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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 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 policies and procedures of 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.

2 REFERENCES

ANSI National Accreditation Board (ANAB), *Forensic Science Testing and Calibration Laboratories Accreditation Requirements*. Document Number AR 3125 (2023).

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).

Minimum Required Operating Standards for National Integrated Ballistic Information Network (NIBIN) Sites, Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) 2022 version

3 TERMS AND DEFINITIONS

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

Adequate:	The principle of being sufficient for a specific requirement.
ADAMS:	Acronym for Authenticated Digital Asset Management System
ANAB:	Acronym for ANSI National Accreditation Board
ANSI:	Acronym for American National Standards Institute
APD:	Initialism for Anchorage Police Department
Assistant Chief:	Assistant Chief, Forensic Laboratories

ATF:	Bureau of Alcohol, Tobacco, Firearms and Explosives.
Chain of custody:	Documentation of all evidence transfers from receipt by the Laboratory until return to the submitting agency.
Chief:	Chief, Forensic Laboratories (FSLA 2) (ANAB, AR 3125, 3.16)
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. For breath alcohol calibration Alaska Scientific Crime Detection Laboratory is the customer.
DRF:	Initialism for Deviation Request Form
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.
FSLA:	Initialism for Forensic Science Laboratory Administrator.
FT:	Initialism for Forensic Technician.
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 Top Management (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, Criminal Justice Planner, Safety Coordinator, Discipline Supervisors, the DNA Technical Manager, Evidence Supervisor 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.
MROS:	Initialism for Minimum Required Operating Standards (for NIBIN Sites)
NIBIN:	Acronym for National Integrated Ballistic Information Network
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
QAR:	Initialism for Quality Assurance Review. This is the process used to evaluate risk associated with non-conforming work and/or preventative action. It includes root cause analysis and corrective/preventative actions if applicable.
RLS:	Initialism for Request for Laboratory Services Form
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 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.

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

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 (GD 3150).

4.1.3.1b All laboratory employees shall annually review the GD 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 Division of Statewide Services 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.

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 or calibration 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 Status.

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.

Any event that or nonconformity could substantially affect the integrity of the laboratory activities and is related to an accreditation requirement or the requirements of the regulatory authorities listed above shall be disclosed to ANAB within 30 calendar days of the occurrence. If the event or nonconformity is identified more than 30 days after the occurrence ANAB shall be notified immediately. See 7.10 Nonconforming Work for more information.

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** and the administrative staff.

The **Chief** (FSLA 2) reports directly to the Alaska Department of Public Safety, Division of Statewide Services.

The **Assistant Chief** (FSLA 1) 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** (FSLA 1) 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 programs, technologies, outsourcing agreements, potential conflicts of interest of contract employees employed by multiple NDIS participating or vendor laboratories, internal and external audit documents, proficiency testing program and test results, quality assurance program, and Quality Assurance Reviews resulting in corrective or preventative actions. The **DNA Technical Manager** has the authority to suspend and resume analytical activity (**Top Management** must be notified as soon as possible when analytical activity has been suspended). The **DNA Technical Manager** reports to the **Assistant Chief**.

Discipline Supervisors (Forensic Scientist IV) have overall responsibility for the technical operations and the resources necessary to ensure quality forensic laboratory operations. **Discipline Supervisors** are responsible for recruitment, hiring, and training 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 discipline manuals are reviewed according to laboratory standards; tracking spending and approving purchases within the limits of their authority; ensuring work conditions, equipment, and procedures are adequate and protect health and

safety; and evaluation of risk, documentation and monitoring of Quality Assurance Reviews in their discipline. **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** and **Evidence Supervisor** fit in this category for laboratory purposes.

Discipline **Technical Leads** serve as a technical advisor for the **Discipline Supervisor**. **Technical Leads** are responsible for the technical content of manuals; working with the **Discipline Supervisors** to ensure that quality control measures are appropriate and are being followed; managing the performance of method development, validations, and verifications; the technical training of new analysts; reviewing and evaluating proficiency test results; preparing and reviewing performance monitoring for the discipline; and participating and providing input in the Quality Assurance Review process. **Technical Leads** have the authority to suspend analytical activity pending review and approval by a member of **Top Management**. The **Technical Leads** report to the **Discipline Supervisors**. Recommendations for **Technical Lead** appointment will come from the **Discipline Supervisor** and are approved by the **Assistant Chief.** This designation is indicated on the organizational chart and memos are kept in the quality assurance records.

The **Scientific Director** of the breath and blood alcohol testing program is responsible for all aspects of the statewide breath and blood testing program. The **Scientific Director** is responsible for the 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, participating and providing input in the Quality Assurance Review process and preparing and reviewing performance monitoring. In addition, the **Scientific Director** is responsible for selection and certification of breath test instruments, certification of breath test operators and breath test supervisors, and implementing and safeguarding the scientific integrity of the breath and blood alcohol program. The **Scientific Director** has the authority to suspend analytical activity pending review and approval by a member of **Top Management**. The **Scientific Director** is appointed by the Commissioner of the Department of Public Safety. This designation is indicated on the organizational chart.

The **NIBIN Program Administrator** duties and authorities as well as minimum qualifications for the role are outlined in the Minimum Required Operating Standards for National Integrated Ballistic Information Network (NIBIN) Sites. **Top Management** designates who will be the **NIBIN Program Administrator** at the ASCDL. This designation is indicated on the organizational chart.

The **CODIS Administrator and Alternate CODIS Administrator** are the central points of contact for CODIS operations in the laboratory. Additional information is provided in the CODIS Administrative Manual. This designation is indicated on the organizational chart.

The **Safety Coordinator** is designated by the **Chief**. This designation is indicated on the organizational chart. The **Safety Coordinator** oversees the safety program of the Laboratory and ensures that it is implemented and always followed. 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 always followed. 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. The laboratory uses the date of hire/appointment/promotion for determining the applicable version of the FBI Quality Assurance Standards for education, experience and training requirements. 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 relate field.

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

To be appointed as discipline **Technical Lead** the forensic scientist shall have a minimum of one year of independent casework in the discipline, successfully complete one external proficiency test in the discipline, and be authorized for Development, Modification, Verification and Validation of Methods in all aspects of the scope of accreditation for that discipline. Recommendations for **Technical Lead** appointment will come from the **Discipline Supervisor** and are approved by the **Assistant Chief**. This designation is indicated on the organizational chart and memos are kept in the quality assurance records.

The **Scientific Director** of the blood and breath alcohol program is the **Technical Lead** of those disciplines and therefore must meet the same requirements as a **Technical Lead**. The **Scientific Director** is appointed by the Commissioner of the Department of Public Safety.

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.

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 or maintenance may participate in a modified NETP indicated on the NETP packet by the **Quality Assurance 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. Training program references, that can be stored electronically, will be stored in the appropriate location in SharePoint. Training programs must include the criteria for acceptable performance.

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

- Examination of unknown samples covering the range of assigned duties and areas within the discipline or components of testing.
- Demonstration of the appropriate use of equipment needed to perform testing.
- A written test report demonstrating the ability to properly convey results and conclusions, express opinions or an interpretation, and their significance.
- A written or oral examination demonstrating the individual's knowledge of the discipline or components of testing, and tasks performed. For modified training plans, this may be combined with the written test report.
- Completion of the Testimony Training Program

Each of the above will be appropriately documented and retained in the training records for that individual. 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 but changes to the training program must be documented in the training 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 completion of training memo is retained in the quality assurance records.

At various points in the training program, after training is completed, and during the first few months of independent casework, **Key Management** will seek feedback regarding the training program's effectiveness, efficiency, and efficacy**.**

- **Discipline supervisors** should use the Training Module Feedback Form when seeking feedback throughout the training program.
- Upon completion, the **Quality Assurance Manager** will seek feedback about the whole program using the Training Program Feedback Form.

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. See 6.2.5 for more details on continuing education requirements.

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.

TESTIMONY TRAINING PROGRAM

All **laboratory employees that issue testing or calibration reports** will have testimony training as a component of their training program. The topics that shall be covered include preparation for responses to the following topics:

- Analyst training and education
- Evidence receipt/handling within the laboratory and discipline
- Laboratory accreditation/quality assurance program
- National standards
- National reports that speak to discipline admissibility
- Explanation of testing procedures
- Quality assurance procedures in testing
- Impartiality (crime lab is part of Department of Public Safety)
- Additional relevant topics associated with the discipline

Testimony training shall include the following:

- Training in appropriate scientific communication including using lay terminology, use of analogies, preparation of charts or demonstrative aids.
- Common terminology associated with court proceedings
    - Notice of Expert (NOE)
    - Grand Jury
    - Evidentiary Hearing
    - Bench Trial
    - Jury Trial (misdemeanor vs felony)
- The role of the expert witness in the courtroom (educate the jury, appropriate demeanor, speak to the jury, how to deal with yes or no questions, referencing notes
    - Educate the jury
    - Speak to the jury
    - Courtroom demeanor
    - Appropriate attire
    - Handling yes or no questions
    - Referencing notes
    - What to do if you know someone on the jury

Testimony training shall include multiple sessions that include opportunities for the trainee to practice providing court-appropriate responses.

Testimony training should include witnessing experienced analysts testify whenever possible (testimony witnessing may include analysts from other disciplines.)

Testimony training will conclude with a final mock trial. The following table outlines the expectations for final mock trials.

Activity	Purpose	Occurrence	Attendees	Participants	Role Playing	Location	Communication Level
Final Mock Trial - Initial	Give realistic experience of what it is like to testify in court. Assess testimony skills. Not intended to cover all court topics but a random selection to better simulate real casework testimony.	End of first training program	Representative sample of all lab staff, a member of top management	Attorneys	None	Courthouse (heavily encouraged)	Layperson
Final Mock Trial - Supplemental	Give realistic experience of what it is like to testify in court. Assess testimony skills. Not intended to cover all court topics but a random selection to better simulate real casework testimony.	End of any supplemental training programs	Representative sample of all lab staff, a member of top management	Attorneys	None	Conference Room or Courthouse (if does not cause delays)	Layperson

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.

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.

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 See section 6.2.2.2 for New Employee Training Program and Discipline Training Program requirements.

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 proficiency tested analysts** should average 16 hours per year over a 3-year cycle of continuing education as outlined in Standard Practice for Forensic Science Practitioner Training, Continuing Education, and Professional Development Programs. 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.

The **discipline supervisors** shall review continuing education records for their direct reports annually, during performance evaluations, to ensure staff are meeting the continuing education requirement.

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 **Discipline 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, Assistant Chief, and Quality Assurance Manager** 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**, **Assistant Chief, and Quality Assurance Manager** also have this authority if proficiency is demonstrated and maintained.

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.

6.3.4a) The laboratory uses the Lenel OnGuard Security System and electronic key cards to control and limit access to laboratory facilities. See Appendix A: Key Control Procedure for more information on electronic access cards.

6.3.4b) 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.

6.3.4c) 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 has 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 or calibration that have a significant effect on the accuracy or validity of the test or calibration 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, calibration result, test result, or total uncertainty of the test result. Each Discipline will have a procedure for calibration of reference materials and measuring equipment. The procedure will ensure the calibration provider can provide traceability to the SI units by means of an unbroken chain of calibrations and comparisons linking the reference standard or measuring equipment 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 or measuring equipment 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. This is met at a minimum by labeling the equipment with the date the 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:

- identity of the equipment and its software and firmware
- manufacturer, type, and serial number or unique identifier
- evidence of verification that equipment conforms with specified requirements, performance checks and/or calibration records
- current location
- calibration certificates, adjustments, date of next calibration as applicable
- documentation of reference materials, results, acceptance criteria, relevant dates, and the period of validity
- maintenance performed and, where appropriate, maintenance plan
- 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. Documentation of compliance with these criteria is kept with the Vendor Approval Form. 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.

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 used in testing or calibration.

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.

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 at quarterly Quality Assurance Meetings with the disciplines.

7 PROCESS REQUIREMENTS

7.1 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

7.1.1 Apart from NIBIN submissions and proficiency test items, all physical evidence accepted by ASCDL for scientific analysis (technical testing report) shall be accompanied by the current version of the Request for Laboratory Services Form (RLS).

The NIBIN Request Form will be used in lieu of individual RLS forms to document what items were included in a specific NIBIN submission. The Proficiency Test Assignment and Completion Form is utilized to document proficiency test items assigned to analysts.

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 Seized Drug Discipline reports schedules of controlled substances. The decision rule is inherent to the standard and agreed on by the customer as it is written in statute.

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 laboratory activities performed. Discipline Procedure Manuals will include methods and procedures for all laboratory activities in that specific discipline to include sampling, handling, preparation of evidence/calibration items, 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.

7.2.1.1.3 Calibration methods used will assess (bias and precision) over an appropriate range of values. Whenever possible, the source of materials used to calibrate measuring instruments will be sourced from a different manufacturer than material used to adjust measuring instruments. When different manufacturers are not available different lot numbers from the same manufacturer may be used.

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 or calibration items. Each discipline will maintain and keep up to date all equipment and instrument instructions, standards, manuals, and reference information relative to testing or calibrations 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 or calibration 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 pre-approved, documented in the case record, technically justified, and reviewed in the technical review process. The mechanism that the laboratory uses for requesting and approving deviations from procedures is the Deviation Request Form Policy (see below).

Customers are contacted when appropriate regarding analytical deviations. Deviations occurring without prior approval will follow the procedures for nonconforming work in 7.10.

DEVIATION REQUEST FORM POLICY

The staff member requesting the deviation from procedure shall fill out the Deviation Request Form. The title for the form is DRF YYYY.MM.DD INT where the date is the date of the request and INT is the initials of the requesting staff member. If more than one deviation request is filled out on a single day by the same staff member the title will be incremented as follows DRF YYYY.MM.DD INT_1.

Deviation Request Forms are uploaded to the appropriate SharePoint document set by the analyst requesting the deviation and the **Approving Authority** is added to the Action Needed By column. If the deviation is approved the **requesting staff member** creates a case activity with the type QA-Approved Deviation in the JusticeTrax case that the deviation relates to (See JusticeTrax LIMS Plus 3.8 Manual for more details on case activities). The case activity will list the title of the Deviation Request Form.

A Deviation Request Form can be used by multiple analysts/cases if appropriate; however, the Deviation Request Form must be specific in the Approving Authority comments if the deviation is approved for more than just the requestor's case. For cases where the deviation request is approved for cases over a long period of time the comments must make this clear. The case number for every case does not need to be added to the deviation request form; however, each case must contain the case activity referencing the deviation request form identifier.

Deviation Request Forms can also be used to document planned deviations from procedures not relating specifically to case work. In this situation, the Deviation Request Form is still filled out, titled, and stored in the appropriate SharePoint document set but no case activity is needed.

If a Deviation Request is denied the Deviation Request Form is still retained in the appropriate SharePoint document set but no case activity is needed in the case file.

Approving Authorities for Deviation Requests are as follow:

Discipline Manual Deviating From	Approving Authority
Forensic Biology*	DNA Technical Manager, * CODIS Administrator approves CODIS Manual deviations
Friction Ridge	Discipline Supervisor and/or APD Lab Staff Supervisor
Scene Investigation	Discipline Supervisor
Impressions	Discipline Supervisor
Firearm and Toolmark	Discipline Supervisor
Seized Drugs	Discipline Supervisor
Toxicology-Testing and Calibration	Scientific Director
Evidence	Evidence Supervisor
Labwide Manuals	Top Management

Approving Authorities should consult with **technical leads** when necessary. Staff members serving in an acting capacity for an Approving Authority role can approve deviations.

Approving Authorities requesting a deviation will have a competent analyst in the discipline sign the deviation request form in the comments as a second approver.

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 All method validation will be conducted according to a written validation plan. Disciplines performing method validation will provide, to the **Quality Assurance Manager,** a copy of the validation plan and a summary of the successful validation. The summary of the validation will include:

- a summary of the data analysis and interpretation
- any criteria required to report a result, opinion, interpretation, or statement of conformity
- identify any limitations of the method

Records of all data and data interpretation will be kept in the discipline records.

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.

7.2.2.3 The validation process will review the range and accuracy of the results obtained from testing or calibration to ensure the new technical method or procedure meets the requirements needed.

7.2.2.4 Disciplines will maintain validation records 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. Procedures for the transportation, receipt, handling, storage, retention, and disposal of calibration items is outlined in the Breath Alcohol Procedure Manual.

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 items are 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.

Calibration items are identified by their unique instrument serial number. All records associated with calibration items are required to include the instrument serial number.

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.

Calibration item condition is recorded upon return to the laboratory. Deviations from normal conditions will be documented in the instrument records. For breath test instruments where the laboratory is not the owner the customer will be notified if an item is not suitable for calibration and cannot be repaired. The record of this communication is kept in the instrument record.

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

TECHNICAL RECORDS (CASE FILE)

The technical record is composed of both administrative and technical documentation.

Administrative records are those that are not generated through testing or calibration activities. These can include:

- Case-related Communications
- Chain of Custody Records
- Submission Information
- Request for Laboratory Services Forms
- Sexual Assault Kit Paperwork

Technical documentation can include:

- Tests Conducted
- Standards and Controls Used
- Diagrams
- Photographs
- Instrumental Data
- Observations
- Calculations
- Work-Product Created

Discipline's Procedure Manuals shall provide more information on the specific content of the technical records for their disciplines.

Technical records are stored at the laboratory primarily in hard copy form, in the LIMS, or in the Digital Asset Management System (ADAMS). Discipline Procedure Manuals will specify the location for technical records that are stored outside of these locations.

All laboratory technical records are identified by a unique identifier. For most testing technical records this identifier is the LIMS case number. For calibration technical records the identifier is the breath test instrument serial number. In circumstances where data is generated that relates to more than one laboratory case (i.e. batch analysis control data) this data may be stored in a single file and referenced in the cases for which it is related. If this occurs, a unique identifier will be created to identify the batch document and this identifier will be present in the technical record for each case in which the data is relevant. An exception to this is the central logs for Forensic Biology database samples. The central logs for database samples contain a list of all associated cases rather than the unique identifier being present in each database technical record. Discipline Procedure Manuals shall address how technical records are identified if a unique identifier other than the LIMS case number or breath test instrument serial number is used.

This unique identifier for hard copy records must be present on each page of the technical record. The unique identifier for electronically stored data must ensure the records are readily identifiable to the test or calibration items to which they pertain. Components of the technical record that are maintained electronically do not require page numbering.

The technical record must contain sufficient information to enable an independent, competent, Forensic Scientist to evaluate the laboratory activities performed and interpret the data. To meet this requirement the following shall occur:

1. Analysts will take notes which must include, but is not limited to, all data obtained through the analytical process. It should also include information regarding the packaging of the evidence as received, whether the package was properly sealed and protected from contamination, 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. All calibration data that supports issued calibration reports will be retained.
2. If an observation, data, or calculation is rejected, the reason, the identity of the individual(s) taking the action, and the date shall be recorded in the technical record. All records will be retained, regardless of whether the information within is rejected, unless specifically outlined otherwise in the relevant Discipline's Procedure Manuals.
3. The operating parameters of all instrumental analyses conducted will be documented; however, all parameters need not be in the technical record for each case. Each Discipline's Procedure Manual will define the location of this information. Any deviations from the established parameters will be recorded and documented in the technical record.
4. Abbreviations and notations are 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.
5. The authorizing analyst, or analyst who signed the report, is responsible for all pages of technical documentation in the technical record unless otherwise noted. When technical records are generated or prepared by an individual other than the analyst who authorizes the report, the individual's name or initials will be on each page of the documentation representing his/her work.
6. The technical record shall contain the date for each laboratory activity including the analyst's review of data and results. A date range is appropriate to record a specific laboratory activity that spans multiple days assuming the activity was being performed each day of the recorded range. For example: If an examination began on Friday and paused over the weekend and then continued Monday and Tuesday. The date for Friday and a date range for Monday through Tuesday would be recorded.

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

Technical records must be created and maintained in a permanent nature. The laboratory primarily uses a LIMS to document notes and observations as well as store documents related to testing or calibration activities. Analysts working within the LIMS will document original observations at the time they are observed, directly into the LIMS. If notes or observations are handwritten, they 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.) Handwritten notes or documents created outside of the LIMS must be uploaded into the LIMS to retain the original observations recorded.

No entry may be made on case notes, calibration records, or other records which hides, obscures, or disguises the true nature of any examinations, results, or conclusions. For hard copy records, prior to being uploaded into the LIMS, 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.

Changes to technical records must be tracked after the records are completed by the **analyst**. Technical records are considered complete when the associated request in LIMS is originally marked draft complete. This date is recorded by the analyst in the request's custom form.

Changes to components of the technical record entered directly into the LIMS are tracked by the audit trail and are available upon request.

- When changes are made to electronic files in the technical record the altered aspects, the person responsible, and the date of the alteration must be clear. If pages are added they will be marked to clearly indicated what was added, by whom, and the date.
- If a data file must be regenerated entirely or the alterations cannot be made clear as described above both the original and corrected data file must be retained.

After a case has been technically and administratively reviewed the only copies of the technical record will be the hard copy file, the electronic record in the LIMS, the electronic record in ADAMS, or the location listed in the Discipline Procedure Manual. Any printed copies are to be shredded once they are no longer needed and additional copies of electronic files should no longer be retained.

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**.

See 8.4 Control of Records (Option A) for information on Technical Record retention policy.

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 Methods for evaluation of measurement uncertainty are documented in the Discipline Procedure Manuals or discipline records. The Discipline Procedure Manuals shall include the following:

- All measurements requiring measurement uncertainty calculations

- Specify the schedule to review and/or recalculate the measurement uncertainty

All methods for evaluation of measurement uncertainty shall include the following:

- Require the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method
- Include the process of rounding the expanded uncertainty
- Require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (coverage factor of 2)
- Require at least one person involved in the measurement uncertainty evaluation/reevaluation be competent in the discipline
- Require new measurement uncertainty evaluations to have the initial reevaluation at a maximum of approximately 1 year from the initial evaluation
- Reevaluation schedules shall consider changes to the components contributing to the measurement uncertainty and the stability of the calculated uncertainty. For example:
    - Equipment replacement
    - Changes to the method
    - Staff Changes
    - Significant changes in the reported uncertainty from the prior evaluation

The **Discipline Supervisor** is responsible for ensuring all measurement uncertainty evaluations/reevaluations are conducted according to the defined schedule and for designating the person/people responsible for conducting the evaluation.

A report summarizing the components and results shall be prepared for each evaluation/reevaluation. This report shall be signed by the person completing the measurement uncertainty evaluation, the **Discipline Supervisor**, and the **Quality Assurance Manager**.

7.6.2 The Laboratory does not perform calibrations of its own equipment. Calibration of breath alcohol instruments will evaluate measurement uncertainty.

7.6.3 The Laboratory has a procedure to estimate the uncertainty of measurement for all reported quantitative values.

7.6.4 Uncertainty of Measurement records are retained for each evaluation and estimation of measurement uncertainty that 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

7.7 ENSURING THE VALIDITY OF RESULTS

7.7.1 The Laboratory will monitor the validity of testing and calibration using 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 will be documented in the technical record. The Laboratory will perform technical review on 100% of scientific examination documentation and reports as well as calibration records and reports prior to release. 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 provided 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 technical record is technically reviewed to include a review of all examination or calibration documentation and the report to ensure:

- Conformance with Laboratory and Discipline procedures
- Data supports the results and/or conclusions (including calculations for accuracy)
- Accuracy of the report
- Associations are properly qualified in the test report
- Test or Calibration 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 or APD will be reviewed on an annual basis during the internal audit. The technical reviewer will not have authored or co-authored components of the technical record or report under review. The Laboratory will perform administrative review on 100% of scientific examination documentation and test reports as well as calibration records and 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 components of the technical record or 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 or calibration report for spelling and grammatical accuracy
- A review of all administrative and examination or calibration documentation to ensure that the records are uniquely identified according to laboratory policies and procedures
- A review of the test or calibration report to ensure that all key information is included
- Chain of custody for testing reports

The administrative reviewer of testing casework 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

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.

TESTIMONY MONITORING

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. Once per accreditation cycle (4-year calendar period), each **analyst authorized to issue reports**, will have a technical review of their testimony performed by a staff member who is technically competent in the discipline at a Forensic Scientist 3 or higher level (or equivalent).

These reviews 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
- Mock court/technical discussions

Evaluations of testimony from individuals external to the laboratory are collected using the following Survey Monkey link.

https://www.surveymonkey.com/r/X226BHQ

Evaluation of testimony from laboratory personnel is documented using the Peer Expert Witness Evaluation Form. This form is used to document both technical and non-technical reviews by laboratory personnel.

It is the **testifying individual's** responsibility to advise their **discipline supervisor** of any pending court appearances and seek testimony feedback. The Survey Monkey link should be provided to prosecutors, defense attorneys, and judges when possible and supervisors should be made aware of court testimony that will allow for technical review of testimony (local, streamed, or telephonic/video testimony).

If 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** in the Witness Evaluation Records. If it is determined that testimony provided did not follow laboratory procedures the procedure for non-conforming work will be followed (see Quality Assurance Review Policy).

At the end of each calendar year the **Quality Assurance Manager** will create a record 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.

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. The Quality Assurance Review Policy will be followed, if applicable.

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. Any proficiency tests determined to be unsatisfactory will require a Quality Assurance Review and remediation shall include successful completion of an additional internal or external proficiency test.

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 technical record. 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 external proficiency results must be consistent with the manufacturers expected result. For consensus-based proficiency tests the consensus result is the expected result. If identification or exclusion is the expected result a result of inconclusive will be considered an unexpected result.

Internal tests require known answers prior to administering the test and the results must be consistent with the answer key. The results should not be known or readily available to the participant being monitored.

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.

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.

Calibration proficiency tests will be performed on an item calibrated by the person being tested. Additional requirements for this are specified in the Breath Alcohol Procedure 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. ANAB will be notified within 30 days of the evaluation of performance when the expected result is not attained during any monitoring activity.

7.7.6 Each discipline **technical lead** will prepare performance monitoring plan annually to submit to the **Quality Assurance Manager**. The performance monitoring plan from each discipline will ensure that a representative portion of the components/parameters and equipment/technologies listed on the Scope of Accreditation has been monitored for each authorized analyst. The goal of performance monitoring is to ensure all analysts are monitored at least once on each component/parameter and equipment/technology in which they perform work during an accreditation cycle. For analysts who are authorized near the end of the accreditation cycle the performance monitoring plan can be modified to not include all components/parameters and equipment/technologies during that accreditation cycle. Performance monitoring plans can utilize a number of monitoring methods to include: external proficiency tests, internal proficiency tests, observation based monitoring, retesting, written exams, etc; however, records must be maintained for all performance monitoring.

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 annual performance monitoring cycle runs from November 1 through October 31st of the following year but aligns with the accreditation cycle to ensure that a sampling of all components, technologies, and personnel are monitored.

Performance monitoring plans/reports shall include:

- The type(s) of monitoring activities that will be used.
- Criteria for successful completion (this may be found in the records of monitoring rather than the plan).
- Results of the performance monitoring.
- What components/parameters and equipment/technologies have been monitored over the accreditation cycle for each participant (not required if all are monitored annually).
- Any unexpected results obtained.
- Any actions taken as a result of performance monitoring.

Unexpected results from performance monitoring will be reported to the **Quality Assurance Manager** immediately and ANAB will be notified within 30 days of the evaluation of the performance monitoring of any unexpected results.

7.7.7 When available, an ISO/IEC 17043 accredited provider with an accrediting body that is a signatory to the APAC MRA or IAAC MLA will be used. If an 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.

Proficiency tests will be assigned to the analyst with a due date 5 business days prior to the provider due date. When an analyst cannot submit the proficiency test by the assigned due date communication with the **Discipline Supervisor** and **Quality Assurance Manager** should occur as to the reason and when the test will be completed.

The laboratory will authorize the proficiency test provider to release test results to ANAB.

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 or calibration 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 reports will include the following:

- All reports issued will list all items requested for that service type even if no work was performed. (See JusticeTrax LIMS-Plus 3.8 Manual Relating Evidence to a Request, and Indicating that a Related Item is Not To Be Retrieved or Analyzed for more information). Discipline

Procedure Manuals shall identify what is to be reported for all items on the report including items collected or created and preserved for future testing and for when partial work is performed.

- All associations in the report will qualify the significance with either a statistic or qualitative statement.
- Communication of the reason for any inconclusive results.
- Reporting of any initial database entry

Discipline Procedure Manuals outline specific reporting language for the disciplines.

7.8.1.2.3 The Breath Alcohol Procedure Manual outlines the required components of calibration reports.

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 except for the Crime Scene Discipline which notes in the report the location testing was performed

7.8.2.1d Case number or instrument serial number (for calibration reports) 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). The laboratory owns all breath instruments and is the customer for calibration reports.

7.8.2.1f Identification of the methods used

7.8.2.1g Item description for testing reports and instrument serial number for calibration reports

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 release date of the report

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 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

7.8.4.1 Where necessary calibration reports will include the following:

7.8.4.1a measurement uncertainty presented in the same unit as that of the measurand and meet ANAB AR 3125 7.8.4.1.a.1

7.8.4.1b when necessary conditions that many have an influence on the calibration report

7.8.4.1c statement about metrological traceability

7.8.4.1d as found and as left results will be provided if available

7.8.4.1e no statements of conformity are needed

7.8.4.1f where appropriate, opinions and interpretations

7.8.4.1.1 No requirement exists to prohibit reporting measurement uncertainty

7.8.4.2 The laboratory does not perform sampling in calibration services

7.8.4.3 The calibration certification shall not contain any recommendation on the calibration interval unless agreed by the customer.

7.8.4.4 No calibration labels are used.

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

7.8.6.1 The laboratory only reports statements of conformity in Seized Drugs. The decision rule for controlled substance schedules is inherent in the standard and prescribed by the Alaska Statutes.

7.8.6.2 Statements of Conformity for seized drugs shall meet the requirements of a, b, and c.

7.8.7 REPORTING OPINIONS AND INTERPRETATIONS

7.8.7.1 Opinions and interpretations will be clearly marked in reports.

7.8.7.2 The 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. The Breath Alcohol Procedure Manual describes the procedure for documenting communications relating to the Breath Program, including opinions and interpretations.

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 LIMS-Plus 3.8 Manual provides information on documenting and tracking amended test reports. The Breath Alcohol Procedure Manual provides information on documenting and tracking amended calibration 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 completely 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 Deviation Request Form Policy. 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 Quality Assurance Review Policy below will be followed.

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

7.10.3 See Quality Assurance Review Policy below.

QUALITY ASSURANCE REVIEW POLICY

Quality Assurance Reviews (QAR) are the process of evaluating risk from either nonconforming work or areas of concern in existing procedures and determining what, if any, action should be implemented. The Quality Assurance Review form is used to document this process and includes documentation and remediation of the incident, evaluation of risk, and any further actions taken.

Risk assessment in a Quality Assurance Review is performed by calculating the Risk Priority Number (RPN). Risk Priority Number is a numerical value calculated and used to evaluate the magnitude of risk. RPN is calculated by evaluating the severity, occurrence, and likelihood of detection of an issue. See Calculating the Risk Priority Number below for more information.

Quality Assurance Reviews include Corrective Action, Preventative Action, and documentation of nonconforming work that does not require action. Quality Assurance Reviews do not include the documentation of nonconforming work that was approved prior to the deviation occurring. See Deviation Request Form Policy for how the laboratory handles approved deviations.

THE LAYOUT OF THE QUALITY ASSURANCE REVIEW FORM

The Quality Assurance Review contains multiple sections that are color-coded to identify the party responsible for ensuring each section is completed. The form is designed to be filled out in order and certain steps may not be applicable depending on if the issue is a nonconformance or preventative action and the Risk Priority Number calculated.

SIGNATURE BLOCKS (ORANGE)

There are two sets of signature blocks that serve to demonstrate the QAR has been reviewed. Analysts shall review the QAR prior to discovery and ensure that the QAR is complete enough for release. The following outlines when QARs are available for release in discovery.

- Any QAR that has an action plan (preventative, Level 1 or Level 2 corrective actions) must have the first set approving the action plan signed by the **Quality Assurance Manager,** at a minimum, prior to releasing the QAR for discovery.
- If no action plan is required, then the completion blocks must be signed by the **Quality Assurance Manager,** at a minimum, prior to releasing the QAR for discovery.

STEP 1

Description (Blue)

The first section under Step 1 is a description of the nonconformance or area of concern. This section includes the staff involved, a citation of the procedure involved, a list of impacted cases, notification of involved analysts, and any plan for remediation. Topics that may be relevant in describing an incident include:

- How the incident was identified.
- Where the incident occurred.
- Information about how the incident occurred.

This section is initiated by the **staff member identifying the deviation**; however, additional staff members/Discipline Supervisors may provide input or technical assistance if needed.

Remediation and/or Discussion, Evaluation of Scope, Risk Priority Number Determination, and Classification (Grey)

The **discipline supervisor** is responsible for approving and describing any remediation taken as well as discussing the potential impact the nonconformity had on affected cases.

The **discipline supervisor** also must evaluate the scope of the incident. This should include the potential for the nonconformity to be present in other work performed by the analyst, by other analysts, and other disciplines, if applicable. This evaluation should include information on what was done to determine if other work may have been impacted.

After the identification and description of the incident the Risk Priority Number must be calculated to determine the magnitude of risk. The Risk Priority Number is determined by the **discipline supervisor** and the section includes space for the **discipline supervisor** to describe the rationale behind the RPN determination. The RPN calculated by the **discipline supervisor** is used to classify the Quality Assurance Review and determine what, if any, action is needed.

The options for classification include:

- **Level 2 Corrective Action:** When a **nonconformance occurs** and the **RPN ≥ 15** root cause analysis and corrective action are required. In this instance, all steps of the Quality Assurance Review will be filled out.
- **Level 1 Corrective Action:** When a **nonconformance occurs** and the **RPN < 15** no action is required; however, it might be determined that corrective action could improve the current procedures and will be implemented. In this circumstance root cause analysis is not required.
- **Nonconformance with No Corrective Action**: When a **nonconformance occurs** and the **RPN < 15** and there is no plan to implement any form of corrective action this classification is used.
- **Preventative Action:** When **no nonconformance has occurred** but an area of concern with current procedures has been identified this classification is selected. If the **RPN ≥ 15** then an action plan is required. If the **RPN < 15** an action plan is optional. No root cause analysis is required for preventative action.

Additional Actions Needed (Green)

After a classification has been determined the **Quality Assurance Manager** will review the RPN calculation and classification and discuss any additional actions needed with the **Discipline Supervisor**. This includes any customer notification when there has been an impact to casework, halting of work, and disclosure to the accrediting body. See 5.4.2 for more information on requirements for disclosure to ANAB.

The **Quality Assurance Manager** can be consulted earlier in the process if the issue is severe or assistance with determining RPN is needed.

STEP 2: ROOT CAUSE ANALYSIS

This step is only required for a Level 2 corrective action; however, it is a tool that may be used for any investigation of any nonconformity. Root cause analysis is used 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. The **Quality Assurance Manager** is responsible for leading the root cause analysis, but the **Discipline Supervisor** and/or **other staff** may be interviewed or asked for assistance. Upon completion of the root cause analysis, the **Discipline Supervisor** and/or **DNA Technical Manager** will work with the **Quality Assurance Manager** and discuss their findings and create an action plan to address the problem and prevent reoccurrence of the nonconformity.

STEP 3: ACTION PLAN

The **Quality Assurance Manager** should work with the **Discipline Supervisor** and **Technical Lead** to determine the action plan. The action plan must include a timeline and should address how the actions described will reduce components of the RPN. Additionally, the action plan will address a timeline and plan for evaluation the effectiveness of the action plan.

Once an action plan is determined the **Quality Assurance Manager** and **Discipline Supervisor** must sign off on the plan, at a minimum. The **DNA Technical Manager** must sign off on all Action Plans involving Forensic Biology.

STEP 4: IMPLEMENTATION

The **Quality Assurance Manager** is responsible for ensuring the timeline and action plan described in step 3 is followed. This section allows for documentation during implementation of the action plan. The **Discipline Supervisors/DNA Technical Manager** are responsible for ensuring timely completion of the action plan.

STEP 5: EVALUATION OF EFFECTIVENESS

The **Quality Assurance Manager** is responsible for ensuring the evaluation of effectiveness plan described in the action plan is carried out. This section serves to record a summary of this evaluation and the results. If it is determined the corrective or preventative action was not effective or had unintended consequences a new Quality Assurance Review will be initiated by the **Quality Assurance Manager**.

STEP 6: COMPLETION

This step is filled out on all Quality Assurance Reviews and serves to document the review by the **Discipline Supervisor** and **Quality Assurance Manager** at a minimum.

CALCULATING THE RISK PRIORITY NUMBER

Risk Priority Number (RPN) is a numerical value determined to evaluate the magnitude of risk. RPN is calculated by evaluating the severity, occurrence, and likelihood of detection of an issue.

Severity: The impact that a nonconformance or area of concern has on a customer, customer decisions, or laboratory operations (scored 1-5).

Occurrence: The frequency or likelihood of a specific nonconformance or area of concern happening (scored 1-5).

Detection: The ability of the laboratory to detect the nonconformance or area of concern with existing procedures (scored 1-5).

RPN = Severity x (Occurrence + Detection)

Appendix F: Risk Priority Number Table describes the numerical rating system for scoring the severity, occurrence and detection of an issue.

For questions on scoring or calculating RPN contact the **Quality Assurance Manager**.

HOW TO INITIATE A QUALITY ASSURANCE REVIEW

A Quality Assurance Review will be filled out at the time a deviation is noted or when an area of concern is identified. The **staff member identifying the deviation or area of concern** should initiate the Quality Assurance Review. Anyone within the laboratory system can initiate a Quality Assurance Review.

The initiator will save the Quality Assurance Review in the appropriate SharePoint document set and if necessary, create a case activity in all case numbers, or instrument serial number cases for calibration, that are involved in the Quality Assurance Review. The title of the Quality Assurance Review will go in the notes field in of the QA- Quality Assurance Review case activity. For preventative actions or nonconformities that do not involve specific cases no case activity is needed. **If additional cases are identified during investigation of the Quality Assurance Review, it is the responsibility of the identifying staff member to add the case activity to those cases.**

HOW TO TITLE A QUALITY ASSURANCE REVIEW FORM

The title of the Quality Assurance Review will be QAR Date Initiated Discipline(s) Affected Initials of the Person Initiating the Quality Assurance Review. (Example: QAR 2022.02.25 Toxicology - Testing BMB). Examples for Discipline options are: Biology, Evidence, Firearm and Toolmark, Friction Ridge, Impressions, Scene Investigation, Seized Drugs, Toxicology – Calibration, and Toxicology – Testing.

If a person is initiating more than one Quality Assurance Review, for the same discipline, on the same day, then the title will be incremented as follows QAR 2022.02.25 Toxicology - Testing BMB_2.

If the Quality Assurance Review affects more than one discipline, upload the QAR into the document set for the discipline in which it was identified and acknowledge the appropriate second discipline in the title. (Example: QRF 2022.02.25 Seized Drugs - Friction Ridge BMB).

If the QAR involves a labwide issue or more than two disciplines, the discipline should be listed as Labwide or All Disciplines and uploaded into the labwide document set. (Example: QAR 2022.02.25 Labwide BMB).

Once a document is titled, when the Quality Assurance Review 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 Manager** prior to storing the document in SharePoint.

PERSONS RESPONSIBLE FOR EACH SECTION OF A QUALITY ASSURANCE REVIEW

The Quality Assurance Review is color-coded to indicate who is responsible for each section of the form. If at any point there is a question to the process the **Discipline Supervisor** or **Quality Assurance Manager** should be consulted. The **Discipline Supervisor** is responsible for verifying that the first step of the form is filled out completely, that the case activities were entered into affected cases, that staff involved were notified of the issue, and that any remediation was appropriate prior to forwarding the form to the **Quality Assurance Manager**.

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 additional input is needed from a staff member, tag the appropriate person in the "Action Needed" column. This will send an email notification to the staff member; however, members of the laboratory should review the actions needed for their name on a regular basis.

If at any point, when filling out the Quality Assurance Review, case numbers are added to the QAR, the person adding the case numbers to the QAR should create a case activity in the case in the LIMS.

When the **Discipline Supervisor** determines the Quality Assurance Review is ready to be reviewed by the **Quality Manager**, the name of the Quality Manager will be selected in the "Actions Needed by" column. If corrective or preventative action is necessary, then the Quality Manager will be notified directly as soon as possible.

IMPORTANT REMINDERS:

The official copy of the Quality Assurance Review is the one stored in SharePoint. When providing documents for discovery always check the case activities of a case for the QAR title and download the document out of SharePoint (ensure signature blocks are signed see Signature Blocks (Orange). Copies of QARs 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.

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 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 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, calculations performed in unlocked data cells, or data transfers performed in casework will be reviewed during the technical and/or administrative review process.

7.11.6.1 The check of manual calculations and data transfers 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, and the Federal Bureau of Investigation Quality Assurance Standards for Forensic DNA Databasing Laboratories.

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, the Procedure for Evidence Management, 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 labwide controlled documents. All labwide controlled documents are approved by a member of **Top Management**.
- 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 **Top Management.**
- The Health and Safety Manual is written by the **Safety Coordinator** and approved by a member of **Top Management**.
- 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. See the SharePoint Working Instructions for details regarding versioning and document control. 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.

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 follow 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. DNA Database records and non-consumed/expunged samples will be maintained indefinitely.

Hard copy case files and Latent Case File Archives (prior to electronic LIMS) are stored in secure locations of the Crime Lab. Laboratory employees needing to review a case file will send a request to the evidence section. Evidence staff will create an electronic case in the LIMS and an electronic chain of custody for the

case file. An evidence barcode will be affixed to the case file (see Evidence Room Manual). Laboratory staff will ensure all transfers between staff for the case file are recorded in the electronic chain of custody. Discipline supervisors also have access to the case file storage areas for instances where evidence staff are not available; however, whenever possible evidence staff should be responsible for retrieving and logging case files. Case files in possession of laboratory staff will be monitored using the evidence in possession over 60-day report that is reviewed monthly.

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 using 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 (recorded in LIMS).
- Annual Fire Extinguisher training for all laboratory employees (recorded in LIMS).
- CPR and AED training for laboratory employees (recorded in LIMS).
- First Aid training for laboratory employees (recorded in LIMS).
- 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 preventative action will include the initiation of the action and the application of controls to ensure effectiveness. See Quality Assurance Review Policy for more information on how preventative actions are documented.

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. See Quality Assurance Review Policy.

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

8.7 CORRECTIVE ACTIONS (OPTION A)

8.7.1 **Any Laboratory member** may identify when nonconforming work or departures from Laboratory's Forensic Quality Assurance Program may have occurred. Any member identifying such potential concerns will immediately notify the **Discipline Supervisor**, **DNA Technical Manager**, **Quality Assurance Manager**, **Assistant Chief**, or **Chief** as appropriate. The **Quality Assurance Manager** will work with the **Discipline Supervisor** to follow the Quality Assurance Review Policy regarding any corrective actions. Level 2 Corrective Actions will include 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 and create an action plan 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 in the action plan to provide the **Quality Assurance Manager** with the information necessary to perform this function. 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 Quality Assurance Review 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*. In addition, the laboratory will participate in the ATF audit program as described in the MROS-NIBIN document. The **NIBIN Program Administrator** will coordinate with the laboratory **Quality Assurance Manager** to facilitate the planning, implementation, documentation, and follow-up of regular ATF audits at the basis set by ATF. All records will be maintained in the laboratory's Quality Assurance Records.

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 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

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.

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 using a Lenel OnGuard security system.

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.

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 following information will be documented and provided to the **Chief**:

- Employee's name
- Employee's key number
- A brief description of the events surrounding the key loss

When a key has been lost, the **Chief** shall decide whether to rekey the affected locks within the Laboratory for security purposes.

If a key is recovered later the key should be placed in the custody of the Key Controller and records changed to reflect the recovery. Written documentation will be provided to the **Chief** and should include:

- Employee's name
- Employee's key number - recovered key
- Date key was lost
- Brief description of events surrounding the finding of the key.

Copies of written documentation associated with key loss/recovery will be stored in the quality assurance records.

Electronic Door Access Keys

Electronic keys are assigned by **Top Management** to individuals who require facility access. Laboratory staff and other building residents are provided access cards based on business and security needs. The **Chief or designee** determines the access levels.

Door access can be provided temporarily through visitor access cards. Visitor access cards are assigned appropriate door access based on business needs and a record of the badge assignment is documented on the Visitor Key Log.

The Door Permission Request Form is used to document long-term door access requests from non-building residents. **Top Management** can approve door permission request forms. Approved Door Permission Request Forms are stored in the quality assurance records.

Access levels will be reviewed and updated annually at a minimum. Access, by laboratory staff, outside normal business hours is monitored quarterly and records of this monitoring are 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 Controlled Documents document library.

CONTROLLED DOCUMENT REVIEW, APPROVAL, AND ISSUANCE

Labwide controlled documents are reviewed and approved by **Top Management**. 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 written by the Laboratory's **Safety Coordinator** and reviewed and approved by **Top Management**. See the SharePoint Working Instructions for more details on how editing and approval permissions are implemented.

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. See the SharePoint Working Instructions for more details on versioning control.

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

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).

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.

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**.

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.

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.

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

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:

- 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.
- 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.
- 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.
- 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.
- 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.
- Contamination – Irregular persons entering the space (specifically DNA) present increased potential for contamination.
- 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.

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

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.

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.

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.

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:

- Subpoenas take precedence over all scheduled time off.
- 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.
- 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.
- 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.
- 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 REPORT AND DISCOVERY DISSEMINATION

INITIAL REPORT DISSEMINATION

When a testing request is complete, the final report will be disseminated to the parties listed on the associated Request for Laboratory Services form and the assigned District Attorney Office.

DISCOVERY REQUESTS

After initial report dissemination, criminal justice practitioners may also request a copy of the report along with other supporting documentation as discovery. The intent of discovery is addressed under Alaska Rules of Criminal Procedure (Rule 16. Discovery). The contents of discovery are considered confidential and shall only be provided through the customer as defined in 3 Terms and Definitions (i.e., 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.)

DISCOVERY LEVELS

There are different levels of discovery provided by the laboratory. The content of each of these levels is described below along with their intended purpose.

LEVEL 1 – INITIAL DISCOVERY

The only record provided in Level 1 discovery is the final report that was disseminated upon testing completion.

LEVEL 2 – FULL DISCOVERY PACKET

Any record that would be relied upon for analysis, reporting, conclusions, opinions, or testimony in a specific case is provided in Level 2 discovery.

All testing disciplines will include the following when fulfilling a Level 2 discovery request:

- Testing Report
- Case Chain of Custody (COC) Report
- Case Info Report (which includes case activities, evidence intake corrections, and request milestones)
- Quality and LIMS Documents Referenced in Case Activities (e.g., QARs, DRFs, COC edit forms)
- Case and Request Attachments (e.g., RLS, instrument printouts, worksheets)

The following discipline specific records will also be provided when applicable:

- Control Pack (Blood/Beverage Alcohol)
- Central Log (Biology)
- Digital Images (Latent Print, Footwear, Firearm/Toolmark, and Crime Scene)

Level 2 Discovery for the breath alcohol discipline includes the following items available on the crime lab webpage:

- Verification of Calibration Reports
- All Instrumental Records (DataMaster DMT Records)
- List of all breath records from all instruments (DataMaster DMT Breath Test Records)
- DataMaster Software Approvals

- Current Breath Test Operator List
- Breath Alcohol Manuals
- Certificates of Analysis for external controls
- Calibration certificates for calibrated equipment (used by calibration program - not DataMaster Calibration)
- In Field Instrument Reviews

The JusticeTrax Manual provides more information about how to create a discovery packet.

Staff should direct criminal justice practitioners to the crime lab website for statements of qualifications and laboratory procedure manuals.

LEVEL 2 - DISCOVERY PROMPTING EVENTS

Failure to provide discovery in a timely manner before trial can lead to continuances as well as prevention of related expert testimony. See Alaska Rules of Criminal Procedure (Rule 16. Discovery) for more details. To minimize the occurrence of these issues, the laboratory will proactively provide Level 2 discovery when a subpoena is issued for expert testimony or when an expert is requested to testify. When Level 2 discovery is requested by the defense, laboratory personnel shall provide the discovery to the defense through the assigned prosecutorial agency.

LEVEL 2 - SUPPLEMENTAL DISCOVERY

Whenever it is determined that Level 2 discovery should be provided, the case record will be reviewed to assess whether this has already occurred. If it has, an abbreviated supplemental Level 2 discovery will be disseminated if anything has changed since the original discovery (e.g., chain of custody, case activities, quality documents). Records that have not changed since the original discovery do not have to be disseminated again after a discovery prompting event.

A supplemental discovery assessment will also occur If there is a significant delay between when an expert is requested to testify and when they are actually preparing to do so (e.g., an unexpected court continuance occurred).

LEVEL 3 – RECORDS NOT COVERED BY LEVEL 1 OR LEVEL 2

Requests made for information not listed above, such as raw data, proficiency test results, training records, accreditation information, validation reports, etc., must go through the **Quality Assurance Manager** to determine next steps. Depending on the feasibility and resources needed, a motion to compel may be requested before the request is fulfilled.

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.

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

METHODS OF DISSEMINATION

All records addressed in this policy will be disseminated via the State E-mail system to the recipient's agency e-mail address whenever possible. Records will not be emailed to personal email accounts.

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 (i.e., police department agencies) to ensure that the PII enclosed in the email is secure.

In instances where the file size is too large to email, the state sponsored Alaska ZendTo program will be used instead.

If the recipient does not have an agency e-mail address, the records will be sent by US mail or picked up in person at the laboratory. In this situation, the format can either be hardcopy or digital media (e.g., USB drive, DVD, etc.).

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. To ensure the integrity of this evidence, it is necessary that all Laboratory facilities be properly secured as follows:

- 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.
- Exceptions will be made in the case of medical emergency or other critical incidents.
- Ultimate access to Laboratory facilities will be determined by the **Top Management**.
- All facility entrance points are monitored by video camera and the recorded video stored for at least 120 days.
- 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 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.

SQL SERVER DATABASES

JTRAX – LOCATED AT GCI SOUTH ANCHORAGE DATA CENTER (GCI SADC)

All Laboratory staff shall have data reader/data writer permission

FORAY ADAMS – LOCATED AT GCI SADC

Laboratory staff access via the Adams application

BREATH ALCOHOL - LOCATED AT GCI SADC

All staff assigned to the breath alcohol program shall have data reader/data writer permission

STORAGE AREA NETWORK (I DRIVE) – LOCATED AT 4805 DR. MARTIN LUTHER KING JUNIOR AVENUE (SCDL)

The Chief shall have full permissions over the I drive

All Laboratory staff shall have full permissions except as follows

- Quality Assurance Program (however so named by the QA Manager)
  - Only Top Management shall have full permissions
  - All other Laboratory Staff shall have read only permissions (may not change or delete)
- Discipline shares
  - All staff have full permissions over all discipline shares

Some subfolders have been locked to allow only specific personnel full permissions; all other users have read only permissions.

PERSONAL DRIVES (P) – LOCATED AT 4805 DR. MARTIN LUTHER KING JUNIOR AVENUE (SCDL)

Permission shall be only to the individual analyst.

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.

LIMS (JUSTICETRAX)

User accounts and user security are created/assigned by the LIMS administrator or designee.

OFFICE OF INFORMATION TECHNOLOGY ACCESS REQUIREMENTS AND RESTRICTIONS.

To 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.

OIT staff will only access Forensic Laboratory information technology resources to the extent necessary to maintain normal operational status (e.g., Backup, connectivity, etc.) and shall make every effort to avoid direct contact with user data unless directed by the **Chief**.

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.

Physical Access Security – Users (including OIT staff) obtain a badge to enter the building. The servers and storage are in access-controlled rooms.

Login Access - OIT staff only, has administrative login access to the keyboard/monitor in the server rooms used by all servers.

Individual server login access is possible only with OIT administrative credentials. – screens lock on servers after 10 minutes.

Data backup – These occur at the SADC every two weeks. The laboratory complies with the OIT backup policy.

POLICY 8 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 Staff**.

SIGN OUT

Vehicle sign out sheet is 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. Additionally the fleet card can be used to pay for parking.

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 9 TESTIMONY POLICY

The purpose of this policy is to describe the laboratory guidance for how testimony should be handled. Court orders and subpoenas are legally binding and may supersede this policy. The laboratory may seek guidance from **DPS legal counsel** before expending resources when deemed necessary.

- In cases in which a laboratory testing report was released, laboratory staff will testify for prosecution or defense counsel.

- In cases where the laboratory has not performed testing in the case, the **discipline supervisor** should contact the prosecution to determine if there will be evidence submitted to the laboratory for analysis in the future.
    - If the prosecution intends to submit evidence this should be communicated to the defense attorney. If, after testing has concluded, the prosecution decides laboratory testimony is not needed laboratory personnel may testify for the defense.
    - If the prosecution does not intend to have evidence tested at the laboratory, the procedure for no lab involvement cases described below will be followed.

- For breath program cases or no lab involvement cases, the **discipline supervisor** will address requests for testimony with the requesting party. 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 for no lab involvement cases 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.

Laboratory analysts are trained to testify to the laboratory chain of custody, evidence handling, item selection, and policy decisions. Laboratory personnel who did not issue testing reports will not routinely testify in court. If there is a specific circumstance that requires additional laboratory personnel, the requesting party should speak to the **discipline supervisor**.

Due to limited resources, the laboratory is opposed to routine testimony at grand jury hearings. If the requesting party feels there is a strong need for a staff member to testify, they should speak to the **discipline supervisor** who will consider the request.

Once a laboratory staff member is noticed up as an expert, one-sided conversation (verbal or written) with opposing counsel should be avoided. See Ethics Opinion No 85-2 (Ex Parte Communication with Experts Retained by Opposing Counsel) for more details.

POLICY 10 LABORATORY STAFF COVERAGE POLICY

The following policy is designed to provide guidance for laboratory staff and discipline supervisors when requesting/approving leave, telework, travel, or situational changes in duty days/shift hours.

The laboratory operational hours are defined as Monday-Friday 6AM-6PM (See Policy 3 Laboratory Occupancy).

The routine minimum staffing levels outlined in this policy are intended to be Monday-Friday 9AM-3PM.

Each supervisor will ensure that the composite of established duty days/hours for their direct reports meets the minimum coverage outlined below. For scientific services, only competent non-supervisory analysts in the associated service will be considered when establishing routine duty days/hours to meet minimum coverage.

Routine minimum staffing levels:

Service	On-Site	Total*
Admin	1	1
Biology	1	2
Blood Alcohol	1	2
Breath Alcohol	1	2
Chemistry Supervisor (FS4)	1	1
Crime Scene	0	1
DNA Supervisor (FS4)	1	1
DNA Tech Manager	0	1
Evidence	2	2
Facilities	1	1
FATM	1	1
Footwear	1	1
Latent Print Examination	0	2
Latent Print Processing	1	2
Physical Supervisor (FS4)	1	1
Seized Drugs	1	2
Top Management	1	1

*If the total is larger than the on-site then the additional person can be on-site or on telework status

Top management will be notified as soon as possible if a supervisor determines that minimum coverage cannot be met. Strategies such as designating an acting supervisor, having staff on telework status report to the lab, and having supervisors competent in the discipline fill in for coverage will be used if deemed necessary.

Further information on Department of Public Safety coverage and leave policies can be found in:

Department of Public Safety Operating Procedures Manual Chapter 113 (Work Hours, Leave, and Payroll)

State of Alaska Division of Personnel and Labor Relations Telework Policy

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.
- During the entry of results the portal will ask if you want to release your results to an accrediting body. Select yes to this prompt. The portal will then ask you to upload a copy of a completed release of results form. The signed form is stored in SharePoint Controlled Documents (Release of Results Form). Download a copy of the form from SharePoint and fill out your test information. If the form is not from the current year notify the Quality Assurance Manager. Once the form is filled out upload it to the portal.
- 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.

APPENDIX F: RISK PRIORITY NUMBER TABLE

Severity	Ranking		Occurrence	Ranking		Detection	Ranking
Management system failure, Major effect on reported results impacting multiple cases or batches of cases. Analyst intent was to mislead.	5		Very High- Failure is frequent or very likely (estimated greater than 25%)	5		Remote: Not likely to be uncovered in laboratory or outside of laboratory.	5
Incorrect results reported, loss or destruction of critical evidence. Major effect on reported results of a single case or batch of cases. Major effect on laboratory staff or customers.	4		High- Failure is repeated or likely (estimated 5-25%)	4		Low: Not likely to be uncovered with existing laboratory preventative measures but may be uncovered outside of lab.	4
Moderate effect on reported results for a single case or batch of cases, laboratory staff, or customers.	3		Moderate: Failure is occasional (estimated less than 5%)	3		Moderate: May be uncovered through existing preventative measures by either analyst or reviewers	3
Low effect on reported results, laboratory staff, or customers	2		Low: Failure is seldom (estimated less than 1%)	2		High: Should be uncovered through existing preventative measures by either analyst or reviewers	2
Virtually no effect on reported results, laboratory staff, or customers, easily correctible	1		Remote: Failure is not likely or improbable.	1		Very High: Likely to be uncovered through existing preventative measures by analyst	1

Likelihood (Occurrence + Detection)

	Unlikely	Minor	Very Low	Low	Moderate	Serious	High	Very High	Critical
Severity	2	3	4	5	6	7	8	9	10
5	10	15	20	25	30	35	40	45	50
4	8	12	16	20	24	28	32	36	40
3	6	9	12	15	18	21	24	27	30
2	4	6	8	10	12	14	16	18	20
1	2	3	4	5	6	7	8	9	10

APPENDIX G: REVISION HISTORY

Location	Revision made
Throughout	Updated formatting, spelling, and grammar as needed.
Technical Records (Case File)	Updated section to accommodate LIMS Plus DNA. 1. Revised the paragraph on unique identifiers needing to be on each page of the technical record and updated batch records. 2. Updated #5 to clarify when other analysts names/initials need to be present in the technical record 3. Removed #6 "The technical record shall indicate personnel responsible for checking data and results." as this was confusing with the technical review documentation and is covered in #5 and #7. 4. Clarified #7 that checking of data and results laboratory activity is checking of data and results prior to draft complete. 5. Moved #8 up where unique identifiers and page numbers are discussed.
Testimony Monitoring	Created a new section from existing information and added survey monkey link.