

Alaska Scientific Crime Detection Laboratory

Quality Assurance Manual

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1 Scope

The Alaska Department of Public Safety 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 laboratory wide manuals, the individual Discipline Procedure Manuals, and the individual Discipline Training Manuals form the Forensic Quality Assurance Program.

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

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2 References

ANSI National Accreditation Board (ANAB), *ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements*. Document Number AR 3125.

International Organization for Standardization /International Electrotechnical Commission (ISO/IEC), *17025 General requirements for the competence of testing and calibration laboratories*, Third Edition 2017-11. Reference Number ISO/IEC 17025:2017 (E).

Joint Committee for Guides in Metrology, *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)*, 3rd edition 2008 version with minor corrections, (JCGM 200:2012).

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

U.S. Department of Justice (DOJ), Federal Bureau of Investigation (FBI), *Quality Assurance Standards for Forensic DNA Testing Laboratories*, 2020 version. (FBI QAS Testing).

U.S. Department of Justice (DOJ), Federal Bureau of Investigation (FBI), *Quality Assurance Standards for DNA Databasing Laboratories*, 2020 version. (FBI QAS Database).

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

APD: Initialism for Anchorage Police Department

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

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Guidance Document: A document distributed in an uncontrolled manner to provide the user a quick resource for guidance, information, or best practice. These documents are ever evolving and there is low risk associated with a task if a change is made to the document and the user is not using the most current version. These could be maintained at the discipline level or by the quality assurance manager.

Investigative Report: This is a report issued by the Laboratory that is meant for aiding law enforcement in the investigation period of a crime. These reports are not prepared with the intention of being admitted into the court room as a scientific analysis. The reports will meet the standards set forth in the ISO 17025:2017 document but are treated differently within the Laboratory than a Technical Report.

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, the DNA Technical Manager, and the APD lab staff supervisor.

Laboratory Employee: All persons employed by the State of Alaska Department of Public Safety Scientific Crime Detection Laboratory and Anchorage Police Department employees with a duty station assignment at 4805 Dr. Martin Luther King Jr AVE and job functions/expectations described in a Memorandum of Understanding between the State of Alaska and the Anchorage Police Department. All persons are responsible for following the State of Alaska Department of Public Safety protocols as defined in this manual as the laboratory quality assurance system is built upon those policies and procedures. Persons employed by APD may be subject to further requirements set forth by that department. MOUs have been established to define these duties and expectations.

LIMS: Acronym for Laboratory Information Management System

MOU: Initialism for Memorandum Of Understanding. This is a document that acts as an agreement (contract) between the Laboratory and another entity and defines the duties and expectations of each party involved.

OSAC: Acronym for The Organization of Scientific Area Committees for Forensic Science (a part of the National Institute of Standards and Technology)

QA: Initialism for Quality Assurance

QRF: Initialism for Quality Revue Form

RLS: Initialism for Requst for Laboratory Services Form

Technical Report: This is a report issued by the Laboratory that is meant to present results, opinions, and conclusions. These reports are prepared with the intention of being admitted into the court room as a scientific analysis. The reports will meet the standards set forth in the ISO 17025:2017 document but are treated differently within the Laboratory than an Investigative Report.

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

SCDL: Initialism for Alaska Department of Public Safety Scientific Crime Detection Laboratory (also referred to as “the Laboratory”)

SOQ: Initialism for Statement of Qualifications (also referred to as curriculum vitae)

Technical Report: This is a report issued by the Laboratory that is prepared with the intention of presentation to the trier of fact. The reports will meet the standards set for in the ISO 17025:2017 document but are treated differently within the Laboratory than an Investigative Report.

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 employees will complete and submit a State of Alaska *Ethics Disclosure Form* to request permission for outside employment, including volunteer work. Personnel employed by APD will submit the form to the Quality Assurance Manager to be stored in the quality assurance records.

4.1.3.1a The State of Alaska ethics information for public employees is provided during the new employee training program. 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 laboratory employees 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 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 laboratory employees assigned to the Biology Discipline and performing laboratory tasks.

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), Sexual Assault Kit Testing (AS 44.41.065), 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.

The DNA Technical Manager manages the technical operations for the Biology Discipline. The DNA Technical Manager is responsible for evaluating all DNA methods and software 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 and resume analytical activity pending review and approval by a member of Top Management. The DNA Technical Manager reports directly to the Chief or the Assistant 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 or the DNA Technical Manager. The APD lab staff supervisor fits in this category for laboratory purposes.

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, reviewing and evaluating proficiency test results, and preparing and reviewing performance monitoring. 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.

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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 employee 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 laboratory employees the authority and resources needed to carry out their duties, including implementation, maintenance and improvement of the quality system.

5.6b All laboratory employees are encouraged to identify and report any deviations from the quality system following 7.10 of this manual.

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. Top Management will administer a staff engagement survey periodically in which staff can provide anonymous feedback. Top Management will review the survey results and plan or review changes needed no later than the annual management review.

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 SCDL and APD. Contract employees will be held to the same standards and expectations as laboratory employees with respect to competency and proficiency testing.

6.2.2 The job descriptions, education, and experience requirements (class specifications) for each position employed by SCDL 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. Laboratory employees hired by an agency other than SCDL will meet the requirements set forth in the MOU.

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 related 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 Firearms and Toolmarks, Friction Ridge, Impressions, and Scene Investigation disciplines shall possess a baccalaureate or an advanced degree with science courses.

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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 laboratory employees 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, and a quiz regarding ethical and quality practices. The Administrative section of the NETP will be modified for laboratory employees hired by an agency other than the State of Alaska. Positions that are administrative, maintenance, or teleworking will participate in a modified NETP indicated on the NETP packet by the QA Manager. 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. Additional training materials will be stored in the appropriate location on SharePoint. The completion of training memo is retained in the quality assurance records. The training records will be maintained by the analyst for an amount of time that allows for review at an onsite accreditation activity at minimum. 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 consider 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. At various points in the training program, after training is completed, and at various points during the first few months of independent casework, Key Management will seek feedback regarding the training programs effectiveness, efficiency, and efficacy. 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:

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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. For modified training plans, this may be combined with the written test report.

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, provide 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. Anchorage Police Department hires laboratory employees under the agreements set forth in the MOUs for the positions specified.

6.2.5c Key Management in coordination with Technical leads 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 and continuing education 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. All

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laboratory employees should average 16 hours per year over a 4-year cycle of continuing education. Each discipline will determine the types of seminars and materials that qualify as continuing education.

A laboratory member receiving technical 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 and 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 or appropriate Technical lead 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 competency memo(s). The Chief and Assistant Chief also have this authority if proficiency is demonstrated and maintained.

6.2.6c Forensic Scientists and the DNA Technical Manager have the authority to report, review and authorize results as defined in each competency memo(s). The Chief and Assistant Chief also have this authority if proficiency is demonstrated and maintained.

Note: A competency matrix is available in the quality assurance records to identify staff with memos of competency for each laboratory task. This matrix does not supersede competency memos however attempts to put the information in a centralized location for the laboratory.

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 digital evidence examination. Access to CODIS database samples under the control of the Laboratory will be restricted to those persons authorized by a member of Top Management and the CODIS Administrator or Alternate Administrator. On an annual basis, minimum, a memo will be prepared listing all persons with authorized access to CODIS database samples and the controlled substances standards.

6.3.5 The Laboratory allows for the following laboratory activities to occur outside of its permanent control:

Scene Investigation (entire scope)

Friction Ridge for Individual Characteristic Database and Physical Comparison (Perform Laboratory Activities, Analysis of Results, and Verification of a Result)

All Disciplines and Components (Review Results, Authorized Results, Technical Review, Express Opinion or Interpretation, Report Results, Authorizes Report)

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 placing in service or returning to service, 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). Key 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 on

the laboratory SharePoint 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 for requests culminating in a Technical Report. Information and documentation (contract) needed for requests culminating in an Investigative Report will be specified in the appropriate Discipline Manual for the request. 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 RLS information made after examination of an evidence item begins are communicated to the agency and documented in the case record 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 the case record 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 methods and procedures for all associated data analysis and interpretation.

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

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 approved, documented in the case record, technically justified and reviewed in the technical review process. Customers are contacted when appropriate regarding analytical deviations. Deviations occurring without prior approval will follow the procedures for nonconforming work in 7.10.

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.

7.2.2.1.1 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 7.3.2b.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 agency case number and item number are considered to be evidence. When submitted for technical analysis, a current RLS must accompany and account for the items received. The Procedure for Evidence Management Manual provides additional information 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. Communication to the customer regarding items accepted by the laboratory for analysis and items collected, created or preserved for future testing will be listed on the technical report with the intended disposition.

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. Only one laboratory number should be assigned to the same event in a single jurisdiction regardless of the number of submitting agencies, suspects, or victims. Submissions involving events committed by a suspect in more than one jurisdiction may be assigned a unique laboratory number for each event. A LIMS generated laboratory file number shall be assigned upon receipt of the first RLS for a case. Any supplemental submissions should be assigned the same laboratory case number as the original submission. Deviations from this, at a minimum, shall be documented in the LIMS. If submissions are determined to be from a single event but were assigned different laboratory numbers, the laboratory case numbers shall be associate to one another. Each CODIS database sample under the control of the Laboratory will be uniquely identified. Individual characteristic database samples 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. Evidence received on ice will be noted in the case record.

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 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. Handwritten 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 date and reason for rejection 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 considered 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 reports prior to release for Technical Reports. Investigative Reports will have technical reviews performed as described in the Discipline Manual. These will cover the same information as the technical review for a Technical Report just at a different percentage of cases as these cases are meant to provide investigative information. 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 cycle (4-year calendar period), 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. If an analyst is not able to get a technical review of testimony in a cycle whether due to no court appearances or inability to have a qualified analyst review the testimony, a technical discussion may be held to determine that the information the analyst would potentially testify about is being presented accurately and appropriately for a jury to understand.

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 JusticeTrax LIMS-Plus 3.8 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. Documentation of Proficiency Test outcomes are stored in the QA records with remaining test documentation stored in the LIMS. 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. All results must be consistent with the reported result by the provider. Internal tests require known answers prior to administering the test and the results must be consistent with the answer key. Disciplines required to report measurement uncertainty may take the uncertainty into account to determine if the results are consistent so long as the method used to evaluate the results is documented in the appropriate Discipline Manual. 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 Each discipline technical lead will prepare a performance monitoring plan annually in November to submit to the Quality Assurance Manager. The plan submitted by the discipline technical lead will select a sampling of components listed in the Discipline Manual under Performance Monitoring. The Quality Assurance Manager will prepare a laboratory plan from the submitted discipline performance monitoring plans to present at the Annual Management Review to ensure conformance to standards 7.7.2.1b and 7.7.4 above. During the Annual Management Review, the plan will be approved by Key Management. In addition to the plan, the technical leads will compile the results of the previous year's monitoring activities to submit at the time they submit the new plan for the next year. The results of the performance monitoring will indicate if all components resulted as expected or if unexpected results were obtained, the actions that were taken to rectify the outcome and obtain expected results and any policies or procedures that were updated as a results of the monitoring. The results will be reviewed at the Annual Management Review. The monitoring activities follow the calendar year but align with the accreditation cycle to ensure that a sampling of all components, technologies, and personnel are monitored.

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 or observation based performance monitoring 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 preparing the report.

7.8.1.1.1 The analyst preparing the report 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 All items accepted by the laboratory for analysis will be listed on the report.

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 receipt of item and the date of sampling if sampling is performed

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 accepted by the laboratory for 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 meets 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 JusticeTrax Manual provides information on documenting and tracking amended 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 laboratory SharePoint. 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 when they occur.

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 There are two types of nonconforming work, approved and unapproved. Approved deviations or nonconforming work is addressed in 7.2.1.7. If a nonconformity is discovered in the Laboratory's testing or results of work or if there is a significant deviation from Laboratory policies that was not approved, the following will occur:

- a) See Quality Review Form Policy below
- b) The deviation or nonconformity will be corrected if allowed and appropriate in coordination with the appropriate Discipline Supervisor and/or DNA Technical Manager or Technical Lead.
- c) See Quality Review Policy on next page
- d) Any further review based on the evaluation of risk will be addressed. The Quality Assurance Manager will review the Quality Review Form to determine if a root cause analysis needs to occur based on the number of occurrences of similar deviations in the previous 12 months. If No, the review is complete. If yes, the process will move to a Corrective Action.
- e) Any corrective action needed will be taken along with a decision about the acceptability of the nonconforming work. The customer will be notified when a corrective action is determined to have an impact to casework.
- 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 corrective actions in the quality assurance records.

7.10.3 See Quality Review Form Policy below

Quality Review Form Policy

Quality Review Forms (QRF) are used in the laboratory to identify a single instance where the quality of the work in that instance needs to be reviewed, corrected, or noted that a policy or procedure was not performed as directed or expected. There is no significant action from a Quality Review other than ensuring the quality of the documented instance is meeting all laboratory standards after the review is performed. Corrective Action Reviews (CAR) are initiated when a single instance could have a major impact on multiple aspects of the quality or reliability of results, if during the event of a quality review it is noted that multiple actions will need to be performed to correct the instance, if it is noted that a policy or procedure needs to be updated to account for multiple deviations, or a review of prior work needs to be performed to ensure previous results were valid and appropriate. Corrective action is implemented when the evaluation in 7.10.1 d indicates that a nonconformity could reoccur, the risk to quality is greatly impacted, or when there is doubt about compliance with the Laboratory's Forensic Quality Assurance Program. (For example: multiple previous cases need to be reviewed for an analyst or discipline to ensure that the instance that occurred was not a systemic or repeated event.) Corrective Actions do not require a QRF to be initiated if it is known that a root cause will need to be identified.

The Layout of the Quality Review Form

The occurrence is noted in the first section of the QRF form. This section will indicate where the deviation occurred and the cases or samples that were included, who was involved (written in the 3rd

person, if direct involvement), how it was identified, and what policy or procedure was deviated from to include the manual and page number. This section should be specific that in the case of a QRF moving forward to a CAR, the Quality Manager knows who to interview and involve in the actions. The second section documents the review if there is a potential for the deviation to occur again in the future in addition to the impact of the deviation to explain that casework or items of evidence were or were not impacted by the deviation. The third section documents how this single instance of deviation was corrected or documented to ensure that all stakeholders would know that the quality of the result, report, evidence item, etc. is still to the highest standard and valid. The fourth section indicates when the Quality Manager was provided with the information regarding the quality review. Note: the quality manager may be informed prior to the QRF completion. The quality manager will perform a review of the QRF to note those involved, the prevalence of the occurrence, and the impact of the occurrence. If the prevalence, impact, or potential for recurrence is high, the Quality Manager may initiate a Corrective Action during the review of the QRF.

How to Initiate a Quality Review Form

A QRF will be filled out at the time a deviation is noted. The staff member identifying the deviation should initiate the QRF. Anyone within the laboratory system can initiate a QRF. The initiator will save the QRF in the appropriate SharePoint document set and if necessary, create a case activity in all case numbers that are involved in the QRF (see the JT38 Manual for more instructions). The title of the QRF will go in the notes field in the Case Activity. There may not be cases identified at the time a QRF is initiated and thus, no case activities would need to be entered.

How to Title a Quality Review Form

The title of the QRF will be QRF Date Initiated Discipline(s) Affected Initials of the Person Initiating the QRF. (Example: QRF 2021.02.25 Toxicology – Testing AML). Discipline Options are: Biology, Firearms and Toolmarks, Friction Ridge, Impressions, Scene Investigation, Seized Drugs, Toxicology – Calibration, and Toxicology – Testing. If a person is initiating more than one QRF for the same discipline on the same date the second QRF will then be .2 (Example: QRF 2021.02.25.2 Toxicology – Testing AML). If the nonconformity or deviation affects more than one discipline, upload the QRF into the document set for the discipline in which it was identified and acknowledge the appropriate second discipline in the title. (Example: QRF 2021.02.25 Seized Drugs – Friction Ridge AML). If the nonconformity touches Evidence, LIMS, Maintenance, or All Disciplines (more than two disciplines will fall under all disciplines), upload the QRF into the lab wide document set and title the document as appropriate (Example: QRF 2021.02.25 Evidence or QRF 2021.02.25 All Disciplines). Once a document is titled, when the QRF is initiated that will be the name for the remainder of the time. Do not change names further down the line. If you have questions about the title, contact the Quality Assurance Manager prior to storing the document in SharePoint.

Persons responsible for each section of a Quality Review Form

The person initiating the QRF will, at a minimum, complete the 1st section of the form. If the person initiating the QRF has substantial knowledge in a discipline affected or the process/procedure that was deviated from, they can complete the 2nd section of the form. If the person initiating the QRF either doesn't have enough knowledge and/or training to complete the 2nd section, the 2nd section will be filled out by another laboratory member that has the knowledge, skills, and abilities to identify the impacts to

the laboratory and evaluate the significance. (For example: if a trainee identifies during an observation session that the trainer deviates from a procedure, the trainee may initiate the QRF but might not have the knowledge to know how the deviation impacts the laboratory process or outcome and the trainer, another qualified analyst, or the supervisor may complete the 2nd section.) The 3rd section can be filled out by anyone that works to remedy the deviation to note their involvement in ensuring the validity of the results or integrity of the evidence involved. Throughout this process, the document sets in SharePoint allow the person modifying a document to assign “Action Needed by” to an individual as well as a field for comments to explain what action is needed. If the initiator of a QRF is not going to complete all sections of the form, they will need to tag the appropriate person in the “Action Needed” column. Members of the laboratory should review the actions needed for their name on a regular basis. When the QRF is ready to be reviewed by the Quality Manager, the name of the Quality Manager will be selected in the “Actions Needed by” column and the comment of “Ready for Final Review” added. If at any point, when filling out the QRF, case numbers are added to the QRF, the person adding the case numbers to the QRF should create a case activity in the case in the LIMS for the QRF (further instructions found in JT38 Manual).

Important Reminders:

The official copy of the QRF is the one stored in SharePoint. When providing documents for discovery always check the case activities of a case for the QRF title and download the document out of SharePoint. Copies of QRFs should not be stored in the LIMS to avoid confusion if updates to a document occur. If in doubt of the steps listed above, contact the Quality Assurance Manager to ensure lab wide consistency when reporting deviations and non-conformities.

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 Alaska Department of Public Safety Scientific Crime Detection Laboratory is to provide scientific support to the criminal justice system to help create a safer Alaska. The 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.

Guidance documents or training materials that are not required for use in disciplines but as aids in training or short term projects are not required to be controlled and are not viewed as a part of the Quality Assurance Program.

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 or SharePoint.

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 a secure location in the Crime Lab. Laboratory 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 30 mins of inactivity to prevent unauthorized access.

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:

- A Health and Safety Manual.
- Annual Bloodborne Pathogen training for all laboratory employees.
- Annual Fire Extinguisher training for all laboratory employees.
- CPR and AED training for laboratory employees.
- First Aid training for laboratory 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 laboratory 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. Key Management 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. The internal audit plan for the next year will be presented at the Annual Management Review with the results from the previous year and should account for review any gaps identified or corrections made to ensure that corrective actions are monitored.

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:

- Changes in internal and external issues that are relevant to the laboratory;
- Fulfillment of Objectives;
- Suitability of policies and procedures;
- Status of actions from previous management reviews;
- Outcome of recent internal audits;
- Corrective and preventive actions;
- Assessments by external bodies;
- Results of inter-laboratory comparisons or proficiency tests;
- Changes in the volume and type of work;
- Customer and personnel feedback;
- Complaints;
- Effectiveness of any implemented improvements and recommendations for improvement;
- Adequacy of resources;
- Results of risk identification;
- Outcomes of the assurance of the validity of results;

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 laboratory 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. 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 laboratory employee shall provide prompt, verbal notification to their immediate Supervisor. Upon verbal notification, the laboratory 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 lossWhen 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 documents will be issued at least 5 business days prior to the effective date to allow time for review and posting before use.

Controlled Document Review, Approval, and Issuance

The Laboratory Quality Assurance Manual is written and reviewed by the Quality Assurance Manager and approved by the Chief. The Procedure for Evidence Management Manual is reviewed and approved by the Evidence Supervisor. The JusticeTrax LIMS-Plus 3.8 Manual is reviewed and approved by the LIMS Administrator. 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 Procedure for Evidence Management Manual and the Health and Safety Manual must be reviewed and updated at least annually. Training manuals, controlled forms, working instructions, and worksheets must be reviewed and updated at least every 36 months from the year 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, 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 laboratory SharePoint.

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

Policy 1	Case Management
Policy 2	Independent Experts or Experts in Laboratory Facilities
Policy 3	Laboratory Occupancy
Policy 4	Scheduled Time Off and Court Conflicts
Policy 5	Disclosure of Scientific Examination Documentation
Policy 6	Laboratory Security
Policy 7	Scientific Examination Report Dissemination
Policy 8	Access to Laboratory Network Resources
Policy 9	Use of Laboratory Vehicles
Policy 10	Testimony Policy

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 nor can video recording occur. 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. Feasibility – The laboratory is arranged in such a way that allowing people or video equipment into the space would hinder the movement of the analyst or the prevent view of the evidence. Additionally, multiple locations in the laboratory space are used at various times throughout analysis with continuous movement by the analyst into and out of lab space and instrument rooms and a stationary location for video equipment would not capture the full analysis.
 - F. Contamination – Irregular persons entering the space (specifically DNA) present increased potential for contamination.
 - G. 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.

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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 building 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. Laboratory 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 employees 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 employees 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. Any deviation will be noted in the case log.
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.
7. The State of Alaska Department of Public Safety requires Personal Identifying Information (PII) to be sent to external information systems in a manner that maintains the security of the information being disseminated. The State of Alaska E-mail system uses the prefix [secure] in the subject line of emails being sent to external information systems (ie: police department agencies) to ensure that the PII enclosed in the email is secure.

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
 - a. Jtrax – located at GCI South Anchorage Data Center (GCI SADC)
 - i. All Laboratory staff shall have data reader/data writer permission
 - b. Foray Adams – located at GCI SADC
 - i. Laboratory staff access via the Adams application
 - c. Breath Alcohol - located at GCI SADC
 - 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. Sharepoint – SCDL is in the process of moving the items in 2, 3, and 4 to the State of Alaska Sharepoint. The Office of Information (OIT) is responsible for the maintenance of the application and has full administrative access. Additional permissions are set by the laboratory's LIMS administrator.
6. LIMS (JusticeTrax)
 - a. User accounts and user security are created/assigned by the LIMS administrator or designee.
7. 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 LIMS administrator or 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 – These occur at the SADC every two weeks. The laboratory complies with the OIT backup policy.

Policy 9 Use of Laboratory Vehicles

Vehicles are for the use of SCDL 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. SCDL 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

The following decision matrix will be used to determine whether the lab will provide expert witness services in court proceedings. It applies to requests from both prosecution and defense counsel:

	Test Report Issued	Breath Program Involvement	No lab involvement ⁴
Pre-trial Interview	YES	YES	MAYBE ⁵
Administrative Hearing			
Grand Jury	MAYBE ^{1,2}	MAYBE ^{1,3}	MAYBE ⁵
Evidentiary Hearing	YES ²	MAYBE ³	MAYBE ⁵
Bench Trial	YES ²	MAYBE ³	MAYBE ⁵
Jury Trial	YES ²	MAYBE ³	MAYBE ⁵
Civil cases	YES ²	NO	NO

¹In general, staff will not participate in a grand jury. Exceptions can be made at the section supervisory level when assistance with interpreting the results of a report is needed. In person testimony will only be granted when the location is in Anchorage, but telephonic/video testimony is always preferred.

²The witness and/or their supervisor should contact the attorney beforehand to determine expected scope of testimony and whether it is needed (e.g. can both parties stipulate to the report results without the expert witness).

³In general, the breath alcohol experts will not testify in basic per se DUI trials. Testimony will be approved on a case by case basis by the Scientific Director when toxicology interpretation and/or addressing instrumental concerns is needed.

⁴No lab involvement but lab has staff member who is currently proficient in subject matter requested.

⁵Testimony services will be granted on a case by case basis by the section supervisor. Current personnel resources and a determination of whether the laboratory has unique in-state expertise to answer probative questions will be considered when making the decision. Testimony services will not be provided to privately retained counsel. If one analyst in a scientific discipline has already testified or is scheduled to testify, ASCDL will not provide another analyst in the same discipline to testify for opposing legal counsel.

Policy 11 Discovery Levels

There are different levels of discovery request, please note there may be a slight variation between different disciplines. The JusticeTrax Manual provides more information about how to create a discovery packet.

LEVEL 1 – Initial Discovery

*Standard report distributed to law enforcement and any listed parties for each request includes:

- Discipline Report

LEVEL 2 – Standard Discovery Request

*In addition to level 1 you will receive the following:

- Bench Notes
- Blood Alcohol Worksheet (Blood Alcohol specific)
- Case Info report (Fingerprint specific)
- Case Activities/Log
- Case Chain of Custody Report
- Case Findings Summary (Fingerprint specific)
- Case Specific Instrument Data Printouts
- Central log (DNA specific)
- Composite Images (Fingerprint/Footwear specific)
- Control pack (Blood Alcohol specific)
- Controlled Substance Notes (Controlled Substances specific)
- Forensic Biology Casework Review Checklist (aka Bench notes- Biology specific)
- Process Summary (Fingerprint specific)
- Quality Documents (QRF or CAR) related to the case
- Request for Laboratory Services (RLS) Form
- Review documentation (Fingerprint/Footwear specific)

LEVEL 3

Contact the laboratory If the information you would like to receive is not listed above (non-case specific quality reviews or corrective actions, raw data, proficiency and training records, accreditation information, DNA raw/electronic data and validations etc.) please contact the appropriate discipline supervisor or the Quality Assurance Manager. Depending on the feasibility and resources needed some information may require court order.

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.

For external proficiency tests purchased from another vendor, the analyst will upload a copy of the submitted test with the submission date and time stamp into the case attachments in the LIMS.

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Appendix F Revision History

2021 R1	2021 R2	Location	Revision made
-	-	All	Updated spelling, grammar, and spacing throughout the manual
-	5	Terms and Definitions	Technical Report
-	9	5.5a	Added software evaluation to DNA Technical Manager and performance monitoring to Technical Lead duties
-	12	6.2.2.2	Added "Additional training materials will be stored in the appropriate location on SharePoint."
-	13	6.2.5c	Added "All laboratory employees should average 16 hours per year over a 4 year cycle of continuing education. Each discipline will determine the types of seminars and materials that qualify as continuing education."
19	20	7.2.1.1.1	Updated to coorelate to ANAB document
19	20	7.2.1.1.2	Updated to coorelate to ANAB document
-	21	7.4.1.1	Added, "Communication to the customer regarding items accepted by the laboratory for analysis and items collected, created or preserved for future testing will be listed on the technical report with the intended disposition. "
24-26	26	7.7.1	Updated technical review of testimony to allow for technical discussions if not technical review occurred during an accreditation cycle.
27	27	7.7.6	Entire Rewrite.
27	28	7.8.1.2.2	Entire Rewrite.
29	30	7.8.8.1	Added information to point to JT manual for tracking amended reports
30	31	7.10	Pointed to approved deviation standard and added more information to the layout and naming of

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			QRFs
-	38	8.8.1.1	Added, "The internal audit plan for the next year will be presented at the Annual Management Review with the results from the previous year and should account for review any gaps identified or corrections made to ensure that corrective actions are monitored."
40	41	Appendix B	Added requirement for 5 business day issue vs. effective date.
54	55	Policy 10	Entire Rewrite.
-	56	Policy 11	New Policy: Discovery Levels