FSL Quality Assurance Manual

DISTRICT OF COLUMBIA DEPARTMENT OF FORENSIC SCIENCES
FORENSIC SCIENCE LABORATORY
QUALITY ASSURANCE MANUAL (ISO/IEC 17025:2017 STANDARDS)

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INTRODUCTION

Quality performance, conforming to recognized standards of good laboratory practice, is the most important goal of the Forensic Science Laboratory (FSL) within the D.C. Department of Forensic Sciences (DFS). As new and improved methods of forensic analysis are developed to meet the expanding needs of the criminal justice system, it is essential for laboratory quality standards to progress in parallel. The FSL is committed to diligently implementing policy and procedure changes to ensure quality in all facets of laboratory operations.

The FSL quality system, represented by the DFS Departmental Operations Manual (DOM), departmental policies, the Quality Assurance Manuals (QAMs) and the Laboratory Operations Manuals (LOMs), provides mechanisms for identifying and implementing the practices that support excellent performance. All units within the FSL are responsible for the incorporation of quality practices and procedures consistent with the requirements of the quality system into daily unit functions.

All FSL employees share in the responsibility for adherence to the established quality measures as well as the overall success of the quality program.

The continued development and improvement of the FSL quality system serves to increase confidence in the resulting work product while strengthening the professional integrity of the FSL and its employees. Through the use of recognized quality practices and procedures, the FSL will continue to produce high quality work and meet the challenges of future laboratory accreditations.

SCOPE

The purpose of the FSL's quality management system is to ensure quality forensic services are provided to the District of Columbia's Criminal Justice System. This quality assurance manual contains or references the policies, practices and procedures of the FSL quality system that ensure technical competence and valid forensic examination results. The QAM, DOMs, and LOMs facilitate achieving this goal and meeting the ISO/IEC 17025:2017 Accreditation requirements.

Accreditation requirements are based on the International Organization for Standardization/International Electrotechnical Commission International Standard 17025 General Requirements for the Competence of Calibration and Testing Laboratories (ISO/IEC 17025:2017), applicable requirements from the International Laboratory Accreditation Cooperation (ILAC), and any supplemental requirements of the agency's accrediting body. The combined requirements of ISO/IEC 17025:2017 and any Supplemental Requirements are hereafter referred to as ISO/IEC 17025:2017. The QAM, DOMs and LOMs also facilitate internal and external audits of the quality system to evaluate the FSL's conformance with ISO/IEC 17025:2017 standards.

GOALS AND OBJECTIVES

It is the objective of the FSL to provide meaningful, timely and effective forensic analysis and interpretation of evidentiary materials when requested by the District of Columbia's Criminal Justice System. In order to meet this objective, the following specific goals have been established:

1. An ongoing dialogue with the law enforcement and legal communities regarding services provided by the FSL. This includes maintaining open lines of communication on active casework as well as the transmittal of policies, procedures and new forensic technology which impact evidence processing and analysis.

2. A case prioritization system which takes into account the needs of the District of Columbia's Criminal Justice System. It is the intent of the FSL to meet court and investigative time frames regarding the processing of evidentiary items. The analysis of specific items will be given priority when needed to answer particular legal or investigative issues.

3. The management and staff commit to providing a work product which is unbiased, scientifically objective and responsive to the needs of the District of Columbia's Criminal Justice System. To this end, each staff member will undergo training and demonstrate competency specific to any analysis before engaging in casework. It is incumbent upon each staff member to maintain currency in the specific forensic disciplines within which s/he is working. Each case will undergo a review process before a report is issued. Proficiency will be demonstrated on an ongoing basis by all analysts through a series of proficiency tests.

4. All personnel work to maintain an integrated approach to the evaluation of case material. To this end, a cooperative spirit and working environment will be maintained between each discipline and unit of the laboratory. The laboratory management will seek to provide a harmonious working environment where a healthy exchange of forensic information is shared amongst all staff members. Frequent staff meetings and technical exchange of information will be encouraged. Each staff member will cooperate in maintaining a safe and secure work environment for themselves and others.

QUALITY TERMINOLOGY

Accreditation: A process by which an authoritative body gives formal recognition that an entity is competent to carry out specific tasks.

Adequate: The principle of being sufficient for a specific requirement.

Administrative documentation: All case related documents that are not technical examination documentation, such as the Case Activities Log documenting case related conversations, test item (evidence) chain of custody receipts, submission paperwork / incident reports, service request documentation, correspondence received/sent, the Administrative Review Checklist and other pertinent information.

Administrative review: A procedure used to check case file documentation and case reports for consistency with laboratory policy and for editorial correctness.

Administrative reviewer: The Unit Manager, designated Technical Leader or qualified designee who conducts an administrative review.

Analysis (Latent Fingerprint Unit): The first step of the ACE-V methodology for fingerprint examinations. The assessment of a friction ridge impression to determine suitability for comparison.

Analyst: An employee or contract employee who conducts and/or directs the analysis of forensic casework samples. Some analysts also interpret data and reach conclusions. Used interchangeably with the term “examiner”.

ANSI-ASQ National Accreditation Board (ANAB): The signatory of the International Accreditation Forum (IAF) multilateral recognition arrangements for quality management systems and environmental management systems; One of two brands of the ANSI- ASQ National Accreditation Board, a non-profit, non-governmental organization that provides accreditation services to public- and private-sector organizations and is jointly owned by the American National Standards Institute (ANSI) and the American Society for Quality (ASQ). ANAB provides ISO/IEC 17025 accreditation for forensic testing laboratories.

Approved Test Provider: A proficiency test provider that has complied with the test manufacturing guidelines established by an accrediting body’s Proficiency Review Committees.

Assessment: A review conducted to compare the various aspects of the laboratory’s quality system with criteria for that performance. Also referred to as an audit.

Association: A determination that a relationship exists between individuals and/or objects.

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/IEC 17025:2017). Also referred to as an assessment.

Best Evidence: A forensic copy (image) of the original evidence that is stored, documented and treated as evidence.

BIPM: The International Bureau of Weights and Measures. An intergovernmental organization through which Member States act on matters related to measurement science and measurement standards.

Calibration: The adjusting or standardizing of any instrument and/or equipment to ensure agreement with a reference standard or working standard of known value.

Case Documentation: All administrative and technical examination documentation for a given case.

Case File: Files containing administrative and technical examination documentation generated or received by a laboratory pertaining to a particular case.

Casework: Laboratory activities concerning the examination of evidence and/or crime scenes.

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

Characteristics: Distinctive details of the friction ridges, including Level 1, 2, and 3 details.

CIPM: The International Committee for Weights and Measures

Comparison: The examination of two or more items, such as cartridges cases or bullets; DNA profiles, or latent impressions to determine whether or not there are any similarities or dissimilarities.

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

Competent: Possessing the requisite knowledge, skills and abilities to perform a job.

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.

Contributor: Law enforcement agencies that submit evidence to the laboratory.

Contract: The agreement between the forensic service provider and the customer. A fee for service is not required.

Control (control sample): A sample analyzed in parallel with experimental samples that is designed to demonstrate that a procedure worked correctly; a standard of comparison for verifying or checking the results of an experiment.

Controlled document: A document that is tracked when issued and/or distributed.

Crime scene: An area, object or person, from which evidence is identified, documented, collected and/or interpreted.

Critical reagent: A reagent that requires special attention because of the impact of the reagent on the quality of testing. Failure of the reagent due to improper preparation or degradation would affect the testing process.

Custody: The care and control of an item implying responsibility for its protection and preservation.

Customer: A person 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.

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

DFS: Department of Forensic Sciences, Washington D.C.

Director: The highest ranking manager.

Discipline: A major area of activity in forensic science.

Discrepancy: Being at variance or different from the accepted consensus.

Document: Information in any medium including, but not limited to, paper copy, computer disk or tape, audio or video tape, electronic file, compact or digital video disc, photograph, overhead, or photographic slide.

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.

DOM: Departmental Operations Manual.

Environmental conditions: Any characteristic of the facilities that could reasonably be expected to impact the quality of the laboratory's work product.

Evaluation (Latent Fingerprint Unit): The determination of a conclusion based upon completion of the analysis and comparison of friction ridge impressions.
Evidence: An item submitted for examination(s).

Examination: An analysis of an item or comparison of items; the procedure utilized by the laboratory analyst to obtain information from evidence in order to reach conclusions concerning the nature of and/or associations related to evidence received by the laboratory. The term examination is equivalent to the term "test" as used in this manual.

Examination documentation: Documents that are technical in nature and support the results and/or conclusions presented in a laboratory report. Examples of documents include diagrams, printouts, photographs, observations, and results of examinations.

Examiner: An employee or contract employee who conducts and/or directs the analysis of forensic casework samples. Some examiners also interpret data and reach conclusions. Used interchangeably with the term "analyst".

Exclusion: The determination by an analyst that there is sufficient quality and quantity of detail / information to conclude the questioned samples being compared did not originate from the same source (i.e., non-identification / exclusion).

External proficiency test: A test provided by a source external to the laboratory.

Firearms Examination Unit (FEU): An operational unit of the Forensic Science Laboratory.

Forensic Biology Unit (FBU): An operational unit of the Forensic Science Laboratory.

Forensic Science: The application of scientific knowledge and methodology to legal problems and criminal investigations.

Forensic Science Laboratory (FSL): A division under the DFS, alongside the Public Health Laboratory and the division of Crime Scene Sciences, responsible for processing forensic evidence.

Friction Ridge: Raised portion of the epidermis on the palmar or plantar skin. One or more connected ridge units of friction ridge skin.

Goal: A statement of purpose that defines the mission of an organization.

IBIS: Integrated Ballistics Identification system that allows for the comparison of digital images of bullets, cartridges, etc. from firearms between laboratories across the nation. The system is managed by the Walsh group and owned by the Bureau of Alcohol, Tobacco, Firearms and Explosives per IBIS User's Manual (IBIS Heritage 3.4.8 2009).

Identification (Firearms): Agreement of a combination of individual characteristics and all discernible class characteristics where the extent of agreement exceeds that which can occur in the comparison of tool marks made by different tools and is consistent with the agreement demonstrated by tool marks known to have been produced by the same tool (AFTE glossary 6th Edition).

Identification (Latent Prints): The decision by an examiner that there are sufficient discrimination friction ridge features in agreement to conclude that two areas of friction ridge impressions originated from the same source. Identifications of an impression to one source is the decision that the likelihood the impression was made by another (different) source is so remote that it is considered as a practical impossibility.

ILAC: The International Laboratory Accreditation Cooperation is an international organization for accreditation bodies that are involved with accreditation of conformity assessment bodies including calibration laboratories using ISO/IEC 17025.

Impression: Transferred impression of friction ridge detail; generic term used for questioned friction ridge detail.

Impartiality: Principle of justice holding that decisions shall be based on objective criteria and not the basis of bias, prejudice, or preferential treatment.

Inconclusive (Firearms):

A. Some agreement of individual characteristics and all discernible class characteristics, but insufficient for an "Identification".
B. Agreement of all discernible class characteristics without agreement or disagreement of individual characteristics due to an absence, insufficiency, or lack of reproducibility.

C. Agreement of all discernible class characteristics, but insufficient disagreement for an "Elimination".

Inconclusive (Latent): The determination by an examiner that there is neither sufficient agreement to render a conclusion of identification, nor sufficient disagreement to render a conclusion of exclusion.

Inconclusive (Forensic Biology): There is not enough data to support an inclusion or exclusion.

Individual characteristic database: A computerized, searchable collection of features, generated from samples of known origin from which individual characteristic information originates (e.g., DNA profiles, friction ridge data, or firearm bullet/cartridge case images).

Internal proficiency test: Proficiency testing program managed and controlled within the laboratory system.

Interlaboratory comparison: Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories.

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 one or more of the following activities: testing; calibration; sampling associated with subsequent testing or calibration.

Laboratory Director: The highest ranking manager within the FSL.

Latent Fingerprint Unit (LFU): An operational unit of the Forensic Science Laboratory.

Latent Print: Transferred impression of friction ridge detail not readily visible; generic term used for questioned friction ridge detail.

LIMS: Laboratory Information Management System. The electronic system DFS uses to track evidence chain of custody, requests for testing, communications and data.

LOM: Laboratory Operations Manual; specific to each division.

Major deviation: A deviation that has the potential to impact the quality system, may affect multiple cases, or is applicable over an extended period of time.

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 operating an organizational unit or program.

May: A word used when an element of the quality system is optional or discretionary.

Measurement of uncertainty: A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed.

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

Minor deviation: A deviation that is not expected to impact the quality system and generally will not have an extended duration.

Must: A word used when an element of the quality system is required.

National Measurement Standards: May be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute such as the National Institute of Standards and Technology (NIST).

Natural science: Chemistry, biology and physics.

NIBIN: The National Integrated Ballistics Information Network computer imaging system that allows for the comparison of digital images of bullets, cartridges, etc. from firearms between laboratories across the nation. The system is managed by the Walsh group and owned by the Bureau of Alcohol, Tobacco, Firearms and Explosives per IBIS User's Manual (IBIS Heritage 3.4.8 2009).

Nonconformity: A situation or condition that does not adhere to policy and/or procedure and has the potential to have a fundamental impact on the quality of the work product or the integrity of the evidence (see Quality Corrective Action Report).

Non-identification: see definition for "Elimination"

Notes: The documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, charts, graphs, photos, and other documents generated that are used to support an analyst's conclusions.

Objective: A measurable, definable accomplishment that furthers the goals of the organization.

Performance Check: A verification that the equipment, instrument, or process is working as expected. Analysis of a control may be used as a performance check.

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

Practice: In this manual, a term used to describe laboratory quality affecting processes that are used by the FSL.

Primary Standard: A standard designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

Principle: A basic rule, assumption or quality; a fixed or predetermined policy or mode of action.

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.

Proficiency Review Committee (PRC): A committee appointed by an accrediting body, whose role is to evaluate the performance of accredited laboratories in proficiency tests.

Proficiency testing: Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

Proficiency tests: Tests to evaluate the continuing capability of analysts and the performance of the laboratory. The expected results of the test are unknown to those individuals taking the test.

Proper seal: A seal that prevents loss, cross-transfer or contamination while ensuring that attempted entry into the container is detectable. A compliant seal may include a heat seal, tape seal, or a lock with, at minimum, the initials of the person creating the seal being placed across the seal onto the container when possible.

Qualified: A term used to identify personnel who successfully complete a training program, pass a competency test and participate in the proficiency testing program.

Qualitative Analysis: Procedures that use visual, microscopic, or instrumental methods to determine the characteristics or constituents of a sample or specimen without regard to quantity.

Quality (LFU): The clarity of the information contained within a friction ridge impression.

Quality Assurance: The planned and systematic actions necessary to provide sufficient confidence that a laboratory's product or service will satisfy given requirements for quality.

Quality Assurance Manual (QAM): A document describing the various elements of the quality system and quality practices of the organization or unit.

Quality control: Activities conducted according to established standards used to monitor the quality of analytical data and to ensure that it satisfies specific criteria.

Quality Corrective Action Report (Q-CAR): A report containing a description of a nonconformity (with great impact to the quality system or frequency of occurrence), a root cause analysis and a description of the action put in place after a nonconformity event to identify and eliminate the cause of the undesirable situation, and to bring the deficiency into conformity with a required standard.

Quality system documentation: Documents of records pertaining to the quality system such as audit reports, Quality Corrective Action forms, deviation forms and testimony evaluations.

Quality manager: An individual designated by 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.

Quality Preventive Action Report (Q-PAR): A report containing a description of a situation with the potential to result in nonconformance to a policy and/or procedure and the description of the action put in place before a potential nonconformity occurs in order to eliminate the cause of an identified undesirable situation and to bring the deficiency into conformity with a required standard.

Quality Assurance records: Documents pertaining to the quality system such as audit reports, Quality Corrective Action reports and testimony evaluations.

Quality system: The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities that contribute to quality, directly or indirectly.

Quantitative analysis: Analysis of a substance that determines the amount or proportion of its constituents.

Questioned sample: An evidence sample to be examined for the purpose of comparison or identification.

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

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

Reference Collection: Data or materials of known origin or property, which are maintained for identification, comparison, or interpretation purposes (e.g., mass spectra, motor vehicle paints or headlamp lenses, drug samples, wood fragments, bullets, cartridges, DNA profiles, laboratory developed population 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 (ISO Guide 30:2015). These materials may be used for the identification of unknown substances, calibration of instruments, assessments of a measurement method, or assigning value to materials.

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 (ISO 17034:2016).

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 (JCGM 200:2012).

Reliability: Possessing the quality of being dependable; may refer to personnel, materials or equipment.

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

Root cause: The fundamental reason for a condition adverse to quality, that, if corrected or precluded, would minimize or prevent that condition, and/or similar conditions, from occurring.

Sample: portion drawn from a whole or population for the purpose of examination/testing, not necessarily representative of the whole (ISO 21043-1:2018).

Sampling: A process or procedure whereby a part of a substance, material or item is taken to provide for testing of a representative sample of 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: A person who employs scientific methods in the examination of evidence in a forensic laboratory.

Secondary evidence: Material derived from an item of evidence.

Senior Deputy Director: Designs, manages and executes forensic science services and programs.

Shall: A word used when an element of the quality system is required.

Should: A word used when an element of the quality system is recommended, but not required.

SI Units: The International System of Units consisting of seven base units that have been adopted by the General Conference on Weights and Measures.

Standard Operating Procedure (SOP): A document that specifies the steps, methods, equipment, and materials necessary to perform a task properly. SOPs are written to provide instruction and standardization of activities affecting quality.

Standards: Something established by authority, custom, or general consent as a model or example.

Sub-discipline: A specific type of analysis within an accredited discipline.

Suitable: The determination that there is sufficiency in an impression to be of value for further analysis or comparison.

Supervisor: A person directly responsible for overseeing the work in an organizational unit.

Technical Leader: A designated employee who is responsible for the technical operations of a laboratory unit and who may stop or suspend unit operations, if necessary.

Technical procedures: Of or relating to a practical subject organized on scientific principles.

Technical review: The review of notes, data, and other documents that form the basis for a scientific conclusion.

Technical reviewer: An employee or contract employee who is a currently or previously qualified analyst in the methodology being reviewed that has been authorized to perform a technical review of, and is not an author of, the applicable report or its contents.

Technical support personnel: A person or contract employee who performs casework related duties within the laboratory at the direction of an analyst.

Tender: The response to the customer request for services. This may include an automated notification.

Testimony: The firsthand authentication of a fact.

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

Unit Manager: A person directly responsible for overseeing the work in an organizational unit.

Validation: The process of performing a set of experiments that establish the efficacy and reliability of a technique or procedure or modification thereof, where the specified requirements are adequate for an intended use.

Value: The determination "of value" by the examiner indicated that sufficient reliable details are present in the print such that, when compared to another print, any of the three conclusions can be reached.

Verification: Confirmation of an examiner's conclusion by another qualified examiner.

Will: A word used when an element of the quality system is required.

4. GENERAL REQUIREMENTS

4.1. Impartiality

4.1.1. Laboratory activities shall be undertaken impartially and are structured and managed so as to safeguard impartiality.

4.1.2. The Laboratory Management System is committed to impartiality and directs laboratory employees to avoid any activity, interest, or association that interferes or appears to interfere with their independent exercise of professional judgment.

4.1.3. Top Management has processes in place to mitigate undue internal or external influences on the professional judgment of all lab management and personnel. Any conflicts of interest or concerns, be it commercial, financial, or otherwise, shall be brought to the attention of the employee's direct supervisor immediately.

4.1.3.1. The laboratory management system:

4.1.3.1.1. Utilizes the *Policy for Outside Employment*. Lab staff shall request permission for outside employment, including volunteer work.

4.1.3.1.2. Has a code of ethics as a part of management's commitment to good professional practice. The District of Columbia ethics information for public employees is provided during the new employee training program. As members of the District of Columbia, the Code of Conduct in the *District of Columbia, Department of Human Resources District Personnel Manual* applies to all laboratory employees. Ethics training also incorporates annual review of the *ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel* document.

4.1.3.1.3. Ensures annual review of the *ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel* document and a record of the review shall be maintained within Qualtrax.

4.1.3.1.4. Ensures appropriate actions are taken when necessary regarding ethical concerns. *[Policy for Investigation of Credible Errors, Policy for Minimizing the Appearance of Conflicts of Interest, and Policy for Responding to Allegations of Negligence]*

4.1.4. Conflicts of interest and risks to impartiality are addressed through binding agreements that ensure testing and calibration activities are conducted in an independent and impartial manner. FSL personnel encountering situations or conditions that could cause undue pressure and adversely affect the quality of the work will inform their FSL Manager immediately. *[Policy for Minimizing the Appearance of Conflicts of Interest and District Personnel Manual, Chapter 18, Employee Conduct]*

4.1.5. Identification of a risk of impartiality shall be brought to the attention of any level of management and a plan to eliminate or minimize the risk will be executed and documented with records stored within Quality Assurance. Procedures utilized to eliminate or minimize risk may follow *DOM07 – Practices for Quality Corrective Actions or DOM08-Procedures for Quality Preventive Actions.*

4.2. Confidentiality

4.2.1. The laboratory shall ensure the protection of confidential information. The laboratory shall not disseminate case related information to any individual or organization other than the customer or the customer's designee, except as required by law or agreed upon between the lab and the customer.

4.2.2. Unless prohibited by law, the customer will be notified when the laboratory is required by law or authorized by contractual agreements to release confidential information to entities other than those listed in 4.2.1.

4.2.3. Information about the customer obtained from sources other than the customer shall be confidential between the customer and the Laboratory. The provider of the information shall be confidential to the Laboratory and shall not be shared with the customer, except as required by law.

4.2.4. Personnel, including any employees, contractors, interns, volunteers, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep

confidential all information obtained or created during the performance of laboratory activities, except as required by law. *[Policy for Social Media, Policy for Outside Employment, Policy for Information Security]*

5. STRUCTURAL REQUIREMENTS

5.1. The Department of Forensic Sciences (DFS) is a public government agency that performs both state and municipal forensic investigations and examinations for the District of Columbia. The Forensic Science Laboratory (FSL) is a division of the DFS. As such, the laboratory is a legal entity, responsible for its laboratory activities.

5.2. The structure of management and structure of overall responsibility for the laboratory are identified in the *FSL Organizational Chart and D.C. Official Code §§ 5-1501.01 et seq.*

5.2.1. The FSL Director is a manager and reports directly to the Director of the Department of Forensic Sciences. In general, the FSL Director is charged with the executive and administrative responsibilities for the operation of the FSL. The FSL Director maintains administrative control and governs the laboratory's activities directly or through subordinates. The FSL Director's responsibilities and authorities are defined in the associated position description. The FSL Director has the authority to make and enforce decisions affecting the FSL.

5.3. The Laboratory conforms to ISO/IEC 17025:2017 (E) and ANAB AR 3125 in the range of laboratory activities as defined on the most current Scope of Accreditation. The Laboratory does not claim conformity with ISO/IEC 17025:2017 (E) nor ANAB AR 3125 for services performed not listed on the Scope of Accreditation.

5.4. The Laboratory performs forensic testing services to meet, at a minimum, the requirements of the District of Columbia, the FBI DNA Quality Assurance Standards, ISO/IEC 17025, ANAB supplemental accreditation requirements, and customer needs. The quality system covers all forensic operations performed by laboratory employees and contracted employees at any site where forensic testing services are performed. The Laboratory is a National DNA Index System (NDIS) participating laboratory and as such conforms to the requirements in the NDIS Operational Procedures Manual and applicable FBI Quality Assurance Standards. Policies and procedures demonstrating this conformance can be found in the Forensic Biology Unit Quality Assurance Manual and SOPs. The proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories will be applied to reporting and non-reporting DNA analysts performing DNA analysis.

5.4.1. The Laboratory conforms to the requirements in the *ANAB Policy on Use of the ANAB Accreditation Symbols and Claims of Accreditation Statutes.*

5.4.2. The Laboratory performs activities under the authority of *D.C. Official Code §§5-1501.01 et seq.* This code is publicly available.

5.5. The Laboratory:

5.5.1. Has organizational chart(s) which show the structure and the interrelationships between management, casework units, and support services. The FSL position in the DFS is shown in the *DFS Organizational Chart.*

5.5.2. Defines the responsibility and authority of all FSL personnel as follows:

5.5.2.1. The FSL Director shall:

5.5.2.1.1. Report directly to the Director of the Department of Forensic Sciences.

5.5.2.1.2. Exercise full authority to coordinate and direct the day-to-day multi-discipline forensic testing activities of the Laboratory and is responsible for assessing and providing recommendations to the DFS Director with regards to laboratory budgeting, staffing, training, and technological needs.

5.5.2.1.3. Promote and support the quality system.

5.5.2.1.4. Appropriately delegate authority to Unit Managers to implement the quality system.

5.5.2.1.5. Initiate a Quality Corrective Action Report (Q-CAR) (or delegate initiation) when a nonconformity has been identified to be of high impact or high frequency of occurrence.

5.5.2.1.6. Initiate a Quality Preventive Action Report (Q-PAR) (or delegate initiation) when an undesirable situation has been identified.

5.5.2.1.7. Meet the minimum education and experience requirements for the applicable position description.

5.5.2.2. The Unit Manager(s) shall:

5.5.2.2.1. Support the quality system.

5.5.2.2.2. Approve the selection and use of technical procedures within the unit through the Qualtrax system; establish criteria for technical procedure validations; and as necessary, review and update technical procedures.

5.5.2.2.3. Initiate a Quality Corrective Action Report (Q-CAR) (or delegate initiation) when a nonconformity has been identified to be of high impact or high frequency.

5.5.2.2.4. Initiate a Quality Preventive Action Report (Q-PAR) (or delegate initiation) when an undesirable situation has been identified.

5.5.2.2.5. Appropriately delegate authority within the laboratory unit to uphold the quality system.

5.5.2.2.6. Ensure FSL personnel understand and apply current quality assurance policies and practices to appropriate situations.

5.5.2.2.7. Ensure the completeness of FSL reports and supporting case documentation.

5.5.2.3. The Unit Technical Leader shall:

5.5.2.3.1. Support the quality system.

5.5.2.3.2. Ensure that all unit personnel receive necessary training and are qualified for their assigned duties.

5.5.2.3.3. Recommend and approve the selection and use of technical procedures within the unit; establish criteria for technical procedure validations; and as necessary, review and update technical procedures.

5.5.2.3.4. Initiate a Quality Corrective Action Report (Q-CAR) (or delegate initiation) when a nonconformity has been identified to be of high impact or high frequency.

5.5.2.3.5. Initiate a Quality Preventive Action Report (Q-PAR) (or delegate initiation) when an undesirable situation has been identified.

5.5.2.3.6. Ensure that FSL personnel understand and apply current quality assurance policies and practices to appropriate situations.

5.5.2.4. The FSL Quality Assurance Specialist shall:

5.5.2.4.1. Have the authority and obligation to ensure that the requirements of the Quality Assurance Program are implemented and maintained through scheduling, coordinating, and evaluating all aspects of the quality system to include audits.

5.5.2.4.2. Control all quality assurance records and is responsible for assessing and providing recommendations to the Senior Deputy Director, DFS Quality Manager and Laboratory Director with regards to laboratory accreditation needs.

5.5.2.4.3. Ensure conformance with ISO/IEC 17025:2017 standards and supplemental guidelines and promote and maintain the quality system for the laboratory units.

5.5.2.4.4. Ensure that FSL personnel understand and apply current quality assurance policies and practices to appropriate situations.

5.5.2.4.5. Ensure that policies and practices within the laboratory units are documented and implemented.

5.5.2.4.6. Initiate a Quality Corrective Action Report (Q-CAR) (or delegate initiation) when a nonconformity has been identified to be of high impact or high frequency.

5.5.2.4.7. Initiate a Quality Preventive Action Report (Q-PAR) (or delegate initiation) when an undesirable situation has been identified.

5.5.2.4.8. Keep the DFS Senior Deputy Director, the DFS Quality Manager, the Laboratory Director, the Unit Manager(s) and the Technical Leader(s) apprised of the status of all open Q-CARs and Q-PARs.

5.5.2.4.9. Communicate the quality system and related policies, practices, and procedures to all employees within the laboratory units.

5.5.2.4.10. Be supervised by the DFS Quality Manager.

5.5.2.5. Analysts shall:

5.5.2.5.1. Ensure compliance with current policies, practices, and procedures.

5.5.2.5.2. Ensure that laboratory procedures are performed in a careful and responsible manner in accordance with current policies and practices.

5.5.2.5.3. Make recommendations and suggestions for improving the FSL quality system as appropriate.

5.5.2.5.4. Coordinate initiation of / initiate a Quality Corrective Action Report (Q- CAR) when a nonconformity has been identified.

5.5.2.5.5. Coordinate initiation of / initiate a Quality Preventive Action Report (Q- PAR) when an undesirable situation has been identified that has the potential to lead to a nonconformity.

5.5.2.5.6. Be accountable to only one immediate supervisor per function.

5.5.3. Documents procedures to ensure consistent application of activities performed and the validity of results through the promulgation of SOPs.

5.6. Laboratory Management has the ultimate authority over the management system and all activities of the laboratory. Management shall:

5.6.1. Ensure forensic personnel have the authority and resources needed to carry out their duties to include implementation, maintenance and improvement of the quality system via following the appropriate policies, procedures, work instructions, and methods when performing laboratory activities.

5.6.2. Report to their immediate supervisor when there are departures from standard work or customer requirements and report any deviations from the quality system to management as appropriate.

5.6.3. Ensure additional resources are requested when needed to carry out activities in accordance with this management system or the customer's requirement and ensure all personnel have appropriate understanding of the management/quality system and how it applies to their respective laboratory activities to prevent or minimize deviations.

5.6.4. Participate in training and various courses to meet the ongoing technical requirements for performing laboratory activities and ensure the effectiveness of laboratory activities.

5.6.5. Identify opportunities and make proposals for improvement to management.

5.7. Laboratory Management shall ensure that:

5.7.1. The FSL routinely meets with stakeholders to ensure there is continual effective communication and meeting the needs of the customer.

5.7.2. The effectiveness of the management system is reviewed and communicated during Management Reviews. Management Reviews are documented and stored on Qualtrax for laboratory personnel to reference. *[DOM09 – Annual Management Reviews]*

5.7.3. During changes and improvements to the management system, the leadership team shall monitor the system and results as appropriate to ensure that the overall integrity is maintained.

6. RESOURCE REQUIREMENTS

6.1. The laboratory has the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

6.2. Personnel

6.2.1. All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent, and work in accordance with the laboratory's management system. The FSL uses qualified technical personnel who are employed by, or under contract to, the DFS. Unit management will ensure that competent contractors and key support personnel are supervised and that they work in accordance with the FSL's quality system.

6.2.2. Competence requirements for lab personnel, related to education, qualification, training, technical knowledge, skills and experience are outlined in unit specific training manuals and/or position descriptions. All case working scientists, regardless of academic qualifications or past work experience, must complete a competency test by achieving the intended results prior to assuming casework responsibilities in the FSL. A trainee's successful completion of the training program and/or competency test will be documented and maintained in the employee's training file.

6.2.2.1. The minimum education and experience requirements that must be met for ensuring competence of personnel regarding employees who authorize results, opinions and/or interpretations are detailed in the applicable position description and meet the minimum educational requirements established within the United States.

6.2.2.1.1. Reporting analysts working in the Forensic Biology discipline of forensic science shall possess a baccalaureate or an advanced degree in a natural science or a closely related field and, if performing DNA analysis and where applicable, shall meet the education requirements of the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories at the time of hiring.

6.2.2.1.2. Current position descriptions for all FSL personnel are maintained in the DFS Human Resources Department records.

6.2.2.2. Each discipline will have a documented training program used to train individuals in the knowledge, skills and abilities to perform all aspects of the position. Training records are held by the DFS Training Unit or designee. The training program and training records will provide evidence that the individual has been properly trained and competency tested. Training programs take into account any past training or work experience an individual may possess. Retraining and maintenance of skills and experience are outlined in *DOM14 – Procedures for Training and Development*. Unit specific training manuals shall include the following, where relevant to job function:

6.2.2.2.1. the knowledge, skills, and abilities needed to perform work;

6.2.2.2.2. general knowledge of forensic science;

6.2.2.2.3. the application of ethical practices in forensic science;

6.2.2.2.4. criminal law, civil law, and testimony;

6.2.2.2.5. provisions for retraining;

6.2.2.2.6. provisions for maintenance of skills and expertise; and

6.2.2.2.7. criteria for acceptable performance.

Note: FSL does not perform case examinations under civil law.

6.2.3. FSL management will ensure the competency of all personnel that operate equipment/instrumentation, perform tests, evaluate test results, author technical reports, perform technical and administrative reviews, and evaluate the significance of deviations. Any personnel undergoing training will be supervised by competent personnel.

6.2.3.1. FSL Management will ensure that all personnel who perform testing, regardless of academic qualifications or past work experience, shall be

competency tested prior to assuming independent casework. The competency test shall include practical examination(s) that cover the spectrum of anticipated tasks related to the test. The intended results of the competency test shall be achieved prior to performing the tasks on an evidentiary item. An authorization memo will be retained by Quality.

6.2.3.2. Personnel who review and authorize results, opinions, interpretations, perform technical reviews, or perform reviews of expert testimony shall meet the competency requirements as specified in 6.2.3.1.

6.2.4. Position descriptions explain the duties, functions, and tasks for each job and are maintained by DFS Human Resources.

6.2.4.1. The laboratory follows *District Personnel Manual, Chapter 14*, which requires immediate supervisors to conduct evaluations for each direct report. All managers provide annual performance evaluations for all eligible employees.

6.2.5. The laboratory has procedures for and retains records for:

6.2.5.1. Competency requirements. Competency requirements are defined within specific unit training manuals and records of competency are retained by the DFS Training Unit or designee.

6.2.5.2. Selection of personnel. Personnel must meet position description requirements and undergo selection process established by the District of Columbia Human Resources Agency. The DFS hiring policy is defined in *OPS01 – Procedures for Interview and Selection Process*. Records of selection of personnel are retained by DFS HR.

6.2.5.3. Training. Training of personnel within a particular testing discipline is defined in unit training manuals. On-going training and re-training is defined in *DOM14 – Procedures for Training and Development*. FBU personnel, as designated by the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories, must meet the hours of continuing education required by the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories each calendar year.

6.2.5.4. Supervision. Supervision of employees is outlined in the *DFS Organizational Chart*. Employees are evaluated on their performance through annual performance reviews defined by the District of Columbia, Human Resources.

6.2.5.5. Authorizations. The Unit Manager, or designee, shall issue authorization memos that identify scientific tasks that FSL employees are approved to conduct. Each unit maintains records of an employee's qualifications and authorizations. The above requirements also apply to contractors.

6.2.5.6. Monitoring of competence. FSL testing personnel participate in annual proficiency testing to monitor individual competency as well as identify areas where improvement may be needed. Proficiency testing applies to FSL personnel documented as competent in a particular forensic discipline, to include all applicable sub-disciplines.

6.2.6. Authorization memos will include authorizations for personnel to perform the functions outlined in sections 6.2.6.2 and 6.2.6.3:

6.2.6.1. Unit Managers and Technical Leaders, or designee, will have the authorization/authority to develop, modify, verify, and validate methods.

6.2.6.2. Forensic Scientists have the authority to perform analysis of results, including opinions and interpretations as defined in each individual's authorization memo(s).

6.2.6.3. Forensic Scientists have the authority to report, review and authorize results as defined in each individual's authorization memo(s).

6.3. Facilities and environmental conditions

6.3.1. The FSL personnel performing work in the Consolidated Forensic Laboratory (CFL) facility shall follow and adopt the DFS Health and Safety program. *DOM13 –Health and Safety* outlines the program and FSL personnel performing work in the CFL facility must adhere to this manual.

6.3.1.1. The DFS Forensic Science Laboratory (FSL) is housed within the CFL at 401 E Street SW, Washington D.C. 20024. The laboratory facility permits the correct performance of forensic examinations. Casework units will ensure that the environmental conditions do not adversely

affect the quality required of any measurement. Any environmental conditions that can affect the results of examinations will be documented in the appropriate standard operating procedure. All examinations require normal laboratory environmental conditions unless noted in a standard operating procedure. Extreme care will be taken when sampling and/or examinations are undertaken at sites other than the CFL facility.

6.3.1.2. If environmental conditions affect the quality of an examination, casework units will monitor, control, and record those conditions as required by a standard operating procedure.

6.3.2. Normal laboratory environmental conditions are controlled and monitored by the building maintenance staff.

6.3.3. Casework units will monitor, control, and record all environmental conditions as listed in the standard operating procedures, methods or specifications, or if those conditions influence the validity of the results. Examinations will be stopped if the environmental conditions could jeopardize the results. If environmental conditions could affect the quality of an examination, the conditions will be recorded in the appropriate case records.

6.3.4. Access to and use of the CFL is controlled, monitored and limited. The DFS Security Office, under control of the Protective Services Division (PSD), maintains documentation of assigned access badges. The Department of General Services (DGS) Facilities Manager maintains documentation and control over the physical keys for the CFL. The FSL Director (or designee) acts as the security access coordinator and determines the access level for each staff member and authorizes access to the testing areas of the FSL. Access levels will be reviewed annually, at minimum. All exterior entrance points have proximity badge readers. Access to the facility is protected by PSD Officers 24/7. Access to all laboratories is controlled by proximity badge readers, biometric scanners, and/or key lock systems. Personnel approved to enter secure evidence areas have biometric access and/or access to key lock systems. All visitors must sign in and require escort to the laboratory spaces. Evidence storage areas are secured and the storage conditions are such as to prevent loss, deterioration, of adverse influences on evidence to maintain integrity of the evidence. This applies both before and after examinations have been performed. FSL units are

responsible for maintaining effective separation between incompatible activities to prevent cross- contamination. *[LOM01 – Procedures for the Examination of Evidence]*

6.3.4.1. The FSL conforms to the policies for security under *DOM01 – Security Procedures*. Laboratory entrance/exit points and the outer perimeter have security control at all times. Personnel entering laboratories must be authorized and all visitors gaining access to laboratories must be escorted.

6.3.5. The FSL Laboratory does not perform laboratory activities outside of its permanent control.

6.4. Equipment

6.4.1. The FSL is furnished with, or has access to, all items needed for the correct performance of forensic examinations. All instruments and equipment having an effect on the accuracy or validity of forensic examination results will be properly maintained and calibrated. Requirements for instrument calibration and maintenance are specified in *DOM05 – Procedures for Instrument Checks and Maintenance.*

6.4.2. In those cases where a casework unit needs to use equipment outside its permanent control, it will ensure that the requirements of ISO/IEC 17025:2017 are met as per unit specific SOP's and as outlined in *DOM05 – Procedures for Instrument Checks and Maintenance*. Laboratory equipment will not be used by non-laboratory personnel without prior approval from the FSL Laboratory Director. If equipment is operated outside of the control of laboratory personnel, the equipment will be performance checked, at a minimum, prior to next use by laboratory personnel. *[DOM05 – Procedures for Instrument Checks and Maintenance]*

6.4.3. Casework units will have procedures for appropriate handling, transportation, storage, use and planned maintenance of portable equipment to ensure proper functioning. *[DOM05 – Procedures for Instrument Checks and Maintenance]*. Unit SOPs will outline any necessary procedures for maintaining measuring equipment to ensure proper functioning and to prevent contamination or deterioration. Laboratory equipment will be used by authorized personnel. Instruction and maintenance manuals will be readily available to personnel.

6.4.3.1. Reagents will be prepared by authorized personnel. Reagents prepared shall be labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number. Each unit will maintain records identifying the preparer, identity of whom performed the quality check of reagent(s), and results of the quality check.

6.4.3.2. Reference collections are documented, uniquely identified and handled to protect the characteristic(s) of interest.

6.4.4. *DOM05 – Procedures for Instrument Checks and Maintenance* outlines the laboratory process for verifying equipment conforms to specified requirements prior to being placed into service.

6.4.5. When necessary, performance checks will be carried out on calibrated equipment according to the appropriate SOP. *[DOM05 – Procedures for Instrument Checks and Maintenance]* All equipment used for measurement shall be capable of achieving measurement accuracy and/or measurement uncertainty required for valid results.

6.4.6. Measuring equipment shall be calibrated when the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or calibration of the equipment is required to establish the metrological traceability of the reported results.

6.4.7. The FSL is not a calibration laboratory or a testing laboratory that performs its own calibrations. The laboratory uses outside vendors to perform calibrations. Each unit will utilize a calibration laboratory accredited to ISO/IEC 17025, with a scope of accreditation covering the calibration performed, for all calibrations where the calibration has a significant effect on the accuracy or validity of the sampling or test result, or total uncertainty of the test result.

6.4.7.1. *DOM05 – Procedures for Instrument Checks and Maintenance* outlines the requirements for the calibration program.

6.4.8. FSL instrumentation requiring calibration will be labeled with the status of calibration as outlined in *DOM05- Procedures for Instrument Checks and Maintenance.*

6.4.9. *DOM05 – Procedures for Instrument Checks and Maintenance* will be followed for equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements.

6.4.10. FSL unit specific SOP's will document established calibration or performance check intervals for each instrument requiring calibration. *DOM05 – Procedures for Instrument Checks and Maintenance* describe interval checks and power interruptions.

6.4.11. Where instrument calibrations or performance checks include correction factors or reference values, the casework units will have measures to ensure that the correction factors or reference values are made available to appropriate personnel.

6.4.12. *DOM05 – Procedures for Instrument Checks and Maintenance* outlines safeguarding for adjustments on instrumentation/equipment.

6.4.13. Units will keep up-to-date records of equipment that can influence laboratory activities. The records will identify descriptors listed in *DOM05 – Procedures for Instrument Checks and Maintenance.*

6.5. Metrological traceability

6.5.1. Disciplines with factors contributing to measurement uncertainty will establish and maintain traceability by means of an unbroken chain of calibrations or comparisons linking the calibration standards to the relevant primary standards of the SI units of measurement.

6.5.1.1. If the outside vendor is conducting a calibration on instrumentation that has a significant effect on the accuracy or validity of sampling or test results, the outside vendor must be accredited to ISO/IEC 17025 by: either an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration to be performed listed on the scope of accreditation; a National Metrology Institute that is a signatory to the BIPM - CIPM Mutual Recognition Arrangement with the calibration to be performed listed in Appendix C of the BIPM key comparison database; or 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.

6.5.1.1.1. If certified reference materials are purchased from a vendor, that vendor must be accredited to ISO 17034 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material.

6.5.1.2. If an external calibration service supplier meeting the above requirement is not available, the laboratory will confirm competence, measurement capability, and measurement traceability for the supplier and the service being purchased and maintain record of the confirmation.

6.5.1.3. The FSL is not a calibration laboratory.

6.5.1.4. The Laboratory will evaluate for applicability of measurement traceability accreditation requirements if a certified reference material is changed in a way that alters the traceable measurement value. The records will be stored in the unit for the certified reference material.

6.5.2. Measurements made by units shall be traceable to SI units. The link to SI units may be achieved by reference to national measurement standards through calibration from a competent laboratory; Certified Reference Material provided by a competency producer with stated metrological traceability to the SI; and/or direct/indirect comparison with national or international standards.

6.5.3. Where traceability of measurements to SI units is not possible and/or not relevant, casework units will establish traceability to other appropriate measurement standards such as certified reference materials or reference standards.

6.5.3.1. Casework units will have procedures for the calibration of their reference standards to ensure that the calibrating organization provides traceability to SI Units by a means of an unbroken chain of calibrations or comparisons linking the reference standards to the relevant primary standards of the SI units of measurement.

6.5.3.2. The FSL does not issue calibration certificates.

6.6. Externally provided products and services

6.6.1. The District of Columbia Office of Contracts and Procurements (OCP) policies and regulations govern the procurement of products and services from external sources. The DFS, follows *DOM19 – Purchasing and Evaluating Services and Supplies* for purchasing externally provided products and services that affect laboratory activities. The laboratory will ensure that all externally provided products and services that affect laboratory activities are deemed suitable when:

6.6.1.1. products or services are to be incorporated into the laboratory activities;

6.6.1.2. products or services are provided, in part or in full, directly to the customer as received by the laboratory; and

6.6.1.3. products are used to support laboratory operations.

6.6.2. The District of Columbia's Office of Contracting and Procurement (OCP) govern the procurement of products and services.

6.6.2.1. Laboratory units shall have defined, approved and documented requirements for all externally provided products or services that affect the quality of tests performed.

6.6.2.2. The procedures for the receipt and storage of reagents, chemicals, standards and consumable materials necessary for forensic examinations are set forth in Appendix A.

6.6.2.3. The laboratory will define criteria and maintain records for evaluation, selection, monitoring of performance and re-evaluation of the external providers of products or services per *DOM19 - Purchasing and Evaluating Services and Supplies.*

6.6.2.4. All products and services must be tested (i.e. validation study, performance checked, or quality control/quality assurance procedures) to ensure compliance with laboratory requirements, and have that compliance documented, prior to use by the laboratory or prior to being provided directly to the customer.

6.6.2.5. The laboratory shall take any and all appropriate action arising from evaluations, monitoring of performance and re-evaluations of external providers by using the *DFS Supplier/Services Evaluation Form.*

6.6.3. The FSL will maintain purchasing documents for supplies, reagents, and consumables with information describing the supplies and services ordered if they affect the quality of examinations.

6.6.3.1. These requests will be reviewed and approved for technical content by the Unit Manager or designee prior to ordering.

6.6.3.2. Authorization memos will contain any information necessary related to the competence required by personnel in conducting evaluations of products and/or services.

6.6.3.3. Laboratory Management will evaluate suppliers of critical consumables, supplies and services following the *DFS Supplier/Services Evaluation Form* and maintain records of the evaluations. These records will be maintained by the FSL.

7. PROCESS REQUIREMENTS

7.1. Review of requests, tenders, and contracts

7.1.1. *LOM01 – Procedures for the Examination of Evidence* provides guidance for the review of requests for examinations. These procedures shall ensure that the:

7.1.1.1. Requirements are adequately defined, documented and understood;

7.1.1.2. The laboratory has the capability and resources to meet the requirements;

7.1.1.3. Where external providers are used, the requirements of 6.6 are applied;

7.1.1.4. Appropriate technical procedures, capable of meeting customer requirements, are selected.

7.1.2. Submission of evidence to the Laboratory indicates the submitting agency agrees the Laboratory will make the determination of the appropriate tests/methods for the discipline selected. Any communications with the customer regarding selected

testing or changes to selected testing will be noted in the case activities/case log area of the case record in the LIMS. The laboratory shall inform the customer when the method requested by the customer is inappropriate or out of date.

7.1.3. The FSL does not provide statements of conformity.

7.1.4. Any significant differences from a contributor's request will be communicated to the contributor by the FSL Director or designee prior to proceeding with laboratory testing.

7.1.4.1. This communication will be documented in the Case Activities Log in accordance with *LOM01 – Procedures for the Examination of Evidence.*

7.1.4.2. Any differences between the request and the approved processes shall be resolved before any laboratory examinations commence. Each process shall be acceptable to both the FSL and the contributor.

7.1.4.3. Deviations requested by the contributor shall not impact the integrity of DFS or the validity of the results.

7.1.5. Any significant deviations from a contributor's request, such as conducting additional examinations that were not requested, will be communicated to the contributor by the FSL Director or designee. This communication will be documented in the Case Activities Log in accordance with *LOM01 – Procedures for the Examination of Evidence.*

7.1.6. Changes in requested examinations made after work has commenced will be communicated to all affected personnel.

7.1.7. FSL employees will communicate with contributors as needed to clarify requests and answer questions concerning the status of the requests. The laboratory will maintain open channels of communication with contributors during lengthy or complex testing processes.

7.1.8. All communications related to reviews and all records related to the contributor's request, including case-related discussions with the contributor in the case file (whether hard copy or electronic), will be documented on a Case Activities Log and maintained in the case file. Printouts of electronic mail may also be maintained in the case file for documenting communications.

7.1.9. The extent of database searches is communicated to customers and updated, when applicable, in reports.

7.2. Selection, verification and validation of methods

7.2.1. Selection and verification of methods

7.2.1.1. Standard operating procedures (SOPs), including validated technical procedures, are a key element in establishing and maintaining quality within the FSL. Thus, it is the policy of the FSL for casework units to have and use written procedures for all laboratory activities within their scope. *[DOM03 – Procedures for Writing Standard Operating Procedures].* Where applicable, SOPs will have sections for the estimation of the measurement of uncertainty; sampling; calculations, including any statistical techniques for the analysis of examination data.

7.2.1.1.1. Test methods involving the comparison of an unknown to a known are outlined by the units. The unit guidelines include:

7.2.1.1.1.1. An evaluation of the unknown item(s) to identify characteristics suitable for comparison; and/or

7.2.1.1.1.2. If applicable, an evaluation of characteristics suitable for statistical rarity calculations, prior to comparison to one or more known items

7.2.1.1.2. FSL is not a calibration laboratory.

7.2.1.2. The Unit Manager or designee will be responsible for maintaining SOPs and supporting documentation such as instructions, manuals and reference data relevant to laboratory activities. He/she will ensure that procedures are readily available to appropriate personnel through the use of the Qualtrax Compliance Software and other sources.

7.2.1.3. The laboratory shall ensure 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 shall be supplemented with additional details to ensure consistent application.

7.2.1.4. When the contributor does not specify the method to be used, the laboratory shall select the appropriate technical procedures to meet the needs of the contributor while taking into account the nature of the evidence and the facts of the case.

7.2.1.4.1. Technical procedures should be published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, as specified by the manufacturer of the equipment or developed by the FSL.

7.2.1.4.2. If the FSL uses a standard operating procedure, it will use the latest edition when possible. The standard operating procedure will be supplemented with additional details to ensure consistent application.

7.2.1.4.3. The FSL will confirm that it can properly use a standard operating procedure prior to introducing it for forensic examinations.

If the standard operating procedure changes the confirmation will be repeated.

7.2.1.4.4. FSL developed technical procedures or procedures adopted by the FSL, including SOPs, are used as appropriate.

7.2.1.5. The laboratory shall verify that it can properly perform methods before introducing them into casework by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary. *[DOM04 – Procedures for Validating Technical Procedures].*

7.2.1.5.1. The reliability of a newly validated technical procedure will be confirmed in-house against any documented performance characteristics of that procedure prior to use on casework.

7.2.1.5.2. Records of performance checks conducted during the validation process will be maintained in the casework units for future reference. Verification shall be repeated to the extent necessary.

7.2.1.6. When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized. The new method will be documented, validated, approved, and communicated to the discipline prior to use in casework.

7.2.1.7. Significant deviations from test methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. The FSL follows *DOM17 – Procedures for Authorizing Deviations.*

7.2.2. Validation of methods

7.2.2.1. Validations for new technical procedures will be performed according to the *DOM04 – Procedures for Validating Technical Procedures* to ensure the procedure produces reliable results. The validation process determines the limitations of the procedure, the conditions under which reliable results can be obtained, and the critical aspects of the procedure that must be carefully controlled and monitored. Units will maintain records of the validation including, but not limited to, the procedure used, the results, and a statement as to whether the technical procedure is fit for its intended use.

7.2.2.1.1. Each unit will ensure the procedure for method validation implementation by following *DOM04 – Procedures for Validating Technical Procedures.*

7.2.2.1.1.1. Encompasses the test process to include data interpretation.

7.2.2.1.1.2. Establishes the data required to report a test result, opinion, or interpretation.

7.2.2.1.1.3. Identifies limitations of the test method, reported test results, opinions and interpretations.

7.2.2.1.1.4. Specifies when a currently validated method, including associated data interpretation, needs additional validation.

7.2.2.1.1.5. Requires a validation plan providing direction for parameter evaluation and parameter acceptance criteria to determine if the method is fit-for-purpose prior to starting a method validation.

7.2.2.2. When changes are made to validated methods, the Unit Manager and/or Technical Leader(s) will determine the influence of the changes and where they are found to affect the original validation will consult the Laboratory Director to perform a new validation.

7.2.2.2.1. Associated data interpretation is considered part of a validated method. When changes are made refer to 7.2.2.2.

7.2.2.3. When validating a technical procedure, the scope and accuracy of performance characteristics will be assessed to ensure that the procedure meets the requirements of a given application and shall be relevant to the contributor's needs.

7.2.2.4. Disciplines will maintain a record of the validation to include the procedure used, requirements specifications, determination of the performance characteristics of the method, results obtained, and a statement of validity of the method detailing as to whether the method is fit for the intended use.

7.3. Sampling

7.3.1. Sampling plans are required when taking part of a representative sample of a substance, material or item to provide for testing and reporting on the whole substance, material or item.

7.3.1.1. Each casework unit, when necessary, will have plans and procedures for the sampling of evidence included in the appropriate SOPs. The sampling plans will address the factors to be controlled to ensure the validity of the examination results.

7.3.2. The sampling method shall describe: the selection of samples or sites; the sampling plan; the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing.

7.3.3. Casework units, as applicable, will document appropriate sampling data and activities relating to the forensic examination process. Records maintained in the FSL file will: include the sampling method used; date and time of sampling; data to identify and describe the sample; identification of the individual performing the sampling; identification of equipment used; any relevant environmental or transport conditions; diagrams of the sampling location as necessary and; if relevant, deviations/additions/exclusions from the sampling method and sampling plan.

7.4. Handling of test or calibration items

7.4.1. The FSL maintains practices for the transportation, receipt, handling, protection, storage, retention and/or disposal of items of evidence. These practices give guidance for protecting the integrity of evidence, protecting the interest of the FSL and the interests of the contributor. [*DOM10 – Procedures for Handling Evidence and Clinical Specimens; LOM01 – Procedures for Examination of Evidence].* The FSL will ensure the integrity of evidence by protecting items from loss, cross-transfer or deleterious change during storage, handling and preparation. Handling instructions provided with an item will be followed. When evidentiary items have to be stored or handled under specified environmental conditions, these conditions will be maintained, monitored and recorded.

7.4.1.1. The FSL uses a Chain of Custody Report to document all internal transfers of evidence in chronological order from the time of receipt. This documentation illustrates that the evidence examined and reported on was that which was received by the FSL. The Chain of Custody Report securely and accurately identifies each person taking possession of an item of evidence or the location of that item. This log includes: A signature (handwritten or electronic), or equivalent identification, of the

person/location receiving and/or transferring the evidence; the unique identifier of the evidence; the date of receipt or transfer and chronological transfers.

7.4.1.1.1. For all internal transfers, tracking evidence on a chain of custody applies to all evidence items received, sub-items created when evidence is sub-divided, and items collected or created and preserved for future testing (e.g., test fired ammunition, latent print lifts, photos, DNA extracts). Appropriate casework units will have procedures for the operation of individual characteristic databases (ICD).

7.4.1.1.1.1. Appropriate casework units will establish whether ICD samples are treated as evidence, reference materials, or examination documentation.

7.4.1.1.1.2. ICD samples under the control of the laboratory shall be uniquely identified.

7.4.1.1.1.3. ICD samples not treated as evidence and under control of the FSL will be uniquely identified. They will also be protected from loss, cross transfer, contamination and/or deleterious change.

7.4.1.1.1.4. Access to ICD samples will be restricted to those persons authorized by the Unit Manager.

7.4.1.1.2. The laboratory shall ensure that the evidence accepted and stored in the laboratory is properly packaged and sealed according to the *DOM10 – Procedures for Handling Evidence and Clinical Specimens*.

7.4.1.1.3. This is done in order to protect the integrity of all items while in the possession of the laboratory.

7.4.1.1.4. Evidence items will be re-sealed as soon as practicable after the requested testing is completed.

7.4.1.1.5. *DOM10 – Procedures for Handling Evidence and Clinical Specimens* describes the measures taken to secure unattended evidence which is in the process of being examined. All evidence not in the process of examination will be maintained in an appropriate storage area.

7.4.1.1.6. Evidence in the process of examination/analysis will not be open- ended. Scientists will make every effort to complete analyses within the goal turnaround times for each unit. Circumstances to which this time frame might need to be extended will be brought to the attention of the Unit Manager or designee.

7.4.1.1.7. Evidence disposition is included in the unit Report of Examination and provided to the requesting customer when the case is fully completed.

7.4.1.1.8. If additional items (e.g., test-fired ammunition, latent print lifts, photos, trace evidence, DNA extracts) were collected or created and preserved for future testing, these items will also be included in the unit Report of Examination.

7.4.2. The FSL will unambiguously identify evidence items using a DFS laboratory number and item number. The identification of evidence will remain in place while the items are in the FSL. These practices ensure that items of evidence are uniquely identified and provide for subdivided and secondary evidence. Evidentiary items will be transferred according to *DOM10 – Procedures for Handling Evidence and Clinical Specimens.*

7.4.2.1. All items of evidence received by the FSL will be unambiguously identified, regardless of request for testing.

7.4.2.2. Each item of evidence will be marked to ensure that it is uniquely identified and traceable to the DFS number. If the evidence does not lend itself to marking, its proximal container or identifying tag will be marked. When original evidence is returned to the owner, marking on the proximal container (e.g., evidence bag) is acceptable.

7.4.3. Upon receipt of the evidence, the condition of the evidence will be evaluated and any conditions adverse to quality will be recorded.

7.4.3.1. When the suitability of an item of evidence for examination is questionable, or there is a discrepancy between the evidence and the request for examination, the Unit Manager or designee will contact the contributor for clarification prior to proceeding with any testing.

7.4.3.2. This communication will be documented in the Case Activities Log. Print- outs of electronic communications may supplement the Case Activities Log in the case file.

7.4.3.3. When the contributor requires an item of evidence to be tested using a deviation from specified conditions, the Report of Examination will include a disclaimer indicating which results may be affected by the deviation.

7.4.4. When evidentiary items have to be stored or handled under specified environmental conditions, these conditions will be maintained, monitored, and recorded.

7.4.5. Any evidence not in the process of examination must be placed in a container to protect it from loss, cross-transfer or contamination and will be stored under proper seal. *[DOM10 – Procedures for Handling Evidence and Clinical Specimens]*

7.4.6. When evidence, such as latent prints and impressions, can only be recorded or collected by photography or digital capture and the print or impression itself is not recoverable, the photograph, negative or digital image of the print or impression will be treated as evidence. This excludes documentation photos of digital evidence where a "best evidence" copy it retained as evidence and the photos only document the condition of the device.

7.4.7. Evidence collected by DFS personnel from a crime scene will be protected from loss, cross-transfer, contamination and/or deleterious change whether in a sealed or unsealed container during transfer to the FSL or appropriate evidence facility. Where appropriate, further processing to preserve, evaluate, document, or render evidence safe shall be accomplished prior to final packaging. Crime scene

evidence will be properly identified, packaged, and entered into the evidence control system as soon as possible.

7.5. Technical records

7.5.1. The FSL will retain technical examination and administrative documentation as part of the case file for a defined period of time in accordance with DFS requirements. The appropriate SOPs will contain adequate information to identify factors affecting the uncertainty of measurement, if applicable. Examination documents will be such that another qualified analyst could repeat the examination under conditions as close as possible to the original *[LOM02 – Procedures for Case Documentation and Report Writing]*. Personnel responsible for the examination of evidence, the verifier, the technical reviewer and the administrative reviewer will be identified in the case file. *[LOM03 – Procedures for Reviewing a Report of Examination].* Original observations, data and calculations are recorded at the time and made identifiable with the specific task.

7.5.1.1. *LOM02 – Procedures for Case Documentation and Report Writing* and *LOM01 – Procedures for the Examination of Evidence* will identify what documents will be maintained in the case file. Documents will be retained according to the *Policy for Retention of Records.*

7.5.1.2. Abbreviations and notations will be acceptable if they are clearly documented and readily comprehensible to the technical and/or administrative reviewer. A list of common abbreviations and/or symbols used will be found in relevant Casework Unit's SOP's or Manuals.

7.5.1.3. Examination documentation will be such that, in the absence of the analyst, another reviewer possessing the relevant knowledge, skills, and abilities could evaluate the examinations performed and interpret the data. *[LOM01 – Procedures for the Examination of Evidence and LOM03 – Procedures for Reviewing a Report of Examination]*

7.5.1.4. Each technical record will be traceable to the corresponding case record, reflecting the date(s) testing was performed and be maintained of a permanent nature.

7.5.1.4.1. Handwritten case documentation will be in ink. Exceptions will be made with environmental conditions, such as

extreme cold or rain, prevent the use of inks. Pencil (including color) may be used for diagrams or tracings. Technical records originally captured in pencil can be maintained in a permanent manner by photocopying, scanning, or taking a photo. Computer generated notes are acceptable, and will be retained within the file system of the secure computer network.

7.5.1.5. Reasons for rejecting test results or observations, the identity of the individual(s) taking the action and the date must be included within the case documentation, when necessary. *[LOM02 – Practices for Case Documentation and Report Writing]*

7.5.1.6. If an adjustment or repair is performed due to a calibration that does not meet specifications, pre and post adjustment/repair data shall be retained.

7.5.2. Amendments to case documentation or records will be tracked to previous versions or to original observations. Both the original and amended data and files must be retained, including the date of the alteration, an indication of the altered aspects and the individual responsible for the alterations *[LOM01 – Procedures for the Examination of Evidence]*.

7.6. Evaluation of measurement uncertainty

7.6.1. Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis. Standard operating procedures, when applicable, will include considerations for estimating the uncertainty of measurement. If the nature of the examination procedure precludes a metrologically and statistically valid calculation of uncertainty of measurement, the units will attempt to identify all the components of uncertainty and produce a reasonable estimate. Casework units will identify each SOP in which uncertainty of measurement may be reported. If a quantitative numerical measurement result is included in an FSL Report of Examination, the uncertainty of measurement must be reported. Additionally, an FSL Report of Examination must not give a wrong impression of the uncertainty of measurement.

7.6.1.1. All units reporting quantitative test results will have and apply a procedure to estimate the uncertainty of measurement. The procedure for estimation of measurement uncertainty:

7.6.1.1.1. Requires the specific measuring device or instrument used for a reported test result to have been included in or evaluated against the estimation of measurement uncertainty for that test method.

7.6.1.1.2. Includes the process of rounding the expanded uncertainty.

7.6.1.1.3. Requires the coverage probability of the expanded uncertainty to be a minimum of 95.45%.

7.6.1.1.4. Specifies the schedule to review and/or recalculate the measurement uncertainty.

7.6.2. The FSL is not a calibration laboratory or a testing laboratory that performs its own calibrations. The laboratory uses outside vendors to perform calibrations.

7.6.3. The Laboratory has a procedure to estimate the uncertainty of measurement when values are reported for the barrel length of a firearm and/or the overall length of a firearm *[FEU01 Examination and Test Fire of Firearms and Weapons]*.

7.6.3.1. Estimation of measurement of uncertainty will be based on knowledge of the performance of the method, previous experience and validation data as well as any significant parameters that affect the measurement result as per unit-specific SOPs.

7.6.4. Records will be maintained by the casework units for evaluation and estimation of uncertainty. The records will include a statement defining the measurement, statement as to how traceability is established to the measurement, equipment used, uncertainty components considered, uncertainty components and how they were evaluated, data used to estimate repeatability/reproducibility, how calculations were performed, and the combined standard uncertainty, coverage factor, coverage probability, and expanded uncertainty.

7.7. Ensuring the validity of results

7.7.1. The laboratory will monitor the validity of results. SOPs will outline quality control procedures for each unit. The following are examples of quality control procedures (where applicable): the use of reference collections, use of certified reference materials, use of positive and negative controls, participation in proficiency testing programs, performance checks on instrumentation, and review of reported results and verifications.

7.7.1.1. *LOM03 – Procedures for Reviewing a Report of Examination* outlines the method and requirements for verifications. The laboratory performs technical review on 100% of scientific examination documentation and reports prior to release. Verifications of results shall be carried out by personnel that are currently authorized to perform testing; the record of verification shall include the identity of the person who performed the verification, when it was performed, the results of the verification, and any discrepancy/conflict resolution shall be recorded. Individuals cannot verify their own work.

7.7.1.2. *LOM03 – Procedures for Reviewing a Report of Examination* outlines the procedures for the technical review of technical records while *DOM16 – Procedures for Monitoring Court Testimony* outlines the procedures for verification of testimony. Both LOMs describe the methods used to ensure thorough review.

7.7.2. Each accredited discipline of the Forensic Science Laboratory will participate in proficiency testing. The DFS Quality Manager or designee will coordinate the ordering and submission of proficiency tests for the Forensic Science Laboratory.

7.7.2.1. Two external proficiency tests per qualified analyst will be successfully completed each year for each accredited discipline/scope in which the Forensic Science Laboratory provides forensic services.

7.7.2.2 External proficiency test results will be submitted to the proficiency test provider by the reporting analyst assigned to the proficiency test on or before the agreed upon due date.

7.7.2.3 Results will be released to the accrediting body of the Forensic Science Laboratory by the DFS Quality Unit.

7.7.3. If monitored data from 7.7.1 and 7.7.2 is found to be outside of the pre-defined criteria, a planned action will be undertaken to correct the problem and prevent incorrect results from being reported. *DOM07 – Practices for Quality Corrective Actions* procedures will be followed.

7.7.4. The laboratory will monitor the performance of personnel by the participation in proficiency testing obtained through external providers meeting ISO/IEC 17025:2017 standards or test providers approved by an accreditation body, and the comparison with results of other laboratories, where available and appropriate. The monitoring will be planned and reviewed. Each analyst performing casework will successfully complete two external proficiency tests per calendar year in his/her forensic science discipline. Casework units will follow the appropriate SOPs when participating in proficiency testing programs. While proficiency tests are to be completed as one would complete casework, proficiency testing participants shall limit their discussion of the test to direct supervisors and technical leaders and not those who are participating in the round of testing.

7.7.5. The process for monitoring of performance by intralaboratory comparison, interlaboratory comparison, proficiency testing or observation-based testing shall ensure results are not known or readily available to the participant being monitored; ensure use of approved methods; ensure appropriate technical records are retained; establish criteria for determining successful completion prior to the monitoring activity; require a mechanism to ensure the quality of intralaboratory comparisons, interlaboratory comparisons and observation-based monitoring prior to the monitoring activity.

7.7.6. The DFS Quality Manager or designee will prepare a plan to ensure conformance to standards 7.7.2.1 and 7.7.4 above. It will be stored in the quality assurance records.

7.7.7. When available an ANAB approved test provider will be used.

7.7.7.1. External proficiency test results will be submitted to the proficiency test provider on or before the agreed upon due date.

7.7.7.2. If an ANAB approved proficiency test provider is not available the Forensic Science Laboratory may use an internal proficiency test in compliance with documented pre-approval.

7.7.8. The DFS Quality Manager or designee will maintain the proficiency testing records to include: monitored discipline; design of the monitoring activity; expected results; records submitted to a proficiency test provider; evaluation of results and action taken for unexpected results; feedback on performance.

7.8. Reporting of results

7.8.1. General

7.8.1.1. In accordance with *LOM03 – Procedures for Reviewing a Report of Examination*, the results of a report shall be reviewed and authorized prior to release.

7.8.1.1.1. The authorizer of results shall review the technical record and document the review. In accordance with *LOM03 – Procedures for Reviewing a Report of Examination*, each FSL unit shall utilize a unit-specific technical review form to complete their full technical case file reviews.

7.8.1.2. FSL personnel will accurately, clearly, unambiguously, and objectively report the results of each examination according to the *LOM02 – Procedures for Case Documentation and Report Writing.* FSL Reports of Examination will include information regarding the examinations conducted and any information necessary for the interpretation of results. All issued reports shall be retained as technical records.

7.8.1.2.1. The results shall be provided in a written report or through electronic access.

7.8.1.2.2. *LOM02 – Procedures for Case Documentation and Report Writing* outline the procedure for writing reports, which covers:

7.8.1.2.2.1. what will be reported for all items received, including items on which no work was performed, items collected or created and

preserved for future testing, and for all (partial and complete) work performed;

7.8.1.2.2.2. qualifying the significance of associations in the report whether by a statistic or a qualitative statement where necessary;

7.8.1.2.2.3. communicating the reason(s) in the report when the reported results are inconclusive; and

7.8.1.2.2.4. reporting of the initial database entry (e.g., DNA profiles, friction ridge, ballistics, biometrics).

7.8.1.2.3. The FSL does not report results of calibration.

7.8.1.3. The Laboratory does not produce simplified reports.

7.8.2. Common requirements for reports (test, calibration or sampling)

7.8.2.1. Where necessary, each report shall include, at minimum, the title; name and address of the laboratory; unique identification of a complete report and clear identification of the end; requesting agency; testing method used; description of item(s); date of sampling (where critical to validity); analysis start and end dates; the report date; a reference to the sample plan (when relevant); a result for each item received by an analyst for the purpose of analysis; the results with the units of measurement (where applicable); additions to, deviations, or exclusions from the method; signature of the person(s) authorizing the report; and clear identification when results are from external providers. All testing under scope of accreditation is performed at the Laboratory. Additional information is provided during the discovery process.

7.8.2.2. The Laboratory shall be responsible for all the information provided in the report except where information is provided by the customer.

7.8.3. Specific requirements for test reports

7.8.3.1. Where necessary the case reports will contain information on specific test conditions, such as environmental conditions; A statement of conformity with requirements (see 7.8.6); where applicable, the

measurement uncertainty presented in the same unit as that of the measurement or in a term relative to the measurement (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;

7.8.3.2. 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 as the measurement result; where appropriate, opinions and interpretations (see 7.8.7); additional information that may be required by specific methods, authorities, customers or groups of customers.

7.8.3.2.1. The Laboratory is not prohibited from including measurement uncertainty in the report.

7.8.3.3. The case records will contain additional information regarding the results of sampling where necessary for the interpretation of the test results in addition to meeting ISO/IEC 17025:2017 (E).

7.8.4. Specific requirements for calibration certificates. The accredited Disciplines of FSL do not issue calibration certificates.

7.8.5. Reporting sampling - specific requirements. Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results: the date of sampling; unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate); the location of sampling, including any diagrams, sketches or photographs; a reference to the sampling plan and sampling method, including confidence levels and corresponding inference(s) regarding the population; details of any environmental conditions during sampling that affect

the interpretation of the results; information required to evaluate measurement uncertainty for subsequent testing or calibration.

7.8.5.1. Unit specific SOPs will define how each unit meets the requirements of this standard if necessary for the interpretation of results.

7.8.6. Reporting statements of conformity

7.8.6.1. The Laboratory does not provide statements of conformity.

7.8.7. Reporting opinions and interpretations

7.8.7.1. When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement.

7.8.7.2. The case report will document the basis upon which the opinions and interpretations have been made.

7.8.7.3. The content of communications, both verbal and written, that involve case specific consultations, opinions, or interpretations will be documented in the case activity/communication log. A verbal communication does not substitute a written report.

7.8.8. Amendments to reports

7.8.8.1. Once an FSL Report of Examination has been issued, any amendments must be made in the form of an Amended Report of Examination according to the *LOM02 – Procedures for Case Documentation and Report Writing.* Any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

7.8.8.2. Amendments to a report after issue shall be made only in the form of a further document which includes the case number and the word "Amended"

7.8.8.3. When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

7.9. Complaints

7.9.1. *DOM15 – Policy and Procedures for Complaints and Inquiries* covers the process of receipt, evaluation, and decision-making regarding complaints and inquiries.

7.9.2. Individuals are encouraged to submit a complaint or inquiry relating to the DFS using the Complaint/Inquiry Form. The form is available on the dfs.dc.gov website. *DOM15 – Policy and Procedures for Complaints and Inquiries* describes the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to Forensic Science Laboratory activities. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.9.3. The process for handling complaints shall include at least the following elements and methods:

7.9.3.1. Description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

7.9.3.2. Tracking and recording complaints, including actions undertaken to resolve them;

7.9.3.3. Ensuring that any appropriate action is taken.

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

7.9.5. Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

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

NOTE: This can be performed by external personnel.

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

7.10. Nonconforming work

7.10.1. The FSL QAM – Section 8.7 and the *DOM07 – Practices for Quality Corrective Actions* will be followed when a nonconformity occurs during the examination process. This policy and practice designates the steps taken for handling quality corrective actions.

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

7.10.3. Where the evaluation indicates that the nonconformity could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the FSL QAM – Section 8.7 and DOM07 – Practices for Quality Corrective Actions will be promptly followed.

7.11. Control of data and information management

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

7.11.2. The LIMS system used by the Laboratory shall be validated for functionality prior to use and when changes or modifications are made. The LIMS administrator is responsible for the notifying and implementing the validation and maintaining the documentation and authorizing use of the system.

7.11.2.1. The Laboratory does not develop its own computer software.

7.11.3. LIMS is protected from unauthorized access, safeguarded against tampering and loss, operates in an environment that complies with laboratory safety and security, maintained to ensure integrity of data and information, and includes recording system failures and taking appropriate corrective actions.

7.11.4. LIMS is managed and maintained on-site.

7.11.5. LIMS System Administrator Guide and DOM18 – LIMS Operational Procedures are available to all personnel in the Qualtrax Document Control and Compliance System.

7.11.6. Any manual calculations (or calculations performed in unlocked data cells) performed in casework will be reviewed during the technical and/or administrative review process.

8. MANAGEMENT SYSTEM REQUIREMENTS

8.1. Options

8.1.1. General

The laboratory has established, documents, implements and maintains a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. The FSL utilizes Option A.

8.2. Management system documentation (Option A)

8.2.1. The FSL has established, documented and maintained a quality system appropriate to its scope of activities and testing methods. The quality system is comprised of a QAM, DOMs, LOMs, SOPs, training manuals, and instructions that assure the quality of test results. All laboratory personnel are required to read, acknowledge, and become familiar with this QAM, DOMs, LOMs, and SOPs for their Unit, as well as all pertinent documents of the quality system within the discipline or area of employment. This review is documented in administrative records within the Qualtrax Document Control and Compliance System. This Program complies with International Standard 17025, the accreditation requirements of ANAB, and the Federal Bureau of Investigation Quality Assurance Standards for Forensic DNA Testing Laboratories (current version).

8.2.1.1. The Laboratory addresses in writing the words associated with the ANAB accreditation requirement. These include: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify.

8.2.2. The QAM, DOMs, LOMs, and SOPs address the competence, impartiality, and consistent operation of the DFS. With the support of the top FSL management and input from personnel, new policies, practices and procedures are developed and implemented when necessary.

8.2.3. Management will communicate with FSL personnel by memorandum(s), meetings or other means regarding the development, implementation and continuous improvement of the quality system. The FSL uses policies, objectives, audit results, data analysis, Quality Corrective Actions, Quality Preventive

Actions and management reviews to continuously improve the effectiveness of the quality system.

8.2.4. The QAM, DOMs, LOMs, SOPs and all other pertinent documents of the quality system are included in, referenced from, or linked to the Qualtrax Document Control and Compliance System. The quality system of the FSL ensures that functions are performed as intended and conform to the requirements of ISO/IEC 17025:2017 standards. The FSL's quality system documentation is comprised of laboratory policies and practices, and unit policies and procedures. The authority to implement change within each category is described below. FSL policy is set forth in this FSL QAM. The policy documents and any subsequent revisions are approved by the FSL Director. FSL practices are found in the LOMs. These practices and any subsequent revisions are approved by FSL Director. Laboratory policies and procedures supplement the FSL policies and practices. Laboratory policies and procedures, and any subsequent revisions are approved by the FSL Director.

8.2.5. All quality documents are authorized and available at all times to laboratory personnel through the Qualtrax Document Control and Compliance System.

8.3. Control of management system documents (ISO/IEC 17025:2017 Laboratory Management System Option A)

8.3.1. The FSL controls the documents that comprise its quality system according to *DOM02 – Procedures for Document Control*. Controlled document distribution will be accomplished by the use of the Qualtrax Document Control and Compliance System.

8.3.2. *DOM02 – Procedures for Document Control* ensures that: all FSL quality documents are approved for adequacy prior to issue by authorized personnel; quality documents are reviewed, and updated as necessary; changes and the current revision status of documents are identified and history of changes noted in the Qualtrax Document Control and Compliance System; relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled via the Qualtrax Document Control and Compliance System; documents are uniquely identified within the Qualtrax Document Control and Compliance System; the unintended use of obsolete documents is prevented; and suitable identification is applied to them if they are retained for any purpose.

8.4. Control of records (ISO/IEC 17025:2017 Laboratory Management System Option A)

8.4.1. The FSL establishes and retains legible records to demonstrate fulfillment of the quality system and ISO 17025:2017 requirements.

8.4.2. All FSL quality and technical records will be legible and readily retrievable from storage in appropriate DFS facilities. The retention times for records are outlined in the *Policy for Retention of Records*. The FSL has policies and standard operating procedures for the identification, collection, organization, accessibility, filing, storage, maintenance and disposal of quality and technical records. Technical and administrative records are identified to the specific test record through the LIMS, by the associated laboratory number. The technical and administrative records of a case packet are specified in *LOM02 – Procedures for Case Documentation and Report Writing.* All electronically stored documentation must be capable of instant retrieval and stored in such a manner as to prevent unauthorized access, destruction or deterioration. The laboratory has back-up measures to ensure that electronic documents are not lost in the event of a failure of the primary storage medium. Each laboratory unit will protect and back-up records stored electronically and have procedures to prevent unauthorized access to or amendment of these records. Each unit is responsible for documenting the procedures for record protection and back-up of electronic records. The DFS follows DC Government Information Technology guidelines as governed by the *Enterprise Cloud and Infrastructure Services (ECIS) agreement*.

8.5. Actions to address risks and opportunities (ISO/IEC 17025:2017 Laboratory Management System Option A)

8.5.1. The effectiveness of the Laboratory's Management System is continually improved through the use of quality objectives, audit results, data analysis, corrective and preventive actions, customer feedback, and management reviews.

8.5.1.1. The laboratory has a Health and Safety Officer to manage the laboratory health and safety program. The safety program is outlined in *DOM13 – Health and Safety* and this document, section 6.3

8.5.2. The documentation of Quality Preventive Actions will include the initiation of the action and the application of action steps and controls to ensure effectiveness.

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

8.6. Improvement (ISO/IEC 17025:2017 Laboratory Management System Option A)

8.6.1. The laboratory shall identify and select opportunities for improvement and implement any necessary actions through a myriad of actions such as annual quality document reviews, results of audits, corrective actions, management reviews, suggestions from personnel, analysis of data, and proficiency testing results.

8.6.2. The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analyzed and used to improve the management system, laboratory activities and customer service.

8.7. Corrective actions (ISO/IEC 17025:2017 Laboratory Management System Option A)

8.7.1. *DOM07 – Practices for Quality Corrective Actions* covers the process for addressing a non-conformity and outlines the reaction to the nonconformity and actions taken to control and correct it.

8.7.2. Implemented corrective actions will be appropriate to the magnitude and risk of the problem. Non-conformities will be evaluated based on impact and frequency. Those of high impact or frequency will route through the Quality Corrective Action process.

8.7.3. Corrective action records are maintained by Quality.

8.8. Internal audits (ISO/IEC 17025:2017 Laboratory Management System Option A)

8.8.1. The FSL follows *DOM06 – Procedures for Internal/External Audits*. The FSL will document whether the management system conforms to the requirements of ISO/IEC 17025:2017 (E) and ANAB AR 3125 in addition to its own laboratory requirements. The Laboratory will provide information on whether the management system is effectively implemented and maintained.

8.8.1.1. Internal audits will be conducted annually as well as prior to the initial accreditation assessment.

8.8.1.2. The Forensic Biology Unit audits will be performed as specified in Standard 15 of the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.

8.8.2. *DOM06 – Procedures for Internal/External Audits* will outline the plan of the audit program along with the audit criteria to be observed.

8.9. Management reviews (ISO/IEC 17025:2017 Laboratory Management System Option A)

8.9.1. *DOM09 – Annual Management Reviews* outlines the timeline for reviews, continued suitability and effectiveness, and adherence to policies and objectives of this document and agency requirements.

8.9.2. Management reviews shall be conducted at least annually, as well as prior to the initial accreditation assessment and cover the following: changes in internal and external issues that are relevant to the laboratory; fulfillment of objectives; suitability of policies and procedures; status of actions from previous management reviews; outcome of recent internal audits; corrective actions; assessments by external bodies; changes in the volume and type of work; customer and personnel feedback; complaints; effectiveness of implemented improvements; adequacy of resources; results of risk identification; outcomes of the validity of results; and other relevant factors, such as monitoring activities and training.

8.9.3. Inputs to management review shall adhere to *DOM09 – Annual Management Reviews.*

8.9.4. Outputs from the management review shall adhere to *DOM09 – Annual Management Reviews.*

9. REFERENCES

9.1 ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland (current revision).

9.2 ISO Guide 30:2015 – Reference Materials

9.3 ISO 17034:2016 – General requirements for the competence of reference material producers

9.4 JCGM 200:2012 – International vocabulary of metrology – Basic and general concepts and associated terms (VIM)

9.5 ISO 21043 – 1:2018 – Forensic sciences – Part 1: Terms and definitions

9.6 ANAB™ ISO/IEC 17025 Accreditation Requirements for Forensic Testing Laboratories, ANSI-ASQ Accreditation Board, Alexandria, VA (current revision).

9.7 Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, (current revision).

9.8 Departmental Operations Manuals (DOMs) (current revisions).

9.9 FSL Laboratory Operations Manuals (LOMs) (current revisions).

9.10 Unit-specific Quality Assurance Manuals (current revisions).

9.11 Unit Standard Operating Procedures (current revisions).

APPENDIX A

FSL PRACTICES FOR RECEIPT AND STORAGE OF REAGENTS, CHEMICALS, STANDARDS AND CONSUMABLE MATERIALS

1. RECEIPT, OPENING, AND VERIFICATION OF COMMERCIAL REAGENTS, CHEMICALS, STANDARDS AND CONSUMABLE MATERIALS

1.1 Upon receipt of all reagents, chemicals, standards and consumable materials, the packing slip will be checked for agreement with the items received as well as against the DFS Purchase Request Form.

1.1.1 Some of the items listed on the invoice might be received in different shipments (e.g., if an item is backordered). Check off the items received in the current shipment.

1.1.1.1 Bring any discrepancies to the attention of the Unit manager.

1.1.2 A copy (hard or electronic) of each packing slip initialed and dated by the receiver will be maintained as a permanent record.

1.2 All incoming reagents / chemicals / standards will have documented:

1.2.1 The date of receipt and/or of inventory of shipment contents.

1.2.2 The initials of the person receiving the reagent / chemical / standard.

1.3 All incoming reagents / chemicals / standards / consumable materials (when applicable) will be checked to ensure the label / packaging clearly reflects the identity of the item and the expiration date.

1.3.1 Commercial reagents / chemicals / standards without a supplied expiration date will be given a date as determined by unit-specific SOPs.

1.4 When a reagent / chemical / standard is opened, it will be marked with the date and initials of the person opening the reagent / chemical / standard.

NOTE: Reagents / chemicals / standards / consumable materials (when applicable) which have passed their expiration date will not be used on casework. However, these reagents /chemicals / standards / consumable materials may be used on non-critical samples (e.g., training samples) and will be appropriately labeled as such.

2 SAFETY DATA SHEET (SDS)

2.1 The SDS received from the manufacturer for each chemical used in the laboratory can be found in the designated Unit SDS record location (hard or electronic). These data sheets will be kept current and readily available to all laboratory personnel.

3 LABORATORY PREPARED REAGENTS AND SOLUTIONS

3.1 All laboratory prepared reagents and solutions will be using good laboratory practices.

3.2 A log will be maintained in each Unit for each laboratory prepared reagent / solution. Each reagent / solution prepared will have the following information recorded in the log:

3.2.1 chemicals used

3.2.2 commercial sources of chemicals

3.2.3 lot numbers of chemicals

3.2.4 expiration date

3.2.5 other pertinent data, if applicable, such as pH, QC check/results, autoclave indicator, etc.

3.2.6 lot / batch number

3.2.7 date prepared (not necessary if lot / batch number is preparation date and preparer's initials)

3.2.8 initials of individual preparing reagent / solution (not necessary if lot / batch number is preparation date and preparer's initials)

NOTE: The lot / batch number assigned to laboratory prepared reagents / solutions will consist of the date prepared (two-digit numerical representation for month, day and year) and the initials of the preparer.

Example: Lot number 101513MSC represents a reagent/solution prepared on October 15, 2013 by Marie S. Curie.

3.3 All laboratory prepared reagents / solutions will be clearly labeled or will include a barcode label. Labels will include the following:

3.3.1 reagent / solution identity

3.3.2 lot / batch number (which is comprised of the date of preparation and the initials of preparer)

3.3.3 expiration date (as specified in the Unit procedure manual or labeled “no expiration”, if applicable)

3.3.4 as appropriate, storage requirements

4 STORAGE AND DISPOSAL

4.1 All chemicals must be stored, used, and disposed of in a manner conforming to established safety requirements for that chemical.

5 CRITICAL REAGENTS

5.1 All critical reagents must be quality control tested / verified for accurate, reliable performance prior to being used on casework. Refer to each Unit manuals for specifics regarding quality control of critical reagents. The results of all quality control tests will be maintained.