

SAN DIEGO POLICE DEPARTMENT CRIME LABORATORY



Quality Manual ISO/IEC 17025:2017 and ANAB AR 3125

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1 QUALITY MANUAL, OBJECTIVES, TERMS AND DEFINITIONS

1.1 Objectives

The San Diego Police Department (SDPD) Crime Laboratory Quality Manual includes administrative, managerial, and technical policies. This quality manual incorporates ISO 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories and ANAB (ANSI National Accreditation board) AR 3125 Forensic Science Testing and Calibration Laboratories Accreditation Requirements. The requirements in Sections 4 through 9 of this document generally correspond to the numbering system in ISO 17025:2017 and ANAB 3125.

Mission Statement

The mission of the San Diego Police Department Crime Laboratory is to provide the Department and the citizens of San Diego with comprehensive, impartial, reliable, accurate and timely scientific analysis of evidence by experts skilled in the latest forensic technologies.

Vision

Our crime laboratory will consistently strive for excellence in meeting the forensic needs of the local criminal justice community. We will be of sufficient size with sufficient budget, staff, and training to be able to meet all reasonable requests for forensic services submitted by detectives of the San Diego Police Department.

Goals

We will maintain a high level of professional competence through training, proficiency testing, and review of casework.

We will advocate professional development through on-going training and participation in professional organizations.

We will maintain our status as an ANAB accredited crime laboratory.

Objectives

The objectives of the quality system will be articulated and reviewed through the crime lab manager's quarterly management reports and the annual management system review.

1.2 Terms and Definitions

Analyst, examiner, specialist – An individual performing competency based laboratory testing in any of the crime laboratory units. These terms are used interchangeably.

Analysis, examinations, processing – The approved testing activities performed in any of the crime laboratory units. These terms are used interchangeably.

Association - A determination that a relationship exists between individuals and/or objects. [SOURCE: ANAB AR 3125]

Audit - A systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

[SOURCE: ANAB AR 3125]

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

[SOURCE: ANAB AR 3125]

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

[SOURCE: ANAB AR 3125]

Complaint - expression of dissatisfaction by any person or organization to the laboratory, relating to the activities or results of that laboratory, where a response is expected.

[SOURCE: ISO/IEC 17025:2017]

Decision rule - rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

[SOURCE: ISO/IEC 17025:2017]

Impartiality - presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the *laboratory*.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even handedness", "detachment", "balance".

Interlaboratory comparison – organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

[SOURCE: ISO/IEC 17025:2017]

Intralaboratory comparison – organization, performance and evaluation of measurements or tests on the same or similar items within the *same* laboratory in accordance with predetermined conditions.

[SOURCE: ISO/IEC 17025:2017]

Manager, supervisor, technical lead, technical manager – a person who has authority by position or temporary assignment.

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

[SOURCE: ISO/IEC 17025:2017]

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

[SOURCE: ANAB AR 3125]

Reference collection – Data or materials of known origin or property, which are maintained for identification, comparison, or interpretation purposes (*e.g.*, mass spectra, motor vehicle paints, firearms, ammunition).

[SOURCE: ANAB AR 3125]

Reference material (RM) – Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

[SOURCE: ANAB AR 3125]

Reference material producer (RMP) – Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference material it produces.

[SOURCE: ANAB AR 3125]

Reference standard – A measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location.

[SOURCE: ANAB AR 3125]

Request – The process utilized by a customer when seeking services from the laboratory.

[SOURCE: ANAB AR 3125]

Validation - verification, where the specified requirements are adequate for an intended use

[SOURCE: ISO/IEC 17025:2017]

Verification - provision of objective evidence that a given item fulfills specified requirements.

EXAMPLE 1 Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 2 Confirmation that a target measurement uncertainty can be met. [SOURCE: ISO/IEC 17025:2017]

EXAMPLE 3: Confirmation of a test result/opinion by performance of the comparison between the unknown and the known by a different person.

[SOURCE: ANAB AR 3125]

2 SUBPOENA, EVIDENCE VIEWING, AND INFORMATION SHARING

2.1 Subpoenas

- 2.1.1 Subpoenas that meet the requirements of <u>Department Procedure 1.11</u> shall be accepted.
- 2.1.1.1 The laboratory clerical staff will be responsible for accepting, processing, and distributing subpoenas. The analyst subpoenaed will initial or sign the subpoena, and return a copy to the clerical unit. Additional subpoena policies are provided in unit manuals, where applicable.
- 2.1.1.2 Subpoenas for DMV matters are generally sent directly to the forensic chemistry unit.
- 2.1.2 The examiner may contact the agency that sent the subpoena to be placed on-call or schedule a specific time for testimony, and discuss the case.
- 2.1.2.1 The forensic chemistry unit staff operates on an on-call basis for alcohol related testimony.
- 2.1.3 If an examiner is unable to testify due to illness or other unavoidable emergency, it is the analyst's responsibility to notify the appropriate person or agency of their condition in a timely fashion.
- 2.1.4 If the examiner has a time conflict due to training or vacation, the examiner should make the appropriate arrangements with the sender of the subpoena. The examiner or their supervisor may try to reschedule a court appearance, or suggest that another examiner testify in their place. If these alternatives are not acceptable to the attorneys handling the case, the court requirements will take precedence. If an analyst receives subpoenas for simultaneous court appearances, they will contact the attorneys involved to coordinate court appearance times.
- 2.1.5 Prosecuting agencies commonly served by the crime laboratory will be notified of an analyst's pre-arranged unavailability for court due to vacation or training. The analyst will notify a member of the clerical unit of dates of unavailability. The clerical unit staff member will prepare a memo stating the dates of unavailability, which will be signed by the analyst's supervisor. The memo will be distributed to the prosecutorial agencies by the clerical unit.

2.2 Viewing of evidence

2.2.1 Laboratory staff will route defense and prosecution requests for viewing of evidence through the case detective. Evidence viewing will typically occur in the property room or the narcotics vault. In most instances, the detective will be present. If the viewing will extend into any laboratory unit, advance coordination with the crime laboratory manager or assistant crime laboratory manager is required.

2.2.1.1 The following conditions will also apply:

- Fresh paper will be used on tables on which evidence is viewed. The exception to this requirement is narcotics and toxicology evidence. Appropriate safety precautions will also be used. If a laboratory staff member is requested to be present for viewing, then that member should stay for the entire viewing. Laboratory analysis will not be done as part of the viewing process.
- b. Equipment will not be provided to attorneys or outside experts.
- c. Viewing of evidence will be documented in EvidenceOnQ or on the property tag if the case has not been entered into EvidenceOnQ.

2.3 Media requests

2.3.1 Any request from the media must be routed through the Captain/Crime Laboratory Manager for approval.

2.4 Meetings with attorneys

2.4.1 Crime laboratory staff will be available to meet with attorneys to discuss reported results. When planning to meet in person or telephonically with defense counsel, the examiner will provide the prosecuting attorney with a courtesy notification prior to the meeting.

3 ELIMINATION DNA DATABASE

- 3.1 The San Diego Police Department Crime Laboratory will maintain a DNA database for elimination purposes. The elimination DNA database is a quality assurance tool that enables the laboratory to recognize when DNA may have been introduced onto evidence at the time of collection, after collection, or through the DNA testing process.
- 3.1.1 The elimination DNA database will contain samples contributed voluntarily by laboratory and property room staff.
- 3.1.2 Interns and volunteers in the forensic biology and crime scene unit will be required to provide DNA samples for the elimination DNA database.
- 3.1.3 Visitors to the forensic biology unit that will access testing areas will be asked to provide DNA samples for the elimination DNA database.
- 3.1.4 Donors will sign a consent form available in PowerDMS prior to sample collection. Signed consent forms for all elimination database samples will be retained by the quality manager.
- 3.1.5 Reference DNA samples for the elimination database will be collected from employees by the quality manager. Samples collected from interns, volunteer, or visitors will be collected by other authorized personnel.
- 3.1.6 Elimination database profiles will be retained in the database indefinitely, unless expungement is requested in writing by the sample donor.
- 3.1.8 Samples (original mouth swabs and extracted DNA) will only be used for validation purposes with the documented consent of the donor. Samples authorized for validation by the donor will be identified with a "v" following the sample identifier code.
- 3.1.9 Elimination DNA samples will be uniquely and anonymously coded. Only the assistant laboratory manager/quality manager will have access to the source of the coded samples. The samples will be provided to the forensic biology unit as anonymous samples for DNA profiling.
- 3.1.10 No personal identifying information will be retained in the elimination DNA database used for comparison to evidence samples.

3.1.11 Policies regarding searching the elimination DNA database samples to evidence profiles will be provided in the forensic biology unit manuals.

3.2 Associations

- 3.2.1 The DNA technical manager will track all potential associations of evidence samples with samples in the elimination database to identify trends. Associations with a likelihood ratio at or above 10,000 will be forwarded to the Quality Manager. Corrective actions will proceed as stated in Sections 8.7.1 a-1a and 8.7.1 a-2.
- The quality manager will be informed by the DNA Technical Manager of any trends detected in potential associations to the elimination DNA database. A root cause analysis will be initiated to identify the cause, if possible.
- 3.2.3 If the association source is internal to the forensic biology unit, the root cause analysis will be conducted jointly by the DNA technical manager and laboratory quality manager.
- 3.2.4 Identifying information of the source of the elimination DNA database sample will be shared with the DNA technical manager only when that sample source is internal to the forensic biology unit.
- 3.2.5 Any corrective actions within the forensic biology unit will be coordinated by the DNA technical manager.
- 3.2.6 Names of donors of any elimination DNA database samples associated to evidence will not appear in the Quality Incident Summary or Corrective Action Report, but may appear in the documentation prepared by the Quality Manager.
- 3.2.7 The release of donor names outside the laboratory to investigators will be at the discretion of the crime laboratory manager or assistant crime laboratory manager/quality manager or by court order.
- 3.2.8 Recoding of samples for the elimination DNA database will be at the discretion of the quality manager or upon request of the sample donor. The release of a name does not mandate the recoding of a sample. Each circumstance surrounding the release of a name will be evaluated to determine if recoding is necessary to preserve anonymity.

4 GENERAL REQUIREMENTS

4.1 Impartiality

4.1.1 Laboratory activities shall be carried out in compliance with written procedures, Department policies, city policies, and personnel regulations intended to safeguard impartiality. Examples include personal conduct, outside employment, and purchasing and contract policies.

The San Diego Police Department Policy Manual can be accessed through the following link: <u>Personal Conduct Policies</u>. Section 9.06 of the SDPD Policy Manual addresses unbecoming conduct, and Section 9.08 of the SDPD Policy Manual addresses gifts and/or gratuities.

- 4.1.2 The laboratory will demonstrate commitment to impartiality primarily through a robust quality assurance program, setting expectations for all employees which are defined in employee performance plans, a requirement that all laboratory employees follow the City of San Diego Code of Conduct, selection of items for analysis as stated in Section 7.1.4, and limiting access to investigative information.
- 4.1.3 To preserve impartiality, no customer shall have the authority to influence results, or seek to have altered the content of laboratory reports in a manner that deviates from the requirements of this document. The laboratory will not allow commercial, financial, legal, or other pressures to compromise impartiality.
- 4.1.3.1a) All Laboratory employees will conduct their activities in accordance with the <u>City of San Diego Code of Conduct</u>. This code defines ethical conduct required by the City.
- 4.1.3.1b) All employees shall review the City's Code of Conduct on an annual basis. The document shall be made available through Power DMS, which will maintain a record of annual review.
- 4.1.3.1c) If it is discovered that an employee has violated the City's Code of Conduct, appropriate action will be taken, including formal discipline as per city policies, if warranted.
- 4.1.4 The laboratory will identify risks to impartiality through:
 - annual management system reports;
 - annual performance reviews for all employees;
 - evaluation of suppliers for externally provided products and services as stated in Section 6.6;
 - annual review of all laboratory policies; and
 - required annual evaluation of, and approval for outside employment.

- 4.1.5 Risks to impartiality will be limited or minimized through policies set within this quality manual and the individual unit manuals. Examples include:
 - the case management process;
 - use of validated methods for analysis;
 - technical and administrative reviews to ensure all technical and quality policies have been followed;
 - court testimony review;
 - the annual review of the City's Code of Conduct; and
 - limiting analyst exposure to task irrelevant information.

If a risk to impartiality is identified, the laboratory will seek to minimize or eliminate the risk through incorporation of additional policy measures.

4.2 Confidentiality

- 4.2.1 All reports and information obtained or created in the course of laboratory activities will be considered confidential. Confidential information will not be placed in the public domain without the permission of the Chief of Police. Laboratory personnel shall only release confidential information without prior approval to:
 - authorized San Diego Police Department employees; or
 - prosecuting agencies in compliance with criminal and civil discovery requests.
- 4.2.1.1 Information presented by laboratory employees at professional conferences, meetings attended by non-SDPD employees, and training events, shall be approved by the employee's supervisor in advance. Presentations shall not contain any case-identifying information related to non-adjudicated cases.
- 4.2.2 When the laboratory is required by law to release confidential information outside of the routine discovery process, the detective assigned to the case or prosecutor (if one is assigned), will be notified of the information provided.
- 4.2.4 All personnel, including contract employees and those performing work on behalf of the SDPD Crime Laboratory, shall keep all information obtained or created during the performance of all laboratory activities confidential, except when providing information for criminal or civil proceedings.

5 STRUCTURAL REQUIREMENTS

5.1 The San Diego Police Department Crime Laboratory is a division of the San Diego Police Department, which has legal responsibility for all laboratory activities.

- A police captain serves as the crime laboratory manager and has overall responsibility and authority over the laboratory. A program coordinator serves as the assistant crime laboratory manager, and has responsibility over all scientific operations that do not fall under the responsibilities of the DNA technical manager. The DNA technical manager has responsibility over all DNA technical operations as required by the FBI Quality Assurance Standards (QAS). The assistant crime laboratory manager reports to the captain. Job descriptions can be found on the City of San Diego public website.
- Laboratory activities listed on the Scope of Accreditation will conform to the requirements of ISO/IEC 17025: 2017 General Requirements for the Competence of Testing and Calibration Laboratories, and the requirements of ANAB AR 3125. The scope of accreditation will be available in Power DMS.
- In addition to the requirements of 5.3, all laboratory activities included on the scope of accreditation will be carried out in a way to meet the requirements of the San Diego Police Department, regulatory authorities such as the California Department of Health Services and the Federal Bureau of Investigation, and organizations providing recognition, to include ANAB. All laboratory activities must be carried out in compliance with laboratory approved methods.
- 5.4.1 The laboratory will use the ANAB accreditation symbol and make claims of accreditation in relation only to those services listed on the scope of accreditation, for which accreditation was granted. In addition, the laboratory will conform to the requirements of PR 1018 ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status. Opinions or interpretations outside the scope of accreditation but based on those results, or included with those results, for which accreditation is held shall be clearly identified as such by a disclaimer.
- 5.4.2 The laboratory will make available the statute, regulation, or legal requirement under which any testing is performed.
- The laboratory is included in the San Diego Police Department's official organization chart. The crime laboratory has a program coordinator (assistant crime laboratory manager), who also serves as the laboratory quality manager, a team of technical and administrative supervisors responsible for technical and clerical operations, and a police property and evidence supervisor who is responsible for the operation of the narcotics vault. All laboratory supervisors and a police lieutenant manage technical and/or support staff within those sections. All positions within the crime laboratory shall be identified in the laboratory organization chart.
- 5.5 b) The forensic biology unit has a DNA technical manager. All sections performing work under the Laboratory's scope of accreditation shall have technical

leaders. The duties for each of these positions is provided in the <u>job description</u> for each classification.

- 5.5 c) Laboratory operations shall be carried out in compliance with the policies and procedures detailed in the laboratory quality manual, and individual unit policy and procedure manuals. All procedure manuals will be available through PowerDMS. All employees shall be responsible for administering the laboratory's procedural, technical, and quality policies.
- The program coordinator/quality manager (assistant crime laboratory manager) will be responsible for:
 - a) implementation, maintenance and improvement of the management system:
 - b) identification of deviations from the management system;
 - c) initiation of actions to prevent or minimize such deviations;
 - d) reporting to the crime laboratory manager on the performance of the management system and any need for improvement; and
 - e) ensuring the effectiveness of laboratory activities.
- 5.6.1 The DNA technical manager, unit technical leads, lieutenant, and unit supervisors will be responsible for:
 - a) identification of deviations from the procedures for performing laboratory activities;
 - b) initiation of actions to prevent or minimize such deviations as stated in Section 8.7; and
 - c) ensuring the effectiveness of unit activities.
- 5.7 Communication regarding the effectiveness of the management system and the importance of meeting the customer's needs and other requirements will be carried out through the following, where appropriate:
 - direct communications with laboratory employees when appropriate, to include tailgates and email;
 - unit meetings and general lab meetings;
 - quarterly Management Reports (QMR) prepared by the crime laboratory manager for the Chief of Police;
 - An annual Management system review conducted by the crime lab manager and the quality manager; and
 - An annual customer service survey, the results of which will be summarized in the QMR.

When changes are made to the management system, they will be planned and implemented in a manner that maintains compliance with all accreditation and regulatory standards.

6 RESOURCE REQUIREMENTS

6.1 General

Management shall provide personnel, facilities, equipment, systems, and support services necessary to manage and perform the activities of all sections under control of the laboratory.

- 6.2.1 All personnel are expected to perform their duties in compliance with <u>Civil Service Class Specifications</u>, the laboratory quality manual, as well as the policy and procedures manuals specific to the section(s) in which they perform work.
- 6.2.2 All personnel working in the laboratory must meet the minimum educational requirements and experience specified in the <u>Job Description</u> for each classification.
 - a) Each section of the laboratory has a documented training program.

 Training programs include competency testing for disciplines included in the scope of accreditation.
 - b) Training plans may be modified by the technical leader, DNA technical manager, or unit supervisor based on the trainee's experience, current expertise, and documented prior training.
 - c) Training and competency requirements must be successfully completed prior to commencement of testing activities, to include analysis of forensic evidence, participation in validation testing, or performance of quality assurance testing.
- 6.2.2.1 If a training program for a specific testing activity does not exist, a customized training plan will be developed and submitted to the quality manager prior to the commencement of training. The training program, will consist of determining the body of knowledge that the trainee needs, an outline of material to be covered, a reading list, practical exercises, and test(s) to assess competency. The training program will be added to the unit manual as soon as practicable.
- 6.2.2.2 All personnel who authorize results, opinions and/or interpretations, meet the minimum educational requirements established in ANAB AR 3125 Forensic Science Testing and Calibration Laboratories, Annex A.
- 6.2.2.3 Training programs will include:
 - a) the knowledge, skills, and abilities needed to perform the work;
 - b) criminal law, civil law, and testimony;
 - c) provisions for maintenance of skills and expertise; and
 - d) criteria for acceptable performance.
- 6.2.2.3.1 All employees new to the laboratory who perform testing activities will also receive training in the application of ethical practices in forensic science and

general knowledge of forensic science, as part of their new employee training. Training materials will be available through Power DMS.

- 6.2.2.3.2 When a new technology or analytical method is introduced into any laboratory section, the affected employees will be trained in the theory behind, and application of, the new method before the method is used for testing activities, or technically reviewing work in which the method was applied. Competency testing may be required depending on the nature of the change.
- 6.2.2.3.3 If a need for retraining is identified as a result of training or casework deficiencies, the unit supervisor, technical leader, or DNA technical manager will develop a training plan based on the unit's training manual and the nature of the deficiencies.
- 6.2.3 Prior to the start of independently performing any function that influences the results of laboratory activities, the quality manager will review all training and competency documentation to verify successful completion of competency tests, and ensure the training plan addressed the trainee's ability to evaluate the significance of deviations.
- 6.2.3.1 All personnel will successfully complete a competency test prior to commencing casework. Competency testing shall include practical examination(s) that cover the spectrum of anticipated tasks related to the testing.
- 6.2.3.2 The requirements of 6.2.3.1 apply to all personnel who review and authorize results, opinions, and interpretations, or perform technical reviews of results or testimony.
- 6.2.4 Duties, responsibilities, and authorities of all personnel will be communicated through:
 - Job descriptions
 - Employee performance plans
 - Laboratory policy and procedure manuals
 - Assignment of work by supervisors
 - Training
 - Laboratory organization chart
- 6.2.5 Personnel policies shall include the following:
 - a) Employees will meet the minimum educational requirements stated in the <u>personnel class specification</u>. Competency is achieved through successful completion of the training program for the laboratory

- activity to be performed, including competency testing, as required in unit manuals.
- b) The laboratory will follow City of San Diego Human Resources policies and procedures regarding selection and supervision of personnel.
 Records associated with these processes are retained according to SDPD Human Resources policies and procedures.
- c) Training requirements are provided in unit manuals.
- d) Authorization of personnel will follow the procedure provided in Section 6.2.6.
- e) Competence of personnel will be monitored through technical and administrative review of test reports, and annual proficiency testing and/or intralaboratory comparisons.
 - Training, competency, and authorization records shall be maintained by the quality manager.
- 6.2.6 After the successful completion of all training and competency requirements, the unit supervisor, or the DNA technical manager for all DNA testing related training, will approve the designated employee to commence with independent testing activities. Training documentation and approval will be provided to the quality manager. The quality manager will authorize the employee to perform testing activities specific to the training completed. Authorization to perform laboratory activities includes, but is not limited to, the following:
 - development, modification, verification, and validation of methods;
 - collection, preservation, and documentation of evidence;
 - analysis of results, including making statements of opinions and interpretations;
 - reporting, reviewing, and authorizing results; and
 - operation of all equipment approved for the authorized testing activities as provided in the unit technical policies.

6.3 Facilities and Environmental Conditions

- 6.3.1 The laboratory environmental conditions are under control of the Department's facilities management staff and are designed to be suitable for all Department activities.
- 6.3.2 Equipment in the laboratory is designed to operate within the temperature ranges expected in the laboratory. Therefore, no specific environmental requirements are necessary for the performance of laboratory activities.
- 6.3.3 Refrigeration used for storage of reagents, reference materials, or evidence will be monitored to ensure operation within temperature specifications, and temperatures will be recorded in accordance to the requirements documented in the unit manuals. Additionally, each unit will control, monitor, and record the environmental conditions (e.g., temperature) for any process (i.e., protocol or method), where those conditions may affect the validity of the results.

- 6.3.4 Facility control be addressed through the following practices:
 - a1) Access to all laboratory areas will be controlled through an electronic access card system and/or keys.
 - a1-1) Electronic access will be approved by the crime laboratory manager, and provided by the SDPD Human Resources division. Keys will be assigned by the quality manager. The quality manager will maintain a key log listing the key numbers assigned to laboratory staff members.
 - a1-2) Electronic card and key access shall be reviewed annually by the quality manager as part of the annual quality system audit.
 - a1-3) Emergency access to the laboratory areas can be attained through the watch commander. Access to the emergency key will be monitored as part of the monthly safety inspection.
 - Access to laboratory areas will be limited to those employees with legitimate business in the designated areas.
 - a3) Service technicians will only be provided limited access to areas required to conduct their contracted function.
 - a4) Visitors will not be given unsupervised access to laboratory areas.
 - b) Requirements will be documented in unit policy manuals when physical separation of areas is required to reduce the possibility of contamination, prevent interference, or any other adverse effects on laboratory functions or testing.
 - c) Laboratory units will ensure there is effective separation between incompatible laboratory activities. Any restrictions or concerns will be documented in the specific unit specific manuals.
- 6.3.4.1 Doors for laboratory areas shall be routinely locked except for the clerical area. All laboratory areas are accessed as described in Section 6.3.4. All electronic access is recorded and maintained by the facilities department. Laboratory doors are monitored by the facilities department, and any key access is registered by the monitoring system. If the key access is after normal business hours, the watch commander's office is notified, and an officer will be dispatched to investigate for unauthorized access. The responding officer may use the emergency master laboratory access card or key to enter the laboratory unit. Laboratory management will be notified of the after-hours key access.
- 6.3.4.2 The watch commander's office will maintain a general electronic access card and key for emergency purposes only. This key will be kept in a scaled envelope and checked for seal integrity during the monthly safety inspection. If the emergency card or key is used, a notation will made by the user on the envelope containing the key, and the key and envelope will be returned to the quality manager for resealing and placement back into the watch commander's office.
- 6.3.5 On occasion, it may be necessary for laboratory personnel to perform testing activities at other facilities. Laboratory activities will only be performed at laboratories accredited to the standards of ISO/IEC 17025:2017 and ANAB 3125, or other suitable accreditation standards as verified by the quality manager.

6.4 Equipment

- 6.4.1 All laboratory employees will have access to equipment that is necessary and appropriate for the testing performed or work conducted. This includes, but is not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus.
- 6.4.2 If laboratory personnel make use of equipment not under the permanent control of the SDPD Crime Laboratory, compliance with the requirements of ISO/IEC 17025: 2017, and ANAB AR 3125 (or similar standards) will be verified by the Quanty Manager. Documentation of compliance will be maintained in the case record.
- 6.4.3 Equipment is stored in the individual laboratory units in which it is used. Chemicals may also be stored in the chemical storeroom. Equipment used for crime scene processing or reconstruction is stored in the crime scene response vehicles. Equipment will be handled, stored, used, and transported in such a way to ensure proper functioning, and prevent contamination or deterioration.
 - a) Performance checks and preventative maintenance will be performed on equipment on a schedule according to specific service contracts or individual unit requirements.
 - b) Microscopes will be serviced annually by an outside vendor, usually during the first calendar quarter of the year. Annual service will be scheduled by the quality manager. Records documenting the annual service of the microscopes and balances will be maintained by the quality manager.
 - c) Balances will be calibrated in the first quarter of each calendar year by an external service provider, as described in Section 6.4.7.1. Balances in the forensic chemistry, firearms, trace evidence units, and narcotics vault will be checked for each of the remaining three quarters by lab technicians or criminalists using NIST traceable weights. Quarterly checks for balances in the narcotics vault will be performed by forensic chemistry personnel.
 - d) Intermediate checks for the barrel length measuring device will be performed as specified in the firearms unit manual.
 - e) Weights used for periodic checks will be stored in a box that has been manufactured to prevent damage during storage and transport.

 Caution must be used when transporting and using these weights to protect against damage to the weights.
 - f) Documentation of routine maintenance, service, and performance checks will be created by the person performing the work and maintained in the unit responsible for the equipment.
- 6.4.3.1 Reagents will be labeled, at a minimum, with the identity of the reagent and the date of preparation or lot number. Records will be maintained in the individual units as to who made the reagent and the components used in preparation.

6.4.3.2 Reference collections maintained by individual units used in the process of making forensic identifications will have each item in the collection documented, and uniquely identified. Reference collections will be handled, transported, and stored in accordance with the laboratory safety manual, chemical hygiene plan, safety data sheet, or unit procedures, to protect the characteristic(s) of interest.

6.4.4 Equipment Performance Requirements

- a) Equipment used for testing will be subject to validation or verification analyses before being placed into service as defined in Section 7.2 and in the relevant unit manual.
- b) Instrumentation and equipment that is being returned to service will be subject to performance testing as specified in the relevant unit manual.
- c) Chemicals and reagents that can influence results will be subjected to quality assurance testing, as per unit policies, before being used in forensic analysis.
- 6.4.5 Validation and verification testing on equipment used for quantitative measurements will include testing to ensure it is capable of meeting the unit's requirements for measurement accuracy and measurement uncertainty. Additional periodic testing will be performed on equipment used for quantitative measurements as specified in unit policy manuals where applicable.
- 6.4.6 Balances, pipettes, and other measuring devices will be calibrated annually according to requirements of this document or as specified in unit policy manuals, where applicable.
- 6.4.7 Calibration programs will be reviewed as part of the annual review of laboratory manuals by the section supervisor and technical lead, or the DNA technical manager, to determine if they are suitable to maintain confidence in the status of calibration. Adjustments will be made when the confidence in the status of calibration is compromised. Documentation of the review is maintained in PowerDMS.
- 6.4.7.1a) Specific equipment calibration programs will have the following documented:
 - a-1) a list of equipment requiring calibration;
 - a-2) any special requirements that must be met by the person or company performing the calibration;
 - a-3) specified requirements for the calibration; and
 - a-4) the interval of calibration.

- 6.4.7.1b) Balances will:
 - b-1) be calibrated with weights traceable to an international standard with measurement uncertainty of the calibrated device provided by the calibration service provider;
 - b-2) be calibrated using weights that encompass the measuring capacity of the balance; and
 - b-3) be calibrated and serviced annually by an outside vendor, usually during the first calendar quarter of the year.

Documentation of the annual balance calibration will be maintained by the quality manager.

- 6.4.7.1c) The barrel length measuring device and NIST ruler will:
 - c-1) be calibrated once every 4 years;
 - c-2) be checked intermediately to verify the calibration status according to the firearms unit procedure;

Documentation of calibration and intermediate calibration verification testing will be maintained by the firearms unit.

- 6.4.8 All equipment requiring calibration shall be labeled to indicate the calibration status and the next calibration due date.
- 6.4.9 If a piece of equipment is shown to be defective in its performance, gives questionable results, or results outside specified requirements, it will be isolated or taken out of service, and marked as such. In addition, the following requirements will apply:
 - a) Any equipment removed from service will require verification testing as stated in Section 6.4.4b before being placed back into service.
 - b) For equipment in the forensic biology section, the DNA technical manager will evaluate any effect on casework. For equipment in the remaining units, the technical lead or supervisor will evaluate any effect on casework. If it is determined that the defect has impacted casework or indicates a deviation from specified requirements, the management of non-conforming work procedure will be initiated as stated in Section 7.10.
- 6.4.10 Intermediate checks necessary to maintain confidence in the performance of the equipment will be carried out as specified in unit policy manuals.
- 6.4.11 Units shall have a documented policy for updating correction factors or reference values changed as a result of calibration or analysis of reference materials, where applicable.

- 6.4.12 Units shall ensure that unintended adjustments to equipment are prevented. This may be accomplished through, but not limited to:
 - a) adequate training on the equipment or procedure;
 - b) password protections on software which limits access to these functions;
 - c) confirmation steps inherent in the software designed to prevent unintended changes.
- 6.4.13 The following records will be maintained for equipment which can influence laboratory activities by the unit responsible for the equipment:
 - the identity of the equipment, including the software and firmware version;
 - b) the manufacturer's name, type identification, and serial number or other unique identification;
 - c) evidence of verification that the equipment conforms with specified requirements;
 - d) the current location;
 - e) calibration dates, results of calibrations, adjustments, acceptable criteria, and the due date of the next calibration interval;
 - f) documentation of reference materials, results, acceptable criteria, relevant dates, and the period of validity;
 - g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment; and
 - h) details of any damage, malfunction, modification to, or repair of, the equipment.

6.5 Metrological Traceability

- 6.5.1 Metrologic traceability of measurement results will be established as specified in unit procedure manuals, where applicable. Procedures shall include, and ensure, the following:
 - a) the specification of the quantity to be measured;
 - b) a documented unbroken chain of calibrations going back to national or international standards;
 - c) that measurement uncertainty for each step in the traceability chain is evaluated:
 - d) that each step in the chain is performed in accordance with approved methods, with the measurement results and with associated, recorded measurement uncertainties;
 - e) that the laboratories performing one or more steps in the chain supply evidence of their technical competence.

Laboratory sections establishing traceability will maintain documentation to support the establishment of traceability.

- 6.5.1.1 Suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials used to establish or maintain metrological traceability, shall be either:
 - a) A National Metrology Institute that is signatory to the BIPM
 (International Bureau of Weights and Measures) CIPM Mutual
 Recognition Agreement with the calibration of measuring equipment
 and/or reference standard to be performed, or the certified reference
 material listed to be purchased, in Appendix C of the BIPM key
 comparison database BIPM Appendix C; or
 - b) A service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Agreement, with the calibration of measuring equipment and/or reference standard to be performed listed in the scope of accreditation; or
 - c) An accredited reference material producer that is accredited to ISO 17037 by an accrediting body that is signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional cooperation or the ILAC Mutual Recognition Arrangement, with the scope of accreditation covering the certified reference material.
- 6.5.1.2 In situations where a supplier that meets 6.5.1.1 is not available, the quality manager will confirm the competence, capability, and metrological traceability for the supplier, product, or service being provided. The quality manager will maintain records to provide objective evidence of conformance to this requirement for at least one full accreditation cycle, or 4 years.
- 6.5.1.3 Instruments used for quantitation of ethanol are calibrated prior to each analytical run. The procedure for calibration is included in the Alcohol Unit Manual. Technical records of calibrations are included in the analytical run file and maintained in the case file.
- 6.5.2 Measurement results will be traceable to the International System of Units (SI) through:
 - a) calibration provided by a competent laboratory as defined in Section 6.5.1.1; or
 - b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI.
- 6.5.3 If the laboratory cannot obtain a certified reference material that is traceable to the SI units, metrological traceability will be demonstrated to an appropriate reference, such as;
 - a) certified values of certified reference materials provided by a competent producer;

b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.6 Externally Provided Products and Services

- 6.6.1 Externally provided products and services used by the laboratory for testing or to support operation of the laboratory, or products that are provided, as received, to other SDPD personnel, will be evaluated to ensure suitability. Specific requirements for evaluation are provided in unit manuals, where applicable.
- 6.6.2 Purchasing services and equipment will be carried out according to the following procedure:
 - a) Purchase of all goods and services will be made in accordance with the City of San Diego's purchasing requirements. Specific requirements for the selection of goods and service suppliers that affect test results are provided in unit manuals, where applicable.
 - b) External providers will be evaluated based on their ability to successfully deliver products and services that meet quality specifications as required in unit manuals. Unit supervisors will ensure suppliers of goods and services are evaluated annually, prior to the start of the following fiscal year. The quality manager will evaluate the balance calibration and microscope service suppliers prior to contracting these services.
 - c) Externally provided products and services will be evaluated to ensure they meet the requirements of their intended use prior to being employed in casework or provided by the laboratory to other SDPD personnel.
 - d) When products or services are identified as not meeting the requirements of the laboratory, action will be taken to address the concern and find a replacement, if necessary.

Records of these activities will be maintained with the purchasing documents by the clerical staff for the current fiscal year plus an additional 5 years.

- 6.6.3 The laboratory shall communicate requirements to external providers for:
 - a) the products and services to be provided;
 - b) the acceptance criteria; and
 - c) competence, including any required qualification of personnel.

This communication will normally take place when a request for quote is made to the service provider, at the time the product is ordered, or in the service contact. Records of this communication will be maintained in the purchasing file.

7 PROCESS REQUIREMENTS

7.1 Review of work requests

- 7.1.1 Work requests are submitted to the laboratory through the LabLynx portal. All work requests will be reviewed by the supervisor, or designee, of the section that will be performing the work to ensure the following:
 - a. The type and purpose of work requested is clear. The evidence items requiring testing are identified by the barcode number. If the evidence has not been converted to the barcode system, the item(s) are uniquely identified by the property tag and item number(s).
 - b. The aboratory is capable of performing the work requested.
 - c. When subcontractors are used, the requirements of Section 6.6 will be applied. The requestor will be informed that the work will be performed by an external provider. The requestor will agree to analysis by a sub-contractor before the evidence is released. Procedures regarding samples sent for toxicology testing are provided in the alcohol policy manual.
 - d. The methods selected for analysis will be capable of meeting the requestor's needs.
- 7.1.1.1 When analysis or processing of evidence is performed in the absence of a work request, e.g., rush or walk-in requests, the supervisor will ensure the conditions of "a" "b" and "d" of this section are met prior to the commencement of work. If the unit supervisor is not available, the analyst performing the work will ensure these same conditions are met. A work request will be submitted as soon as possible by the officer or detective requesting the work.
- 7.1.1.2 The latent print, forensic chemistry, and DNA units proactively perform work in the absence of a work request in accordance with unit policies.
- 7.1.1.3 When results are communicated in a manner other than in a test report or during testimony, they will be documented in the case record according to Section 7.8.7.3.
- 7.1.1.4 Crime scene response typically occurs as the result of a verbal request due to the timing of the crime. An entry will be made in LabLynx by the section supervisor for case tracking purposes by the unit supervisor as soon as possible after the completion of the scene work.

- 7.1.2 If a method of analysis or examination requested is considered to be inappropriate or out of date, the decision and the reason will be communicated to the requestor. The communication will be documented on the work request which remains with the case record if other laboratory activities proceed, or in the comments section in LabLynx.
- 7.1.3 Requests for statements of conformity to a specification for a test result will be provided upon request. The communication will include the policy requirements as well as justification for how the decision rule was applied.
- 7.1.4 All work requests will be evaluated by the supervisor, or designee, of the unit performing the work. Items will be selected for analysis based on:
 - the potential for analysis to provide meaningful results determined through empirical evaluation;
 - the potential for analysis of selected items to satisfy the criminal charge(s)
 - probative value (can the item be tied to the crime scene)
 - legal limitations (CODIS entry), and
 - efficiency and preservation of resources.

This practice is communicated to the requestor via the work request portal in LabLynx by the following statement: "ITEMS ANALYZED AND METHODS USED ARE AT THE DISCRETION OF THE LABORATORY MANAGEMENT AND/OR ANALYST," and in the agreement with the Chief of Police.

Changes will not be made to work requests that compromise the integrity of the lab or the validity of results to be reported.

- 7.1.4.1 Policies related to toxicology analysis are provided in <u>Department Order</u> 3.14.
- 7.1.5 The potential for changes to work requests is communicated via the work request portal in LabLynx by the following statement: "ITEMS ANALYZED AND METHODS USED ARE AT THE DISCRETION OF THE LABORATORY MANAGEMENT AND/OR ANALYST." For the preceding statement, the title of examiner is considered synonymous with analyst for some disciplines in the laboratory.
- 7.1.6 Once work has been assigned to an analyst, any subsequent changes to the work request or the work performed will be reviewed and approved by the section supervisor (or designee) prior to the commencement of work, to ensure conformance to Sections 7.1.1 and 7.1.2. The approval of changes will be communicated to the requestor and the analyst(s) performing the work.

- 7.1.7 Laboratory staff will remain available during normal business hours to provide assistance with work request submissions, answer questions regarding work performed, facilitate access to laboratory services and personnel, and monitor the laboratory's performance with respect to the work performed.
- 7.1.8 The work request will be initialed by the individual conducting the review. Changes to work requests will be documented in the technical record or in the comments section in LabLynx. The work request will be retained as part of the technical record. Records of pertinent communications regarding the requirements of the requestor or the results of laboratory activities will be documented in the technical record. Examples of pertinent discussions may include, but are not limited to, recommendations made for future testing, the need for additional references, or an explanation of the meaning of reported results.
- 7.1.9 The extent of database (e.g., CODIS, IBIS, ALPS) searches will be communicated in the analytical report. The original case detective or investigating unit will be notified of any updates, or changes, to the level of database searches.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

- 7.2.1.1 Only methods determined to be appropriate for the intended laboratory activity, including evaluation of measurement uncertainty, will be used. The determination of appropriateness is generally done through verification or validation of the methods.
- 7.2.1.1.1 Only methods determined to be appropriate for data analysis and interpretation associated with testing will be used. The determination of appropriateness is determined through validation of the method.
- 7.2.1.1.2 The evaluation of unknown items will be performed prior to the comparisons to knowns. Evaluation will include identification of characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity. Procedures and criteria for evaluation will be specified in unit manuals, where applicable.
- 7.2.1.2 All policies, procedures, and supporting documentation such as instructions, standards, manuals, and reference data relevant to laboratory activities shall be kept up to date and shall be made readily available to personnel employing the method. Current, approved versions of laboratory manuals will be available through Power DMS. Laboratory staff will have access to all manuals in the disciplines in which they perform work, as well as the quality manual.

- 7.2.1.3 Testing will be performed using methods within the latest approved version of the manuals. Technical methods shall provide sufficient detail to ensure consistent application.
- 7.2.1.4 Selection of methods for analysis is communicated via the work request portal in LabLynx by the following statement: "ITEMS ANALYZED AND METHODS USED ARE AT THE DISCRETION OF THE LABORATORY MANAGEMENT AND/OR ANALYST." Methods of analysis are posted on the City of San Diego public website at: https://www.sandiego.gov/police/services/crime-laboratory-documents.
- 7.2.1.5 All methods shall be subject to verification prior to use, to ensure required performance expectations can be achieved. Performance verification can be demonstrated through the analysis of appropriate controls, standards, and samples similar to those expected in casework. Samples used for verification shall not be those that were used for validation of the method. Records of verification will be retained by the unit.
- 7.2.1.6 Method development shall require a documented plan submitted to the quality manager prior to initiation of testing. Method development activities will only be conducted by competent personnel with access to adequate resources to complete the method development. Method development will be assessed throughout the course of its development to ensure the goals and the needs of the customer will be met. Any modifications to the method development plan will be submitted to the quality manager before further testing proceeds.
- 7.2.1.7 Modifications to any laboratory method must be technically justified, may require verification testing as stated in Section 7.2.1.5, require approval prior to implementation by the DNA technical manager for methods intended for the forensic biology unit, or the unit supervisor for all other laboratory units. Documentation of modifications will be maintained by the unit performing the work.
- 7.2.1.8 The potential for method modification is communicated to the requestor via the work request portal in LabLynx by the following statement. "ITEMS ANALYZED AND METHODS USED ARE AT THE DISCRETION OF THE LABORATORY MANAGEMENT AND/OR ANALYST."

7.2.2 Validation of methods

7.2.2.1 The laboratory will validate standard methods used outside their intended scope or otherwise modified, and laboratory-developed methods. Validation will be completed prior to applying the method to casework. Validation may include, but is not limited to, the following:

- a) evaluation of the influence of matrix, sample age, environment, and sample type;
- b) determination of limits of detection, limits of quantitation; measurement uncertainty, and reproducibility; and
- c) comparison of results achieved with other validated methods.

DNA validations will follow the requirements of the QAS.

- 7.2.2.1.1 Validation will include, but is not limited to, the following:
 - a) analysis and interpretation of associated data;
 - b) determining the minimum data, or range of data, required for interpretation, or for which opinions can be reported; and identifying the limitations associated with the method.
- 7.2.2.2 When changes are made to a validated method, the influence of those changes shall be determined through testing to demonstrate they do not affect the validity or accuracy of the method. If the validity or accuracy of the method is affected, a new validation will be performed.
- 7.2.2.3 Performance characteristics of validated methods will be relevant to the needs of the San Diego Police Department.
- 7.2.2.4 At the completion of a validation, a validation summary will be prepared and submitted to the quality manager. The validation summary will include:
 - a) the validation procedure used;
 - b) a specification of the requirements;
 - c) determination of the performance characteristics of the method (e.g. limit of detection, measurement uncertainty, limit of quantitation or reporting);
 - d) results obtained; and
 - e) a statement of the validity of the method, detailing its fitness for the intended use.

Records of validation and resulting data will be maintained by the quality manager or the unit performing the validation.

7.4 Handling of test or calibration items

- 7.4.1 Department policies for impounding, releasing, and disposing evidence are provided in <u>Administrative Regulation 3.02</u>. Evidence in the laboratory will be handled, packaged and stored in a manner to avoid deterioration, loss, deleterious change, or contamination.
 - a) Evidence will be obtained by the analyst assigned to perform the work, most often from the property room or the narcotics vault. Evidence can be provided to the analyst, from the officer or detective requesting

- walk-in analysis. Additional policies regarding latent print and firearms evidence are provided in the respective unit manuals.
- b) Evidence is stored in secure sections of the laboratory while in the custody of laboratory personnel. Additional procedures to minimize contamination, deterioration, loss, damage to the evidence are provided in individual unit manuals, where applicable.
- c) Evidence collected at crime scenes will be transported to the laboratory by the person collecting the evidence in a manner that protects its integrity, and prevents loss or contamination. Additional procedures for handling evidence items collected at crime scenes are provided in the crime scene unit manual.
- d) Evidence will be returned to the property room, narcotics vault, or the detective after testing is complete. Evidence collected from crime scenes is impounded in the property room or the narcotics vault after processing by the crime scene unit.
- e) Storage, retention, release, and disposal of non-narcotic evidence, when outside of the laboratory's control, is the responsibility of the San Diego Police Department Property Room, and is handled according to their procedures.
- f) Procedures regarding storage, retention, and disposal of narcotic evidence are provided in the narcotics unit manual.
- g) Evidence will not remain in the possession of an analyst for greater than one year unless the supervisor has reviewed the assessed reason for the prolonged analysis and has approved an extension.
- h) Evidence in transport to and from the laboratory, or between laboratory units, will be sealed or secured in a manner to prevent loss, damage, or contamination. Procedures for transporting firearms to and from the shooting room are provided in the firearms unit manual.
- i) Requests for release of evidence will be routed to the case detective, property room, or narcotics vault.

7.4.1.1 The following requirements apply to all evidence items:

- a) Evidence collected by laboratory personnel will be packaged in secure containers that will be sealed before impounding in the property room. Evidence will be in a sealed container when received from and returned to the property room. Large items (e.g. doors, car fenders) may be received and returned unpackaged as long as they are properly marked with case number and item number. If possible, the area of interest will be covered or otherwise protected from loss or damage.
 - 1-a) Evidence will be stored, packaged, and sealed in a manner to protect the integrity of the item(s), as required by this section.Additional requirements intended to protect the integrity of evidence are provided in unit manuals, where applicable.
 - 1-b) In the event evidence is inadvertently received unsealed, including when the seal has been broken, the analyst will document the condition of the seal, as received, in the case notes. If the condition of the seal indicates the item may have been compromised as a result, the analyst will consult with the

- unit supervisor and the requestor before proceeding with analysis. Documentation of this communication will be retained in the case record.
- 1-c) Weapons stored in the CSU gun locker can remain unsealed, but will be properly packaged and sealed prior to impounding the items, with the exception of officer's guns related to OIS investigations.
- 1-d) If evidence is received unsealed by the narcotics vault, the vault staff member processing the evidence will seal the package, initial and date the seal, and mark the seal with "SBV" (sealed by vault).
- 1-e) Evidence received for walk-in analysis may be un-sealed when received from and returned to the requestor.
- 2-a) Evidence will be re-sealed as soon as possible after the completion of laboratory activities.
 - Evidence containers must be sealed in a manner to preserve the integrity of the evidence. The seal shall be applied in a manner to detect tampering. Container openings will be sealed with evidence tape or evidence seals across the longest direction of the opening. The analyst will initial and date the seal. The analyst's initials and date will flow from the seal to the package.
- 3-a) If the entirety of an evidence item must be consumed for the purpose of analysis, the laboratory will receive permission from the assigned prosecutor before proceeding. If there is an objection to the laboratory consuming the evidence, laboratory analysis will not proceed. The analyst will notify the detective of this communication.
- 3-b) In cases where no prosecutor is assigned, a notification will be sent to the detective informing them of the decision to consume the sample. Three business days will be given to the detective to provide an opportunity to respond. The analyst will proceed with evidence consumption in the absence of a response. These communications will be maintained in the technical record.
- b) Evidence can remain unsealed while in secure sections of the laboratory. Items awaiting completion of analysis shall be maintained in a manner to protect the evidence from loss, contamination, or deleterious change (e.g. items may be closed or covered). Additional procedures to secure and protect unattended items within the laboratory or at crimes scenes are provided in unit manuals (where applicable.
- c) EvidenceOnQ is the evidence management database used by the SDPD. (Older evidence may still be documented using property tags.)
 - 1-a) Chain of custody will be documented for all evidence item transfers involving laboratory personnel.
 - 1-b) Chain of custody for all evidence transfers that occur through the property room or narcotics vault are captured and documented in EvidenceOnQ, or on the item's property tag, where applicable.

- 1-c) Transfers of test items within laboratory units, or when walk-in requests are received, are documented on a laboratory internal chain of custody form (PD-482 or other unit form) when not recorded in EvidenceOnQ. Additional procedures for evidence transfers are provided in unit manuals, where applicable.
- 1-d) Additional requirements for chain of custody documentation in the case record, if any, are provided in the unit manuals.
- When a new piece of evidence is collected or created (e.g., ESDA lifts, latent print lifts, trace evidence) it will be entered into EvidenceOnQ and assigned a new barcode number by the analyst collecting the item. Information identifying the new item, and from which barcode it originated, will be added to the Comments section in EvidenceOnQ, under the original and new barcode numbers. The chain of custody is initiated at this point. DNA extracts are considered work product and are addressed in the forensic biology unit manual.
- An electronic signature is required by EvidenceOnQ at the time of transfer. Transfers involving evidence under the property tag system require written signatures and dates on the tag. Procedures for collection of narcotics evidence from various locations in the Department, and blood or urine samples from Room 138, are provided in the narcotics vault procedure manual. Chain of custody will securely and accurately identify:
 - 1-a) the individuals transferring and receiving the items(s), as well as the location the item is transferred from,
 - 1-b) the item(s) being transferred, and
 - 1-c) at a minimum, the date of transfer in chronological order.
- e) The disposition of evidence of items received by an analyst will be communicated in the report.
- f) Items collected or created and preserved for future testing will be addressed in the report or the report appendix.
- 7.4.2 All evidence items impounded in the property room or the narcotics vault will be assigned a unique barcode number using EvidenceOnQ according to the requirements of <u>Administrative Regulation 3.02</u>. Laboratory personnel impounding evidence items will include a description of the item in EvidenceOnQ. The barcode number will be provided to the analyst in the work request, and the barcode label will be affixed to the item packaging. The barcode number remains with the item indefinitely, even after the evidence is destroyed.
 - a) When items are sub-divided for testing by a laboratory employee, such as one or more swabs collected from an item, the sub-divided item(s) will be identified by amending the item's barcode number, e.g., Barcode 12345678-1. The information will be documented in the technical record and referred to in reports as such. Items do not have to be sub-divided if they are being noted for inventory purposes only.

- Additional procedures for sub-dividing items are provided in unit manuals, where applicable.
- b) Items with a barcode number that are in the process of analysis will be identified by the barcode number or the amended number in the analytical record. If another identifier is used in the process of examination, such as an abbreviated number or item number, the record will clearly associate the identifier to the barcode number. When no barcode number exists for the item, the designated unique identifier will be used, such as the property tag and item number.
- c) Evidence that has not been (or will not be) impounded in the property room will not have a barcode number assigned. This typically occurs with walk in requests, or officer's weapons and other property belonging to an officer collected in an officer involved shooting investigation. If available, the analyst will use a serial number as a unique identifier. If no serial number is available, the analyst will designate a unique identifier that allows identification based on the item's distinct characteristics to distinguish it from other items being examined. Any identifier used will be documented in the case notes.
- d) Each individual item of evidence processed or analyzed will be marked with the barcode number or unique identifier and the analyst's initials. Firearms evidence is often uniquely identified with a serial number that is entered into EvidenceOnQ; therefore, marking this evidence only with the analyst's initials is acceptable. Verifiers will also mark the item or container with their initials.
- e) When evidence cannot be marked directly, or when marking the evidence will potentially destroy or contaminate the evidence, the item will be placed in a proximal container or have a tag affixed. In these instances the proximal container or tag will be marked with the unique identifier and analyst's initials.
- f) All items will be identified in reports using the barcode number, amended number, or the unique identifier assigned if a barcode number has not been created for the item.
- g) Procedures for impounding photographic images collected and maintained as evidence are provided in the crime scene unit manual.
- h) Procedures for impounding data recovered from mobile devices are provided in the forensic technologies unit manual.
- i) Crime laboratory personnel must provide an interoffice memorandum to the property room, signed by their supervisor, to obtain impounded money in amounts over \$20.00 for examination.
- 7.4.2.1 Section 7.4.2 shall apply to all items received, collected, and created by the laboratory.
- 7.4.3 Any discrepancy between the item description and the item condition as received will be documented in the case notes.

- 7.4.3.1 When a discrepancy is identified, or when there is concern about the suitability of an item for testing, the officer or detective will be consulted for further information or instructions before testing begins.
- 7.4.3.2 Corrections to evidence item descriptions will be made in EvidenceOnQ. The communication with the requestor will be documented in the "Comments" section in EvidenceOnQ, as well as in the case notes. If testing will not be assigned in the case as a result of the discrepancy, record of the communication will be added to the "Additional Information" section in LabLynx.
- 7.4.3.3 When the officer or detective acknowledges the discrepancy or the concern regarding the item's suitability for testing, but still requests the item be tested, the analyst will include a disclaimer in the report indicating which results may be affected by the deviation.
- 7.4.4 Specific landling requirements, such as refrigeration or freezer storage, are specified in the unit manuals, where applicable. When items must be stored under specified conditions, those conditions will be maintained, monitored, and recorded by the unit responsible for handling or storing the item.

7.5 Technical Records

- 7.5.1 Technical records for each laboratory activity shall contain the results, report, and if possible, identification of factors affecting the measurement result and its associated measurement uncertainty. In addition
 - a) Technical records shall be:
 - sufficient to enable the repetition of the laboratory activity under similar conditions;
 - ii) in hard copy or electronic format;
 - iii) sufficient, if possible, to identify factors affecting results and associated measurement uncertainty.
 - b) Technical records shall include the date on which the laboratory activity was performed and identify the analyst performing the work.
 - c) Original observations, data, and calculations shall be recorded at the time they are made and identifiable to the specific task. Technical records shall identify the person responsible for checking data and results. Each page of notes numbered, with total number of pages referenced on the first page of notes (e.g. page 1 of x).
- 7.5.1.1 Technical records to support reported laboratory activities will be maintained. Additional supporting records for DNA testing are stored on the forensic biology network according to unit policies. Data resulting from failed analyses shall be referenced in the technical record, but need not be included in the technical record, or retained.

- 7.5.1.1.1 When photographs are taken during the examination of evidence that are not incorporated into the technical record, casework digital images will be saved in the Lab Images folder on the SDPD LAN by the examiner. The clerical unit will move these images to the designated case folder on the SDPD LAN. The forensic biology unit will save casework digital images in the designated case folder on the forensic biology network.
- 7.5.1.1.2 When information from prior reports is used, either internal or external, only pages that contain information included in the report authorized by the analyst will be maintained in the technical record.
- 7.5.1.2 Abbreviations used in technical records that are specific to the laboratory will be defined in the unit manual, or in the case notes, where applicable.
- 7.5.1.3 Technical records to support all elements of a report will be such that another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data.
- 7.5.1.4 Notes will either be taken in ink or entered directly into a computer. Pencil is acceptable for drawings, sketches or tracings; however, records created in pencil shall be photocopied or scanned so they can be maintained in a permanent manner.
- 7.5.1.4.1 Electronically captured notes can be printed and maintained in the case file, stored on the Department LAN, or stored on the forensic biology network. Additional requirements for electronically stored data will be provided in unit manuals, where applicable.
- 7.5.1.4.2 Completed technical records, including the reports and associated data are stored as hard copy files, electronically, or a combination of both. The case number, or incident number when a case number does not exist, will be used when saving records, with the exception of data associated with an analytical batch. Procedures for naming data related to an analytical batch will be provided in unit manuals, where applicable.
- 7.5.1.5 If an observation, data, or calculation is rejected, the reason will be recorded in the technical record. The individual(s) rejecting the data shall initial and date the rejected information.

- 7.5.2 Any amendments to technical records will be tracked to previous versions or original data. If a mistake is made in the record, the incorrect information is to be crossed out without erasing, making illegible, or deleting the original information. The correct information will be entered alongside. All such alterations, or interlineations, will be initialed by the person making the correction or addition. If the corrections or interlineations are done on a date other than that listed on the notes page, the date will also be noted with the initials. Otherwise, it is understood that the change was made on the date of the notes page.
 - a) Any irregularity, such as lost original pages, etc., shall be documented in the technical record before the submission for technical review.
 - b) Notes added to the record after technical review, or after the report has been distributed to the requestor, will be identified as such. The total number of pages will be adjusted to reflect the added pages. If the addition includes technical information, the pages will be technically reviewed.
 - c) Laboratory employees will not use any correction fluids or correction tape on laboratory records.
 - d) When changes are made to hard copy case records that have been previously scanned and saved on the Department LAN, the electronic version must also reflect that change. The amended note page will be scanned behind the original note page, retaining the originally scanned page.
 - e) If an examiner chooses to rewrite or type notes from a crime scene to make them more legible, the original notes and rewritten notes will be maintained in the case record. The examiner will indicate "REWRITTEN" (or similar verbiage) at the top of each page of the transcribed notes.

7.6 Evaluation of measurement uncertainty

- 7.6.1 The laboratory will identify the contributions to measurement uncertainty for all quantitative results reported. Evaluation of measurement uncertainty will take into account all contributions that are of significance, using the appropriate methods of analysis.
- 7.6.1.1 Methods of analysis for evaluating measurement uncertainty will ensure the following.
 - a. The specific measuring device or instrument used for a reported result is included in, or evaluated against, the estimation of measurement uncertainty for that method.
 - b. The method includes the process of rounding the expanded uncertainty.
 - c. The coverage probability of the expanded uncertainty is a minimum of 95.45% (can be referred to as approximately 95%).
 - d. The schedule to review and/or recalculate the uncertainty is specified.

- 7.6.3 Procedures for evaluating measurement uncertainty will be provided in unit manuals, where applicable.
- 7.6.3.1 Measurement uncertainty shall be evaluated, or estimated when applicable, for all reported quantitative results according to procedures in unit manuals, where applicable.
- 7.6.4 The following records will be maintained by the unit responsible for evaluation or estimation of measurement uncertainty:
 - a) a statement defining the item measured;
 - b) a statement of how traceability is established for the measurement;
 - c) the instrument or measuring device used;
 - d) all uncertainty components considered;
 - e) all uncertainty components of significance and how they were considered;
 - f) data used to estimate repeatability, intermediate precision, and/or reproducibility:
 - g) all calculations performed; and
 - h) 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 following procedures will be used to monitor the validity of results. Data will be recorded in such a way to detect trends, when possible. Monitoring activities include, where appropriate, but are not limited to the following:
 - a) use of reference and quality control materials as specified in unit manuals, where applicable;
 - b) use of equipment that has been calibrated to produce traceable results, where applicable;
 - c) functional check(s) as specified in unit manuals for specific equipment, and periodic maintenance of measuring and testing equipment;
 - d) use of reference materials or working standards, where applicable;
 - e) intermediate checks on measuring equipment and testing reagents, where applicable as specified in unit manuals;
 - f) replicate testing using the same or different methods, where applicable;
 - g) retesting of retained items for controlled substance identification, and verification, where applicable;
 - g-1 verification of a result will be carried out by an individual who is authorized to perform the testing;
 - g-2 a record of the verification will be made, and the record will identify who performed the verification, the date it was performed, and the result of the verification;
 - g-3 a record of the resolution of any discrepancy found through verification;

- h) correlation of results from different characteristics of an item, when available;
- i) intralaboratory comparisons completed by each analyst as required in Section 7.7.2; and
- j) technical and administrative review of technical records and reports, and testimony review.

The following requirements apply to technical review:

- j-1 The individual performing the technical review, to include testimony review, must have been competency tested to perform the testing or work that is being reviewed.
- j-2 An individual may not technically review their own work.
 j-3 All laboratory reports and related records shall be technically reviewed.
 No results will be communicated to the customer prior to technical review.
- j-4 Testimony for individuals other than those performing DNA testing shall be reviewed at a minimum once every four years on a schedule consistent with the laboratory accreditation schedule. Testimony for individuals performing DNA testing will be reviewed annually, as per QAS requirements. Testimony review will:
 - include each discipline for which an individual is authorized to perform work as listed on the laboratory's scope of accreditation;
 - be documented using the Testimony Review form;
 - be discussed with the individual providing testimony;
 - be done by direct observation of the testimony or through review of transcripts; and
 - will be tracked by the quality manager to ensure testimony is reviewed in each discipline.
 Records of testimony review shall be retained as part of the
 - Records of testimony review shall be retained as part of the management system documents for at least 4 years or one full accreditation cycle.
- j-5 Technical review of technical records will be documented in the technical record with the reviewer's signed initials and the date the review was completed. Results provided prior to the release of a written report, e.g., verbally or emailed, will be documented in the technical record. The reviewer's initials indicates the work performed was within policy requirements.

Technical review will ensure compliance with the following requirements:

- The notes are complete and legible.
- Chain of custody reflects evidence transfers to and from the analyst.
- Disposition of evidence is stated in the report.
- Discs and images are marked with identifying information.
- Data for relevant traceable controls is present.
- Verification of identifications is completed, if required, and the verification is documented.
- Where results, opinions and interpretations are made, they have been detailed in the report and stated in the case record.

- Where no results, opinions or interpretations can be reached, the reason(s) for the inability to reach conclusions is/are stated in the report.
- Methods are clearly reflected in the technical record.
- Notes identify any unsealed evidence received.
- Manual calculations performed are correct.
- Data transfers are correct.
- All changes made to the case are identified by the individual making the change, and the date, if different than the date on which the original data was recorded.
- Associations are properly qualified in the test report,
- The test report contains all required information.
- j-6 Results are accurate, and opinions and interpretations are properly qualified and supported by the technical record.
- j-7 All work was done in compliance with the applicable laboratory manuals.
- j-8 If a discrepancy is found, the reviewer will notify the report author and provide an opportunity to correct the information. The new information will be reviewed by the same individual performing the original review. If the original reviewer is no longer available, the entire record will be reviewed by another competent reviewer.
- j-9 Disagreements between analysts that arise during technical review will be mediated by the unit technical lead, or DNA technical manager. If the disagreement involves the technical lead, or DNA technical manager, another analyst will be designated by the unit supervisor to mediate the issue(s). If the topic of the disagreement involves the subjective opinions of testing results, the disagreement will be resolved in a manner consistent with unit policies specific to the issue.

Additional requirements for technical review will be provided in unit manuals, where applicable.

7.7.1.1 All reports will be administratively reviewed prior to release. Administrative review will ensure:

- Notes are complete and legible.
- Notes pages include the case or incident number, analyst's initials, date, and page number.
- Corrections are made in the appropriate format.
- The report is in the proper format; correct grammar and spelling are used.
- The report includes all key information.
- Documentation of external case conversations (detectives, attorneys, outside experts) leading to substantive casework decisions and/or interpretations are included in the record.
- The analyst's signature is in place.
- The technical review has been completed.

- 7.7.1.1a An analyst may not administratively review their own work. The individual performing the administrative review must have reviewed the current version of the quality manual and unit policy manual.
- 7.7.1.1b Administrative review of reports will be documented in the technical record. For alcohol cases, the reviewer's signature on the batch report signifies an administrative review of the record.
- 7.7.1.1c Reports will not be administratively reviewed prior to the technical review.
- 7.7.1.1d If a discrepancy is found during administrative review, the reviewer will notify the report author and provide an opportunity to correct the information. The new information will be reviewed by the same individual performing the original review. If the original reviewer is no longer available, the entire record will be reviewed by another competent reviewer.
- 7.7.2 The laboratory will participate in proficiency testing. Where proficiency tests are not available, intralaboratory comparisons will be used. Each unit supervisor, or the DNA Technical Manager of the DNA unit, will submit a proficiency test plan prior to submitting annual proficiency test orders. Each plan will be reviewed by the quality manager prior to ordering tests for the following year.
- 7.7.2.1 At least one proficiency test in each discipline on the laboratory's scope of accreditation will be successfully completed each calendar year. The laboratory will authorize the release of these results from the test provider to ANAB.
- 7.7.3 Data resulting from monitoring activities listed in Sections 7.7.1 and 7.7.2 will be evaluated by the quality manager and the unit supervisor responsible for the activity. The DNA technical manager will evaluate all DNA proficiency tests. The results of monitoring will be used to control and improve laboratory activities when appropriate. When results from monitoring activities are found to be outside of predefined criteria, an investigation will be conducted to identify the source of the error. The quality manager will evaluate the impact on laboratory activities, and will implement and monitor corrective actions, when appropriate.
- 7.7.4 All personnel who perform testing shall complete at least one proficiency test per calendar year in each discipline on the scope of accreditation in which they conduct work. If a proficiency test is not available for the testing activity, an intralaboratory comparison will be used. In the event that the preceding options are not available, observation based performance monitoring may be used. DNA examiners will complete two proficiency tests in each calendar year as required by the QAS.

- 7.7.4a For crime scene processing, intralaboratory comparisons consisting of a mock crime scene or observation based monitoring may be used in addition to annual proficiency testing.
- 7.7.4b A proficiency test is not required during a proficiency test cycle in which a competency test is performed for the same discipline if the competency test meets the requirements for interlaboratory or intralaboratory comparisons.
- 7.7.5 Proficiency testing, interlaboratory and intralaboratory comparisons, and observation based monitoring programs will meet the following criteria:
 - a) The results of the test will not be known or readily available to the individual taking the test;
 - b) Only current, approved laboratory methods will be used.
 - c) Notes and data supporting the results will be provided by the analyst completing the test, as relevant;
 - d) Proficiency tests and interlaboratory comparisons will require the examiner to correctly include or exclude consistent with the test preparation or conforming to the responses of other participants. Additional criteria for determining successful completion of all other tests and monitoring activities, will be provided in unit manuals, unit forms, or will be determined by the unit supervisor prior to the administration of the test or observation of the monitoring activity.
 - e) Proficiency tests will be obtained by an approved provider as stated in Section 7.7.7. Interlaboratory comparisons, intralaboratory comparisons, and observation based monitoring will be planned and administered to assess the performance of the testing activity being evaluated. Plans for intralaboratory comparisons or observation based monitoring will be reviewed by the quality manager, prior to the monitoring activity.
 - f) Proficiency tests from a prior release may be used if the test materials are repacked and relabeled in a manner intended to conceal the original test identifier from the participant.
- 7.7.5.1 All proficiency tests, interlaboratory, and intralaboratory comparisons will be technically and administratively reviewed prior to submission to the test provider. Completion of the review shall be documented with the reviewer's initials, and the date of completion, indicating the work performed was within policy and procedural requirements. Analysts may not review their own proficiency tests.
- 7.7.5.2 The following requirements apply to technical review of proficiency tests, interlaboratory, and intralaboratory comparisons:
 - a) The individual performing the technical review must have been previously authorized to perform the testing or work that is being reviewed.

- b) If the individual performing the review is scheduled to complete the same test in the current cycle, they may not perform the review until their test has been through the complete review process and the final results are submitted.
- c) Complete and legible analytical notes are provided.
- d) The technical record reflects the dates when testing activities occurred, or when changes were made to the original data.
- e) Media and images are marked with identifying information.
- f) Data for required controls are present and within required ranges.
- g) Methods are reflected in the technical record and performed within technical specifications.
- h) Manual calculations performed are correct and based upon measurements documented in the technical record.
- i) Data transfers are correct.
- j) Results, opinions and interpretations are documented and supported by the technical record.
- k) Results, opinions and interpretations are properly qualified in the technical record.
- l) Where no results, opinions or interpretations can be reached, the reason(s) is/are stated in the technical record.
- m) Where inconclusive results, opinions and interpretations are made, the reasons(s) is/are stated in the technical record.
- n) Verification of identifications and exclusions are completed and documented, if required.
- o) Terminology provided by the test provider is used unless prohibited by laboratory procedure.
- p) Associations are properly reported.
- q) Any changes to the results, opinions, or interpretations as a result of the technical review are documented in the test record, to include the reason for change.
- 7.7.5.3 The following requirements apply to administrative review of proficiency tests, interlaboratory, and intralaboratory comparisons:
 - a) Technical review is completed.
 - b) Notes pages include the test identifier, analyst's initials, date(s) the work was performed, and page numbers.
 - c) The analyst's full name is on page 1 of the technical record.
 - d) Corrections are made in the appropriate format.
 - e) The test response is submitted in the proper format; correct grammar and spelling are used.
 - f) The test response includes all requested information related to analyses performed.
 - g) Documentation of communications leading to changes in the test made after the report was submitted for technical review are included in the record.
 - h) Reports that are intended for submission to the test manufacturer are submitted to the suppliers web portal, and the data entered matches the data provided in the analytical record.

- 7.7.5.4 If a technical or reporting error is identified in a proficiency test during the review process, the following shall occur before any changes are made:
 - a) The analyst completing the test will be notified of the error.
 - b) A Quality Incident Summary (QIS) will be completed by the analyst;
 - c) The QIS will be provided to the DNA technical manager or the supervisor in all units other than Forensic Biology.
 - d) The DNA technical manager or unit supervisor will proceed with corrective actions required by Sections 8.7.1 a-1b, where appropriate; and
 - e) The quality manager will be notified and will determine if a Corrective Action Report (CAR) is required.
- 7.7.5.5 No changes will be made to proficiency test records as the result of comparison to responses by other test participants, or results provided by the test provider.
- 7.7.6. The quality manager will:
 - a) monitor and record the submission and outcome (e.g., pass or fail) of all proficiency tests, interlaboratory, and intralaboratory comparisons, and observation based monitoring to ensure conformance with Sections 7.7.2.1, and 7.7.4: and
 - 7.7.2.1. and 7.7.4; and
 b) vary proficiency tests and comparisons to cover the spectrum of activities performed and methods used within a discipline, as deemed necessary by the unit supervisor or DNA technical manager.
- 7.7.7 Proficiency test, intralaboratory comparison, and observation based monitoring programs in each unit shall meet the following additional requirements:
 - a) Where available and appropriate, the laboratory will use a proficiency test provider that is accredited to ISO/IEC 17043 by an accrediting body that is signatory to the APLAC MRA or IAAC MLA⁵ and has the applicable proficiency test(s) on its scope of accreditation.
 - b) Where not available or appropriate for the work conducted, the laboratory will gain approval from ANAB for alternate means by which the laboratory's performance can be assessed.
 - c) Results will be submitted to the proficiency test provider, if applicable, on or before the provider's due date.
 - d) The DNA technical manager will be responsible for the timely submission of all DNA tests. The unit supervisor will be notified of all test assignments, and is responsible for monitoring the individual's progress to ensure a timely submission.
 - e) The quality manager will authorize final submission of all tests, and release of test results to ANAB, for all non-DNA tests. The DNA technical manager will perform these functions for all DNA tests.
 - f) Proficiency tests will be evaluated by comparing the submitted results to information provided by the test provider, e.g., pass or fail. This evaluation will be performed by the unit supervisor or the quality

manager for all sections other than forensic biology. Proficiency tests for forensic biology will be evaluated by the DNA technical manager or designee.

- The following records will be maintained by the quality manager for all 7.7.8 intralaboratory comparisons, interlaboratory comparisons, proficiency tests, and observation based monitoring:
 - a) discipline(s) monitored;
 - b) design of the monitoring activity;
 - expected results;
 - records submitted to the proficiency test provider, when applicable;
 - e) technical records to support the reported results;
 - evaluation of results and action taken for unexpected results; and f)
 - m kon i. feedback on individual performance provided to the participant. g)

7.8 Reporting Results

7.8.1 General

- 7.8.1.1 Technical records will be reviewed and authorized prior to release by the analyst responsible for the report. The analyst authorizing the results will sign the report and include the date of authorization in the signature block. If any technical data, result, opinion, or interpretation is amended as a result of further review, the date of authorization will be updated.
- 7.8.1.1.1 The authorizer (author) of the results will document the review of the complete technical record by initialing each page. Additional requirements for review of results are provided in unit manuals, where applicable.
- 7.8.1.2 Results will be provided accurately, clearly, unambiguously and objectively in a test report. Reports shall include all information agreed upon with the SDPD Chief of Police, necessary for the interpretation of results, and all information required by the method used. All issued reports shall be retained as part of the technical record.
- 7.8.1.2.1 Results of testing activities will be provided in a written report. Results of narcotics and alcohol analysis will also be reported through the Narcotics Results database, which is made available electronically to SDPD officers and detectives. Procedures for issuance and review of results in the Narcotics Results database are provided in the forensic chemistry unit manual.
- 7.8.1.2.2. Written reports will include the following:
 - a) Identification of all items on which testing was performed, including those that were discontinued during the process of analysis, and identification of items collected, created, or preserved for future testing.
 - b) A statistic or qualitative statement to qualify the significance of association. Procedures for qualifying the significance of associations are provided in unit manuals, where applicable.
 - c) The reason for results reported as inconclusive.
 - d) Information on the initial database entry (e.g., DNA profiles, AFIS, IBIS).

Additional reporting requirements are provided in unit manuals, where applicable.

7.8.1.2.3 An accounting of all items received, including those that have no testing performed on them will be included in the technical record, but may not be addressed in a test report.

- 7.8.1.3 In addition to the requirements listed in 7.8.1.2.2, reports will include the elements identified in 7.8.2 to 7.8.8. The laboratory will prepare reports in accordance with an agreement between the Crime Laboratory and the Chief of Police. Elements required in ISO/IEC 17025:2017 and ANAB AR 3125 Sections 7.8.2 to 7.8.7 that are not included in test reports will be readily available and provided upon request.
- 7.8.1.3.1 The agreement on reporting between the Crime Laboratory and the Chief of Police will include which requirements of ISO/IEC 17025:2017 and ANAB AR 3125 Sections 7.8.2 to 7.8.7 will not be included in test reports.

7.8.2 Common requirements for test reports

7.8.2.1 Each report shall include the following information:

- a) A title, to include the unit performing the analysis, and the report version for supplemental reports;
- b) the name of the laboratory;
- c) the location of performance of laboratory activities, when the location is not the SDPD laboratory (i.e., off-site questioned document analysis, crime scene, search warrant, or vehicle processing location);
- d) page numbers for reports greater than 1 page, with an identification of the total number of pages, and a signature block identifying the end of the test report;
- e) the name or command of the individual requesting the work;
- f) identification of the method or DNA test kit used;
- g) the barcode number, or other unique identifier when no barcode number is available, a description, and when necessary the condition of the item, for all items tested;
- h) the date of issue of the test report, identified by the date of administrative review;
- i) the results for all items tested with, where appropriate, units of measurement;
- j) additions, deviations, or exclusions from the method
- k) name and signature of the person authorizing the report, and
- l) initials of the technical and administrative reviewers, including the date for each of these activities.

The general format for reports is provided below. Additional requirements for reports and alternate acceptable formats are provided in unit manuals, where applicable.

SAN DIEGO POLICE DEPARTMENT CRIME LABORATORY ____UNIT REPORT

The report title will reflect the unit doing the work, or a special type of report, such as:

CRIME SCENE REPORT, VEHICLE EXAMINATION, REPORT AMENDMENT, SUPPLEMENTAL REPORT X, etc.)

VICTIM: DOE, Jane Last names of suspect and victim to

be in all uppercase letters in the

header only.

SMITH, John SUSPECT:

CHARGE: 211 P.C.

CASE #: XX-XXXXXXX

INCIDENT #:

INV. UNIT: Rank. Last name

(or OFFICER/DETECTIVE) DATE OF INCIDENT: SCENE LOCATION:

TITLE: (CRIMINALIST, DOCUMENT EXAMINER, etc.)

When information such as a case number or suspect is not provided, the field can be removed entirely, or the report will state "not listed," or use similar verbiage.

The body of the report will have section headings in bold uppercase font. Required and optional section headings include the following:

BACKGROUND (optional) may include task relevant information about a crime scene or identify amended information.

EVIDENCE EXAMINED or EVIDENCE COLLECTED (required)

The barcode number, or other unique identifier, and a brief description of the item will be provided.

The analytical methods or testing kit will be identified (required).

OPINIONS AND INTERPRETATIONS (required)

32/50 Merriweather 10 point font will be used when available.

Additional page headers will be formatted as follows:

UNIT N	IAME	
Case #	(and Sup)	plemental Report # or Report Amendment, if applicable)
Page _	of	(can be placed below the signature block)

The signature block will be in bold font, and will identify the name, title and date of authorization. Below the signature block will be spaces for the initials of the technical reviewer, the date of technical review, and the initials of the administrative review along with the date of issuance.

- 7.8.2.11 Additional work performed in a case subsequent to the release of a report will be provided through the issuance of a supplemental report. Supplemental reports, other than those for narcotics analysis, will identify the numeric supplemental version. This will be done through sequential numbering of the supplemental reports (e.g., Supplemental Report 1). Instructions for supplemental narcotics analysis reports will be provided in the seized drugs manual.
- 7.8.2.1.2 The laboratory will not produce reports based on the test results of external providers.
- 7.8.2.2 The laboratory will be responsible for all information provided in a report, except when the information is provided by the individual requesting the work. Information provided by the requestor will be clearly identified. In addition, a disclaimer will be included in the report when the information supplied by the customer can affect the validity of results. (e.g. Opinions and interpretations rendered in this report are based, in part, on information provided by the detective, and can affect the validity of the results reported.)

7.8.3 Specific requirements for test reports

- 7.8.3.1 Test reports shall, where necessary for the interpretation of results, include the following:
 - a) information on specific test conditions;
 - b) where relevant, a statement of conformity with requirements or specifications; (see 7.8.6);
 - c-1) where applicable, measurement uncertainty for quantitative results in the same units as that of the item measured or in a term relative to the item measured (e.g., percent) when:
 - it is relevant to the validity or the application of the test results;
 - it is required by the customer;
 - it affects conformity to, or evaluation of, a specification limit stated by a regulatory body, a statute, case law, or other legal requirement;
 - c-2) The measurement uncertainty, when reported, shall:

- include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability;
- be in the format of y ± U;
- be limited to, at most, two significant digits, unless there is a documented rationale for reporting additional significant digits, as provided in unit manuals, where applicable; and
- be reported to the same number of significance (i.e., same number of decimal places or digits) as the measurement result.
- d) opinions and interpretations when testing has been completed as required in Section 7.8.7;
- e) additional information as required by specific methods, authorities, legal requirements, or customers.
- 7.8.3.1.1 The laboratory shall have objective evidence of the regulation, statute, case law, or other legal requirement which specifies the format for reporting of a result.

7.8.6 Reporting statements of conformity

- 7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory will document the decision rule employed, taking into account the level of risk associated with the decision rule employed, and apply the decision rule. Risk factors evaluated will be provided in the technical record. Where the decision rule is prescribed by the customer regulations, or normative documents, a further consideration of the level of risk is not necessary.
- 7.8.6.2 When a statement of conformity is included in a test report, the statement will clearly identify:
 - a) to which results the statement of conformity applies;
 - b) which specifications, standards or parts thereof are met or not met;
 - c) the decision rule applied (unless it is inherent in the requested specification or standard).

7.8.7 Reporting opinions and interpretations

7.8.7.1 Opinions and interpretations expressed in test reports shall only be authorized by personnel who have met the competency requirements stated in Sections 6.2.3 and 6.2.6 for the reported category of testing. The basis for opinions and interpretations shall be provided in the technical record.

- 7.8.7.2 The opinions and interpretations expressed in test reports shall be clearly identified as such, and shall be based on the results obtained from the tested items, or observations made of physical evidence (e.g., in crime scene reconstruction).
- 7.8.7.3 When opinions and interpretations are directly communicated by dialog, including verbal and email communications, a record of the communication will be included in the technical record. Opinions and interpretations must be technically reviewed prior to release. See section 7.7.1 i-3.

7.8.8 Amendments to test reports

- 7.8.8.1 When an issued report needs to be amended, any change of information shall be clearly identified in the report, and the reason for the change included in the "Background" section.
- 7.8.8.2 Amendments to a report that has been issued will be made in the form of a further document which will include "Report Amendment" in the title.
- 7.8.8.2.1 When a report amendment is related to a technical issue, the new report will replace the original report. Technical and administrative reviews will be required.
- 7.8.8.2.2 If the correction is related to a non-technical issue, such as an administrative correction, the amended report will only indicate the corrected information. The report amendment will not include the analytical information provided in the original report; therefore, it will not replace the original report. This amended report requires administrative review, but a technical review is not required.
- 7.8.8.2.3 All amended reports addressing technical issues will be reviewed by the technical lead or DNA technical manager prior to issuance. The analyst preparing the report will ensure that any required re-labeling of evidence and/or technical records has been completed.
- 7.8.8.2.4 If the report error is discovered in the process of writing a Final-Seized Drug Analysis Report or a Supplemental Report, the amendment can be identified in the final or supplemental report, i.e. Supplemental Report 1/Report Amendment. These reports will also be reviewed by the technical lead or DNA technical manager when the amendment addresses a correction involving technical issues.
- 7.8.8.3 When it is necessary to issue a report amendment, this shall be uniquely identified by the case or incident number and the report authorization date.

If an amended report replaces a previous report, the report will also include the following statement: "This report replaces the original report dated xx/xx/xxxx."

Complaints 7.9

- 7.9.1 The captain/crime laboratory manager will document the receipt and nature of complaints regarding laboratory services or the management system. The crime laboratory manager will evaluate the merits of the complaint, decide if an investigation will be conducted, identify the person responsible for the investigation, and will make decisions based on the outcome.
- 7.9.2 A description of how a complaint was handled shall be made available to any interested party upon request. Upon receipt of a complaint, the crime laboratory manager will confirm that the complaint relates to laboratory activities, and shall address the complaint. The crime laboratory manager will be responsible for all decisions at all levels of the handling process for complaints. This complaint handling and resolution process will be documented and retained by the crime laboratory manager.
- All complaints received by any laboratory personnel will be forwarded 7.9.3 to the captain/crime laboratory manager. The crime laboratory manager will determine which laboratory services or management system requirements the complaint is related to. The following procedure will be followed for addressing complaints, where appropriate:
 - The nature of the complaint will be determined (i.e., customer service, a-1) management system, or technical.

 The complaint will be discussed with the unit supervisor and/or quality
 - a-2) manager.
 - A fact-finding investigation may be conducted. a-3)
 - SDPD and City regulations will be followed. a-4)
 - The laboratory service or management system requirement identified a-5) in the complaint will be addressed.
 - Management system nonconformances, risks, and opportunities will be a-6) identified and/or evaluated.
 - Opportunities to improve services will be identified. a-7)
 - At the completion of an investigation, a decision on the resolution will a-8) be made by the crime laboratory manager.
 - b) Complaints and their resolution will be tracked by the crime laboratory manager. The documentation will identify:
 - the specific complaint;
 - the date it was received;
 - the person making the complaint;
 - the outcome of any investigation;
 - actions taken to resolve the complaint;
 - communications with the complainant regarding the receipt, the investigation, and the resolution of the complaint, if any; and

- follow-up activities or monitoring.
- c) The captain/crime laboratory manager and/or quality manager will ensure that any actions taken to resolve a complaint are effective by monitoring any changes made in the resolution of the complaint.
- 7.9.4 The person assigned to investigate the complaint, will be responsible for gathering and verifying all necessary information to assess the validity of the complaint.
- 7.9.5 Whenever possible, the captain/crime laboratory manager will acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.
- 7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.
- 7.9.7 Whenever possible, the captain/crime laboratory manager will give formal notice of the end of the complaint handling process to the complainant, as well as actions taken to resolve the complaint.

7.10 Nonconforming work

- 7.10.1 When any aspect of laboratory activities or results of activities do not conform with laboratory procedures or the agreed requirements of the customer, (e.g., results of monitoring activities fail to meet specified criteria, expired test reagents are used, instrument is used beyond specified calibration intervals), the following will occur:
 - a-1) The unit supervisor or technical lead will evaluate and manage all unit specific nonconforming work, with the exception of the forensic biology unit.
 - a-2) The DNA technical manager will evaluate and manage all forensic biology related nonconforming work.
 - a-3) The quality manager will evaluate and manage all management system nonconformities.
 - b) Actions resulting from nonconforming work (including halting or repeating of work and withholding of reports, as necessary) will be based upon the following risk levels established by the laboratory.
 - **Level 1** The nonconformance is identified as an isolated incident with no more than one case affected, no trends identified, and no reasonable risk of a recurrence.
 - Level 2 The nonconformance impacts multiple cases, identifies a trend, or has a reasonable potential for recurrence, except as stated in (c) below.

- c) DNA types in reagent blanks will be addressed according to the forensic biology unit policy manual.
- d) An evaluation will be made of the significance of the nonconforming work, including impact analysis on previous results. If it is determined that previous results are affected, the quality manager will be notified and will assist in determining further actions.
- d) A decision will be made as to the acceptability of the nonconforming work.
- e) Where necessary, the requestor will be notified and/or the work will be recalled.
- f) The quality manager will be responsible for approving the resumption of work for non DNA testing activities. The DNA technical manager will approve the resumption of work related to DNA testing activities, and will inform the quality manager prior to work resuming.
- 7.10.2 The laboratory will retain records of nonconforming work and actions as specified in Section 7.10.1, bullets b) to f).
- 7.10.3 Where the evaluation indicates that the nonconforming work could recur, or there is doubt about the conformity of the laboratory's operations with the management system, the laboratory will implement corrective action. The quality manager, if not already involved in the process, will be notified and will ensure the appropriate corrective action is implemented as required in Section 8.7.

7.11 Control of data and information management

- 7.11.1 Access to data and information needed to perform laboratory activities will be provided to all laboratory employees. Access to electronically maintained data and information is provided through the SDPD LAN, the forensic biology network, and PowerDMS.
- 7.11.2 Laboratory information management system(s) used for the collection, processing, recording, reporting, storage, or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented, and validated before implementation.
- 7.11.2.1 Computer software developed by the laboratory will be validated prior to use, and records will be maintained by the unit performing the validation.
- 7.11.3 The laboratory's information management system uses computerized and non-computerized systems. Computerized systems are managed by the City of San Diego Department of Information Technology (DoIT). The laboratory's clerical

staff will maintain the paper file system. The City of San Diego <u>Information Security Policy</u>, <u>Information and Communications Technology Acceptable Use Policy</u>, laboratory security procedures as stated in Section 6.3.4, clerical unit procedures, and the requirements of this document will be followed to ensure the laboratory information management systems shall:

- a) be protected from unauthorized access;
- b) be safeguarded against tampering and loss;
- c) be operated in environments that comply with laboratory specifications; and provide conditions which safeguard the accuracy of manual recording and transcription; and
- d) be maintained in a manner that ensures the integrity of the data and information.
- 7.11.3.1 Laboratory information management system failures will be recorded by the section supervisor responsible for maintaining the information management system. The DNA technical manager will record system failures for the DNA Sample Information Management System (SIMS). Documentation in response to an information management system failure shall include the nature of the failure, the immediate actions, and the corrective actions taken.
- 7.11.4 When laboratory information management systems are managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.
- 7.11.5 Instructions, manuals and reference data relevant to the laboratory information management system(s) will be made readily available to personnel, where available. Instructions on use of laboratory specific information management systems in use are provided through employee training, where applicable.
- 7.11.6 Calculations and data transfers shall be checked during technical review.
- 7.11.6.1 The check of calculations and data transfers are performed as part of the technical review of the technical record. The documentation of the completion of the technical review process will indicate this information has been reviewed and who performed the check.

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1.1 General

The laboratory's management system shall establish, document, implement, and maintain policies and activities that are capable of supporting and demonstrating consistent achievement of the requirements of the accreditation standards as outlined in ISO 17025:2017 and ANAB AR 3125, to assure the quality of laboratory results.

8.2 Management system documentation

- 8.2.1 The captain/crime laboratory manager and assistant crime laboratory manager/quality manager shall be responsible for establishing policies and objectives for the fulfillment of the purposes of the accreditation standards as outlined in ISO 17025:2017 and ANAB AR 3125. The quality manager shall be responsible for documenting, maintaining, and ensuring the policies and objectives are acknowledged and implemented at all levels of the laboratory, except where noted in this document.
- 8.2.1.1 When the following words (or forms of the same word) are used in ISO 17025:2017 and ANAB AR 3125, the laboratory will address the requirement in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify
- 8.2.2 The laboratory shall maintain policies and objectives to address competence, impartiality, and consistent operation
- 8.2.3 Laboratory management will provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness, as required by this document.
- 8.2.4 All documentation, processes, systems, and records, related to the fulfillment of the requirements of this document shall be included in, referenced from, or linked to the management system.
- 8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities. Access to management system documentation will be provided through PowerDMS, the SDPD LAN, and the forensic biology network.

8.3 Control of management system documents

- 8.3.1 The laboratory shall control documents (internal and external) that relate to the fulfillment of this document (e.g., policy manuals, technical procedures, and required forms). Documents can be on various media, such as hard copy or digital.
- 8.3.2 The quality manager will be the issuing authority for all controlled documents. The quality manager shall ensure the following.
 - Documents will be approved for adequacy by the unit supervisor, or DNA technical manager (for the forensic biology unit), prior to issue. The name of the person approving the document will be included on page 1.
 - b) Documents will be reviewed annually by the unit technical lead or DNA technical manager, and the unit supervisor(s), and updated as necessary.
 - c) Changes and the revision status of documents shall be identified.
 - d-1) The quality manager will post, archive, and schedule review of all management system documents in PowerDMS, with the exception of forensic biology technical documents. These functions will be performed by the DNA technical manager for forensic biology documents.
 - d-2) Documents will be made available to relevant laboratory staff through PowerDMS and the forensic biology network. Document access for each employee will be controlled.
 - d-3) Mobile devices with internet access will be provided to laboratory personnel performing testing activities at off-site locations for the purpose of accessing PowerDMS
 - e) Documents shall be uniquely identified by the title of the document and the date of authorization included on page 1.
 - f) Obsolete documents stored in PowerDMS, the SDPD LAN and the forensic biology network shall be marked as archived and made unavailable to staff members.
 - g) Documents stored on the City public website are not intended use by laboratory employees. These documents will be watermarked as "ARCHIVE" or NOT INTENDED FOR LABORATORY USE."
 - h) Documents will have a footer with the page number and total number of pages, the date of approval or version number, and the name of the document (document name is not required in the footer on the first page).
- 8.3.2.2 When a document is replaced in PowerDMS, the option to "add a new file and publish as a revision" will be selected. This option will automatically archive previous versions of the document and require review by assigned personnel. PowerDMS will label this obsolete document with a blue A for "Archived." Archived documents are only accessible to DMS administrators.

8.3.2.3 Working copies of documents will be maintained on the SDPD LAN, G drive, in the supervisor folder, or on the forensic biology network. Access to these folders shall be limited to laboratory supervisors and managers. The DNA technical manager will keep working copies of forensic biology documents on the forensic biology network in a secure folder.

8.4 Control of records

- 8.4.1 Legible records of testing and management system activities shall be created and retained as required by this document.
- 8.4.2. Case records and casework documentation will be tracked by Department case number, incident number, batch identification number, or external agency case number.
- 8.4.2.1 Hard copy files of technical records will be scanned to the SDPD LAN and filed, both in hard copy and electronic format, numerically, by year. The clerical unit will be responsible for managing these files.
- 8.4.2.1.1 All laboratory staff members shall have access to hard copy and electronic case records with the exception of SDPD Internal Affairs cases. Laboratory staff retrieving technical records from the clerical files must complete an out-card and put it in place of the removed file. The person removing the records will return them to the clerical staff to be refiled.
- 8.4.2.1.1.1 Lab records needed by former laboratory employees for testimony purposes must be obtained from the prosecuting attorney.
- 8.4.2.1.2 Records related to internal affairs investigations will be retained in the crime laboratory manager's office. A card will be placed in the main laboratory file indicating the location of the case record.
- 8.4.2.1.3 Electronic records related to forensic biology testing and management activities are stored on the forensic biology network.
- 8.4.2.1.4 The forensic technology unit NAS serves as temporary storage, with the data extracted from mobile devices saved to media and impounded in the property room.
- 8.4.2.2 Electronic files of technical records stored on the SDPD LAN shall be available only to laboratory staff. Folder permissions shall be limited so that only the clerical staff and lab management can add, move, or delete files or folders from the location on the Department LAN where case files are located.

- 8.4.2.3 Access to technical records maintained in electronic format on the forensic biology network or the forensic technology unit NAS will be limited to staff members in those respective units. The quality manager will also have access to the forensic biology network.
- 8.4.2.4 The laboratory will retain the current year and two previous years' hard copy technical records. After the retention period in the laboratory, homicide and sex crime hard copy case files will be transferred to the SDPD Records Section. All other hard copy case files will be purged at the end of the three year retention period. If records of testing activities set for purging are identified as "ongoing," the records will be retained until such time as they are no longer required. Technical records stored electronically are maintained indefinitely.
- 8.4.2.5 Records associated with the quality system or management system will be stored on the SDPD LAN, forensic biology network, and/or PowerDMS.
- 8.4.2.6 Management system records will be maintained indefinitely.
- 8.4.2.7 The SDPD LAN and the forensic biology network will be backed up on a regular basis by DOiT according to their policies.
- 8.4.2.8 Purged records will be destroyed by a company contracted by the SDPD. Selection of this service provider is outside of the laboratory's control.

8.5 Actions to address risks and opportunities

- 8.5.1 When risks or opportunities associated with the laboratory activities are identified by any member of the laboratory, the captain/crime laboratory manager, assistant crime laboratory manager/quality manager, or authorized personnel, shall consider those risks and opportunities in order to:
 - a) give assurance the management system achieves its intended results;
 - b) enhance opportunities to achieve the purpose and objectives of the laboratory;
 - c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
 - d) achieve improvement to laboratory activities and objectives.
- 8.5.1.1 When risks or opportunities associated with the safety program are identified by any member of the laboratory, the captain/crime laboratory manager and safety program manager shall consider those risks and opportunities as described in Section 8.5.1.

- 8.5.1.2 The laboratory will use the following tools to identify risks and opportunities:
 - internal and external audits
 - quality incident evaluations, corrective actions, and follow-up monitoring
 - information provided by customers or lab personnel
 - technical and administrative review of casework
 - evaluation of proficiency test results
 - customer satisfaction survey
- When risks or opportunities are identified by the laboratory, the captain/crime laboratory manager and assistant crime laboratory manager/quality manager, or the DNA technical manager, shall (as appropriate) work with staff to:
 - a-1) evaluate the impact of the risk or opportunity on the management system and/or testing activities to include reporting of results;
 - a-2) evaluate the impact on customer service;
 - a-3) determine if a change to laboratory procedures is necessary;
 - a-4) identify necessary changes to the laboratory management system or procedures;
 - b-1) proceed with the corrective action process, procedural changes, or training, as appropriate;
 - b-2) communicate the action implemented to affected staff members and/or customers; and
 - b-3) evaluate the effectiveness of these actions through follow up monitoring by the person implementing the corrective action.
- 8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results, and will be determined at the time of the evaluation.

8.6 Improvement

- 8.6.1 When opportunities are identified by any member of the crime laboratory, the captain/crime laboratory manager, assistant crime laboratory manager/quality manager, DNA technical manager, or authorized personnel, shall select and implement any necessary action. Improvements will be identified through, but not limited to, the following:
 - internal and external audits
 - annual review of policies and procedures
 - quality incident evaluations, corrective actions, and follow-up monitoring
 - suggestions provided by customers or lab personnel
 - information obtained from attendance at seminars, conferences, or training events
 - availability of new technologies
 - customer satisfaction survey

8.6.2 The laboratory will conduct an annual customer satisfaction survey, distributed by the captain/crime laboratory manager, to evaluate its own effectiveness in delivering forensic services. Additionally, the crime laboratory manager, or designee, will attend meetings with the SDPD command staff in which feedback is often provided. Feedback obtained from these sources will be used, when appropriate, to improve the management system, laboratory activities, and customer service.

8.7 Corrective actions

8.7.1 When a nonconformity occurs, as stated in Section 7.10, the laboratory shall:

- a-1a) react to the nonconformity by completing one or both of the following, as appropriate:
 - A quality incident summary (QIS) submitted by the analyst to the unit technical lead or DNA technical manager, using the quality incident summary form, to monitor any malfunction or problem lab equipment, when calibration or control measures fail, when a technical policy or procedure was violated in the process of analysis, when monitoring activities were not completed as scheduled, or when a potential association is made to the elimination DNA database with a likelihood ratio below 10,000;
 - a corrective action report (CAR) when the conditions in 8.7.1 a-2) apply
- a-1b) document and monitor these incidents, and as applicable:
 - take action to control and correct it
 - address the consequences
 - ensure follow up action is completed and is effective
- a-2) complete a corrective action report (CAR) when any of the following conditions apply:
 - Incorrect test results were reported based on a systemic policy or procedural violation, or method failure.
 - Unethical actions by an employee result in incorrect reporting of testing activities, or the inability to perform testing due to the evidence being compromised.
 - Proficiency test or intralaboratory comparisons are determined to be not passing.
 - A nonconformance prevents the reporting of test results, and there
 is no remaining evidence or extract on which to perform further
 testing.
 - Evidence under the control of the laboratory has been misplaced, damaged, or unintentionally destroyed, when the original piece of evidence cannot be re-sampled.
 - A compromise in, or failure of, laboratory equipment, that affected reported results or the integrity of evidence.
 - An association is made to the elimination DNA database with a likelihood at or above 10,000.
 - A trend is identified that indicates continued non-conformance to any laboratory process.

- b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - reviewing and analyzing the nonconformity
 - determining the cause of the nonconformity, if possible
 - determining if similar nonconformities exist, or could potentially occur
- c) implement any action needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during prior planning, if necessary;
- f) make changes to the management system, if necessary;
- complete all corrective actions within 30 days, unless an extension is approved by the quality manager.
- 8.7.1.1 The technical lead or DNA technical manager will complete the CAR for nonconformances to technical issues. The unit supervisor will complete the CAR for nonconformances to administrative issues. The CAR will be submitted to the quality manager.

The quality manager will complete the CAR for nonconforming work related to the management system, or when multiple units are involved.

- 8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.
- 8.7.3 Documentation of QISs and CARs will be maintained in the technical record when the incident is related to a case in which the laboratory has performed work. The unit technical lead or DNA technical manager will retain incident summaries for which no technical records exist, and will maintain an incident summary log. The quality manager will retain all CARs and will maintain a CAR summary log. Records shall be retained as evidence of:
 - a) the nature of the nonconformity, cause(s), and any subsequent actions taken:
 - b) the results of any corrective action.
- 8.7.3.1 Corrective action reports will be summarized in the analytical report or provided in a separate document. All records of corrective actions will be provided upon disclosure of the complete technical record
- 8.7.3.2 Electronic signatures will be collected through PowerDMS to acknowledge all CARs. Electronic signatures will be required for the crime laboratory manager, unit technical lead or DNA technical manager as appropriate, and the supervisor of the affected unit.

8.8 Internal audits

- 8.8.1 Internal audits shall be conducted for all sections of the crime laboratory to provide information on whether the management system:
 - a) conforms to the laboratory's requirements for the management system, including the laboratory activities, the requirements of ISO17025:2017, ANAB AR 3125, and the FBI Director's Quality Assurance Standards for DNA testing Laboratories;
 - b) is effectively implemented and maintained.
- 8.8.1.1 Internal audits shall be conducted annually.
- 8.8.2 The quality manager shall plan, establish, implement and maintain the audit program as follows:
 - a-1) Laboratory staff members shall be used as auditors, and shall receive training on audit procedures prior to commencing.
 - a-2) Auditors will review policies and procedures for the unit being evaluated, as well as the quality manual, prior to the audit, and will conduct the audit to evaluate conformance to these requirements.
 - a-3) When determining the scope of the audit, the importance of laboratory activities shall be taken into consideration.
 - a-4) The results of previous audits will be reviewed as part of the current audit to evaluate the effectiveness of corrective or improvement actions.
 - a-5) Auditors will report the results of the audit to the quality manager through submission of the completed audit form.
 - b-1) Internal audits shall include direct observation of a sample of accredited services within each discipline.
 - b-2) An audit form will be provided to auditors which will define the criteria and scope for each audit. Opportunities for improvement may be assessed and provided at the conclusion of the audit.
 - c) The laboratory manager shall be informed of the results of each audit.
 - d) Remediation actions shall be assigned by the quality manager to the DNA technical manager, technical lead, or supervisor as appropriate. Implementation of actions identified will be completed within 30 days unless another date is agreed upon by the quality manager and the person responsible for the implementation.
 - e) The quality manager shall retain all audit records.

8.9 Management reviews

8.9.1 The captain/crime laboratory manager and assistant crime laboratory manager/quality manager shall review the management system in order to ensure its continuing suitability, adequacy, effectiveness, and compliance with the stated policies and objectives of ISO 17025:2017 and ANAB AR 3125.

- 8.9.1.1 The captain/crime laboratory manager shall conduct a quarterly review and provide the results to the Chief of Police. The captain/crime laboratory manager's report (Quarterly Management Report) will address, where appropriate, the elements addressed in Section 8.9.2 a, b, d, h-l, and o. Those elements in 8.9.2 that are not addressed in the quarterly management review will be assessed in the review of the management system performed by the Quality Manager on an annual basis. This review will be conducted after the completion of the calendar year in which the activities occurred.
- 8.9.2 The inputs to the management review shall be recorded and shall include information related to the following:
 - a) changes in internal and external issues that are relevant to the laboratory;
 - b) fulfillment of objectives;
 - c) suitability of policies and procedures;
 - d) status of actions from previous management reviews;
 - e) outcome of recent internal audits;
 - f) corrective actions;
 - g) assessments of external bodies;
 - h) changes in volume and type of work or in the range of laboratory activities;
 - i) customer and personnel feedback;
 - j) complaints;
 - k) effectiveness of any implemented improvements;
 - 1) adequacy of resources;
 - m) results of risk identification,
 - n) outcomes of the assurance of the validity of results to include proficiency testing and intralaboratory comparisons; and
 - o) other relevant factors, such as monitoring activities and training.
- 8.9.3 The outputs of management review shall record all decisions related to at least:
 - a) the effectiveness of the management system and its processes;
 - b) improvement of the laboratory activities related to the fulfillment of the requirements of accreditation;
 - c) provision of required resources;
 - d) any need for change.

9 DISCLOSURE OF SIGNIFICANT CHANGES, EVENTS, AND NONCONFORMITIES

9.1 General

- 9.1.1 The crime laboratory shall inform ANAB of significant changes, events, and nonconformities relevant to its accreditation. Notice and disclosure to ANAB will be submitted electronically to QualityMatters@anab.org.
- 9.1.2 Notice of changes will be submitted within thirty calendar days of the change. Relevant changes include:
 - a change in legal, or organizational status
 - a change in the laboratory's placement within the organizational structure of the City of San Diego
 - a change in the director or quality manager
 - a change in the policies impacting accredited testing, calibration, or inspection activities
 - a change in the physical addresses of locations where accredited testing activities occur
 - a change in capability to provide accredited services listed on the scope of accreditation
 - significant changes to resources (e.g., staffing levels, equipment, facilities) supporting laboratory services
 - other such matters that may affect the ability of the forensic service provider to fulfill the requirements of accreditation
- 9.1.3 Any significant event or significant nonconformity related to an accreditation requirement for which there is a reasonable expectation that knowledge of the event or nonconformity by interested parties external to the forensic service provider would call into question the quality of the laboratory's work or the integrity of its personnel will be disclosed within thirty calendar days upon the director or quality manager recognizing it as significant.
- 9.1.4 The laboratory will provide to ANAB what action(s) were implemented, or plan to implement, in accordance with Sections 7.10 and/or Section 8.7 of this document.

10 ON-CALL POLICY AND PROCEDURES

10.1 On-call program

- 10.1.1 The laboratory shall have staff available after operational hours to provide services to the Department.
- 10.1.2 On-call personnel will include crime scene specialists, criminalists, polygraph examiners, property and evidence clerks, supervisors, and managers.
- 10.1.3 Crime lab services will include crime scene processing, suspect processing, search warrants, crime scene reconstruction, polygraph examinations, and evidence impounding.
- 10.1.4 The supervisor or manager on-call will be available to answer general questions, locate additional resources, aide in the management of complicated or multiple crime scenes, and provide other assistance required. The supervisor or manager on-call will not be expected to respond to crime scenes.
- 10.1.5 Employees placed in an on-call status shall be compensated for such time in accordance to provisions of their respective MOUs.
- 10.1.6 On-call personnel will be provided a Department mobile phone, or may elect to use their personal phone.
- 10.1.7 Personnel on-call will be available for contact 24-hours a day. Should personnel miss a call, they are expected to respond within 15 minutes of missing the call. Expected response time to the scene is within 2 hours if they must pick up equipment at the laboratory prior to the scene. Expected response time to the scene is within 1 hour if they are traveling directly to the scene.
- 10.1.8 On-call rotations for the upcoming year shall be set prior to the beginning of each calendar year. In general, the schedules will be determined by the personnel responsible for the on-call service provided. These schedules will be provided to the clerical staff for dissemination throughout the Department to affected units.
- 10.1.9 The weekly call rotation shall be 1 week, starting on Tuesday at 0730 hours.
- Department vehicles will be assigned to the on-call crime scene specialist and criminalist. Additional laboratory vehicles may be available as needed.