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1 Scope

The Alaska Scientific Crime Detection Laboratory’s Quality Assurance Manual has been written by the Quality Assurance Manager and approved by the Chief, Forensic Laboratories. The Quality Assurance Manual is the foundation for the Laboratory’s Forensic Quality Assurance Program. The Quality Assurance Manual, the Health and Safety Manual, the individual Discipline Procedure Manuals, and the individual Discipline Training Manuals form the Forensic Quality Assurance Program.

All employees are responsible for performing work within the policies and procedures of the Laboratory’s Forensic Quality Assurance Program.
2 References


National DNA Index System (NDIS) Operational Procedures Manual, FBI Laboratory. Current Version


3 Terms and Definitions

Terms and definitions given in the ISO/IEC 17025:2017 (E), ANAB AR 3125, and JCGM 200:2012 also apply to this document unless defined.

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

ADAMS: Acronym for Authenticated Digital Asset Management System

ANAB: Acronym for ANSI National Accreditation Board

ANSI: Acronym for American National Standards Institute

Assistant Chief: Assistant Chief, Forensic Laboratories

Chain of custody: Documentation of all evidence transfers from receipt by the Laboratory until return to the submitting agency.

Chief: Chief, Forensic Laboratories (ANAB, AR 3125, 3.16)

Corrective Action Report (CAR): A document detailing the course of action taken to determine the root cause of a deviation from expected results, minimize its impact and recurrence.

CODIS: Acronym for Combined DNA Index System

Controlled document: A document distributed in a controlled manner to ensure that recipients receive subsequent revisions and replace previous versions to ensure current information is being utilized. Examples of Controlled Documents include but are not limited to the Quality Assurance Manual, Discipline Procedure Manuals, and Discipline Training Manuals.

CTS: Acronym for Collaborative Testing Services a proficiency test provider used by the Laboratory.

Customer: The submitting agency, a different law enforcement agency at the written direction of the submitting agency, the assigned district attorney or their agent, the municipal prosecutor or their agent.

Examination documentation: Case record documents with reference to procedures followed, tests conducted, standards/controls used, observations and results of examinations stored in the LIMS.

Examination record: Case record documents for one specific case stored in the electronic case file in the LIMS.

FA: Acronym for Forensic Assurance a proficiency test provider used by the Laboratory.

Issuing authority (ies): Personnel authorized to direct and implement document revisions. This will typically be the Chief, Assistant Chief, Quality Assurance Manager, DNA Technical Manager, Discipline Supervisors, CODIS Administrator, or Scientific Director of the Forensic Alcohol Program.
Key Management: Laboratory Management that includes the Chief, Assistant Chief, Quality Assurance Manager, Safety Coordinator, Discipline Supervisors, and the DNA Technical Manager.

LIMS: Acronym for Laboratory Information Management System

RLS: Acronym for Request for Laboratory Services Form

Top Management: The Chief, Assistant Chief, and the Quality Assurance Manager have laboratory wide authority.

SCDL: Acronym for Scientific Crime Detection Laboratory (also referred to as “the Laboratory”)

SOQ: Acronym for Statement of Qualifications (also referred to as curriculum vitae)
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 directs laboratory employees to avoid any activity, interest, or association that interferes or appears to interfere with their independent exercise of professional judgment. Any conflicts of interest or concerns shall be brought to the attention of the employee’s direct supervisor immediately.

4.1.3 The Laboratory Management System ensures there are no undue internal and external influences on the professional judgment of all laboratory management and personnel. Laboratory staff will complete and submit a State of Alaska Ethics Disclosure Form to request permission for outside employment, including volunteer work.

4.1.3.1a The State of Alaska ethics information for public employees is provided during the new employee training program. As members of the Department of Public Safety (DPS) Standards of Conduct Chapter 101 in the Alaska Department of Public Safety Operating Procedures Manual (OPM) applies to all laboratory employees. Ethics training will also incorporate the ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel document (PR 3150).

4.1.3.1b All forensic personnel shall annually review the PR 3150 ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel document and a record of the review shall be maintained in the quality assurance records.

4.1.3.1c The Laboratory Management System will take appropriate actions when necessary.

4.1.4 The Alaska Scientific Crime Detection Laboratory is an element within the Office of the Commissioner within the Alaska Department of Public Safety. At a minimum, the Laboratory shall identify risks to its impartiality annually.

4.1.5 Identification of a risk of impartiality will be brought to the attention of Top Management and a plan to eliminate or minimize the risk will be executed and documented. This will be stored in the quality assurance records.

4.2 Confidentiality

4.2.1 The Laboratory Management System shall ensure the protection of confidential information. The Laboratory notifies the customer of the potential release of information to specific entities when the RLS is created. Case related information should not to be disseminated by the Laboratory to any individual or organization other than the customer except as described in the RLS notification. Policy 7 outlines scientific examination report dissemination.

4.2.2 Unless prohibited by law, the customer will be notified when the Laboratory is required by law or authorized by contractual arrangements to release confidential information to entities other than those listed in the RLS notification. Record of this notification will be stored in the LIMS.
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 Laboratory staff 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.

5 Structural Requirements

5.1 The State of Alaska Department of Public Safety Scientific Crime Detection Laboratory provides forensic services as a governmental and publicly funded laboratory.

5.2 Top Management has overall responsibility for the Laboratory.

5.2.1 The Chief has full authority over the laboratory to include staff, budget, goals, and direction of the Laboratory and is responsible for administering, directing, and implementing the SCDL forensic operations. A full list of duties is available in the position description.

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 State of Alaska, federal authorities as related to the FBI DNA Quality Assurance Standards, ISO/IEC 17025, ANAB accreditation requirements, and to satisfy the needs of the customer. The Laboratory Management 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 Discipline Manuals. The proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and the Quality Assurance Standards for DNA Databasing Laboratories will be applied to DNA analysts and technical support personnel 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 the Alaska Statutes and the Alaska Administrative Code. DNA Registration System (AS 44.41.035) and Forensic Alcohol Testing Regulations (13 AAC 63) are readily available.

5.5a The Laboratory has an organizational chart demonstrating the management structure of SCDL and its place within the Alaska Department of Public Safety. The organizational chart is maintained by the Quality Assurance Manager.

The Chief reports directly to the Alaska Department of Public Safety, Office of the Commissioner.
The Assistant Chief is responsible for exercising a substantial latitude of authority to act in the absence of the Chief. The Assistant Chief exercises full supervisory authority to coordinate and direct the day-to-day multi-discipline forensic investigation, testing, and analysis activities of the Laboratory through reporting of supervisors in their respective forensic disciplines and is responsible for assessing and providing recommendations of substantial weight to the Chief with regards to laboratory budgeting, staffing, training, and technological needs. The Assistant Chief reports directly to the Chief.

The Quality Assurance Manager (Forensic Scientist IV) has the authority and obligation to ensure that the requirements of the Forensic Quality Assurance Program are implemented and maintained through scheduling, coordinating, and evaluating all aspects of the quality system including audits. The Quality Assurance Manager ensures compliance with ISO/IEC 17025:2017 (E) and the ANAB AR 3125. The Quality Assurance Manager is the controller of all quality assurance records and is responsible for assessing and providing recommendations to the Chief and Assistant Chief with regards to laboratory accreditation needs. The Quality Assurance Manager reports directly to the Chief.

Discipline Supervisors (Forensic Scientist IV) are the human resources and quality assurance interface within the discipline. Discipline Supervisors are responsible for recruitment and hiring of new employees, approving time sheets/leave requests for direct reports, evaluating interpersonal skills and tracking performance metrics of direct reports, case management for the disciplines under their supervision, ensuring manuals are reviewed according to laboratory standards, tracking spending and approving purchases within the limits of their authority, ensuring work conditions, equipment, and procedures protect health and safety, and monitoring and documenting appropriate corrective measures in relation to discrepant results. Discipline Supervisors have the authority to suspend analytical activity pending review and approval by a member of Top Management. The Discipline Supervisors report directly to the Assistant Chief.

The DNA Technical Manager manages the technical operations for the Forensic Biology Discipline. The DNA Technical Manager is responsible for evaluating all DNA methods used by the Laboratory and for proposing new or modified analytical procedures to be used by the analysts. The DNA Technical Manager is also specifically responsible for review and approval of the following for the Forensic Biology discipline: procedures, validations and methods, modifications to methodology, academic transcripts and qualifications of analysts and technicians, training program, tech, outsourcing agreements, internal and external audit documents, proficiency testing program and test results, quality assurance program, and Quality Review Forms and Corrective Action Reports. The DNA Technical Manager has the authority to suspend analytical activity pending review and approval by a member of Top Management. The DNA Technical Manager reports directly to the Assistant Chief.

Technical Leads have overall responsibility for all technical operations and the resources necessary to ensure quality forensic laboratory operations. Discipline Technical Leads are responsible for technical content of manuals, managing the performance of validations, the technical training of new analysts, ensuring quality control measures are being followed, and reviewing and evaluating proficiency test results. Technical Leads have the authority to suspend analytical activity pending review and approval by a member of Top Management. The Assistant Chief designates an individual as Technical Lead for each Discipline. This designation is indicated on the organizational chart.
The CODIS Administrator and Alternate CODIS Administrator are the central points of contact for CODIS operations in the laboratory. Additional information is provided in the CODIS Administrative Manual. This designation is indicated on the organizational chart.

The Safety Coordinator is designated by the Chief. This designation is indicated on the organizational chart. The Safety Coordinator oversees the safety program of the Laboratory and ensures that it is implemented and followed at all times. The Safety Coordinator provides educational opportunities in the areas of biological/chemical spill control, evacuation procedures, and hepatitis vaccination to laboratory personnel. The Safety Coordinator or a designee manages the chemical inventory of the laboratory. The Safety Coordinator may develop a safety committee to assist with the program.

5.5b The Laboratory Management System specifies the responsibilities and authority of all forensic personnel through position descriptions and competency memos. Each laboratory member is accountable to only one immediate supervisor per discipline. The Laboratory ensures adequate supervision and technical guidance of all employees including those in training. This supervision is performed by individuals familiar with the policies and procedures of the Laboratory and technical guidance performed by individuals familiar with the methods and procedures as well as the purpose and evaluation of the methods and procedures.

5.5c The Alaska Scientific Crime Detection Laboratory has and maintains a Forensic Quality Assurance Program which documents procedures necessary to assure the consistent application of activities and validity of results to include analysis and data interpretation to arrive at a result, opinion or interpretation.

5.6a The Quality Assurance Manager ensures the quality system is implemented and followed at all times. The Laboratory Management System provides all forensic personnel the authority and resources needed to carry out their duties, including implementation, maintenance and improvement of the quality system.

5.6b All personnel are encouraged to identify and report any deviations from the quality system to the Quality Assurance Manager or other Key Management as appropriate.

5.6c The Quality Assurance Manager in collaboration with the appropriate key managerial members will initiate action to prevent or minimize deviations.

5.6d All personnel are encouraged to report to Key Management on the performance of the management system and any need for improvement.

5.6e The Laboratory Management System shall ensure the effectiveness of laboratory activities. The Quality Assurance Manager will retain documents in the quality assurance records.

5.7a Key Management ensures processes are established within the Laboratory through regular meetings, email communications, written communications, and discussions with individuals. Communications include discussions on the effectiveness of the quality, administrative, and technical operations of the Laboratory. Key Management is responsible for communicating the importance of meeting customer requirements and for having in place operational procedures, which will provide adequate means of compliance with all applicable state laws.
5.7b Key Management will plan and implement all changes to the Forensic Quality Assurance Program to ensure the integrity of the Laboratory Management System. Records will be stored in the quality assurance records.

6 Resource Requirements

6.1 General

The Laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

6.2 Personnel

6.2.1 The Laboratory utilizes qualified technical personnel employed by the Laboratory. Contract employees will be held to the same standards and expectations as employees with respect to competency and proficiency testing.

6.2.2 The job descriptions, education, and experience requirements (class specifications) for each position are available online via the Workplace Alaska website under Job Class Specifications. Training, technical knowledge, skills, and experience requirements are documented in Discipline Training Manuals. The DNA Technical Manager and all Forensic Scientists performing DNA analysis must also meet the education, training, and experience requirements set forth by the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories and the FBI Quality Assurance Standards for DNA Databasing Laboratories at the time of hiring.

6.2.2.1 The Chief shall possess a baccalaureate degree or higher from an accredited college in natural science or physical sciences, forensic sciences, criminalistics or a closely related field.

The Assistant Chief shall possess a baccalaureate degree or higher from an accredited college in natural science or physical sciences, forensic sciences, criminalistics, or a closely relate field.

The DNA Technical Manager shall possess a master’s degree from an accredited college in biology, chemistry, or forensic science and shall meet all of the educational requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories.

Forensic Scientists performing casework in the Biology discipline shall possess a baccalaureate or an advanced degree in a natural science or a closely related field and shall meet the educational requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories.

Forensic Scientists performing casework in the Crime Scene, Firearms/Toolmarks, Footwear, and Friction Ridge disciplines shall possess a baccalaureate or an advanced degree with science courses.

Forensic Scientists performing casework in the Seized Drugs discipline shall possess a baccalaureate or an advanced degree in a natural science or a closely related field.

Forensic Scientists performing casework in the Toxicology discipline shall possess a baccalaureate or an advanced degree in a natural science, toxicology, or a closely related field.
Forensic Technicians and Criminal Justice Technicians working as technical support in any discipline shall meet the educational requirements specified in the job description.

6.2.2.2 All employees hired by the Laboratory will complete the New Employee Training Program (NETP) within 90 days of the start date. The NETP includes general knowledge of forensic science, application of ethical practices in forensic science, information regarding criminal law, civil law, and testimony. Each Discipline will have a formal documented training program used to train individuals in the knowledge, skills and abilities to perform all aspects of the position held. The completion of training memo is retained in the quality assurance records. The training records will be maintained by the analyst. The training program and training records will be sufficiently detailed to provide evidence that the individual has been properly trained and competency tested. Training programs may take into account any past training or work experience an individual may possess. The training program includes provisions for retraining, maintenance of skills and experience, and criteria for acceptable performance. Key Management provides for continuing education and maintenance of skills and abilities of personnel by providing for training, availability of literature, and encouraging personnel to continually develop their scientific skills and knowledge. If retraining is deemed necessary, a specific plan for that individual will be developed by the Discipline Supervisor in collaboration with the DNA Technical Manager or Technical Lead, as appropriate, and the Quality Assurance Manager. This plan would include at a minimum the scope of the retraining required, a plan of action to accomplish the retraining, and the trainer(s) assigned. Any retraining or competency testing performed will be documented.

6.2.3 Key Management will ensure the competency of all personnel that operate equipment and instrumentation, perform laboratory activities, and evaluate the significance of deviations. Any personnel undergoing training will be supervised by competent personnel.

6.2.3.1 Key Management will ensure that all Forensic Scientists performing casework satisfactorily complete a competency test for each discipline to cover the applicable components of testing and test methods prior to assuming casework responsibilities. A competency memo will be issued and retained in the quality assurance records for that individual.

The following shall be included in the training program of all Forensic Scientists that issue laboratory reports:

Examination of unknown samples covering the range of assigned duties and areas within the discipline or components of testing.

Demonstration of the appropriate use of equipment needed to perform testing.

A written test report demonstrating the ability to properly convey results and conclusions, express opinions or an interpretation, and their significance.

A written or oral examination demonstrating the individual’s knowledge of the discipline or components of testing, and tasks performed.

Each of the above will be appropriately documented and retained in the training records for that individual.

6.2.3.2 Personnel who review and authorize results, an opinion or an interpretation, or perform technical review of results or testimony, meet competency requirements as specified in 6.2.3.1.
6.2.4 The position descriptions (PD) explain the duties, functions, and tasks for each job and are maintained by the administrative support personnel. Competency memos and authorizations are stored in the quality assurance records and are available to personnel upon request to the Quality Assurance Manager.

6.2.5a Competency requirements are determined by the Discipline Supervisors in cooperation with the DNA Technical Manager or discipline Technical Leads. The requirements are recorded in the Discipline Training Manuals.

6.2.5b The Laboratory follows the State of Alaska Department of Administration Personnel and Labor Relations Standard Operating Procedures for the selection of personnel and retains the records according to State of Alaska 2 AAC 07.113.

6.2.5c Key Management will provide for the continuing education and training of all laboratory personnel. Identifying training needs, providing this training to personnel, and evaluating the effectiveness of this training is the responsibility of the Discipline Supervisors.

Discipline Supervisors can identify training needs through one on one conversation with their discipline members, during discussions of performance evaluations, and in discipline meetings.

Discipline Supervisors will provide occasions for each member to attend education courses when such attendance will directly benefit the effectiveness or efficiency of services provided.

Key Management will provide opportunities for training whenever possible and appropriate to ensure the best utilization of personnel resources.

Each competency tested Forensic Scientist performing DNA analysis must meet the hours of continuing education required by the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories and the FBI Quality Assurance Standards for DNA Databasing Laboratories each calendar year.

A laboratory member receiving training is responsible for completing such training in a satisfactory and professional manner and will complete an evaluation of the training received for scientifically relevant training. This evaluation will be documented in the training record in the LIMS. Laboratory members are encouraged to improve their knowledge and skills through a variety of educational opportunities such as literature readings, attending conferences, and other professional meetings.

6.2.5d Each laboratory member is accountable to only one immediate supervisor per discipline. The Laboratory maintains an organizational chart that depicts the supervisory structure. Archived organizational charts are available upon request from the Quality Assurance Manager.

6.2.5e The Chief or Assistant Chief shall authorize an individual to authorize reports and express opinions or interpretations based on documentation from the Discipline Supervisor or DNA Technical Manager through the Quality Assurance Manager. Authorization to perform other laboratory tasks shall come from the DNA Technical Manager or Technical Lead through the appropriate supervisor to the Quality Assurance Manager. The Quality Assurance Manager will retain records of all forensic personnel to include educational qualifications, new employee training, and competency memos. The competency memo will be issued upon completion of a training program or module that includes the scope of competency and date authorized for casework or performance of the laboratory task.
6.2.5f The Laboratory performs Performance Evaluation Reports in accordance with the State of Alaska Department of Administration Personnel and Labor Relations Rater’s Guide. Evaluations are retained by the administrative section.

6.2.6a The DNA Technical Manager and discipline Technical Leads have the authority to develop, modify, verify, and validate methods. Other competent staff have the authority to assist or perform these tasks as defined in each individual’s competency memo(s).

6.2.6b Forensic Scientists and the DNA Technical Manager have the authority to perform analysis of results, including statements of conformity or opinions and interpretations as defined in each individual’s competency memo(s).

6.2.6c Forensic Scientists and the DNA Technical Manager have the authority to report, review and authorize results as defined in each individual’s competency memo(s).

Note: A competency matrix is available in the quality assurance records to identify staff with memos of competency for each laboratory task.

6.3 Facilities and Environmental Conditions

6.3.1 Laboratory facilities will be appropriate to facilitate performance of all aspects of testing and provide for storage of records, supplies, space for equipment and instruments and shall not adversely affect the validity of results.

6.3.2 All examinations require normal laboratory environmental conditions unless noted in a procedure. Normal laboratory environmental conditions are controlled and monitored by the building maintenance staff.

6.3.3 Examinations will be stopped when 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 laboratory testing areas is limited and controlled. The Chief or designee determines the access level. Access levels will be reviewed and updated annually during the internal audit at minimum. The Laboratory will take measures to prevent contamination, interference, or adverse influences on laboratory activities. The Laboratory Management System will review these measures annually during the Annual Management Review. The Laboratory will provide effective separation between incompatible activities or testing. Disciplines will monitor and review the effectiveness of separation, at a minimum, annually during the internal audit.

6.3.4.1 The Laboratory entrance/exit points and the outer perimeter have security control at all times. The internal testing areas of the Laboratory have a locking system. Security codes, cards, and keys for the laboratory’s individual interior forensic discipline laboratories will be issued to individuals by the Chief or designee. These items will be accounted for and documented as described in the Key Control Procedure (Appendix A) and Policy 3 Laboratory Occupancy. The laboratory facility is monitored by an intrusion alarm system. The laboratory facility has a fire detection system. Evidence storage areas are secured and have limited and controlled access. The storage conditions are designed to prevent loss, deterioration and contamination as well as maintain the integrity and identity of the evidence. Discipline Supervisors will implement appropriate measures to prevent unauthorized access to computers used for
6.3.5 The Laboratory does not perform laboratory activities outside of its permanent control except for the Crime Scene Discipline as described in the Discipline Manual.

6.4 Equipment

6.4.1 Key Management will ensure that all equipment necessary for laboratory activities are available to laboratory personnel.

6.4.2 Laboratory equipment will not be used by non-laboratory personnel without prior approval from the Chief. 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.

6.4.3 Each Discipline shall have procedures for the safe handling, transport, storage, use and planned maintenance of equipment. Discipline Procedure Manuals 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 the appropriate personnel.

6.4.3.1 Reagents prepared in the disciplines will be labeled with, at a minimum, the identity of the reagent, the date of preparation or lot number. Each Discipline will maintain records that will identify the identity of the preparer, the components used in preparation, who performed the quality control check and the results of the quality control check. Reagents will be prepared by authorized personnel.

6.4.3.2 Disciplines utilizing reference collections maintained for identification, comparison or interpretation purposes will document, uniquely identify and properly control the reference collection.

6.4.4 Equipment and its software used for casework will meet the accuracy requirements set forth in the Discipline Procedure Manuals. Prior to use in casework, equipment will be calibrated or performance checked as described in the Discipline Procedure Manuals.

6.4.5 Each Discipline will have a documented procedure for the calibration of equipment used for testing that have a significant effect on the accuracy or validity of the test result. All equipment described above will be calibrated prior to being put into service.

6.4.6 The Laboratory shall calibrate measuring equipment when the measurement accuracy or measurement uncertainty affects the validity of the reported results and/or calibration of the equipment is required to establish metrological traceability of the reported results.

6.4.7 Each Discipline 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. Each Discipline will have a procedure for the calibration of their reference standards. The procedure will ensure the reference standards are calibrated by a provider that can provide traceability to the SI units by means of an unbroken chain of calibrations and comparisons linking the reference...
standards to the relevant primary standards of the SI units of measurement. Reference standards will only be utilized for calibration purposes; unless it can be documented that additional use will not invalidate their performance as reference standards. Reference standards will be calibrated before and after any adjustment. Reference standards will be traceable to SI units of measurement or to certified reference materials. Internal reference materials will be checked to verify their suitability.

6.4.7.1 Each Discipline will have a list of the equipment and reference standards requiring calibration, specifications for the calibration, laboratory specified requirement for the calibration, and the interval of calibration.

6.4.8 Where practicable, Laboratory equipment requiring calibration will be labeled with the status of calibration to include date calibration was performed and date next calibration is due.

6.4.9 Any equipment that has been shown to be defective or operating outside of limits specified in Discipline Procedure Manuals will be taken out of service and marked as such. The equipment will be repaired and, once reliability has been demonstrated by calibration and/or performance checks, returned to use. A determination will be made if any test results were affected. The procedure for nonconforming work will be followed, if necessary.

6.4.10 Discipline Procedure Manuals will outline any performance checks required on equipment. Discipline procedures will establish the time frame for checking based on the specifics of the testing performed with the equipment. Calibration checks will not be less stringent than the manufacturer’s recommendations. Each Discipline will have procedures to perform checks on reference, primary or working standards and reference materials to maintain confidence in their performance. Each Discipline will have documented procedures for routinely checking the reliability of their reagents.

6.4.11 Discipline Procedure Manuals will ensure that any necessary correction factors are correctly updated.

6.4.12 Discipline personnel will ensure that equipment is safeguarded from any adjustments that would invalidate the test and/or calibration results.

6.4.13 Laboratory instruments and equipment will be labeled and uniquely identified. Disciplines will keep equipment records to include:

- a) identity of the equipment and its software and firmware;
- b) manufacturer, type, and serial number or unique identifier;
- c) evidence of verification that equipment conforms with specified requirements, performance checks and/or calibration records;
- d) current location;
- e) calibration certificates, adjustments, date of next calibration as applicable;
- f) documentation of reference materials, results, acceptance criteria, relevant dates, and the period of validity;
- g) maintenance performed and, where appropriate, maintenance plan;
- h) repair records.

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 Disciplines should utilize competent external calibration services that can demonstrate measurement capability and traceability and meet the criteria set forth in ANAB AR 3125 6.5.1.1. The calibration certificates issued by these entities will contain the calibration results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification. The accredited Disciplines of the Alaska Scientific Crime Detection Laboratory do not issue calibration certificates.

6.5.1.2 In situations where a supplier that meets 6.5.1.1 is not available, the competence, capability, and metrological traceability for the supplier and the external product of service being purchase will be confirmed and retained in the quality assurance records.

6.5.1.3 The Laboratory does not calibrate its own equipment.

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 Discipline records for the certified reference material.

6.5.2 Measurements made by disciplines should be traceable to SI units. The link to SI units may be achieved by reference to national measurement standards.

6.5.3 Where traceability of measurements to SI units is not possible and/or relevant, Disciplines will establish traceability to other appropriate measurement standards such as certified reference materials or reference standards. The accredited Disciplines of the Alaska Scientific Crime Detection Laboratory do not issue calibration certificates.

6.6 Externally Provided Products and Services

6.6.1 The Laboratory shall ensure suitable externally provided products and services that affect laboratory activities are used when they are intended for incorporation into the Laboratory’s own activities, are provided, in part or in full, directly to the customer by the Laboratory as received from the external provider, and are used to support the operation of the Laboratory. The Laboratory is responsible for subcontractor work unless the submitting agency specifies the subcontractor to be used. The Laboratory will only subcontract with a competent subcontractor that complies with International Standard 17025 or another Forensic Laboratory Accrediting Body.

6.6.2 State purchasing guidelines govern the procurement of products and services for the Laboratory. The Purchasing Procedure (Appendix C) describes the selection and purchase of supplies and services including those that affect the quality of tests performed. The Laboratory will maintain a record of all approved subcontractors used for testing. Disciplines using a subcontractor will define how documentation generated by the subcontractor is retained. The Laboratory will ensure that purchased supplies, reagents and consumable materials affecting the quality of tests are not used until they have been verified as complying with the requirements defined in the test methods or calibrations performed. Each Discipline will maintain records of these actions taken to verify compliance.
6.6.3 The Laboratory will maintain purchasing documents for supplies, reagents and consumable materials. These purchasing documents will be reviewed and approved based on technical content by the Discipline Supervisor (or designee). Laboratory Management will evaluate suppliers of critical consumables, supplies and services following the Purchasing Procedure (Appendix C) and maintain records of the evaluations. The completed Vendor Approval for Critical Supplies and Services Forms will be stored in the LIMS and will expire within one year or with the expiration of the vendor’s accreditation, whichever is sooner. These will be reviewed annually during the internal audit.

7 Process Requirements

7.1 Review of Requests, Tenders and Contracts

7.1.1 The Procedure for Evidence Management Manual provides evidence intake procedures. The RLS is considered the contract between the Laboratory and the customer. Review of requests for work is managed by the appropriate Discipline Supervisor or designee. The Laboratory will advise the submitting agency in writing prior to any work performed by an external provider (subcontracted). Review of requests for subcontracted work is managed by the appropriate Discipline Supervisor or designee. The Laboratory will use test methods, including sampling, that are appropriate for the analysis and which meet the needs of the customer.

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 on the RLS. The RLS notifies the customer upon opening of this agreement. 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.

7.1.3 The Laboratory does not provide statements of conformity.

7.1.4 Laboratory personnel evaluate the Request for Laboratory Services Form prior to the examination of evidence to ensure that the Laboratory has the capability to perform the request. Any discrepancies will be resolved before laboratory activities commence.

7.1.5 Agencies are notified when changes are made to requested examinations. This notification is documented in the LIMS.

7.1.6 Any changes to the Request for Laboratory Services information made after examination of an evidence item begins are communicated to the agency and documented in case activities/case log in the LIMS.

7.1.7 Laboratory staff communicate with agency representatives to clarify requests when needed and to advise on the status of the requests.

7.1.8 Communications with agencies regarding evidence submissions are documented in case activities/case log in the LIMS.

7.1.9 The extent of database searches will be communicated to the customer and updated as needed by the Discipline Supervisor of the relevant database.
7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and Verification of Methods

7.2.1.1 The Laboratory will use appropriate methods and procedures for all tests performed. Discipline Procedure Manuals will include methods and procedures for all testing performed in that specific discipline to include sampling, handling, preparation of evidence to be tested, and, where appropriate, an estimation of the measurement of uncertainty with statistical techniques for analysis of test data.

7.2.1.1.1 Discipline Procedure Manuals will describe the method by which comparison of an unknown to a known are evaluated.

7.2.1.2 The breath alcohol discipline of SCDL is not accredited.

7.2.1.2 Discipline Procedure Manuals will include or reference instructions on the use and operation of all equipment and instruments used by that specific discipline. Discipline Procedure Manuals will describe the handling and preparation of evidence for testing. Each discipline will maintain and keep up to date all equipment and instrument instructions; standards; manuals and reference information relative to testing performed.

7.2.1.3 Methods used by the Laboratory will either be validated laboratory-developed methods or published in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or specified by the manufacturer of the equipment. Technical Leads will ensure that all methods operate properly before using them for testing and Discipline Supervisors will approve the use of the method.

7.2.1.4 See 7.1.2

7.2.1.5 Methods validated outside of the Laboratory will be evaluated prior to implementation. This will include reliability testing by the discipline through a documented in-house performance verification. This verification will be maintained in the discipline records for future reference.

7.2.1.6 The Discipline Supervisor (the DNA Technical Manager for the Forensic Biology discipline) will coordinate the introduction of any new test methods used in the Discipline. The Discipline Supervisor or the DNA Technical Manager will consult with the Quality Assurance Manager and the appropriate Technical Lead during the development of the new method. The new method will be documented, validated, approved, and communicated to the discipline prior to use in casework.

7.2.1.7 Any significant deviations from test methods will be documented in the case record, technically justified and documented through the technical case review process. Customers are contacted when appropriate regarding analysis deviations.

7.2.2 Validation of Methods

7.2.2.1 Validations will be performed on all new technical methods or procedures to demonstrate reliable and accurate results for the intended use of the method or procedure. Validation of new methods or procedures for the Laboratory will confirm, by examination and objective evidence, that the requirements for the intended use of the new method or procedure have been met.
7.2.2.1 Disciplines performing method validation will provide to the Quality Assurance Manager a summary of the successful validation that includes the associated data interpretation, establishes the data required to report a result, opinion, or interpretation, and identified limitations of the method, reported results, opinions, and interpretations.

7.2.2.2 When changes are made to validated methods, the DNA Technical Manager or Technical Leads will determine the influence of the changes and where they are found to affect the original validation will consult the Discipline Supervisor and Quality Assurance Manager 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 The validation process will review the range and accuracy of the results obtained from testing to ensure the new technical method or procedure meets the requirements needed.

7.2.2.4 Disciplines will maintain a record of the validation to include the procedure used, requirements, 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 The Laboratory will have a documented sampling plan for disciplines that take a representative sample of a substance or material for testing and report on the whole substance or material. The sampling plan will be available at the location where sampling is undertaken and will address the factors to be controlled to ensure the validity of the testing.

7.3.2 The sampling method shall meet the requirements of ISO/IEC 17025:2017 (E) 7.3.2 and ANAB AR 3125 7.3.2.1.

7.3.3 When a sampling plan is utilized it will be documented in the case records in LIMS and at a minimum will meet the standards set forth in ISO/IEC 17025:2017 (E). Disciplines that use sampling plans will describe any additional requirements in the Discipline Procedure Manuals. Deviations from the sampling plan require prior approval from the Discipline Supervisor, DNA Technical Manager, and/or Technical Lead and will be documented in LIMS.

7.4 Handling of Test or Calibration Items

7.4.1 Procedures for the transportation, receipt, handling, storage, and retention of evidence items will be outlined in the Procedure for Evidence Management Manual to ensure the integrity of the evidence and protect the interests of the Laboratory and the submitting agency.

7.4.1.1 Items received at the Laboratory with an RLS are considered to be evidence. The Procedure for Evidence Management Manual provides a procedure for meeting this standard. The appropriate Discipline Procedure Manuals will outline procedures for the operation of individual characteristic databases. The CODIS individual characteristic database is treated as reference materials. The Laboratory does not have any individual characteristic databases under its control that are treated as evidence.
7.4.2 Evidence received at the Laboratory will be assigned a unique identifier comprised of the Laboratory case number and item number. This identifier is retained and documented in the LIMS. The LIMS provides a system to sub-divide evidence items as well as documents all transfer of items within and from the Laboratory. Each CODIS database sample under the control of the Laboratory will be uniquely identified.

7.4.2.1 All items received at The Laboratory are subject to 7.4.2.

7.4.3 Upon receipt of evidence, departures from normal or specified conditions will be documented in the LIMS. If the suitability of an item of evidence for examination is questionable or the request for examination is unclear, the submitting agency will be contacted. This communication will be documented in the LIMS.

7.4.4 The Laboratory maintains, monitors, and records conditions when items need to be stored or conditioned under specified environmental conditions. Disciplines define where these records are stored.

7.5 Technical Records

7.5.1 All Analysts will keep notes which adequately document the basis for any findings concerning evidence analyzed and tests performed in every case for which they have evidentiary analysis responsibilities. Analysts will document original observations, data and sufficient information to establish an audit trail and issue a report. All records will indicate the identity of the personnel that performed each aspect of the case by documenting in the examination notes. The start and end date of the analysis will be documented for each case in the LIMS. The start date is the date analysis or evidence examination begins. The end date is the date the analyst finalizes the case sending it for technical and/or administrative review. All notes and case files are stored at the Laboratory either in hard copy form or in the LIMS. The operating parameters of all instrumental analyses conducted will be documented. Each Discipline’s Procedure Manual will define the location of these instrumental records. Any deviations from the established parameters will be recorded and documented in the examination notes of the case in the LIMS. The analyst’s name or initials along with the Laboratory’s unique case number will be present on every page of the case examination records. Instrument-generated records meet this requirement if they include the printed case number and date. For each page of the examination documentation, a numbering system will be used which indicates the total number of pages used. This is not required for case data maintained completely within the LIMS. It is the responsibility of all analysts to prepare a report which contains the results and conclusions of analyses performed for every case for which they have evidentiary analysis responsibilities. When technical records are prepared by an individual other than the analyst who interprets the findings, the individual’s handwritten initials will be on each page of the documentation representing his/her work. The Laboratory’s unique case numbers will be present on all data generated when data from multiple cases is recorded on a single printout. This printout may be stored in a single file and referenced in the multiple files for which it was produced. The Laboratory does not allow the use of double-sided pages in case files.

7.5.1.1 Case documentation must include, but is not limited to, data obtained through the analytical process. It should also include information regarding the packaging of the evidence as received, in particular whether the package is properly sealed and protected from contamination, where applicable and any discrepancies noticed between the evidence received and the RLS. All documentation of procedures, standards and controls used, observations made, results of the tests performed, charts,
graphs, photographs, digital images, video prints, communications, etc., which are used to support the analyst’s conclusions, must be preserved. After a case has been technically and administratively reviewed the only copies of the case file will be the hard copy file or the electronic record in the LIMS. Any printed copies are to be shredded once they are no longer needed. Only photocopied or printed copies of electronic case files will be taken from the Laboratory. The exceptions are Crime Scene, Latent Print, and Footwear/Tire Track case files that contain items needed for court. Any other exceptions to this policy must be approved by a member of Top Management.

7.5.1.2 Abbreviations and notations will be acceptable if they are clearly documented and comprehensible. Discipline Procedure Manuals will contain a list of common abbreviations, acronyms, and/or symbols that are used by their personnel.

7.5.1.3 Case records to support conclusions must be such that in the absence of the original analyst, another person qualified in that Discipline through training and experience could evaluate the testing performed and interpret the data.

7.5.1.4 Case notes, records of observations, and other examination documentation must be of a permanent nature. Hand written notes and observations should be in ink, not pencil. Pencil may be appropriate for crime scene notes, diagrams or tracings, or when environmental conditions prevent the use of ink.

7.5.1.5 Examination notes will include observations, data and calculations. These notes will be documented at the time of examination and identifiable to the specific task. If an observation or result is rejected by the analyst the reason must be documented in the examination documentation.

7.5.1.6 The Laboratory does not perform calibrations within an accredited discipline.

7.5.2 No entry may be made on case notes or other records which hides, obscures or disguises the true nature of any examinations, results, conclusions, and interpretations. If an error is made, the incorrect information should be marked through with a single line and initialed. Erasures or use of correction fluids is not allowed. Interlinear additions must be initialed and dated by the person adding the information. Amendments to the technical record are tracked by the LIMS system and are available upon request to the quality assurance manager or the LIMS administrator.

7.6 Evaluation of Measurement Uncertainty

7.6.1 Disciplines identify contributions to measurement uncertainty. Contributions that are of significance shall be taken into account using appropriate methods of analysis and discipline procedures shall maintain documents of the evaluation that demonstrated the significance.

7.6.1.1 The method of analysis for evaluation of measurement uncertainty shall meet ANAB AR 3125. Methods are documented in the appropriate Discipline Manual.

7.6.2 The Laboratory does not perform calibrations within an accredited discipline.

7.6.3 The Laboratory has a procedure to estimate the uncertainty of measurement when values are reported for the weight of controlled substances, the concentration of blood alcohol, the concentration of alcohol in a liquid, the barrel length of a firearm and/or the overall length of a firearm.
7.6.4 Estimation of the uncertainty of measurement was based on knowledge of the performance of the method and previous experience as well as any significant parameters that affect the measurement result to include:

- Statement of the measurand
- Statement of the measurement traceability
- Equipment used
- All uncertainty components considered
- All significant uncertainty components and their evaluation
- Data used to estimate repeatability and/or reproducibility
- All calculations
- The combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty
- The schedule to review and/or recalculate the measurement of uncertainty.

7.7 Ensuring the Validity of Results

7.7.1 The Laboratory will monitor the validity of testing through the use of quality control procedures. Each Discipline Procedure Manual will outline the quality control procedures for that specific Discipline. The following are examples of quality control procedures:

- Use of reference collections;
- Use of certified reference materials;
- Use of positive and negative controls;
- Participation in proficiency testing programs;
- Performance Checks on instruments and equipment;
- Review of reported results and Verifications.

Discipline Procedure Manuals will specify the controls and standards utilized in each method or procedure. All controls and standards utilized in casework will be documented in the examination documentation. The Laboratory will perform technical review on 100% of scientific examination documentation and test reports prior to release. Verifications are performed as specified in Discipline Procedure Manuals. The technical review process ensures the conclusions are reasonable within the constraints of the validated technical knowledge and supported by the examination documentation. Technical reviews are documented in the LIMS. The Discipline Supervisor, Technical Lead, or the DNA Technical Manager will resolve any differences in opinion between the case analyst and the reviewer. Each case record is technically reviewed to include a review of all examination documentation and the test report to ensure:

- Conformance with Laboratory and Discipline procedures;
- Data supports the results and/or conclusions (including calculations for accuracy);
- Accuracy of the test report;
- Associations are properly qualified in the test report;
- Test report contains all required information.
Additional guidelines for the technical review process may be outlined in the Discipline Procedure Manuals. Technical reviews will be conducted by a qualified competency tested analyst who has extensive knowledge of the Discipline through casework, supervision, training and/or regular casework review. The reviewer will have knowledge of the Laboratory’s technical procedures. A memo will be approved by a member of Top Management to authorize an analyst as competent to perform technical reviews. Credentials of approved technical reviewers not employed by SCDL will be reviewed on an annual basis during the internal audit. The technical reviewer will not have authored or co-authored the examination records or test report under review. The Laboratory will perform administrative review on 100% of scientific examination documentation and test reports. The administrative review process ensures the completeness, correctness and clarity of the test reports issued. Administrative reviews are documented in LIMS and the administrative reviewer will not have authored or co-authored the examination records or test report under review. Administrative reviews will be performed by a technician, analyst, or forensic supervisor. At a minimum, the administrative review will include:

- A review of the test report for spelling and grammatical accuracy;
- A review of all administrative and examination documentation to ensure that the records are uniquely identified according to laboratory policies and procedures;
- A review of the test report to ensure that all key information is included;
- Chain of custody.

The administrative reviewer will review the Request for Laboratory Services Form, the test report, bench notes and all additional case documents, in the LIMS, to ensure agreement with the following areas:

- Requesting agency
- Agency case number
- Laboratory case number
- Officer name
- Agency item numbers and descriptions.

The Laboratory will monitor the testimony of all testifying personnel. Each testifying individual will have an evaluation of their testimony at least once per calendar year. Court monitoring provides constructive feedback both positive and any needed improvement.

This may be accomplished through one of the following methods:

- Direct observation by a laboratory member, court officer, or other individual present in the court room;
- Communication by Key Management with a court officer;
- Review of court transcripts by a technically competent analyst.

The Witness Evaluation Forms are used to obtain testimony feedback. The form should be returned directly to the Laboratory’s Quality Assurance Manager. The Quality Assurance Manager will review the form and provide a copy to the testifier’s Supervisor. The Supervisor will provide the testimony feedback to the testifier.
If the feedback indicates needed improvement, the testifier's Supervisor will seek further information to determine the course of action to be taken. This communication will be documented as well as any remedial action that is taken. This documentation will be retained by the Quality Assurance Manager.

It is each individual’s responsibility to advise their Supervisor of any pending court appearances and seek testimony feedback. At the end of each calendar year Discipline Supervisors will notify the Quality Assurance Manager of any Discipline personnel that did not testify. The Quality Assurance Manager will retain testimony monitoring records and any remedial actions taken for not less than ten years.

Once per accreditation, each analyst, testifying in court, will have a technical review of their testimony performed by the appropriate Technical Lead or DNA Technical Manager. Testimony by the Technical Lead or DNA Technical Manager will be technically reviewed by a Forensic Scientist that is technically competent in the discipline. This review can be in person or by review of court transcripts at a later date. The record of the review shall be maintained in the quality assurance records.

Identifications that require an independent check on a critical finding (verification) will be performed by another currently qualified and proficiency tested analyst and documented in the case record. Established criteria for individual sections that necessitate a verification are listed in each Discipline’s Procedure Manual.

7.7.2 Each Discipline of the Laboratory will participate in proficiency testing. The Quality Assurance Manager will coordinate the ordering and submission of proficiency tests for the Laboratory. See Appendix E for further information.

7.7.2.1 At least one external proficiency test will be successfully completed each year for each discipline of forensic science the Laboratory provides service in and will release the results to ANAB.

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. Discipline Procedure Manuals will provide additional guidance for that specific Discipline. Quality Review and Corrective Action procedures will be followed.

7.7.4 Each analyst performing casework will successfully complete at least one internal or external proficiency test per calendar year in his/her forensic science discipline.

7.7.5 Laboratory members will perform proficiency tests by utilizing the same test methods, technical review, verification, and administrative review procedures as are normally applied to casework. Each proficiency test will have a case file in the LIMS and will be logged in as directed in the Themis User Manual. In addition, Proficiency Tests will be submitted as per Appendix E for Collaborative Testing Services (CTS) and Forensic Assurance (FA). Any proficiency test provided by another company will be addressed on a case by case basis. All proficiency test documentation is maintained in the quality assurance records. Dates of proficiency testing are each identified by the due date to the proficiency test provider. Proficiency tests will be turned in to the test provider at least 5 business days prior to the proficiency test provider due date. Any deviation from this deadline must be approved by the Quality Assurance Manager. Proficiency test results are evaluated based on the discipline. Blood alcohol results must fall within two standard deviations of the grand mean reported by the provider with the reported uncertainty of measurement range considered, if applicable. Controlled substances, firearm, serial number restoration, toolmark, latent print, crime scene, footwear, and biological screening results must
be consistent with the reported result by the provider. Should any variations of results arise within these categories of testing, the Discipline Supervisor and Quality Assurance Manager will evaluate on a case by case basis. DNA results are evaluated by the items listed under sub-category 13.1.7 of Standard 13 (proficiency testing) of the FBI QAS audit documents and checklists (current version) for forensic DNA testing and DNA databasing laboratories. DNA profile typing data must have no analytical errors. Results and conclusions reported must be consistent with the DNA section standard operating procedures and interpretation guidelines.

7.7.6 The Quality Assurance Manager will prepare a plan to ensure conformance to standards 7.7.2.1b 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. If an ANAB approved proficiency test provider is not available the Laboratory may use an internal proficiency test in compliance with documented preapproval.

7.7.8 The Quality Assurance Manager will maintain the proficiency testing records and proficiency testing program records to include:

- Disciplines Monitored
- 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 the individual performance provided to the participant

7.8 Reporting of Results

7.8.1 General

7.8.1.1 Laboratory results shall be reviewed and authorized prior to release by the analyst.

7.8.1.1.1 The analyst is the authorizer of the results and the review is documented in the LIMS by submitting the results for technical review.

7.8.1.2 The Laboratory will issue reports that accurately, clearly, unambiguously and objectively provide the result of each test performed. Comparative examinations resulting in the elimination of an individual or object will be clearly communicated in the laboratory report.

7.8.1.2.1 The results shall be provided in a written report. Preliminary verbal results can be provided to the customer by the authorizer of the results prior to a written report being completed. If preliminary results are provided, the analyst will clearly indicate to the customer that the information given is:

- Preliminary in nature
- Subject to Change
- Requires a technical and administrative review

The analyst will document in the LIMS a record of the release of information including the information provided, the person the information was provided to, and when the information was provided.
7.8.1.2.2 Discipline Procedure Manuals shall identify what will be reported for all items received by an analyst for the purpose of analysis, 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); require qualifying the significance of associations in the report whether by a statistic or qualitative statement; require communicating the reason in the report when the reported results are inconclusive; require reporting of the initial database entry; and require reporting of an association resulting from a database search.

7.8.1.2.3 The Laboratory does not perform calibration services in an accredited discipline.

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 Each report shall include the following information (or reasons for not including information)

7.8.2.1a A title

7.8.2.1b Name and address of the laboratory

7.8.2.1c All testing is performed at the Laboratory with the exception of the Crime Scene Discipline which notes in the report the location testing was performed

7.8.2.1d Case number on each page or pagination uniquely identify that all its components are recognized as a portion of a complete report and a clear identification of the end

7.8.2.1e The agency and name of the submitting officer (contact information is on the RLS which is stored in the case record; notification when RLS opens)

7.8.2.1f Identification of the methods used

7.8.2.1g Item description

7.8.2.1h Date of item creation in the LIMS and associated package (Package Chain of Custody in the case record gives date package was received at the Laboratory but item creation indicates when the item was removed from the box and accepted by the Laboratory.)

7.8.2.1i Analysis start and end dates

7.8.2.1j The report creation date

7.8.2.1k When relevant a reference to the sample plan used

7.8.2.1l A result for each item received by an analyst for the purpose of analysis (Result - Not Analyzed indicates that an item wasn’t tested and therefore isn’t associated to any other result in the report)

7.8.2.1m Result with units of measurement if applicable

7.8.2.1n Additions to, deviations, or exclusions from the method

7.8.2.1o Signature of the analyst authorizing the report
7.8.2.1p clear identification when results are from external providers

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 and will be noted when necessary.

7.8.3 Specific Requirements for Test Reports

7.8.3.1 Where necessary the case reports will contain the following:

7.8.3.1a Information on specific test conditions

7.8.3.1b A statement of conformity with requirements

7.8.3.1c measurement uncertainty presented in the same unit as that of the measurand and meet ANAB AR 3125 7.8.3.1.c.1

7.8.3.1d opinions and interpretations

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

7.8.3.2 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) 7.8.5

7.8.4 Specific Requirements for Calibration Certificates

The accredited Disciplines of SCDL do not issue calibration certificates.

7.8.5 Reporting Sampling – Specific Requirements

Discipline Manuals will define how the Laboratory meet the requirements of this standard if necessary for the interpretation of results.

7.8.6 Reporting Statements of Conformity

The Laboratory does not provide statements of conformity.

7.8.7 Reporting Opinions and Interpretations

7.8.7.1 Opinions and interpretations will be clearly marked in laboratory reports.

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 activities/case log. A verbal communication does not substitute a written report.

7.8.8 Amendments to Reports

7.8.8.1 An amended report will be issued, when a change to a distributed report is necessary, which clearly communicates the reason for the amended report. The Themis User Manual provides information on amending and correcting reports.
7.8.8.2 The amended report will state “This amended report serves to replace the report issued on date.” And will have a new Report Creation Date.

7.8.8.3 If necessary to issue a complete new report, the report shall be uniquely identified by the new Analysis Start and End Dates and Report Creation Date and will state “This amended report serves to replace the report issued on date.”

7.9 Complaints

7.9.1 Laboratory employees will deal with complaints as outlined in the Alaska Department of Public Safety Operating Procedures Manual (OPM), Chapter 111. Any staff member receiving a complaint should resolve the issue, if it is within their responsibility, or notify the appropriate member of Key Management for resolution. Records of non-case specific complaints will be documented in the LIMS under the Quality Assurance Site in the Document Library “CUSTOMERQ” folder. Records of case specific complaints will be documented in the case activities/case log area of the case record in LIMS.

7.9.2 Members of Key Management will deal with complaints that relate to laboratory activities. This will be documented in the Supervisor Meeting minutes.

7.9.3 The process for handling complaints is outlined as stated in 7.9.1.

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

7.9.5 The Laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome when allowable.

7.9.6 The outcomes to be communicated to the complainant shall be made by or reviewed and approved Key Management not involved in the original activities in question.

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 If a nonconformity is discovered in the Laboratory’s testing or results of work or if there is a significant deviation from Laboratory policies, the following will occur:

   a) The appropriate Discipline Supervisor and/or DNA Technical Manager will be notified of the nonconformity as soon as possible via Quality Review Form. The Quality Assurance Manager will be informed.

   b) An evaluation of the significance/risk of the nonconformity will occur. This evaluation will be documented on the Quality Review Form.

   c) The Quality Assurance Manager will review the Quality Review to determine if a root cause analysis needs to occur. If yes, the process will move to a Corrective Action.

   d) Any corrective action needed will be taken along with a decision about the acceptability of the nonconforming work.

   e) The agency is notified, when appropriate, of the nonconformity.
f) The Discipline Supervisor and/or DNA Technical Manager will authorize, if ceased, the resumption of work after consulting with a member of Top Management.

7.10.2 The Laboratory retains records of nonconforming work and actions in the quality assurance records.

7.10.3 Corrective action is implemented when the evaluation in 7.10.1b and c indicate that a nonconformity could reoccur or when there is doubt about compliance with the Laboratory’s Forensic Quality Assurance Program.

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 When computers or automated equipment are used for casework, Discipline Supervisors will ensure that procedures are established and implemented for protecting the integrity and confidentiality of data and computers and automated equipment are properly maintained to ensure the integrity of data.

7.11.4 The LIMS system is managed and maintained by the Office of Information Technology in conjunction with an offsite vendor. The Laboratory ensures that the operator of the system complies with all applicable requirements of this document.

7.11.5 The Laboratory has relevant manuals for the LIMS system that are readily available to personnel in addition to the LIMS system’s own help function.

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.

7.11.6.1 The check of manual calculations is part of technical review.

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 Laboratory utilizes 8.1.2 Option A.

8.2 Management System Documentation (Option A)

8.2.1 The mission of the State of Alaska Department of Public Safety Scientific Crime Detection Laboratory will be to provide forensic services to the Alaskan community through Scientific Analysis,
Integrity, and Training. These overall objectives are met through the implementation of the Forensic Quality Assurance Program. This Program complies with International Standard 17025, the accreditation requirements of ANAB, the Federal Bureau of Investigation Quality Assurance Standards for Forensic DNA Testing Laboratories (current version), and the Federal Bureau of Investigation Quality Assurance Standards for Forensic DNA Databasing Laboratories (current version).

8.2.1.1 The Laboratory addresses in writing the words associated with the ANAB accreditation requirement 8.2.1.1.

8.2.2 The documents of the Forensic Quality Assurance Program are reviewed and updated as necessary to improve the effectiveness of the program. All personnel are required to familiarize themselves with the Quality Assurance Manual, Health and Safety Manual, the Discipline Procedure Manuals, and procedures specific to the scope of their responsibility.

8.2.3 Key Management provides evidence of their commitment to the development, implementation, and continual improvement of the effectiveness of the Laboratory Management System through discussions at regular supervisor meetings, monthly laboratory staff meetings, and discipline meetings.

8.2.4 The Forensic Quality Assurance Program is comprised of the Laboratory Quality Assurance Manual, Discipline Procedure Manuals, Discipline Training Manuals, and Health and Safety Manual. The authority to approve and revise Forensic Quality Assurance Program documentation is defined as follows:

Laboratory policy is set forth in this Quality Assurance Manual. The Quality Assurance Manual is approved by the Chief. Any revisions to the Laboratory Quality Assurance Manual are approved by the Chief or designee.

Laboratory technical procedures are found in each Discipline’s Procedure Manuals and/or Discipline Work Instructions. The Procedure Manuals and Work Instructions are written by technically competent analysts and approved by the Discipline Supervisors and/or the DNA Technical Manager. Any revisions to the Procedure Manuals and Work Instructions are approved by the Discipline Supervisors and/or the DNA Technical Manager.

Laboratory training procedures are found in each Discipline Training Manual. The Training Manuals are approved by the Discipline’s Supervisor and/or the DNA Technical Manager. Any revisions to the Training Manuals are approved by the Discipline’s Supervisor and/or the DNA Technical Manager.

Each new Laboratory employee will complete the New Employee Training Program. The New Employee Training Program is approved by the Quality Assurance Manager and any revisions are approved by the Quality Assurance Manager.

The Health and Safety Manual is approved by the Safety Coordinator. Any revisions to the Health and Safety Manual are approved by the Safety Coordinator.

8.2.5 All documents in the Forensic Quality Assurance Program are authorized and available at all times to laboratory personnel through the Laboratory’s internal network drive.
8.3 Control of Management System Documents (Option A)

8.3.1 All documents that comprise the Forensic Quality Assurance Program are controlled and maintained according to the Controlled Documents Procedure (Appendix B) by the Quality Assurance Manager.

8.3.2 All documents in the Forensic Quality Assurance Program are reviewed and approved by the appropriate person prior to issue. The Quality Assurance Manager will maintain a master controlled documents list according to the Controlled Documents Procedure (Appendix B). This list identifies the current revision of all controlled documents to preclude the use of invalid and/or obsolete documents. The Controlled Documents Procedure (Appendix B) ensures that all documents in the Forensic Quality Assurance Program are periodically reviewed and revised when necessary to ensure compliance, are current versions and invalid and/or obsolete documents are promptly archived to assure against unintended use, and once obsolete are suitably marked and retained. All documents in the Forensic Quality Assurance Program are uniquely identified. Each document contains the date issued, issuing authority, revision identification, and page numbering system. Changes will be identified in the Revision History of each document as outlined in the Controlled Documents Procedure (Appendix B). The Laboratory does not allow the amendment of controlled documents by hand. Manuals are changed/updated via document revisions only.

8.4 Control of Records (Option A)

8.4.1 The Laboratory will maintain quality and technical records. Records will be stored in the LIMS system, the quality assurance records, Discipline records and/or hard copy case records. Examples of the quality assurance records include but are not limited to information from assessments, management reviews, corrective and preventive actions taken, and training /continuing education records. Training and continuing education records are stored either in the quality assurance records or within the individual’s training records in the LIMS. Hard copy documents can be digitized for storage only after a review of the scans for legibility and completeness is completed prior to disposal of hard copies. Disposal of records will be in compliance with the current version of the Alaska State Archives Records and Information Management Service Policies and Procedures Manual.

8.4.2 Laboratory records will be legible, appropriately stored and readily retrievable. Retention times for quality assurance records will be a minimum 10 years. All examination documentation and case records are stored for a minimum of 50 years. Hard copy case files (prior to electronic LIMS) are stored in the records room # 1125 of the Crime Lab. Employees needing to review a case file will retrieve the file and place an OUT card in the file drawer/box to indicate who has control of that case file. All files or parts of files are to be returned to the location from which they were retrieved and the OUT card removed. All electronic case files will be stored in the LIMS. All records will be stored in a secured and confidential manner. The LIMS is stored securely by the Office of Information Technology under the Department of Administration personnel. The LIMS will auto-logoff timeout after 3 hours of inactivity to prevent unauthorized access but allow analysts sufficient analysis time.

8.5 Actions to Address Risks and Opportunities (Option A)

8.5.1 The effectiveness of the Laboratory’s Management System is continually improved through the use of the documents of the Forensic Quality Assurance Program, quality objectives, audit results, data analysis, corrective and preventive actions, and management reviews.
8.5.1.1 The Chief will designate a Safety Coordinator to manage the Laboratory safety program. The safety program will include:

- Annual Bloodborne Pathogen training for all employees.
- Annual Fire Extinguisher training for all employees.
- CPR and AED training for employees.
- First Aid training for employees.
- Periodic in-house training on safety issues. This may include annual review of biological/chemical spill control, evacuation procedures, hepatitis vaccination, and safety training opportunities.
- Documentation of employees participating in safety training (in-house, external).
- Monitoring compliance with OSHA requirements (e.g. Regular checks on exhaust hoods, fire extinguishers, eye washes, Safety Data Sheets (SDS), etc. and appropriate record-keeping).
- Maintenance of the Laboratory’s chemical inventory, with associated hazard warnings and employee access to Safety Data Sheets.

8.5.2 The documentation of the preventive action will include the initiation of the action and the application of 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 (Option A)

8.6.1 Laboratory Management will proactively identify areas of needed improvement or potential sources of nonconformities. When identified, action plans will be developed, implemented, and monitored. Documentation will be maintained in the quality assurance records.

8.6.2 The Laboratory utilizes customer surveys to obtain feedback from the agencies regarding evidence submissions. Feedback from surveys will be reviewed by Top Management.

8.7 Corrective Actions (Option A)

8.7.1 Any Laboratory member may identify when nonconforming work or departures from Laboratory’s Forensic Quality Assurance Program may have occurred. Any member identifying such potential concerns will immediately notify the Discipline Supervisor, DNA Technical Manager, Quality Assurance Manager, Assistant Chief, or Chief as appropriate. The Discipline Supervisor, DNA Technical Manager, and/or the Quality Assurance Manager will initiate the corrective action process with a root cause analysis to ensure that the cause, rather than just a symptom, of the nonconformance will be prevented from occurring again. The root cause analysis should take into consideration all possible sources of nonconforming work to include an evaluation of the methods, procedures, equipment, supplies, training, work environment, customer agency needs, etc. Upon completion of the root cause analysis, the Discipline Supervisor and/or DNA Technical Manager will meet with the Quality Assurance Manager and discuss their findings. If needed, the Discipline Supervisor and/or DNA Technical Manager and Quality Assurance Manager will select the corrective action and implement to
address the problem and prevent reoccurrence of the nonconformity. It is the responsibility of the Quality Assurance Manager, with assistance from the Discipline Supervisor, Technical Lead, and/or the DNA Technical Manager, to verify and monitor the effectiveness and implementation of the corrective action plan. A general timeline will be created at the beginning of each corrective action report by the Discipline Supervisor, Technical Lead, and/or the DNA Technical Manager to provide the Quality Assurance Manager with the information necessary to perform this function. A Summary of Corrective Action Report Form will be completed by the Quality Assurance Manager when a Corrective Action is finalized and the Form will be uploaded to the Laboratory’s website. The Laboratory will perform an audit of the appropriate areas, as soon as possible, when nonconformities could affect the Laboratory’s compliance with the Forensic Quality Assurance Program, International Standard 17025, or ANAB AR 3125.

8.7.2 Implemented corrective actions will be appropriate to the magnitude and risk of the problem. The corrective action process will be documented on the Corrective Action Report Form. This documentation will be maintained by the Quality Assurance Manager.

8.7.3 Corrective action records are maintained in the quality assurance records.

8.8 Internal Audits (Option A)

8.8.1 The Laboratory will conduct internal and external audits on a predetermined schedule. The Quality Assurance Manager will plan and organize the laboratory audit. The Laboratory 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. Laboratory members will be trained and instructed about their audit responsibilities by the Quality Assurance Manager or designee and will assist in the audits as requested. The Forensic Biology audits will be performed as specified in Standard 15 of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories.

8.8.1.1 Internal audits will be conducted at least annually at the direction of the Quality Assurance Manager.

8.8.2 The Laboratory will take timely corrective actions if an audit reveals that the effectiveness of operations or correctness of testing or calibration may be in question. Documentation of the internal audits will include at a minimum the scope of the audit, audit findings, and any corrective actions that may arise from the audit. Internal audits will include direct observation of a sample of accredited services within each discipline. Records of internal audits will be retained in the quality assurance records for a period of at least ten years. Should corrective actions arise from an internal audit; the follow up activities will verify and document the implementation and effectiveness of the corrective actions taken.

8.9 Management Reviews (Option A)

8.9.1 Key Management Review will be held annually within 60 days of the final completion of the annual internal audit and will also include future planning for The Laboratory. Records of Laboratory Management reviews will be stored in the quality assurance records for at least ten years.
8.9.2 Key Management will conduct reviews of the Laboratory Management System and testing and/or calibration activities to ensure their continuing suitability and effectiveness. The review will take account of:

- Suitability of policies and procedures;
- Reports from management and supervisory personnel;
- Outcome of recent internal audits;
- Corrective and preventive actions;
- Assessments by external bodies;
- Results of inter-laboratory comparisons or proficiency tests;
- Changes in the volume and type of work;
- Customer feedback;
- Complaints;
- Recommendations for improvement;

Other relevant factors, such as quality control activities, resources and staff training.

8.9.3 The Quality Assurance Manager will document the annual review of the Laboratory Management System along with any findings and/or actions that arise from the review. Any actions will be carried out in a timely manner.
Appendix A Key Control Procedure

1. All controlled laboratory keys shall be stamped with numbers for tracking purposes. This Key Control procedure includes laboratory door keys, electronic keys, and evidence locker keys.

2. Top Management will be assigned the responsibility of being the Key Controller of all electronic keys and facility master keys. Discipline Supervisors shall be the Key Controller for all discipline specific areas as required. Discipline procedure manuals will outline the handling of discipline specific keys. All evidence related, non-electronic keys are tracked in the JusticeTrax LIMS utilizing the chain of custody in the “Management” case. Common/Day Use lockers in the discipline laboratories are excluded from tracking. Electronic keys are controlled through the use of a Lenel OnGuard security system.

3. Electronic keys are assigned by Top Management to individuals who require facility access. Permissions to access areas of the facility are granted based on need. As an example:
   A. Department of Public Safety employees have general building access (entrance/exit, hallways) and access to specific rooms as required (telecommunication closets, conference rooms).
   B. Vendors may be granted general building and instrument room access as needed.

4. When a SCDL employee leaves the Department, the Supervisor shall be responsible for obtaining the controlled keys before the employee leaves and for returning the controlled keys to the appropriate Key Controller within five days. For those keys tracked in the LIMS, the Key Controller will show the return of the keys and retain the keys for future assignment. For electronic keys, the profile will be deactivated.

5. Laboratory employees are responsible for exercising due care in preventing loss of facility keys. If a key is lost or stolen, the SCDL employee shall provide prompt, verbal notification to their immediate Supervisor. Upon verbal notification, the SCDL employee shall submit a memorandum to the Chief. The written report shall include:
   (1) Employee's name
   (2) Employee's key number
   (3) A brief description of the events surrounding the key loss
   When a key has been lost, the Chief shall decide whether or not to rekey the affected locks within the Laboratory for security purposes.

6. If a key is recovered at a later date, a memorandum shall be written to the Chief by the employee originally responsible for that key. The key should be placed in the custody of the Key Controller and records changed to reflect the recovery. The memorandum should include:
   (1) Employee's name
   (2) Employee's key number - recovered key
   (3) Date key was lost
   (4) Brief description of events surrounding the finding of the key.

Copies of these memorandums will be stored in the quality assurance records.
Appendix B  Controlled Documents Procedure

The Forensic Quality Assurance Program documents are controlled to ensure the documents have been approved for use and only current versions of the documents are in use. Controlled documents are posted on the Laboratory’s internal network drive.

Controlled Document Review, Approval, and Issuance

The Laboratory Quality Assurance Manual, Procedure for Evidence Management Manual, The Themis User Manual, and the JusticeTrax User Manual are reviewed and approved by the Chief. The Discipline Procedure Manuals, Discipline Work Instructions, and Discipline Training Manuals are written by the Technical Leads and are reviewed and approved by the Discipline Supervisors and/or the DNA Technical Manager. The CODIS Manual is reviewed and approved by the CODIS Administrator. The Health and Safety Manual is reviewed and approved by the Laboratory’s Safety Coordinator. All reviewed and approved manuals are sent to the Quality Assurance Manager. The Quality Assurance Manager will issue the manuals to the appropriate laboratory staff by placing them on the internal network drive.

Controlled Document Maintenance

The Quality Assurance Manager or designee will maintain the official controlled documents, place them on the internal network drive and archive all versions of the controlled documents. The Quality Assurance Manager will maintain a Master Controlled Documents List. It will contain a list of all controlled documents indicating the active version and a list of the most recently archived version of each document.

Controlled Document Revisions

Revisions to controlled documents are reviewed and approved by the same authorities that approved the original document. Any revised or new text is identified in the revision history of each controlled document. Changes in issuing authority will be documented in the revision history or approval from a member of Top Management will be documented. Worksheets are excluded from revision history requirement. The current document will be archived and the new version will be posted on the Laboratory’s internal network drive by the Quality Assurance Manager or designee. All archived controlled documents are marked with a visible watermark and the status updated to “archived”.

All Discipline Procedure Manuals, the Laboratory Quality Assurance Manual, the Laboratory User’s Guide, the Procedure for Evidence Management Manual and the Health and Safety Manual must be reviewed and updated at least annually no later than September 15. Training manuals, controlled forms, working instructions, and worksheets must be reviewed and updated at least every 36 months from the date of last issue. Any externally controlled documents are updated when a new version is posted by the issuing authority. This review is performed by the same authorities that approved the manual. During this review process the staff may submit suggested changes to the manual. If a manual is reviewed and does not require an update then the reviewer will email the Quality Assurance Manager to document the review and that updates are not required at this time. At any time, a laboratory member may submit suggested changes to a manual to the approving authority for consideration.
Appendix C Purchasing Procedure

Each Discipline will maintain a copy of records of purchased supplies, reagents, and consumable materials that affect the quality of tests. These supplies, reagents, and consumable materials will not be used in casework until their reliability has been verified. Each Discipline will have procedures to ensure the quality and reliability of supplies, reagents, and consumable materials. These procedures will also include the actions taken if a product fails to meet the quality standard set.

Vendors of supplies, reagents, and consumable materials that affect the quality of tests will be evaluated utilizing the Vendor Approval for Supplies and Services Form. The evaluation documentation will be maintained in the LIMS in the Quality Assurance Site Document Library “Vendor Forms” folder.

Reagent grade chemicals are purchased unless otherwise specified in a Discipline Procedure Manual.

Packing or shipping receipts are maintained to demonstrate receipt of the ordered supplies, reagents, or consumable materials that could affect the quality of tests.

The individual verifying the receipt of these items will notate the receipt of each ordered item on the packing or shipping receipt. Signature or initials and date will be placed on the receipt as well.
### Appendix D  Laboratory Policies

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Policy 1 Case Management

It is the goal of the Laboratory to process all evidence in a timely manner while maintaining the highest quality of analytical results. All requests for laboratory service (RLS) submitted to the crime lab require data entry of the case into the Laboratory Information Management System (LIMS).

1. Cases are generally worked in the order received. Exceptions are made based on rush requests made by the customer. These requests are normally based on court dates or the need for investigative information. Cases having court mandated deadlines and/or those providing immediate investigative leads will receive priority attention. Then cases may be evaluated for probative value by the appropriate Supervisor. Discipline Supervisors or their designee evaluate and approve rush requests when appropriate. Reasons for approved rush requests should be documented in the LIMS.

2. Examination of evidence procured from the laboratory evidence unit, or by any other means, should be performed as soon as possible and completed within 60 days of an analyst receiving the evidence. If an examination cannot be completed within 60 days, the case analyst should notify the Discipline Supervisor.

3. When the scientific examination is complete, the evidence should be expeditiously returned to the appropriate storage facility (laboratory evidence unit or unit refrigerated/frozen storage). Evidence that has undergone complete processing should not be stored in the laboratory. Exceptions to this are found in discipline manuals where specific items are retained in the laboratory.

4. If case processing cannot begin due to lack of standards/exemplars, lack of information from the officer or prosecutor, or for any other reason outside of the control of the Laboratory, then communication to the parties necessary to resolve the issue shall be initiated and documented in the LIMS. The communication should contain appropriate statements informing the recipient(s) that an analysis will be performed once the necessary items/information are received. If no response is received within 30 calendar days, the request can be suspended and evidence may be returned. This shall be documented in the LIMS and the request for service cancelled.

5. If a request from the submitting agency or District Attorney is received to withdraw the request for analysis, or if in the opinion of the supervisor, processing the case will provide no useful information, then the request for service may be cancelled. When a request is cancelled, communication detailing who, when and why the request was cancelled shall be sent to the affected parties, and documented in the LIMS.

It is the responsibility of the Discipline Supervisor to monitor case progress and ensure cases are completed in a timely manner.
Policy 2 Independent Experts or Experts in Laboratory Facilities

1. Attorneys or independent experts (non-Laboratory employees) are not permitted to perform or view scientific examinations in Crime Laboratory areas. The reasons for this policy are as follows:

   A. Liability - Outside personnel are not familiar with the Crime Laboratory, its potential hazards, safety rules, OSHA mandated Chemical Hygiene Plan, Exposure Control Plan, and specific equipment operation.

   B. Security - Outside personnel would be disruptive to the normal work routine since all other regular case work would have to be stopped and secured while they were using the facility. To do otherwise would undoubtedly raise questions and possible objections on other cases. Laboratory security requires a continuous escort for visitors. Valuable examination time would be lost by Laboratory personnel providing this escort service.

   C. Property Damage - The Laboratory utilizes a myriad of sophisticated instrumentation. State funding has been provided to ensure that Laboratory personnel can operate this equipment in a proper manner. It would be impossible to determine the competency of others prior to their use of the Laboratory's specific make and model of instrumentation.

   D. Fiscal Responsibility - Use of state equipment by outside experts would prevent its use for current case examination by Laboratory personnel. It must be realized that private experts represent a commercial and often lucrative enterprise. Therefore, it should be incumbent upon them to provide their own equipment and supplies, rather than having state facilities made available to them at the State’s expense.

   E. Defense attorneys have the right under the Alaska Rules of Criminal Procedure to have evidence reanalyzed at a laboratory of their choice, rather than disrupting Laboratory operations.

2. Attorneys or non-Laboratory Forensic Experts will make arrangements to view evidence by contacting the case officer or prosecutor who will then coordinate the time and place of viewing with appropriate Laboratory personnel.
Policy 3 Laboratory Occupancy

1. Due to safety considerations, no one should be alone in the laboratory while conducting scientific examinations, particularly those involving chemical or biological reagents, firearms, or other hazardous materials.

2. Personnel may work alone in the office area to conduct administrative duties such as: scientific report review; reports, paper or memo preparation; court preparation; latent print verification reviews; etc. Personnel may also operate analytical instrumentation workstations for data handling and printing of analytical results.

3. The Laboratory’s routine operational hours shall be from 6:00 AM to 6:00 PM Monday through Friday. Employees shall maintain a routine schedule approved by their Supervisor within the operational hours of the Laboratory.

4. Anyone who wishes to work outside of routine operational hours in the laboratory must have prior approval of their Supervisor.
Policy 4 Scheduled Time Off and Court Conflicts

Forensic staff by virtue of the very nature of the job has a professional obligation, as well as a legal responsibility, to respond to every subpoena received. When scheduled time off (vacation, day off, training, etc.) conflicts with a subpoena, the following protocol shall be followed:

1. Subpoenas take precedence over all scheduled time off.

2. When a verbal request for appearance in court is received, the scientist/technician should request a written subpoena be sent to serve as the official notification.

3. Unresolved scheduling conflicts involving court settings are to be brought to the attention of the scientist/technician’s supervisor as soon as they develop. The Chief may also be informed as needed.

4. Under no circumstances is a scientist/technician to advise a prosecutor that they will not respond to a court request due to interference with time off, however, it is acceptable to discuss scheduled vacation time with a prosecutor to determine if alternate plans for the court appearance are possible.

5. At the discretion of the supervisor, and with concurrence from the prosecutor, court/time off conflicts may be resolved by having the evidence reanalyzed, giving testimony from the Laboratory records, or telephonic testimony. However, should neither of these remedies be feasible and testimony still required the scientist/technician will be expected to alter time off plans to allow testimony to be given.
Policy 5 Disclosure of Scientific Examination Documentation

1. Routine disclosure of scientific examination documentation will include those items utilized for rendering an expert opinion in the case at hand and will be provided upon request from the prosecutor’s office.

2. Discipline Procedure Manuals, Laboratory Quality Assurance Documents, and other documents related to the operation of a discipline or the Laboratory are posted on the Laboratory’s website including archived manuals.

3. Raw data files pertaining to instrumental analysis will not be retained with the exception of data from genetic analyzers.

4. Copyrighted or licensed materials will not be copied or disseminated by the Laboratory and can only be released by the owner of the information or documents.

5. Public information not proprietary to the Laboratory (vendor, instrument or software manuals, journal articles or papers) will not be provided by the Laboratory.
Policy 6 Laboratory Security

The Laboratory routinely handles evidence related to all types of criminal matters. This evidence includes firearms, drugs, hazardous materials, and many other types of evidence. In order to ensure the integrity of this evidence, it is necessary that all Laboratory facilities be properly secured as follows:

1. Non-Laboratory personnel may not be in those areas of the laboratory where evidence is present unless a laboratory employee is also present. At no time will non-laboratory personnel be alone in an area where there is unsecured evidence.

2. Exceptions will be made in the case of medical emergency or other critical incidents.

3. Ultimate access to Laboratory facilities will be determined by the Top Management.

4. All facility entrance points are monitored by video camera and the recorded video stored for at least 120 days.

5. Where doors are equipped with an electronic reader, all reader events are stored for at least 120 days.

AST evidence personnel co-occupy the evidence vault and work areas of the evidence area. They do not have access to any discipline laboratory spaces.
Policy 7 Scientific Examination Report Dissemination

1. The method for dissemination of scientific examination reports shall be by State E-mail system to the customer’s agency e-mail address.

2. If the customer does not have an agency e-mail address, then the scientific examination report will be sent by US mail.

3. Reports may not be e-mailed to personal e-mail accounts (such as gmail, yahoo).

4. A customer may pick up a paper copy of the scientific examination report in person.

5. Instances where the scientific examination report is too large to email, the analyst will use the state sponsored Alaska ZendTo program to distribute the information according to the above method.

6. In the event of a special project in which multiple reports will be going to the same agency at the same time, an encrypted secure flash drive that meets Alaska Criminal Justice Information Services standards will be used to store the data. The flash drive should be transferred in person to the appropriate agent or mailed via secure delivery using tracking.
Policy 8 Access to Laboratory Network Resources

The Laboratory utilizes various networked information technology devices to store case files, notes, manuals, protocols, and other electronic documents. These devices are administered by the Office of Information Technology (OIT) under the Department of Administration.

Permissions (read, write, delete) are granted by OIT division staff at the request of the Chief. Discipline Supervisors shall make requests to the Chief (who ultimately will decide on the level of access) on behalf of their staff and themselves. The Chief shall make requests of OIT division staff to grant/deny the requested permissions. Full permissions shall mean full control. Read only shall include read, read & execute, and list folder contents.

1. SQL Server Databases – located at 5700 E. Tudor Road (Headquarters)
   a. Jtrax
      i. All Laboratory staff shall have data reader/data writer permission
   b. Breath Alcohol
      i. All staff assigned to the breath alcohol program shall have data reader/data writer permission

2. Storage Area Network (I drive) – located at 4805 Dr. Martin Luther King Junior Avenue (SCDL)
   a. The Chief shall have full permissions over the I drive
   b. All Laboratory staff shall have full permissions except as follows
      i. Quality Assurance Program (however so named by the QA Manager)
         1. Only Top Management shall have full permissions
         2. All other Laboratory Staff shall have read only permissions (may not change or delete)
      ii. Discipline shares
         1. All staff have full permissions over all discipline shares
         2. Some subfolders have been locked to allow only specific personnel full permissions, all others users have read only permissions.

3. Personal Drives (P) – located at 4805 Dr. Martin Luther King Junior Avenue (SCDL)
   a. Permission shall be only to the individual analyst.

4. Jtrax Share – located at 4805 Dr. Martin Luther King Junior Avenue (SCDL)
   a. Security for files located in the Jtrax share are controlled and audited by the JusticeTrax software and as such, all laboratory staff shall have full permissions over the share.

5. LIMS (JusticeTrax or Themis)
   a. User accounts and user security are created/assigned by the Chief or his designee.

6. Office of Information Technology access requirements and restrictions.
   a. For the purpose of administration of the environment, OIT division staff maintain full administrative access of all systems and controls residing at the network hardware, and operating system levels.
   b. OIT staff will only access Forensic Laboratory information technology resources to the extent necessary to maintain normal operational status (eg. Backup, connectivity, etc) and shall make every effort to avoid direct contact with user data unless directed by the Chief.
c. OIT will make every effort to coordinate efforts with the Chief when performing service, repair, and upgrades to information technology resources that may impact the Forensic Laboratory.
d. Physical Access Security – Users (including OIT staff) obtain a badge to enter into the building. The servers and storage are in access controlled rooms.
e. Login Access - OIT staff only, has administrative login access to the keyboard/monitor in
the server rooms used by all servers.
   i. Individual server login access is possible only with OIT administrative credentials. – screens lock on servers after 10 minutes.
f. Data backup – All data is stored on the CrimeLab NetApp SAN – it is backed up to tape once a day and snapshots of the data are taken 3 times/day (tape backup horizon – 3 months; snapshot backup horizon – 1 week). These tape backups are conducted over the LAN to 5700 E. Tudor Road snapshots are stored on the NetApp SAN at 4805 Dr. Martin Luther King Junior Avenue (SCDL).

Access to the backed up files is restricted to OIT administrators.
Policy 9 Use of Laboratory Vehicles

Vehicles are for the use of crime lab personnel needing transportation for Department business only. State vehicles are monitored by DOT operating cost, replacement cost, fuel and repairs are all paid monthly by the Administrative Assistant.

**SIGN OUT**
Vehicle sign out sheet is located in the administrative section near vehicle keys.

**FLEET CARD**
A fleet credit card is provided for fuel expenses. This can be used at the pump. Employees should fill the gas tank when vehicle is less than half full.

**MAINTENANCE**
If you notice something wrong with the SCDL vehicles please notify maintenance staff. Examples would include: flat tire; vehicle damage; oil light; check engine light.

**PULLED OVER**
Registration is either in the glove box or center console of the state vehicle. Insurance is provided through State of Alaska. Incidence should be reported to the operator’s supervisor as soon as safely possible.

**TRAFFIC COLLISION**
If you are operating a state vehicle and are involved in a collision notify your supervisor as soon as safely possible and follow Department of Public Safety protocols.
Policy 10 Testimony Policy

1. The Laboratory performs analysis and/or formulates opinions at the request of law enforcement.
2. Where the Laboratory has performed analysis and/or formulated opinions at the request of law enforcement, an appropriate analyst will testify at an evidentiary hearing or trial (at the request of the court, prosecution, or defense) as to the already performed analysis and/or formulated opinions.
3. The scope of already performed analysis includes interpretation of the analysis results.
4. Testimony Requested by defense attorneys in criminal cases or any attorney in civil cases:
   a. The State of Alaska legislature provides funding to the Alaska Public Defender Agency (PDA) and the Alaska Office of Public Advocacy (OPA) to retain and present expert testimony on behalf of the clients those agencies represent.
   b. Accordingly, the Laboratory does not conduct analysis nor have its analysts formulate opinions at the request of attorneys at PDA or OPA.
   c. Privately retained council are responsible for retaining and presenting expert analysis and testimony from experts outside the Alaska Scientific Crime Detection Laboratory.
Appendix E  Proficiency Testing (CTS and FA)

For external proficiency tests purchased through Collaborative Testing Services (CTS) the following outlines the internal Laboratory process.

- The Quality Assurance Manager or designee will assign the test in the CTS portal online to the appropriate proficiency test taker.
- The Quality Assurance Manager or designee will create the case assignment in the LIMS and take the proficiency test material to the evidence section.
- The proficiency test taker will perform the analysis and enter the results in the CTS portal online.
- The test taker will submit the test results to their respective discipline group (Biology, Firearms, Latent Prints, Alcohol, Drugs) for administrative review in the online portal prior to submission.
- To administratively review the test, the reviewer will “claim” the test from the discipline group in the online portal and ensure that the information in the LIMS matches the results that are entered to be submitted online.
- After the results are administratively reviewed in the portal, the test will be submitted to CTS via the online portal. The proficiency test taker will place a copy of the submitted test with the submission date and time stamp into the case attachments (with the RLS) in the LIMS.

For external proficiency tests purchased through Forensic Assurance (FA) the following outlines the internal Laboratory process.

- The Quality Assurance Manager or designee will create the case assignment in the LIMS and take the proficiency test material to the evidence section.
- The proficiency test taker will perform the analysis as per Quality Assurance Manual and enter the results in the FA worksheet accessible using the Login and Password associated with the evidence.
- The proficiency test taker will enter the results and then email the test results through the FA system to the appropriate person for administrative review.
- To administratively review the test, the reviewer will review the email received from FA and ensure that the information in the LIMS matches the results that are entered to be submitted online. The reviewer will email the proficiency test taker when the review is complete.
- After the results are administratively reviewed, the proficiency test taker will log into the FA system and the test will be submitted to FA via the FA online submission and selecting an email be sent to the Quality Assurance Manager. The proficiency test taker will place a copy of the submitted test with the submission date and time stamp into the case attachments (with the RLS) in the LIMS.
# Appendix F  Revision History

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<th>2019 R1</th>
<th>Location</th>
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<td>-</td>
<td>All</td>
<td>Updated spelling, grammar, and spacing throughout the manual</td>
</tr>
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<td>-</td>
<td>-</td>
<td>Throughout</td>
<td>Updated Discipline titles to match new scope of accreditation.</td>
</tr>
<tr>
<td>4</td>
<td>-</td>
<td>3 Terms and Definitions</td>
<td>Removed Administrative records</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>4.1.4</td>
<td>Changed Statewide Services to Office of the Commissioner</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>4.2.1</td>
<td>Changed &quot;The Laboratory shall not…” to &quot;The Laboratory notifies…” And removed the exception to this policy.</td>
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<td>6</td>
<td>6</td>
<td>4.2.2</td>
<td>Changed &quot;than those listed in 4.2.1&quot; to &quot;than those listed in the RLS notification&quot;.</td>
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<td>8</td>
<td>7</td>
<td>5.5a</td>
<td>Change title of the position to which the chief directly reports</td>
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<td>9</td>
<td>-</td>
<td>5.5b</td>
<td>Removed Expectations of Employee Performance,</td>
</tr>
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<td>10</td>
<td>10</td>
<td>5.7b</td>
<td>Changed records will be stored in the &quot;LIMS&quot; to &quot;quality assurance records&quot;.</td>
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<td>11</td>
<td>11</td>
<td>6.2.3</td>
<td>Changed &quot;performing casework&quot; to &quot;performing laboratory activities&quot; Removed the portion that is also covered in 6.2.6</td>
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<td>11</td>
<td>11</td>
<td>6.2.3.1</td>
<td>Changed &quot;category of testing&quot; to &quot;components of testing&quot;. Added &quot;Demonstration of the appropriate use of equipment needed to perform testing.&quot;</td>
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<td>Line</td>
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<td>Change</td>
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| 11   | 12   | 6.2.5e  | Moved from 6.2.2.2 "The Chief or Assistant Chief shall authorize an individual to authorize reports and express opinions or interpretations based on documentation from the Discipline Supervisor or DNA Technical Manager through the Quality Assurance Manager. Authorization to perform other laboratory tasks shall come from the DNA Technical Manager or Technical Lead through the appropriate supervisor to the Quality Assurance Manager."
| 13   | 13   | 6.2.6a  | Added “other competent staff have the authority to assist or perform these tasks as defined in each individual's competency memo(s)."
| -    | 13   | Note under 6.2.6c | Added "Note: A competency matrix is available in the quality assurance records to identify staff with memos of competency for each laboratory task."
| -    | 17   | 7.1.2   | Added "The RLS notifies the customer upon opening of this agreement."
| 21   | 21   | 7.5.2   | Removed "Changes to electronic data are tracked through the audit tracking system of the LIMS. Changes made to completed electronic cases will be tracked through the audit tracking system in the LIMS. Cases are considered complete when the end date has been recorded by the analyst or technician and the case is sent for technical and/or administrative review." and Added "Amendments to the technical record are tracked by the LIMS system and are available upon request to the quality assurance manager or the LIMS administrator."
| -    | 26   | 7.8.2.1e | Added notification when RLS opens
| -    | 27   | 7.8.2.2 | Added "and will be noted when necessary"
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<th>Appendix A 2, 3</th>
<th>Changed The Chief to Top Management</th>
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<td>35</td>
<td>35</td>
<td>Appendix A 4.</td>
<td>Changed employee to SCDL employee and Added, &quot;For electronic keys, the profile will be deactivated.&quot;</td>
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<td>Appendix C</td>
<td>Removed &quot;critical&quot;</td>
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<td>45</td>
<td>Policy 7</td>
<td>Added 5 and 6</td>
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<td>Appendix E</td>
<td>Updated the submission information for both companies</td>
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