.

The following list provides guidelines on how employees avoid conflict of interest situations. Employees shall not:

- Falsify records, prepare fraudulent reports, or make false claims;
- Seek or use privileged or confidential company information, or data from any customer, for any purpose beyond the scope of employment;
- Conduct non-laboratory business on laboratory time, or use company facilities or equipment to conduct outside interests in business, unless prior approval has been obtained;

- Solicit business on their own behalf (rather than the laboratory) from a customer;
- Be employed by, or affiliated with, organizations whose products or services compete with laboratory products or services;
- Have employment that negatively affects or interferes with their performance of laboratory duties;
- Compete with the laboratory in the purchase, sale, or leasing of property or goods;
- Allow association, family, or friends to influence business decisions to their benefit - decisions must be made on a strictly business basis, always in the best interest of the laboratory;
- Make any decision that provides gains or benefits to the employee and/or others;
- Have personal financial dealings with an individual or company that does business with the laboratory which might influence decisions made on the laboratory's behalf. It is recognized that laboratory staff know many law enforcement officers, who contract with the lab for testing of their evidence. It is also recognized that some lab staff are related to officials / officers employed by law enforcement agencies within the State. It is the policy of FCS that whenever possible, an analyst will not work on a case that is submitted to the lab by a relative or individual with whom the analyst has financial interactions.

4.1.4 When a risk is identified, the laboratory documents how it eliminates or minimizes the risk using the Laboratory Risk and Opportunity Review Form.

Additional State of Maine Information and Requirements

In order to avoid involvement of personnel in activities that would diminish confidence in the operational integrity of the laboratory, each employee of the FCS is covered by various policies of the State of Maine, the Maine Department of Health and Human Services, and the Maine Bureau of Human Resources, covering topics such as drug and alcohol abuse, personal problems (Employee Assistance Program), discrimination (including sexual harassment), etc. These policies are posted on the State of Maine Intranet at:

- http://www.maine.gov/dhhs/policies/
- http://www.maine.gov/bhr/rules_policies/policy.htm

4.2 Confidentiality

4.2.1 The laboratory is responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. All employees, contractors, and interns of the FCS must sign a confidentiality statement annually reminding them of the requirement to keep all results confidential and not to release results of case information to anyone other than authorized individual and/or agencies. The laboratory informs the customer in advance, of the information it intends to place in the public domain. Exceptions to this policy are information that the customer makes publicly available, reports generated by the laboratory containing general result data, without identifying information, for grant/administrative purposes, general result data reports generated to fulfill MOU requirements, or when agreed between the laboratory and the customer (e.g., for the purpose of responding to complaints), all other information is considered propriety information and will be regarded as confidential. Prior approval by DHHS management, in the form of a signed MOU or other record, must be obtained. The Employees' Confidentiality Statement prevents employees from disclosing any confidential information acquired by them during official duties and specifies penalties for violations of the State's Code of Ethics. Each employee receives the Confidentiality Policy and signs the Confidentiality form as part of their initial hire paperwork and must review and re-sign this form annually. The signed agreement is retained in each employee's Human Resources file.

4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned will, unless prohibited by law, be notified of the information provided. The laboratory produces various monthly reports, which are required to fulfill specific MOU data sharing agreements. These reports only contain general result data and are only distributed to appropriate individuals.

4.2.3 Information about the customer obtained from sources other than the customer (e.g., complainant, regulators) will be confidential between the customer and the laboratory. The provider (source) of this information will be confidential to the laboratory and will not be shared with the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, will keep confidential all information obtained or created during the performance of laboratory activities.

The following sets forth the policy of the FCS regarding the release of laboratory test results and records.

- After the report has been released, the results are available to the appropriate members of the HETL staff, the agency conducting the investigation or submitting the evidence and the Attorney General's Office or the District Attorney's Office of the jurisdiction involved;
- A log of all phone or email conversations will be kept regarding the dissemination of information/results. Refer to SharePoint for the FCS Phone Communication Log form. Upon completion, the Phone Log or email will be placed in the appropriate case file;
- Records are available to the submitting agency and/or prosecuting agency upon submission of a Discovery Request Form;
- Results WILL NOT be released to the defendant or anyone not meeting the definition listed above. Any requests from individuals not listed above will be asked to contact the appropriate District Attorney's Office or have their attorney contact the FCS directly;
- Verbal results may be given following technical review. While giving any verbal results, due care should be taken to clearly explain the limitations (e.g., "preliminary indications are that…, but need to be confirmed");
- The analyst is also available to discuss the case with the defense attorney with a Discovery Request Form signed by the prosecution;
- The evidence is also available to be viewed by the defense. Prior arrangements must be made to schedule a date and time to view the evidence. No active casework may be in progress in that specific lab and all other evidence and case folders must be secured out of sight during the visit;
- In the case of electronic transmission of test results by telephones, facsimile or other electronic or electromagnetic means, the policy as set forth above, shall apply. Test reports will be available to the clients electronically for most cases after the notary signature is applied.

Additional State of Maine Information and Requirements

Information about cases (including results) is stored on the Local Area Network (LAN) of HETL. Access to this information is controlled by passwords on a need to access basis. The State of Maine Office of Information Technology (OIT) maintains the LAN and all their employees are bound by the confidentiality policies of the State of Maine. To protect the electronically stored information, regularly scheduled backups are performed by OIT. Reports and results can be faxed or emailed to authorized individual and agencies. A record is kept with information such as who sent the fax, to whom, etc. Supporting documents may also be sent electronically. Records of such exchanges are kept in the case folder.

FOAA/FOIA and Discovery Requests

Due to the sensitive nature of the work conducted at FCS, confidentiality is of the utmost importance. As most of the work conducted at FCS is part of active criminal investigations, the information and data generated is NOT subject to FOAA or FOIA requests in compliance with Title 16, §804: Limitation on dissemination of intelligence and investigative record information.

Additionally, due to the FCS's unique position of being a primarily criminal justice affiliated section inside of a public health organization, care must be taken to ensure that the dissemination of information is legally appropriate.

Refer to the FCS Discovery Request Policy for detailed information.

Defense attorney/defendant discovery requests should be redirected to the prosecutor for the case in question. The FCS will not provide discovery information to a defendant of a current criminal investigation. Discovery requests for cases that have been completed will be redirected to the assigned prosecutor's office or court.

5. Structural Requirements

5.1 Legal Identification

The Forensic Chemistry Section is part of the Maine Health and Environmental Testing Laboratory (HETL) and is a legal entity based on its government status responsible for forensic laboratory activities. HETL is headed by a Chief of Laboratory Operations, with a Forensic Technical Director in charge of the day-to-day activities. The analytical areas covered by the

HETL (Parent Organization) include forensic chemistry, environmental testing, and clinical testing.

Maine Health and Environmental Testing Laboratory
Forensic Chemistry Section
47 Independence Drive, SHS 12
Augusta, ME 04330
(207) 287-2727
https://www.maine.gov/dhhs/mecdc/public-health-systems/health-and-environmental-testing/

5.2 Management Responsibility

The Chief of Laboratory Operations has overall responsibility for the entirety of the HETL laboratory. The Forensic Technical Director has overall responsibility for the FCS. The management staff of HETL seeks to provide the forensic, managerial, and technical personnel the authority and resources necessary to carry out their duties including the implementation, maintenance, and improvement of the management system. The Forensic Technical Director and/or the Quality Manager will ensure personnel are made aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the quality management system through training, laboratory meetings and/or electronic communications. The overall top management of HETL resides with the Chief of Laboratory Operations. Key management of the FCS includes the Forensic Technical Director, Quality Manager and Unit Supervisors. The Forensic Technical Director, Quality Manager, and the employees of the FCS share the responsibility for the quality activities, as well as for ensuring compliance with the current versions of ISO/IEC 17025 & ANAB AR 3125.

The responsibilities of management are as follows:

Chief of Laboratory Operations (Public Service Manager II) – has the overall responsibility for all laboratory staff. Responsibilities include:

- Develops primary goals, operating plans, policies, and short- and long-range objectives for the laboratory and implements these following approval;
- Establishes organizational structure and delegates authority to subordinates;
- Leads the laboratory towards objectives and reviews results of business operations;
- Determines action plans to meet the needs of customers and government agencies;

- Represents organization to major customers, government agencies and the public.

Forensic Technical Director (Chemist III) – has the overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations within the FCS. When necessary, the Forensic Technical Director will appoint the Quality Manager or Unit Supervisor(s) to act on their behalf during the Forensic Technical Director's absence. Responsibilities include:

- Daily planning, organization and technical operations in the FCS;
- Ensuring their subordinates follow established quality assurance procedures and practices;
- Is knowledgeable of the scope of all processes performed in the FCS;
- Provides the necessary resources (personnel, equipment, supplies) for the laboratory activities they oversee, to ensure confidence in the laboratory's results;
- Ensures personnel are trained for the duties they perform - includes substitutes when regular personnel are absent;
- Issue authorizations to perform work;
- Review results of all testing activities and validations;
- Maintains current job title requirements;
- Maintains records and manages all aspects of testing activities;
- Maintains records for and manages all subordinates.

Quality Manager (Chemist III) – has defined responsibilities and authority for the preparation, issue, review, audit, and upkeep of the FCS quality management system. The Quality Manager has direct access to the highest level of management at which decisions are made concerning laboratory policy and/or resources. Responsibilities include:

- Ensures that the Quality Manual and Management System are established, implemented and maintained in accordance with the ISO/IEC 17025 and ANAB AR3125 standards;
- Manages the internal audit program by selecting internal auditors and scheduling/coordinating internal audits and evaluating results of quality system audits;
- Coordinates laboratory accreditation activities;
- Evaluates instrument calibration and maintenance records;
- Maintains training records of laboratory personnel;
- Assesses the adequacy of test report reviews (Technical and Administrative);
- Validates (and/or assist with) new technical procedures;

- Investigates technical problems, proposes corrective actions and verifies implementation;
- Recommends training to improve the knowledge of laboratory personnel;
- Proposes corrections and improvements within the quality system;
- Handles the maintenance and distribution of the Quality Manual and associated documents;
- Maintains a master list of current versions of quality documentation;
- Monitors the Management System;
- Reports on the performance of the Management System to senior management for review and as a basis for improvement of the Management System;
- Supervises the laboratory's interlaboratory proficiency testing program by administering proficiency tests and evaluating results.

Safety Officer (SO) – has been designated by the HETL Chief of Laboratory Operations with the responsibility and authority to ensure that all health and safety requirements are implemented and enforced (see the HETL Chemical Hygiene Plan for more information). Additionally, the FCS has a designated individual(s) to assist the SO and to ensure that a Health and Safety Program is implemented within FCS.

5.3 Range of Laboratory Activities

The testing carried out in the FCS that conforms to the requirements of ISO/IEC 17025 as a Forensic Testing Laboratory is as follows:

Forensic Testing Disciplines	
Toxicology - Blood Drug - Urine Drug - Blood Alcohol	Seized Drug

The scope of tests/services performed by the FCS is listed in the Scope of Accreditation and is detailed to the specifications of the accrediting body (currently ANAB). The most current scope and other accreditation documentation is stored on the FCS laboratory network.

Additionally, the FCS conducts biannual calibration of breath alcohol testing instrumentation in accordance with **State of Maine 10-144 CODE OF MAINE RULES Chapter 269.**

5.4 Requirements

The FCS carries out its testing activities to meet the requirements of the ANAB ISO/IEC 17025 Forensic Testing Laboratory Accreditation Program.

The FCS is committed to carrying out its testing activities to satisfy the needs of its customers to the maximum extent possible within the constraints of the resources available to the FCS.

The management system of the FCS covers the work carried out in the permanent facility of the laboratory, and in the courtroom where testimony may be offered by analysts. Any references to "annual" or "yearly" for any requirements under this manual and other standard could be implied to mean a calendar year.

5.4.1 The FCS conforms to requirements in ANAB document PR1018 - Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status. Only approved accreditation symbols will be included on FCS materials, and any reference to accreditation by all staff will include the standard to which the lab is accredited to and the type of accreditation. Any work performed outside of the scope of accreditation shall have the ANAB logo removed from the CoA and include a comment that the work performed was outside of the scope of accreditation.

5.4.2 The FCS performs testing under Maine State Law Title 17-A, Chapter 45, Title 29-A, Chapter 23 and DHHS rules 10-144 Chapter 266, Chapter 267 and Chapter 270.

5.5 Organization

a) The organization and management structure of the HETL FCS has been organized to satisfy the needs of the customer and regulatory authorities and to meet the international standards ISO/IEC 17025 and ANAB AR3125. Organizational charts indicating management structure, interrelationships between the sections, and the location of the FCS within the HETL are available with the Forensic Technical Director and will be updated as the structure changes. The FCS organizational chart will be updated when new employees are added and/or when the relationship of FCS within the parent organization changes.

b) The responsibility, authority and interrelationship of all personnel who manage, perform, or verify work affecting the results of laboratory activities is detailed in the organizational chart and section 5.6.

c) Laboratory procedures are documented to the extent necessary to ensure the consistent application of laboratory activities and the validity of results. The FCS has established and documented its Management System and procedures in the Quality Manual, Procedure Manuals, Biological Safety Manual, and Training Manuals. While the FCS does have its own Biological Safety Manual, it also follows the Chemical Hygiene Manual and the Resource Conservation Recovery Act (RCRA) Plan of the HETL.

5.6 Authority and Resources

The laboratory has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) Implementation, maintenance and improvement of the Management System;

b) Identification of deviations from the management system or from the procedures for performing laboratory activities;

c) Initiation of actions to prevent or minimize such deviations;

d) Reporting to laboratory management on the performance of the management system and any need for improvement (see section 8.9.1);

e) Ensuring the effectiveness of laboratory activities (see section 8.9.2);

Management responsibility and authority details are outlined in section 5.2 of this Quality Manual. The specific authority and resource details for other personnel are as follows:

Chemist III (Unit Supervisors)

- Respond to customer inquiries and provides professional advice;
- Determine technical training needs of personnel;
- Conduct employee performance reviews;

- Maintain open and constructive communication;
- Supervise quality assurance activities within the section;
- Approve unit members timesheets;
- Schedule vacation and coverage;
- Ensure that all health and safety regulations are followed;
- Ensure that all Human Rights Legislation are complied with;
- Oversee quality and invoicing for tests performed;
- Prioritize workload and assign casework;
- Facilitate operational concerns within their assigned unit;
- Ensure accurate and consistent testing procedures through the validation of all current procedures;
- Coordinate purchasing requests;
- Ensure that the operational needs are within budget and advising management of any discrepancies;
- Is knowledgeable of all processes included in the Scope within their assigned unit;
- Provides technical guidance in areas of testing within their assigned unit;
- Ensures equipment is maintained and calibrated and schedules maintenance as necessary.

Chemists I and II (Technical Staff)

- Maintain records of all quality activities as documented in procedures and test methods;
- Conduct casework and maintain chain of custody information;
- Provide testimony related to casework testing and results;
- Handle samples and performing analyses according to procedures and test methods;
- Develop, validates, and implements new procedures;
- Sign reports when designated with signing authority;
- Maintain instrumentation and equipment;
- Report deficiencies or malfunctions to the assigned unit supervisor;
- Report laboratory needs for purchase to the assigned unit supervisor;
- Improve laboratory and/or quality activities on a continuous basis;
- Assist with other laboratory activity as needed.

Evidence Technician and Administrative Personnel

- Receive evidence from various law enforcement agencies and maintains chain of custody;

- Identify evidence packaging/submission deficiencies and notify submitting agency;
- Responsible for organization and location of evidence while in the laboratory, except during the time it is being analyzed by a Chemist;
- Distribute evidence to Chemists for analysis;
- Coordinate the return of evidence to the submitting agency or destruction of evidence;
- Perform work functions and keeps records as per approved procedures and/or laboratory policies;
- Notarize Certificates of Analysis and distributes reports to customers;
- Maintain and retains copies of all tests and analytical reports in a manner and for a period specified by regulatory or accrediting bodies;
- Improve laboratory and/or quality activities on a continuous basis.

5.7 Communication and Integrity

Laboratory management ensures that:

a) Communication within the FCS follows both vertical and horizontal lines. Horizontal lines of communication exist and are encouraged for addressing common, day to day operation of the laboratory and effectiveness of the management system. A more formal vertical line of communication exists to address necessary operational and personnel issues. Top management shall communicate to the staff the importance of meeting customer requirements as well as statutory and regulatory requirements.

6. Resource Requirements

6.1 General

The laboratory has available the personnel (section 6.2), facilities (section 6.3), equipment (section 6.4), systems/traceability (section 6.5) and support services (section 6.6) necessary to manage and perform all laboratory activities. These resource requirements have been established to ensure the laboratory is able to perform its process requirements (section 7).

6.2 Personnel

6.2.1 All internal and external laboratory personnel that have influence over laboratory activities act impartially, are competent and work in accordance with the management system. FCS personnel are either directly employed or contracted through temporary employment agencies.

6.2.2 The requirements for each job function that influences the results of laboratory activities will be documented. The job descriptions, minimum required education, qualifications, training, technical knowledge, skills and experience for all the positions at FCS are available on SharePoint and on the State's intranet website: http://www.maine.gov/cgi-bin/bhrsalary/jobs.pl (see also see ANAB GD3152).

6.2.2.1 Personnel who authorize results, opinions and/or interpretations shall meet the minimum educational requirements for the hired position as outlined in job description records.

6.2.2.2 The laboratory training program is designed to emphasize and teach the skills and knowledge required to achieve the minimum standards of competence and good laboratory practices within the analysts' specific area of work. The training program will also include training in expert testimony.

- All new employees hired to analyze specimens will undergo a training program. The length and content of training will be decided by the Unit Supervisor, depending upon qualifications and nature of prior experience;
- The specific training protocols are detailed in the respective discipline Training Manuals. Written examinations shall achieve a score of 80% or greater. Upon completion of each task, the trainer will document the task. All training records will be retained;
- If the results of the training program are deemed unacceptable or insufficient, retraining may be required. Unit training manuals will detail the requirements for retraining;
- When the trainee has completed the training program, the appropriate competency tests will be prepared for State Certification, and for authorization to work independently;
- If a State Certification has lapsed, a full or modified retraining program will need to be completed depending upon the reason and length of the

lapse,. The extent of the retraining program will be determined by the Unit Supervisor.

6.2.3 The laboratory ensures that personnel have the competence to perform laboratory activities for which they are responsible, and be able to evaluate any deviations, their significance, and determine the appropriate action to be taken. Upon completion of the training program, analysts shall continue to participate in continuing education each year to maintain and expand their knowledge in the field.

6.2.3.1 All analysts, regardless of qualifications and experience, shall undergo a competency test before assuming casework responsibility in the FCS. This competency test will be performed after the successful completion of a training program and will also serve to meet the criteria for State Certification (see section 6.2.6) and accreditation authorization. The competency testing for analysts shall include:

- Examination of sufficient unknown samples to evaluate the individual's ability to perform the spectrum of anticipated tasks;
- A written mock report to demonstrate their ability to convey results and conclusions and their significance;
- A combined written and oral examination to assess knowledge of the testing/tasks they will be performing and associated job requirements such as legal knowledge, quality programs, ethics, and testimony. A minimum grade of 80% is required on the written examination;
- A mock trial to simulate giving testimony.

6.2.3.2 A minimum of 16 hours of continuing education shall be required annually per FCS member. Chemists are encouraged to join professional organizations related to their forensic disciplines as well as pursuing additional related certification(s). The hours can consist of:

- Conferences or other trainings (in person or remote/virtual);
- Related college courses;
- Reading peer reviewed publications (may be available through the intranet at The Public Health Library: Digital Library: Maine CDC);
- Training sessions held by FCS management.

These hours shall be tracked by FCS personnel in the Continuing Education Tracking spreadsheet located on the FCS laboratory network. Certificates should be uploaded by the analyst into their respective training folder.

6.2.4 Laboratory management shall communicate to personnel a list of the expected duties, responsibilities, and authorities when they commence in the position, and this is reviewed annually during performance reviews. These duties are also listed in section 5.6.

6.2.5 The FCS has a procedure documenting how the laboratory determines the:

- Competence requirements (see section 6.2.3.1);
- Selection of personnel (see sections 6.2.1, 6.2.2 and 6.2.2.1);
- Training of personnel (see section 6.2.2 and Training Manuals);
- Supervision of personnel (see section 6.2.4);
- Authorization of personnel (see below and section 6.2.6);
- State Certification of personnel (see below);
- Monitoring of competence of personnel (see section 7.7).

The Department of Health and Human Services (DHHS) also has set forth additional specific technical qualifications necessary for an individual to be certified by the DHHS. The FCS will authorize each analyst based on the requirements of ISO 17025:2017 and AR3125. A record of this authorization will be kept by the Forensic Technical Director. Analysts can be authorized to conduct case reviews even though they currently are not certified by DHHS in a specific area; this may be done by analysts who are no longer actively working specific types of cases but may have worked them in the past, still retain subject matter expertise, and actively participate in the annual Proficiency Testing program for that discipline.

6.2.6 The laboratory authorizes personnel to perform specific laboratory activities, including, but not limited to the following:

- Receipt of evidence;
- Use and maintenance of equipment;
- All testing in specified disciplines;
- Analysis of results, including statements of conformity or opinions and interpretations;
- Writing reports;
- Authorization of results (technical review);

- Authorization of reports (administrative review and notarization of reports);
- Performing internal audits;
- Development, modification, verification and validation of methods.

Additional State of Maine Requirements and Information

State Certification Requirements

In addition to the accreditation requirements for analysts listed in this manual, FCS analysts are required to be certified through the State of Maine as well.

https://www1.maine.gov/sos/cec/rules/10/chaps10.htm

Certification for Seized Drug Chemist

To be certified as a seized drug analyst, an individual must meet the requirements set forth in Chapter 266 of the Department of Health and Human Services Rules entitled "Certification Standards for Persons Conducting Chemical Analyses for the Detection and Identification of Drugs."

The initial certification test requires the proper identification of drug(s) in five samples. The results of the analyses will be submitted along with any data used to reach the analyst's conclusions. Data should be sufficient to identify the drug(s) for forensic purposes. The successful applicant will correctly identify all five samples. This Certification is valid for one year. The samples are prepared internally or are obtained through an approved proficiency test vendor such as CTS, etc.

Recertification for Seized Drug Chemist

Recertification is conducted every year. Each certified analyst will be given one unknown sample that must be properly identified and include all data submitted (see previous paragraph). The correct analysis is necessary for continued certification.

The proficiency samples are prepared internally or are obtained through an outside agency such as CTS, etc. The proficiency samples should be drugs that would reasonably be encountered in routine casework. The quantity of sample should be what is normally encountered in routine casework. Results should be submitted in a reasonable period of time, usually two weeks.

Participation in a recognized, approved and accredited proficiency program, and correctly analyzing samples from the PT, can be used to meet recertification requirements. Samples in addition to the PT samples need not be examined.

Certification for Alcohol Chemist

To be certified as an alcohol analyst, an individual must meet the requirements set forth in Chapter 267 of the Department of Health and Human Services Rules entitled "Certification Standards for Persons Conducting Chemical Analyses of Blood and Breath for the Purpose of Determining the Blood Alcohol Level."

The initial certification proficiency test requires correct identification of the concentration of ethanol in five samples. The results of the analyses will be submitted along with any data used to reach the analyst's conclusions. The successful applicant will correctly identify all five samples. The proficiency samples are obtained through an outside agency – CAP, FDLE, CTS, etc.

Recertification for Alcohol Chemist

Recertification is done semi-annually. Each certified analyst is provided a minimum of three unknown samples and asked to determine the concentration of ethanol with all data submitted (see previous paragraph). The correct analysis of all samples is necessary for continued certification. The proficiency samples are obtained through an outside agency – CAP, FDLE, CTS, etc.

Certification for DUI Drug Chemist

To be certified as a blood or urine drug analyst, an individual must meet the requirements set forth in Chapter 270 of the Department of Health and Human Services Rules entitled "Rules for Sample Collection and Drug Testing in Suspected O.U.I."

The initial certification proficiency test will consist of identifying the drug(s) in at least five samples. The results of the analyses will be submitted along with any data used to reach the analyst's conclusions. Data should be sufficient to identify the drug for forensic purposes. The successful applicant will correctly identify all samples. The proficiency samples are obtained through an outside agency such as CAP.

Recertification for DUI Drug Chemist

Recertification is completed annually. Each certified analyst will be given at least one spiked urine or blood sample containing an unknown controlled substance(s) to be identified with all data submitted. The correct analysis is necessary for continued certification. The proficiency samples are prepared internally or are obtained through an outside agency such as CAP.

6.3 Facilities and Environmental Conditions

6.3.1 The facilities and environmental conditions are suitable for the laboratory activities and do not adversely affect the validity of results. Functional areas of the laboratory will have adequate workspace appropriate for the job to be performed. This includes:

- Sufficient space will be provided near work areas for storage of supplies, equipment, and tools;
- Adequate space will be available for long and short-term storage of records, and for reference works and other literature;
- Appropriate space will be available for each instrument, and for the nearby storage of accessories and supplies;
- Work areas will be designed to provide efficient flow of evidence from the time of its receipt until its return;
- Airflow will be designed to minimize or prevent cross contamination. If possible, bio-vestibules will be used to separate laboratory areas from common areas; otherwise, laboratories will establish a means of ensuring and preserving a definite distinction between laboratory areas and common areas;
- Effective separation will be provided between neighboring areas in which there are incompatible activities;
- Adequate exhaust hoods and biological safety cabinets will be provided and will have sufficient airflow to support a safe environment;
- Adequate lighting will be provided for all work areas;
- Adequate plumbing and wiring will be available and accessible for all tasks;
- Heating, cooling, humidity control, and general ventilation will be adequate;
- A fire detection system must be in place;
- All laboratory entrance and exit points will be controlled;
- The laboratories must be secured during vacant hours by means of door alarms and security monitoring.

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.

Temperature and Humidity Checks

Daily temperature and humidity readings, as applicable, for refrigerators, freezers, evidence storage, and lab areas, shall be recorded using certified calibrated digital thermometers and stored on the FCS laboratory network for days in which laboratory activities are performed. Acceptability ranges will be listed on the specific log forms. If temperature is suspected of causing any instrument or QC issues, the set ranges may be evaluated and adjusted by building control if necessary.

6.3.3 Measurements to ensure proper environmental conditions where testing is likely to be affected by changes in the environment will be monitored. In cases where such environmental changes cast doubts about reliability, testing will be suspended until the validity of the results can be re-established.

Measures to control facilities are implemented, monitored, and periodically reviewed to include:

a) Access to and use of areas affecting laboratory activities. The Chief of Laboratory Operations or Forensic Technical Director will grant room access to employees based on needs of the operation. Room access is controlled through programmed magnetic cards.

Emergency contact information is stated on the outer doors of the FCS on the 2nd and 3rd floors of HETL.

Laboratory Access

All exterior entrance/exits and the entire outer perimeter of the laboratory are monitored 24/7 by security cameras through the Bureau of General Services – Building Control Division. Additionally, forensic hallways and evidence are monitored 24/7 by security cameras. Cameras are set to high priority, and the footage is stored for 6 months. The Forensic Technical Director has access to review the footage on the cameras.

Access to all Forensic Chemistry labs and offices is controlled through a proximity card reader locking mechanism. Only authorized personnel will have access to these areas and/or be issued keys by Building Control to controlled areas. A list of authorized individuals and the area of access is maintained by the Forensic Technical Director or Building Manager. Building Control maintains physical keys which are assigned to authorized individuals. An employee of the FCS will always accompany visitors to operational areas of the laboratory.

Persons submitting evidence will sign in and be issued a law enforcement visitor's badge which will grant access to the 2nd floor for evidence drop off, where all evidence will be received and logged. Law Enforcement Officers are authorized to be left unattended in the 2nd floor corridor and forensic wing hallway while they wait for a member of the FCS to assist them.

In the case of a non-life-threatening emergency, Building Control will contact the Forensic Technical Director or Chief of Laboratory Operations for access into restricted areas. The Forensic Technical Director or another authorized individual will personally accompany and remain with the responders while in the restricted area.

In the case of life-threatening emergencies, medical and emergency personnel will use whatever means are necessary to access all areas to save lives or prevent the loss of lives or property. A master key is located in the KnoxBox which is built into the outside of the building. Only the Fire Department and authorized individuals have access to the keys in the KnoxBox. If a key is removed from the KnoxBox, an alert will be sent to the Chief of Laboratory Operations, Forensic Technical Director and Building Control.

During operational hours (6 am to 6 pm), access to the administrative office, evidence storage and evidence processing areas are controlled by limited distribution of access cards/keys. All labs and office areas in the FCS shall remain locked when unattended.

If access is required after normal operational hours, permission must be granted through Building Control, from the Chief of Laboratory Operations and/or the Forensic Technical Director.

b) Prevention of contamination, interference, or adverse influences on laboratory activities. Preserving the integrity of evidence is crucial for proper interpretation and future admissibility at trial. Every effort should be made to avoid potential cross-contamination of all evidentiary items.

c) Effective separation between areas with incompatible activities. Seized Drug and Toxicology analyses are performed in separate areas of the laboratory with dedicated instrumentation available for each.

6.4 Equipment

6.4.1 The laboratory has access to equipment including measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables, and auxiliary apparatus as required for the correct performance of laboratory testing. Discussions and actions following the annual Management Review Meeting will ensure that the laboratory is furnished with all items of sampling, measurement, and test equipment required for the correct performance of all testing. Certified reference materials (CRMs) or standard reference materials (SRMs) from reference material producers (RMPs) meeting the requirements of ISO 17034 will be used in all testing where traceability is required, and when available in tests where traceability is not required. The CRM product information sheet/certificate will be retained by the Quality Manager. All reference materials will be verified and approved by reviewing the CoA and by comparison to a previous lot (if applicable), peer- reviewed library or published literature. The documentation of this approval and the method of approval will be retained. Any internal reference materials will be checked as far as is technically and economically practical.

6.4.2 In those cases where the laboratory needs to use equipment outside its permanent control, the Forensic Technical Director and/or Quality Manager will ensure that the requirements of ISO/IEC 17025 are met. When equipment goes outside direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the

equipment is checked and has shown to be satisfactory before the equipment is returned to service.

6.4.3 Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including manufacturer's manuals) shall be readily available for use by the appropriate laboratory personnel. In order to provide for the safe handling, transport, storage, use and planned maintenance of equipment to ensure proper functioning and prevention of contamination or deterioration, all the equipment used for measuring properties shall be subject to the following procedures:

- Manufacturer's recommendations for safe handling, transport, storage, and use of the equipment shall be followed;
- Each unit shall have its own plan for maintenance of each instrument, following the manufacturer's recommendations;
- All such equipment shall be subjected to quality control measures specified in the procedure manuals of each unit. Positive and negative controls shall be used to ensure proper functioning of the equipment.

The following general precautions shall be taken to avoid contamination or deterioration when handling, transporting, storing, and using reference standards and reference materials to protect their integrity:

- Personal protective equipment shall be worn and changed as necessary between reference materials;
- Reference materials shall be dispensed into clean laboratory equipment or containers;
- All reference standards and reference materials shall be stored and secured to ensure quality and safety.

6.4.3.1 All prepared reagent containers shall be labeled with the following information:

- Reagent name;
- Date of preparation/receipt;
- Initials of the preparing analyst;
- Storage conditions;
- Hazard warning (if necessary);
- Expiration date.

Reagent sheet records will be maintained identifying the following information:

- Date of preparation or lot number;
- Identity of person who prepared the reagent;
- Approval of reagent;
- Storage requirements (as applicable);
- Components used in the preparation and their expiration date.

Results from reagent testing shall be recorded on the reagent sheet and/or be in the appropriate batch data for the first use of the reagent. When applicable, all units of the FCS shall routinely check the reliability of applicable reagents. The reliability testing will occur before or concurrently with the test and checks will be documented and retained. Expired reagents shall not be used for casework unless rechecked and approved before use. If an expired reagent is rechecked and approved, a new expiration date must be assigned.

6.4.4 The laboratory verifies that equipment (and its software) shall conform to specified requirements of the testing conducted before being placed or returned into service. Each instrument that may have significant impact on test results shall undergo a performance check or calibration to ensure that it meets the required specifications before being placed into service.

6.4.5 The laboratory shall verify that equipment and its software used for measurement can achieve the measurement accuracy or measurement uncertainty required to provide a valid result.

6.4.6 All equipment having significant effect on the validity of test results shall be calibrated before being put into service. Conformance with the most current policy of ANAB is required.

Measurement equipment shall be calibrated when:

- The measurement accuracy or measurement uncertainty affects the validity of the results;
- Calibration of the equipment is required to establish the metrological traceability of the reported result.

Note – Equipment that may affect the validity of the reported results includes use of a

balance to perform a mass measurement, temperature measurements, and those used to obtain a measurement result calculated from multiple quantities.

The equipment that fits the requirements described above must only be sent to "competent calibrators" (see requirements listed in section 6.4.7).

6.4.7 The FCS calibration requirements are established below and will be reviewed and adjusted, as necessary, to maintain confidence in the status of calibration. The below calibration requirements will outline a list of the equipment requiring calibrations, specifications for the calibration laboratory, specified requirements of the calibration and the interval of calibrations. Procedures to check the calibration of equipment shall be established based on the specific requirements of the testing being carried out. It will normally be necessary to conduct a performance verification check after any shut down and following service or other substantial maintenance. In general, calibration check intervals shall not be less stringent than manufacturer's recommendations.

Instrumentation

Calibration – Instruments will be calibrated using standards specified in the Instrument QC Check log and/or the instrument SOP for the specific discipline.

Maintenance – Requirements will follow vendor recommendations where possible and will be outlined in the instrument maintenance procedure within the specific discipline SOP. When maintenance is conducted, reports and/or invoices indicating the type of service will be stored in the maintenance log for that specific instrument.

Notebooks containing calibration and maintenance logs will be kept for the various instruments. These logs will be stored near their respective instruments. As the FCS moves towards paperless documentation, some instruments have spreadsheets/ workbooks to document calibration and maintenance.

Preventative maintenance and/or repairs will be performed by the manufacturer of the instrument, if possible, or an approved qualified service provider.

The instrument must pass a QC check prior to returning to service after any major in-house maintenance/repairs, repairs by a vendor, or preventative maintenance performed

by a vendor. Examples of major in-house maintenance include, but are not limited to, cleaning the MS Source, changing to a new column with similar properties, and trimming the column.

Balances and Weights

Calibration – Balances will be calibrated annually by a 17025 accredited calibration laboratory, whose scope includes appropriate balance calibration.

Balances used to report weights will be checked at least monthly with Class 1, Class 2, and/or Ultraclass weights.

Class 1, Class 2, and Ultraclass weights are calibrated annually by an approved vendor employing materials traceable to NIST national standards, and shall be an ISO 17025 accredited calibration lab, whose scope of accreditation includes calibration of mass weights. Weights will be noted as being in or out of tolerance on the calibration report provided by the vendor.

Maintenance – See Unit Procedure Manuals.

Pipettors and Dilutors

Calibration – Pipettors and Dilutor will be checked annually by an approved ISO 17025 accredited calibration laboratory whose scope meets the needs of HETL. Pipettors and dilutors will be noted as passing or failing calibration on the calibration report provided by the vendor. Pipettes used for quantitation will have at least three check points during calibration.

Handheld pipettors used for quantitative analysis methods will be checked quarterly in house using a calibrated balance and DI water. Records of these verifications will be maintained by the Quality Manager. Acceptability values will be below the most stringent Uncertainty of Measurement calculation for the specific method.

Centrifuges and pH Meters

Calibration – pH meter will be calibrated annually by an approved vendor and will be

denoted as passing or failing on the calibration report provided by the vendor. Additionally, an in-house QC check will be performed prior to each use. The pH must be within ±0.5 units to pass the QC check.

Maintenance – Centrifuges and pH Meters will be maintained annually by a service provider listed on the approved vendors list, when possible.

Microscopes

Maintenance – Microscopes will be cleaned annually by a service provider listed on the approved vendors list, when possible.

Quantitative Glassware

Calibration – Glassware used for quantitative analysis will be calibrated once every 5 years by an approved ISO 17025 vendor whose scope meets the needs of HETL. Pass or fail will be noted on the certificate provided by the vendor and will be labeled on the storage container. If glassware is suspected to be compromised between calibration intervals, it shall be removed from casework and sent for calibration before resuming use.

Fume Hoods, Powder Hoods, and Biosafety Cabinets

Maintenance – hoods will be certified annually by an approved vendor. Certification for hoods is handled by HETL.

6.4.8 Instruments requiring external calibration checks (e.g. balances, weight sets and pipettes) shall be labeled to indicate the status of calibration, the date of the previous calibration occurred and the recalibration due date.

6.4.9 Any 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. Such items will be isolated or clearly labeled as “OUT OF SERVICE,” until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall, where appropriate, examine the effect of the defect or departure from specified limits on previous tests and initiate the management of the nonconforming work procedure (see section 7.10.1).

6.4.10 When necessary, procedures or a prior plan shall be in place for performance checks to ensure instruments maintain proper calibration. These checks will be performed according to the method or procedure associated with the specific test or calibration. Any intermediate checks that are required, following unscheduled maintenance or repairs, will be listed in the appropriate test method associated with the equipment.

Evaluation of performance checks will help determine the stability of the equipment, the method specifications, any risks associated with a failed check and ensure the calibration interval is sufficient.

As the nature and scope of the performance check can vary depending on the specific situation, a procedure or plan may be developed at the time the check is needed and documented on the performance check form. The goal of most performance checks will be to determine that any established lower limits of detection/quantitation can still be met following any service, repair, calibration or similar event, but may require further testing.

6.4.11 Whenever calibrations give rise to a set of reference values or correction factors, the laboratory will ensure the records maintained shall reflect such changes to the requirements, and correction factors will be updated and implemented, as appropriate, to meet the specified requirements, where present.

6.4.12 The laboratory will take practicable measures to ensure instruments, including hardware and software, are safeguarded from adjustments that could potentially invalidate the test results. Access to instruments is restricted to only approved employees and instruments will only be used by authorized analysts. Instrument methods will not be modified from established, validated parameters. If a method needs to be modified, the modification will be fully evaluated, verified, and approved before being used with casework samples. A minor modification will require a QC check verification, while a major modification will require a validation (see section 7.2.2.1).

6.4.13 When practicable, equipment, if significant to the results, will be uniquely identified. For ease of identification within case folders, equipment may be uniquely named and said name shall be recorded in case notes. The Forensic Technical Director and/or Quality Manager shall maintain records for equipment that could potentially influence laboratory

activities. These records will be retained with the maintenance logs for each instrument, the QC check binder for each unit, or the master equipment list maintained by the Quality Manager. The records include the following, where applicable:

- The identity of equipment, including software and firmware version;
- The manufacturer's name, model number, and serial number or other unique identification;
- Evidence of verification that equipment conforms with specified requirements;
- The current location within the laboratory;
- Manufacturer's manuals and reference to their location;
- Calibration dates, results of calibration, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
- Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
- The maintenance plan and history, where relevant to the performance of the equipment;
- Details of any damage, malfunction, modification to, or repair of, the equipment.

6.5 Metrological Traceability

6.5.1 The laboratory establishes and maintains metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

6.5.1.1 To ensure metrological traceability, the laboratory will use products and services from suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials that meet at least one of the requirements listed below:

- A National Metrology Institute that is a signatory to the BIPM – CIPM Mutual Recognition Arrangement with the calibration of measuring equipment and/or reference standard to be purchased or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB);
- A service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be purchased listed in a scope of accreditation;

- An accredited reference material producer that is accredited to ISO 17034 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material to be purchased.

In a situation where section 6.5.1.1 cannot be met, the laboratory will evaluate and confirm the competence, capability, and metrological traceability for the supplier of the product or service being purchased. Records of the objective evidence of the evaluation and confirmation will be retained.

The laboratory will not calibrate its own equipment.

When a certified reference material is diluted or changed in a way that alters the traceability measurement value, the equipment used to make the dilution or change will be evaluated for applicability of measurement traceability to meet accreditation requirements if the contribution of uncertainty of the equipment to the total uncertainty of the analysis is significant.

6.5.2 The laboratory ensures that measurement results are traceable to the International System of Units (SI) through one of the following:

- Calibration provided by a competent laboratory (laboratories that fulfil the requirements of ISO/IEC 17025 are considered competent);
- Certified values of certified reference materials provided by a competent producer with stated metrological traceability to SI (reference material producers that fulfil the requirements of ISO 17034 are considered competent);
- Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

Whenever possible, reference standards calibration shall be traceable to SI units (International System of Units) or a national measurement standard (i.e. NIST) through the use of Certified Reference Materials (CRMs) or Standard Reference Materials (SRMs), purchased from a competent producer.

Measuring equipment shall be traceable to International System of Units (SI) of

measurement. Competent external calibration services shall be used. Calibration certificates shall include measurement uncertainty. Traceability needs to be ensured when calibrating equipment that is used for quantitative analysis, if the contribution of uncertainty of the equipment to the total uncertainty of the analysis is significant.

6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory demonstrates metrological traceability to an appropriate reference. For example:

- Certified values of certified reference materials provided by a competent producer;
- 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 and Services

6.6.1 The laboratory ensures that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

- Are intended for incorporation into the laboratory's own activities;
- Are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;
- Are used to support the operation of the laboratory.

Note – Products can include measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include calibration services, sampling services, testing services (subcontractor laboratories), facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

In the case of subcontracted work, it is the FCS that is responsible to the client regarding shipping of evidence, communication with the sub-contractor and forwarding of analytical reports to the client. The subcontractor shall report their results to the FCS either in writing or electronically. Data or test results from subcontractors shall be identified as such when reported by the FCS (see section 6.4.7 for procedures related to services).

6.6.2 The FCS recognizes the significance of maintaining and adhering to policies that enforce a consistent process for the purchase, receipt, and storage of supplies and services integral to reliable analysis. The procedures set forth serve as a guide to ensure the necessary compliance. The laboratory shall have a procedure and retain records for:

a) Defining, reviewing and approving the laboratory's requirements for externally provided products and services
   - Upon identifying a need for a service, reagent or consumable material, the analyst will add the product to the monthly order form, central warehouse request form (including the necessary information to fulfill that request), or request a service through the Unit Supervisor;
   - Upon receipt of requested reagents and consumables, the analyst will inventory the product against the packing slip; initial, date, and save the receipt documentation. The product will then be evaluated to determine if it is in an acceptable condition and of appropriate quality (as defined in the applicable unit procedure manual) before being used or stored. If the product is deemed unsatisfactory, reasonable action will be taken as determined by the Unit Supervisor. All reagents will be dated upon receipt, dated and initialed upon opening or documented appropriately if single use or when space is limited on packaging;
   - Once reagents and consumables are received, they will be stored in accordance with manufacturer's recommendations.

b) Defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers.
   - Purchase requests will be reviewed and approved by the Unit Supervisor or appointed designee prior to completion of the order. These requests will contain a description of services and supplies ordered;
   - Vendors of services and supplies affecting the quality of analysis will be evaluated, and a list documenting the manner of evaluation and approval will be maintained. A review of the approved vendor list will be completed monthly.

c) Ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant

requirements of ISO/IEC 17025, before they are used or directly provided to the customer.

- FCS shall subcontract analysis of evidence only to competent subcontractors when necessary. A competent subcontractor is defined as one accredited under one or more of the following programs: ISO/IEC 17025 or ABFT (American Board of Forensic Toxicology). The competence of the subcontractors shall be verified by obtaining evidence regarding their current accreditation and scope. A register of all the subcontractors used will be maintained by the Forensic Technical Director and/or Quality Manager. This register indicates how the competence was verified for each subcontractor;
- All equipment, services, reagents, and consumable materials that affect the quality of analysis shall not be used until inspected or verified in compliance with the specifications and requirements defined in specific procedure manuals;
- Any certificates of analysis or other documentation indicating quality or purity of product will be stored according to lot number;
- Reagent sheets will be kept to document laboratory prepared reagents. This will include initials of analyst, date of preparation, assigned lot number, lot number(s) of reagents used, and result, or a reference to the results, of reagent check, and approval of the reagent.

d) Taking any actions arising from the evaluations, monitoring of performance and re-evaluations of the external providers.

6.6.3 The laboratory communicates its requirements to external providers for:

- The products and services to be provided;
- The acceptance criteria;
- Competence, including any required qualification of personnel;
- Activities that the laboratory or its customer, intends to perform at the external provider's premises.

7. Process Requirements

7.1 Review of Requests, Tenders and Contracts

7.1.1 Evidence for analysis is submitted by Law Enforcement Agencies, the Attorney General's Office, and District Attorney's Offices. On occasion, samples may be submitted for analysis by non-criminal justice agencies (such as hospitals, clinics, schools, etc.) to determine any issues related to public health. While the physical contract document is usually between the laboratory and submitting agency, the laboratory acknowledges there may be multiple agencies with the authority to act as the customer for one case. In the case of OUI related samples the laboratory considers the Bureau of Highway Safety and Bureau of Motor Vehicles, in addition to the submitting agency and District Attorney's Office, as customers. The laboratory will ensure communication with the appropriate customer(s) regarding any changes to the contract.

Information from a Receipt/Contract for Examination form, shipping label, or other applicable document, is entered into LIMS to generate an electronic evidence tracking number. This specifies information about the agency submitting the evidence and about the evidence being submitted. The evidence should be accompanied by a Receipt/Contract for Examination form, indicating the types of examination(s) being requested by the submitting agency.

The customer shall indicate on the Receipt/Contract for Examination form, the type of evidence submitted, and examination requested. Laboratory personnel shall ensure that the laboratory offers the appropriate test method for the customer's request prior to accepting the evidence. When samples are delivered to the lab by US Mail or other courier, or drop box, FCS staff will complete the Receipt/Contract for Examination form, indicating the way the sample was sent to FCS. If the type of analysis is not indicated in accompanying paperwork, the analyst may determine the appropriate test method, which will be communicated to the customer on the report. Alternatively, customers may be contacted to determine the type of analysis needed. In some cases, the type of analysis may be determined in advance by the customer and communicated to the laboratory.

The Receipt/Contract for Examination Request Form serves the purpose of an acceptable agreement (contract) between the customer and the FCS. The Receipt/Contract for Examination form is to be returned to the investigating officer or agency as a review of the examination sought by the customer and tender of the HETL regarding their request. The laboratory will also ensure that:

- The requirements are adequately defined, documented and understood. By submitting evidence to the FCS, the customer(s) agrees to allow the laboratory to select the test methods to be used to analyze the evidence;
- The laboratory has the capability and resources to meet customer requests. In cases where the evidence being submitted and/or the analyses requested is uncommon, the evidence receiving person must seek advice/review from a Chemist or Supervisor from the concerned unit before making any decisions about accepting the evidence;
- Where external providers are used, the requirements of section 6.6 are applied. The laboratory reserves the right to subcontract to another laboratory if necessary. The laboratory advises the customer of the potential for samples to be subcontracted on the Receipt/Contract for Examination Request Form and by signing the form the submitting agency is acknowledging that notification. The laboratory's review of submission documentation shall also cover any subcontracted cases;
- The appropriate methods or procedures are selected and can meet the customers' requirements. After reviewing evidence, in cases where the scope of analysis is unclear due to lack of information, or the probative nature of various pieces of evidence, analysts and/or FCS Management will discuss the issue with either the District Attorney's Office or with the submitting agency and decide on the course of action to be taken. In such cases the appropriate test method capable of meeting the customer's requirements will be selected. The laboratory reserves the right to analyze the evidence as necessary without prior notification to the submitting agency.

7.1.2 The laboratory informs the customer when the method requested by the customer is inappropriate or out of date.

7.1.3 When the customer requests a statement of conformity to a specification or standard for the test (e.g. the weight of the drug identified is greater than a specific statute) the specification or standard, and the decision rule are clearly defined. Unless inherent in the requested specification or standard, the decision rule selected is communicated and agreed to by the customer.

7.1.4 Any major differences between the request and the contract are resolved prior to laboratory activities commencing. Minor differences shall be communicated to the

customer on the Certificate of Analysis. Each contract must be acceptable to both the laboratory and the customer. The laboratory reserves the right to analyze the evidence as necessary without prior notification to the submitting agency. Deviations requested by the customer must not impact the integrity of the laboratory or the validity of the results.

7.1.5 The customer will be informed of any deviation from the contract on the Certificate of Analysis. Any significant changes in the normal procedure used in the analyses will be communicated to the submitting agency submitting or the Attorney General/District Attorney's Office. Records of such conversations or other communications will be maintained in the case file.

7.1.6 Any amendments to the requested analysis shall be communicated to the customer. The laboratory shall work with the customer if an amendment is needed to the type of testing requested to ensure any changes to the contract are agreed upon by the customer. The laboratory will make note of any changes to the contract in the case file if the contract is amended after work has commenced.

7.1.7 The laboratory cooperates with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed. With prior arrangements, the representatives of the Attorney General's Office, District Attorney's Office, Defense Counsel or the Law Enforcement Agencies submitting the evidence can tour the lab and discuss the testing that is being performed on their evidence. These representatives will have no access to the evidence or information pertaining to requests from other clients.

The requests from the clients regarding the exact examinations to be conducted and the pieces of evidence to be examined for testing will be marked on the Receipt/Contract for Examination form. Once the evidence is opened and inventoried by an analyst, it may be necessary to discuss with the Attorney General, District Attorney's Office or Law Enforcement Agency the exact examinations to be conducted and the pieces of evidence to be examined. Such discussions are not only permitted but are also encouraged. Records of such discussions are maintained in the case file.

7.1.8 Records of reviews, including any significant changes, shall be maintained. Written records of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract shall be

documented using the Phone Communication Form and/or email and shall be retained in the case file.

7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and verification of methods

The laboratory shall use appropriate methods and procedures for all tests within its scope for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. The methods used during case analysis are well known and widely utilized. The methods include, but are not limited to:

- Immunoassay;
- Infrared absorption spectrophotometry;
- Gas chromatography;
- Liquid chromatography;
- Mass spectrometry;
- Literature references;
- Microscopy;
- Data analysis and interpretation.

All the methods for items to be tested, when applicable and appropriate, shall include procedures for:

- Sampling;
- Handling;
- Storage;
- Preparation;
- Validation.

When appropriate, the methods shall also include estimations of measurement uncertainty and the statistical methods for analysis and evaluation of calibration data.

All the methods used by the FCS shall:

- Meet the clients' needs and are appropriate for the tests conducted and reported;

- Preferably those that are published in peer reviewed journals and authoritative texts and are based on the latest standards accepted in those areas of forensic science (if possible and appropriate);
- Validated or well recognized and accepted in the respective scientific fields.

The procedures to be used for examination in the laboratory shall be only those that have been approved and are included in the appropriate procedure manuals.

7.2.1.1 All test methods that involve the comparison of an unknown sample to a known standard shall require the evaluation of the unknown sample's identifying characteristics to ensure the sample is suitable for comparison before making a comparison to a known standard. The criteria for these comparisons will be listed in the appropriate SOP for the test method.

Units shall have written procedures for use and operation of equipment, handling, and preparation of items to be tested. Protocols for each analytical method routinely used in casework are maintained in the individual unit procedure manuals. These manuals include the standards and quality controls required and the minimum requirements for the interpretation of analytical data and reporting of a preliminary or complete analysis.

The laboratory ensures that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application.

When the customer does not specify the method to be used, the laboratory selects an appropriate method and will report the method chosen on the Certificate of Analysis. The laboratory reserves the right to analyze the evidence as necessary without prior notification to the submitting agency. The procedures to be used for examination in the laboratory shall be only those that have been approved and are included in the appropriate procedure manuals.

The laboratory verifies that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Once the validation process has been completed, but before use of the procedure in casework, the procedure and validation will be reviewed by appropriate laboratory personnel. Records of such

validations shall be maintained. If the method is revised by the issuing body, verification is repeated to the extent necessary.

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. Such plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured. As method development proceeds, periodic review is carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan must be approved and authorized.

Guidelines for Validation and Verification

Validation Procedure and Scope

Validation studies are an important component of forensic science which provides objective evidence that a testing method, instrument, or software is robust, reliable, reproducible, and fit for its intended purpose. The FCS employs the following procedure for validation and verification studies.

When a compound or compounds are to be added to an existing method for quantitative or qualitative purposes or a new method/software/instrument is to be validated, a written validation plan (Toxicology Validation Plan Form or Seized Drug Validation Plan Form) shall be proposed to the Review Team (Unit Supervisor, Quality Assurance Manager, and Forensic Technical Director) for approval. This plan should address the following areas and appropriate acceptance criteria, if applicable.

For Toxicology Unit validations, the plan shall include: Outline, safety evaluation, description of test materials, analytical methods, procedure, performance expectations, bias, precision, accuracy, calibration model, limit of detection (LOD), limit of quantitation (LOQ), uncertainty of measurement (UoM), carryover study, Interference study, stability study and references cited.

For Seized Drug Unit validations, the plan shall include: objective and scope, performance specification, analytical method, reference materials, safety evaluation, description of test materials, performance characteristics, selectivity, matrix effects, accuracy,

precision, range of LOD, robustness, ruggedness, UoM, carryover study and references cited.

Upon completion of the validation plan, a validation conclusion form and validation summary form shall be written to summarize data and show results from the validation plan. Both documents shall be sent to the Review Team for final approval and authorization for casework.

A file of the finalized validation project shall be created to contain any method development documents, approved validation plan, approved validation summary, approved validation conclusion, draft SOP, worksheets, and any other relevant documentation.

Validation of Methods

The following processes will be subjected to validation before being put into casework to verify that a procedure performs as expected:

- Nonstandard methods;
- New methods (lab developed or from external sources);
- Existing methods being used outside their scope;
- Major modifications to existing methods.

The validation is as extensive as is necessary to meet the needs of the given application or field of application.

Minor Modifications

Minor modifications to an existing procedure which do not materially affect the performance of the test do not require additional validation studies. These modifications should affect the efficiency and/or effectiveness of the test without affecting the results. A QC check verification will be performed with minor modifications before use in casework. Examples of minor modifications can include, but not limited to, trimming of a column and replacement of a column with similar properties.

Note – The techniques used for method validation can be one of, or a combination of, the following:

- Calibration or evaluation of bias and precision using reference standards or reference materials;
- Systematic assessment of the factors influencing the result;
- Testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
- Comparison of results achieved with other validated methods;
- Interlaboratory comparisons;
- Evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method;
- Determining the LOD.

Major Modifications

If a significant modification (significance is determined by personnel in the appropriate discipline) has been made to a previously validated procedure, the modification will be evaluated by comparison of results generated by the modified procedure with results generated by the current procedure using appropriate samples. These modifications should produce results of the same or improved quality as compared with those produced by the previously validated procedure. A revalidation of the method will be necessary before the modified method is approved for casework.

Examples of a major modification can include, but not limited to, a change in gradient, change in detector parameters (outside of a tune) such as changing the source temperature or replacing of the source/optics, installation of a column with different properties, use of a different pH buffer in a method, a change in detection ranges, a change in carrier gas, or any other major change from the validated method.

7.2.1.2 Whenever a validation is performed the laboratory will ensure the validation includes:

- Associated data analysis and interpretation;
- Establishes the data required to report a result, opinion, or interpretation;
- Identifies limitations of the method, reported results, opinions, and interpretations.

When changes are made to a validated method, including changes to data analysis or interpretation, the influence of such changes must be determined and where they are found to affect the original validation, a new method validation is performed (see section 7.2.2.1).

The validation will meet the needs of the customer and will consider the bias, accuracy, reproducibility, repeatability, selectivity, sensitivity, measurement range, the measurement of uncertainty of the results, and the robustness that is required of the analysis, if determined appropriate for the method. The validation process necessary to demonstrate that a particular analytical method is suitable for the intended purpose will be contained in a validation plan, established prior to the start of validation.

The laboratory retains the following records of validation:

- The validation procedure used;
- Specification of the requirements;
- Determination of the performance characteristics of the method;
- Results obtained;
- A statement on the validity of the method, detailing its fitness for the intended use.

Deviation from Laboratory Procedures

There are times when deviation from documented policies or procedures is necessary. A deviation from procedure would generally be decided on before the analysis takes place.

Minor Deviation

A deviation that is not expected to alter the result and generally will not have an extended duration. They may be initiated with the concurrence of the Unit Supervisor and/or the Quality Manager and documented on the Deviation Request Form. The deviation will be documented in the case notes when applicable to casework and with relevant materials for non-case work activities. The concurrence of the Unit Supervisor and/or Quality Manager will be documented alongside of the description of the deviation.

Major Deviation

A deviation that is applicable over an extended period of time, over a range of circumstances, or has the potential to generate different results. When there is a need for a major deviation from a policy, procedure or requirement, the requestor will complete a Deviation Request Form to be submitted to the Unit Supervisor for review. The requestor will:

- Indicate the applicable policy, procedure or requirement;
- Describe the requested deviation;
- State the reason for the deviation;
- Specify the instance(s) for which the deviation is requested.

The Unit Supervisor, Forensic Technical Director and Quality Manager will evaluate the merits/risks of the deviation from a technical viewpoint. These may include, but are not limited to:

- Contamination;
- Security;
- Defensibility;
- Integrity;
- Safety.

If the merit of the proposed change outweighs the risks and drawbacks, the Forensic Technical Director and/or Quality Manager may authorize the deviation and specify a duration period for the deviation. Copies of the Deviation Request Form will be placed in the respective case folders and a comment will be listed on the CoA.

7.3 Sampling

Sampling refers to a procedure that enables one to arrive at conclusions about the members of the population, by studying the behaviors of a few samples chosen from the population.

7.3.1 The FCS shall have a sampling plan and method(s) for sampling when it carries out sampling of substances, materials or products for subsequent testing. Sampling requirements should be detailed at the time of submission or upon conference with the investigating officer or representative from the prosecutor's office, if necessary.

When no specific sampling instructions have been provided by the customer for cases involving multiple similar samples, sampling decisions are made based on statistically

valid methods that are recommended/accepted by major peer institutions (such as SWGDRUG, DEA or ASTM). Sampling plans are described in the discipline specific procedure manuals.

7.3.2 The sampling plan and method(s) describe:

- The selection of samples;
- The statistical sampling plan with a stated level of confidence that shall be used if an inference will be made to report on the whole population;
- Preparation and treatment of the samples(s) required for testing.

7.3.3 The case file will either explain the sampling plan or will reference the procedures/customer consultations in this regard. The laboratory retains records of sampling data within the case record. These records will include, where relevant:

- Reference to the sampling plan used;
- Date and time of sampling;
- Data to identify and describe the sample (e.g. item number, subitem number, and item description);
- Identification of the personnel performing sampling;
- Identification of the equipment used for the sampling and testing;
- Environmental or transport conditions, if relevant to sample condition;
- Diagrams or other equivalent means to identify the sampling location when appropriate;
- Deviations from the sampling plan. When the customer requests a deviation, it shall be recorded in the case record with appropriate sampling data and test results.

7.4 Handling of Test or Calibration Items

The laboratory will have procedures for receipt, handling, protection, storage, retention and disposal or return of evidence, including all provisions necessary to protect the integrity of the evidence, and to protect the interests of the laboratory and the customer. Precautions are taken to avoid deterioration, contamination, loss or damage to the evidence during handling, transporting, storage and preparation for testing.

7.4.1 For all evidence:

a) All evidence received in the FCS is to be properly sealed upon submission. Evidence submitted without a proper seal will be properly sealed upon submission, by either the submitter or the evidence technician. Before being subjected to examinations, and after the examinations are complete, all evidence will be stored in a secured, limited access storage area equipped with appropriate security to protect the integrity of all items. During evidence examination, if it is found that the evidence is not properly sealed, the analyst shall note this on the case worksheet and on the Certificate of Analysis. Evidence should be re-sealed after examination as soon as practicable. The evidence sealed for storage will always carry a unique identification number, proper seals, and the initials of the person sealing the evidence on or across the seal when possible.

b) Evidence is not to be left unattended and should be always stored in a secure location. While items are in the process of being examined, they shall be stored in locked, and/or limited access areas. All examined evidence should be returned to the evidence room when analyses are complete. Analysts who anticipate a substantial delay in their examination, should transfer items from their custody to the evidence room until their examination can be resumed. Access to the evidence room as well as to the rooms where the evidence is examined is controlled by key/electronic access as determined by the Chief of Laboratory Operations or the Forensic Technical Director.

c) A chain-of-custody is to be maintained to securely track and accurately identify all items of evidence. When evidence is subdivided in the laboratory, sub-divided items shall also be tracked. The chain-of-custody shall include:
   - The individual(s) or location(s) receiving or transferring the item(s);
   - The item(s) being transferred;
   - The chronological order of all transfers, minimally including the date.

   A chain-of-custody is required for all items that are collected and preserved for future testing. Items considered collected and preserved for future testing pertain to items sampled and not tested within the dates of analysis for that specific case. If items are sampled for testing during the analysis period, these items will not be recorded on the chain-of-custody.

d) A disposition of all items received is communicated to the customer regarding the disposition on the Certificate of Analysis

Note – An item being tracked could contain multiple components and be tracked as one item.

Note – Documentation of internal transfers does not need to include use of personal storage locations.

7.4.2 Every item of evidence received by the FCS is marked uniquely for identification as generated through the LIMS system. This identification number shall be retained throughout the life of the item in the laboratory. The LIMS system will accommodate a sub-division of an item.

The unique identification generated through the LIMS system covers all items received. Each item of evidence shall be marked for identification in such a manner as to ensure that it is uniquely identifiable and traceable to the unique case number. If the evidence does not lend itself to marking, its proximal container or identifying tag shall be marked.

7.4.3 In all cases where the evidence being examined by an Chemist varies significantly from the description on the Receipt/Contract for Examination Form and/or packaging, the Unit Supervisor, Forensic Technical Director, Quality Manager, or another Chemist will verify the discrepancy. No further work will be conducted until reconciliation between the analyst and the submitter (or their representative) is accomplished and a record of the communication is maintained.

The discrepancy will be noted on the Discrepancy Form and the Chemist, Unit Supervisor, Quality Manager, and/or the Forensic Technical Director will take appropriate actions to address the discrepancy. The completed Discrepancy Form will be filed in the case folder. Examples of discrepancies include but are not limited to:

- Inventory discrepancies;
- Weight discrepancies;
- Inconsistent suspect and/or victim names;
- Agency case number.

Misspellings and typographical errors are not considered significant discrepancies.

7.4.4 To avoid deterioration, loss, or damage, all biological and food evidence will be stored in the freezer or refrigerator. Temperatures of refrigerators and freezers used for storage of evidence and materials are routinely checked during workdays to ensure that they are operating correctly. If it is determined that a refrigerator and/or freezer is not operating correctly, the Unit Supervisor(s), Forensic Technical Director and/or Quality Manager will take appropriate action to preserve any evidence/material stored inside.

Where a sample, or portion of a sample, is to be held, the laboratory has storage and security arrangements that protect the condition and integrity of the sample.

7.5 Technical Records

7.5.1 The laboratory ensures that case records contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty. The case record shall accurately record and maintain all observations, data, and calculations made during the analysis of evidence samples. Options for recording observations include, but are not limited to, written notes, photography, drawing, photocopying, or scanning. The case record shall include a description of the condition and identification of evidence items, the date and identity of personnel responsible for each laboratory activity and for checking data and results. The case record shall specify the method(s) and/or technique(s) used to analyze the evidence. All observations, data, and calculations will be recorded at the time they are made. If an observation, or test result is rejected, the reason, identity of individual taking the action, and the date shall be recorded in the technical record.

Documentation of all significant aspects of the analytical procedures and other aspects of the laboratory operation related to the reliability and interpretation of analytical results are necessary to:

- Support the scientific conclusions in the laboratory report/CoA;
- Permit supervisory/peer review of the work product;
- Allow for re-evaluation of the data by outside scientific observers;
- Provide a foundation for the introduction of the work product into a court of law;
- Provide an audit trail by which management can demonstrate and verify the continued quality of the laboratory work product.

Examples of administrative documentation include the evidence receipt, chain of custody record, the description of the evidence, the report, records of conversations with customers, etc.

The laboratory maintains a file on every case submitted for analysis; specifics of each type of case are located in the discipline specific procedure manuals.

The FCS considers all technical data as technical records. This includes, but not limited to, case folders (also referred to as case records), proficiency tests, all data generated from tests and QC procedures, reagent and maintenance logs, and calibration records.

Case records will be identified by their unique laboratory case numbers. All other records will be appropriately identified by descriptive titles.

Abbreviations and/or symbols and their meanings being used in the examination documentation specific to the FCS shall be maintained and made accessible to all personnel (SharePoint). General scientific abbreviations/symbols are viewed as common knowledge and need not be explicitly detailed. Chemical abbreviations are maintained in the HETL Chemical Hygiene Plan.

Examination documentation refers to documents (either in the case folder, or kept in a central location) that are necessary to arrive at the conclusions drawn in the report. Examples include notes, observations, instrumental printout, etc. This documentation shall be such that, in the absence of the analyst preparing the report, another competent reviewer could evaluate what analysis was performed and interpret the data.

All the examination documentation shall be permanent in nature; all handwritten material will be in ink. Corrections shall be made with a single strike-out and initialed. Nothing in the handwritten format will be obliterated or erased.

If an observation, data, or 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.
When instrumental analyses are conducted, the operating parameters shall be documented in a test method, recorded in a logbook, recorded in the examination record, etc. The instrumental method used in the analysis should appear on instrumental data

printouts. It is not required to include a printout of the entire instrumental method in the case file.

All technical data generated during analysis shall contain, at minimum, the laboratory case number and the initials of the analyst.

All administrative documentation pertaining to a case shall, at minimum, be identified by the laboratory number of that case.

When examination documentation is prepared by an individual other than the analyst interpreting the findings and signing the report, the initials of that individual shall be recorded on the documentation representing his/her work. For cases where an analyst has another individual transcribe information, this shall be documented in the case file.

The unique case identifier for each case for which data was generated shall be appropriately recorded on the printout when data from multiple cases is recorded on a single printout or worksheet.

When examination records are recorded on both sides of a page, each side shall be treated (identified and initialed) as a separate page.

7.5.2 The laboratory ensures that amendments to technical records can be tracked to previous versions or to original observations. Change(s) made to completed examination records generated shall be tracked. Examination records shall be considered completed prior to technical or administrative review of the records. Original and amended data and files must be kept and shall include the date of alteration, an indication of the altered data and personnel responsible for the alterations.

Note – Contemporaneous revisions are not considered amendments.

7.6 Evaluation of Measurement Uncertainty

7.6.1 The method of analysis for evaluation of measurement uncertainty shall:

- Require the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method;

- Include the process of rounding the expanded uncertainty;
- Require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%);
- Specify the schedule to review and/or recalculate the measurement uncertainty.

7.6.2 The laboratory shall not calibrate its own equipment.

7.6.3 Measurement uncertainty is evaluated for all tests reporting a quantitative value. When appropriate, units shall have and use a test method for estimating uncertainty of measurement. Units shall identify the significant components of uncertainty and make a reasonable estimation and shall ensure that the form of reporting of the results does not give the wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and measurement scope and shall use, for example, previous experience and validation data.

7.6.4 The following are the analyses in which numerical values from quantitative analyses appear in the reports issued by the FCS:

- Alcohol Determination;
- Blood Drug Determination;
- Controlled Substances – Reporting of weights.

Note – When measurement uncertainty has been established and verified for a specific method, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

7.6.5 When estimating the uncertainty of measurement, all uncertainty components which are of importance shall be considered using appropriate testing procedures. Documentation containing the following information, if applicable, will be maintained:

- Statement defining the measurand;
- Statement defining how traceability is established for the measurement;
- Equipment (measuring device or instrument) used;
- Uncertainty components considered;
- Uncertainty components of significance and how they were evaluated;
- Data used to estimate repeatability and/or reproducibility;
- All calculations;

- Combined standard uncertainty, the coverage factor, the coverage probability and the resulting expanded uncertainty.

7.7 Ensuring the Validity of Results

7.7.1 Test methods shall have quality control procedures for monitoring the validity of a test. Quality control data shall be recorded in such a way that trends are detectable, and where practicable, statistical techniques shall be used to review the data. Wherever possible and applicable, positive control quantitative data will be plotted or monitored so that any trends can be spotted. Statistical control charts will be used to monitor the performance of the system whenever possible. Quality control may include, but is not limited to, the following:

- Regular use of certified reference materials and/or internal quality controls;
- Use of second source CRMs;
- Use of alternate instrumentation;
- Functional check(s) of measuring and testing equipment;
- Use of check or working standards with control charts, where applicable;
- Intermediate checks on measuring equipment;
- Replicate tests using the same or different methods;
- Retesting (verification) of items/reanalysis;
- Review of reported results;
- Participation in a proficiency testing program.

Wherever possible, Standard Reference Materials (SRM's), Certified Reference Materials (CRM's), or secondary standards developed in the FCS will be used to monitor the test being carried out.

Appropriate standards and controls will be specified in the laboratory methods and their use will be documented n the case record.

Laboratory personnel who issue findings based upon examination documentation generated by another chemist must complete and document the review of all relevant pages of examination documentation in the case record. This policy also applies to situations where analysis is conducted by one chemist and is interpreted and reported by another chemist. The author of a test report shall have thoroughly reviewed the analytical

data or results. The application of the Chemist's initials shall serve as objective evidence that the work of another has been reviewed and accepted.

Technical Review

After analysis has been completed and before the CoA is released, all casefiles shall undergo Technical Review. Technical reviews determine whether the appropriate examinations have been performed to support the results and conclusions reported by ensuring:

- The test report is accurate, and the conclusions are reasonable within the constraints of validated scientific knowledge and supported by the examination documentation in the case record;
- There is conformance with proper technical procedures/test methods and applicable lab policies and procedures without bringing in personal preferences of the reviewer;
- Associations have been properly qualified in the test report;
- The test report contains all required information including, but not limited to the sampling plan and methods of analysis utilized and any deviations.

Technical Reviews:

- Shall be conducted on 100% of all casework;
- Shall be conducted by those who have expertise in that discipline, have been previously certified and authorized to perform that testing, and actively participating in the annual proficiency testing program for that discipline. Analysts conducting Technical Review need not have a current State of Maine Certificate or authorization with the discipline for which they are reviewing cases but must take an annual proficiency test in the discipline and be currently authorized to conduct such review by the Forensic Technical Director;
- Shall be conducted on expert report letters and conversion reports requested by customers;
- Shall not be conducted by the author(s) of the report.
- Do not need to be conducted on casefile review reports for testimony as no new work is performed on the evidence.

If an error relating to the technical analysis of the case is discovered, the Technical Reviewer shall reject the case and return the folder to the analyst for correction. Such

action requires the analyst to correct the issue and begin the technical review process again. All changed documents, reports, and review forms shall be retained in the case file.

Note – Technical Reviews, while important to the laboratory quality assurance program, should not shift the perceived responsibility for the scientific findings from the analyst to the reviewer.

The reviewer will sign and date the batch worksheet and/or Case Review Form to signify that the notes have been reviewed.

Administrative Review

After Technical Review, and before the report is signed, notarized, and released to the customer, all casework will undergo Administrative Review. Administrative reviews will ensure consistency with laboratory policy and for editorial correctness by reviewing:

- Proper format of the report;
- Use of correct grammar, spelling or content;
- All documentation in the casefile contains the case number and initials of the analyst;
- Completeness of the case filer (copy of the final report/Certificate of Analysis, Case Review Form, any preliminary, supplementary or corrected reports, worksheets and case notes, evidence receipt, hard copies of data, etc.).

Administrative Reviews:

- Shall be conducted on 100% of all casework;
- Shall be conducted by the Unit Supervisor(s), Quality Manager or Forensic Technical Director; Chemist's may conduct Administrative Reviews when authorized by the Forensic Technical Director;
- Shall not be conducted by the author(s) of the report or the technical reviewer of the report;
- Shall be conducted on casefile reviews for testimony, expert report letters and conversion reports requested by customers.

If an error is discovered during an Administrative Review on the CoA (typo for example), but before the report is issued, the analyst will create a new report. The original report with the error will be retained in the case folder, but the new report is not a Revised or

Amended report. The new report must be at least Administratively Reviewed a 2nd time. The 2nd Administrative Review can be documented on the same case review form. Administrative reviews will ensure that the reports are satisfactory to be released to the clients.

Upon completion of the Administrative Review the Case Review Form (SharePoint), or batch worksheets will be signed and dated by the administrative reviewer.

All reports are issued only after they have undergone technical (authorization of results) and administrative review (authorization of reports). Discrepancies discovered during review that result in changes shall be traced. Instances where a discrepancy is found after a report has been issued (signed, notarized and sent to customer), a 'Revised' (Amended) report will be issued. Additionally, the 'Revised Report Form" will accompany the new report, and specifically details what report is being 'revised/amended' and what changed on the Revised report.

In case of a dispute during review between an analyst and the reviewer, the Quality Manager and/or Forensic Technical Director (or higher personnel if necessary) shall make the decision. In the case of a dispute between an analyst and the Quality Manager and/or Forensic Technical Director, the Forensic Technical Director shall make the final decision.

If during a Technical Review an error is discovered on the Report (before being signed and issued to the customer), the analyst will create a new report. The original report with the error will be retained in the case folder, but the new report is not a Revised or Amended report. The Administrative Reviewer will review the corrected Report. If a report is to be issued on a case where no analysis has been conducted, there is no Technical Review, only an Administrative Review.

Testimony Monitoring

Testimony monitoring shall be performed for each analyst in each discipline at least once per calendar year (if possible) by an individual currently, or previously, competent in the test method, and actively participating in the annual proficiency testing program for that discipline. If a competent analyst is not able to observe testimony in person, a review of the testimony transcript may be performed to satisfy the annual technical review requirement.

Other additional (non-technical) methods for testimony monitoring may include:

- Observation by the Quality Manager or Forensic Technical Director;
- Observation by another analyst;
- Observation by Prosecutor, Defense Attorney, or Judge.

Testimony monitoring will be documented using the Courtroom Monitoring Form (SharePoint). In addition, analysts shall record information about their testimony, such as date, case number prosecutor on the FCS Testimony Tracking spreadsheet located on the FCS laboratory network.

Testimony evaluation shall include topics such as:

- Knowledge of subject;
- Clarity;
- Communicating ability (explaining scientific terms and procedures to the jury or judge);
- Neutrality between defense and prosecution questions.

In case the testimony is found unsatisfactory, the Unit Supervisor shall discuss any shortcomings with the analyst. If subsequent testimony of the analyst is again found to be unsatisfactory, the Unit Supervisor, in consultation with the Forensic Technical Director and representatives from the legal community, will decide on any remedial action to be taken.

Records of courtroom testimony reviews shall be maintained for at least one ANAB assessment cycle.

7.7.2 The laboratory monitors its performance by comparison with results of other laboratories where available and appropriate. This monitoring is planned and reviewed and includes participation in proficiency testing.

7.7.2.1 The process for monitoring performance by comparison with results of other forensic service providers shall at a minimum:

a) Ensure successful completion of at least one proficiency test for each discipline prior to accreditation being granted in that discipline; and

b) Ensure each discipline on the scope of accreditation successfully completes, per calendar year, at least one proficiency test for each discipline in which accredited services are provided, with authorized release of the test results to ANAB from the test provider.

Note – For proficiency tests taken at the end of one calendar year, evaluation of successful completion can occur in the subsequent calendar year.

7.7.3 The results of such monitoring will be reviewed by the Quality Manager and discussed with the Unit Supervisor and Chemist. If the data is found to be outside criteria given in a Test Method, suitable corrective action will be taken (see section 8.7.1). Data from monitoring activities is analyzed, used to control and, if applicable, improve the laboratory's activities (see sections 7.7.5-7.7.8).

7.7.4 The performance of all Chemists shall be monitored. This monitoring shall ensure that all Chemists who perform testing shall successfully complete at least one intralaboratory comparison, interlaboratory comparison, or proficiency test per calendar year in each discipline on the scope of accreditation in which the individual works. If the preceding options are not available or appropriate, observation-based performance monitoring is acceptable.

The monitoring should be varied over time to cover all aspects of assigned job functions but does not have to include all aspects of the work performed each time.

7.7.5 Proficiency Testing

The purpose of the proficiency testing program is to ensure the quality of analytical work carried out in the laboratory. These control measures test the analysts as well as the laboratory procedures and quality assurance practices for their suitability.

Sources of proficiency samples from approved external vendors, observation-based monitoring, and in-house proficiency tests are administered routinely to those performing casework. A minimum of one proficiency test sample per analyst, per year will be conducted by analysts performing seized drug testing, urine drug testing, and blood drug testing. Likewise, a minimum of one proficiency test per analyst will be

performed semi-annually (every six months) by analysts performing blood alcohol determination. Additionally, blood alcohol analysts must prepare and run a calibration curve with their proficiency test.

The Quality Manager shall maintain records of all proficiency tests and subsequent follow-up/corrective actions.

The process for monitoring of performance by intralaboratory comparison, interlaboratory comparison, proficiency testing or observation-based testing shall at a minimum:

- Ensure that results are not known or readily available to the participant being monitored;
- Ensure use of approved methods;
  Establish criteria for determining successful completion prior to the monitoring activity;
- Require a mechanism to ensure the quality of intralaboratory comparisons, interlaboratory, comparisons and observation-based monitoring prior to the monitoring activity.

All proficiencies, to the extent possible and practicable, will be treated as regular cases received in the laboratory and subjected to processes normally applied to casework including, testing by the laboratory's approved methods of analysis and quality control (including technical and administrative review). The laboratory will ensure the testing includes a representative sample of the methods and equipment/technologies within each discipline listed on the scope of accreditation.

7.7.6 The FCS requires a minimum of one proficiency test per analyst per year successfully completed for seized drugs, urine drug testing and blood drug testing, and twice per year for blood alcohol determination to maintain ANAB authorization AND state certification. If available, this proficiency is obtained from a provider that is accredited to ISO/IEC 17043. If an accredited provider is not available or not appropriate for the work conducted, the laboratory will gain approval from ANAB for alternative means by which the laboratory's performance can be assessed. The laboratory will submit the proficiency test to the appropriate provider on, or before, the agreed upon due date.

7.7.7 Evaluation of Proficiency Testing

Qualitative proficiency tests shall be evaluated by comparing the achieved result to the expected result. If a compound is part of the current applicable testing menu, the test will be considered passing if all achieved results match expected results. If not, the test will be considered failed unless a root cause investigation determines an acceptable reason for the missed compound.

Breath and blood alcohol quantitative proficiency tests where a consensus result is provided shall be evaluated by comparing the achieved quantitative values to the consensus quantitative values. The test will be considered passing if all achieved quantitative values are within ±2 standard deviations or ±10% (whichever is greater) of the reported consensus mean value. If a quantitative value falls outside of the acceptable range, the test is considered failed unless a root cause investigation determines an acceptable reason for the difference.

Breath alcohol quantitative proficiency tests utilizing a known, traceable reference material shall be evaluated by comparing the achieved quantitative values to the expected value of the reference material. The test will be considered passing if all achieved quantitative values are within ±10% or ±0.005 g/210 L (whichever is greater) of the nominal quantity value. If a Performance Statistic (En) value is provided that may also be used for evaluation, with a value < 1 being considered satisfactory. If a quantitative value falls outside of those ranges, the test is considered failed unless a root cause investigation determines an acceptable reason for the difference.

Blood drug quantitative proficiency tests will be evaluated by comparing the achieved quantitative values to the consensus quantitative values. The test will be considered passing if all achieved quantitative values are within ±2 standard deviations, ±20% of the consensus result, or ± the current calculated uncertainty of measurement for that compound (whichever is greater) for that panel of the reported mean value. If a quantitative value falls outside of those ranges, the test is considered failed unless a root cause investigation determines an acceptable reason for the difference.

7.8 Reporting of Results

7.8.1 General

The results shall be provided in a written report as a Certificate of Analysis. The CoA is considered complete when it has been technically and administratively reviewed, signed and notarized.

7.8.1.1 A CoA shall be generated for all cases submitted to the FCS. This includes cases where the FCS has received notification of adjudication before work is completed, and when the client cancels the request before work is completed.

- When associations are made, the significance of the association shall be communicated clearly and qualified properly on the CoA.
- Results will be listed for all items received, including items where no testing was performed, items where partial testing was performed, and items that have been collected or created and preserved for future testing.
- When "no identification" conclusions are reported, the reasons that identifications were not made shall be clearly communicated in the report.
- When no definitive conclusions can be reached (e.g. results are "inconclusive") the reasons shall be clearly communicated in the report.

7.8.1.2 When results are reported in a simplified way, the agreement with the customer shall specify which information in sections 7.8.2 through 7.8.7 of ISO/IEC 17025:2017 will not be included in a written report or through electronic access.

7.8.2 Common Requirements for Reports

Each test report and certificate of analysis generated by the FCS shall include, unless the laboratory has a valid reason for not doing so, the following information:

a) a title (e.g., "Test Report");
b) the name and address of the Health and Environmental Testing Laboratory;
c) The location of performance of the laboratory activities;
d) Unique identification (case number) of the test report and on each page to ensure that the page is recognized as part of the test report. A clear identification of the end of the test report shall be by signature and a notary statement;
e) The name and address of the client;
f) Identification of the method used;

g) A description of the item(s) tested, the condition of the item(s) tested, and unambiguous identification of the item(s) tested;
h) Date of receipt of the evidence;
i) The date(s) of performance of the laboratory activity;
j) The date of issue of the report;
k) When applicable, reference to the sampling plan;
l) Astatement to indicate the results relate only to the tested items;
m) The test results with, where appropriate, the units of measurement;
n) Any deviations from the test method;
o) The name(s), title(s), and handwritten signature of the analyst authorizing the test report (notarization);
p) When the CoA contains results by subcontractors, these results shall be clearly identified as such;
q) Notary statement.

Note – A legal requirement that dictates the information to be included in a report is a valid reason to not include one or more listed report elements.

Note – o) Authorization of the report does not have to be performed by the same person(s) who authorized the results (see ISO/IEC 17025:2017, section 7.8.1.1).

The laboratory is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer will be clearly identified. In addition, a disclaimer will be put on the report when the information is supplied by the customer and can affect the validity of results. The format of test reports will be designed to minimize the possibility of misunderstanding or misuse.

7.8.3 Specific Requirements for Test Reports

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

a) Any deviations from, additions to or exclusions from the test procedure, and information on specific test conditions such as environmental conditions, if necessary for interpretation;

b) Where appropriate, any additional information required by clients and information about compliance with any requirements (see section 7.8.6);

c) Where applicable, a statement on the estimated uncertainty of measurement for numerical values presented in the same unit as that of the measurand or in a term relative to the measurand (e.g., percent) when:
- It is relevant to the validity or application of the test results;
- A customer's instruction so requires; or
- The measurement uncertainty affects conformity to a specification limit;

The measurement uncertainty shall:
- Be included in the report or an annex to the report when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement;
- Include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability;
- Be in the format of $y \pm U$;
- Be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and
- Be reported to the same level of significance (i.e., same number of decimal places or digits) as the measurement result.

d) Opinions and interpretations where appropriate and needed (see section 7.8.7);

e) Additional information which may be required by specific methods or customers.

7.8.3.1 If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a result or prohibits including measurement uncertainty in the report, the FCS will:
- Have objective evidence of the regulation, statute, case law or other legal requirement; and
- Have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.

7.8.4 The FCS is not a calibration laboratory.

7.8.5 Reporting Sampling – Specific Requirements

When appropriate and necessary for the interpretation of results, when the laboratory is responsible for the sampling activity, in addition to the requirements listed in section 7.8.2, reports containing the results of sampling shall include the following:

- A reference to the sampling plan and procedure used;
    - If statistical sampling is used, the report shall contain the confidence level and corresponding inference regarding the population.
- The date of sampling, and unique identification of the material or product sampled;
- If necessary, the location of sampling, including any diagrams, sketches or photographs;
- Details of any environmental conditions during sampling that may affect the interpretation of the test results;
- Any standards or other specification for the sampling method or procedure, and deviations;
- Information required to evaluate measurement uncertainty for subsequent testing.

7.8.6 Reporting Statements of Conformity

The laboratory does not make statements of conformity, unless requested by the customer. When a statement of conformity to a specification or standard is provided, the laboratory must document the decision rule employed, taking into account the level of risk associated with the decision rule employed, and apply the decision rule.

The laboratory reports on the statement of conformity, such that the statement clearly identifies:

- To which results the statement of conformity applies;
- Which specifications, standards or parts thereof are met or not met;
- The decision rule applied (unless it is inherent in the requested specification or standard).

7.8.7 Reporting Opinions and Interpretations

The basis upon which results, opinions and interpretations are made shall be documented in the laboratory case record. Results, opinions and interpretations shall be clearly stated in the CoA and only personnel authorized for the expression of opinions and interpretations may release the respective statement.

The opinions and interpretations expressed in reports must be based on the results obtained from the tested items and shall be clearly stated in the CoA.

When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue will be retained.

7.8.8 Amendments to Reports

The FCS shall issue separate test reports (revised) for any amendments, addition, or change to the original test report. When it is necessary to issue a new test report, it shall be uniquely identified (date of issue) and shall contain a reference on the Revised Report Form (SharePoint) indicating the report it replaces and the change(s) from the original report.

Revised / Amended Certificates of Analysis / Report

A Revised / Amended Report will be issued when the information in the original issued was incorrect, or when additional information is available that may affect any reported results or information.

Revised / Amended Certificates / Reports shall be stamped **"REVISED".**

Note – For appearance, the addition of the "REVISED" stamp will not be separately initialed by the author of the Revised Report. The signature of the analyst on the report shall serve to take ownership of the stamp.

For reports where only an administrative change has been made, an administrative review and the Revised / Amended Report Form will be completed to reflect the nature of the revision(s) and the original report that is being replaced. Both the Revised / Amended Report, and the Revised / Amended Report Form will be sent to the customer.

For reports where technical changes have been made, the new work will be technically and administratively reviewed, and the Revised / Amended Report Form will be completed to reflect the nature of the revision(s). Both the Revised / Amended Report and the Revised / Amended Report Form will be sent to the customer.

After review, a copy of the original Certificate of Analysis and any revised Certificate of Analysis shall be kept in the case record.

Re-examination Certificates of Analysis / Report

A Re-Examination Report will be issued at the request of the customer or due to the inability of the original examiner to testify. The case shall be re-analyzed in the same manner (or as near as possible) as originally reported.

A Certificate of Analysis for a case which was re-examined under the same case number shall be stamped "RE-EXAMINATION REPORT". For appearance, the addition of the "RE-EXAMINATION REPORT" stamp shall not be separately initialed by the author of the new report. The signature of the analyst shall serve to take ownership of the stamp.

When appropriate or necessary, a new case number will be issued, and the previous case number referenced in the reports. Certificates of Analysis for a case which was re-examined under a new case number will NOT be stamped "RE-EXAMINATION REPORT", but reference to the original report will be made in the Certificate of Analysis.

Re-examination casefiles will undergo both technical and administrative review, before a new report is issued.

Casefile Review Prior to Testimony/Reviewed Report for Testimony

In the instance where the original analyst is not available to provide testimony, a second, certified and authorized analyst may review the entire case filer, and come to an independent conclusion as to the results of the tested evidence for testimonial purposes. The results shall be reviewed in accordance with the current policies and procedures in place at the time of the initial analysis. This conclusion shall be documented on the Casefile Review Prior to Testimony Form which shall undergo an administrative review prior to be sent to the customer. This report does not require technical review or

notarization, as no new testing has been performed and the original report will not be admitted as evidence.

REPRINT Report

The customer may request a replacement report when the original signed/notarized report has been lost. The replacement report shall bear an original signature/notary seal. The new report shall be stamped 'REPRINT" to differentiate it from the original report that has been lost. For appearance, the addition of the "REPRINT" stamp shall not be separately initialed on the new report. The signature of the analyst shall serve as 'ownership' of the addition.

REPRINT reports will not undergo technical or administrative reviews.

The "Report Issued Date" may differ slightly from the original report due to the case being "signed out" of the Laboratory Information Management System after the initial report has been created by the analyst.

Amendments to a report after issue are made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report" or an equivalent form of wording. Such amendments will meet all requirements of this document.

Amendments to a report after issue are made only in the form of a new report and will be stamped **"REVISED"** (see section 7.8.8.1). Such amendments will meet all requirements of this document.

When it is necessary to issue a completely new report, this will be uniquely identified and will contain a reference to the original that it replaces (see section 7.8.8.1).

7.9 Complaints

7.9.1 External Complaints

All complaints received from clients or complaints concerning the quality related aspects of the management system shall be brought to the attention of the Chief of Laboratory

Operations by forwarding one copy of the complaint. The resolutions to such complaints shall be finalized only with the approval of the Chief of Laboratory Operations.

The recipient of an oral complaint will notify the complainant that they must submit their complaint in writing to invoke appropriate consideration. The recipient will provide the complainant with the address/contact for the written complaint.

It is then incumbent on the complainant to completely and concisely describe the situation or condition that he or she feels is unsatisfactory in a written format.

The Forensic Technical Director and Quality Manager and/or the Chief of Laboratory Operations, upon receipt of the complaint, will investigate the condition(s) stated in the complaint. If the condition(s) can be verified, the complaint will be reviewed to determine its validity.

Following the verification and validity review, the Quality Manager, Forensic Technical Director, or the Chief of Laboratory Operations shall begin to document the complaint on the Complaint Tracking Form (SharePoint). Customer notification regarding the status of the complaint shall be made and documented on the form.

The Quality Manager and Forensic Technical Director will investigate the situation, condition or act that caused the complaint and will recommend to the Chief of Laboratory Operations a remedial course of action.

Upon completion of actions dealing with a complaint, the Chief of Laboratory Operations must review and approve the complaint tracking form to ensure the actions were sufficient. The Chief of Laboratory Operations or the Forensic Technical Director shall notify the complainant of the actions taken. The completion date and notification date will be documented. The final disposition of the complaint is maintained by Chief of Laboratory Operations or his designee.

Internal Complaints

Complaints from employees about the Management System shall be submitted on the Quality Issues Reporting Form (SharePoint) to the Forensic Technical Director and/or Quality Manager.

Dependant on the severity of the complaint, the Forensic Technical Director and/or Quality Manager will keep the Chief of Laboratory Operations apprised of these complaints and the actions being taken. If a corrective action is needed, the appropriate procedure/forms shall be used. Copies of all these documents shall be maintained by the Quality Manager for at least one full accreditation cycle.

7.9.2 A description of the handling process for complaints will be made available to any interested party on request. Upon receipt of a complaint, the laboratory confirms whether the complaint relates to laboratory activities that it is responsible for and, if so, will deal with the complaint. The laboratory is responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The process for handling complaints includes at least the following elements and methods (see section 7.9.1):

- Description of the process for receiving, validating, investigating the complaint and deciding what actions are to be taken in response to it;
- Tracking and recording complaints, including actions undertaken to resolve them;
- Ensuring that any appropriate action is taken.

7.9.4 The laboratory is responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the laboratory acknowledges receipt of the complaint and provides the complainant with progress reports and the outcome.

7.9.6 The outcomes to be communicated to the complainant are made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

7.9.7 Whenever possible, the laboratory gives formal notice of the end of the complaint handling to the complainant.

7.10 Nonconforming Work

7.10.1 To err is human and as such the laboratory could experience technical or administrative nonconformities. Such occurrences are averse to the quality of the work product and/or

the integrity of evidence. The Forensic Chemistry Section has a procedure that is implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria).

Identification of nonconforming work or problems with the management system can occur at various places within the management system and technical operations. Examples are customer complaints, quality control, instrument calibration, proficiency testing, checking of consumable materials, staff observation or supervision, test report review, management reviews, and internal or external audits.

Deviations from desired analytical outcomes that are discovered through the quality measures employed during analysis and designated by the management system are not usually considered to be nonconformities for purposes of this procedure. They must be satisfactorily resolved before completing analysis and sending the case record for technical review. These deviations may be treated as nonconformities, if appropriate. Similarly, routine checks of equipment may be out of specifications for use in casework and require troubleshooting; this would not be considered a nonconformity as along as it is resolved appropriately.

The procedure shall ensure that:

a) The responsibilities for the management of nonconforming work lies with the Forensic Technical Director. The authority for investigation may be delegated by the Forensic Technical Director to either the Quality Manager or Unit Supervisor;

b) Nonconformities will be assessed via a risk matrix. The likelihood that the risk will occur if unaddressed and the potential impact that the risk event will have on the laboratory will guide management response strategies. Any or all the following actions may be taken when nonconforming work is identified:
   - Suspend analyst from casework;
   - Issue amended report;
   - Reanalyze the evidence;
   - Submit evidence to a referee laboratory;
   - Verify quality assurance measures;

- Review prior casework;
- Retrain employee;
- Counsel employee;
- Monitor employee;
- Issue a performance plan;
- Issue a competency test;
- Issue a proficiency test;
- Remove equipment/instrument from service;
- Change policy and/or procedure;
- Notify the customer;
- Notify ANAB (see 5.4.2).

c) An evaluation of the significance of the nonconforming work is made using a risk matrix. The matrix is composed of two intersecting factors: the likelihood that the risk event will occur if unaddressed and the potential impact that the risk event will have on the laboratory. Depending on the likelihood and severity of the risk, a number will be assigned which correlates with the degree of risk. The matrix does not have clearly demarcated categories, but rather allows for some flexibility in risk categorization and response;
    - The Forensic Technical Director or the investigating authority will determine where the nonconforming work fits in the risk matrix within one week of receipt of the notification. The Quality Manager will be notified and will procedure accordingly.

	Insignificant	Minor	Significant	Major	Catastrophic
Certain	Medium 5	High 10	Very High 15	Extreme 20	Extreme 25
Likely	Medium 4	Medium 8	High 12	Very High 16	Extreme 20
Moderate	Low 3	Medium 6	Medium 9	High 12	Very High 15
Unlikely	Very Low 2	Low 4	Medium 6	Medium 8	High 10
Rare	Very Low 1	Very Low 2	Low 3	Medium 4	Medium 5

Likelihood Rare – improbable to happen again
Unlikely – possible to happen again

Moderate – expected to happen again
Likely – almost sure to happen again
Certain – guaranteed to happen again

Impact	Insignificant	Error in evidence handling, casework or the quality system No impact to the customer(s) No breech of ethics No safety concerns
	Minor	Error in evidence handling, casework or the quality system Impact on the customer(s) without a violation of the Terms of Service No breech of ethics Minor safety concerns
	Significant	Systemic or serious errors in evidence handling, casework or case records Impact on the customer(s) and a violation of the Terms of Service that can be remediated without major impact to the case No breech of ethics Moderate safety concerns
	Major	Loss or destruction of evidence or analytical error in reporting Impact on the customer(s) and the Terms of Service that cannot be remediated Breech of ethics Major safety concerns that can be mitigated
	Catastrophic	Negligent or purposeful destruction of evidence or willful breech of quality policy Significant impact to the customer or the case Criminal behavior Major safety concerns that cannot be mitigated Impact on the customer and the Terms of Services that cannot be remediated and threatens to negatively impact the

credibility of the laboratory, one or more of its personnel and/or ANAB accreditation

d) Action to remedy the nonconformity is initiated immediately, together with any decision about the acceptability of the nonconforming work;
   - Any employee who identifies a potential serious risk shall inform his/her supervisor as soon as possible, preferably before the end of the business day. The Forensic Technical Director has the authority to implement any short-term response he or she deems necessary;
   - The employee who discovered the nonconformity shall complete the Report of Nonconforming Work and email to the Quality Manager within five business days from the identification;
   - If the nonconformity requires a corrective action plan, the investigating authority will document the matter using the Corrective Action Report form;
   - The Corrective Action Report will be approved by either the Forensic Technical Director or Quality Manager.

e) Where necessary, the customer is notified, and the laboratory report is recalled;

f) If work was suspended, the investigating authority (Quality Manager / Unit Supervisor / Forensic Technical Director) authorizes the resumption of casework.

7.10.2 The laboratory retains records of nonconforming work and actions as specified in section 7.10.1.

7.10.3 Based on the risk matrix, nonconforming work will fall into one of the following categories:

Level	**Score**	**Potential Response**
Very Low / Low	1 – 4	No further action required
Medium	5 – 9	Improvement plan or corrective action plan

High / Very High	10 – 16	Corrective action plan ANAB notification
Extreme	17 – 25	Corrective action plan Customer(s) notification Cessation of work ANAB notification

Where the evaluation indicates that the nonconforming work is likely to recur, or there is concern about the conformity of the laboratory's operation with its own management system, the laboratory will implement corrective action.

7.11 Control of Data and Information Management

7.11.1 The laboratory has the necessary access to the data and information needed to perform laboratory activities.

7.11.2 The laboratory information management system(s) (LIMS) used for the collection, processing, recording, reporting, storage or retrieval of data are validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they are authorized, documented and validated before implementation. Most of the software supplied with the instruments shall automatically undergo validation while validating the instruments. In cases of any major updates in software, the updates will undergo appropriate verifications before being put in service.

Any computer software that is developed by the user shall be validated, and records of the validation will be maintained. Any use of excel forms to perform complex calculations shall be verified and approved before use. Any changes to those forms or the instrument export data, which would cause a change in the calculation, will require a reverification before approval for use.

7.11.3 The LIMS:

- Is protected from unauthorized access by use of unique, individual logins on a restricted network. Confidentiality of the data entry will be governed by section 4.2 of this manual;
- Is safeguarded against tampering and loss. Any data stored in electronic form will be protected by measures as described in section 8.4 of this manual;
- Computers and automated equipment shall be maintained as per the recommendations of the manufacturers and the State of Maine OIT;
- Is maintained in a manner that to ensure the integrity of the test data;
- Includes recording system failures and the appropriate immediate and corrective actions. These records are maintained by the STARLIMS Administrator for the parent organization HETL.

7.11.4 The LIMS is not managed off-site or maintained through an external provider. The application and databases are on State of Maine servers and the support for the application and database are performed by State of Maine employees.

7.11.5 The laboratory ensures that instructions, manuals and reference data relevant to the LIMS are readily available to personnel.

7.11.6 All calculations as well as transfers of data shall undergo checks during the technical review of the case records.

Additional State of Maine Information and Requirements

The Laboratory Information Management System (LIMS) in used at DHHS is StarLIMS v. 11.

The Document Management Software used at HETL is SharePoint.

8. Management System Requirements

8.1 General

8.1.1 The management system for the FCS has been established through the documentation of this Quality Manual, Analytical Procedure Manuals (Seized Drugs, Blood Drug, Urine Drug, and Alcohol Analysis), and Training Manuals. This quality manual has been structured in

the same format as the ISO/IEC 17025:2017 standard to support and demonstrate the consistent achievement of the requirements of ISO/IEC 17025 and assuring the quality of laboratory results.

8.1.2 This quality manual fulfils the management system requirements of ISO/IEC 17025 through the implementation of sections 8.2-8.9 of this quality manual.

8.2 Management System Documentation

8.2.1 Laboratory management maintains the policies and objectives of this quality manual to meet the requirements of ISO/IEC 17025 ensuring technical competence and an internationally recognized management system. Laboratory management ensures that the policies and objectives of this quality manual are acknowledged and implemented by every employee of the laboratory. All personnel concerned with testing activities within the FCS will familiarize themselves with the quality documentation and implement the policies and procedures in their work.

The following words used in ISO 17025:2017, or in this document, will be addressed in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify.

8.2.2 HETL management will comply with ISO/IEC 17025. The objective of the FCS Quality Assurance Program is to ensure the accuracy and precision, as well as the reliability of laboratory results produced for our customers, or at the request of regulatory or accrediting bodies. Management, administrative, statistical, investigative, preventive, and corrective techniques will be employed to maximize reliability of the data. The policies and objectives of this quality manual address competence, impartiality and consistent operation of the laboratory. A *Quality Policy Statement* has been issued within this Quality Manual under the authority of the Forensic Technical Director.

The ***Quality Policy Statement*** for the FCS laboratory is as follows:

The FCS will strive to meet the following standards of service:

- To develop and put into service methods capable of meeting the customer's needs for precision, accuracy, sensitivity, and specificity;

- To ensure all staff members receive training in basic quality assurance, in sufficient depth to enable them to carry out the provisions of this manual;
- To establish a baseline for the level of routine performance quality against which to measure the effectiveness of quality improvement efforts;
- To make any changes in routine methodology found necessary to make it compatible with performance needs;
- To monitor the routine operational performance of the FCS and analytical staff through participation in appropriate inter-laboratory testing programs, proficiency testing programs recognized by accrediting bodies, and to provide for corrective actions as necessary;
- To improve and validate the FCS's methodologies by participation in method validation studies.

The purpose of the management system is to develop quality activities that shall emphasize the prevention of quality problems rather than detection and correction of problems after they occur. As such:

- All FCS personnel will familiarize themselves with the Quality Manual and will implement those policies and procedures in their work;
- The laboratory shall use procedures that are generally acceptable in the field or supported by data gathered and recorded in a scientific manner;
- The laboratory shall retain copies of all tests and analytical reports in a manner and for a period specified by regulatory or accrediting bodies;
- The laboratory shall have a comprehensive calibration program involving all instrumentation used for making determinations, the results of which are reported;
- The laboratory shall use appropriate reagents and chemicals, certified when necessary, and appropriately calibrated instrumentation;
- The laboratory shall establish and maintain a total intra-laboratory quality control system to assure continued precision and accuracy of laboratory results;
- The laboratory shall participate in an external testing program as prescribed by ANAB, and any other accrediting organizations that the laboratory is associated with;
- Management is committed to impartiality, good professional practice and quality of services provided to the customer. Tests are performed in accordance with stated standardized methods and customers' requirements. Requests to perform

tests that may jeopardize an objective result or have low scientific validity are rejected;

- Standards of service include customer satisfaction, accurate testing, and providing results in a timely manner when possible. Excellence in laboratory activities is promoted by providing all employees with the knowledge, training and tools necessary to achieve the required level of competence for the completion of accurate and timely work;
- The purpose of the management system related to quality is to manage business operations consistently and to meet the needs of our customers;
- Management is committed to complying with ISO/IEC 17025 and to continually improve the effectiveness of the management system and testing performed by the FCS. The objective of this Quality Manual is to document the compliant policies and associated procedures that are integrated into our daily activities. Continual improvements are established, implemented and locked into the management system;
- To assess risks and opportunities and follow-up with appropriate actions.

8.2.3 HETL management will comply with ISO/IEC 17025 and will continually improve the effectiveness of the management system. This is established through control of the management system documentation, control of records, actions to address risks and opportunities, improvement opportunities, corrective actions, internal audits and management reviews. Upon request of an internal or external auditing agency the management of HETL shall provide evidence of its commitment to the development and implementation of the management system and the continual improvement of its effectiveness.

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of ISO/IEC 17025 are included in, referenced from, or linked to this management system.

The FCS Quality Manual describes the overall policies that must be followed by all FCS personnel. Procedure Manuals contain analytical procedures as well as applicable QA/QC measures. The requirements in these manuals can only be more restrictive than those spelled out in the FCS Quality Manual.

Units covering multiple categories of testing may use separate manuals for those categories of testing.

Units shall have training manuals that outline the programs used for training and evaluation in those disciplines/categories of testing.

The Chemical Hygiene Plan and Biological Safety Manual are part of the Safety Manual and describe the procedures/programs used in the Maine Health and Environmental Testing Laboratory to ensure a healthy and safe working environment and practices. (The Safety Manual is not a document directly under the control of the FCS but rather is maintained by the Parent Organization HETL).

8.2.5 All personnel involved in laboratory activities have access to current, approved parts of the management system documentation and related information applicable to their responsibilities.

8.3 Control of Management System Documents

8.3.1 The laboratory controls the documents (internal and external) that relate to the fulfilment of this quality manual. All internally generated documents that are part of the management system of the FCS shall be controlled. Externally generated documents, referenced documents, and forms (e.g. relevant ASTM standards, instrument manuals (if applicable), ISO/IEC 17025, safety manual, etc.) shall not be controlled. A list of externally controlled documents will be maintained if a specific procedure from the externally generated document is required and referenced in a laboratory procedure.

Internally generated manuals and forms (Controlled) will be in electronic form residing on SharePoint and shall contain a 'Footer' that includes at least the name and number of the document, date of issue, revision date (if applicable), and who approved (or issued) the document, page number and total number of pages.

Additionally, controlled documents and uncontrolled forms may only be changed by management granted specific access and password control. However, all FCS personnel can view documents and forms stored on SharePoint.

8.3.2 The laboratory ensures that:

- Documents are approved for adequacy prior to issue by authorized personnel;
- All internally generated controlled documents that form part of the management system will be reviewed annually and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;
- Changes and the current revision status of documents are identified. Handwritten changes to controlled documents are not allowed;
- Relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled. The controlled copies of manuals and forms will be easily accessible to staff via SharePoint;
- Documents are uniquely identified. Internally generated controlled documents shall have a unique identifier along with the following information on every page: Title, approving/issuing authority, effective date, date of last revision, and page number (current) with total number of pages;
- Discontinued versions (controlled documents) will be archived. Obsolete documents (manuals and externally generated documents) shall be clearly marked to indicate that they are not current and removed from the work area.

The Quality Manager will review and approve all forms and documents of the FCS.

Master Lists

Master lists of all internally generated and externally referenced documents and forms will be maintained by the Quality Manager. The master lists show the current status of the controlled documents and forms, latest approval date, and title of the document.

NOTE – Equipment and software manuals maintained only for general reference purposes are not subject to document control requirements. In this context, “general reference purposes” means that laboratory personnel are not required by the laboratory to follow specific procedures or work instructions contained in the equipment or software manual.

8.4 Control of Records

8.4.1 The laboratory ensures that records to demonstrate fulfilment of the management system are established, retained and legible.

8.4.2 The laboratory has implemented the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time and disposal of its records. The laboratory retains records for a period consistent with its contractual and legal obligations. Access to these records must be consistent with the confidentiality commitments and these records must be readily available; additional requirements regarding technical records are outlined in section 7.5.

Identification

Case folders (also referred to as case records or casefiles) will be identified by their unique laboratory case numbers. All other records will be appropriately identified by descriptive titles displayed on the records.

Collection

The personnel identified for each record are responsible for collecting the record.

Indexing

Case folders will be indexed by their unique laboratory case number. All case files will be maintained under locked condition during non-business hours.

Access

All case files will be maintained in a secure manner.

Records are legible and are accessible to individuals on a need-to-know basis. However, case folders are not accessible to anyone without authorization. Filing, applicable to current or active records, will be done in such a way that those records will be easily accessible to all individuals who need them to perform their duties. Applicable QC data is kept either near the instruments themselves, on the FCS laboratory network, in a central location in each unit, or in the case folder. Recent records of audits, proficiency evaluations, complaints, quality reviews, corrective actions, testimony evaluations, etc., shall be filed on site, and/or published on SharePoint.

Copies of the contents of case files shall not be provided to anyone outside the FCS without a discovery request.

When information from case files and records must be removed from the laboratory for purposes such as court testimony, every effort should be made to avoid the loss of original documentation. Removal of case files for testimony should be documented on the casefile sign-out sheet maintained by the Evidence Unit.

Filing

All completed case folders are maintained in the file storage room until transfer to Maine State Archives. Upon transfer to Maine State Archives, a request must be made to Archive's personnel for retrieval of a case folder.

Storage

Case folders will be maintained on site by the HETL for a period of no less than 2 years. After which the case folders will be maintained by the Maine State Archives for a period of 18 years, for a total of 20 years retention.

The records of audits, proficiency evaluations, complaints, quality reviews, corrective actions, testimony evaluations, etc. from at least the last two years will be stored on site and then transferred to Maine State Archives for a period of 18 year, for a total of 20 years retention.

Records of training and continuing education will be stored on site for a period of at least two years. These records may be retained by the specific analyst, and/or the Forensic Technical Director / Quality Manager and then transferred to Maine State Archives for a period of 18 years, for a total of 20 years retention.

Disposal

Case records (folders and files) can be disposed of when the retention time has elapsed. Disposition may be to discard or destroy the records as determined by State of Maine Records Retention Policy.

Employees will not release the content of case files or case evidence to any individual or entity that does not have the authority to possess the information, as described above in the **Access** subsection of 8.4.2.

The LIMS provides standard reports to assist in the management of the laboratory. Certificates of Analyses (un-signed and un-notarized) are available within the system and accessible by all laboratory personnel approved to have access to FCS casework via LIMS. Records stored on network servers are backed-up by the State of Maine Office of Information Technology (OIT).

A password is required to access department computers and network.

Amendments to records on LIMS are tracked by an audit trail.

FCS staff are responsible for maintaining electronic back-up of instrument data. All analytical data collected on instrument computers will be backed-up to the FCS laboratory network, external hard drive, or CD/DVD as available.

Copies of all CDs/DVDs, external hard drives and/or other back up materials shall be stored within the laboratory for at least two years and then transferred to Maine State Archives for a period of 18 years, for a total of 20 years retention.

8.5 Actions to Address Risks and Opportunities

8.5.1 The laboratory considers the risks and opportunities associated with laboratory activities in order to:

- Give assurance that the management system achieves its intended results;
- Enhance opportunities to achieve the purpose and objectives of the laboratory;
- Prevent or reduce undesired impacts and potential failures in the laboratory activities;
- Achieve improvement.

Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventative 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.

During validations of procedures, particular attention will be paid to identify potential sources of nonconformities of a technical nature or concerning the management system, as well as problems such as contamination. Appropriate preventive actions will be built into the validated procedure.

FCS personnel can suggest preventive actions for any potential nonconformity to the Forensic Technical Director or Quality Manager.

Quality is attained and sustained through the active participation of all Laboratory staff. Employees are encouraged to maintain vigilance in their observations and review of quality assurance related activities. The Laboratory is committed to continued improvement of the effectiveness of the management system through the use of:

- Quality Policy and Objectives as defined in the Quality Manual;
- Internal and External Audits;
- Analysis of Data / Case Files;
- Corrective / Preventative Actions;
- Management Reviews.

Risks and opportunities related to health and safety shall also be considered and discussed with the HETL Safety Officer.

8.5.2 The laboratory will periodically perform a risk and opportunity evaluation using the Laboratory Risk and Opportunity Review Form on SharePoint. This evaluation will help the laboratory assess any potential risks and opportunities in various areas and provide instructions for implementation of preventative actions and improvements into the management system. The effectiveness of these actions and improvements will be evaluated during the annual management review.

8.5.3 Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.

8.6 Improvement

8.6.1 The laboratory identifies and selects opportunities for improvement and implements the necessary actions. Quality is attained and sustained through the active participation of all laboratory personnel. Employees are encouraged to maintain vigilance in their observations and review of quality assurance related activities.

The laboratory has implemented a continual improvement philosophy within the management system. Every employee in the laboratory is encouraged to suggest new ideas for improving services, processes, systems, productivity and the working environment.

Opportunities for improvement of services are identified by anyone within the organization on a continual basis from feedback on operations, audits, nonconformances and management reviews.

Improvement opportunities are evaluated by management. They are implemented through the Unit Supervisor who ensures that the improvements are validated as outlined in section 7.2 and that appropriate level of quality control is performed on an ongoing basis.

8.6.2 The FCS shall solicit feedback from customers either by conducting a survey (at least annually), or by providing customers with a link to an online survey regarding the laboratory's service to customers. The information gathered shall be used for making improvements in the management system, and services provided to the clients.

8.7 Corrective Action

8.7.1 When a nonconformity occurs:

a) The FCS reacts to the nonconformity and, as applicable, takes action to control and correct it, and address the consequences.
   - Any employee who identifies a potential nonconformity shall inform his/her supervisor as soon as possible, preferably before the end of the business day. If the nature of the nonconformity is serious, the employee shall notify the Forensic Technical Director as soon as possible. The Forensic Technical Director has the authority to implement any short-term response he or she deems necessary;

- Nonconformities shall be addressed and resolved in a timely manner.

b) The Forensic Technical Director shall evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by reviewing and analyzing the nonconformity, determining the causes of the nonconformity, and determining if similar nonconformities exist, or could potentially occur.
   - The employee who discovered the nonconformity shall complete the Report of Nonconforming Work Form and submit it to the Unit Supervisor, Quality Manager and Forensic Technical Director within five business days from the identification;
   - The Forensic Technical Director and/or Quality Manager will evaluate the circumstances within one week of receipt of the notification. The Forensic Technical Director and/or Quality Manager will use the risk matrix to evaluate the potential impact and likelihood of recurrence and assign a category value based on that assessment. The Forensic Technical Director will assign the investigation to themselves, the Quality Manager or the Unit Supervisor;
   - The Quality Manager will be notified and will assign a Corrective Action Report (CAR) number if a corrective action plan is required;
   - The investigating authority will document the matter using the Corrective Action Report form. The CAR will document the following:
     - The nonconformity;
     - The event(s) which identified the nonconformity;
     - The extent of the nonconformity;
     - The effect(s) of the nonconformity on the quality of work and/or integrity of evidence;
     - Any response to date;
     - The root cause of the nonconformity;
     - A recommended course of action and schedule to correct the problem; and
     - A recommended course of any follow-up activities.
   - The Corrective Action Report will be approved by either the Forensic Technical Director or Quality Manager.
   - A formal root cause analysis may be conducted but is not always required. Determination of root cause(s) may happen at the discretion of

either the Forensic Technical Director or the Quality Manager. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration. Root cause determination may identify multiple contributing factors for the nonconformity, but there is generally only one underlying cause.

c) When a nonconformity occurs and corrective action is needed, management selects and implements the actions most likely to eliminate the problem and to prevent recurrence. Any of the following corrective actions may be implemented:
   - Suspend analyst from casework;
   - Issue amended report;
   - Reanalyze the evidence;
   - Submit evidence to a referee laboratory;
   - Verify quality assurance measures;
   - Review prior casework;
   - Retrain employee;
   - Counsel employee;
   - Monitor employee;
   - Issue a performance plan;
   - Issue a competency test;
   - Issue a proficiency test;
   - Remove equipment/instrument from service;
   - Change policy and/or procedure;
   - Notify the customer;
   - Notify ANAB (see section 5.4.2).

d) When a nonconformity occurs, the FCS monitors the results to ensure that the corrective actions taken have been effective.
   - A review will be conducted by the Quality Manager and recorded on the Corrective Action Report;
   - Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with the International Standard, the Quality Manager shall ensure that the appropriate areas of activity are audited in accordance with section 8.8 (Internal Audits) as soon as possible.

e) When a nonconformity occurs, the FCS shall update risks and opportunities determined during planning, if necessary.

f) When a nonconformity occurs, the FCS shall make any required changes resulting from the corrective action investigation, which shall be documented in the Corrective Action Report and implemented.

g) When a nonconformity occurs, the FCS will complete the corrective action procedure in a timely manner. The plan should be in place within 30 days of discovery of the nonconformity and completed within 90 days after the corrective action plan is approved. If more time is needed to complete the corrective action plan, the Forensic Technical Director and Quality Manager must approve the extension and the Quality Manager will document the reason for the extension.

8.7.2 Corrective actions are appropriate to the magnitude and risk of the issue.

8.7.3 The laboratory retains records as evidence of:
- The nature of the nonconformities, cause(s) and any subsequent actions taken;
- The results of any corrective action.

8.8 Internal Audits

8.8.1 An internal audit is an on-site, formal inspection and review of the FCS's Quality Control System, taking place on a periodic basis, to verify the effectiveness of the laboratory's quality program and management system conforms to the requirements of this manual. Any additional audits needed by any accrediting or regulatory body are in addition to this audit. This procedure applies to the following internal functions: Procurement of materials, laboratory security, evidence handling, proficiency testing, laboratory testing, personnel training, reports, courtroom testimony and other areas that affect the quality of laboratory output.

The laboratory conducts internal audits at planned intervals based on a pre-defined schedule each year to provide information on whether the management system:
- Conforms to:
  - The requirements of this quality manual and laboratory activities;

  - The requirements of appropriate international standards ISO/IEC 17025.
- Is effectively implemented and maintained.

8.8.2 The laboratory shall:

a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;
b) define the audit criteria and scope for each audit;
c) ensure that the results of the audits are reported to relevant management;
d) implement appropriate correction and corrective actions without undue delay;
e) retain records as evidence of the implementation of the audit program and the audit results.

The steps to be followed by the FCS in conducting the system audit are:

- Notification of the dates and times of the planned audit;
- Conduct the audit;
- Post audit conference / meeting with staff;
- Follow-up to determine if deficiencies discovered during the audit have been corrected.

The audit will include / cover:

- Staff's awareness of the Quality Manual;
- Analytical procedure selection, control and validation;
- Control of reagents and standards;
- Equipment calibration and maintenance records;
- Adequacy of case reports and notes and their disposition;
- Evidence handling procedures;
- Proficiency testing ;
- Personnel training records;
- Handling of deficiencies and remedial action;
- Direct observation of a sampling of testing within each discipline.

During an audit, a certain number of case files from each unit covering a wide range of activities will be made available. All cases will be examined to ensure that the work has

been carried out according to the applicable Procedure Manual as well as the Quality Manual.

Any analyst authorized to perform internal audits may be assigned to participate. If staffing levels allow, each unit shall be audited by a technical auditor, an analyst who is currently or has been previously certified in that discipline, and an administrative auditor who may have no knowledge of the work performed in that discipline. These assignments shall be communicated with the audit announcement and schedule notification sent by the Quality Manager.

The audit findings and any corrective actions that arise from the audit shall be recorded.

The Quality Manager will prepare a report providing a plan of action to correct any deficiencies found in the audit. This report will be presented by the Forensic Technical Director and Quality Manager to the Chief of Laboratory Operations as part of the Management Review.

The Quality Manager will ensure that any corrective actions are implemented within the time limits proposed by the FCS itself. This follow up report will be sent to the Chief of Laboratory Operations within one month of completion.

In cases where the audit findings indicate doubts about the quality of the work or correctness of test results, corrective actions shall be undertaken and completed promptly by procedures outlined in section 8.7.1 of this manual. When appropriate, FCS shall contact the customers that have been or are likely to be affected.

The implementation and effectiveness of the corrective actions taken because of an internal audit will be checked during the next internal audit. If there is a recurrence of the same problem(s) despite corrective actions, it may be that the corrective action was ineffective. Further corrective actions may be needed in such cases.

8.9 Management Reviews

8.9.1 Review of the Management System and the testing activity at the FCS shall be conducted at least once every calendar year, to ensure their continued suitability and effectiveness. The Forensic Technical Director and Quality Manager, in conjunction with the Chief of

Laboratory Operations will conduct the review. The Management System review checklist on SharePoint will be used as a guide to ensure coverage of relevant topics.

8.9.2 The results of the review will be discussed in a meeting and will cover at minimum:

- Changes in internal and external issues relevant to the laboratory;
- Fulfilment of objectives;
- Suitability of policies and procedures;
- Reports from managerial and supervisory personnel;
- Status of actions from previous management reviews;
- Outcome of recent internal audits;
- Corrective and preventive actions;
- Proficiency test results;
- Assessments by external bodies;
- Changes in the volume and type of the work or in the range of laboratory activities;
- Customer and personnel feedback;
- Complaints;
- Recommended improvements;
- Effectiveness of any implemented improvements;
- Adequacy of resources;
- Results of risk identification;
- Review of impartiality;
- Outcomes of assurance of the validity of results;
- Other relevant factors, such as monitoring activities and training.

8.9.3 The outputs from the management review meeting are a record of all decisions and actions related to at least:

- The effectiveness of the management system and its processes;
- Improvement of the laboratory activities related to the fulfilment of the requirements of the management system;
- Provision of required resources;
- Any need for change;

A record of the proceedings will be kept and the Quality Manager will retain all the documents pertaining to the management review for at least one ANAB cycle of accreditation.

9. Revision History

Revision Number	Date of Revision	Description
0	24Jun2019	Publication of Quality Manual to ISO 17025:2017 & AR3125
1	16Jul2019	Section 5.2 was expanded with additional information and responsibilities Section 5.5 b) added reference to section 5.6 Section 5.6 Evidence Technician was added Section 6.4.1 included reviewing the COA as a method to verify a CRM Section 6.4.11 was edited to remove a redundancy Section 7.2.2.1 – Major Modification was edited to remove the word "can" in the last sentence Section 7.5.1.6 was edited to reflect the correct standard Section 7.6.3.1 Blood Drug Determination was removed until the method validation is completed and online Section 8.2.1.1 was added Revision History added
2	14Aug2019	Section 7.7.1 was edited to add a current, or previously, competent analyst must observe testimony for each discipline annually, and clarified other methods, additional methods for testimony monitoring.
3	23Sep2019	Section 6.3.2 and 6.4.7 temperature log section was expanded to add where acceptable ranges can be found and if they may need to be revaluated. Section 6.4.7 added quantitative pipettes will be checked quarterly in-house.

		Section 7.11.3 expanded upon the limited access to the STARLIMS system.
4	02Oct2019	Section 6.2.2.2 and Section 6.2.3.1 additional requirements for successful completion of written examinations for training and competency added.
5	04Dec2019	References to File Storage Room (Rm 119) were added throughout document. Room 176 was changed to key card access instead of key access. Quarterly pipette maintenance was clarified to refer to hand held pipettes only.
6	05Dec2019	Quarterly pipette check acceptability ranges revised to be within most recent method uncertainty calculations. Revision numbers corrected.
7	11Mar2020	Section 6.2.5 under the **Certification for Alcohol Analyst** section a closing " was added. Under **Recertification for DUI Analyst** blood was added as a sample type. Section 7.6.3.1 Blood Drug Determination was added. Section 7.7.7 frequency of proficiency testing was changed to once a year for urine drug and blood drug Section 8.7.1 was modified to perform a root cause analysis prior before determining if a CAR is required. Entire section organized and revised.
8	06April2020	Section 7.11.2.1 expanded upon use of excel forms and required verifications.
9	27Apr2020	Blood Drug added throughout. Re-examination SOP in section 7.8.8.1 modified to better describe re-examinations which are assigned a new case number.
10	10Sep2020	Major revision. The following sections were updated/revised. Section 3, Customer; Section 4.1.4 and Details following Section 4.1; Section 4.2; Section 6.2.6; Section 6.4.7; Section 7.1.1; Section 7.4.1.1 c); Section 7.7.1; Section 7.7.5; Section 7.7.8; Section 7.8.1.2.2; Section 7.10; Section 8.3.1; Section 8.4.2; Section 8.7.1.

11	14Mar2021	Removed all ASCLD/LAB references.
12	28 Jul 2021	Updated 7.1.1 to notify customers about potential subcontracting on the Receipt/Contract for Examination Form to coincide with contract update.
13	27 Oct 2021	- Updated Chief of Operations name - Minor grammar and punctuation corrections - 4.2.4 E-mail correspondence added to communication documentation, and providing copies or records to defense counsel was updated. Details section updated to remove first bullet point since it was redundant - 6.3.2 Humidity monitoring and calibrated thermometers were added - 6.3.4.1 and 6.4.7 B16 PIN Key Pad and surveillance cameras added - 7.7.5 and 7.7.7 the number of rounds per year was added - 7.7.8 was expanded and pass/fail criteria were added - 6.2.3.2 and 7.7.1 updated to state technical reviewers must have been previously certified and authorized to perform testing
14	04/12/2022	- Updated Chief of Operations title, removed acting - Updated Evidence Technician's Office location - Spelling and grammar - Added Safety Officer/CHO could be contracted to external agency - Added specific DHHS Rule Chapters - Clarified that Building Control provides access to keys - 6.3.4.1 updated to allow Law Enforcement Officers to be unattended while dropping off or picking up evidence in the Evidence Technician's Office - 7.1.4 Added guidance for minor discrepancies - 7.4.1.1 – guidance for evidence submitted without a proper seal. Updated SDD retention of evidence. - 7.4.4 updated to include food evidence storage - 7.5.1.2 added language relating to common abbreviations
15	02/14/2023	- Ownership of temperature forms changed to a HETL QA officer instead of the Safety Officer

		- Technical lead references removed and changed to Section Supervisor or designee - Section 7.7.1 updated to state technical and administrative review shall be conducted on expert report letters and conversions requested by customers. Admin review also updated to state it cannot be conducted by the technical reviewer of the report. Technical review does not need to be conducted on casefile review reports for testimony, but admin review shall be competed on those reports. Updated to indicate that technical reviewer for case files, reports, and testimony must be actively participating in the annual PT program. Added note that testimony review is only required when testimony occurs in that discipline for that year. - 7.7.5 updated to require an annual PT for anyone performing technical review in a specific discipline - Emergency contact information updated to reference new door signs posted on each room. - Definitions: added Associate Director of Laboratory Services, added review report for testimony, added external accreditation cycle. Merged case file and case folder and included batch in the definition name. Updated Interlaboratory comparison. - 7.9.1 updated to clarify who is involved with the complaint tracking process. - 7.8.8.1 – Casefile Review Prior to Testimony section added - 8.8.2 updated to include the timing of the audit annually and audit assignments per discipline. - Section 4 Details, Documents, References and Records: post-mortem added, and HETL mission statement added - 6.4.3 reference to SOP manual for DEA controlled substance reference material handling. - 8.4.2 added that removal of files for testimony shall be document on a sign-out sheet. Clarified retention must be a total of 20 years for all items listed. - 5.2 updated roles and responsibilities - 5.5 added RadChem to list of sections at HETL - 7.1.1 updated to allow analyst to determine appropriate test selection and communicate test method on report. Changed to customers *may* be contacted to determine type of analysis needed.

		- 7.5.1 – removed copies of reference library spectra from what is included in a urine drug case following method validation update - 7.7.3 – added results to be reviewed with the supervisor and analyst - 7.7.8 removed “blood” from quantitative alcohol proficiency test evaluation - 7.6.3.1 removed “blood” from alcohol determination - 5.4.1 included the use of the symbol and mentions to being accredited in the standard. - 6.3.4.1 – updated to include law enforcement visitor badges assigned to visitors for evidence drop off - 6.4.7 – added heat block and incubator temperature checks done by certified digital thermometer, quantitative pipettes must include at least 3 check points in the calibration, and hood maintenance - 6.6.2 c- added “or a reference to results” and approval for the reagent sheet bullet - Address and room numbers updated throughout following move. - Grammar, spelling, and formatting updated throughout. - Removed PIN pad and camera mention for evidence room. Have yet to be installed in Greenlaw building.
16	7/10/2023	- Section 2 last sentence removed - 4.1.4 Quote removed - 4.2.4 added verbal results may be given, expanded on requirements for the defense to view any evidence - 5.2 Chemist III removed designating technical responsibility for each discipline/category of testing - 5.4.1 added “Any work performed outside of the scope of accreditation shall have the ANAB logo removed from the Certificate of Analysis and include a comment on the COA that the work performed was outside of the scope of accreditation.” - 6.2.3 reworded for clarity, added examples of continuing education for ongoing training opportunities - 6.2.3.1 added examples for written exam material - 6.2.3.2 and 6.2.5 added technical review must continue to participate in annual PT for discipline - 6.2.6 reworded for clarity: authorizer of results is the technical reviewer; authorizer of reports is the administrative reviewer and the notary public.

		- 6.3.2 added evidence storage to areas that are monitored - 6.3.4.1 expanded on information regarding emergency access, notifications, and camera monitoring - 6.4.3.1 added note that expired reagents shall not be used for casework unless rechecked and approved, with a new expiration date assigned. - 6.4.7 added evidence storage areas - 6.4.10 updated in relation to the procedure required for performance checks - 7.2.2.1 updated to clarify that a tune does not qualify as a change in detection parameters, elaborated on examples. - 7.8.1.1.1 clarified who is considered the authorizer of results - 7.8.2.1 (o) reworded for clarity, authorizer of reports is the notary public. Valerie Leathers authorization will be updated to reflect clarification in Quality Manual.
17	29Dec23	- Quality Manager review/approval added throughout as an option where Forensic Lab Director was referenced, where appropriate - Temperature control chart being controlled by HETL QA Officer removed, chart is now maintained by Forensic section - Knox box access expanded to include authorized individuals - 7.1.3 added the weight of drug being over specific statutory limit - 7.1.6 revised - 7.1.7 removed the option to monitor testing and revised to allowing access to tour the lab and discuss testing - 7.2.1.5 updated to state validation records will be maintained, but not in the current section performing testing - 7.7.8 updated to include criteria for evaluation of breath alcohol proficiency tests. Blood drug evaluations updated to be compared to consensus result and added ±20% as an evaluation criteria. Updated with “whichever is greater” where more than one acceptance criteria could be used to evaluate the results. Updated to include supervisor, quality manager, and forensic lab director to review the PT results form. Updated to include disclosure to ANAB if unexpected results are obtained. - 7.10.1 updated to include notification to accrediting body if work is recalled - 8.3.2 Supervisor added to those able to review and approve documents and forms

18	20May24	Annual Review – only small grammatical changes made AJH
19	03June24	Changed Interim Associate Director to Jennifier Jamison following email notification from Director of CDC and updated Acting Forensic Laboratory Director to Ellen A Fraser.
20	20June24	Removed mark up tracking feature on this word document.
21	30July24	Updated the Associate Director to Samson Omole.
22	17Mar25	Major revision