



# Quality Manual

This document serves as the Quality Manual for:

## Forensic Chemistry Section

Maine Health and Environmental Testing Laboratory  
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This Quality Manual meets the requirements of ISO/IEC 17025:2017 and is the main document for our Management System.

The Management System is outlined in section 8.

The Quality Policy Statement is detailed in section 8.2.2.

The Range of Laboratory Activities is addressed in section 5.3.



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## About this Document

This document is reviewed at least annually by the Forensic Lab 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 Forensic Chemistry acknowledge the existence of any updated version.

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# Quality Manual

## 1. Scope

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

## 2. Normative References

### Reference List

ANAB, ISO/IEC 17025:2017 and AR3125 - ANSI National Accreditation Board Forensic Science Testing Laboratories Accreditation Requirements.

ISO /IEC 17025:2017 International Organization of Standardization / International Electrotechnical Commission – General requirements for the competence of testing and calibration laboratories, 2017.

ANAB, ISO/IEC GD3150 - Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel

ISO/IEC Guide 99 (also known as JCGM 200), 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 Drugs (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



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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, ISO/IEC 17025:2017-Forensic Science Testing Laboratories Accreditation Requirements, (document #AR-3125)

**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** - The highest-ranking manager within an individual laboratory. May also be referred to as Chief of Laboratory Operations.



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**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** – The official laboratory report that communicates the results, opinions and interpretations made during the analysis of evidence samples.

**Certified Reference Material** – 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.

**Competency (Proficiency) test** - The evaluation of a person's knowledge and ability to perform independent work in any functional area of forensic casework.

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



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**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** (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 Laboratory Director and Associate Director of Laboratory Services*



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**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** – (aka 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** – (aka 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** – the 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)** - See Forensic Laboratory.

**Forensic Laboratory** - A laboratory (with at least one full-time scientist) which examines physical evidence in criminal matters and provides opinion testimony with respect to such physical evidence in a court of law.





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**Forensic Laboratory Director** – The Chemist III assigned to oversee the daily operations of a particular unit within the 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 Proficiency Test** – A proficiency test administrated 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 laboratory 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.



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**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.

**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 is able to meet the requirement, it shall meet the requirement.

**Procedure** - 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. See also: *Instructions*

**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** – 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.



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**Quality Assurance** - 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** - 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/Quality Assurance Manager** (however named) - 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.

**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.



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**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 in order to make an inference about the whole population.

**Scientist (see 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** – (old term-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.



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**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.

**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 Lab Director, Quality Manager, 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 are undertaken impartially, and structured and managed to safeguard impartiality.

4.1.2 Laboratory management are committed to impartiality.



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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 other pressures and influences that may affect the quality of their work are in place and reviewed by employees annually.

4.1.3.1 The management system will ensure:

- a) The FCS has a code of ethics as part of the management's commitment to good professional practice (ANAB, ISO/IEC GD3150 - Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel).
- b) The FCS code of ethics is reviewed annually by all personnel, and record of that review will be maintained.
- c) If a violation of the FCS code of ethics is identified, appropriate actions will be taken to rectify the violation.

4.1.4 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. The impartiality risk review will occur during the annual management review. All laboratory employees are encouraged to bring impartiality concerns to the Forensic Laboratory Director.

Notes – relationships do not necessarily present a laboratory with a risk to impartiality. A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding) and payment of a sales commission or other inducement for the referral of new customers.

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.

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

## Details, Documents, References and Records



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- A formal management system has been implemented to ensure confidence in laboratory operations. Technical competence is ensured through the policies outlined in this Quality Manual. Impartiality is assessed through audits and approvals. Judgment is ensured through the hiring of qualified personnel and by continuously refining, upgrading, and improving his or her skills. Operational integrity is reviewed by management on a regular basis at management review meetings to ensure continued suitability and effectiveness of the management system. Any problems are acted on immediately, through corrective action if necessary.
  
- The organization and management structure of the laboratory, and the relationships between management, technical operations, support services and the management system is defined through the aid of an organizational chart. The Chief of Laboratory Operations and/or the Quality Manager retain both current and past organizational charts.

The Forensic Chemistry Section is a part of the Maine Health and Environmental Testing Laboratory (HETL) headed by a Chief of Laboratory Operations (Public Service Manager II), with a Forensic Lab Director in charge of the day-to-day activities. The analytical areas covered by the Maine Health and Environmental Testing Laboratory (Parent Organization) include controlled substances, forensic toxicology, environmental testing, and clinical testing.

The mission statement of the HETL is to isolate, identify, analyze, and monitor any biological, chemical, or radiological hazards which are capable of causing harm. We will assist other agencies in the prevention, treatment, and control of such hazards which threaten the community or environment. These essential services shall be provided cost effectively through a fee schedule established with the flexibility of making them available regardless of the public's ability to pay. Other roles include consultation with other agencies on state policy development and the quality assurance oversight of services provided by the public and private sectors.

## **Core functions:**

### **RAPID RESPONDER TO SUSPECTED OUTBREAKS AND CONTAMINATION EVENTS:**

- The HETL, in concert with public health agencies and other laboratories, will have the capability to rapidly identify, track and contain outbreaks and sources of biological or chemical public health threats.

### **INTEGRATED INFORMATION MANAGER:**

- The HETL will provide an important link for the accumulation, blending, and distribution of scientific information in the support of public health programs. The HETL will also provide expert consultation on analytical data generated at the HETL and data generated elsewhere.

### **ENVIRONMENTAL MONITOR:**

- The HETL will be a leader in epidemiological surveillance and environmental testing. Laboratory data will provide necessary information to assess and monitor environmental health. Low detection level analyses will provide an indicator of change before significant health effects can occur.

### **ADVOCATE FOR APPROPRIATE AND HIGH-QUALITY TESTING:**



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- The HETL will be recognized as the source of quality information and serve as the standard for municipal and private laboratory performance. Certification of other laboratories will be based upon standards set here and the federal standards defined by laws and regulations.

#### **REFERENCE SERVICE PROVIDER:**

- The HETL will expand its role as the reference testing site for Maine and provide a model of efficient, low cost, quality testing that assesses public and environmental health through appropriate testing.

#### **TECHNICAL AND OPERATIONS RESEARCH LEADER:**

- The HETL will be recognized as a source of state-of-the-art technology, both technical and operational. The HETL will have direct connectivity to technological advancement within the State.
- The HETL will assist the state in test selection for investigative research.

#### **PUBLIC SAFETY ENFORCEMENT:**

- The HETL will provide analytical, technical, and enforcement capability to help control the abuse of alcohol & drugs and the attendant public health consequences.

The mission of the Forensic Chemistry Section (hereafter referred to as the FCS) is to provide accurate, reliable, and timely analysis and subsequent testimony in the areas of controlled substances and toxicology (blood alcohol determination and blood/urine drug testing). The service is provided primarily to Criminal Justice Agencies of the State of Maine in regard to evidence submitted, although the Forensic Lab Director may authorize the occasional acceptance of other work related to governmental agency investigations.

The FCS assists in the criminal justice process and serves as an investigative aid to the Criminal Justice System. The Section 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 solid dose 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.

- Management decisions shall maintain neutrality, fairness, independence, balance and objectivity, ensuring ethical business practices and that data is never altered or falsified.





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- 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 married 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.

Firm adherence to this code of values forms the foundation of our credibility. Personnel involved in dishonest activities are subject to a range of disciplinary action including dismissal.

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. All of these policies are posted on the State of Maine *Intranet* at:

<http://www.maine.gov/dhhs/policies/> and  
[http://www.maine.gov/bhr/rules\\_policies/policy.htm](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



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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 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.

Records are available to the submitting agency and Prosecuting Agency upon request. Record access is available to Defense Counsel through the discovery process outlined in FCS's SOP Manual.



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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, the defense attorney representing the defendant with proper authorization for Release of Information signed by the subject, the Attorney General's Office or the District Attorney's Office of the jurisdiction involved.

Results will be provided when the inquirer presents appropriate case information, such as:

Name of Caller  
Contact Phone Number  
Name of Agency/Office  
Subject's Name  
Agency Case Number  
HETL Case Number  
Subject's DOB (for OUI incidents)

Results will not be released to defense counsel until the subject/defendant has signed the Authorization for Release of Information form and the form is returned to the FCS or a discovery request is received from the defense counsel. This form will be retained in the specific case folder. This form is available on the DHHS website:

<http://www.maine.gov/dhhs/privacy/authorization-release.pdf>

A log of all phone or email conversations will be kept regarding the dissemination of information/results. Refer to SharePoint for the Section's Phone Log document. Upon completion, the Phone Log or email will be placed in the appropriate case file.

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 DA'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.



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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.

Hard copies of case folders are not to be given directly to the subject/defendant or defense counsel. A copy of the case folder may be provided to defense counsel upon completion of the Authorization for Release of Information form or through a discovery request. The FCS's policy for the distribution of completed laboratory reports and case folders is contained in FCS's SOP Manual.

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.

## Details, Documents, References and Records

- Some information about cases (including results) is stored on the Local Area Network (LAN) of the Maine Health and Environmental Testing Laboratory. 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. In order 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.

## 5. Structural Requirements

### 5.1 Legal Identification

The laboratory is a legal entity based on its government status, that is legally responsible for its laboratory activities. The Forensic Chemistry Section is a part of the Maine Health and Environmental Testing Laboratory (HETL) headed by a Chief of Laboratory Operations (Public Service Manager II), with a Forensic Lab Director in charge of the day-to-day activities. The analytical areas covered by the Maine Health and Environmental Testing Laboratory (Parent Organization) include controlled substances, forensic toxicology, environmental testing, and clinical testing.

Maine Health and Environmental Testing Laboratory  
47 Independence Drive, SHS 12



# Quality Manual

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 and the FCS Director have overall responsibility for the laboratory. The management staff of the 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 and to identify the occurrence of departures from the management system from the procedures for performing tests and to initiate actions to prevent or minimize such departures. The Forensic Lab 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 the Health and Environmental Testing Laboratory resides with the Chief of Laboratory Operations. Key management of the laboratory includes these positions as well as the Chemist III's of all the sections. In the event that top management is not available in the laboratory, management responsibilities will first fall to the Forensic Lab Director, then to the respective Chemist III or Chemist II in each discipline area. In the absence of a FCS Chemist III, the responsibility for the day-to-day operations of that section will fall to the top management, or their deputies, and the technical operation of the section will fall to a designated individual. The Forensic Lab Director, the Quality Manager, and the employees of the FCS share the responsibility for the quality activities, as well as for ensuring compliance with the current version of ISO/IEC 17025. However, primarily it is the duty of the Quality Manager to initiate, maintain, and coordinate the management system.

The details of management are as follows:

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

- develops primary goals, operating plans, policies, and short and long range objectives for the laboratory; 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.



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FCS 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 Lab Director will appoint a staff member to act on their behalf during the Forensic Lab 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, in order 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 - The Quality Manager has defined responsibilities and authority for ensuring that the quality management system is implemented and followed at all times. The Quality Manager is responsible for the preparation, issue, review, audit and upkeep of the Quality Program. 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 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.



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Safety Officer – The Health and Environmental Testing Laboratory Safety Officer (SO) has been designated by the Chief of Laboratory Operations. This position may be contracted to an external agency. The SO has the responsibility and authority to ensure that all health and safety requirements are implemented and enforced at all times. Please see the 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.

NOTE: Specific job descriptions, education and training requirements for the positions within the Forensic Chemistry Section are available on SharePoint or with the Forensic Lab Director.

## 5.3 Range of Laboratory Activities

The testing carried out at FCS that conforms to the requirements of ISO/IEC 17025 as a Forensic Testing Laboratory is in the following sections and categories of testing:

| <u>Section</u>     | <u>Categories of Testing</u>   |
|--------------------|--|
| Forensic Chemistry | Controlled Substance Analysis, Blood and Urine Drug Testing, Blood Alcohol Determination |

The scope of tests/services (Scope of Accreditation) performed by our laboratory is listed in the Scope of Accreditation and is detailed to the specifications of our Accreditation Body.

## 5.4 Requirements

The FCS carries out its testing activities in such a way as to meet the requirements of the ANAB International Accreditation Program (which includes ISO/IEC 17025:2017 and other supplemental requirements).

The FCS is also committed to carrying out its testing activities so as to satisfy the needs of its clients (Evidence Submitting Agencies, Maine Attorney General’s Office and the District Attorney’s Office) 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



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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. (Ex: The Forensic Chemistry Section of HETL is accredited by ANAB as a Forensic Testing Laboratory to ISO 17025:2017 standards.) 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.

- 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 Maine Health and Environmental Testing Laboratory has been organized to satisfy the needs of the customer and regulatory authorities and to meet the international standards ISO 17025. Organizational charts indicating management structure, interrelationships between the sections, and the location of the FCS within the Maine Health and Environmental Testing Laboratory are available with the Forensic Lab Director and will be updated as the structure changes. The Forensic Chemistry 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 are detailed in the organizational chart and section 5.6.

Maine Health and Environmental Testing Laboratory is composed of the following divisions:

Microbiology  
Inorganic Chemistry  
Organic Chemistry  
Radiological Chemistry  
Forensic Chemistry

Management responsibility and authority details are outlined in section 5.2 of this Quality Manual.

- 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 in the Quality Manual, Standard Operations Procedures (SOP), Analytical Procedure Manuals (Solid Dose Drugs, Blood and Urine Drug, and Alcohol Analysis), Biological Safety Manual, and Training Manuals. While the FCS does have its own





# Quality Manual

Biological Safety Manual, it also follows the Chemical Hygiene Manual and the RCRA Plan of the HETL (parent organization) and participates in the HETL Safety Program.

## 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 8.9.1);
- e) Ensuring the effectiveness of laboratory activities (see 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:

### Supervisors (Chemist III)

- respond to customer inquiries and provides professional advice;
- hire personnel;
- orient new personnel;
- determine technical training needs of personnel;
- conduct employee performance reviews;
- maintain open and constructive communication;
- supervise quality assurance activities within the section;
- 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;
- facilitate operational concerns in their area;
- 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/are knowledgeable of the scope of all processes under their section;
- provides technical guidance in areas of testing under their section;



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ensures equipment is maintained and calibrated, reporting all deficiencies (e.g., equipment malfunctions) in the appropriate manner.

## Chemists I and II (Technical Staff)

- maintain records of all quality activities as documented in procedures and test methods;
- conduct casework;
- provide testimony related to casework testing and results;
- handle samples and performing analyses according to procedures and test methods;
- write procedures and test methods;
- develop, validates, and implements new procedures;
- sign reports when designated with signing authority;
- maintain equipment;
- report deficiencies or malfunctions to the supervisor;
- identify and record nonconformities;
- identify and record improvements;
- correct nonconformities;
- improve laboratory and/or quality activities on a continuous basis.

## Evidence Technician and Administrative Personnel

- receive evidence from various law enforcement agencies and maintains chain of custody;
- identify evidence packaging/submission deficiencies and notifies submitting agency;
- responsible for organization and location of evidence while at the laboratory, except during the time it is being analyzed by a Chemist;
- distribute evidence to Chemist 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;
- identify and records nonconformities;
- identify and records improvements;
- correct nonconformities;
- improve laboratory and/or quality activities on a continuous basis.

## 5.7 Communication and Integrity

Laboratory management ensures that:

- a) Communication within the Forensic Chemistry Section 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



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management shall communicate to the staff the importance of meeting customer requirements as well as statutory and regulatory requirements;

- b) Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

## Details, Documents, References and Records

- The Scope of tests / Scope of accreditation outlines the laboratory activities that conform to ISO/IEC 17025. Document is retained with Forensic Laboratory Director.
- The parent organization maintains the most current organizational chart for the entire organization, while the FCS maintains an unofficial organizational chart for the FCS.
- Management is committed to complying with ISO/IEC 17025 and continually improving the effectiveness of the management system.
- The results of the management system are regularly reviewed during management review (see section 8.9) and continual improvements are made as outlined in section 8.6 to ensure the integrity of the management system. Management communications (oral and written) pertaining to the effectiveness of the management system, meeting customer requirements and meeting statutory and regulatory requirements provide an underlying message that these are foundational to our success in ensuring ongoing business relationships and avoiding disruption in operations.

## 6. Resource Requirements

### 6.1 General

The laboratory has available the personnel (6.2), facilities (6.3), equipment (6.4), systems/traceability (6.5) and support services (6.6) necessary to manage and perform all laboratory activities. These resource requirements have been established to ensure our laboratory is able to perform our process requirements (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 shall only use personnel either directly employed or contracted through temporary employment agencies.



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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 the State's intranet website: <http://www.maine.gov/cgi-bin/bhrsalar/jobs.pl> and also on SharePoint. Also see 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.

## Specific Objectives

All new employees hired to analyze specimens will undergo a training program.

The specific training protocols are detailed in the respective Training Manuals. For all training section protocols, all required 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.

The length of training will be decided by the Forensic Lab Director, depending upon qualifications, length and nature of prior experience.

If the results of the training program are deemed unacceptable or insufficient, retraining may be required. Each sections' training manual will detail the requirements for retraining.

When the trainee has completed the training program, appropriate proficiency / competency tests will be prepared for State Certification, and for authorization to work independently.

If a State Certification has lapsed for any reason and depending upon the reason and length of the lapse, a full or modified retraining program will need to be completed. The extent of the retraining program will be determined by the Forensic Chemistry Director.

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, and their significance, and determine the appropriate action to be taken. Each discipline will have a documented training program that includes a training manual. Upon completion of the training program, analysts shall continue to participate in trainings and continuing education each year to maintain and



# Quality Manual

expand their knowledge in the field. Trainings may consist of in person or remote sessions such as attending a conference, webinar, or lecture, reading journal articles, and attending training sessions put on by the Forensic Lab Director, Quality Manager, or Supervisor.

- 6.2.3.1 All the 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 6.2.5). 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; and a written or 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. All analysts shall achieve a score of 80% or greater for any written competency exams. Analysis of DHHS samples for competency and State Certification, or a mock case, prepared by authorized analyst, may be used toward meeting the competency requirements. All technical support personnel must successfully complete a competency test before working independently on case work and signing reports.
- 6.2.3.2 Technical Reviews shall be conducted by those who have expertise and have been previously certified and authorized in that particular testing discipline. Analysts conducting Technical Review need not have a current State of Maine Certificate in the discipline for which they are reviewing cases but must have previously been certified and authorized to conduct such work, continue to take an annual proficiency test in the discipline, and be currently authorized to conduct such review by the Forensic Lab Director.
- 6.2.4 Each manager or supervisor communicates to their direct reports a list of the expected duties, responsibilities, and authorities when they commence in the position and this is reviewed during performance reviews.
- 6.2.5 The FCS has a procedure documenting how the laboratory determines the:
- competence requirements (see 6.2.3.1);
  - selection of personnel (see 6.2.1, 6.2.2 and 6.2.2.1);
  - training of personnel (see 6.2.2 and Training Manuals);
  - supervision of personnel (see 6.2.4);
  - authorization of personnel (see below and 6.2.6);
  - State Certification of personnel (see below);
  - monitoring of competence of personnel (see 7.7).



# Quality Manual

The Department of Health and Human Services (DHHS) has set forth specific technical qualifications necessary for an individual to be certified by the DHHS. The Forensic Chemistry Section will also authorize each analyst based on the requirements of ISO 17025:2017 and AR3125. A record of this authorization will be kept by the Forensic Lab 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 State reviewers, or 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 PT program for that discipline.

## Certification for Drug Analyst

To be certified as a 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."

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

The initial certification proficiency test requires 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 five years. The proficiency samples are prepared internally or are obtained through an outside agency such as CTS, etc.

### *Recertification for Drug Analyst*

Recertification is conducted every five years. 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 drugs may be adulterated with common diluents. 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 Proficiency Test 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 Analyst



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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.”

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

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 Analyst**

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 Analyst**

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.”

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

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 Analyst**

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.



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- 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.

## Details, Documents, References and Records

- Job descriptions have been established for every key job position and are maintained on Sharepoint and Maine's Intranet.
- Note – Management defines the minimum levels of qualification and experience necessary for competence within the laboratory.
- Continued competence is monitored and where this is not achieved, the need to retrain personnel is required.
- Laboratory activities must be either performed or supervised by an experienced person with the required degree and relevant practical work experience.
- Personnel holding technical positions whereby they are the recognized expert for the laboratory are authorized to develop, modify, verify and validate methods.
- Personnel responsible for analysis of results, statements of conformity, opinions and interpretations are authorized to do by the FCS Director.
- Personnel responsible for reporting, reviewing and authorizing results are authorized by the FCS Director.

## 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 objective includes:





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- 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. This objective includes:

## Temperature Checks



# Quality Manual

HETL temperature log forms are used to record daily temperature checks for refrigerators, freezers, evidence storage, and lab areas, on normal working days, using certified digital calibrated thermometers. 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 reevaluated.

## Humidity Monitoring

Humidity will be monitored for lab areas and evidence storage areas on normal working days using certified digital calibrated thermometers and recorded on the HETL temperature log form. Acceptability ranges will be listed on the specific log forms. If humidity is suspected of causing any instrument or QC issues, the set ranges may be reevaluated.

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 the reliability, the use of the tests will be suspended.

6.3.4 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 Lab Director, or his/her designee, will grant room access to employees based on needs of the operation. Room access is controlled through programmed magnetic cards.

(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. Integrity of evidence is maintained through two practices:

1. Proper Handling
2. Proper Packaging

## Specific Objectives

### Proper Handling

All laboratory personnel will handle submitted materials in a manner that assures the integrity of the evidence. Prior to initiating and during the processing of evidence, the analyst will employ the following practices, but need not document adherence to:



# Quality Manual

- The work area will be clean and free of debris
- All glassware and tools will be clean
- All evidence will be stored under proper seal
- Reagents and solvents will be kept in closed containers

## Proper Packaging

All evidence must be packaged in a manner to ensure its integrity. Therefore, all evidence must be retained under proper seal. **Proper seal** is defined as: containers sealed to prevent the loss of contents and secured in a manner such that entering the container results in obvious damage or alterations to the container's seal.

(c) effective separation between areas with incompatible activities.

- Solid Dose Drug processing is separate from Toxicology sample preparation and extraction, and samples are run on separate instruments

6.3.4.1 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 Lab 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.

## Public Access

- Visitors to the HETL will use the public laboratory entrance or be escorted through other entrances by staff.
- Persons submitting evidence will sign in and be issued a law enforcement visitor's badge which will grant access to the 2<sup>nd</sup> floor for evidence drop off, where all evidence will be received and logged. Law Enforcement Officers are authorized to be left unattended in the 2<sup>nd</sup> floor corridor and Forensic wing hallway while they wait for a member of the FCS to assist them.
- Anyone entering the operational area of the laboratory will sign in and be issued a visitor card. Visitors will be escorted at all times by an authorized staff member.
- It is the responsibility of the HETL staff to be sure the name is legible on the sign in sheet. A visitor card will be issued to the individual.
- All cards should be accounted for at the end of the day. The person escorting



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the visitor to and from the FCS is responsible for ensuring the visitor has signed in and out of the lab and has returned the visitor card to the receptionist staff upon exiting the facility.

## Emergency Access

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

In 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 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 Operations and Forensic Lab Director.

**Emergency Contact Information: see signs posted on all doors.**

- (b) 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 Lab Director has access to review the footage on the cameras.
- (c) All Forensic internal entrance/exit doors and access to controlled areas are controlled through locks or a proximity card reader locking mechanism. Only authorized personnel will have access to these areas. A list of authorized individuals and the area of access is maintained by the Forensic Lab Director. An employee of the FCS will always accompany visitors to the operational areas.
- (d) The records pertaining to the accountability of keys and magnetic cards for the electronic security system used by FCS are documented and maintained by the FCS supervisor and the Bureau of General Services – Building Control Division. Information about access granted to different employees is constantly available to the Bureau of General Services – Building Control Division. Access to the areas and distribution of access cards/keys is limited to individuals designated by the Chief of Laboratory Operations or the Forensic Lab Director.



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Access cards and keys are to be turned in to the Forensic Lab Director upon termination of employment. In case the card is not returned, the card can be deactivated immediately. Personnel will notify the Forensic Lab Director of any lost or missing access card as soon as possible.

- (e) All forensic laboratories, file storage areas, and evidence storage are monitored by a door alarm system and surveillance camera by the Bureau of General Services – Building Control Division. Card reader bypass alerts will notify the Chief of Operations and Forensic Lab Director any time a door is open without the use of a proximity card. Analysts are not permitted to work alone in the lab during non-operational hours.
- (f) During operational hours, 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 Forensic section shall remain locked when unattended.

## Evidence Storage

Evidence shall be kept secure in the evidence room, freezer, safe, refrigerator or evidence cabinet.

For short term storage of evidence which is being worked on, the laboratory area can be used, provided the area is secured by locked doors when the area is unoccupied or by placing “in process” materials in a metal lock box, locked evidence cabinet, or locked refrigerator/freezer. The processing rooms are monitored by the Bureau of General Services – Building Control Division during non-business hours.

NOTE: Controlled Functional Areas - Access to the functional areas of Forensics is limited to individuals determined by the Forensic Lab Director and the Chief of Laboratory Operations. The list of individuals is contained in the Key Log and Card Access Log maintained by the Forensic Lab Director.

## Details, Documents, References and Records

- Central laboratory supplies and services, such as water purification systems, air supply, and sample storage, are appropriate to facilitate proper performance of tests.
- Laboratories are ventilated to reduce the levels of contamination, lower humidity and control temperature. Laboratory test areas are air-conditioned.
- Bench tops are made of impervious, smooth, easily cleaned, materials.



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- Reference materials and certified reference materials are kept separated from samples (log-in and storage). Sample log-in and storage are segregated, in a separate area from the testing laboratory, and include proper sanitation to exclude the possibility of cross-contamination.
- Access to the laboratory is restricted to authorized personnel. The authorized personnel are made aware of the following items:
  - the intended use of the area
  - the restrictions imposed on working within such areas
  - the reasons for imposing the restrictions
- Controlled use of cleaning and pest control materials is exercised. The laboratory complies with the HETL health and safety requirements. Any special procedures required by a test method are detailed within that test method.

## 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 that could influence the result. 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. In those cases where the laboratory needs to use equipment outside its permanent control, the Forensic Lab Director and Quality Manager will ensure that the requirements of our accrediting bodies are met. 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, comparison to a previous lot, comparison to a published library, and/or comparison of published literature, where appropriate. 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 practicable.

6.4.2 In those cases where the laboratory needs to use equipment outside its permanent control, the Forensic Lab Director and/or Quality Manager will ensure that the requirements of ISO/IEC 17025 are met. When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.



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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:

- The manufacturer's recommendations for safe handling, transport, storage, and use of the equipment shall be followed;
- Each section shall have its own plan for maintenance of each instrument, following the manufacturer's recommendations;
- All such equipment will, at all times, be subjected to quality control measures specified in the manuals of each section. The controls (positive and negative), wherever appropriate, shall be used to ensure proper functioning of the equipment (i.e., examining standards, often in the course of routine casework).

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

- When required, wear personal protective equipment and change as necessary between reference materials.
- Dispense reference materials into clean laboratory equipment or containers.
- All reference standards and reference materials shall be stored and secured to ensure quality and safety. Please see the SOP Manual for guidance on handling DEA controlled (non-exempt) certified reference materials.

6.4.3.1 All reagents prepared in the laboratory shall be labeled and the labels shall, at least, contain information about the name of the reagent, date of preparation, the initials of who prepared it, and storage conditions.

Reagent sheet records will be maintained identifying who made the reagent and the components used in preparation. The information such records must contain is:

- Date of preparation or lot number;
- Identity of person who prepared the reagent;
- Approval of reagent;
- Storage requirements (as applicable);



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- Components used in the preparation and their expiration date.

Results from reagent testing shall be recorded on the Reagent sheet and/or be located in the appropriate batch data for the first use of the reagent. When applicable, all sections of the FCS shall routinely check the reliability of reagents used in those sections. The reliability testing will occur before use or, if appropriate, concurrent 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.

- 6.4.3.2 Reference collections shall have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest.
- 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.

Where appropriate, each instrument that may have significant impact on test results, before being placed into service or after any repairs, shall undergo a performance check, calibration, or autotune/check tune to ensure that it meets the required specifications, according to the program specified by each section (Also see 6.4.2).

- 6.4.5 The laboratory will verify that equipment (and its software) used for measurement is capable of achieving 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 is calibrated when:

- the measurement accuracy or measurement uncertainty affects the validity of the results, and/or
- 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





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calibrators”: competent calibrator requirements for the FCS will be outlined 6.4.7.

- 6.4.7 The FCS calibration requirements are established below and will be reviewed and adjusted as necessary in order 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.

## Specific Objectives

### **Temperature Checks**

Daily temperature checks are recorded for refrigerators and freezers, labs and evidence storage locations on normal working days using certified digital calibrated thermometers and recorded on the HETL temperature log form. Acceptability ranges will be listed on the specific forms. If temperature is suspected of causing any instrument or QC issues, the set ranges may be reevaluated.

Temperatures will also be checked and recorded for heat blocks and incubators with certified digital calibrated thermometers, where the temperature can affect the results of the test. The temperature for the heat block or incubator shall be within  $\pm 3$  °C of the temperature listed in the SOP for the method. If the temperature is outside of this range, the heat block or incubator will not be used until the temperature is within range. Temperatures are recorded on associated batch documents using digital calibrated thermometers.

### **Humidity Monitoring**

Humidity will be monitored for lab areas and evidence storage areas on normal working days using digital calibrated thermometers and recorded on the HETL temperature log form. Acceptability ranges will be listed on the specific log forms. If humidity is suspected of causing any instrument or QC issues, the set ranges may be reevaluated.

### **Instruments - (GC, MSD, FTIR, Randox, LC-MS/MS)**

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



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Maintenance: 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.

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 lab, 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 tolerance or out of tolerance on the calibration report provided by the vendor.

Maintenance: Annually (at least) in conjunction with Calibration.

## **Pipettors and Dilutor**

Calibration - Pipettors and Dilutor will be checked annually by an approved ISO 17025 Calibration lab whose scope meets the needs of HETL. Pipettors and the dilutor 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.

Hand held 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 Meter**

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



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Calibration – pH meter will be calibrated annually by an approved vendor. Pass or fail will be noted by the vendor. Additionally, an in-house QC check will be performed prior to each use. The pH must be within  $\pm 0.5$  units to pass the QC check.

## 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.

## Calibration and Maintenance Logs

Notebooks containing calibration and maintenance logs will be kept for the various instruments. These logs will be stored near their respective instruments.

- 6.4.8 Whenever practicable, instruments requiring external calibration checks (e.g. balances, weight sets and pipettes) shall be labeled to indicate the status of calibration, including the date when last calibration occurred and the date when recalibration is due.
- 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.



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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 in the sections 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. Balances will only be calibrated by a competent calibration service and no adjustments will be made to the balances between calibrations.

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 7.2.2.1).

6.4.13 When practicable, each item of equipment, if significant to the results, will be uniquely identified. For ease of identification within case folders, instruments / lab items may be uniquely named and said name shall be recorded in case notes. The Forensic Lab 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 section, 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;



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- 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.

## Details, Documents, References and Records

- Measuring and testing equipment is uniquely identified through a serial number and/or unique name. Measuring and testing equipment includes any instrument that could potentially affect the quality of test results.
- The information related to service and maintenance is kept in individual equipment files and/or binders. Other information kept in these files and/or binders may include:
  - date received and date placed in service;
  - condition when received (e.g., new, used, refurbished);
  - dates and results of calibration and/or verification and date of next calibration and/or verification.
- The procedures for each piece of measuring equipment are located in close proximity to the equipment for easy reference.
- Calibration labels are used to identify the calibration status of equipment showing measurement traceable information.
- Measuring equipment that has failed calibration or is deemed out of service is labeled as "Out of Service."

## 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:



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- 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.

6.5.1.2 In a situation where 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.

6.5.1.3 The laboratory will not calibrate its own equipment.

6.5.1.4 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.



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Note – metrological traceability is the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

Whenever possible, reference standards calibration shall be traceable to 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.

## Details, Documents, References and Records

- Calibration results from laboratories conforming to ISO/IEC 17025 provide metrological traceability. A record of the laboratory's conformance to ISO/IEC 17025 is referenced through their calibration records.
- Certified values of certified reference materials from reference material producers conforming to ISO 17034 provide metrological traceability.
- Demonstration of conformity to ISO/IEC 17025 is accomplished through third party recognition (such as an accreditation body), external assessment by customers or self-assessment. The International metrological traceable chain may include:
  - calibration and measurement capabilities provided by national metrology institutes and designated institutes that have been subject to suitable peer-review processes. Such peer-review is conducted under the International Committee for Weights and Measures Mutual Recognition Arrangement);
  - calibration and measurement capabilities that have been accredited by an accreditation body subject to the International Laboratory Accreditation Cooperation (ILAC) Arrangement



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or to Regional Arrangements recognized by ILAC have demonstrated metrological traceability.

- Reference materials, including calibration standards, used in chemical measurement are prepared so that the point of measurement is similar or equivalent to that of the samples. The matrix, prior to the addition of the analyte does not have a detectable concentration of the analyte. Reagents used in the preparation of reference materials, including calibration standards, are of certified purity.

## 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. Reference 6.4.7 for procedures related to services.

- 6.6.2 The forensic laboratory 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
    - o 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





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- (including the necessary information to fulfill that request), or request a service through a supervisor
- Upon receipt of requested reagents and consumables, the analyst will inventory the product against packing slip; initial, date, and save 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 sectional SOP) before being used or stored. If the product is deemed unsatisfactory, reasonable action will be taken as determined by 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 a 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;
- In case it becomes necessary to subcontract testing of evidence, FCS shall subcontract analysis of evidence only to competent subcontractors. 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 Lab 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 sectional SOPs.
  - 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



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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.

## Details, Documents, References and Records

- Packing slips are checked against package content labels and matched with the Purchase Order if accepted. Once accepted, the packing slip is dated and initialed as evidence of compliance. Certificates of analysis (COA) and packing slips are maintained on file after the COA is checked to ensure the received item meets minimum specifications.
- Chemicals are purchased with manufacturer's certificates where possible. Due regard is paid to the manufacturer's recommendations on storage and shelf life.
- Consumable materials are stored according to the appropriate test method or procedure.
- Audits or tender evaluation is conducted to qualify suppliers of critical services (testing and/or calibration services) prior to use. The criteria for evaluation may include, but is not limited to the following:
  - historical vendor;
  - scope and accreditation;
  - certificate of analysis.
- An approved list of external service providers with evidence of compliance is maintained by the Quality Manager.
- Issues that arise with externally provided products and/or services through evaluations, monitoring of performance and re-evaluations require that actions be taken using the nonconforming work process found in section 7.10.

## 7. Process Requirements

### 7.1 Review of requests, tenders and contracts



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- 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) for any changes to the contract.

Information from a Receipt/Contract for Examination form, (SharePoint) shipping label, (or other document) is entered into StarLims (or current laboratory information management system) 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 suggested 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 manner in which the sample 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 (i.e. all fatal or near fatal OUI related blood samples will be tested for the presence of ethanol and drugs).

Evidence Log-in procedures are specified in the **Evidence Receiving Manual**.

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:



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- the requirements are adequately defined, documented and understood. By submitting evidence to the Laboratory, the customer(s) agrees to allow the laboratory to select the test methods to be used to analyze the evidence. The evidence receiving person is authorized to take in evidence if the analysis requested/evidence being submitted conforms to the evidence/analysis that is normally received/conducted by the FCS;
- the laboratory has the capability and resources to meet the requirements. 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 section 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 are capable of meeting the customers' requirements (if internal or routine customer, this procedure may be simplified). 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 Forensic Lab Director or Quality Manager) will discuss the issue with either the District Attorney's Office or with the agency submitting the evidence 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 considered to be 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 to, and agreed with, 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 our laboratory and the customer. The laboratory reserves the right to analyze the evidence as necessary without prior



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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 agency submitting the evidence or the Attorney General/District Attorney's Office. Records of such conversations or other communications will be maintained in the case records of the concerned cases.
- 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 (from the District Attorney's Office or from Law Enforcement Agencies) will, however, 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. These discussions will lead to improving the quality of the service being given to the clients by making the examinations conducted more useful and probative to the clients. Records of such discussions are maintained in the respective case records.

- 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 Log Form (SharePoint) and/or email and shall be retained in the casefile.



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## 7.2 Selection, verification and validation of methods

### 7.2.1 Selection and verification of methods

7.2.1.1 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, thin layer chromatography, gas chromatography, liquid chromatography, mass spectrometry, color tests, literature references and 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.

7.2.1.1.1 The laboratory shall use appropriate methods and procedures for data analysis and interpretation which are documents in each section's associated procedure manuals.

7.2.1.1.2 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



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the sample is suitable for comparison **before** making a comparison to a known standard. The criteria for these comparisons will be listed in the SOP for the test method.

7.2.1.2 All the sections 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 Section Procedure Manuals. These manuals include the standards and controls required and the minimum requirements for the interpretation of analytical data and reporting of a preliminary or full analysis.

All the information available in the laboratory about all the methods shall be up to date and readily available to all personnel that need to access such information. (see section 8.3).

7.2.1.3 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.

7.2.1.4 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.

7.2.1.5 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 (Forensic Lab Director, Quality Manager, Chemist certified by the DHHS in that discipline or a scientist who demonstrates specific expertise for that methodology) and outside experts as needed. Records of such validations shall be maintained. If the method is revised by the issuing body, verification is repeated to the extent necessary.

7.2.1.6 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.



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7.2.1.7 Any discrepancies in the evidence will be resolved before any work commences, or if work has already begun, as soon as practical. The Forensic Lab Director, Quality Manager, or another chemist will witness any significant discrepancy between what is found in the evidence container and what is labeled on the Receipt/Contract for Examination Request Form. No further testing will be conducted until reconciliation between the analyst and the submitter (or their representative) is accomplished. The discrepancy will be noted on the Discrepancy Form (SharePoint) and the chemist, Quality Manager, and/or the Forensic Lab Director will take appropriate actions to correct the discrepancy. All discrepancies will be filed in the specific case folder.

## **Deviation from laboratory procedures**

There are times when deviation from documented policies or procedures is necessary. Deviations are of two types:

**Minor** – a deviation that is not expected to alter the result and generally will not have an extended duration. Examples include: a change of the sample solvent, an increase of injection volume, shortening the solvent front or extending the hold time at the end of a method, increasing the number of scans for FTIR, of performing an examination with reduced quantities of samples and reagents due to the limited size of sample.

**Major** – a deviation that is applicable over an extended period of time, over a range of circumstances or has the potential to generate different results. Examples include: alternate equipment or the substitution of reagents.

## **Specific Objectives: Deviations**

**Minor deviations** may be initiated with the concurrence of the Forensic Lab Director / 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 Forensic Lab Director / Quality Manager will be documented alongside of the description of the deviation.

When there is a need for a **major deviation** from a policy, procedure or requirement, the requestor will complete a Deviation Request Form (SharePoint). The requestor will: indicate the applicable policy, procedure or requirement; describe the requested deviation; specify the instance(s) for which the deviation is requested; and state the reason for the deviation. The





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requestor will then submit the Deviation Request form to the Forensic Lab Director / Quality Manager for authorization.

The Forensic Lab Director / Quality Manager will: evaluate the merit/risk of the deviation from a technical viewpoint. The Forensic Lab Director / Quality Manager will determine the negative consequences and/or risks introduced by the proposed change. These may include, but are not limited to: contamination, security, defensibility, integrity and safety. If the merit of the proposed change outweighs the risks and drawbacks, the Forensic Lab Director / Quality Manager may authorize the technical aspect of the deviation, and specify a duration period for the deviation. Copies of the Deviation will be placed in the respective case folders and a comment will be listed on the Certificate of Analysis.

## 7.2.2 Validation of methods

7.2.2.1 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.

### Major Modification

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 can be used in 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.



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## Minor Modification

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 lower limit of detection.

7.2.2.1.1 Whenever a validation is performed the laboratory will ensure the validation includes the associated data analysis and interpretation; establishes the data required to report a result, opinion, or interpretation; and identifies limitations of the method, reported results, opinions, and interpretations.

7.2.2.2 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 7.2.2.1)

7.2.2.3 The validation will meet the needs of the client and will take into account 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



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analytical method is suitable for the intended purpose will be contained in a validation plan, established prior to the start of validation.

7.2.2.4 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.

## Details, Documents, References and Records

- Methods developed in-house are validated and authorized before use. Where available, Standard Reference Materials (SRMs) or Certified Reference Materials (CRMs) are used to determine any systemic bias, or where possible results are compared with other techniques, preferably based on different principles of analysis. Determination of uncertainty must be part of this validation process and is essential for ongoing quality control.

## 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. This kind of sampling is only carried out in the Controlled Substances discipline. In all the other sections the results in the report only refer to the items actually tested.

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

When no specific sampling instructions have been provided by the client 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) that issue guidelines in this regard. The plan of such sampling is available in the Controlled Substances procedures manual and is readily available to the analysts.

7.3.2 The sampling method describes:

- the selection of samples;



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- 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 record will either explain the sampling procedures or will reference the procedures/client 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, additions to or exclusions from the sampling method and sampling plan. When the customer requests deviations, additions or exclusions from the sampling plan, it shall be recorded in the case record with appropriate sampling data and test results.

## 7.4 Handling of test or calibration items

7.4.1 Records of the transfer of evidence within FCS shall be maintained in the form of chain of custody. 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.

7.4.1.1 For all evidence received:

a) All evidence received in the FCS is to be properly sealed. Likewise, evidence not in the process of examination/analysis shall be maintained in a secure, limited access storage area under proper seal. In both the cases the initials or other identification of the person creating the seal must be present, across the seals/sealing tape when possible. Before being subjected to examinations, and after the examinations are complete, all evidence will be sealed and stored in a secured, limited access storage area equipped with appropriate security to protect the integrity of all items. Evidence submitted without a proper seal will be properly sealed upon submission, by either the submitter or the evidence technician. If, during evidence examination,



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it is found that the evidence is not properly sealed, the analyst shall note this on the case worksheet and that will be communicated to the customer 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 (laboratory number and the item number), proper seals, and the initials of the person sealing the evidence on or across the seal when possible.

Evidence collected from a crime scene by laboratory personnel shall be protected from loss, cross transfer, contamination and/or deleterious change, whether in a sealed or unsealed container, during transportation to an evidence facility. Where appropriate, further processing to preserve, evaluate, document, or render evidence safe shall be accomplished prior to final packaging. Evidence collected from a crime scene shall be appropriately identified, packaged and entered into the evidence control system as soon as practical.

b) Evidence is not to be left unattended and should be stored in a secure location at all times other than during testing. 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 as early as possible. 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 Lab Director depending upon need-to-have access basis.

c) A chain-of-custody is required for all items received and any 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. Analysts should sample and test items within a reasonable time frame while actively working on a case.

d) 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:

1. the individual(s) or location(s) receiving or transferring the item(s); and
2. the item(s) being transferred; and



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3. the chronological order of all transfers, minimally including the date.

e) A disposition of all items received is communicated to the customer regarding the disposition on the certificate of analysis. The long-term storage of evidence for which analysis has been completed shall be for a minimum of six months, if not retrieved by the submitting agency, after the final report is issued on the completed case; and

f) Communication to the customer is made and recorded regarding items collected and preserved for future testing.

Note: c) An item being tracked could contain multiple components and be tracked as one item.

d)1) 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.

7.4.2.1 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 actual evidence being examined by an analyst varies significantly from the description on the evidence receipt and/or packaging, the Forensic Lab Director, Quality Manager, or another chemist will witness the discrepancy between what is found in the evidence container and what is labeled on the Receipt/Contract for Examination Form. 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 (SharePoint) and the chemist, Quality Manager, and/or the Forensic Lab Director will take appropriate actions to correct the discrepancy. The completed Discrepancy form will be filed in the case folder.

When the customer requires the evidence to be tested acknowledging a deviation from specified conditions, the laboratory will include a disclaimer in the report indicating which results may be affected by the deviation, if the Chemist working the case has determined the deviation could impact test results. It is incumbent on the Chemist working the case to



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determine if noted discrepancy rises to the level requiring documentation in the report.

Examples of discrepancies include (but are not limited to): inventory discrepancies, discrepancies in weight, no match between suspect and/or victim names, agency case number, etc. Misspellings and typographical errors are not 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 Forensic Lab Director and/or Quality Manager will take appropriate corrective action to preserve any evidence/material stored inside.

## Details, Documents, References and Records

- The laboratory conforms to applicable regulations or contractual arrangements. The condition of sample may include or relate to damage, quantity, preparation, packaging or temperature.
- Preparation may include removal of moisture, isolation of a sample to be tested, homogenization or subsampling.
- Where a sample, or portion of a sample, is to be held secure 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 contains 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 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 of, 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.



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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/Certificate of Analysis
- 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 evidence receipt, chain of custody record, the description of the evidence, the report, records of conversations with clients, etc.

The laboratory maintains a file on every case submitted for analysis. The completed case file consists of different items based on the type of case. Examples of what may be found in a case or batch file is listed below:

## ALCOHOL DETERMINATION CASES

- Copy of the final report/Certificate of Analysis
- Any preliminary, supplementary or corrected reports
- Collection kit's suspect/police information paperwork
- Forensic Chemistry Alcohol Worksheet and Case notes
- Case Review (technical/administrative)
- Evidence Receipt/Contract for Examination form
- Hard copies of data that support the conclusion of the analyst
- Chain of Custody (once the evidence has been returned/destroyed)

## CONTROLLED SUBSTANCES CASES

- Copy of the final report/Certificate of Analysis
- Case Review Form (technical/administrative)
- Any preliminary, supplementary or corrected reports
- Forensic Chemistry Solid Dose Drug Worksheet and Case notes
- Evidence Receipt/Contract for Examination form





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- Hard copies of data that support the conclusion of the analyst
- Copies of reference or library spectra used for identification
- Chain of Custody (once the evidence has been returned/destroyed)

## URINE DRUG DETERMINATION CASES

- Copy of the final report/Certificate of Analysis
- Case Review Form (technical/administrative)
- Any preliminary, supplementary or corrected reports
- Forensic Chemistry Urine Drug Worksheet and case notes
- Evidence Receipt/Contract for Examination form
- Hard copies of data that support the conclusion of the analyst
- Chain of Custody (once the evidence has been returned/destroyed)

## BLOOD DRUG DETERMINATION CASES

- Copy of the final report/Certificate of Analysis
- Case Review Form (technical/administrative)
- Any preliminary, supplementary or corrected reports
- Forensic Chemistry Blood Drug Worksheet and case notes
- Evidence Receipt/Contract for Examination form
- Hard copies of data that support the conclusion of the analyst
- Chain of Custody (once the evidence has been returned/destroyed)

7.5.1.1 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 displayed on the records.

7.5.1.2 If any abbreviations or symbols are being used in the examination documentation and such abbreviations or symbols are specific to a section of the FCS, a list of such abbreviations and symbols, and their meanings, shall be maintained and made accessible to all section employees. (see SharePoint). Common abbreviations such as g for gram, or HCL for Hydrochloric Acid are viewed as common knowledge, should be readily recognized by another qualified analysts, and need not be explicitly detailed in the abbreviations document. Chemical abbreviations are



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maintained in the HETL Chemical Hygiene Plan.

- 7.5.1.3 Examination documentation refers to all those 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 was done and interpret the data.
- 7.5.1.4 All of the examination documentation shall be of permanent nature. All handwritten material will be in ink, except for TLC plates, which will be marked with pencil. The only permissible way of making corrections in any documents is by a single strike-out and initials. Nothing in the handwritten format will be obliterated or erased.
- 7.5.1.5 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.
- 7.5.1.6 If any adjustment or repairs are performed due to an instrument not meeting set criteria, records will be maintained for data run before and after the repair.
- 7.5.1.7 When instrumental analyses are conducted, the operating parameters are recorded. Operating parameters may be documented in a test method, recorded in a log book, recorded in the examination record, etc. The instrumental method used in the analysis should appear on instruments printout, and that is sufficient. It is not required to include in the case file a printout of the entire instrumental method.
- 7.5.1.8 All case notes, spectra and other data generated during analysis will contain the laboratory case number and the initials of the analyst.
- 7.5.1.9 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 on the documentation representing his/her work. For cases where an analyst has another individual transcribe information (i.e. a trainee assists during description, etc.) an explanation of the different handwriting shall be made.
- 7.5.1.10 All administrative documentation pertaining to a case shall at least be identified by the laboratory number of that case.
- 7.5.1.11 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



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worksheet.

- 7.5.1.12 When examination records are recorded on both sides of a page, each side shall be treated (identified and initialed) as a separate page.
- 7.5.1.13 When an independent check (verification) on a critical finding is carried out, it shall be conducted by an individual having expertise gained through training and casework experience in the testing discipline and a record of the review shall be made to indicate that the critical finding has been checked and agreed to, by whom, and when the check was performed.
- 7.5.2 The laboratory ensures that amendments to technical records can be tracked to previous versions or to original observations. Any change(s) made to completed examination records generated and/or maintained in an electronic form shall be tracked. Examination records shall be considered completed prior to any technical or administrative review of the records. Both the original and amended data and files must be kept, including the date of alteration, an indication of the altered aspects 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 will 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



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method and measurement scope and shall use, for example, previous experience and validation data.

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

Alcohol Determination

Controlled Substances – Reporting of weights

Blood Drug Determination – Quantitative results

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.

## Details, Documents, References and Records

Repeatability and reproducibility data are components of measurement uncertainty and are determined as a first step towards producing estimates of this parameter. The uncertainty of measurement is available on the certificate of analysis or calibration certificate from a competent provider.

7.6.4 When estimating the uncertainty of measurement, all uncertainty components which are of importance shall be taken into account using appropriate testing procedures. The documentation containing the following information, if applicable, will be maintained in the forensic chemistry section:

- a. Statement defining what is being measured? (e.g. purity of powder of cocaine)
- b. Statement of how traceability is established for the measurement
- c. The equipment (measuring device or instrument) used
- d. All uncertainty components considered
- e. All uncertainty components of significance and how they were evaluated
- f. Data used to estimate repeatability and/or reproducibility
- g. All calculations performed
- h. The combined standard uncertainty, the coverage, the coverage probability and the resulting uncertainty

## 7.7 Ensuring the validity of results



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7.7.1 The Test Methods shall have quality control procedures for monitoring the validity of a test. The 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, the quantitative data about the positive controls will be plotted or monitored, so that any trends can be spotted. Statistical control charts will be used whenever possible and useful to monitor the performance of the system. Quality control may include, but is not limited to, the following:

- regular use of certified reference materials and/or internal quality control;
- 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 difference methods;
- retesting (verification) of items/reanalysis;
- review of reported results;
- participation in a proficiency testing program.

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

Appropriate standards and controls will be specified in the laboratory methods and their use will be recorded or referenced in 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 Chemists initials shall serve as objective evidence that the work of another has been reviewed and accepted.

When a verification of a result (technical review) is carried out:

- it shall be conducted by an individual who is currently authorized to perform the testing (See 6.2.6);



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- a record of the verification shall be made, and the record shall identify who performed the verification, when it was performed, and the result of the verification; and
- the resolution of any discrepancy shall be recorded.

## Technical Review

After analysis and before the report is released all casework will undergo Technical Review. This review determines whether the appropriate examinations have been performed to support the results and conclusions reported.

- Technical Review will be conducted on 100% of all forensic cases.
- Technical Reviews shall be conducted by those who have expertise in that particular testing 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 Lab Director.
- Technical review shall be conducted on expert report letters and conversion reports requested by customers.
- Technical reviews shall not be conducted by the author(s) of the report. Technical reviews do not need to be conducted on casefile review reports for testimony as no new work is performed on the evidence.

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 Lab 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 Lab Director, the Forensic Lab Director shall make the final decision.

If during a Technical Review an error/typo 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.



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All casework will undergo a Technical Review. This review determines whether the appropriate examinations have been performed to support the results and conclusions reported. The review shall ensure that 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; it shall ensure that there has been conformance with proper technical procedures/test methods and applicable lab policies and procedures without bringing in personal preferences of the reviewer; technical review shall ensure that associations have been properly qualified in the test report; and that the test report contains all required information including, but not limited to the sampling plan and methods of analysis utilized and any deviations.

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

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.

## Administrative Review

After technical review, and before the report is signed, notarized, and released to the customer, all casework will undergo **Administrative Review**. This review is used to check case records and case reports for consistency with laboratory policy and for editorial correctness.

- Administrative Review will be conducted on 100% of all forensic cases.
- The Forensic Lab Director / Quality Manager will conduct the Administrative Review. Another Chemist may conduct Administrative Reviews when authorized by the Forensic Lab Director.
- Administrative Reviews shall not be conducted by the author(s) of the report or the technical reviewer of the report.
- Administrative reviews shall be conducted on casefile reviews for testimony, expert report letters and conversion reports requested by customers.

If during an Administrative Review an error is discovered on the Report (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 2<sup>nd</sup> time. The 2<sup>nd</sup> Administrative Review can be documented on the same case review form. Administrative reviews will ensure



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that the reports are satisfactory to be released to the clients.

Administrative reviews will cover: proper format of report; any grammar, spelling or content errors; all pages contain the case number; all pages contain the initials of the analyst; and completeness of the case folder (copy of the final report/Certificate of Analysis, Case Review Form, any preliminary, supplementary or corrected reports, Forensic Chemistry worksheets and case notes, evidence receipt, hard copies of data, etc.).

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

## Testimony Monitoring

Every discipline within the FCS will be subjected to observation and review for at least one court testimony per calendar year by a competent analyst, when testimony occurred that calendar year. The points on which the testimony will be evaluated 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 supervisor shall discuss with the analyst these shortcomings. If the next testimony of the analyst is also found to be unsatisfactory, the supervisor, in consultation with the Laboratory Director and the Legal Community, will decide on the line of action.

The testimony observation and review must be performed for each discipline at least once annually 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 a 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 Lab Director
- Observation by another analyst
- Observation by Prosecutor, Defense Attorney, or Judge.





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The FCS Supervisor will review the information and take suitable action if necessary. Refer to SharePoint for the Laboratory's Courtroom Monitoring Form. The records of courtroom testimony review shall be maintained for at least one ANAB assessment cycle, or five years, whichever is longer.

- 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 location 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 supervisor, if that person is different from the Quality Manager, and analyst. After reviewing proficiency test results, if the data is found to be outside criteria given in a Test Method, suitable corrective action will be taken as outlined in Section 8.7.1. Data from monitoring activities is analyzed, used to control and, if applicable, improve the laboratory's activities. See 7.7.5-7.7.8 for Proficiency Test review criteria.

- 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 conducts work. In the event that the preceding options are not available or appropriate, observation-based performance monitoring is acceptable.

Note - 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.

Note - Solely performing verifications or solely reviewing and authorizing results (technical



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review) are considered to be testing or calibration and are subject to these requirements.

## 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 for their adequacy.

Sources of proficiency samples from Collaborative Testing Services, CAP, PA Department of Public Health, Florida Department of Law Enforcement, DOT/NHTSA, Forensic Assurance, 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 solid dose drug testing, urine drug testing, and blood drug testing. Likewise, a minimum of one proficiency test sample per analyst will be performed semi-annually (every six months) by analysts performing blood alcohol determination. The laboratory will ensure a minimum of two rounds per year for all disciplines, when possible.

The Quality Manager or Forensic Lab Director 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:

- a) ensure that results are not known or readily available to the participant being monitored;
- b) ensure use of approved methods;
- c) establish criteria for determining successful completion prior to the monitoring activity;
- d) require a mechanism to ensure the quality of intralaboratory comparisons, interlaboratory, comparisons and observation-based monitoring prior to the monitoring activity; and
- e) for calibration laboratories, require intralaboratory comparisons, interlaboratory comparisons and proficiency tests to be performed using an item that was calibrated by the person performing the comparison or test.

7.7.6 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



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accreditation.

- 7.7.7 The FCS requires a minimum of one proficiency test sample per analyst per year for solid dose drugs, urine drug testing and blood drug testing, and twice per year for blood alcohol determination. 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.
- 7.7.8 After completing a competency test, every analyst as well as technicians performing testing at the FCS will undergo at least one proficiency test (external or internal) in their forensic discipline(s) every subsequent calendar year, successfully.

Qualitative proficiency tests shall be evaluated by comparing the achieved result to the expected result. If a compound is part of the current testing menu, if applicable to the section, the test will be considered passing if all achieved results match expected results. If a compound is part of the current testing menu and is not identified by the analyst, 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  $\pm 2$  standard deviations or  $\pm 10\%$  (whichever is greater) of the reported consensus 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.

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  $\pm 10\%$  or  $\pm 0.005$  g/210L (whichever is greater) of the nominal quantity value. If a Performance Statistic ( $E_n$ ) 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.



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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  $\pm 2$  standard deviations,  $\pm 20\%$  of the consensus result, or  $\pm$  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.

## Specific Objectives

The State of Maine has specific requirements covering the Certification of Analysts. Refer to Section 6.2.5 of the Quality Manual for specifics that cover:

Initial Certification for Drug Analyst  
Recertification for Drug Analyst  
Certification for Alcohol Analyst  
Recertification for Alcohol Analyst  
Certification for DUI Drug Analyst  
Recertification for DUI Drug Analyst

The laboratory shall have each analyst undergo one proficiency test in every discipline of testing that he/she is authorized to perform casework and/or perform technical review every calendar year.

The laboratory shall participate annually in, and successfully complete, at least one external proficiency test for each discipline in which it provides services. ANAB approved test providers shall be used where available. Whenever there is not an ANAB approved test provider, the laboratory shall locate and use a source of an external test in the discipline, if available. If a test is not available an observation based monitoring method may be utilized.

The laboratory shall maintain records of proficiency testing. After receiving the results of the proficiency test, the Supervisor and Quality Manager shall review the results of the proficiency tests with the analyst and fill out the laboratory's Proficiency Document (SharePoint). The Forensic Lab Director will sign off on the form after the review has been completed. After reviewing proficiency test results, if necessary, suitable corrective action will be taken as outlined in Section 8.7.1.

Any unexpected results on a proficiency test, including not identifying compounds because they are not included in the validated testing menu or compounds present in the sample below the



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established limit of detection, must be disclosed to ANAB. The records of proficiencies will be maintained for a minimum of one cycle of accreditation of ANAB or five years, whichever is longer.

## 7.8 Reporting of results

### 7.8.1 General

7.8.1.1 Results in the form of a Certificate of Analysis, and case records, are reviewed and authorized prior to release.

7.8.1.1.1 The authorizer of results (technical reviewer) shall review the technical record and document the review.

7.8.1.2 The results of each test or series of tests carried out by the FCS shall be reported accurately, clearly, unambiguously and objectively, and in accordance with applicable procedures incorporated in its manuals. All issued reports are retained as technical records.

A case will be considered “complete” when the report is written, the analyst’s signature is applied, and the report notarized.

7.8.1.2.1 The results shall be provided in a written report as a Certificate of Analysis.

7.8.1.2.2 A Certificate of Analysis (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
- When comparative examinations result in the elimination of a suspected individual or object, the report must clearly communicate the elimination



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7.8.1.3 When agreed with the customer, the results may be reported in a simplified manner. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer will be readily available.

7.8.1.3.1 When results are reported in a simplified way, the agreement with the customer shall specify which information in 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 (test, calibration or sampling)*

7.8.2.1 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 an identification in order 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) a statement 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 Certificate of Analysis 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 7.8.1.1)



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7.8.2.2 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*

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

- 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;
- Where appropriate, any additional information required by clients and information about compliance with any requirements (see 7.8.6);
- 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.
- opinions and interpretations where appropriate and needed (see 7.8.7);
- additional information which may be required by specific methods or customers.

7.8.3.1.1 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:



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- a) have objective evidence of the regulation, statute, case law or other legal requirement; and
- b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.

7.8.3.2 Where the laboratory is responsible for the sampling activity, test reports will meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

7.8.4 *FCS is not a calibration laboratory*

7.8.5 *Reporting sampling – specific requirements*

7.8.5.1 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 7.8.2, reports containing the results of sampling shall include the following:

- a reference to the sampling plan and procedure used;
  - o 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; and
- 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*

7.8.6.1 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.

7.8.6.2 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).





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## 7.8.7 Reporting opinions and interpretations

7.8.7.1 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 Certificate of Analysis and only personnel authorized for the expression of opinions and interpretations release the respective statement.

7.8.7.2 The opinions and interpretations expressed in reports must be based on the results obtained from the tested and shall be clearly stated in the Certificate of Analysis.

7.8.7.3 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

7.8.8.1 The policy of the FCS is to 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**

Revised / Amended Report will be issued when the information in the original issued was not correct, or when additional information is available. This may be from additional testing, a correction to, or addition of biographical information (DOB, defendant name etc).

Revised / Amended Certificates / Reports shall be stamped **“REVISED”**.

(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).

Revised / Amended reports which have only an administrative change will undergo Administrative Review only and the Revised / Amended Report Form (SharePoint) will be completed to reflect the nature of the revision 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.

If the Reason for revision involves re-analysis of the sample, the new work will be Technically and Administratively Reviewed, and the Revised / Amended Report Form (SharePoint) will be



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completed to reflect the nature of the revision / reason for re-analysis. 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**

### Re-Examination Report

A Re-Examination Report will be issued when, at the request of the client or due to the inability of the original examiner to testify, a case is re-analyzed in the same manner (protocol) as reported in the original report, or as near as possible to the original manner.

Certificates 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 will 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-examinations will undergo both Technical and Administrative review, before a report is issued.

## **Casefile Review Prior to Testimony/Reviewed Report for Testimony**

When testimony is required for a case, and the original analyst is not available to provide testimony, a second, certified and authorized analyst may review the entire folder, including all data associated with the results, and come to their own 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 Form Prior to Testimony, which shall undergo an administrative review prior to be sent to the customer. This report does not require technical review, as no new testing has been performed, and does not require a notary, as the report will not be admitted as evidence in of the analyst being present.



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## REPRINT Report

On occasion the original report that is signed, notarized and sent to the customer becomes lost. The customer requests a replacement report that bears an original notary seal (not a copy of the initial report). In this instance, a replacement copy of the original report is signed, notarized and sent to the customer. Technical and Administrative reviews are not required. The report is stamped 'REPRINT' to differentiate between the original report that has been lost. The addition of the stamp "REPRINT" is not separately initialed on the report, but rather the signature of the analyst shall serve as 'ownership' of the addition.

It is recognized that the 'Report Issued Date' of the REPRINT may differ slightly from the original report. This is caused by the case being 'signed out' of the Laboratory Information System after the initial report is created by the analyst. It is important to note, that the findings are the same between the reports.

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.

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

7.8.8.3 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 7.8.8.1)

## 7.9 Complaints

7.9.1 All complaints received from clients or complaints concerning the quality related aspects of the management system submitted by laboratory personnel shall be brought to the attention of the Chief of Laboratory Operations by forwarding one copy of the complaint. The resolutions/answers 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.



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The complainant will completely and concisely describe the situation or condition that he or she feels is unsatisfactory in a written format.

The Forensic Lab Director/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 Lab 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 or Forensic Lab Director will investigate the situation, condition or act that caused the complaint and will recommend to the Director a course of action, if necessary, to remediate as appropriate.

The Chief of Laboratory Operations or his designee shall maintain all documents, or copies thereof, pertaining to such complaints.

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

The Forensic Lab Director / 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, or 5 years, whichever is longer.

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 Lab Director shall notify the complainant of the actions taken. The completion date and notification date will be documented.

- 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



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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 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 As soon as any instance of testing or reports that do not conform to the policies detailed in this manual or the sectional procedures/QA-QC manuals, or an instance of procedures not achieving the desired objectives is discovered, an investigation will immediately be conducted. The type of correction used to address the nonconforming work will be depending on the significance or frequency of the nonconforming event. Corrections may range from an on the spot correction, for insignificant or infrequent occurrences, a correction stemming from completion of the Quality Issue Reporting form, or corrections resulting from the Corrective Action procedure, for significant or frequently occurrences. The procedure ensures that:

- the responsibilities and authorities for the management of nonconforming work are defined. An investigation will be conducted by the Forensic Lab Director or his/her designee about whether the nonconformance could have affected or is likely to affect other cases. During the investigation the Chief of Laboratory Operations will make a decision regarding stopping testing operations or removal of a chemist from testing, if so warranted.



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- corrective actions, if necessary, will be taken by the Forensic Lab Director or his/her designee as outlined in Section 8.7.1. Decisions will also be made about the acceptability of the nonconforming work;
- an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results. The investigation will initially be conducted by the Forensic Lab Director or his/her designee (as appropriate) and will focus on the seriousness of the nonconformance. (see 8.7.1b);
- a decision is taken on the acceptability of the nonconforming work. Correction(s) shall be prompt and appropriate given the acceptability of the nonconformity;
- where necessary, the customer and accrediting body shall be notified and work is recalled. In cases where the nonconformance is of a serious nature (it is likely to change the conclusions materially, or for a large number of cases) the client (Evidence Submitting Agencies, Maine Attorney General and District Attorney's Office) will be notified and, if applicable, the work recalled. The nonconformance will be brought to the attention of the Chief of Laboratory Operations;
- the authority to resume operations of the laboratory after closure or reinstatement of a chemist rests in the Chief of Laboratory Operations and may involve consultation with the Forensic Lab Director/Quality Manager.

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

7.10.3 The significance and frequency of the nonconforming work will be evaluated for each instance. If the evaluation deems the event to be significant, indicates the possibility of a recurrence of such nonconformity, or raises a doubt about compliance with the laboratory's policies and procedures, the corrective action procedure, as outlined in Section 8.7.1 of this manual, will be promptly followed.

## 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) 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



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with the instruments shall automatically undergo validation while validating the instruments. In cases of any major updates in software, the updates will undergo appropriate validations before being put to use.

7.11.2.1 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 laboratory information management system(s):

- is protected from unauthorized access by use of unique, individual log-ins on a restricted network. Confidentiality of the data entry will be governed by section 4.2 of this manual. The laboratory does not transmit raw electronic data;
- 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 laboratory information management system 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 laboratory information management system(s) 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.

## Details, Documents, References and Records

- The Laboratory Information Management System (LIMS) in used at DHHS is StarLIMS v. 11
- The Document Management Software used at HETL is SharePoint.



# Quality Manual

## 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, Standard Operations Procedures (SOP), Analytical Procedure Manuals (Solid Dose 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 (Option A)

- 8.2.1 Laboratory management has established and documented this quality manual. 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.
- 8.2.1.1 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 The management of the Maine Health and Environmental Testing Laboratory (HETL) is committed to good professional practices. As such, the HETL management will comply with ISO/IEC 17025. The objective of the Laboratory 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. An overall *Quality Policy Statement* has been issued within this Quality Manual under the authority of the FCS Director.

The **Quality Policy Statement** for our laboratory is as follows:

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





# Quality Manual

- 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 technology, in sufficient depth to enable them to carry out the provisions of this manual.
- To establish a baseline for the level of quality of the FCS's routine performance 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 laboratory staff concerned with forensic testing activities within the laboratory 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, fresh 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.



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- The laboratory shall participate in an external testing program as prescribed by ANAB, and any other accrediting organizations that the laboratory is, and will be, associated with.
- Management is committed to impartiality, good professional practice and quality of services provided to the customer. Tests are always performed in accordance with stated standardized methods and customers' requirements. Requests to perform tests that may jeopardize an objective result or have low 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 our 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 the HETL and the FCS 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 the employees in the FCS. Procedure Manuals of various sections contain analytical procedures as well as the QA/QC measures applicable only to those sections. The requirements in these manuals can only be more restrictive than those spelled out in the FCS Quality Manual.

Sections that have numerous and detailed QA/QC procedures applicable only to those sections may have separate sectional QA/QC manuals.



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

All sections 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 has access to the parts of the management system documentation and related information that are applicable to their responsibilities.

## Details, Documents, References and Records

- The effectiveness of the management system is assessed in several ways:
  - by a program of planned internal audits, covering all aspects of laboratory activities of the management system;
  - by regular management reviews of the suitability and effectiveness of the management system;
  - by analysis of potential and actual problems as shown by customer complaints and supplier and subcontractor assessments.
  
- The results of the management system that are regularly reviewed during management review (see section 8.9) and the implementation of improvements (see section 8.6) are evidence of management's commitment.

## 8.3 Control of management system documents (Option A)

- 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 Documents that are part of the management system of the FCS are:

Manuals / Procedures: Quality Manual, SOP's, Analytical Procedures, Training Manuals, etc



# Quality Manual

Internally generated manuals (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.

Copies of internally generated Controlled Documents and Forms (uncontrolled) shall be stored on SharePoint and have limited "write" access (make changes) and unlimited "read" access.

Note – documents are policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

## 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. Hand written 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, Original date of issue, date of latest approval (revision), and page number (current) with total number of pages.;
- For the convenience of the analysts, forms regularly used may be maintained in a central location in the respective sections. As soon as a form is discontinued or revised, copies of obsolete forms shall be removed by Forensic Lab Director or his/her designee. 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 Forensic Lab Director, Quality Manager, or Supervisor 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 Forensic Lab Director/ Quality Manager. The master lists show the current status of the controlled documents and forms, latest approval date, and title of the document within each section. NOTE: Equipment and software manuals maintained only for general reference purposes are not subject to document control requirements. In this context, "general



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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.

## Availability of Controlled Documents

All controlled documents and forms will be stored on SharePoint. A printed copy of any controlled manual or procedure will be deemed ‘uncontrolled’.

## Details, Documents, References and Records

- The Quality Manual is approved for adequacy by the FCS Director prior to issue and this record is maintained on file by the Quality Manager. The Quality Manual (including policies and quality policy statement) is reviewed on an annual basis during and updated as necessary. Changes to the Quality Manual are highlighted by summarizing on the last page of the Quality Manual under Revision History. The revision status is listed as the Revision Number (and Date of Revision) in the header of the Quality Manual. The Quality Manager oversees the distribution of controlled copies of the Quality Manual ensuring that the most current version is available. The Quality Manual is uniquely identified as the Quality Manual.
- Internally generated procedures and documents are peer-reviewed for adequacy and approved by the most appropriate level of management and/or supervision prior to issue. These procedures and documents are reviewed on an annual basis and the record of this review is maintained in SharePoint. Updated versions are produced as necessary and replace obsolete versions. The revision number in the header is updated accordingly. Changes to these procedures and documents are maintained in SharePoint. A unique code is generated for each procedure or document for identification.
- Page numbering and total number of pages has been used as a useful reference and process of checking for the completeness of the Quality Manual and procedures.
- Obsolete versions of the Quality Manual and procedures are maintained in an archive location for historical and legal purposes. Legislative guidance is followed when a retention period is applicable.
- Forms used for recording information are uniquely identified with a title. A date is used in the footer of the form for version control purposes.

## 8.4 Control of records (Option A)



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- 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) 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.

Examination results must be reviewed for technical accuracy and editorial correctness prior to their release to any external entity.

Employees will not release results, evidence, or the content of case files to any individual or entity that does not have the authority to possess the information. Persons with this authority are appropriate members of the HETL staff, the agency conducting the investigation, the agency submitting the evidence, the defense attorney representing the defendant\*, the Attorney General's Office, and the District Attorney's Office of the jurisdiction involved.

Results will be provided when the inquirer provides appropriate case information such as:

Name of Caller  
Contact phone number  
Name of Agency/Office  
Subject's Name  
Agency Case Number  
HETL Case Number



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Subject's DOB (for OUI incidents)

\*Results will not be released to a defense attorney until the subject/defendant has signed the Authorization for Release of Information form :

<http://www.maine.gov/dhhs/privacy/authorization-release.pdf> and the form returned to the FCS. This form will be retained in the specific case folder. When providing verbal results, due care should be taken to clearly explain the limitations (e.g. "preliminary indications are that..., but need to be confirmed"). Case evidence will not be released to the defense attorney, or another testing laboratory, without authorization from the investigating agency or the District Attorney's Office of the jurisdiction involved.

A log of all phone conversations will be kept regarding the dissemination of information/results. Refer to (SharePoint) for the Section's Phone Log document. Upon completion, the Phone Log will be placed in the appropriate case file.

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 DA's Office or have their attorney contact the FCS directly.

Copies of the contents of case files shall not be provided to anyone outside the FCS without a documented request. (SEE SOP Manual – Discovery Requests).

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 loss of original documentation. Removal of case files for testimony should be documented on the casefile sign-out sheet maintained by the evidence technician.

All "to be assigned" case folders are maintained in a file cabinet located in the evidence technician's office. This office will be locked when unoccupied.

All "in-process" folders will be maintained in a secure processing area or the analyst's desk.

All "post-processing" folders will be maintained in a secure processing area, the analyst's desk, the evidence technician's office, or the file storage room.

## 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



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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 State Records 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 one full cycle of accreditation or 5 previous years will be stored in the FCS Supervisor's office and then transferred to Maine State Archives for a period of 15 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 five years or one full cycle of accreditation with ANAB International. These records may be retained by the specific analyst, and/or the Forensic Lab Director / Quality Manager and then transferred to Maine State Archives for a period of 15 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.

Records are legible and are accessible to individuals on a need to know basis. For example, the Quality Manual is available to all the personnel via SharePoint. However, case folders are not accessible to anyone not authorized as stated above. 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. The calibration records are kept either near the instruments themselves, in a central location in each section, or in the case folder. Recent records of audits, proficiency evaluations, complaints, quality reviews, corrective actions, testimony evaluations, etc., shall be filed in the Forensic Lab Director or Quality Manager's cabinet, and/or published on SharePoint.

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 employees 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.





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The FCS staff are responsible for maintaining electronic back-up of instrument data. All analytical data collected on instrument computers will be backed-up to an 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.

## 8.5 Actions to address risks and opportunities (Option A)

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.

All personnel can suggest preventive actions for any potential nonconformity to the Forensic Lab 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



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- 8.5.1.1 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 form on Sharepoint. This form will help the laboratory assess any potential risks and opportunities in various areas and provide instructions for implementation of 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.

## Details, Documents, References and Records

- Management and laboratory personnel consider risks and opportunities for laboratory activities on a regular basis. Plans and actions are implemented under the guidance of the management system.
- A *Risk and Opportunity Review* is performed as an initial review and may be performed when significant changes occur to the management system and/or laboratory.
- Opportunities can lead to expanding the scope of laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

## 8.6 Improvement (Option A)

- 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 staff. Employees are encouraged to maintain vigilance in their observations and review of quality assurance related activities.
- 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.

## Details, Documents, References and Records

- 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.



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- Opportunities for improvement of operations and processes are identified by managers on a continual basis from ongoing feedback on operations, audits and through management reviews. Opportunities for improvement of services are identified by anyone within the organization.
- Inputs for improvement opportunities are obtained from the following sources:
  - customer satisfaction surveys and any other customer feedback;
  - employees, suppliers, and other interested parties;
  - internal and external audits of the management system;
  - records of service nonconformities.
- Opportunities for improvement may also be identified on a special project basis. The following are listed only as examples:
  - improving usefulness of bench space;
  - reducing excessive inspection/testing;
  - reducing excessive handling and storage;
  - reducing test failures.
- Opportunities for improvement from daily feedback on operational performance (i.e., internal audits, customer feedback, test /calibration failures) are evaluated by the Technical or Quality Manager.
- Service improvement opportunities are evaluated by management. They are implemented through the supervisor of the laboratory 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.

## 8.7 Corrective action (Option A)

8.7.1 When nonconformity occurs, an investigation will be conducted by the Forensic Lab Director, Quality Manager, or a designee about the significance of the nonconforming work and whether the nonconformance could have affected or is likely to affect other cases. As part of this investigation the laboratory shall:

- react to the nonconformity and, as applicable:
  - i. take action to control and correct it,
  - ii. address the consequences.
- evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - i. reviewing and analyzing the nonconformity,
  - ii. determining the causes of the nonconformity,
  - iii. determining if similar nonconformities exist, or could potentially occur.
- complete the Quality Issue Reporting form, if necessary;
- implement any corrective actions, if necessary;



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- periodically review the effectiveness of any prior corrective actions taken;
- updates risks and opportunities determined during planning, if necessary;
- makes changes to the management system, if necessary.

Events which shall initiate the completion of the Quality Issue Reporting form and a root cause investigation include:

- When Quality Control criteria are consistently not being met
- When laboratory SOP's are consistently not followed
- When proficiency test results do not meet expected results
- When concern that a major problem or potential problem exists in the laboratory

The analyst generating the data is responsible for reviewing all results against the established limits. Any non-conforming work is immediately evaluated as potential out-of-control events. Examples of some out-of-control events may be: Laboratory Control Sample failures, blank contamination, poor precision, preparation errors, calibration failures, and matrix spike failures, etc. If data is outside accepted limits, the analyst should review and evaluate the data and all associated Quality Control elements together before making a decision as to the acceptability of the data. Once all QC items have been considered, the analyst should immediately take the appropriate actions if a potential out-of-control event is suspected.

When departures or non-conforming work from the management system have been identified, the analysis of samples affected by the event shall be stopped and the reason for the non-conformance investigated, resolved and documented.

Upon discovery of an error or non-compliance, the Forensic Director/ Quality Manager (or designee) will begin an investigation to determine the source, frequency, and significance of the error. The significance matrix below can be utilized to assist with this determination.



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|                         |        |                                    |                                    |                                    |
|-------------------------|--------|------------------------------------|------------------------------------|------------------------------------|
| Potential Impact/Risk   | High   | Quality Issue Reporting Form & CAR | Quality Issue Reporting Form & CAR | Quality Issue Reporting Form & CAR |
|                         | Medium | Quality Issue Reporting Form       | Quality Issue Reporting Form       | Quality Issue Reporting Form & CAR |
|                         | Low    | Correction                         | Correction                         | Quality Issue Reporting Form       |
|                         |        | Low                                | Medium                             | High                               |
| Frequency of Occurrence |        |                                    |                                    |                                    |

If the nonconforming work is deemed to be frequent or significant enough the Quality Issue Reporting Form shall be completed and a cause analysis performed. During the root cause investigation, the Forensic Laboratory Director will make a decision regarding stopping testing operations or removal of a chemist from testing, if so warranted. The root cause investigation shall be evaluated by the Forensic Lab Director or Quality Manager to determine the need for a corrective action.

Instances that affect the quality of the laboratory’s ability to comply with set procedures or ISO/IEC 17025 will necessitate root cause investigation as soon as possible to identify and rectify the nonconformance.

If the root cause investigation results in a corrective action, the following procedures are to be followed by the Forensic Lab Director/Quality Manager. Once a CAR has occurred, the risks and opportunities to the laboratory will be evaluated and recorded on the corrective action form. Corrective actions will be reviewed during annual management review and assessed for effectiveness at least annually.

### Corrective Action Procedure General

The Laboratory policy is that a corrective action shall be implemented when a root cause investigation determines significant nonconforming work (departures from policies and procedures) in the quality management system or technical operations rises to the level of a corrective action.



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The corrective action will be documented on the Corrective Action Form (SharePoint). The completed form will be sent to the Quality Manager. The Quality Manager is responsible for the efficiency of the quality program. Every corrective action must be completed as soon as possible from the date the quality issue was reported. The Quality Manager will keep the Chief of Laboratory Operations apprised of corrective action issues.

The purpose of this section is to detail the protocol for Corrective Actions. Problem identification, corrective actions, and resolutions are tracked via Quality Issue Reporting Forms and Corrective Action Reports (CARs). All corrective actions, when significant nonconforming work or departures from the policies and procedures in the management system or technical operations are discovered, or significant instances of procedures not achieving the desired objectives have been identified, shall be undertaken generally by the Forensic Lab Director/Quality Manager upon completion of the Quality Issue Reporting Form and root cause investigation. If the Forensic Lab Director / Quality Manager is involved in the Corrective Action, the Chief of Laboratory Operations shall step in to oversee the root cause investigation and corrective action. Problems with the management system or technical operations of the FCS may be identified through a variety of activities such as: internal or external audits, management reviews, feedback from clients, staff complaints about quality, reviews of cases, proficiencies, etc.

The underlying purpose of the corrective action process is to identify significant instances that may adversely affect the data. Corrective actions also help:

- To standardize the laboratory's procedure for handling events requiring corrective action. Every situation should be evaluated individually, but there are some basic guidelines that should be followed.
- To record actions taken when SOPs are not followed so that the data produced is supported with a documented sequence of events.
- To document occurrences in the lab that may affect the integrity of laboratory results.
- To provide a learning tool for individuals involved in the problem investigation and corrective action plan
- To provide a means for tracking recurring problems that may need further investigation into the root cause of the problem

## Root Cause Analysis

All employees have the ability to initiate a request for a potential corrective action by filling out



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the Quality Issue Reporting Form (SharePoint) and submitting it to the Forensic Lab Director/Quality Manager.

All problems or errors are to be evaluated as to their causes, by the Forensic Lab Director/Quality Manager, and a corrective action is initiated if required. An initial evaluation of the significance/class of the error, detailed below, should be made prior to the root cause investigation. Upon submission of the Quality Issue Reporting Form, or the identification of non-conforming work through another means, a root cause investigation will begin by the Forensic Lab Director/Quality Manager. The causes of problems could include client requirements, the selection of items analyzed, lack of communication with the client, methods and procedures, personnel skills and training, consumable materials, or equipment and its calibration. During the root cause investigation, the Forensic Laboratory Director will make a decision regarding stopping testing operations or removal of a chemist from testing, if so warranted.

The root cause analysis starts by determining the nature of the error:

- **Analytical/System/Environmental Errors**
  - The method(s) is to be discontinued until the cause of the error is established.
- **Operator/Equipment/Material Errors**
  - The cause of the error is to be determined.
  - Similar analytical work performed by the analyst, or performed using the suspected equipment/material will be reviewed. This review shall consist of checking an appropriate number of similar cases performed prior and subsequent to the discovery of the error.
- **Clerical/External/Customer Requirement Error**
  - The cause/type of the error will be determined. The supervisor will determine if any procedural changes are necessary to prevent further errors of this type.

After the error is classified, the Forensic Director/Quality Manager will continue the investigation until the root cause has been determined and the Quality Issue Reporting Form has been completed. Upon completion of the root cause evaluation, it will be determined if a corrective action is required and, if so, the non-conforming work shall be classified as Class I, Class II or Class III, which are detailed below.

## Classification of Corrective Actions



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Upon submission of the Quality Issue Reporting Form, or the identification of non-conforming work through another means, a root cause investigation will begin by the Forensic Lab Director/Quality Manager. If the root cause investigation has determined a corrective action is required, Forensic Lab Director/Quality Manager will begin by filling out the Corrective Action Form on Sharepoint and classify the non-conforming work/CAR into one of three classes with the respective corrective actions:

|                        |        |           |          |          |
|------------------------|--------|-----------|----------|----------|
| Potential Impact/Risk  | High   | Class I   | Class I  | Class I  |
|                        | Medium | Class II  | Class II | Class I  |
|                        | Low    | Class III | Class II | Class II |
|                        |        | Low       | Medium   | High     |
| Frequency of Occurance |        |           |          |          |

- Class I - The nature and cause of the inconsistency raises immediate concern regarding the quality of the laboratory work product. The Chief of Laboratory Operations will be notified for all Level I CARs.

Examples of a Class I inconsistency may include an erroneous identification, false identification or false positive. Corrective action taken as a result of a Class I inconsistency must include analysis of another (new) set of comparable samples by the person(s) responsible for the inconsistency and a review of comparable casework.

The Chief of Laboratory Operations must be notified upon the discovery of a significant error (i.e. Class I Error). At which time the Chief of Laboratory Operations will form a Corrective Action Committee, consisting of the Chief of Laboratory Operations, the Forensic Lab Director, Quality Manager, and a staff member from another area of the Health and Environmental Testing Laboratory with subject matter expertise. The Committee will investigate the Root Cause, Recommend Corrective Actions and determine what, if any, retrospective investigation will be conducted.

Analytical work using this method(s) prior to the date of the discovery of the error will be reviewed to determine the validity of the work reported. Prior to re-implementation of





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casework, appropriately assigned analysts will conduct any testing requested by the Corrective Action Committee and/or the Quality Manager. These tests will then be reviewed and discussed with the Forensic Lab Director/Quality Manager. The supervisor will determine if additional training or re-training is required for the particular problem. The Chief of Laboratory Operations will be apprised of the cause or causes found and the steps taken to correct the problem.

- Class II - The inconsistency is due to a problem which may affect the quality of the work but is not significant or frequent enough to cause immediate concern for the overall quality of the laboratory's work product.

Examples of a Class II inconsistency may include a missed identification (failure to identify) or a false negative. Corrective action taken as a result of a Class II inconsistency may include a review of comparable casework and may include analysis of another (new) set of comparable samples by the person(s) responsible for the inconsistency.

- Class III - The inconsistency is determined to have minimal effect or significance, has a low potential for reoccurrence, is not systematic, and does not significantly affect the fundamental reliability of the laboratory's work.

An example of a Class III inconsistency may include an administrative or transcription mistake. Corrective action taken as a result of a Class III inconsistency may include individual counseling regarding acceptable procedures or may be addressed by the Forensic Lab Director or Quality Manager, and may be documented in the case record or the personnel file of the analyst.

## Selection and Implementation of Corrective Actions

When corrective action is needed the solution most likely to eliminate the problem and prevent recurrence shall be selected and implemented. The appropriate action may differ with each situation. In some instances, data may be reported, but in others, case work may need to be recalled, and samples re-examined. The process for corrective action shall establish a reasonable timeframe for completion for each corrective action.

Corrective actions shall be appropriate to the magnitude and risk of the problem.

When the control of the testing returns within acceptable limits as set by the manufacturer, SOP or policy, the corrective action is complete and is documented on the Corrective Action Form. After the review of this documentation, the Quality Manager approves or, if unresolved, suspends the resumption of sample analysis until satisfactory corrective action indicates the analysis is again in conformance.



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All required changes resulting from corrective actions shall be documented and implemented by the Forensic Lab Director / Quality Manager and shall be communicated to the analysts.

In cases where the corrective action is of a serious nature (it is likely to change the conclusions materially, or for a large number of cases) the client (Evidence Submitting Agencies, Maine Attorney General and District Attorney's Office) will be notified and, if applicable, the work recalled. The nonconformance will be brought to the attention of the Chief of Laboratory Operations.

## Monitoring of corrective actions

The Forensic Lab Director/Quality Manager, to help ensure the same nonconformance does not occur again, shall monitor the results of corrective actions. Verification and Close Out of corrective actions will be performed after a sufficient amount of time has passed to ensure the correction was appropriate and had the desired effect. The results of corrective actions shall be monitored during the subsequent internal audits, by looking into previous corrective actions. The laboratory will also re-evaluate the risks and opportunities associated with the corrective action and determine what effect it could have for the FCS and management system.

Historical corrective action reports may be reviewed to identify long-term trends or recurring problems. The root cause of the problem shall be identified if long term trends or a reoccurrence has been identified during review. All documentation associated with the CAR, i.e. raw data or reissued reports shall retained either directly in case folder/file (i.e., Revised Report) or with the Forensic Lab Director / Quality Manager.

## Additional Audits

Where the identification of a nonconformance or departures of a serious nature is discovered that casts doubts on the laboratory's compliance with its own policies and procedures or on its compliance with ISO/IEC 17025, the laboratory will ensure that the appropriate areas of activity are audited in accordance with 8.8.1 as soon as possible. The implementation and effectiveness of the corrective actions taken as a result of an internal audit will be checked during the next internal audit. If there is a recurrence of the same problem(s) in spite of corrective actions, it may be that the corrective action was ineffective. Further corrective actions may be needed in such cases.

8.7.2 Corrective actions are appropriate to the effects of the nonconformities encountered and outlined in 8.7.1.

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



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- the results of any corrective action.

## 8.8 Internal audits (Option A)

8.8.1 This section describes the conduct of Operations Audit. A system 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, as described in the several sections of this manual.

This audit is an internal audit (conducted from inside the organization). 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:
  - i. the requirements of this quality manual and laboratory activities,
  - ii. the requirements of appropriate international standards such as ISO/IEC 17025.
- is effectively implemented and maintained.

8.8.1.1 Internal audits shall provide information on whether the management system conforms to the requirements of this document.

Internal audits shall be conducted at least annually, as well as prior to the initial accreditation assessment.

8.8.2 Internal audits will be conducted at least once every calendar year, typically within the first quarter of that calendar year, to ensure continued compliance with the Management System and ISO/IEC 17025. This audit will address all elements of the management system, including testing activities. See SharePoint for Audit Checklist used to document compliance / non-compliance.

The Quality Manager will be responsible for planning, scheduling, and organizing internal audits.

The Quality Manager will be responsible for arranging for the conduct of Quality System Audits. The audit will be carried out by the Forensic Lab Director / Quality Manager, and/or their designee.

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

- Notification of the dates and times of the planned audit



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- 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

To audit casework, a certain number of cases from each section 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 Procedure Manual of that section, as well as the Quality Manual.

Any analyst authorized to perform Internal Audits may be assigned to participate in the annual audit. If staffing levels allow, each section 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.

A report will be presented by the Forensic Lab Director and Quality Manager to the Chief of Laboratory Operations as part of the Management Review.

The Forensic Lab Director or Quality Manager will prepare a report giving a plan of action to correct the deficiencies found in the audit. The report will be sent to the Chief of Laboratory Operations within one month of completion.

The Quality Manager will ensure that the corrective actions are implemented within the time limits proposed by the section itself.

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 clients that have been, or are likely to be affected.



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

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

## Details, Documents, References and Records

- All elements of this Quality Manual will be audited each year and all relevant laboratory records are available to personnel conducting the audit. These audits are performed to verify operations continue to comply with the requirements of this Quality Manual and are effective.
- It is the responsibility of the Quality Manager to plan and organize audits as required by the schedule and requested by management. Audits are performed by trained and qualified personnel who are independent of the activity to be audited. Personnel are not to audit their own activities except when it can be demonstrated that an effective audit will be carried out. Audits are performed through the aid of a checklist prepared in advance to minimize the possibility of overlooking any details during the audit.
- When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the test or calibration results, timely corrective action is taken and customers are notified if investigations show that laboratory results may have been affected.
- Nonconformities that can be resolved easily are to be corrected immediately, ideally during the audit. Records are made on the audit checklist. Nonconformities that require a more involved resolution are recorded through the corrective action system and resolved as described in section 8.7.
- Corrective actions and customer modifications must be kept on record for each audit finding that casts doubt as described in this section.
- Records are made of the activity being audited, the audit findings and corrective actions that arise. Management ensures that corrective actions are discharged within an appropriate and agreed timeline.
- The appropriate manager is responsible for ensuring that corrective actions are sufficiently recorded. Follow-up is performed by the auditor and recorded when corrective action is complete and deemed effective. The audit records are kept in the laboratory.

## 8.9 Management reviews (Option A)



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- 8.9.1 Management review of the Management System and the testing activity at the FCS will be conducted at least once every calendar year, and prior to the initial accreditation assessment, to ensure their continued suitability and effectiveness. The Forensic Lab Director / 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 least the following points:
- 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 reviews for at least one ANAB cycle of accreditation or five (5) years, whichever is longer. The actions that arise out of the management review will be carried out as early as possible and necessary. The Quality Manager will also maintain the records of such actions.



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## 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<br>Section 5.5 b) added reference to section 5.6<br>Section 5.6 Evidence Technician was added<br>Section 6.4.1 included reviewing the COA as a method to verify a CRM<br>Section 6.4.11 was edited to remove a redundancy<br>Section 7.2.2.1 – Major Modification was edited to remove the word “can” in the last sentence<br>Section 7.5.1.6 was edited to reflect the correct standard<br>Section 7.6.3.1 Blood Drug Determination was removed until the method validation is completed and online<br>Section 8.2.1.1 was added<br>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 reevaluated.<br>Section 6.4.7 added quantitative pipettes will be checked quarterly in-house.<br>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.  |



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| 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 <b>Certification for Alcohol Analyst</b> section a closing “ was added. Under <b>Recertification for DUI Analyst</b> blood was added as a sample type.<br><br>Section 7.6.3.1 Blood Drug Determination was added.<br><br>Section 7.7.7 frequency of proficiency testing was changed to once a year for urine drug and blood drug<br><br>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.<br><br>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 | <ul style="list-style-type: none"> <li>- Updated Chief of Operations name</li> <li>- Minor grammar and punctuation corrections</li> <li>- 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</li> <li>- 6.3.2 Humidity monitoring and calibrated thermometers were added</li> <li>- 6.3.4.1 and 6.4.7 B16 PIN Key Pad and surveillance cameras added</li> <li>- 7.7.5 and 7.7.7 the number of rounds per year was added</li> <li>- 7.7.8 was expanded and pass/fail criteria were added</li> <li>- 6.2.3.2 and 7.7.1 updated to state technical reviewers must have been previously certified and authorized to perform testing</li> </ul> |





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| 14 | 04/12/2022 | <ul style="list-style-type: none"> <li>- Updated Chief of Operations title, removed acting</li> <li>- Updated Evidence Technician’s Office location</li> <li>- Spelling and grammar</li> <li>- Added Safety Officer/CHO could be contracted to external agency</li> <li>- Added specific DHHS Rule Chapters</li> <li>- Clarified that Building Control provides access to keys</li> <li>- 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</li> <li>- 7.1.4 Added guidance for minor discrepancies</li> <li>- 7.4.1.1 – guidance for evidence submitted without a proper seal. Updated SDD retention of evidence.</li> <li>- 7.4.4 updated to include food evidence storage</li> <li>- 7.5.1.2 added language relating to common abbreviations</li> </ul>   |
| 15 | 02/14/2023 | <ul style="list-style-type: none"> <li>- Ownership of temperature forms changed to a HETL QA officer instead of the Safety Officer</li> <li>- Technical lead references removed and changed to Section Supervisor or designee</li> <li>- 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 completed 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.</li> <li>- 7.7.5 updated to require an annual PT for anyone performing technical review in a specific discipline</li> <li>- Emergency contact information updated to reference new door signs posted on each room.</li> <li>- 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.</li> <li>- 7.9.1 updated to clarify who is involved with the complaint tracking process.</li> <li>- 7.8.8.1 – Casefile Review Prior to Testimony section added</li> <li>- 8.8.2 updated to include the timing of the audit annually and audit assignments per discipline.</li> <li>- Section 4 Details, Documents, References and Records: post-mortem added, and HETL mission statement added</li> <li>- 6.4.3 reference to SOP manual for DEA controlled substance reference material handling.</li> </ul> |



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|    |           | <ul style="list-style-type: none"> <li>- 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.</li> <li>- 5.2 updated roles and responsibilities</li> <li>- 5.5 added RadChem to list of sections at HETL</li> <li>- 7.1.1 updated to allow analyst to determine appropriate test selection and communicate test method on report. Changed to customers <i>may</i> be contacted to determine type of analysis needed.</li> <li>- 7.5.1 – removed copies of reference library spectra from what is included in a urine drug case following method validation update</li> <li>- 7.7.3 – added results to be reviewed with the supervisor and analyst</li> <li>- 7.7.8 removed “blood” from quantitative alcohol proficiency test evaluation</li> <li>- 7.6.3.1 removed “blood” from alcohol determination</li> <li>- 5.4.1 included the use of the symbol and mentions to being accredited in the standard.</li> <li>- 6.3.4.1 – updated to include law enforcement visitor badges assigned to visitors for evidence drop off</li> <li>- 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</li> <li>- 6.6.2 c- added “or a reference to results” and approval for the reagent sheet bullet</li> <li>- Address and room numbers updated throughout following move.</li> <li>- Grammar, spelling, and formatting updated throughout.</li> <li>- Removed PIN pad and camera mention for evidence room. Have yet to be installed in Greenlaw building.</li> </ul> |
| 16 | 7/10/2023 | <ul style="list-style-type: none"> <li>- Section 2 last sentence removed</li> <li>- 4.1.4 Quote removed</li> <li>- 4.2.4 added verbal results may be given, expanded on requirements for the defense to view any evidence</li> <li>- 5.2 Chemist III removed designating technical responsibility for each discipline/category of testing</li> <li>- 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.”</li> <li>- 6.2.3 reworded for clarity, added examples of continuing education for ongoing training opportunities</li> <li>- 6.2.3.1 added examples for written exam material</li> <li>- 6.2.3.2 and 6.2.5 added technical review must continue to participate in annual PT for discipline</li> <li>- 6.2.6 reworded for clarity: authorizer of results is the technical reviewer; authorizer of reports is the administrative reviewer and the notary public.</li> <li>- 6.3.2 added evidence storage to areas that are monitored</li> </ul>  |



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|    |         | <ul style="list-style-type: none"> <li>- 6.3.4.1 expanded on information regarding emergency access, notifications, and camera monitoring</li> <li>- 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.</li> <li>- 6.4.7 added evidence storage areas</li> <li>- 6.4.10 updated in relation to the procedure required for performance checks</li> <li>- 7.2.2.1 updated to clarify that a tune does not qualify as a change in detection parameters, elaborated on examples.</li> <li>- 7.8.1.1.1 clarified who is considered the authorizer of results</li> <li>- 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.</li> </ul>   |
| 17 | 29Dec23 | <ul style="list-style-type: none"> <li>- Quality Manager review/approval added throughout as an option where Forensic Lab Director was referenced, where appropriate</li> <li>- Temperature control chart being controlled by HETL QA Officer removed, chart is now maintained by Forensic section</li> <li>- Knox box access expanded to include authorized individuals</li> <li>- 7.1.3 added the weight of drug being over specific statutory limit</li> <li>- 7.1.6 revised</li> <li>- 7.1.7 removed the option to monitor testing and revised to allowing access to tour the lab and discuss testing</li> <li>- 7.2.1.5 updated to state validation records will be maintained, but not in the current section performing testing</li> <li>- 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 <math>\pm 20\%</math> 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.</li> <li>- 7.10.1 updated to include notification to accrediting body if work is recalled</li> <li>- 8.3.2 Supervisor added to those able to review and approve documents and forms</li> </ul> |