SAN DIEGO POLICE DEPARTMENT
CRIME LABORATORY

Quality Manual

ISO/IEC 17025:2017 and ANAB AR 3125

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March 26, 2025

1 QUALITY MANUAL OBJECTIVES, TERMS AND DEFINITIONS

1.1 Introduction

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

To provide the sworn personnel of the San Diego Police Department and partner agencies with information to assist them in their investigations.

Vision

- To consistently strive for excellence in meeting the forensic needs of the local criminal justice community.
- To provide reliable scientific examinations backed by validated and accredited processes.

Goals

- Maintain professional competence through training and proficiency testing.
- Produce quality results supported by forensically reliable technologies.
- Support professional growth through on-going training and development opportunities..
- Maintain status as an ANAB accredited crime laboratory.

Objectives

The objectives of the quality system will be articulated and reviewed through the 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, testing – The approved laboratory 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 – An 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 – A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement. [SOURCE: ISO/IEC 17025:2017]

Derivative Evidence – impounded evidence that was derived (i.e., taken or collected) from another piece of original evidence (e.g., DNA swabs from a firearm, latent print lifts, or tape lifts).

Impartiality – The 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 laboratory activities.

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 a customer utilizes when seeking services from the laboratory. [SOURCE: ANAB AR 3125]

Sub-items – evidence items to be examined/analyzed that are part of a larger group of items under a single barcode.

Validation - A determination that the specified method or process is adequate for an intended use. [SOURCE: ISO/IEC 17025:2017]

Verification – Ensuring with objective evidence that a given item (e.g., instrument) 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 SUBPOENAS, EVIDENCE VIEWING, AND INFORMATION SHARING

2.1 Subpoenas

2.1.1 Subpoenas that meet the requirements of Department Procedure 1.11 shall be accepted.

2.1.1.1 The laboratory administrative support staff will be responsible for accepting, processing, and distributing subpoenas.

2.1.1.2 Supervisors serving subpoenas will legibly sign/initial and note the date of service.

2.1.1.3 Analysts will acknowledge receipt of the subpoena with signature (or initials) and date. Analysts will return signed subpoena to the administrative support staff as soon as possible.

2.1.1.4 Additional subpoena policies are provided in unit manuals, where applicable.

2.1.1.5 Subpoenas for DMV matters are generally sent directly to the forensic chemistry unit.

2.1.2 The analyst is responsible for contacting the agency that sent the subpoena and complying with any special instructions on the subpoena.

2.1.2.1 The analyst may ask to be placed on stand-by or schedule a specific time for testimony.

2.1.2.2 The forensic chemistry unit staff operates on a rotation basis for alcohol-related testimony.

2.1.3 If an analyst cannot testify due to illness or other unavoidable emergency, it is their responsibility to notify the appropriate person or agency of their condition in a timely fashion.

2.1.4 If a time conflict exists with a subpoena due to training or vacation (see 2.1.5), the analyst should make the appropriate arrangements with the sender of the subpoena.

2.1.4.1 Testimony may be rescheduled or another analyst (such as the technical reviewer) may testify. The court may dictate other alternatives.

2.1.4.2 If subpoenas are issued for simultaneous court appearances for different cases, the analyst will contact the attorneys involved to coordinate appearance times.

2.1.5 Prosecuting agencies commonly served by the crime laboratory will be notified when an analyst is unavailable for court due to vacation or training.

2.1.5.1 Analyst will notify a member of the administrative support unit of the dates of vacation or training.

2.1.5.2 Administrative support staff will prepare a memo indicating what dates an analyst is unavailable, which will be signed by the analyst's supervisor, and distributed to the prosecutorial agencies by the administrative support staff.

2.2 Viewing of evidence

2.2.1 Defense and prosecution requests for evidence viewing will be referred to the case detective.

2.2.1.1 If the viewing will occur in any laboratory unit, advance coordination with the Crime Laboratory Upper Management is required.

2.2.1.2 The following conditions will also apply:

a. All laboratory policies/procedures to minimize contamination will apply to evidence viewing.
b. Appropriate safety precautions will be used.
c. Laboratory staff member(s) requested to be present for viewing, will remain for the entire viewing.
d. Laboratory analysis will not be done as part of the evidence viewing process.
e. Laboratory equipment will not be provided to attorneys or outside experts.
f. Viewing of evidence will be documented in Evidence-On-Q or on the property tag if the case has not been entered into Evidence-On-Q.

2.3 Media requests

2.3.1 Any request from the media must be routed through the Crime Laboratory Upper Management 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 analyst will provide the prosecuting attorney with a courtesy notification before the meeting.

3 ELIMINATION DNA DATABASE

3.1 The San Diego Police Department (SDPD) 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 or during testing.

3.1.1 The elimination DNA database will contain samples contributed voluntarily by laboratory, property room staff, or other individuals as deemed appropriate for quality assurance purposes.

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 Service technicians accessing the forensic biology unit testing areas will provide DNA samples for the elimination DNA database, which will be collected by appointed personnel.

3.1.4 Donors will sign a consent form available in PowerDMS prior to sample collection. A scan of the signed consent form will be retained.

3.1.5 Reference DNA samples for the elimination database will be collected from employees, interns, and volunteers by the Quality Manager, or their Supervisor.

3.1.6 Elimination database profiles will be retained in the database indefinitely unless expungement is requested in writing by the sample donor.

3.1.7 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.

3.1.8 Elimination DNA samples will be uniquely and anonymously coded. Only the Captain/Crime Laboratory Manager and Quality Manager will have access to the identity of the source of the coded samples. The samples will be provided to the forensic biology analysts as anonymous samples for DNA profiling.

3.1.9 No personal identifying information will be retained in the elimination DNA database used for comparison to evidence samples.

3.1.10 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 All potential associations of evidence samples with samples in the elimination

database will be tracked to identify trends. Corrective actions will proceed as stated in Sections 8.7.1 a-1a and 8.7.1 a- 2.

3.2.2 A root cause analysis will be initiated to identify the cause, if possible, of any trends observed in elimination DNA database associations.

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 Quality Manager or Forensic Biology Supervisor.

3.2.4 Identifying information on 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 Upper Management or by court order.

3.2.8 Recoding 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 SDPD Policy Manual can be accessed through the following link: Personal Conduct Policies. 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 a commitment to impartiality through:

- a robust quality assurance program;
- defined employee performance plans;
- following the City of San Diego Code of Conduct;
- a defined work request process as stated in Section 7.1.4; and
- only providing access to task-relevant investigative information.

4.1.3 All laboratory testing and reporting will be conducted as outlined by the requirements of this document and unit manuals. The laboratory will not allow commercial, financial, legal, or other pressures to compromise impartiality.

4.1.3.1 All Laboratory employees will conduct their activities in accordance with the City of San Diego Code of Conduct. This code defines ethical conduct required by the City.

4.1.3.2 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.

4.1.3.3 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;
- 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 document 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 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 or procedural measures.

4.2 Confidentiality

4.2.1 All reports and information obtained or created in the course of laboratory activities will be considered confidential.

4.2.1.1 Confidential information will not be placed in the public domain without the permission of the Chief of Police.

4.2.1.2 Unless prior approval is obtained, laboratory personnel shall only release confidential information to:

- authorized SDPD employees;
- Investigators from partner agencies (i.e., Harbor PD or San Diego City School Police); or
- prosecuting agencies in compliance with criminal and civil discovery requests.

4.2.1.3 Information presented by laboratory employees at professional conferences, meetings attended by non-SDPD employees, and training events, shall be approved by laboratory management 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.

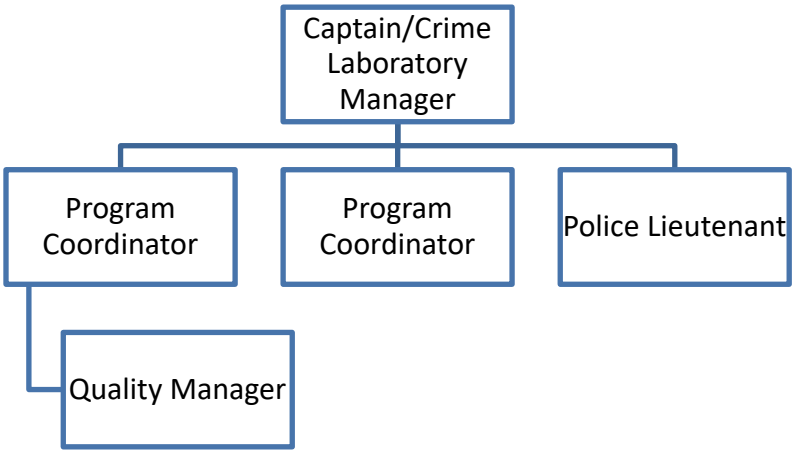
4.2.3 Information related to a request will not be disclosed outside of the investigative unit the request originated from, their direct chain of command, or the prosecution team without approval from the requestor, or their chain of command.

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

5.2 The Crime Laboratory Upper Management is defined as follows:



- The police captain / crime laboratory manager has overall responsibility and authority over the laboratory.
- The Program Coordinators and a Lieutenant serve as Assistant Crime Laboratory Managers and have responsibility over laboratory operations.
- There will be a designated Quality Manager, responsible for the laboratory's accreditation requirements.

The full organizational chart for the Crime Laboratory is available in the laboratory's document management system (PowerDMS).

5.3 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.

5.4 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 SDPD, 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.

5.5 The SDPD Crime Laboratory's organization and management structure is defined in:

a) The laboratory is included in the SDPD's official organization chart.

b) The crime laboratory's organizational chart. All positions within the crime laboratory shall be identified in the laboratory organization chart. The organization chart is available in PowerDMS. The duties for each of these positions is provided in the job description for each classification.

c) All laboratory manuals will be available through PowerDMS.

5.6 The Crime Laboratory Upper Management will be responsible for:

- implementation, maintenance, and improvement of the management system;
- identification of deviations from the management system;
- initiation of actions to prevent or minimize such deviations;
- reporting on the performance of the management system and any need for improvement; and
- ensuring the effectiveness of laboratory activities.

5.6.1 The DNA Technical Manager, unit technical leads, 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 a) 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:

- Command briefings with the Chief's Office;
- General laboratory meetings, supervisor meetings, or direct communications with laboratory employees;
- Unit meetings;
- Annual Management System reviews; and
- Annual customer service surveys.

b) 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 Civil Service Class Specifications, 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 job description 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) The training program must ensure the trainee's ability to:
- recognize deviations from established policy and procedures; and
- follow the documented policies for non-conforming work.
c) 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.
d) Training and competency requirements must be successfully completed prior to commencement of testing activities, including analysis of forensic evidence, participation in validation testing, or performance of quality assurance testing.

6.2.2.1 All personnel who authorize results, opinions and/or interpretations must meet the minimum educational requirements stated in the personnel class specification and ANAB AR 3125 -Forensic Science Testing and Calibration Laboratories, Annex A.

6.2.2.2 Training programs will include:

a) the knowledge, skills, and abilities needed to perform the work;
b) general knowledge of forensic science;
c) the application of ethical practices in forensic science;
d) criminal law, civil law, and testimony;
e) provisions for maintenance of skills and expertise; and
f) criteria for acceptable performance.

6.2.2.3 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.

6.2.2.3.1 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.

6.2.2.3.2 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 ensure the training and competency testing has been properly documented and the records are retained.

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 and 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 The Laboratory will follow and retain records for the following:

a) Competency requirements for each discipline/function will be outlined in the unit training manuals.
b) Selection of personnel will follow City of San Diego Human Resources policies and procedures for hiring. Hiring records will be retained according to SDPD Human Resources policies and procedures.
c) Training requirements for personnel will be provided in the unit training manuals.
d) The laboratory organizational chart will outline the inter-relation between the different classifications of personnel employed by the laboratory.
e) Authorization of personnel will follow the procedure provided in Section

6.2.6.

f) Competence of personnel will be monitored through technical and administrative review of test reports, annual proficiency testing, and/or intralaboratory comparisons.

6.2.6 Personnel must be authorized prior to performing independent laboratory activities. Authorization to perform laboratory activities includes, but is not limited to, the following:

a) development, modification, verification, and validation of methods;
b) evaluation, collection, preservation, and documentation of evidence;
c) analysis of results, including making statements of opinions and interpretations;
d) reporting, reviewing, and authorizing results; and
e) operation of all equipment approved for the authorized testing activities as provided in the unit technical policies.

6.2.6.1 Unit supervisors (or DNA technical manager) will evaluate training and competency tests and upon determination of successful completion will inform the Quality Manager that the individuals are qualified for specified laboratory activities.

6.2.6.2 Based on the notification of qualification, the Quality Manager will authorize personnel for the specified laboratory activities.

6.2.6.3 Records will be retained for the training, competency test, qualification notification, and authorization.

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 Any equipment in the laboratory that requires temperature ranges for testing outside of standard building temperatures will be documented in unit manuals.

6.3.3 Refrigerators or freezers used for storage of reagents, reference materials, or evidence will be monitored to ensure operation within temperature specifications.

6.3.3.1 Temperatures will be controlled in accordance with the requirements documented in the unit manuals.

6.3.3.2 Each unit will 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 will 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 Upper

Management and provided by the SDPD Human Resources division. Keys will be assigned by the Crime Laboratory Upper Management. A key log will be maintained listing the keys assigned to laboratory staff.

a1-2) Emergency access to the laboratory areas can be attained through the Watch Commander.

a2) 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 to laboratory areas where testing occurs shall be routinely locked.

6.3.4.2 Electronic access is recorded, and records will be maintained by the facilities department.

6.3.4.3 If a physical key is used after normal business hours, the watch commander's office is notified, and an officer will be dispatched to investigate for unauthorized access.

6.3.4.4 The Watch Commander will maintain a general electronic access card and key for emergency purposes only.

6.3.5 If laboratory personnel perform testing activities at other facilities, they 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 testing equipment not under the permanent control of the SDPD Crime Laboratory, the equipment must be maintained in compliance with the requirements of ISO/IEC 17025: 2017, and ANAB AR 3125 (or similar standards). Compliance will be verified and documented in the case record.

6.4.3 Unit manuals must provide procedures for handling, transport, storage, use, and planned maintenance of equipment to ensure proper functioning and prevent contamination or deterioration of test materials.

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 external service provider. Records documenting the annual service will be retained.
c) Balances will be calibrated each calendar year by an external service provider, as described in Section 6.4.7.1. Balances in forensic chemistry, trace evidence, and the narcotics vault will be checked for each of the remaining three quarters using NIST traceable weights. Quarterly checks for balances in the narcotics vault will be performed by forensic chemistry personnel. Records documenting the service will be retained.
d) Weights used for periodic checks will be stored appropriately to prevent damage during storage and transport.
e) 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 used for testing will be subject to validation or verification analyses before being placed into, or returned to, service as defined in Section 7.2 and in the relevant unit manual.

a) Chemicals and reagents that can influence results will be subjected to quality control 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.

a) Additional periodic testing required on equipment used for quantitative measurements will be performed 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, 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.

6.4.7.1 Calibration programs will have the following documented:

a) a list of equipment requiring calibration;
b) any special requirements that must be met by the person or company performing the calibration;
c) specified requirements for the calibration; and
d) the interval of calibration.

6.4.7.2 Balances will:

a) be calibrated with weights traceable to an international standard with measurement uncertainty of the calibrated device provided by the calibration service provider;
b) be calibrated using weights that encompass the measuring capacity of the balance; and
c) be calibrated and serviced annually by an outside service provider, usually during the first quarter of the calendar year.
d) Documentation of the annual balance calibration will be maintained as a quality system record.

6.4.7.3 The barrel length measuring device and NIST ruler will be calibrated once every 4 years.

a) 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 6.4.4 before being placed back into service.
b) For equipment in the forensic biology section, the DNA Technical Manager will evaluate any effect on casework.
c) For equipment in the remaining units, the technical lead or supervisor will evaluate any effect on casework.
d) If it is determined that casework has been affected, or a deviation from specified requirements has occurred, the non-conforming work policies will be initiated (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 by the unit responsible for equipment which can influence laboratory activities:

a) 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 competence, capability, and metrological traceability for the supplier, product, or service being provided will be evaluated. The evaluation records, to provide objective evidence of conformance to this requirement, will be maintained for at least one full accreditation cycle, or 4 years.

6.5.1.3 Instruments used for quantification 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 or partners, will be evaluated to ensure suitability. Specific requirements for evaluation are provided in unit manuals, where applicable.

6.6.2 Services and equipment will be purchased in accordance with the City of San Diego's purchasing requirements. In addition, the following will be adhered to:

a) Selection of goods and service suppliers that affect test results will have specifications provided in unit manuals.
b) External providers will selected based on their ability to successfully deliver products and services that meet specifications required in unit manuals.
c) The performance of service providers will be monitored through validations, verifications, quality control analysis, or review of calibration certificates for the provided products or services.
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 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 Requests for laboratory services or analysis will be submitted through the Evidence-on-Q portal.

7.1.1.1 All work requests will be reviewed by a unit supervisor, or designee, of the section that will be performing the work to ensure the following:

a) The evidence items requiring testing are documented (i.e., with barcode or property tag and item number) and the type of analysis required is understood.
b) The laboratory 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.

7.1.1.2 Rush requests will require the approval of laboratory management. The unit supervisor, or analyst must ensure the conditions of 7.1.1a, b, and d are met prior to the commencement of work. A written request must be obtained prior to the report being issued.

7.1.1.3 Walk-in requests will be conducted according to policies in the unit manuals.

7.1.1.4 The latent print, forensic chemistry, firearms, and DNA units will proactively perform work in the absence of a work request in accordance with unit policies.

7.1.1.5 When results are communicated in a manner other than in a test report or during testimony (i.e., verbally or through email), they will be documented in the case record according to Section 7.8.7.3.

7.1.2 Crime scene response typically occurs through of a verbal request. An entry will be made in Lab-on-Q by the unit supervisor for case tracking purposes as soon as possible after the completion of the scene work.

7.1.3 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 or communication log which remain with the case record if other laboratory

activities proceed.

7.1.4 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.

7.1.5 Analysis will not begin until the work has been agreed to between the laboratory and the requestor. Agreement will be documented through the supervisor, or designee, initialing the request.

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

7.1.5.2 Policies related to toxicology analysis are provided in Department Order 3.14.

7.1.6 Any deviations to work requests will be communicated with the requestor.

7.1.7 Once work has been started, any subsequent changes to the request, or the work performed, must be approved by the supervisor, or designee, prior to the commencement of the additional, or modified work. The supervisor, or designee will ensure conformance of any changes to the request with Sections 7.1.1 and 7.1.2. The approval of changes will be communicated to the analyst(s) performing the work.

7.1.8 Laboratory staff will be available during normal business hours to assist with work request submissions, answer questions regarding work performed, facilitate access to laboratory services and personnel, and monitor the laboratory's performance regarding the work performed.

7.1.9 Changes to work requests will be documented on the work request, or in the technical record., 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 recommendations made for testing or a release of results prior to the report being issued.

7.1.10 The extent of database (e.g., CODIS, IBIS, ALPS) searches will be communicated in the 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 the 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 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 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 validation prior to use, to ensure required performance expectations can be achieved. Records of validations will be retained. Any revisions to a validated method will require, at minimum, a verification to ensure similar, or better results will be obtained.

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 Deviations from any laboratory method must be technically justified, and will be documented. Modifications:

7.2.1.7.1 May require verification testing as stated in Section 7.2.1.5;

7.2.1.7.2 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;
7.2.1.7.3 Will be documented in the technical record; and
7.2.1.7.4 Will be communicated to the requestor.

7.2.2 Validation of methods

7.2.2.1 The laboratory will validate new methods, standard methods used outside their intended scope or otherwise modified, and any laboratory-developed methods. The validation shall be as extensive as is necessary to meet the needs of the given application. Validation will be completed prior to applying the method to casework.

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) Determining data analysis and interpretation parameters;
b) determining the minimum data, or range of data, required for interpretation, or for which opinions can be reported; and
c) 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 that 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 SDPD.

7.2.2.4 At the completion of a validation, a 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.

7.3 Sampling – The laboratory only reports results to the tested portion of any item and will not make statements or conclusions with respect to any untested material.

7.4 Handling of test or calibration items

7.4.1 Evidence in the laboratory will be handled, packaged, and stored in a manner to avoid deterioration, loss, deleterious change, or contamination. The laboratory

will follow department policies for impounding, releasing, and disposing of evidence that are provided in Administrative Regulation 3.02.

a) Evidence will be obtained by the analyst assigned to perform the work from the property room or the narcotics vault. Evidence may be obtained from:
    - an officer or detective requesting walk-in analysis;
    - internally from another analyst;
    - Additional policies may be found in the individual unit manuals.
b) Evidence will be 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 will be provided in individual unit manuals, where applicable.
c) Evidence collected at crime scenes will be transported 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.
e) Procedures regarding storage, retention, and disposal of narcotic evidence are provided in the narcotics vault manual.
f) Evidence will not remain in the possession of an analyst for greater than one year unless the supervisor has approved an extension.
g) 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 will be provided in the firearms unit manual.
h) 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 evidence items:

a) Evidence collected by laboratory personnel will be sealed before impounding in the property room. The seal shall be:
    1. With evidence tape;
    2. Marked with the analyst's initial and date with the writing across the packaging and evidence tape.
    3. Re-sealed as soon as practicable after the completion of laboratory activities.
b) Evidence will be in a sealed container when received from and returned to the property room.
    1. If evidence is inadvertently received unsealed, or with a broken seal, it will be documented in the technical record.
    2. If the condition of the seal or the packaging 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. This consultation will be documented in the technical record.
    3. Large items (e.g., doors, car fenders) may be received and returned unpackaged if 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.
4. Evidence can remain unsealed while in secure sections of the laboratory.
5. 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).
6. Firearms stored in the CSU or Firearms Unit gun lockers, or from walk-in analysis request can remain unsealed.
7. 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).

c) Chain of custody for evidence item transfers will be documented within the Evidence-on-Q database. Chain of custody for evidence from prior to 2011, may be documented using the original paper property tags with wet signatures and dates. Chain of custody will be documented for:
1. transfers of test items within or between laboratory units;
2. walk-in requests are received, will be documented on a laboratory internal chain of custody form (PD-482) or other unit form when not recorded in Evidence-On-Q. Additional procedures for evidence transfers will be provided in unit manuals, where applicable.
3. new evidence collected or created by laboratory personnel (e.g., DNA swabs, latent print lifts, or trace evidence) will be entered into Evidence-On-Q and assigned a new barcode number.
4. Information regarding derivative evidence will be added in Evidence-on-Q under the barcode the derivative evidence originated from.
5. Procedures for collection of narcotics evidence from various locations in the Department, and blood or urine samples from Room 138, will be provided in the narcotics vault procedure manual.

d) Chain of custody documentation outside Evidence-on-Q will identify:
1. the individual(s) or location(s) receiving or transferring the item(s);
2. the item(s) being transferred; and
3. the chronological order of all transfers, minimally including the date.

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.

7.4.1.2 DNA extracts are considered work product and are addressed in the forensic biology unit manual.

7.4.1.3 Consumption of evidence policies

a) Evidence from cases submitted for analysis with an assigned prosecutor may not be consumed without permission from the prosecutor.

b) Evidence from cases submitted without an assigned prosecutor may be consumed without permission from the requestor.

7.4.2 All evidence items impounded in the property room or the narcotics vault will be assigned a unique barcode number using Evidence-on-Q as per Department Procedure 3.02.

7.4.2.1 All items received, collected, or created by the laboratory will have a unique identifier (either barcode or property tag/item number combination).

7.4.2.2 The barcode label will be affixed to the item packaging when impounding an item.

7.4.2.3 When sub-items are divided for testing/analysis by a laboratory employee, the sub-item(s) will be uniquely identified by amending the item's original barcode number (e.g., Barcode 12345678-1). The item's unique identifier will be:

a) documented in the technical record;
b) documented in Evidence-on-Q; and
c) used in reporting;

7.4.2.4 Sub-items are not required to be uniquely identified if the items are only being noted for inventory purposes.

7.4.2.5 Items will be identified by their unique identifier (either barcode or property tag/item number combination) in the analytical record.

7.4.2.6 Where evidence has no barcode number assigned (e.g., walk-in requests, weapons and other property belonging to an officer collected in an officer involved shooting investigation) it will be identified by serial number or by 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 technical record.

7.4.2.7 Each item of evidence processed or analyzed, or its proximal packaging, will be marked with the barcode number or unique identifier and the analyst's initials. Evidence or packaging already marked with a unique identified only requires the analyst's initials.

a) Verifiers will also mark the item or container with their initials.

7.4.2.8 Procedures for impounding digital images collected and maintained as evidence will be provided in the crime scene unit manual.

7.4.2.9 Procedures for impounding data recovered from mobile devices will be provided in the forensic technology unit manual.

7.4.2.10 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.

7.4.3 Any discrepancy between the item description and the item condition as received will be documented in the technical record.

7.4.3.1 When a discrepancy is identified, or when there is concern about the suitability of an item for testing, the requestor will be consulted for further information or instructions before testing begins.

7.4.3.2 Corrections to evidence item descriptions will be made in Evidence-On-Q. The communication with the requestor will be documented in the "Comments" section in Evidence-On-Q, as well as in the technical record.

a) If the request will not be assigned in the case because of the discrepancy, the requestor will be contacted by the unit supervisor or designee.

7.4.3.3 When the requestor 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.

7.4.3.4 Specific handling 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 signed report, notes and test results, and if applicable, factors affecting the measurement result and its associated measurement uncertainty. In addition:

a) Notes shall be taken in hard copy or electronic format and be sufficient to:
   i) identify the items examined, the tests performed, and the results obtained;
   ii) enable the repetition of the laboratory activity under similar conditions;
   iii) to identify factors affecting results and associated measurement uncertainty;
   iv) identify the date on which the laboratory activity was performed and identify the analyst performing the work.
b) Notes regarding analysis (relevant observations, data or results, or calculations) shall be recorded at the time they are made and be identifiable to the specific task.
c) Notes shall identify the person responsible for checking data and results.
d) Notes pages shall be numbered, with total number of pages referenced on the first page of notes (e.g., page 1 of x).

7.5.1.1 All technical records to support reported laboratory activities will be maintained.

7.5.1.1.1 Additional supporting records for DNA testing that do not form part of the technical record will be stored on the forensic biology network according to unit policies.

7.5.1.1.2 Data resulting from failed analyses shall be referenced in the technical record, but need not be included in the technical record, or retained.

7.5.1.1.3 Digital images that are part of the technical record will be saved in the Lab Images folder on the SDPD LAN by the analyst.
a) The administrative support unit will move these images to the designated case folder on the SDPD LAN.
b) The forensic biology unit will save casework digital images in the appropriate case folder on the forensic biology network.
c) Additional digital image requirements will be provided in unit manuals, where applicable.

7.5.1.1.4 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 technical record, where applicable.

7.5.1.3 Technical records to support a report will be such that another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what items were examined, what tests were performed, what results were obtained, and could evaluate and interpret the data in accordance with laboratory and unit manuals.

7.5.1.4 Notes will either be taken in ink or entered directly into a computer.

7.5.1.4.1 Records created in pencil shall be photocopied or scanned for inclusion in the technical record.

7.5.1.4.2 Electronically captured notes will be printed and maintained in the technical record, 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.

7.5.1.4.3 Completed technical records, including the reports and associated data are stored as hard copy files, electronically, or a combination of both depending on statute of limitations.

7.5.1.4.4 The case number, or event 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.

7.5.1.4.5 Intermediate notes taken while at an instrument may be transcribed into official notes pages of the technical record without keeping the intermediate note paper.

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.

a) If a mistake is made in the record, the incorrect information will be crossed out without erasing, making illegible, or deleting the original information. The correct information will be entered alongside.
b) All alterations, or interlineations, will be initialed by the person making the correction or addition. The date of the change will be noted with the initials if the change was made on a date other than the date page.
c) Any irregularity, such as lost original pages, etc., shall be documented in the technical record before the submission for technical review.
d) 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.
e) Laboratory employees will not use any correction fluids or correction tape on laboratory records.
f) When changes are made to hard copy technical records that have been previously scanned and saved on the Department LAN, the electronic version must also reflect the change(s).
g) If an analyst 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 analyst 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 consider 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.

7.6.2 Units of the SDPD Crime Laboratory do not perform calibrations.

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 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 indicate the work performed was within policy requirements.

Technical review will ensure compliance with the following requirements:

- Notes are complete and legible.
- Chain of custody is complete in Evidence-on-Q (or in the notes for internal transfers).
- Disposition of evidence is stated in the report.
- Notes identify the condition of the evidence received (sealed vs unsealed).
- The technical record reflects the dates when testing activities occurred, or when changes were made to the original data.
- Media and images are marked with identifying information.
- Data for relevant controls are present and within required ranges.
- Verification of identifications is completed, if required, and the verification is documented.
- Methods are reflected in the technical record and performed within technical specifications.

- Manual calculations performed are correct and based upon measurements documented in the technical record.
- Data transfers are correct.
- Where results, opinions and interpretations are made, they have been detailed in the report and are supported and stated in the technical 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 and technical record.
- Where inconclusive results, opinions and interpretations are made, the reasons(s) is/are stated in the technical record.
- Verification of identifications and exclusions are completed and documented, where required.
- All changes made to the technical record are identified by the individual making the change, and dated as required by 7.5.2b).
- Associations are properly qualified in the test report and technical record.
- The 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 event number, analyst's initials, date, and page number.
- Corrections are made in the appropriate format as required by 7.5.2b).
- The report is in the proper format; correct grammar and spelling are used.
- The report includes all required 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.

7.7.1.2 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(s).

7.7.1.3 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.

7.7.1.4 Reports will not be administratively reviewed prior to the technical review.

7.7.1.5 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, or where proficiency tests are not available, intralaboratory comparisons.

7.7.2.1 Each unit supervisor, or the DNA Technical Manager (for the DNA unit), will submit a proficiency test plan prior to submitting annual proficiency test orders.

7.7.2.2 At least one proficiency test in each discipline on the laboratory's scope of accreditation will be successfully completed each calendar year.

7.7.2.3 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.

7.7.3.1 The DNA Technical Manager will evaluate all DNA proficiency tests.

7.7.3.2 The results of monitoring will be used to control and improve laboratory activities when appropriate.

7.7.3.3 When results from monitoring activities are found to be outside of pre-defined criteria, an investigation will be conducted to identify the source of the error.

7.7.3.4 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 are authorized to 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.

7.7.4.1 If a proficiency test is not available for the testing activity, an intralaboratory comparison will be used.

7.7.4.2 Observation-based performance monitoring may be used if intra-laboratory comparisons are not available.

7.7.4.3 DNA analysts will complete two proficiency tests in each calendar year as required by the QAS.

7.7.4.4 A proficiency test is not required during a proficiency test cycle in which a competency test is performed for the same discipline. The competency test meets the requirements of 7.7.5.

7.7.5 Proficiency testing, 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;
d) Proficiency tests and interlaboratory comparisons will require the analyst 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) ANAB will be notified within 30 days when the consensus result is not attained during any monitoring activity, even when the results of that activity are deemed satisfactory by the laboratory.
g) 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 and intralaboratory comparisons will be technically and administratively reviewed prior to submission to the test provider.

7.7.5.2 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.

7.7.5.3 Analysts may not review their own proficiency tests.

7.7.5.4 The following requirements apply to technical reviewer 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.

7.7.5.5 Proficiency tests, interlaboratory, and intralaboratory comparisons will be technically reviewed based on the applicable components of 7.7.1 j-5).

7.7.5.6 Terminology provided by the test provider will be used unless prohibited by laboratory procedure.

7.7.5.7 The following are the criteria evaluated in 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 supplier's web portal, and the data entered matches the data provided in the analytical record.

7.7.5.8 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 in Forensic Biology; or
   - Supervisor in all other 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.

7.7.5.9 No changes will be made to proficiency test records based on comparison to responses by other test participants, or results provided by the test

provider.

7.7.6. The Quality Manager, or Supervisor or DNA Technical Manager will:

a) monitor and record the submission and outcome (e.g., satisfactory/not satisfactory) of all proficiency tests, interlaboratory, and intralaboratory comparisons, and observation-based monitoring to ensure conformance with Sections 7.7.2 and 7.7.4; and
b) vary proficiency tests and comparisons to cover the spectrum of activities performed and methods used within a discipline.

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 MLA[5] 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 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, DNA Technical Manager, or Unit Supervisor will ensure final submission of all tests, and release of test results to ANAB.
f) Proficiency tests will be evaluated by comparing the submitted results to information provided by the test provider.
g) This evaluation will be performed by the:
   - unit supervisor or the quality manager for all sections other than forensic biology.
   - the DNA Technical Manager, or designee, in Forensic Biology.

7.7.8 The following records will be maintained for all intralaboratory comparisons, interlaboratory comparisons, proficiency tests, and observation-based monitoring:

a) discipline(s) monitored;
b) design of the monitoring activity;
c) expected results;
d) records submitted to the proficiency test provider, when applicable;
e) technical records to support the reported results;
f) evaluation of results and action taken for unexpected results; and
g) feedback on individual performance provided to the participant.

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.

7.8.1.1.1 The review will be documented by the authorizer by initialing each page of the technical record.

7.8.1.1.2 The analyst authorizing the results will sign the report and include the date of authorization in the signature block.

7.8.1.1.3 Additional requirements for review of results are provided in unit manuals, where applicable.

7.8.1.1.4 If any technical data, result, opinion, or interpretation is amended as a result of further review, the date of authorization will be updated.

7.8.1.2 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, or partner agencies, necessary for the interpretation of results, or 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).
e) Additional reporting requirements are provided in unit manuals, where applicable.

7.8.1.2.3 An inventory 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.

7.8.1.3.1 The agreement on reporting between the Crime Laboratory and

the Chief of Police, or with other partner agencies, 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.

7.8.1.3.2 The laboratory will prepare reports in accordance with the agreements between the Crime Laboratory and the Chief of Police, or other partner agencies.

The SDPD Crime Laboratory currently has simplified reporting agreements with:

- The Chief of the San Diego Police Department
- The Chief of the Harbor Police
- The Chief of the San Diego School District Police

These agreements are available in PowerDMS

7.8.1.3.3 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.

7.8.1.4 Laboratory Unit may also issue communications to customers in the form of notifications (e.g., CODIS Hits, FTU data extractions, or Ten Print Latent Inquiries).

Additional information will be provided in Unit manuals, where applicable. Notifications:

7.8.1.4.1 Will not be used to communicate SDPD test results;

7.8.1.4.2 Do not require technical review; and

7.8.1.4.3 Do not require administrative review.

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;
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 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 issuance 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. Merriweather 10-point font will be used when available.

SAN DIEGO POLICE DEPARTMENT
CRIME LABORATORY
_____UNIT REPORT

CRIME SCENE REPORT, VEHICLE EXAMINATION, or REPORT AMENDMENT, etc. (optional)

VICTIM:
SUSPECT:
CHARGE:
CASE #:
EVENT #:
INVESTIGATIVE UNIT: **Investigator Rank and Last Name**
DATE OF EVENT: (optional)
SCENE LOCATION: (optional)
TITLE:

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

EVIDENCE EXAMINED or EVIDENCE COLLECTED
(optional if evidence was analyzed/tested for a separate report e.g., comparison of previously analyzed evidence to a reference tested in another case)
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.

OPINIONS AND INTERPRETATIONS

DISPOSITION

Signature Block

Name
Title
Date

Technical Review: ____ Date: _____ Administrative Review: ____ Date of Issue: _____

Additional page headers (if needed) will be formatted as follows:

UNIT NAME
Case # (or Event #, and Report Amendment, if applicable)
Page X of Y

7.8.2.1.1 Victim and suspect last name will be in CAPS in the header (only).

7.8.2.1.2 When information such as a case number or suspect is not provided, the report will state “not listed”.

7.8.2.1.3 Additional reports for work performed after the issuance of a first report will be identified by the author and issuance date. Instructions for supplemental narcotics analysis reports will be provided in the seized drugs manual.

7.8.2.1.4 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.

7.8.2.2.1 Information provided by the requestor will be clearly identified.

7.8.2.2.2 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 as stated in section 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 in the format of $y \pm U$;
- be limited to, at most, two significant digits, unless there is a documented rationale for reporting additional significant digits, 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 any regulation, statute, case law, or other legal requirement which precludes reporting as stated in 7.8.3.1.

The SDPD Crime Laboratory is not a calibration laboratory (ISO 7.8.4), nor does it report based on a sampling plan (ISO 7.8.5)

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:
- a) document the decision rule employed;
- b) consider the level of risk associated with the decision rule employed; and
- c) apply the decision rule.
- d) Risk factors evaluated will be provided in the technical record.
- e) 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.

7.8.7.2 The basis for opinions and interpretations shall be provided in the technical record.

7.8.7.3 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).

7.8.7.4 Communications of results or opinions and interpretations that are directly communicated (i.e., verbally or through email) with the requestor, or other entity permitted to receive the information (e.g., Deputy District Attorney), prior to issuance of the report will be documented in the technical record.

- a) Opinions and interpretations must be technically reviewed prior to release as stated in section 7.7.1 j-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 where appropriate, 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 All amended reports in the DNA unit addressing technical issues will be reviewed by DNA Technical Manager prior to issuance.

7.8.8.2.3 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 only requires administrative review.

7.8.8.2.4 The analyst preparing the report will ensure that any required re-labeling of evidence and/or technical records has been completed.

7.8.8.2.5 If the report error is discovered in the process of writing a Final-Seized Drug Analysis Report, the amendment can be identified in the final report. These reports will be reviewed by the unit technical lead when the amendment addresses a correction involving technical issues.

7.8.8.3 Report amendments shall be uniquely identified by the case or event number and the date of issue.

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

7.9 Complaints

7.9.1 The Captain/Crime Laboratory Manager will document the receipt and nature of complaints regarding laboratory services or the management system.

7.9.1.2 The Crime Laboratory Manager will:

7.9.1.2.1 confirm that the complaint relates to activities the laboratory is responsible for

7.9.1.2.2 evaluate the merits of the complaint;

7.9.1.2.3 decide if an investigation will be conducted;

7.9.1.2.4 identify the person responsible for the investigation; and

7.9.1.2.5 make decisions based on the outcome; and

7.9.1.2.6 documented and retain records for the handling and resolution of the complaint,

7.9.2 A description of how complaints are handled shall be made available upon request.

7.9.3 All complaints received by the laboratory will be:

7.9.3.1 forwarded to the Captain/Crime Laboratory Manager;
7.9.3.2 handled according to the elements of 7.9.1.2, SDPD, and City regulations;
7.9.3.3 tracked and recorded, to include resolutions; and
7.9.3.4 resolved in an appropriate manner, as determined by the Crime Laboratory Manager.

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., expired test reagents are used, instrument is used beyond specified calibration intervals), the following will occur:

7.10.1.1 Nonconforming work within a unit will be evaluated by the technical lead, unit supervisor, or DNA Technical Manager (for any Forensic Biology nonconforming work)

7.10.1.2 Nonconforming work within the management system will be evaluated by the Crime Laboratory Upper Management.

7.10.1.3 Evaluations will be made on the impact of the noncoforming work with regard to other cases or results.

7.10.1.4 Actions taken (including halting or repeating work and withholding of reports, as necessary) will be based upon the following risk levels:

7.10.1.4.1 Level 1: Test specific (i.e., single test or sample affected)
7.10.1.4.2 Level 2: Batch specific (i.e., multiple samples or cases affected

within a single analyst)

7.10.1.4.3 Level 3: Systemic (i.e., occurring across multiple analysts)

7.10.1.5 The Quality Manager will be notified in the event of elimination database matches above LR values of 100, or for Level 2 and 3 nonconformances.

7.10.1.6 Decisions will be made on the acceptability of the nonconforming work. More information may be provided in specific unit manuals.

7.10.1.7 Where necessary, the requestor will be notified, and work (or reports) recalled.

7.10.1.8 The Quality Manager will be responsible for approving the resumption of work for non-DNA testing activities.

7.10.1.8.1 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.

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.

7.10.3.1 The Quality Manager 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 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 (e.g., Excel workbooks, Access databases, or macros) 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.

7.11.3.1 The laboratory’s administrative personnel will maintain the paper file system.

7.11.3.2 Computerized systems will conform to the City of San Diego Department of Information Technology (DoIT) requirements.

7.11.3.3 All City of San Diego policies (e.g., Information Security Policy, Information and Communications Technology Acceptable Use Policy will be followed to ensure systems are:

7.11.3.3.1 protected from unauthorized access;
7.11.3.3.2 be safeguarded against tampering and loss;
7.11.3.3.3 be operated in environments that comply with laboratory specifications; and provide conditions that safeguard the accuracy of manual recording and transcription; and
7.11.3.3.4 be maintained in a manner that ensures the integrity of the data and information.

7.11.3.4 Laboratory information management system failures will be recorded by the section supervisor responsible for maintaining the information management system.

7.11.3.5 The DNA Technical Manager will record system failures for the DNA Sample Information Management System (SIMS).

7.11.3.6 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 that this information has been reviewed and who performed the check.

8 Management System Requirement

8.1 The Crime Laboratory will abide by the requirements of Option A in section 8.1 of ISO 17025-2017

8.1.1 Crime Laboratory Upper Management 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 (Option A)

8.2.1 Crime Laboratory Upper Management 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.

a) 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.

b) 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.

8.2.2 The laboratory shall maintain policies and objectives to address competence, impartiality, and consistent operation.

8.2.3 Crime Laboratory Upper Management will provide evidence of commitment to the development and implementation of the management system and to continually improve 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.

8.3 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 or DNA Technical Manager (for Forensic Biology specific documents) will be the issuing authority for all controlled documents. The Quality Manager shall ensure the following.

a) Documents will be approved 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, supervisor, or DNA Technical Manager, and updated as necessary.
c) Changes and the revision status of documents shall be identified.
d) Current versions of manuals will be available through PowerDMS (both on-site and on mobile devices through the PowerDMS app), and forensic biology network (for forensic biology unit documents).
e) Documents shall be uniquely identified by the title of the document and the date of authorization included on page 1.
f) Obsolete documents will be archived in PowerDMS and any hard copies removed from circulation.
g) Laboratory documents available through the city public website are not intended for use by laboratory employees.
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 (a document name is not required in the footer on the first page).

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, event 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 administrative support unit will be responsible for managing these files.

8.4.2.2 All laboratory staff members shall have access to hard copy and electronic case records except for SDPD Internal Affairs cases. Laboratory staff retrieving technical records from the administrative 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 administrative personnel to be refiled.

8.4.2.3 Reports and technical records will not be provided by the laboratory to former employees, even for testimony purposes.

8.4.2.4 Records related to internal affairs investigations will be retained in the Captain/Crime Laboratory Manager's office. A card will be placed in the main laboratory file indicating the location of the case record.

8.4.2.5 Some electronic records that supplement forensic biology testing technical records and management activities will be stored on the forensic biology network.

8.4.2.6 Some electronic records that supplement forensic technology unit technical records and management activities will be stored on the NAS or cloud-based server.

8.4.2.7 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 administrative personnel and lab management can add, move, or delete files or folders from the locations where case files are located.

8.4.2.8 Access to electronic 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.

8.4.2.9 The laboratory will retain technical records for the current year and five previous years' in hard copy. 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.

8.4.2.10 Records associated with the quality system or management system will be stored on the SDPD LAN, forensic biology network, and/or PowerDMS.

8.4.2.11 Management system records will be maintained indefinitely.

8.4.2.12 The SDPD LAN and the forensic biology network will be backed up on a regular basis by DoIT according to their policies.

8.4.2.13 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 Crime Laboratory Upper Management shall consider risks and opportunities for laboratory activities and the safety program, identified by any member of the laboratory, in order to:

a) give assurance that 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 laboratory activities;
d) achieve improvement to laboratory activities and objectives.

8.5.2 When risks or opportunities are identified by the laboratory, the Captain/Crime Laboratory Manager, Assistant Crime Laboratory Managers, Quality Manager, or the DNA Technical Manager, shall (as appropriate) work with staff to:

a) evaluate the impact of the risk or opportunity on the management system and/or testing activities to include reporting of results;
b) evaluate the impact on customer service;
c) determine if a change to laboratory procedures is necessary;
d) identify necessary changes to the laboratory management system or procedures;
e) proceed with the corrective action process, procedural changes, or training, as appropriate;
f) communicate the action implemented to affected staff members and/or customers; and
g) 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 Crime Laboratory Upper Management will select and implement any necessary action.

a) 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, Assistant Crime Lab Manager, or Quality Manager, to evaluate its own effectiveness in delivering forensic services.

8.6.3 Crime Laboratory Upper Management personnel, or designee(s), attending meetings with the SDPD command staff may also use feedback obtained from these meetings, 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) React, control, correct, or address any nonconformity by completing one or both of the following, as appropriate:
   1) A quality incident summary (QIS) submitted by the analyst to the unit technical lead or DNA Technical Manager to monitor any:
      - malfunction or problem lab equipment;
      - calibration or control measure failures;
      - technical policy or procedure violation in the process of analysis;
      - monitoring activities not completed as scheduled; or
      - when a potential association is made to the elimination DNA database with a likelihood ratio below 10,000;
   2) A corrective action report (CAR) when the conditions in 8.7.1 1) apply and any of the following have also occurred:
      - Incorrect test results were reported.
      - Testing cannot be performed due to the evidence being compromised.
      - Proficiency test or intralaboratory comparisons are determined to be unsatisfactory.
      - 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.
      - A casework 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.
      - Actions by an employee have been deemed unethical.

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;
g) complete all corrective actions within 30 days, unless an extension is approved by the Quality Manager.

Note: The technical lead or DNA Technical Manager will complete the CAR for nonconformances to technical issues.

Note: The unit supervisor will complete the CAR for nonconformances to administrative issues. The CAR will be submitted to the Quality Manager or Captain/Crime Laboratory Manager.

Note: The Quality Manager or Captain/Crime Laboratory 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 The records for quality incident summaries and corrective actions shall be retained and document:

a) the nature of the nonconformity, cause(s), and any subsequent actions taken;
b) the results of any corrective action.

8.7.4 Summaries of the 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.

8.7.5 The unit technical lead or DNA Technical Manager will retain documentation of all QISs pertinent to their units.

8.7.6 The unit technical lead or DNA Technical Manager will retain logs of all QISs to identify trends.

8.7.7 The Quality Manager or Captain/Crime Laboratory Manager will retain all CARs and will maintain a CAR summary log.

8.7.8 Electronic signatures will be collected through PowerDMS for all CARs. Electronic signatures will be required for the Crime Laboratory Upper Management, unit technical lead or DNA Technical Manager as appropriate, and the supervisor of the affected unit.

8.7.9 If a QIS or CAR has identified a nonconformance where actions by an employee have been deemed unethical, the laboratory will notify the District Attorney's Office.

8.8 Internal audits

8.8.1 Internal audits shall be conducted annually for all sections of the crime laboratory to provide information on whether the management system:

a) conforms to the laboratory's own requirements for the management system and testing activities;
b) conforms to the requirements of ISO17025:2017, ANAB AR 3125, and the FBI Director's *Quality Assurance Standards for DNA testing Laboratories*;
c) is effectively implemented and maintained.

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.
d) Crime Laboratory Upper Management shall be informed of the results of each audit.
e) 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.
f) The Quality Manager shall retain all audit records.

8.9 Management reviews

8.9.1 Crime Laboratory Upper Management shall conduct an annual review of the management system to ensure its continuing suitability, adequacy, effectiveness, and compliance with the stated policies and objectives of ISO 17025:2017 and ANAB AR 3125.

8.9.2 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;
l) 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, autopsies, crime scene reconstruction, polygraph examinations, and evidence impounding.

10.1.4 The supervisor on-call will be available to answer general questions, locate additional resources, aid in the management of complicated or multiple crime scenes, and provide other assistance required. The supervisor 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 with the 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. The expected response time to the scene is within 1 hour if they are traveling directly to the scene. The expected response time to the scene is within 2 hours if they must pick up equipment at the laboratory prior 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 administrative support 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.

10.1.10 Department vehicles will be assigned to the on-call crime scene specialists and criminalists. Additional laboratory vehicles may be available as needed.