



Ada County Sheriff's Office
Forensic Lab
Quality Assurance Manual
Version 5.0

Ada County Sheriff's Office Forensic Lab

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1 Scope

The Quality Assurance Manual covers the requirements specified in International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2017 and American National Standards Institute (ANSI)-National Accreditation Board (ANAB) Forensic Science Testing and Calibration Laboratories Accreditation Requirements and is the foundation of the Ada County Sheriff's Office (ACSO) Forensic Laboratory's quality management system. This document identifies general requirements for competence, impartiality, and consistent operations.

The Quality Assurance Manual, Health and Safety Manual, discipline analytical methods, and training manuals shall be adhered to while conducting tests, creating items that are subject to testing, and while processing crime scenes. Conformation with these documents helps facilitate assurance in the competence of the laboratory and acceptance of results. All laboratory employees are responsible for performing work within these policies and procedures.

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2 References

Ada County Procurement Policy & Procedure Manual

Ada County Sheriff's Office Policy Manual with Procedures

ANAB, *ISO/IEC 17025:2017 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements*. Document Number AR 3125

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

Joint Committee for Guides in Metrology, International vocabulary of metrology – Basic and general concepts and associated terms (VIM), 3rd edition 2008 version with minor corrections, (JCGM 200:2012). Basic and general concepts and associated terms (VIM) for scientific definitions associated with measurement uncertainty. A copy of this document can be found at www.bipm.org/en/publications/guides/vim.html

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3 Terms and Definitions

Accuracy

The closeness of agreement between a test result or measurement result and the true value.

Accreditation

A process by which an accrediting body provides formal recognition that an entity meets various standards, which lends confidence in their ability to competently carry out specific tasks.

Accreditation Cycle

Time period between full on-site assessments by the accrediting body, generally four years.

Administrative Documentation

Documentation received or generated by the laboratory that does not constitute information or data resulting from testing, which is related to the case but does not support the conclusions.

Administrative Review

Review for non-technical matters of the case file and report prior to release to the customer.

Annual

Once per calendar year (January 1 to December 31).

Association

A determination that a relationship exists between individuals and/or objects based upon testing.

Audit

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

Authority

Right or obligation to act on behalf of the department or agency.

Calibration

The adjusting or standardizing of an instrument and/or equipment to ensure agreement with an indicated standard or value to ensure accuracy and precision.

Case File

Administrative and examination documentation pertaining to a case that is received or generated by the laboratory.

Case Record

A case or test record is all administrative and examination documentation pertaining to a case that is received or generated by the laboratory. Information in the case record may be in the case file or in other locations, which are designated as extensions of the case file. This may include electronically stored data, digital images, quality control documentation, etc.

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Certified Reference Material

A reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities.

Chain of Custody

A chronological record of evidence transfers, including an individual or place, from initial receipt until its final disposition. Having possession/custody of the evidence implies responsibility for its protection and preservation.

Competency Test

Evaluation of a person's knowledge, skills, and/or ability to perform specific tasks or conduct examinations in a forensic discipline and/or category of testing prior to independently performing a task or casework.

Control

A sample analyzed in parallel with evidentiary samples and designed to demonstrate that a procedure worked correctly and that data is valid.

Controlled document

A document distributed in a manner to ensure that recipients receive subsequent revisions and replace previous versions to ensure current information is being utilized.

Corrective Action

The overall actions taken and plan or process used to address a nonconformity and to eliminate the cause of a detected nonconformity or other undesirable situation.

Customer

An individual, group, or agency (internal or external to the forensic service provider) at whose request or on whose behalf the laboratory provides a product or service.

Document Control

Process of ensuring that controlled documents prescribing activities that affect quality or specifying quality requirements, including revisions, are reviewed for adequacy, approved for release by authorized personnel, and available for use to personnel performing the prescribed activities.

Equipment

Instrument or device used to measure, record, or identify any entity, and having a significant effect on the accuracy or validity of the result of the test, calibration or sampling, as determined by requirements in the technical procedures.

Evidence Storage

A secure location used to house items of evidence.

Examination Documentation

Documentation including reference to methods, tests conducted, standards and controls used, observations and results of examinations or tests, diagrams, printouts, photographs, spectra, chromatograms, and/or other material used by the analyst to reach a conclusion.

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Examination Record

Case record documents for a specific case which are stored in the electronic case file in the LIMS.

Impartiality

Without bias or influence on laboratory activities (e.g., absence of or resolved conflicts of interest).

Individual Characteristic Database (ICD)

A computerized, searchable collection of features, generated from individual characteristic database samples of known origin (e.g., fingerprints of known individuals, test fired ammunition).

Interlaboratory Comparison

A test used for performance monitoring that is prepared internally or externally and consists of the same or similar item(s) tested and/or processed by at least two individuals from different laboratories, which enables the results to be compared.

Internal Audit

Documented review process conducted by ACSO personnel for obtaining evidence and addressing them objectively to determine whether, and the extent to which, the laboratory fulfills stated requirements, standards, policies, and procedures.

Intralaboratory Comparison

A test used for performance monitoring that is prepared internally or externally and consists of the same or similar item(s) tested and/or processed by at least two individuals in the same laboratory, which enables the results to be compared. Previously called an internal proficiency test.

Laboratory

Body that performs testing, calibration, and/or sampling associated with subsequent testing or calibration.

LIMS

Digital Laboratory Information Management System holds case files, images, and tracks history.

Management Review

Annual review performed by management to assess the laboratory management and quality systems and its testing activities in order to ensure continuing suitability and effectiveness and to introduce necessary changes or improvements.

Measurand

Quantity intended to be measured.

Measurement Uncertainty

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Method

The course of action, technique, or procedure followed in conducting a specific analysis and/or comparison.

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Metrology

The science of measurement and its application. It also covers basic principles governing quantities and units.

Nonconformity

Any aspect of work or testing that does not agree with established laboratory, technical, or quality system methods or requirements.

Notes

The record of standards, controls, instruments used, observations made, results of tests performed, charts, graphs, photos, and other records generated that are used to support an examiner's conclusions (i.e., case notes).

Objective evidence

Data supporting the existence or verity of something; may be obtained through observation, measurement, test, or other means.

Objectives

General statements that address critical issues by breaking down goals into smaller, more specific pieces. Objectives drive actions and represent the general end toward which efforts are directed.

Opinions and Interpretations

A formal expression of judgement based upon the analyst's evaluation of observations or data.

Performance Check

Operations run to determine if equipment produces results consistent with specified parameters, which is conducted when new equipment is used with existing procedures, when equipment is moved, when existing equipment is modified or maintenance could change its performance, or to determine if a validated method is fit for purpose and performs as expected.

Precision

The closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions. Precision is quantified by the standard deviation.

Preventative Action

Action intended to eliminate the cause of a potential nonconformity or other undesirable potential situation.

Primary standard

Designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quality.

Proficiency test

A test provided by and reported to a source external to the laboratory that enables intralaboratory and/or interlaboratory comparisons to evaluate the continuing capability of the participant and laboratory.

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Qualified

A term used to identify personnel who successfully complete their assigned training program, demonstrate competence, and participate in proficiency testing, when applicable.

Quality Assurance

Those processes and systematic actions necessary to provide confidence that the laboratory's work product and services will satisfy given requirements for quality.

Quality Control

Activities conducted according to established standards, used to monitor the quality of analytical data and to ensure that it satisfies specified criteria.

Quality Records

Documentation pertaining to the quality system such as, but not limited to, audit reports, corrective actions, deviations, and testimony evaluations.

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).

Reference Material

Material, sufficiently homogenous 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 and may be used for the identification of unknown substances, instrument calibration, assessments of a measurement method, or assigning value to materials.

Reference Standard

A sample acquired or prepared that has known properties for the purpose of calibrating equipment and/or for use as a control in examinations.

Root Cause

The fundamental reason(s) for a nonconformity.

Sample Selection

The process of selecting an item(s) to test, or a portion(s) or an item(s) to test, based on training, experience, and competence. In sample selection, there is no assumption of homogeneity. The report is clear that results only apply to the item(s) and/or portion(s) tested.

Sampling

Taking a part of a substance, material, or product for testing in order to reach a conclusion or make an inference about and report on the whole. Should only be used when there is a reasonable assumption of homogeneity and according to a procedure.

Sampling Plan

For an item that consists of a multi-unit population (e.g., tablets, baggies, bindles), the plan is a statistically valid approach to determine the number of sub-items that must be tested in order to make an inference about the whole population.

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Sampling Procedure

A defined procedure used to collect a sample(s) from the larger whole, to ensure that the value obtained in the analysis is representative of the whole, and may include details about size and number of sample(s) to collect, location from which to collect, and a method to ensure the homogeneity of the larger whole or to make it so.

Shall

Used when an element of the management system is required. Synonyms: will, must.

Should

Used when an element of the management system is recommended, but not required.

SI Units

The International System of Units (SI), commonly known as the metric system, is the international standard for measurement, which consists of seven base units (i.e., meter, kilogram, second, ampere, kelvin, candela, and mole) from which all other measurements can be derived; prefixes indicate multiplication or division by a power of ten.

Subcontractor

A non-ACSO entity that independently performs a service for the Laboratory that is within the Scope of Accreditation.

Submission

A single instance of providing evidence and/or a request for laboratory examination.

Technical Review

A review of the examination documentation used as basis of findings/conclusions.

Traceability

Property of a measurement result or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties.

Validation

Confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

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4 General requirements

4.1 Impartiality

4.1.1 Forensic Laboratory activities shall be undertaken in an impartial and objective manner and in accordance with the ISO/IEC 17025:2017 requirements, ANAB accreditation requirements, and the documents of the Laboratory management system. All Laboratory employees have the ethical and professional responsibility to base analyses and investigations on the physical evidence available. Work shall be free from bias, preconceived conclusions, political pressure, or other adverse and undue influences.

4.1.2 Laboratory management directs Laboratory employees to avoid any activity, interest, or relationship that interferes or appears to interfere with their independent exercise of professional judgment. All staff are expected to perform their duties in an ethical, professional, competent, and impartial manner when working a case, performing a review, or testifying in court.

4.1.3 Each laboratory employee is responsible to ensure that laboratory activities and professional judgement are not impacted by undue internal or external influences. Situations in which there is perceived pressure to perform duties in a manner that is not independent, impartial, or objective, or that could adversely affect the quality of the work shall be brought to the attention of Laboratory management. This includes, but is not limited to, off-duty employment, a current or past personal connection with a case subject, or financial involvement with a vendor. If the Laboratory management is involved, the issue may be reported outside of the Laboratory, starting with the Police Services Bureau (PSB) Central Services Lieutenant and/or continuing up the Chain of Command, as appropriate.

Potential conflicts will be evaluated to ensure that activities do not diminish confidence in the competence, impartiality, judgment, or operational integrity of the analyst or Laboratory. When the conflict or factor is deemed to be significant, other personnel shall be assigned to the task, whenever practicable. If it is not possible to assign another analyst, other actions shall be taken to aid the employee and/or to mitigate significant influence (e.g., oversight, support, additional technical review, etc.). Employees shall not be subject to any retribution for reporting and recusing themselves from an investigation or examination, when it is appropriate.

4.1.3.1 Ethics information is included in new employee training. As members of the Ada County Sheriff's Office, the Code of Ethics (Chapter 1, Section 1.1) in the ACSO Policy Manual with Procedures applies to all laboratory employees. Ethics training also incorporates the ANAB *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel*, which is reviewed annually by all forensic staff. Record of this review shall be maintained in the quality records.

Appropriate actions are taken when there is a concern regarding impartiality or other ethical violation. Personnel are subject to discipline according to ACSO policies and procedures.

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- 4.1.4 The Laboratory is a division within the Ada County Sheriff's Office. However, the relationship does not present a risk to impartiality, as employee compensation is not based on reported findings. The Laboratory shall consider risks to its impartiality at least once an accreditation cycle and is typically accomplished through internal audits and/or management reviews. Identification of potential risks shall be an ongoing effort and participation is encouraged from every member of the Laboratory staff.
- 4.1.5 Objective evidence of compliance with these policies shall be realized through on-going review of work product. Identified risks to impartiality will be brought to the attention of Laboratory management and a plan to eliminate or minimize the risk will be executed and documented. Such actions may include, but are not limited to, excluding examiners from working on cases where they know a case subject(s), separate duties for employees in a relationship, and fair application of evidence submission and analysis polices. Incident resolution depends on the severity. Documentation of potential and realized risks shall be stored in the quality records.

4.2 Confidentiality

- 4.2.1 The Laboratory management system shall ensure all records are held secure and in confidence. Confidential records are not subject to public disclosure without due process of law. Every employee has the responsibility to safeguard all confidential information and communications from unauthorized distribution. In addition, employees shall not access or disclose any confidential information regarding cases except where legally authorized. All requests, evidence, and case-related information are considered confidential. Electronic records shall be protected and secured to prevent unauthorized access or amendment. The Electronic Confidentiality Agreement shall be retained in the quality records.

Independent of discovery or public records requests, reports shall only be released to the submitting agency, prosecuting attorney with jurisdiction, and/or defense attorney, when the work is being performed for them. Conflicts in confidentiality or changes regarding to whom reports or copies of reports are released should be addressed and approved by the Forensic Lab Manager.

- 4.2.2 Results may be released to other agencies/parties with prior documented approval of the customer. Unless prohibited by law, the customer shall be notified when the Laboratory is required by law or authorized by contractual agreement, to release confidential information to an entity other than those authorized. Authorized entities include, but are not limited to, law enforcement with a legitimate need for the records, prosecuting attorneys, and those with valid court orders or subpoenas. Documentation of prior approval or notice of information released shall be stored with the case record in the LIMS. Questions related to release of records should be addressed to Laboratory management. See section 7.8.1.3 for information regarding releasing verbal results.
- 4.2.3 If information about the customer is disclosed to the Laboratory from a source other than the customer (e.g., complainant, regulators), this information shall be confidential between the customer and the Laboratory. The source of this information shall be

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confidential and shall not be shared with the customer, unless agreed by the source or as required by law. A disclosure agreement shall be documented in the quality records.

- 4.2.4 Staff, subcontractors, personnel of external bodies, or individuals acting on the Laboratory's behalf, shall keep confidential all information obtained or created during the performance of lab activities, except as required by law. Confidential information shall not be used for any purpose beyond the scope of employment.

5 Structural requirements

5.1 The Laboratory is a governmental and publically funded lab that is part of the Ada County Sheriff's Office (ACSO).

5.2 The Forensic Lab Manager has overall responsibility and authority to make and enforce decisions affecting the Laboratory.

5.2.1 The Lab Manager has full authority over the laboratory to include staff, budget, goals, and direction and is responsible for administering, directing, and implementing ACSO Forensic operations. The Lab Manager ensures that all policies, rules, procedures, directives, goals, and/or guidelines are clear and consistent with ACSO policy and State and Federal Law. A full list of duties is available in the position description.

5.3 The Laboratory conforms to ISO/IEC 17025:2017 and ANAB AR 3125, in the range of laboratory activities as defined on the most current Scope of Accreditation. The Laboratory does not claim conformity to accreditation for services performed that are not listed on the Scope of Accreditation.

5.4 The Laboratory performs forensic services to meet, at a minimum, the requirements of the Laboratory quality system documents, ACSO Policies and Procedures, ISO/IEC 17025:2017 standard, and ANAB supplemental requirements, and to satisfy the needs of the customer. This covers all forensic operations performed by laboratory employees and contracted employees at any site where forensic testing services are performed.

5.4.1 The Laboratory conforms to the requirements in the ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status. If accreditation is referenced in a Laboratory report or other communication, testing, opinions, or interpretations outside of the Scope of Accreditation shall be clearly identified by a disclaimer or reference to the Scope of Accreditation document. The Laboratory ensures that the representation of accreditation status is not misleading and that there is no implication that a result, product, process, system, or person is approved by the accreditation body in any communications, including testimony.

5.4.2 The Laboratory shall make readily available any testing performed under the authority of a statute, regulation, or other legal requirement by an external third-party.

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- 5.5 The organization charts depicting the placement of the Forensic Laboratory within ACSO and the Laboratory staff are retained in the quality records. Position descriptions and responsibilities for all personnel are maintained by ACSO Human Resources.

Each laboratory employee is accountable to only one immediate supervisor. The Forensic Lab Manager reports to the PSB Central Services Lieutenant. The Forensic Quality Manager and Forensic Scientists report to the Forensic Lab Manager.

The Forensic Lab Manager supervises all Laboratory staff in the office, field, and laboratory settings. The Lab Manager has the responsibility and authority to interview and hire new employees, approve time sheets and coordinate schedules, evaluate performance and set work priorities, oversee inventory and maintenance of supplies and equipment and monitor expenses, manage complaints, and ensure work conditions and equipment are sufficient for scene processing and laboratory analysis. The Lab Manager has the authority to suspend analytical operations for an analyst, a discipline, or the laboratory system at any time.

The Forensic Quality Manager has the responsibility and authority to ensure that the management system related to quality is implemented and followed at all times. The Quality Manager is responsible for ensuring compliance with ISO 17025:2017, ANAB AR 3125, any other applicable standards, and overall adherence to the quality system. The Quality Manager controls the quality records and is responsible for assessing and providing recommendations to the Lab Manager with regards to laboratory accreditation needs. The Quality Manager is responsible for the overall management of nonconforming work and has the authority to suspend analytical operations for an analyst, a discipline, or the laboratory system at any time when a significant quality issue is identified. The Lab Manager and Technical Leads may provide input to corrective or preventive action plans, however, the Quality Manager generally has final authority to determine the appropriate course of corrective action.

Technical Leads have overall responsibility for discipline technical operations and the resources necessary to ensure quality forensic laboratory operations. Technical Leads provide technical oversight of the quality assurance program in daily operations and act as subject matter experts for their discipline(s). Technical Leads are responsible for the technical content of manuals, managing validations, technical training of new analysts, and monitoring quality control measures and analysis, to include compliance with the ISO/IEC 17025:2017 standard, ANAB accreditation requirements, and other applicable standards for their respective discipline(s). Technical Leads have the authority to suspend analytical activity pending review and approval by the Lab Manager or Quality Manager. Technical Leads report directly to the Quality Manager in the performance of their quality assurance duties. The Lab Manager designates an individual as Technical Lead for each discipline. This is indicated on the Laboratory organizational chart.

The Lab Manager designates an individual as Health and Safety Coordinator. The Health and Safety Coordinator, along with the Lab Manager and Quality Manager, provides continuing support and monitoring of the health and safety system. The Health and Safety Coordinator provides educational opportunities on an annual basis and manages the chemical inventory of the Laboratory.

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To be successful, the Forensic Laboratory quality management system must have the support and commitment of all personnel. All Laboratory members are responsible for identification and reporting of any recognized quality affecting situations. All Laboratory staff have authority to suspend casework, discontinue the use of specific methods, or take an instrument out of service within their area of responsibility. Once suspended, work may not resume until authorized by the Quality Manager.

The Laboratory specifies the responsibilities and authority of forensic personnel through position descriptions and competency memos. Individuals are authorized to perform specific tasks and to utilize equipment in each discipline in which they perform work. Authorizations are typically granted after completion of training assignments, previous work experience, competency testing, or any combination of these. Authorization records are stored in the quality records.

The Laboratory shall maintain its policies and procedures to the extent necessary to ensure the consistent application of laboratory practices and the validity of processing and test results. The documents will be communicated to, understood by, available to, and implemented by the appropriate personnel.

Documents are controlled to ensure that they are adequate, approved for use, and that only current versions are used. These documents include administrative, technical, and quality policies and may be internally generated or from external sources. Examples include, but are not limited to, the Quality Assurance Manual, discipline training manuals and analytical methods, accreditation standards, and controlled memoranda.

5.6 All Laboratory personnel have the authority and resources needed to carry out their duties, including:

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

5.7 Laboratory management encourages all staff to improve the effectiveness of the quality system by initiating improvements and/or notifying management when quality concerns are recognized. Laboratory management shall ensure that all employees are informed and have input regarding the effectiveness of the management system. These communications may be in the form of meetings, interviews, written correspondence, or policy and procedure review. All feedback shall be considered and applied, where practicable, to improve the management system, collection and testing activities, and/or customer service.

The importance of meeting customer requirements in addition to statutory and regulatory requirements is communicated to Laboratory staff and the Sheriff's Office. Feedback from customers will be sought through an annual customer satisfaction survey. The Lab Manager will evaluate all responses and attempt to use feedback to improve services.

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When changes to the management system are planned and/or implemented, the potential impact shall be considered beforehand and the integrity of the management system shall be maintained. All employees are responsible for ensuring system integrity when modifications are necessary. Changes that may affect accreditation should be approved by the Lab Manager or Quality Manager prior to implementation.

6 Resource requirements

6.1 General

The Laboratory shall have available the personnel, facilities, equipment, systems, and support services necessary to manage and perform crime scene and laboratory activities listed on the Scope of Accreditation.

6.2 Personnel

6.2.1 General Requirements

Laboratory personnel, whether employed by or under contract to ACSO, who influence laboratory activities are expected to act impartially, to be competent in performing work duties, and to adhere to the Laboratory management system. The Laboratory utilizes qualified technical personnel. Contract employees will be held to the same standards and expectations as employees with respect to competency and proficiency testing.

6.2.1.1 Periodically, the Laboratory welcomes student interns/externs on a volunteer basis.

Externships are used mainly to explore interests and curiosities whereas internships act as the bridge from student life to professional life. These individuals are typically collegiate students selected in collaboration with the Lab Manager and ACSO Human Resources staff. All interns/externs undergo established pre-employment checks prior to beginning and are supervised by the Lab Manager. The Internship/Externship is designed to prepare students for a forensic career and to further evaluate the established training program.

6.2.2 Background and Training Requirements

The Forensic Lab strives for and intends to employ high quality personnel. All personnel shall be aware of the competencies and specific duties required of their position. Job descriptions include requirements for education, experience, duties, responsibilities, and authorities. Personnel shall meet the minimum educational requirements specified in the job descriptions. Current job descriptions for all Laboratory personnel are maintained by ACSO Human Resources and are readily available to all personnel in the quality records. Requirements for training, technical knowledge, skills, and demonstration of abilities are documented in discipline training manuals.

6.2.2.1 Forensic Scientists who issue reports that include test results or express opinions and/or interpretations shall possess a baccalaureate or an advanced degree in a chemical, physical, or biological science, or in forensic science.

6.2.2.2 Forensic laboratory management shall ensure that all disciplines have a documented training program that provides the knowledge, skills, abilities, and experience to perform their assigned duties. Staff must exhibit the ability to convey results and

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conclusions and the significance of them before being declared competent to create items that could be used for testing or to perform casework.

The Laboratory ensures adequate supervision and technical guidance of all employees including those in training. This supervision is performed by a trained and experienced individual(s) familiar with the policies and procedures of the Laboratory. Technical guidance is performed by the Technical Lead or a qualified designee who is trained and experienced in the methods and procedures and the purpose and evaluation of the methods and procedures for the relevant discipline.

The documented training program shall be used to establish the requirements necessary to ensure competency. The scope and duration for training for each employee shall be determined by their assignment, education, and experience. The discipline Technical Lead may modify the training program based on the trainee's credentials. Past work experience and training may be substituted for elements of the training program to the extent that it has been demonstrated to be relevant and sufficient. Documentation of previous training records shall be obtained when practical.

Each discipline training program shall include:

- a) the knowledge, skills, abilities, and experience to perform their assigned duties;
- b) general knowledge of forensic science;
- c) the application of ethical practices in forensic science;
- d) criminal and civil law as they pertain to forensic science and courtroom testimony;
- e) provisions for retraining;
- f) provisions for maintenance of skills and expertise; and
- g) criteria for acceptable performance.

Training program activities should also include:

- the review of relevant written materials, such as peer reviewed journal articles, books, and section specific analytical methods;
- observation of experienced personnel performing relevant functions, such as crime scene investigation; and
- laboratory exercises that demonstrate practical skills.

Training manuals should be reviewed periodically and revised as needed to ensure they are kept up-to-date. Ideally, this process occurs prior to and/or after being utilized by a trainee.

If retraining is deemed necessary, a specific plan for that individual shall be developed by the discipline Technical Lead. At a minimum, this documented plan shall include the scope of the retraining required and actions to establish or reestablish competency. The existing training manual may be used or a new training module may be developed, as required. In cases where retraining is required for an analyst removed from casework a follow-up competency or proficiency test shall be issued.

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Successful completion of the training program is generally achieved by obtaining passing scores on exams and successful demonstration of skills related to sample handling and testing methods in accordance to established approved methods. The discipline Technical Lead is responsible for determining successful completion of the training program and recommendation for performing independent casework or retraining. The Lab Manager or Quality Manager shall review the recommendation and confirm completion of the training requirements prior to issuing a competency memo.

6.2.3 Competency

Management shall ensure the competency of all personnel who operate equipment and instrumentation, perform laboratory activities, and evaluate the significance of deviations. The Forensic Lab shall maintain record of competency tests in the LIMS and/or quality records. Records of competence and/or authorizations confirmed are available to all Lab staff in the quality records and shall include the date awarded.

- 6.2.3.1 All Forensic Scientists, regardless of academic qualifications or past work experience, shall satisfactory complete a competency test in each category of testing prior to assuming responsibility for laboratory casework or crime scene duties, including the review and authorization of results and expressing opinions or interpretations. Competency testing shall include, at a minimum, practical examination(s) to cover the anticipated spectrum of assigned duties and to evaluate the ability to perform testing methods or tasks. Laboratory personnel must achieve the intended result(s) prior to performing laboratory tasks on a test item. Competency testing can be for an individual task or for a group of tasks.

Competency testing may also include:

- Demonstration of the appropriate use of equipment needed to perform testing;
- A written or oral examination to demonstrate knowledge of the forensic discipline, components of testing, and tasks performed (oral examination topics/questions shall be documented);
- Demonstration of the ability to properly convey results and conclusions, express opinions or interpretations, and their significance; and
- Courtroom testimony through a mock trial or oral examination to gauge the ability to communicate technical information and to maintain objectivity and composure.

After a prolonged absence from a discipline, which is indicated by greater than twelve months leave and/or missing or not performing an annual proficiency test or other form of monitoring in the discipline(s), a competency or proficiency test shall be taken before returning to casework. A competency test is also required prior to conducting casework for any new methodologies or equipment introduced in the analyst's absence.

- 6.2.3.2 Personnel who perform technical review of results and testimony shall meet the competency requirements specified for those performing the tasks being reviewed. Technical reviews shall be conducted by individuals authorized by lab management

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and based on expertise gained through training and casework experience. Contract reviewers shall be competent and have knowledge of the lab's technical procedures and management system.

6.2.4 Communication

Forensic Lab management communicates to staff their duties, responsibilities, and authorities. Job duties and responsibilities are provided in job descriptions, which are maintained by ACSO Human Resources. Authorization to perform these duties and responsibilities is conferred upon fulfilling training requirements and demonstration of competency. Authorizations will be communicated to staff, at a minimum, through email. Current job descriptions and authorizations are available to staff in the quality documents.

6.2.5 Procedures and Documentation

Discipline Technical Leads determine the competency requirements which are documented in the training manual and any additional training program records.

Recruitment and selection of personnel follows the ACSO Policy Manual with Procedures. The Lab Manager or designee works with ACSO Human Resources staff to develop job descriptions for laboratory positions. Job descriptions shall include educational requirements, duties, responsibilities, and authorities. Records related to job descriptions and postings are maintained by Human Resources.

Discipline training manuals are controlled documents stored in the quality records. Training records will be sufficiently detailed to provide evidence that staff has been properly trained and that their ability to perform the tasks of their specific discipline(s) has been assessed. The training records will be maintained by the analyst. The Technical Lead shall review analyst training documentation to confirm compliance with program requirements for the discipline and recommend supervised or independent casework, supplemental training, or retraining, as needed. Documentation of this review shall be maintained in the quality records.

Forensic Lab management shall formulate goals with respect to the education, training, and skills for laboratory personnel. Forensic Lab management shall conduct annual personnel evaluations according to ACSO human resource's procedures, which includes setting individual training or continuing education goals. Lab staff are encouraged and supported to partake in technical and/or professional development opportunities.

Continuing education opportunities include:

- attendance at meetings, seminars, and conferences
- participation in scientific working groups or professional organizations
- review of current and applicable literature
- submittal of content for publication in professional journals
- presentations at technical meetings
- participation in college-level and other specialized courses
- completion of webinars or other online training

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The process of applying for training is completed through ACSO Training Division's Training Request Web Site. An evaluation of training is completed following attendance at training with a submitted request. Training assessment occurs at least annually and is a documented part of the management review. Curriculum vitae for all laboratory staff members should be updated annually, or more frequently if significant changes occur. Curriculum vitae are kept in the quality records and a current version should also be available on the website. Training records not maintained by the Laboratory shall be available by request from ACSO Training Division.

Each staff member has one immediate supervisor. The Laboratory maintains an organizational chart that depicts the supervisory structure. Supervision records not kept by the Lab are retained by ACSO Human Resources.

Discipline Technical Leads authorize personnel to perform specific tasks including, but not limited to, sampling, creating test items, testing, issuing reports, giving opinions, interpreting findings, conducting technical reviews, and operating specific instruments and equipment. Authorization may be granted for individual tasks or as a group covered by a training program module(s). Authorization to work in a discipline authorizes an analyst to complete casework, operate equipment associated with the discipline training manual, conduct technical reviews, and perform applicable verifications unless noted in the work authorization. Written authorization and supporting documentation are reviewed and approved by the Quality Manager and/or Lab Manager before independent casework begins. Authorization documentation is retained in the quality records.

Competency is monitored continually through casework reviews and annually through competency or proficiency testing and/or other forms of monitoring (e.g., intralaboratory or interlaboratory comparisons, testimony monitoring, internal audits with direct observation, and external assessment). Documentation for monitoring and other assessments of competence are maintained in the LIMS and/or quality records.

6.2.6 Authorization

Authorizations are issued by the responsible Technical Lead and approved by the Lab Manager or Quality Manager. Personnel shall be granted authorizations to perform specific laboratory activities, including, but not limited to, the following: operation of equipment; method development, modification, verification, and validation; analysis of results, including statements of conformity or opinions and interpretations; and authorization of results through issuing reports and performing reviews. Authorization to work in a discipline authorizes an analyst to complete casework, operate equipment associated with the discipline training manual, conduct technical reviews, and perform applicable verifications unless noted in the work authorization.

The Forensic Lab shall maintain records of the relevant authorization(s) of all technical personnel, including contracted personnel. This information is available to all lab staff and shall include the date on which authorization and/or competence is confirmed. A competency matrix is available in the quality records to readily identify staff authorizations.

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6.3 Facilities and environmental conditions

6.3.1 Laboratory facilities shall have appropriate energy sources, lighting, and environmental conditions to facilitate correct performance of the tests. The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests are undertaken at sites other than a permanent laboratory facility.

6.3.2 When there are specific requirements for facilities or environmental conditions necessary for the performance of a particular laboratory activity or test they shall be documented in the appropriate analytical method. Concerns related to facility or environmental conditions that could affect casework should be brought to the attention of the appropriate Technical Lead and Lab Manager and investigated. These conditions should be documented in the case record when there is a concern.

6.3.3 The laboratory shall monitor, control, and record environmental conditions as required by the relevant specifications, methods, and procedures or where they influence the validity of the results. Any requirements shall be specified in the analytical methods and, if applicable, records shall be retained in the discipline or quality records. Collection activities or tests shall be stopped when the environmental conditions jeopardize the results of the tests and the Lab Manager will be notified as soon as practicable.

6.3.4 Access to the ACSO building and Forensic Laboratory is limited, controlled, and monitored. The measures below shall be periodically reviewed, usually through internal audits or performance monitoring, and updated as needed:

- a) Access to and use of laboratory testing areas is controlled and limited to authorized personnel. Non-Forensic staff are not allowed unrestricted access to operational areas of the laboratory. All visitors must be accompanied by lab personnel. The Lab Manager or designee determines the access level. Access to and use of areas affecting the quality of the tests shall be controlled.
- b) It is the responsibility of each employee to prevent contamination, interference, or adverse influences on laboratory activities through appropriate measures. Examples include ensuring good housekeeping in the laboratory, limiting individuals in the laboratory during analysis, and utilizing appropriate evidence storage areas; see discipline analytical methods for specifics. Additionally, computers should be locked or powered down when not actively in use.
- c) There shall be effective separation between neighboring areas in which there are incompatible activities. Separation may be achieved by time and/or space. The Laboratory shall ensure each employee has enough working space to accomplish assigned tasks without the risk of mishandling or contaminating evidence.

6.3.4.1 Access to areas where testing occurs shall be secure and controlled. The ACSO building is accessed via doors with a keypad or keyed lock. Each employee has a unique security access code. Distribution of keys to access the building is limited to individuals designated by the Lab Manager.

Entrance/exit points for the operational areas of the laboratory are security controlled at all times. Laboratory staff are issued keys to access the laboratory. Key

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distribution is limited to individuals designated by the Lab Manager and are documented in a key log. Key logs shall be audited annually and contain the following information:

- unique key number and total number of keys for each lock;
- custody/location of each key;
- identity and signature/initials of individual receiving a key; and
- date assigned.

Visitors may access the Laboratory at the discretion of Lab personnel. Escorts are required at all times when evidence is not secured.

Visitors shall sign the visitor log, as determined by the following:

- Internal visitors have a background security check performed for ACSO or Ada County employment (e.g., Sheriff, Police Services Bureau Captain and Lieutenant, detectives/deputies, IT, maintenance, custodial staff, etc.). These visitors do not need to sign the visitor's log.
- External visitors have no internal background security check performed for ACSO or Ada County employment (e.g., external auditors, approved vendors, tour attendees, etc.). These visitors shall sign the visitor's log. They should be kept under general observation when accessing administrative areas of the facility.

Laboratory doors are locked when not occupied by laboratory staff during operational hours. During non-operational hours the laboratory is monitored by an intrusion alarm. Lab staff each has a personal code to disarm the alarm. This alarm shall be tested annually.

Laboratory evidence storage areas shall be controlled with limited access to prevent theft or interference and to ensure evidence integrity and preservation. Evidence storage conditions shall be such as to maintain the identity and integrity of the evidence and to prevent loss, deterioration, and contamination.

6.3.5 When laboratory activities are performed at locations outside of the Laboratory's permanent control, staff shall ensure that the facilities and/or environmental conditions are suitable prior to performing activities. Technical requirements for accommodations and environmental conditions that could affect the examination results shall be included in the analytical methods and documented in the case record, as necessary. Crime scene processing locations are often beyond the control of the Laboratory; however, staff shall ensure that conditions do not invalidate results or adversely affect the ability to obtain quality samples or measurements.

6.4 Equipment

6.4.1 The Forensic Lab shall be furnished with and/or have access to sampling, measurement, and test equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus) required for the correct performance of forensic examinations and testing identified within its scope. Instruments and equipment having a significant effect

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on the accuracy or validity of forensic testing results are properly calibrated and maintained. Requirements for instrument calibration and maintenance are described in the applicable discipline analytical method(s) manual and/or instrument calibration/maintenance record.

6.4.2 In cases where the Forensic Lab needs to use equipment outside its permanent control, it shall ensure that the requirements of the Forensic management system are met. When, for whatever reason, equipment goes outside of its direct control, the Laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

6.4.3 The Forensic Lab shall have procedures for safe handling, transport, storage, use, and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration. Up-to-date instructions on the use and maintenance of equipment shall be readily available for use by the appropriate personnel.

The following general precautions shall be taken to avoid contamination or deterioration when handling, transporting, storing and using reference materials:

- Personal protective equipment will be used when appropriate.
- Steps will be taken to avoid contamination of the reference materials (e.g., use of clean tools and containers, not returning excess material to storage containers).
- Reference materials shall be appropriately stored and secured to ensure their integrity.

The following additional precautions shall be taken to protect the integrity of reference weights and length standards used to verify balances, calipers, and micrometers:

- They will be stored and transported in the manufacturer's original packaging or an equivalent container.
- Appropriate gloves and/or forceps will be used when handling.

Discipline analytical methods shall define equipment/instrument operation, maintenance and calibration schedules, and verification procedures that are not covered in the Quality Assurance Manual.

6.4.3.1 Reagents made in the lab shall be labeled with, at a minimum, the identity of the reagent and the date of preparation or Lab assigned lot number. The lot number shall be the date prepared and the initials of the preparing analyst (e.g., 011019SG). Records shall be maintained identifying who made the reagent and the components used in preparation. If conducive to testing the reliability of the reagents prior to use, documentation confirming the reagent worked as expected should also be present. Reliability testing shall occur before use, if appropriate, or concurrent with the test and shall be further described in the appropriate analytical method. This includes, but is not limited to, the use of controls, reagent expiration, and documentation.

6.4.3.2 Disciplines utilizing reference collections (e.g., mass spectra, drug samples, and cartridges) maintained by the lab for identification, comparison, or interpretation

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purposes will document, uniquely identify, and properly handle the reference collection to protect the characteristic(s) of interest.

- 6.4.4 Before being initially placed into service or returned to service, equipment shall be calibrated or performance checked to establish that it meets the specified requirements defined in the discipline analytical methods. Equipment not currently in service shall be appropriately labeled to indicate that it may not be used for casework.
- 6.4.5 Equipment and its software used for measurement that has a significant effect on the accuracy or validity of the test result, shall be capable of achieving the measurement accuracy and/or measurement uncertainty required by the discipline analytical method, where applicable.
- 6.4.6 All equipment used for tests having a significant effect on the accuracy or validity of the test results shall be calibrated before put into service. The Laboratory shall ensure that measuring equipment is calibrated when the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or calibration of the equipment is required to establish metrological traceability of the reported results.
- 6.4.7 Each discipline shall have procedures for calibration of equipment that has a significant effect on the results of testing. Reference standards that are considered critical to the outcome of a test shall be calibrated. Reference standards are calibrated by organizations that can provide traceability as described in 6.5.1.1 and 6.5.1.2.
- Reference standards (e.g., balance weights) shall be calibrated before and after any adjustment. If mishandling of standards brings accuracy into question, the standards shall be taken out of service and recalibrated. Reference standards used to check accuracy of other equipment or instruments shall not be used for other purposes. All calibrations and adjustments to these materials will be documented. Calibration/performance check records are maintained in the quality records, preferably in a location near the instrument or equipment.
- 6.4.7.1 Each discipline shall have a list of the equipment and reference standards requiring calibration, specifications for the calibration, laboratory specified requirement for the calibration, and the interval of calibration.
- 6.4.8 Whenever practicable, Forensic Lab equipment that requires calibration shall be labeled, or otherwise identified, to indicate the status of calibration, including the date when the last calibration was performed and the date the next calibration is due.
- 6.4.9 Equipment that has been subjected to overloading or mishandling, that gives suspect results, or that has been shown to be defective or outside limits specified in the appropriate discipline analytical method, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled/marked as being out of service until it has been repaired and/or shown to perform correctly. Whether or not any previous test results were affected by the defect or departure from specified limits shall be evaluated. The procedure for nonconforming work (Section 7.10) will be followed, if necessary.

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6.4.10 Procedures and schedules for intermediate checks needed to maintain confidence in the calibration status of equipment and/or reference, primary, or working standards and reference materials shall be contained in the discipline analytical methods.

6.4.11 When calibration and reference material data include reference values or correction factors, the Forensic Lab shall ensure that any necessary correction factors are correctly updated and implemented, as appropriate.

6.4.12 Test equipment, including hardware and software, shall be safeguarded from adjustments which could invalidate the test results, by being secured in and restricting access to the Forensic Lab. Results of equipment quality control checks are reviewed to ensure that no inadvertent adjustments have been made.

6.4.13 Records shall be maintained for each item of equipment that is significant to the analysis or test result. The records shall include the following, where applicable:

- The manufacturer's name, type identification, and serial number or other unique identification;
- Evidence of verification that equipment conforms with specified requirements;
- The current location, where appropriate;
- Dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
- Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
- The maintenance plan and maintenance carried out to date, where relevant to equipment performance; and
- Details of any damage, malfunction, modification to, or repair of the equipment.

6.5 Metrological traceability

6.5.1 Equipment that has a significant effect on the measurement result and the associated uncertainty shall be traceable by means of a documented and unbroken chain of calibrations or comparisons, each contributing to the uncertainty, and linking the calibration standards (e.g., NIST-traceable weights) to an appropriate reference. The Laboratory utilizes calibrated and traceable reference standards and certified reference materials to establish metrological traceability of measurement results to ensure the validity of results. The Forensic Lab shall safely handle, transport and store these measurement standards to prevent contamination or deterioration and to protect their integrity.

6.5.1.1 When external calibrations are performed, service providers that demonstrate competence, measurement capability, and traceability will be used. Calibration certificates from these providers shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification. When available, suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials used to establish or maintain measurement traceability shall be either:

- A National Metrology Institute (e.g., NIST) that is a signatory to the BIPM – CIPM Mutual Recognition Arrangement with the calibration to be performed or

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reference standard/certified reference material to be purchased in Appendix C of the BIPM key comparison database (KCDB); or

- A service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be performed listed in the scope of accreditation; or
- An accredited reference material producer that is accredited to ISO/IEC 17034 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material.

6.5.1.2 Where a supplier that meets specifications in 6.5.1.1 is not available, the Laboratory will confirm the competence, capability, and metrological traceability for the supplier and the product or service being purchased. Documentation of this assessment shall be retained in the quality records.

6.5.1.3 The Forensic Lab is not a calibration laboratory.

6.5.1.4 If a certified reference material is changed in a way that alters the traceable measurement value, then the equipment used to alter the certified reference material shall be evaluated for applicability of measurement traceability accreditation requirements; only calibrated and traceable equipment will be used to alter the traceability measurement value. For example, if a certified drug standard of a specific concentration is used for quantitative measurements and requires dilution only a calibrated and traceable pipette will be used. Documentation will be stored in the relevant discipline records.

6.5.2 Where possible, measurement results obtained from reference standards (e.g., NIST-traceable weights) shall be traceable to the International System of Units (SI) units through:

- a) Calibration provided by a competent laboratory (i.e., meeting the requirements specified in 6.5.1.1);
- b) certified values of certified reference materials provided by a competent producer (e.g., fulfill requirements of ISO 17034) with stated metrological traceability to SI units; or
- c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

6.5.3 Where metrological traceability of measurements to SI units is not possible and/or not relevant, disciplines shall establish traceability to another appropriate measurement reference. This may include certified values of certified reference materials provided by a competent producer or 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 (e.g., proficiency test materials).

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6.6 Externally provided products and services

6.6.1 The Laboratory ensures the suitability of externally provided products and services (e.g., measurement standards and equipment, consumables, reference materials, calibration or testing services, equipment maintenance services, and proficiency testing services) affecting laboratory activities when they:

- are intended to be incorporated into Forensic Lab activities;
- are provided to the customer by the Laboratory, in part or in full, as received; or
- are used to support Laboratory operations.

6.6.2 Each discipline shall specify the equipment, supplies (including reagents and consumables), and services that influence the quality of tests in the applicable analytical method(s). Supplies and services shall be selected to meet the technical and quality requirements of the discipline. The purchase, receipt, and storage of reagents and consumables that influence the quality of the test(s) shall follow the procedures below.

When purchasing a new chemical (i.e., a chemical not currently in the laboratory's Chemical Inventory), the requestor will work in conjunction with the discipline Technical Lead and the Health and Safety Coordinator prior to ordering the chemical to ensure that the chemical is labeled, handled, and stored properly. Chemicals received in the Lab shall be labeled with, at a minimum, the identity of the reagent, lot number, the received date, and initials of the receiving analyst. Chemicals without a manufacturer lot number shall be assigned a Lab lot number, which shall be the date received (i.e., January 10, 2019 = Lot Number 011019).

Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. The description of items for purchase shall be specific enough to ensure the appropriate item is purchased and may include type, class, grade, precise identification, specifications, other technical data, or the quality required. These purchasing documents shall be reviewed for technical content by the preparer. Previously purchased supplies and services need not receive approval prior to ordering. First-time purchases shall be approved by the Technical Lead and/or Lab Manager prior to release.

Purchased supplies (including reagents and consumable materials) that influence the quality of the test(s) shall not be used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the applicable discipline analytical method. All supplies shall comply with any specified requirements before being placed into use. Documentation of the inspection/verification shall be maintained.

Upon receipt, supplies will be inspected and verified as complying with the purchase request by checking the packing slip against the purchase request and against what was actually received to ensure all are in agreement. The item received will be considered to be verified and approved if the labels and shipping documents (i.e., packing slip) match what was ordered. The person receiving the material shall indicate verification/approval by marking their initials and the date received on the packing slip.

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A Certificate of Analysis is acceptable documentation that the item received meets specification. The item shall be considered verified, if accompanied by a certificate of analysis and documentation of the order quantity and identity of the product. Documentation that the order was checked, including the order form and packing slip, and the Certificate of Analysis shall be maintained.

If the shipping documents and/or items received do not match the order form, the supplies shall not be placed into service until the problem is resolved. Any discrepancies in the order shall be recorded on the order document and retained with the purchasing records. In addition, if the resolution includes returning the item, this will be noted on the shipping document. Purchasing records not retained by the Lab are maintained by the ACSO Finance Division.

The Lab shall continually evaluate suppliers of supplies and services that affect the quality of testing. This is often performed through the regular course of business as the products or services are utilized. Evaluation records will be maintained in the quality records.

Vendor evaluation shall be based on the following criteria:

- Ability to provide a service/product that meets the documented requirements of the discipline analytical method and/or the Quality Assurance Manual.
- Ability of vendor to provide the service/product in necessary time frame.

As applicable, evaluation may also include the following:

- Ability of vendor to provide technical support, when necessary.
- Ability of vendor to provide adequate instruction or on use of the service/product.
- Vendor accreditation documents (status and scope).

Documented evidence of vendor accreditation status and scope shall be retained in the discipline and/or quality records. Equipment shall be serviced by the manufacturer or a service vendor demonstrably capable of providing the service (e.g., certified by the manufacturer, past performance, etc.).

Vendors who are evaluated and selected as part of the contract/procurement process will be considered approved and may be added to the Approved Vendor List. No additional documentation is required in these instances. An approved vendor may be removed from the approved list if quality concerns are identified. Removal of a vendor shall be communicated to the appropriate staff.

When the Forensic Lab subcontracts work, this work shall be placed with a competent subcontractor. A competent subcontractor is one that is accredited to and complies with ISO/IEC 17025 or ISO/IEC 17020. The Forensic Lab is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

The Forensic Lab shall maintain a register of all subcontractors used for tests and/or reviews. Evidence of compliance with ISO/IEC 17025 or ISO/IEC 17020 regarding the Scope of Accreditation for the work in question may be retained in the lab or can be found

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online through the accrediting body. Amendment of the register is the responsibility of the Quality Manager or applicable Technical Lead.

- 6.6.3 When orders for externally provided goods or services are placed, the Laboratory follows the procurement procedures of the Finance Division. The requirements for the order, any pertinent acceptance criteria, and/or competence/qualification requirements for personnel are communicated to the supplier through the procurement process. This process extends to providers who perform services at sites other than the Forensic Lab, such as contract employees working off-site.

The Laboratory communicates its requirements to external providers through the use of purchase orders, legal contracts, and memorandums of understanding. These detail the products and services to be provided, acceptance criteria, competence, and location of activities, as applicable.

7 Process requirements

7.1 Review of requests, tenders, and contracts

- 7.1.1 A request for service may be initiated by submission of an evidence processing request, a verbal request, or other written request (e.g., email or text). By submitting evidence for analysis or requesting laboratory services, the customer acknowledges that they agree with the terms and conditions of the Forensic Lab. A signed agreement is established with a representative from each agency for which the Lab performs services. The agreement establishes conditions for the work to be performed, which includes, but is not limited to, item and method selection, report content, release of results, etc. The agreement shall be available on the Forensic Lab website.

The request review is documented by an accepted case, which is added to the LIMS. The review of a request shall ensure the following:

- Customer needs regarding the evidence including the examination(s) desired are adequately defined, documented, and understood.
- The lab has the capability and resources to meet the customer requests.
- The tests selected are capable of meeting the customer requirements.

The review shall also cover any work that is subcontracted by the lab. The Laboratory shall advise the customer of work to be subcontracted in writing. When appropriate, the customer's approval, preferably in writing, is gained before subcontractor work is initiated.

If it is determined that the Forensic Lab will not be able to fulfill the request for service, the customer shall be notified. If the Forensic Lab can offer an alternative service, the difference between the requested service and the alternate service shall be resolved before work commences.

- 7.1.2 Submission of evidence to the Laboratory indicates the submitting agency agrees that the Forensic Lab will select the appropriate method(s) on behalf of the customer. If a customer requests a method that is inappropriate or out of date, documentation of the

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communication to notify the customer shall be retained, preferably with the case record in the LIMS.

7.1.3 The Laboratory does not report statements of conformity (e.g., pass/fail, in-tolerance/out-of-tolerance).

7.1.4 Differences between the request or tender and the contract will be resolved before work commences. Each contract shall be acceptable both to the lab and the customer.

Non-standard methods may be used when necessary to meet the customer's request. When this occurs, the method developed shall have been validated appropriately before use. Changes to or deviations from established procedure shall be approved by the discipline Technical Lead. If a deviation from the documented sampling procedure is requested by the customer or deemed appropriate by the analyst, the deviation process shall be followed.

7.1.5 The customer shall be informed of any substantive deviation from the contract. However, services for Crime Scene Investigation may be extended beyond the original request without the customer being notified beforehand. Notification to customers shall be retained in the LIMS.

7.1.6 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to affected staff members as soon as possible. Changes initiated by the Forensic Lab are communicated to the customer.

7.1.7 The Forensic Lab strives to maintain good working relationships with its customers. Employees shall communicate with customers or their representatives, as needed, to clarify their requests and to inform regarding the request status.

7.1.8 Records of reviews, including any significant changes, shall be maintained in the LIMS. By creating the request in LIMS, the Forensic Scientist is recording that the request for service has been reviewed. Records of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract are retained in a communication log, email, or equivalent record, and should be attached to the case record in the LIMS.

7.1.9 The extent of database searches (e.g., AFIS) used in forensic casework is communicated to the customer through the report and is updated as needed. Investigative leads resulting from searches are communicated to customers through verbal communication and/or laboratory reports, which are documented in the case record.

7.2 Selection, verification, and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 The Forensic Lab shall use appropriate procedures and methods for all laboratory activities. This includes methods and procedures for the sampling, handling, transport, storage, and preparation of evidence items, the operation of relevant

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equipment, and, where appropriate, an estimate of the measurement of uncertainty and statistical techniques for analysis of data.

7.2.1.1.1 The Lab shall use appropriate methods and procedures for data analysis and interpretation.

7.2.1.1.2 Analytical methods that involve the comparison of an unknown to a known shall specify criteria for evaluation of the unknown in order to determine whether the unknown has characteristics suitable for comparison (e.g., friction ridge detail in a latent print, criteria for evaluation of mass spectrometry fragments, etc.). This determination shall be made prior to comparison with the known item(s).

7.2.1.1.3 The Forensic Lab does not perform calibration services.

7.2.1.2 Each forensic discipline shall have an analytical method applicable to the work performed. Analytical methods shall include or reference instructions on the use and operation of all equipment and instruments used by that discipline and shall describe the handling and preparation of evidence for testing. The analytical methods will be periodically reviewed to ensure that they are up to date.

All methods, procedures, and supporting documentation (e.g., standards, manuals, instructions, reference data, etc.) relative to testing performed are maintained and updated by the appropriate discipline. Documents are readily available to Laboratory personnel.

7.2.1.3 The Laboratory shall ensure that the latest valid version of a method is used, unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application. If the methods from external sources are used, the section Technical Lead will review the method during manual revisions to ensure it is in compliance with the most current version.

7.2.1.4 The Forensic Lab selects the appropriate method(s) on behalf of the customer. This is communicated to the customer on the website and is available upon request. Technical Leads shall ensure that all methods operate properly before utilizing them for testing casework.

The Laboratory preferably uses standard methods, which are published in international, regional, or national standards, by reputable technical organizations, or in relevant scientific text or journals, or provided/specified by the equipment or instrument manufacturer. Standard methods are considered already validated when used as is, but are verified as working in-house prior to using for casework.

Non-standard methods, laboratory-developed methods, or standard methods used outside of their intended scope or otherwise modified may also be used if they are appropriate for the intended use, documented, properly validated, and approved for use.

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7.2.1.5 The Forensic Lab shall confirm that it can properly use an externally validated method prior to introducing it for forensic examinations. Reliability of the method shall be demonstrated in-house against any documented performance characteristics. Records of the performance verification shall be reviewed and approved by the discipline Technical Lead and Quality Manager or Lab Manager and retained in the discipline and/or quality records. If the issuing body revises the method, the performance check shall be repeated, to the extent necessary, to ensure the method works in-house.

7.2.1.6 Method development is a planned activity that shall be assigned to competent personnel authorized to perform the tasks. Method development plans are approved by the appropriate Technical Lead and the Quality Manager or Lab Manager to ensure that personnel are equipped with adequate resources for the project. The process shall be periodically reviewed to ensure it continues to meet customer needs. Any modifications to the development plan shall be approved and authorized.

7.2.1.7 Deviations from laboratory activities shall be reviewed, justified, and approved prior to the deviation. Analytical method deviations shall be approved by the appropriate Technical Lead. Deviation from a quality procedure shall be approved by the Quality Manager. Documentation shall be retained in the case record, report, and/or quality records, as appropriate.

The Laboratory selects the best method for conducting analyses, thus it is not typically necessary to obtain customer approval for each deviation. Customer agreement shall be obtained prior to substantive test method deviation.

7.2.2 Validation of methods

7.2.2.1 The Forensic Lab shall validate all non-standard, laboratory-developed, standard methods used outside of their intended scope, and modified standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. Validations are completed by authorized personnel, then reviewed and approved by the appropriate Technical Lead and the Quality Manager or Lab Manager.

7.2.2.1.1 A validation plan shall be established that provides parameter evaluation and acceptance criteria to assess the ability of the method to produce accurate and reliable results. Known samples representative of those encountered in casework shall be examined to determine if the method generates acceptable results. The plan shall be approved by the discipline Technical Lead and the Quality Manager or Lab Manager prior to starting the validation.

Method validation shall:

- Encompass the test process, including data analysis and interpretation;
- Establish the data required to report a result, opinion, or interpretation;
- Identify limitations of the method, reported test results, opinions, and interpretations.

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7.2.2.2 If changes are made to a validated method, the influence of the changes shall be determined by the discipline Technical Lead. If the changes are found to affect the original validation, a new method validation shall be performed. The new validation shall encompass, at a minimum, the specific areas affected by the changes to the method. Data used to determine the influence of the changes shall be retained.

7.2.2.3 The performance characteristics of validated methods (e.g., measurement range, accuracy, uncertainty, detection limits, specificity and/or selectivity of the method, reproducibility, etc.), as assessed for the intended use, shall be relevant to customer needs and consistent with specified requirements.

7.2.2.4 All data and documentation relating to the validation shall be retained in the discipline and/or quality records. Validation records shall include, but are not limited to, record of the following:

- the procedure used for the validation;
- specification of the requirements;
- determination of the performance characteristics of the method;
- results obtained; and
- a statement as to whether the method is valid and fit for the intended use.

7.3 Sampling

7.3.1 As applicable, each discipline shall document in their analytical method a sampling plan based on appropriate statistical methods. The sampling plan and method are readily available to affected laboratory personnel at the location where sampling is undertaken and will address the factors to be controlled to ensure the validity of the testing.

7.3.2 For disciplines that utilize sampling methods, the procedure requirements will be described in the analytical method and must include:

- the selection of samples or sites;
- the sampling plan, including statistical sampling at a stated level of confidence if an inference will be made to report on the whole population; and
- how the sample is prepared from the received evidence to produce the item used for subsequent testing.

7.3.3 Sampling shall be documented in the case record. If necessary for the interpretation of test results and conclusions, the sampling plan used will be included in the report.

Documentation of sampling shall include the following, where relevant:

- Reference to the sampling method(s) used;
- The date and time of sampling;
- Unambiguous identification of the sample (e.g., number, amount, name);
- Identification of the individual performing sampling;
- Identification of the equipment used;
- Details of any environmental or transport conditions during sampling that may affect the interpretation of the test results;
- Means to identify the sampling location (diagrams, sketches, photographs, etc.); and
- Deviations from the documented sampling procedure is requested by the customer or deemed appropriate by the analyst, prior approval from the discipline Technical

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Lead is required. If approved, detailed documentation shall be retained with the case notes in the LIMS.

7.4 Handling of test or calibration items

7.4.1 The Forensic Lab shall have appropriate facilities for avoiding deterioration, loss, or damage to the evidence during storage, handling, and preparation. Specific procedures can be found in discipline analytical methods, where appropriate. All employees share in the responsibility of ensuring that evidence is not lost, contaminated, or otherwise compromised.

Special handling instructions provided with the evidence shall be followed unless the customer agrees to a change. When multiple laboratory sections are assigned to an evidentiary item, forensic scientists discuss and document case approach to determine appropriate actions to prevent the potential loss or contamination of evidence. To ensure the integrity of the evidence and to protect the interests of the Laboratory and the customer, the following procedures will be used.

Off-site evidence collection

Evidence collected from off-site (e.g., crime scene) by Lab staff shall be protected from loss, cross-transfer, contamination, and/or deleterious change, whether in a sealed or unsealed container, during transport to the Forensic Lab or ACSO Property and Evidence. Where appropriate, further processing to preserve, evaluate, document, or render evidence safe shall be accomplished prior to final packaging. Evidence collected from off-site shall be appropriately identified, packaged, and submitted to ACSO Property and Evidence as soon as practical.

Receipt of evidence

Evidence may be submitted to the Forensic Lab by one of the following methods:

- ACSO Property and Evidence
The Chain of Custody (COC) on the item(s) shall be signed/initialed by the receiving analyst and dated when evidence is personally obtained from property. The COC is also documented in the ACSO Property and Evidence electronic tracking system.
- Personal/Individual delivery
The COC on the item(s) shall be signed/initialed by the receiving analyst and dated when evidence is directly received in the laboratory. The item(s) will be secured by the receiving analyst in a temporary storage locker. Large items may be secured in the locked lab.
- Shipped evidence (e.g., First Class U.S. Mail, Fed Ex, UPS)
The COC on the item(s) shall be signed/initialed and dated by the person who signed for/received the shipment. The evidence will be secured by the receiving analyst in a temporary storage locker. Large items may be secured in the locked lab.
- Electronic transfer of digital images or data
Electronically-received digital images will be accepted on a case-by-case basis. If accepted, the COC will begin when the image is received (e.g., time/date on email). In the Evidence Submission description field enter the number of images received and how received. The electronic evidence shall be transferred to the appropriate case file in the LIMS. Information about the file names and format, if available, should be

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recorded in the case record. Copies of these images may be returned to the submitting party. The discipline analytical method shall have procedures in place to ensure the images will be handled in a way to maintain their integrity.

Submission evaluation

Evidence items received will be inventoried against the Evidence Processing Request or equivalent to ensure that the items listed are the items received. If a discrepancy is noted it will be documented on the Evidence Processing Request or in case correspondence and the customer notified.

Evidence labels

All evidence examined shall be marked with the laboratory case number, the unique item number, and the analyst's initials. Should the evidence item not lend itself to marking, this shall be noted and the proximal container(s) shall be marked.

Evidence examination

Evidence is considered to be in the process of examination from the time it is initially opened/accessed for analysis until completion of exams and release of the report. The process of examination shall not be open-ended and shall be based upon a justifiable expectation of frequent examination. When the process of examination is lengthy (e.g., greater than 1 year), justification shall be recorded in the case record.

When not being actively accessed, evidence should be maintained in designated temporary evidence storage. Access to personal storage locations shall be limited to personnel designated by the Lab Manager and items shall be secured to prevent loss or contamination. Items shall be re-sealed following completion of analysis and retained in secure storage until transferred for further examinations or return to the customer.

Evidence return

Evidence shall be returned in the same manner it was received. (i.e., if obtained from ACSO Property, it is returned to ACSO Property).

Specific evidence procedures:

Digital images generated by Lab staff

The intended purpose of documentary images is to record observations and/or analytical results. File format shall be at the analyst's discretion, if not defined by the analytical method. The original images should be archived as soon as practicable. Enhancement of these images may be performed without being tracked.

The intended purpose of examination quality images is to record detail so an analyst can use the image to perform a comparison. The specific image resolution and file format requirements shall be defined in the discipline analytical method. Enhancements of examination quality images will be made on a work copy. The enhancements and the order they were applied will be documented either in the case notes or electronically (e.g., Photoshop or LIMS). Any examination quality image used to support a result or

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conclusion will be a part of the case record and stored in an unalterable fashion. The original images should be archived as soon as practicable.

Not all digital images captured are considered evidence and, therefore, may not necessitate retention and/or tracking. Discipline analytical methods shall detail procedures for handling of digital images.

Firearms

Any firearm submitted to the Forensic Lab shall be in a safe condition (e.g., sticker acknowledging safety check, action secured open with a zip-tie, flex cuff through the barrel, etc.). When a firearm is submitted in a sealed package, it shall be received into the Forensic Lab and the safe condition will be confirmed by the first analyst that breaks the packaging seal. Every analyst that handles the firearm shall ensure that the weapon is safe prior to examining it, transferring it to another examiner, or returning it.

Biohazard materials

Any evidence items with potential biohazard material (e.g., blood, semen, urine, saliva, etc.) should be clearly and boldly labeled with a biohazard label affixed to the outside of the container.

Syringe with needle

The syringe must be the only drug item in the case or must be needed to establish probable cause. If there are other suspected controlled substances they will be analyzed first. In the event the other items do not contain controlled substances, then the syringe can be submitted for analysis if still required for the case. The syringe should also be analyzed when necessary to support the probable cause, even if other suspected controlled substances are present in the case. If the conditions above are not met, the syringe may be analyzed at the request of the submitting party.

Liquid contents in evidence containers

Liquid contents submitted within evidence containers are considered potential evidence.

Latent print standards/exemplars (e.g., tenprint cards, palm print standards)

Latent Print standards and exemplars are not considered evidence when they are printed copies from a database. All other latent exemplars will be treated as evidence.

7.4.1.1 The following are requirements for all items of evidence received into the Laboratory:

Evidence packaging

Evidence containers should be appropriate for the item(s) contained. If evidence is received in a manner that is likely to cause deleterious change, analysis should be prioritized and/or the evidence should be repackaged appropriately. Documentation of inappropriate packaging and any actions taken shall be retained in the case record.

Evidence seals

Unless it is not physically possible, evidence shall be properly sealed before submission to the Forensic Lab. A proper seal is one which protects the integrity of

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the item by preventing loss, cross-transfer, and contamination. Attempted entry to the container shall be detectable by use of tamper-evident seals (e.g., heat seals, gum/adhesive seals, tape, or the equivalent). Staples are not acceptable seals.

Sealed evidence shall be initialed/signed and, when possible, markings should cross over the seal in such a way as to provide visual indication of entry into the evidence package if the seal is broken. A seal originating from laboratory personnel shall also include the date.

Evidence directly transported to the lab for immediate analysis (e.g., test firing a weapon) or in temporary storage does not need to be sealed. Exceptions may be made for large or bulky items that do not easily lend themselves to sealing. Additional exceptions may be found in discipline analytical methods. All unsealed evidence shall be stored in a manner to minimize potential loss, cross-transfer, or contamination of the evidence.

Containers/items shall be re-sealed as soon as practicable following completion of analysis and retained in secure storage until transferred for further examinations or return to the customer.

Evidence storage (when not in process of examination)

Evidence shall be sealed and stored under secured conditions (locked laboratory door, locked cabinet, limited access, etc.) when not under the direct control of laboratory personnel. Each analyst will be designated a secure storage location as their primary evidence locker. Other storage locations may be designated as temporary evidence storage lockers, as needed.

Unattended evidence (in the process of examination)

Evidence shall be in a secure laboratory area when not under the direct control of the analyst. If the examiner needs to leave for a short time period, evidence does not need to be returned to a storage location. Examples of short periods of time may include, but are not limited to, rest breaks, meal periods, phone calls, and short conferences.

Evidence should be kept in an evidence locker or a secure temporary evidence storage area during the hours the laboratory is vacant. In the event that evidence needs to be kept out to allow for drying or another justifiable reason, it should not be disturbed. Interior doors may be closed and locked, taped, or otherwise marked to indicate temporary evidence storage, if necessary.

Work product, however defined by a given discipline (e.g. extracted DNA product), is not treated the same as evidence, but should be maintained such that the risk of loss, contamination, and/or deleterious change is minimized.

Chain of Custody (COC)

The COC on all evidence received, from the time of initial submission of evidence to the Lab system to the time of evidence return, shall be documented and retained. The official chain is the handwritten chain on the evidence packaging. The COC shall

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securely and accurately identify the individual(s) or location(s) receiving or transferring the item(s), identify the item(s) being transferred, and the chronological order and date of all transfers. It is not necessary to include and identify personal storage locations for internal evidence transfers.

When evidence is subdivided, collected, or created in the Lab (e.g., , latent print lifts, trace evidence, DNA cuttings, etc.) and preserved for future testing, these items shall be tracked through a documented COC record to the same extent that the original items of evidence are tracked. Test-fired ammunition for the purpose of database entry is not considered evidence and, therefore, does not have seal and COC requirements.

Evidence Disposition

The disposition of all evidence items received shall be communicated in the report (e.g., returned to the agency, forwarded internally or externally for additional analysis, or consumed during analysis). The report shall also reflect items collected or created and preserved for future testing. Digital images will be retained by the laboratory.

7.4.2 All evidence shall be itemized, assigned a unique item (exhibit) number, and recorded in the LIMS. The analyst initially entering evidence for a case will be responsible for assigning evidence exhibit numbers for the entire submission. Analysts shall log the evidence into the LIMS and check previous submittals to ensure the exhibit number is unique. When possible, the item number will be the same as the item number given by the submitting party.

If a single item or group of items is subdivided, meaning an item(s) originally designated as a single item is/are subsequently assigned unique identifiers, the unique sub-item number(s) shall be the original number followed by a period and a sequential number, starting from 1, or the original number followed by a letter starting from A (e.g., NW1 split into two would be NW-1.1 and NW-1.2, or NW-1A and NW-1B). A parent item may also retain the original designator while an item(s) within, taken from, or collected from it is given a sub-item number. For example, a gun and ejected cartridge or a wallet containing money could be labeled as NW-1 and NW-1A.

The item identifier shall be consistent and retained throughout the life of the evidence item and is used during evidence transfers to, within, and from the Laboratory. Reference to the item shall be consistent in the report and other documentation.

7.4.2.1 All evidence items received, including those not tested, are identified using the LIMS.

7.4.3 Upon receipt of the test item, abnormalities or departures from specified conditions, as described above or in analytical methods, shall be recorded. When there is doubt as to the suitability of an item for testing, when an item does not conform to the description provided on the Evidence Processing Request form, or when the test required is not specified in sufficient detail, the lab shall consult the customer for further instructions. This consultation shall occur prior to proceeding and the results shall be documented in the case record.

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If the customer requests that evidence be tested, despite the deviation(s) from specified conditions, a disclaimer shall be included in the report that clearly indicates which results may be affected by the deviation.

- 7.4.4 If evidence must be stored under specified environmental conditions, those conditions shall be maintained, monitored, and recorded. Discipline analytical methods shall specify any conditions and requirements. Records shall be retained in the relevant discipline.

7.5 Technical records

- 7.5.1 Technical records shall include the results, a report, and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated uncertainty and to enable the lab activity to be repeated under conditions as close as possible to the original. Records of observations shall adequately document the basis for any findings concerning evidence analyzed and tests performed.

Examination records shall include the date and identity of the Lab staff responsible for each aspect of the case (e.g., sampling, performing tests, checking data and results). Minimally, the start and end dates of the analysis shall be documented. The start date is the date analysis or evidence examination begins. The submission of the case record for technical and/or administrative review shall denote the end date, unless noted otherwise.

Original observations, data, and calculations shall be recorded at the time they are made and shall be identifiable to a specific task. The analyst's name, initials, or signature (handwritten or secure electronic) and the unique Lab case identifier shall be present on every page of the case examination records. When examination records are prepared by an individual other than the analyst who interprets the findings, prepares the test report, and/or testifies concerning the records, the preparing individual's name, initials, or signature shall be on the page(s) of examination records representing his/her work.

- 7.5.1.1 The case record shall consist of all examination and administrative records. The beginning page of the examination record shall indicate the total number of pages (e.g., page 1 of 5). All records, received or generated by the Forensic Lab, for a specific case, shall be identified by the unique Lab case identifier. The Lab case identifier shall be present on all data generated when data from multiple cases is recorded on a single printout.

The following are examples of documents that are maintained, when applicable:

Administrative documentation

- Evidence Processing Request form
- evidence inventory and description
- communication logs
- analysis report
- documentation of technical and administrative review
- discovery request
- quality incidents or preventative/corrective actions
- administrative documents from the customer (e.g., search warrants)

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Examination documentation

- raw data
- photographs
- worksheets
- case associated notes
- analysis notes
- graphs and chromatograms
- standards and controls
- other documents produced and used to reach a conclusion

7.5.1.2 Definitions of abbreviations, acronyms, and/or symbols commonly used in examination records by Lab personnel is retained in the quality records; those that are universally recognized (e.g., etc., USA, %) need not be included.

7.5.1.3 Examination records to support reported results, opinions, and interpretations shall be such that in the absence of the original analyst, another competent reviewer could evaluate what was done and interpret the data. When instrumental analysis is performed, operating parameters shall be recorded.

7.5.1.4 Examination records prepared by Lab staff shall be of a permanent nature. Hand written notes and observations should be legible and in ink. Pencil may be appropriate for crime scene notes, diagrams or tracings, or when environmental conditions prevent the use of ink. While original notes may be recopied, all original notes must be maintained as a permanent component of the case record unless a legible and accurate copy is captured electronically.

7.5.1.5 When an observation, data, or result is rejected, the reason for the rejection, the identity of the individual(s) rejecting the result or observation, and the date shall be recorded in the case record.

7.5.1.6 The Forensic Lab is not a calibration laboratory.

7.5.2 Changes or alterations made to hardcopy examination records shall be initialed by the person making the change. Mistakes are not erased, made illegible, or deleted. When striking out information in a case record, a single line is drawn through the error and initialed; a correction may be entered alongside, if appropriate. Changes made to completed examination records generated and/or maintained in an electronic form shall be tracked through LIMS. Examination records shall be considered completed prior to technical or administrative review. Changes and alterations after the review process has started must be dated and initialed.

7.6 Evaluation of measurement uncertainty

7.6.1 Where required, disciplines shall identify contributions to, estimate, and report measurement uncertainty. When estimating the measurement uncertainty, all uncertainty components which are of significance in the given situation, including those arising from sampling, shall be taken into account using appropriate methods of analysis. Sources contributing to the uncertainty include, but are not necessarily limited to, the reference

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standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

7.6.1.1 Affected discipline analytical methods shall have and apply a procedure for estimating measurement uncertainty when required for interpretation of the test result (e.g., controlled substance weight). The procedure shall:

- require the specific measuring device or instrument used for a reported test result to be included in or evaluated against the estimation of measurement uncertainty for that test method;
- include the process of rounding the expanded uncertainty;
- require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and
- specify the schedule to review and/or recalculate the measurement uncertainty.

7.6.2 The Forensic Lab is not a calibration laboratory.

7.6.3 When the nature of the test method prohibits rigorous, metrological, and statistically valid calculation of measurement uncertainty, the affected discipline shall attempt to identify the components of uncertainty and make a reasonable estimation. Estimation shall be based on knowledge of the performance of the method (theoretical principles or practical experience), the measurement scope, validation data, and any significant factors that may affect the measurement result.

7.6.3.1 Measurement uncertainty shall be evaluated, or estimated when applicable, for all reported quantitative results.

7.6.4 Disciplines must maintain records of their measurement uncertainty estimations. These records shall include:

- a statement defining the measurand;
- a statement of how traceability is established for the measurement;
- the equipment used (e.g., measuring device or instrument);
- all uncertainty components considered;
- all uncertainty components of significance, including those that arise from sampling, and how they were evaluated;
- data used to estimate repeatability, intermediate precision, and/or reproducibility;
- all calculations performed; and
- 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 Monitoring Tests Performed

The Forensic Lab shall use a variety of quality control procedures for monitoring the validity of tests performed. Discipline analytical methods shall specify the appropriate procedures, controls, and standards for monitoring. The selected methods should be appropriate for the type and volume of the work performed. Monitoring data shall be

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recorded so that trends are detectable and, when practical, statistical techniques can be applied to the review of these results.

This monitoring shall be planned, recorded, and reviewed and shall include, where appropriate, but not be limited to, the following:

- use of certified and/or internally generated reference materials and reference collections;
- use of positive and negative controls;
- use of alternative instrumentation that has been calibrated to provide traceable results;
- functional check(s) of measuring and testing equipment;
- use of check or working standards with control charts, where applicable;
- intermediate checks on measuring equipment;
- replicate tests using the same or different methods;
- retesting of retained items;
- correlation of results for different characteristics of an item;
- review of reported results; and
- participation in proficiency test programs and intralaboratory comparisons.

Verification

Disciplines, such as latent examinations, that make conclusions based on comparisons shall have a verification performed when the conclusion results in a significant association. This shall be defined in the discipline analytical method. Verification of results shall be conducted by an individual who is currently authorized to perform the testing. The verification shall be recorded and identify who performed the verification, when it was performed, and the result. If the conclusion is not agreed upon, the conclusion shall move to a less finite opinion (e.g., A latent is concluded to be excluded; the verifier does not agree so the reported conclusion is inconclusive.). This discussion and the resolution of any discrepancy shall be clearly documented in the case record.

Technical review of examination records and reports

The reviewer is responsible for ensuring that established policies and procedures have been followed and that conclusions reached are accurate (i.e., reasonable and supported by the examination documentation) and properly qualified.

The following shall be followed for technical review:

- Reviews shall be conducted by authorized individuals that have been competency tested to perform the work being reviewed.
- Technical reviews shall not be conducted by the author or co-author(s) of the examination records or test report under review.
- Disciplines with at least two trained and authorized analysts shall perform 100% technical review prior to the release of a report. For disciplines without two trained and authorized analysts, at least 10% of cases shall be technically reviewed.
- Ensure the following, at a minimum:
 - conformance with proper technical methods and applicable laboratory policies and procedures;
 - the requested service(s) has been met or, if not, the customer was informed;

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- that test parameters (e.g., instrument operating parameters) were appropriate for the examination;
- deviations from established procedures associated with the case file are maintained as part of the numbered pages of the examination documentation;
- standards and controls were appropriate for the procedure(s) and documented in the case record;
- results, interpretations, conclusions, and opinions are communicated accurately, clearly, and unambiguously, and are supported by the examination documentation;
- conclusions and associations are properly qualified in the report and supported by the technical record, where necessary or required; and
- that the report contains all required information.

Administrative Review

Administrative reviews are generally performed with the technical review. While it is preferred that administrative review be performed by a qualified technical reviewer, it may be performed by any analyst or supervisor. Administrative review is the final review of the case record and report prior to being released to the customer. Administrative review is performed for all requests and by someone other than the author of the report.

At a minimum, the administrative review shall include:

- a review of the test report for spelling and grammatical accuracy;
- a review of all administrative and examination records to ensure that they are uniquely identified according to laboratory policy and/or analytical methods; and
- a review of the test report to ensure that all key information is included.

Record of the technical and administrative review is documented in the LIMS. This indicates that the conclusion has been checked and agreed to, by whom, and when. All changes made to administrative and technical records as a result of verification, technical review, or administrative review shall be tracked in the case record/LIMS.

When an area of concern is identified that cannot be resolved between the analyst and the reviewer, a mutually agreed to third individual shall be consulted for resolution. This individual shall preferably be the discipline technical lead or another analyst that performs technical review in the discipline. Documentation of the individuals involved and the outcome shall be included in the case file. An analyst shall not be forced to report or testify to a conclusion they do not agree with.

Technical review of testimony

Court testimony shall be reviewed to monitor performance of each analyst that testifies during the calendar year. Annually, as available and appropriate, one individual from each Lab discipline shall undergo a technical review of testimony. Technical review may be accomplished by direct observation, transcript, video, or audio review. The individual performing the technical review must have been competency tested in the tasks related to the testimony subject. Non-technical reviews may be solicited from an officer of the court, an attending detective, or another Forensic Scientist. Feedback, both positive and that needing improvement, shall be provided to the testifying analyst. The Testimony Review

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Form shall be completed and signed by the witness and reviewer. If the feedback is less than satisfactory, the Supervisor and/or appropriate discipline Technical Lead will act to remediate the issue (e.g., communications training, remedial technical training, or review of analytical methods). If qualified staff do not have an opportunity to testify during a calendar year, or testifies without monitoring, as described, the discipline Technical Lead or Lab Manager shall provide documentation of the occurrence and reason(s) to the Quality Manager. Testimony records are retained in the quality records.

7.7.2 The Forensic Lab shall monitor its performance by comparison with results from other laboratories, where available and appropriate. This shall be a planned activity, which includes participation in proficiency testing and/or other interlaboratory comparisons. The proficiency program is a means of verifying that technical procedures are valid and that the quality of each analyst's work is maintained. Analysts are monitored to the extent of their casework authorizations. The Lab Manager or Quality Manager will coordinate the ordering of proficiency tests for the Laboratory.

7.7.2.1 The Forensic Lab shall successfully complete at least one external proficiency test per year for each discipline in which it holds or seeks accreditation, if one is available. Results shall be authorized for release to ANAB from the test provider.

7.7.3 Data from monitoring activities shall be analyzed, used to control, and, if applicable, improve Lab activities. Where results or data from monitoring activities are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. The criteria are included in the appropriate analytical methods.

7.7.4 Each analyst engaged in testing activities shall successfully complete at least one proficiency test, interlaboratory comparison, or intralaboratory comparison per calendar year in each forensic discipline on the Scope of Accreditation in which they perform casework, to the extent which they are authorized. Monitoring should be varied over time to cover all aspects of assigned job functions, but does not have to include all aspects of the work performed each time. Within an accreditation cycle, each analyst should be monitored to assess all aspects of assigned job functions. Those who perform limited tasks which may influence results (e.g., verification, review) shall also be monitored. A competency test may take the place of a proficiency test during the first calendar year that an analyst is authorized to conduct casework. Observation-based monitoring may be used to monitor performance if the options above are not available or are inappropriate. If an individual misses their annual monitoring they shall successfully complete a competency test, proficiency test, or another approved qualifying test prior to resuming independent casework.

7.7.5 Staff are aware they are participating in performance monitoring, but results are not made available to the analyst until after submission. Results shall not be viewed by or otherwise shared with other analysts participating in the same examination. This includes performance of verification or review prior to completion and submission of results.

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The test taker is responsible to complete assigned tests as they would normal casework (i.e., log into LIMS, itemize evidence, produce case records, and a formal report) within listed timelines and following all provided instructions. When completing proficiency or other monitoring tests, analysts shall follow approved technical procedures and utilize the same test methods, verification, and review procedures as are normally applied to casework. Any instructions regarding exceptions to working like normal casework will be indicated in test instructions. If the assigned analyst is unable to work the test as they would normal casework, they shall document the reason(s) in the case notes.

Documentation for performance monitoring shall include, but is not limited to, the following:

- a unique test or LIMS request number;
- how samples were obtained or created and the expected response(s);
- identity of the test taker;
- dates of analysis and completion;
- proficiency test results (e.g., copy of the proficiency test case report);
- any discrepancies noted;
- an indication that the test has been reviewed;
- details of Corrective or Preventive Actions taken, when necessary; and
- all data supporting the conclusions.

Each participant is responsible for submitting the test results to the test provider by the assigned due date. The test taker will be notified of the results via email.

Internally prepared comparison tests or observation-based monitoring shall be made to minimize contamination and ensure quality. This can be accomplished by using clean new materials (sterilized swabs, newly purchased cloth in packaging) and/or using known reference material that has been checked. The quality of the test will be documented as part of the case record.

Proficiency tests and other performance monitoring is evaluated both in terms of conformance to the expected results and the quality of supporting documentation. Results must be consistent with the result(s) reported by the provider. Discrepancies between reported and expected results shall be evaluated by the discipline Technical Lead and Quality Manager or Lab Manager to determine if the results are consistent with Lab policies and procedures. If discrepancies are significant (e.g., erroneous identification or false-positive finding), the test is deemed unsatisfactory and corrective action is initiated. Corrective actions may also be implemented for less significant issues (e.g., missed identification or false-negative finding). Monitoring is successfully completed by either obtaining the expected results, completing appropriate corrective actions, or documenting why an inconsistent result does not necessitate subsequent action.

7.7.6 The Quality Manager shall maintain a plan for the current accreditation cycle to ensure annual completion of required discipline proficiency tests and appropriate monitoring of personnel who perform testing. The plan shall ensure that the minimum tests assigned to personnel represent the types of tests, components/parameters, and equipment/technologies routinely encountered in each discipline listed on the Scope of Accreditation.

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7.7.7 Approved proficiency test providers, those that operate in accordance with the ISO/IEC 17043 standard, shall be used when available and appropriate to ensure the quality of the test. If an approved provider is not available, the Lab shall obtain documented approval from ANAB, via the Alternative Proficiency Test Request Form (FM 3041), prior to utilizing an alternate test provider or an alternate method of monitoring (e.g. intralaboratory comparison or observation-based monitoring). Proficiency test results shall be submitted on or before the due date established by the provider. Any exceptions will be documented.

7.7.8 Proficiency test, interlaboratory comparison, intralaboratory comparison, or observation-based testing records shall include, but is not limited to, the following:

- discipline(s) monitored;
- design of the monitoring activity;
- expected results;
- records submitted to a proficiency test provider, when applicable;
- appropriate technical records;
- evaluation of results and action taken for unexpected results; and
- feedback on individual performance provided to the participant

All proficiency test documentation is maintained in the LIMS and/or quality records.

7.8 Reporting of results

7.8.1 General

7.8.1.1 Analysts are responsible for preparing accurate, complete, and organized technical records and reports. The results shall be reviewed and authorized by the analyst prior to release.

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

7.8.1.2 The results of each test or series of tests carried out by the Laboratory shall be reported accurately, clearly, unambiguously, and objectively. Results are typically conveyed in a test report, and shall include all information per the customer agreement, and necessary for the interpretation of the test results, and all information required by the analytical method used. All issued reports shall be retained as technical records and are readily available in the LIMS.

7.8.1.2.1 The results shall be released in a written report, electronically or hard copy, following technical and/or administrative review. The report shall only be released to the prosecutor's office with jurisdiction and/or the submitting agency. Results may be released to other entities through discovery, court order, and/or public records requests.

Preliminary results may be provided to the customer prior to technical and/or administrative review, either verbally or via email, by the authorizer of the results prior to completing the written report (See 7.8.1.3).

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7.8.1.2.2 Discipline analytical methods shall include a procedure for reporting results that requires the following:

- Identification of what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for all work performed (partial and complete). This does not apply to the receipt of known individual characteristic database samples. No laboratory report is required if a request for testing is cancelled by the customer or responsible prosecutor's office prior to examination.
- The significance of an association to be clearly communicated and properly qualified, whether by a statistic or qualitative statement. Associations for multiple results may be qualified by a single statistic or qualitative statement if the statistics are identical or, where applicable, meet or exceed a defined minimum threshold.
- Clear communication of the reason(s) when no definitive conclusion can be reached (i.e., the reported results are inconclusive).
- Reporting of initial database entries (e.g., AFIS) and association(s) resulting from a database search.

7.8.1.2.3 The Forensic Lab does not perform calibration services.

7.8.1.3 Results may be reported in a simplified way and preliminary results may be given prior to technical and/or administrative review when there is a written agreement with the customer. Any information listed below in 7.8.2 to 7.8.7 that is not reported shall be readily available in the case record.

When there is an agreement established with the customer for reporting in a simplified manner, the agreement shall specify which information in 7.8.2 through 7.8.7 will not be included in the written report or available through electronic access. Requirements in ISO/IEC 17025:2017 7.8.2 through 7.8.7 are applicable even if results are reported in a simplified way.

When necessary, preliminary results may be reported to the customer; however, the analyst shall clearly indicate that the information is preliminary in nature, is subject to change, and that it requires technical and administrative review. The analyst documents in case notes and/or LIMS a record of the release to include the information provided, the person to whom the information was provided, and when the information was provided. This shall be followed by a formal written report once the casework has been completed. The final technical reviewer shall ensure that the report is consistent with the previously released verbal or email results. If there is a discrepancy, the reporting analyst shall clearly communicate this to the customer.

7.8.2 Common requirements for reports (test or sampling)

7.8.2.1 The following must either be included on reports or in the case record if they are omitted for simplified reporting:

- A title.
- The name and address of the Laboratory.

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- All testing is performed at the Laboratory with the exception of Crime Scene Investigation, which notes the location where testing was performed in the report.
- The case number and page number(s), formatted to indicate the total number of pages (e.g., page 1 of 3 or 1/3), uniquely identify that all components are part of the complete report and the end.
- The name of the customer/requesting individual and, if external, the submitting agency and agency case number (contact information is stored in the LIMS case record).
- Identification of the method used.
- An unambiguous description of all evidence analyzed for a specific service request including the laboratory exhibit number (or other unique identifier) and, when necessary, the condition of the item.
- Reference to other items of evidence taken into the possession of the reporting analyst but not examined or analyzed.
- The date of receipt of the test items, and date of sampling, if this is critical to the validity and application of the test results. This will be defined in the discipline's analytical method, if applicable.
- The date(s) of performance of the laboratory activity.
- The report issue date, which shall be the same as or later than the date of all changes in the report.
- Reference to the sampling plan and sampling method used by the laboratory or other bodies, where these are relevant to the validity or application of the results;
- A statement to the effect that the results relate only to the items tested or sampled.
- The results with, where appropriate, the units of measurement.
- Additions to, deviations, or exclusions from the method.
- Signature block with signature (may be digital) and title of person authorizing the test report.
- Clear identification of any test results that were generated by external providers/subcontractors.
- Disposition of evidence. Including reference to further work to be performed by other disciplines or laboratories.

Any information not specified above, but pertaining to the case and the tests performed shall be maintained in the case record, as it is not possible to include all the case related information in a report. Reference to previous laboratory reports may be included at the discretion of the reporting analyst.

7.8.2.2 Reports shall be issued with the title of the testing conducted. The format is designed to minimize the possibility of misunderstanding or misuse. The Lab is responsible for all information provided in its reports, except for information provided by the customer (e.g., names, agency case numbers, etc.). Customer provided data that is included in the report shall be clearly identified. A disclaimer shall be added to the report when customer supplied data regarding evidence items (e.g., weights or volumes) can affect the validity of results. Where the Lab is not responsible for sampling the evidence, the report shall state the results apply to the sample as it was received.

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7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:

- information on specific test conditions (e.g., environmental).
- a statement of conformity with requirements or specifications (where relevant, see 7.8.6).
- where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when it is relevant to the validity or application of the test results, the customer requests the information, or when the measurement uncertainty affects conformity to a specification limit.

The measurement uncertainty shall:

- be included in the report or an annex to the report when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement;
 - include the measured quantity value, y , along with the associated expanded uncertainty, U , and the coverage probability;
 - be in the format of $y \pm U$, as appropriate;
 - be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and
 - be reported to the same level of significance (*i.e.*, same number of decimal places or digits) as the measurement result.
- opinions and interpretations, where appropriate (see 7.8.7).
 - additional information that may be required by specific methods or customers.

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

7.8.3.2 When the Lab is responsible for sampling, the test report shall be in accordance with the requirements in section 7.8.5 where necessary for the interpretation of the test results.

7.8.4 Specific requirements for calibration certificates

The Forensic Lab does not perform calibration services.

7.8.5 Reporting sampling – specific requirements

In addition to the requirements listed in 7.8.2, when sampling is performed reports shall include the following, where necessary for the interpretation of results:

- the date of sampling;
- unique identification of the item or material sampled (e.g., name of the manufacturer, the model, and/or serial numbers, as appropriate);
- the location of sampling, including any diagrams, sketches or photographs;
- a reference to the sampling plan and method;
- if statistical sampling is used, the report shall contain the confidence level and corresponding inference regarding the population.

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- details of any environmental conditions during sampling that affect the interpretation of the results; and
- information required to evaluate measurement uncertainty for subsequent testing.

7.8.6 Reporting statements of conformity

The Laboratory does not report statements of conformity (e.g., pass/fail, in-tolerance/out-of-tolerance).

7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions or interpretations are included in test reports, they will be provided by technical staff who have completed appropriate training and are authorized to express opinions and interpretations.

7.8.7.2 When opinions and interpretations are included in a report, the Forensic Lab shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report. Inconclusive results shall be qualified, including a qualifying statement describing why no conclusions can be drawn.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained in the case record.

7.8.8 Amendments to reports

7.8.8.1 When a previously issued report requires amendment to correct errors, make an addition to, or otherwise modify the content, the new report shall clearly communicate any information changed and, where appropriate, the reason for the change(s).

Communication of changes is generally accomplished with a readily apparent statement at the beginning of the report (e.g., "This report has been amended to correct the previously reported agency case number. All results and conclusions remain the same."). To highlight information changed, corrected or new text may be displayed in a different font (e.g., bold, italics) and removal of content can be indicated with a strike-out.

Amendments to issued reports shall be brought to the attention of the discipline technical lead and/or management, as appropriate. Initiation of quality investigation or corrective action is at the discretion of management.

7.8.8.2 Amendment to a report after issue shall be made in the form of a new report. Amended reports shall meet all reporting criteria and the title shall include the word "Amended".

7.8.8.3 A statement inserted at the beginning of the Amended Report shall reference the original report (e.g., "Refer to the Original Report dated 01/01/19"). This statement should be readily apparent to the reader (e.g., bold-lettered) and may be combined with the statement regarding changes made. The new report shall be technically

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and/or administratively reviewed, as appropriate. Documentation of the review shall be attached to the LIMS case file. The original report shall be left in the case record, watermarked to indicate that it has been amended, and titled to indicate that it is the original report and not for release.

7.9 Complaints

- 7.9.1 The Forensic Lab considers complaints as opportunities to evaluate the Laboratory services and management system with the possibility of improvement. All complaints received from an employee, customer, or other parties shall be investigated and documented regardless of the severity of the concern. Any Laboratory staff that become aware of a complaint shall notify the Lab Manager as soon as practicable. Complaints are generally handled by the Forensic Lab Manager. Complaints regarding serious issues that may be illegal, immoral, or unethical are addressed according to ASCO policies and procedures.
- 7.9.2 Upon receipt of a complaint, the Lab shall confirm whether it relates to laboratory activities that it is responsible for and, if so, must document actions taken to address the original complaint. Staff members receiving a complaint may resolve the complaint, if it is within their responsibility, but must document the occurrence and notify the Lab Manager. Lab management has the responsibility to ensure that complaints are resolved appropriately and is responsible for all decisions at all levels of the handling process. A description of the handling process shall be available upon request.
- 7.9.3 Complaints shall be documented by the recipient and/or directed to the Lab Manager for evaluation. Documentation should fully describe the complaint and include the name and contact information of the complainant. Upon receipt, complaints are reviewed and investigated to determine the appropriate decisions and actions needed to resolve the complaint.
- The Lab Manager tracks and records complaints. Documentation shall include, at a minimum, the original complaint, facts of the investigation, any action taken to remedy and improve, and communications. These records are maintained in the case record, quality records, and/or Lab Manager's records, as appropriate. Review by an appropriate Lab staff member and/or follow-up with the complainant may be sought in order to determine whether actions taken are appropriate for resolving the initial concern. The complaint investigation and resolution shall not result in any discriminatory actions.
- 7.9.4 The Laboratory is responsible for gathering and verifying necessary information to validate the complaint.
- 7.9.5 Whenever possible, the complainant is notified that the Laboratory received the complaint and is updated with relevant progress reports and the outcome.
- 7.9.6 The final resolution to be communicated to the complainant shall be made by, or reviewed and approved by, an individual(s) not involved in the activities in question, including external personnel.

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7.9.7 Whenever possible, the complainant shall be formally notified when the complaint handling is determined to be complete.

7.10 Nonconforming work

7.10.1 Crime scene or laboratory activities that do not conform to the management system or agreed customer requirements constitute nonconforming work. This includes mistakes or unapproved departures from approved procedures. Nonconforming work may be identified through a variety of activities, including but not limited to, case review, internal audits, assessments, management reviews, proficiency testing, testimony evaluation, etc.

All Laboratory staff have the authority to suspend casework, discontinue the use of specific methods, or take an instrument out of service within their area of responsibility. Any staff member involved in or aware of nonconforming work issues shall report the concern to the Quality Manager and/or Lab Manager as soon as practicable. The discipline Technical Lead should also be notified if the incident involves nonconforming testing or an unapproved departure from a discipline-specific technical procedure. The Lab Manager and Quality Manager have the authority to regulate analytical operations (e.g., halt or repeat work, withhold reports, etc.) for an analyst, a discipline, or the laboratory at any time, and shall authorize the resumption of work, if ceased, after consultation with the discipline Technical Lead.

Actions taken are based upon the assessed risk level (i.e., the impact and likelihood to recur). Unless a single occurrence significantly impacts the quality or reliability of the services or test results, it is generally handled as a quality incident. The risk assessment shall be discussed and justified in the nonconformance evaluation/action plan.

The Quality Manager is responsible for the overall management of nonconforming work and shall determine if it will be tracked as no action needed, a quality incident, or corrective action (Sections 8.7). The Lab Manager, Technical Leads, and/or appropriate technical staff may be involved to ensure accurate reporting, to decide the acceptability of the nonconforming work, and to ensure that it is resolved appropriately.

7.10.2 The Laboratory retains records of nonconforming work and actions in the LIMS and/or quality records.

7.10.3 Where evaluation indicates that the nonconforming work is likely to recur, or that there is doubt about the Laboratory's compliance with its own management system, corrective actions (Section 8.7) shall be implemented.

7.11 Control of data and information management

7.11.1 Laboratory staff shall have access to the data and information needed to perform laboratory activities.

7.11.2 ACSO uses commercially available off-the-shelf LIMS software that is used within the designed application range for the acquisition, processing, recording, reporting, storage, or retrieval of data.

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7.11.2.1 The Laboratory does not develop its own software.

7.11.3 The laboratory information system(s) shall:

- Be protected from unauthorized access;
- Be safeguarded against tampering and loss;
- Be operated in an environment that complies with provider or laboratory specifications;
- Be maintained in a manner that ensures the integrity of the data and information; and
- Include recording systems failures and the appropriate immediate and corrective actions.

7.11.4 The LIMS system is managed and maintained by the Lab Manager in conjunction with an offsite vendor. System operators shall comply with all applicable requirements of this document.

7.11.5 The relevant instruction materials, manuals, and reference data regarding the LIMS are retained in and available to all staff through the LIMS.

7.11.6 Manual calculations and data transfers that are relevant to examinations and are subject to human error shall be subject to appropriate checks in a systematic manner, which is included as part of the technical review.

7.11.6.1 The technical review shall indicate that the check was performed and by whom.

8 Management system requirements

8.1 Options

8.1.1 General

The Forensic Lab management system is established, documented, implemented, and maintained in a manner that supports and demonstrates compliance to ISO/IEC 17025:2017 standards and ANAB supplemental requirements. The Laboratory management system is implemented in accordance with Option A.

8.1.2 Option A

The Laboratory management system addresses the following, at a minimum: management system documentation, control of management system documents, control of records, actions to address risks and opportunities, improvement, corrective actions, internal audits, and management reviews.

8.2 Management system documentation (Option A)

8.2.1 The Quality management system is designed to continually improve the level of services provided and to assure the credibility of the Forensic Lab. Laboratory management will establish, document, and maintain policies and procedures appropriate to the scope of its activities for the fulfillment of ISO/IEC 17025:2017 accreditation standards and ANAB supplemental requirements. All employees are required to familiarize themselves with the Quality Assurance Manual and implement the policies and procedures in their work.

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Laboratory policies and objectives will be communicated to, understood by, available to, and implemented by the all levels of personnel, as appropriate.

All employees shall work to continually maintain the highest degree of quality and integrity of laboratory services and to ensure that forensic conclusions are scientifically sound and valid. To this end, all laboratory analyses and related services performed by the laboratory shall meet generally recognized standards of the forensic community and its accrediting organizations.

8.2.1.1 The following words associated with ANAB accreditation requirements signify that the Forensic Lab addresses the requirement in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, and specify.

8.2.2 Laboratory policies and objectives shall address the impartiality, competence, and consistent operation to the extent necessary to assure the quality of the collection/test activities and/or results. All staff are required to familiarize themselves with the Quality Assurance Manual, Health and Safety Manual, and discipline analytical methods specific to the scope of their responsibility. Adherence to Laboratory documents helps staff to maintain expertise and analytical abilities, to promote confidence, and to conform to accreditation requirements.

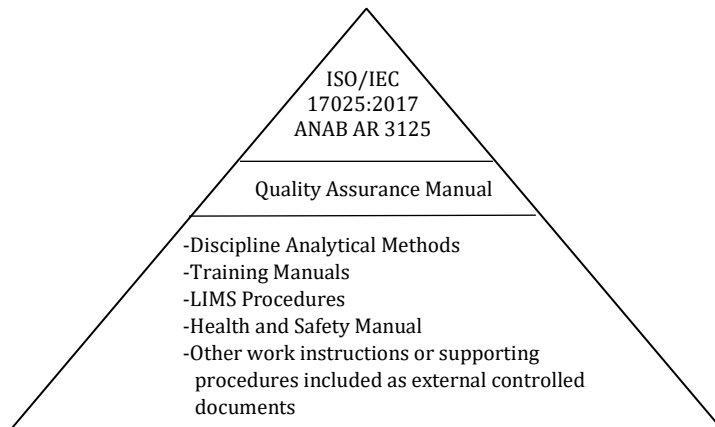
8.2.3 All Laboratory staff is committed to complying with the accreditation requirements and the policies and procedures described herein. Laboratory management shall proactively strive to continually improve the effectiveness of the quality management system through annual management review activities, at a minimum. The improvement process will be conducted as a positive learning experience. All employees are encouraged to share their experiences in order to contribute to the success of this program.

Quality management system documents are regularly reviewed and updated, as needed, to improve the effectiveness of the quality program. Changes are implemented, as appropriate, when conditions having an adverse impact on the quality management system are identified.

8.2.4 The management system documentation includes all technical and supporting procedures and records, including quality records. The documentation, procedures, and records may be used by staff to oversee and review the effectiveness of the quality program in order to ensure adherence to Laboratory policies and procedures and conformance to accreditation requirements. The technical and supporting policies and procedures utilized in the management system are structured as outlined on the following page.

The Forensic Quality Assurance Program is comprised of the Laboratory Quality Assurance Manual, discipline analytical methods and training manuals, and Health and Safety Manual. Each document is intended to work in conjunction with the others, but should a conflict arise, the standards in this manual will supersede those of the individual disciplines unless the discipline requirements are more restrictive than those in this manual. Discipline-specific manuals shall not be less stringent than this manual.

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8.2.5 All employees have access to the parts of the management system documentation applicable to their duties and responsibilities. These documents are readily available electronically via the network drive. Additional quality management system documents (worksheets, log forms, technical review forms, instrumentation manuals, etc.) are available electronically or in hard copy form. The Lab Manager, Quality Manager, and discipline Technical Leads typically have the authority to approve and/or revise Forensic quality assurance documentation. Specific authorizations can be found in the quality records.

8.3 Control of management system documents (Option A)

8.3.1 Documents that are part of the Forensic Lab management system shall be controlled to ensure that they are adequate, approved for use, and that only current versions of the documents are in use. These documents contain administrative, technical, and quality policies and may be internally generated or from external sources.

Examples include, but are not limited to, the following:

- Discipline training manuals and analytical methods
- Accreditation standards and requirements
- Controlled memoranda
- Quality Assurance Manual
-

8.3.2 Prior to issue, documents supplied to Lab personnel as part of the management system shall be reviewed and approved for use by authorized personnel. Prior to approval, documents shall be distributed to appropriate Lab staff with adequate time for review and comments. A list of approved management system documents is maintained and readily available to all lab staff.

Documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements. This includes a review of the management system documents, at least once during the accreditation cycle, to ensure that documents are current and relevant.

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During the draft stage of document revision, changes or new text shall be identified in the document through highlighted text, track changes, or some other equivalent and communicated method. After revision, a history section at the end of the document will identify updates. The history section will briefly describe the section(s) altered and changes made. Comparison of archived to current documents will serve as thorough documentation of changes.

Amendment of documents by hand shall not be permitted. If it is necessary to immediately update a portion of a controlled document the review and comment portion may be a short time period with limited personnel. However, a review must be performed and all affected personnel must be notified of the changes.

Authorized versions of management system documents are available to all staff electronically. Current versions are maintained on the county secure computer network that has limited accessibility. All lab staff have the capability to access the controlled documents both in the lab and in the field.

Management system documents generated by the lab shall be uniquely identified. Identification shall include: the document title, revision number, date of issue, approving authority, page numbering, and a history chart, which also indicates the end of the document.

Internally controlled documents that are no longer in use are electronically watermarked as obsolete and archived in the quality records. It is the responsibility of the Lab staff to ensure that any printed versions of manuals are current or marked obsolete.

8.4 Control of records (Option A)

8.4.1 The Laboratory shall keep legible quality and technical records that demonstrate compliance with the standards and requirements of the accreditation program. Records shall be stored and retained in such a way that they are readily retrievable.

Quality records provide documented support of the conformity of the quality management system. The records shall include, but are not limited to, the following (where applicable):

- reports from internal audits
- management reviews
- corrective and preventive actions
- logs
- worksheets
- electronic files
- databases
- method and equipment validation documents
- equipment verification records
- reagent and chemical QC logs
- training records
- proficiency and competency test records
- courtroom testimony monitoring records

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- chemical inventory records
- continuing education records
- reference collection records
- case file records

8.4.2 Records shall be stored in an environment suitable to prevent damage, deterioration, and loss. All records shall be held secure and in confidence. Forensic Lab staff has access to quality system records necessary to perform their job functions. Quality documentation that is digitally stored is saved on Ada County's secure server which is backed up daily.

Original technical notes and reports are digitally stored on the Laboratory Information Management System (LIMS) that backs up to a secure cloud. Access to LIMS is limited to lab personnel and is password protected. LIMS retains a history of all reports accessed and limits alterations with controlled access. LIMS is both password protected and has user restrictions.

All communications that form the basis for decisions in casework must be documented in the case record. These communications may include, but are not limited to, communications with the agency, the Prosecuting Attorney, another Forensic Lab staff member, or any combination thereof. The date, the individual(s) with whom the communication took place, and the conversation (in substance) will be documented.

At a minimum, the records will be retained for a period of five years. Otherwise, retention of technical and quality records is guided by the Ada County Policy for record retention. Disposal of records may occur at any time after the retention schedule has been met. Disposal may be by any means that render the records unreadable (e.g., shredding or burning). Internally controlled documents are archived in the quality records when no longer in use.

8.5 Actions to address risks and opportunities (Option A)

8.5.1 Risks and opportunities are identified through management system activities in order to continuously improve the effectiveness of the quality management system. This may include, but is not limited to, assessment of policies, quality objectives, audit/assessment results, data analysis, preventative/corrective actions, personnel training programs, case record and testimony reviews, proficiency testing, and customer feedback.

The Laboratory shall consider and evaluate risks and opportunities associated with crime scene and laboratory activities in order to: give assurance that the management system achieves its intended results; enhance opportunities to achieve the Laboratory objectives and fulfill its purpose; prevent, or reduce, potential failures in order to provide continued quality work to customers; and achieve improved processes.

8.5.1.1. Risks and opportunities related to health and safety are considered by all staff and are communicated to and addressed by the Health and Safety Coordinator or Lab Manager.

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8.5.2. When risks are identified that may have a negative impact on activities or when opportunities are identified that would likely result in improvements, the Laboratory plans actions to address them and how to integrate and implement the actions into its management system. For risks associated with nonconforming work, actions shall be taken to reduce or eliminate the likelihood of recurrence. The effectiveness of the actions is evaluated through auditing and management review activities.

The preventive action process may be used to document the plan, integration, implementation, and assessment of actions. Documentation of preventive actions shall include the initiation of the action and the application of controls to ensure effectiveness.

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of testing/processing activities or results.

8.6 Improvement (Option A)

8.6.1 The Forensic Lab shall continually improve the effectiveness of its management system by identifying areas of needed improvement. Improvement opportunities may be identified through a variety of activities including, but not limited to, management review, corrective and preventive actions, risk assessment, internal audits and external assessments, reviewing technical procedures, proficiency tests, and suggestions from personnel.

Suggestions for improvement opportunities shall be solicited during the management review, but may be communicated to the appropriate staff at any time. These opportunities are evaluated to determine if their implementation will improve efficiency and effectiveness.

Preventive actions are opportunities for improvement. It is a proactive process to institute improvements rather than a reaction to identified problems or complaints. Personnel are encouraged to identify needed improvements and potential sources of nonconformities, either technical or concerning the management system.

Opportunities for improvement should be brought to the attention of the Lab Manager, Quality Manager, or appropriate Technical Lead who shall evaluate the suggestion and work with the submitting individual to develop a preventive action plan. Actions most likely to reduce the chance of nonconformities and/or to take advantage of opportunities for improvement shall be selected and implemented. The Preventative Action Report shall be used for documentation.

Changes to Laboratory policies and procedures resulting from preventive actions shall be documented in the appropriate manual(s). Dependent upon the impact of these preventive actions, they may be communicated to laboratory employees by email, memorandum, etc. for immediate implementation prior to manual changes. Upon completion, the Quality Manager shall close the Preventative Action Report and, if needed, specify a date to evaluate the effectiveness of the action(s). At a minimum, the effectiveness shall be evaluated during the yearly management review.

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8.6.2 The Laboratory shall seek feedback from customers through an annual customer satisfaction survey. Additional feedback may be received through formal and informal mechanisms, including but not limited to testimony evaluation, meetings, conversation, complaints, and other written or oral communications. The Lab Manager will review and evaluate all responses. The feedback shall be documented, analyzed, and used to improve the management system, collection and testing activities, and customer service.

8.7 Corrective actions and quality incidents (Option A)

8.7.1 Corrective actions and quality incidents are categorized based on the nature of the nonconforming work (Section 7.10) to include, but not limited to, the following: likelihood to recur, doubt about compliance with Laboratory policies and procedures, the reliability of test result(s) is in question, or the potential that erroneous/invalid results have been reported. The analyst(s) involved in the incident shall be notified as soon as practicable, if either process is initiated. When the issue involves multiple employees, the Lab Manager should be consulted.

The Quality Manager, Lab Manager, or responsible Technical Lead will initiate documentation of the process. Documentation shall be sufficient to describe the quality concern and impact assessment, and should include the following whenever possible: case number(s) involved, date(s) of occurrence, any indication of systemic quality concerns, and subsequent action(s) taken.

Nonconforming work that is determined to have no risk to or impact on the quality of the work product, may not require action. Quality Incident forms are used to document nonconforming work with limited or no impact on the work product. Determination of the root cause is not required.

Corrective Actions Reports are used to address nonconforming work that is determined to have a significant impact on the quality of the work product. The process shall start with an investigation to determine the root cause(s). The objective of any root cause analysis is to analyze all relevant information and contributing factors to ensure the cause, rather than a symptom(s), of the nonconformance will be prevented from recurrence. The root cause analysis should take into consideration all possible sources of nonconforming work to include an evaluation of the methods, procedures, equipment, supplies, training, work environment, customer agency needs, etc. Documentation shall also include an anticipated timeline for completion of each action and the date when each action is completed.

If needed, select and implement actions most likely to correct, eliminate, and/or prevent recurrence of the problem. Actions shall be to a degree appropriate to the magnitude and the risk of the problem. Actions shall also be taken to address the consequence of the nonconforming work, including, but not limited to, issuing amended reports, notifying customers, and notifying ANAB, if appropriate. The Quality Manager, Lab Manager, and/or discipline Technical Lead generally determines the appropriate corrective action.

Changes to lab policies and procedures resulting from corrective actions will be documented in the appropriate manual(s). Dependent upon the impact of these corrective

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actions, they may be communicated to lab employees by e-mail, memorandum, etc. to allow for immediate implementation prior to actual manual changes.

Where nonconformities cast doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with accreditation requirements, the Laboratory shall audit the appropriate area(s) of activity as soon as practicable. An additional audit should be necessary only when a serious issue or risk to the management system or agency is identified.

When an analyst has been removed from casework, or when required by the corrective action plan, a competency or proficiency test will be issued prior to resuming casework duties. After completion, the Lab Manager or Quality Manager shall authorize the return to the job function.

The Quality Incident or Corrective Action Report form shall be closed by the Quality Manager; it and any supporting documentation shall be retained in the quality records.

It is the responsibility of the Quality Manager, with assistance from the Lab Manager and/or Technical Leads, to verify and monitor the effectiveness and implementation of the corrective action taken. The Quality Manager may specify follow-up action and/or a timeframe to confirm the effectiveness of the corrective action(s) taken. This may involve review of casework or audit of the discipline or activity. At a minimum, the effectiveness shall be evaluated during the yearly management review.

8.7.2 Implemented corrective actions shall be appropriate to the magnitude and risk of the concern.

8.7.3 The corrective action process shall be documented on the Corrective Action Report form. Corrective action records are maintained by the Quality Manager and stored in the quality records.

8.8 Internal audits (Option A)

8.8.1 The Laboratory shall conduct internal audits to ensure that the management system is effectively implemented and maintained, and that it conforms to current internal policies and procedures, accreditation standards, and supplementary requirements.

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

8.8.2 The internal audit shall be planned by the Quality Manager and completed by trained and qualified staff that are, if possible, independent of the section being audited. The audit will include direct observation of a sample of accredited services within each discipline. Checklists or other records shall be produced by the internal auditors; objective evidence for any finding or nonconformance will be provided. The Quality Manager shall prepare a summary report of the internal audit that includes, at a minimum, the scope of the audit, audit findings, and any resulting corrective actions. The audit summary shall be reviewed by the Lab Manager.

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When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the test results, the Laboratory shall take timely corrective action, and shall notify the customers in writing if investigations show that the Laboratory results may have been affected. Follow up audit activities shall verify and document the implementation and effectiveness of the corrective action taken. Records of internal audits shall be retained in the quality records on the network drive.

8.9 Management reviews (Option A)

8.9.1 Management shall, in conjunction with Technical Leads and any other appropriate staff, perform a documented review of the Laboratory management system and collection/testing activities to ensure their continued suitability and effectiveness.

8.9.1.1 The management review shall be conducted at least annually.

8.9.2 The review shall include, but is not limited to, the following topics:

- a) changes in internal and external issues that are relevant to the laboratory;
- b) fulfilment of objectives;
- c) suitability of policies and procedures;
- d) status of actions from previous management reviews;
- e) outcomes of recent internal audits;
- f) corrective actions;
- g) assessments by external bodies;
- h) changes in the volume and type of the 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; and
- o) other relevant factors, such as monitoring activities and training.

8.9.3 Management review documentation shall include decisions and actions related to the following:

- a) the effectiveness of the management system and its processes;
- b) improvement of the Laboratory activities related to fulfilment of ISO/IEC 17025:2017 standards and ANAB's requirements;
- c) provision of required resources; and
- d) any need for change.

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History of Quality Assurance Manual

SECTION & COMMENTS	DATE ADOPTED	AUTHOR	REVIEWER(S)
<p>4.3.2.3 changed the requirement of total # of pgs to the end of document indicated by history page</p> <p>4.4.1.1 The review of the request is documented as accepted when the case is entered into the LIMS</p> <p>4.11.1.2 deleted. This is repeated from 4.11.1.1</p> <p>4.11.1.1 added requirement of using a corrective action form which establishes a timeline for all actions and completion of the CAR</p> <p>4.13.2.6 added that signature or initial is acceptable</p> <p>5.2.5.1 added that work authorizations cover use of equipment, technical reviews, and verifications unless notes in the work authorization.</p> <p>5.4.2 deleted portion stating that the selection of methods is communicated to the customer on the lab submittal form.</p> <p>5.8.1.1 changed chain of custody to state official internal chain is ACSO property and official external is handwritten.</p>	5/1/18	Wheatley	Brown Campbell Herink Kidwell Jensen
<p>5.9.2 Quality control positive defined as "yes"</p> <p>4.15.2 outline the areas covered in the management review</p> <p>5.6.2.2.1.1 added "When the calibration of equipment does not have a significant effect on sampling, the test result, or uncertainty of measurement, objective proof will be included in the discipline analytical method"</p> <p>5.8.1.1 changed official chain to be handwritten on evidence packaging. And all internal transfers must be documented to include temporary storage locations.</p> <p>5.9.3.4 added "Internally prepared tests will be made to minimize contamination and ensure the quality of the test. This is done by using clean new materials (sterilized swabs, newly purchased cloth in packaging), using known reference material that has been checked. The quality of the test will be documented as part of the proficiency test case record."</p> <p>5.9.3.6 added "the test taker will be notified of the results via email. The results will be attached to the LIMS case record. It is the responsibility of the test taker to communicate if the results are not understood"</p>	6/4/18	Wheatley	Brown Campbell Herink Kidwell Jensen

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SECTION & COMMENTS	DATE ADOPTED	AUTHOR	REVIEWER(S)
<p>5.6.3.2 Where possible, reference materials shall be traceable to SI units of measurement or to certified reference materials.</p> <p>Certified reference material shall be used unless one is not available. If a certified reference material is not available an internally developed may be used. Internally developed reference materials shall be checked against published references or certified reference material as far as is technically and economically practicable. Documentation of traceability must be maintained in the laboratory.</p>	8/8/18	Wheatley	LK, EH, KB, HC, RJ
<p>Modified 2.3 and removed hyperlink; 2.4 removed; 4.1.5.4 changed should to "shall only be released.."; modified numbering for 4.1.5.4.1; 4.1.5.7 Added Quality Assurance Manager; 4.2.2/4.2.2.1 updated name for ANAB Guiding Principles; 4.2.5 replaced acronym from chart; 4.2.6.2 removed training record retention; 4.4.1.1 modified wording to match website; 4.5.4 modified location for compliance documents; 4.6.2.2 removed laboratory chemical database for chemical ID; 4.9.1 removed incident form reference; 4.11.1.1 removed CAR assignment to supervisor; 4.13.2.2.1 specified end date; 4.14.2.2.1 modified technical record date requirement; removed 4.14.5; 5.2.5 added training record location; 5.3.4.1.1/5.3.4.1.2/5.3.4.1.1.3 modified visitor levels; 5.4.5.2.1 Removed validation form; 5.4.7.1 added "...included as part of the technical review"; 5.6.2.2.2 altered wording for sections; 5.7.3 added "as appropriate" to required documentation; 5.8.1.1 clarified temporary storage; 5.8.1.1.2.1-5.8.1.1.2.4 updated seal requirements; 5.8.1.1.3 removed disciplines define to general acceptance statement; 5.8.4 removed Syringe section B and removed authorization requirement to discard liquids; 5.8.4.1 and 5.8.4.2 modified for clarification; added 5.8.4.7 evidence disposition; 5.9.3.6 removed results attached to LIMS; 5.10.1 clarified conditions for release of results to internal/external customers; 5.10.2 added bullet for disposition of evidence and removed portion of identification of results and/or conclusions; 5.10.3.3 modified report release wording to include by order/request; 5.10.9 altered requirements for report and review for amended report; general grammatical and formatting changes.</p>	7/8/19	Guess	Brown Campbell Kidwell Wheatley

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SECTION & COMMENTS	DATE ADOPTED	AUTHOR	REVIEWER(S)
Revised to follow ISO/IEC 17025:2017 standards and ANAB 3125 accreditation requirements; additional modifications throughout.	2/4/20	Guess	Brown Campbell Herink Kidwell Wheatley