ARKANSAS STATE CRIME LABORATORY

QUALITY MANUAL

DIRECTOR:

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CONTENTS

1 SCOPE 6
1.1 International Standard: General Requirements 6
1.2 International Standard: Scope 6
1.2.1 ANAB Program 6
2 NORMATIVE REFERENCES 7
3 TERMS AND DEFINITIONS 8
4 GENERAL REQUIREMENTS 14
4.1 Impartiality 14
4.1.1 General 14
4.1.2 Personnel 15
4.1.3 Fiscal 15
4.1.4 Risks to impartiality 16
4.1.5 Actions taken in response to risk 16
4.2 Confidentiality 16
4.2.1 Statute 16
4.2.2 Third-party release 16
4.2.3 Third-party source 16
4.2.4 Scope of confidentiality 16
5 STRUCTURAL REQUIREMENTS 17
5.1 Establishment 17
5.2 Management 17
5.2.1 Director 17
5.2.2 Assistant Director (AD) 17
5.2.3 Quality Assurance Manager (QAM) 18
5.2.4 Health and Safety Manager (HSM) 18
5.2.5 Chief Forensic Pathologist (State Medical Examiner) 19
5.2.6 Other staff 20
5.3 Scope of laboratory activities 20
5.4 Normative documents 20
5.4.1 Use of accreditation symbols 20
5.4.2 Statutory authority 21
5.5 Laboratory operations 21
5.5.1 General 21
5.5.2 Authorities and interrelationships 21
5.5.3 Quality Manual 21
5.6 Quality management 22
5.7 Management system communication and integrity 22
6 RESOURCE REQUIREMENTS 23
6.1 General 23
6.2 Personnel 23
6.2.1 General 23
6.2.2 Competence requirements 24
6.2.3 Competence of Staff 27
6.2.4 Duties, Responsibilities, and Authorities 28
6.2.5 Personnel Requirements 28
6.2.6 Authorizations 28
6.3 Facilities and Environmental Conditions 29
6.3.1 General 29

6.3.2 Documentation 29
6.3.3 Monitoring Records 29
6.3.4 Control of Facilities 29
6.3.5 External Activities 33
6.4 Equipment 33
6.4.1 Access 33
6.4.2 Outside Equipment 33
6.4.3 Proper Functioning 33
6.4.4 Performance Verification 36
6.4.5 Fitness for Service 36
6.4.6 Calibration Requirement 36
6.4.7 Calibration Program 36
6.4.8 Labelling 38
6.4.9 Out of Service 38
6.4.10 Intermediate Checks 38
6.4.11 Correction Factors 38
6.4.12 Equipment adjustment 39
6.4.13 Equipment Records 39
6.5 Metrological Traceability 39
6.5.1 General 39
6.5.2 Traceability to the International System of Units 41
6.5.3 Alternate Traceability 41
6.6 Externally-Provided Products and Services 41
6.6.1 General 41
6.6.2 Records 43
6.6.3 Communication 43
7 PROCESS REQUIREMENTS 44
7.1 Review of Requests, Tenders, and Contracts 44
7.1.1 General 44
7.1.2 Inappropriate requests 45
7.1.3 Statements of conformity 45
7.1.4 Resolution of differences 45
7.1.5 Deviation from the contract 45
7.1.6 Amendment of the contract 45
7.1.7 Cooperation with customers 45
7.1.8 Records of review 46
7.1.9 Database search extent 46
7.2 Selection, Verification, and Validation of Methods 46
7.2.1 Selection and verification of methods 46
7.2.2 Validation of methods 48
7.3 Sampling 51
7.3.1 General 51
7.3.2 Sampling method 51
7.3.3 Sampling records 52
7.4 Handling of Test Items 52
7.4.1 General 52
7.4.2 Item identification 57
7.4.3 Deviations 58
7.4.4 Environmental conditions 59
7.5 Technical Records 59

7.5.1 General 59
7.5.2 Amendments to technical records 61
7.6 Evaluation of Measurement Uncertainty 62
7.6.1 Uncertainty components 62
7.6.2 Calibration 63
7.6.3 Estimation procedure 63
7.6.4 Required records 63
7.7 Ensuring the Validity of Results 64
7.7.1 General 64
7.7.2 Interlaboratory comparisons 68
7.7.3 Monitoring activity analysis 68
7.7.4 Individual proficiency testing 68
7.7.5 Proficiency testing requirements 68
7.7.6 Proficiency test schedule 70
7.7.7 Proficiency test sourcing 70
7.7.8 Proficiency test records 70
7.8 Reporting of Results 71
7.8.1 General 71
7.8.2 Common requirements for reports 73
7.8.3 Specific requirements for test reports 74
7.8.4 Specific requirements for calibration certificates 75
7.8.5 Reporting sampling—specific requirements 75
7.8.6 Reporting statements of conformity 75
7.8.7 Reporting opinions and interpretations 75
7.8.8 Amendments to reports 76
7.8.9 Supplemental Reports 76
7.9 Complaints 77
7.9.1 General 77
7.9.2 Transparency of process 77
7.9.3 Complaint process 78
7.9.4 Responsibility 78
7.9.5 Communication 78
7.9.6 Independent evaluation 78
7.9.7 Notice of completion 78
7.10 Nonconforming Work 78
7.10.1 General 78
7.10.2 Records of nonconforming work 80
7.10.3 Corrective action implementation 80
7.11 Control of Data and Information Management 80
7.11.1 Access to information 80
7.11.2 LIMS validation 81
7.11.3 LIMS requirements 81
7.11.4 Off-site LIMS 81
7.11.5 LIMS documentation 81
7.11.6 Calculations and data transfers 81
8 Management System Requirements 82
8.1 Options 82
8.1.1 General 82
8.1.2 Option A 82
8.1.3 Option B 82

8.2 Management System Documentation (Option A) 82
8.2.1 Policies and objectives 82
8.2.2 Mission and Quality Policy Statements 83
8.2.3 Commitment to management system 87
8.2.4 Documentation 87
8.2.5 Accessibility 87
8.3 Control of Management System Documents (Option A) 87
8.3.1 Controlled documents 87
8.3.2 Controlled document policies and procedures 88
8.4 Control of Records (Option A) 91
8.4.1 Records 91
8.4.2 Record policies and procedures 92
8.5 Actions to Address Risks and Opportunities (Option A) 93
8.5.1 Risks and opportunities 93
8.5.2 Planning 94
8.5.3 Proportionality 94
8.6 Improvement (Option A) 95
8.6.1 Improvement 95
8.6.2 External feedback 95
8.7 Corrective Actions (Option A) 95
8.7.1 Nonconformities 95
8.7.2 Proportionality 97
8.7.3 Records 98
8.8 Internal Audits (Option A) 98
8.8.1 Internal audits 98
8.8.2 Audit policies and procedures 98
8.9 Management Reviews (Option A) 100
8.9.1 Management review 100
8.9.2 Inputs 100
8.9.3 Outputs 100
9 Annex A (Normative) 101
9.1 Educational requirements 101
9.2 Quality Assurance Concern workflow 101

1 SCOPE

This manual follows the requirements specified by ANSI-ASQ National Accreditation Board (ANAB), which is based on the ISO/IEC 17025:2017 standards and the 2017 ANAB ISO/IEC 17025:2017 — Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125).

1.1 INTERNATIONAL STANDARD: GENERAL REQUIREMENTS

The International Standard (ISO/IEC 17025:2017) specifies the general requirements for competence to carry out sampling and testing. It covers testing using standard methods, non-standard methods, and laboratory developed methods.

1.2 INTERNATIONAL STANDARD: SCOPE

The International Standard is applicable to each discipline performing tests, regardless of the number of personnel or the extent of the scope of testing activities. When the laboratory does not undertake one or more of the activities covered by the International Standard, then the requirements of those clauses do not apply.

1.2.1 ANAB PROGRAM

As part of the ANAB program, ANAB includes additional accreditation requirements to the International Standard to address items specific to forensic science testing (e.g., examination of crime scenes, recovery of evidence, laboratory examination/analysis, interpretation of findings, and presentation of the conclusions reached for investigative or intelligence purposes or for use in court). The broad field of forensic science involves the examination and/or analysis of a wide range of items and substances.

The Arkansas State Crime Laboratory is accredited through ANAB in the disciplines and activities listed in its scope document. The laboratory does not claim accreditation for any work not performed under its scope. If any activity not covered under the laboratory's scope is listed on a report of laboratory analysis, it will be clearly identified and disclaimed[1].

[1] For example, "*Note*: *The listed evidence was collected by the laboratory*. *Collection of this evidence is not covered by the laboratory's scope of accreditation*."

2 NORMATIVE REFERENCES

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. Each document's location is referenced in brackets.

- ISO/IEC Guide 99, International vocabulary of metrology — Basic and general concepts and associated terms (VIM) [Qualtrax]
- ISO/IEC 17000, Conformity assessment — Vocabulary and general principles
- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories
- ANAB ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125)
- Arkansas Code Annotated (A. C. A.) §§ 12-12-301 through 12-12-313 [Qualtrax]
- Quality Assurance Standards for Forensic DNA Testing Laboratories, 2009 [Qualtrax]
- Quality Assurance Standards for Forensic DNA Databasing Laboratories, 2009 [Qualtrax]

3 TERMS AND DEFINITIONS

ADJUSTMENT

The process performed to correct a measuring system in order to meet the required specifications.

Example: Daily adjustment of a balance, using a certified reference mass, before use.

ADMINISTRATIVE SAMPLING

An application of sample selection, in which samples are selected for testing in order to meet statutory guidelines.

APPROVAL AUTHORITY

Personnel who are authorized to approve controlled documents.

ASSOCIATION

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

AUDIT

A systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled (ISO/IEC 17000:2004).

CALIBRATION

A process (with established measurement uncertainty) which establishes a relation between the response of a measuring instrument and known quantity values (e.g., from certified reference standards), which may be used to obtain a measurement result from an instrument response. This should not be confused with the routine adjustment of a measuring system (see "adjustment").

Examples: Calibration of micropipettes or balances to a NIST-traceable standard by an outside vendor.

CAN

"Can" indicates a possibility or a capability. The antecedent is allowed, but not required.

See also: shall, should, and may.

CHAIN OF CALIBRATIONS

An unbroken sequence of calibrations from the measuring system in question to a national (or international) measurement standard, where each calibration contributes to the total measurement uncertainty.

CHEMICAL

A substance or compound used for its constant chemical composition or characteristic properties.

Examples: Acidic or basic solutions, Davidow solvent

COMPETENCY TEST

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

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

CONTRACT
The agreement between the forensic service provider and the customer. A fee for service is not required.

Example: Acceptance of a submission sheet from a customer by the ASCL.

CONTROL
A substance or compound used to determine whether a method and/or instrument is responding as expected.

Examples: Positive and negative controls

CONTROLLED DOCUMENT
A document with a specified revision, approval authority, and revision approval date, distributed in a manner which ensures that the recipients of controlled copies receive subsequent revisions and replace previous revisions.

Examples: Forms required for use by management, Quality Manuals, Training Manuals, administrative policies, and organizational charts.

CRITICAL
A critical consumable, supply, or service is one which must meet one or more crucial specifications to ensure the quality of test results.

CUSTOMER
A person or organization that could (or does) receive a product or a service that is intended for, or required by, this person or organization. A customer can be internal or external to the forensic service provider.

DECISION RULE
A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

DIRECTOR
The highest ranking manager.

DISCIPLINE
A major area of activity in forensic science.

DOCUMENT
Information in any medium including, but not limited to: paper copy, computer disk or tape, audiotape, videotape, photograph, overhead, or photographic slide.

DOCUMENT CONTROL

The process for ensuring that controlled documents (including revisions) are reviewed, approved, and issued by authorized personnel, and distributed to personnel performing the prescribed activities. Additionally, document control ensures that the current revision is readily available for use and archived copies are stored appropriately.

IMPARTIALITY

The presence of objectivity. Objectivity means that conflicts of interest do not exist, or sare resolved so as not to adversely influence the subsequent activities of the laboratory.

INDIVIDUAL CHARACTERISTIC DATABASE

A computerized, searchable collection of features, generated from samples of known origin from which individual characteristic information originates (e.g., DNA profiles, friction ridge data, or firearm bullet/cartridge case images).

INTERLABORATORY COMPARISON

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

INTRALABORATORY COMPARISON

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

ISSUING AUTHORITY

Personnel who are authorized to publish approved controlled documents.

KEY MANAGEMENT

Assistant Director, Chief Medical Examiner, Section Chiefs, and the DNA Technical Leader.

LABORATORY

A body that performs testing and/or sampling associated with subsequent testing.

LABORATORY-DEVELOPED METHODS

Laboratory-developed methods are new methods, or modifications of standard or non-standard methods, created by the laboratory.

MAY

"May" indicates a permission. The antecedent is allowed, but not required.

See also: shall, should, and can.

MEASURAND

A quantity or object to be measured.

MEASUREMENT

The process of experimentally obtaining one or more results that describe a property of the measurand.

NON-STANDARD METHODS

Non-standard methods are methods or procedures published by reputable technical organizations, such as Scientific Working Groups (SWGs), Technical Working Groups (TWGs), relevant scientific texts or journals, or the manufacturer of the equipment.

PERFORMANCE VERIFICATION

Objective confirmation that the performance requirements of a measuring system have been achieved.

Examples: balances, internal IR polystyrene compared to a known polystyrene reference to confirm that the instrument/equipment is fit for service.

PRACTICABLE

Able to be successfully put into practice (i.e., possible).

PROFICIENCY TESTING

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

QUALITY RECORDS

Quality records include any documents that record conformity to the quality management system.

Labwide records include, but are not limited to: reports from internal audits, controlled document review and approval, management reviews, and records of corrective and preventive actions.

Discipline-specific records include, but are not limited to: method and equipment verification records, reagent and chemical QC logs, training records, proficiency and competency test records, courtroom testimony monitoring records, chemical inventory records, reference collection records, and audit records.

REAGENT

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

Examples: Marquis, Duquenois-Levine, ninhydrin, phenolphthalein, sodium rhodizonate solution

Note: Not all chemicals used in casework are reagents. Reagents typically undergo a chemical reaction which is used an analysis. Chemicals used to adjust/maintain pH, for solubility, or other similar purposes are not reagents.

RECORD

A document that contains analytical results or documentation of performed activities. These records include, but are not limited to:

- analytical notes (e.g., instrumental data, analytical worksheets, and packaging notes),
- logs (e.g., equipment, reagent, chemical, training, proficiency, competency, and testimony), and
- quality control documents (e.g., corrective action requests, preventive action requests).

REFERENCE
A reference standard or a reference material. It may also be referred to as a measurement standard.

REFERENCE MATERIAL
A traceable material used for the calibration, performance verification, or adjustment of a measurement device. These materials are normally accompanied by documentation issued by an authoritative body.

Examples: Drug standards, instrument tuning compounds (e.g., PFTBA, polypropylene glycol)

REFERENCE STANDARD
A standard (traceable through a chain of calibrations) used for the calibration, performance verification, or adjustment of other measurement devices.

Examples: NIST traceable weights and rulers

REQUEST
The process utilized by a customer when seeking services from the forensic service provider.

Example: The customer completes an evidence submission sheet and provides associated evidence to the ASCL for analysis.

SAMPLING
Selection of a sample for testing, according to a procedure. The approach to sampling can be either non-statistical or statistical..

SAMPLING PROCEDURE
A defined procedure used to collect a sample (or samples) from the larger whole. The sampling procedure may include details about size and number of samples to be collected, locations from which to collect the samples, and a method to ensure the homogeneity of the larger whole (or to make it so).

SHALL
"Shall" indicates a requirement. "Shall" is synonymous with "will" and "must".

See also: should, may, and can.

SHOULD
"Should" indicates a recommendation. The antecedent is encouraged, but not required.

See also: shall, may, and can.

STANDARD METHODS
Methods published in international, regional or national standards.

Example: ASTM 1412-12 (Standard Practice for Separation of Ignitable Liquid Residues from Fire Debris Samples by Passive Headspace Concentration with Activated Charcoal)

TECHNICAL ORGANIZATIONS

Groups of subject-matter experts who develop and promulgate consensus documentary standards and guidelines intended to ensure that a sufficient scientific basis exists for each discipline.

Examples: Scientific Working Groups (SWGs), Technical Working Groups (TWGs), Organizations of Scientific Area Committees (OSACs)

TECHNICAL RECORDS

Technical records (i.e., case records) include all examination and administrative documentation as part of individual laboratory case files.

Note: Technical records for CODIS are in the CODIS Hit Verification Packet and CODIS Sample Packet.

TENDER

The response to the customer request for services. This may include an automated notification.

Example: The ASCL initials the submission sheet to indicate the receipt of evidence and enters the case information into the LIMS.

TOP MANAGEMENT

Director, Assistant Director, and Quality Assurance Manager.

TRACEABILITY

A property of a measurement whereby the result can be related to a reference through a documented and unbroken chain of calibrations, each contributing to the measurement uncertainty.

UNCONTROLLED COPY

A copy of a controlled document provided for informational purposes only.

Examples: A copy provided to an external assessor, or a copy required for legal discovery.

VALIDATION

A verification, where the specified requirements are adequate for an intended use.

VERIFICATION

A provision of objective evidence that a given item fulfils specified requirements.

4 GENERAL REQUIREMENTS

4.1 IMPARTIALITY

The ASCL strives to ensure impartiality in its activities. The following policies/arrangements insulate the staff from financial, personal, or other pressures that may affect their work.

4.1.1 GENERAL

The ASCL structures, manages, and undertakes its activities in an impartial manner.

The ASCL has managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance, and improvement of the management system, and to identify the occurrence of departures from the management system or from test procedures, and to initiate actions to prevent or minimize such departures.

The structure of the management system is defined in the laboratory's organization charts. Qualifications and job descriptions can be found in the appropriate quality manual. Each subordinate is accountable to only one immediate supervisor for any given job function.

All cases may be prioritized based upon a system that allows for a timely response. Unless priority requests are made, cases should be analyzed in chronological order. Priority requests may be based upon:

- A request from an Investigating Officer
- A request from a Court Official (including court dates and court orders)
- A threat to public safety (e.g., homicide, rape, other violent crime)

Other cases or types of cases may be prioritized at the request of the Section Chief, Assistant Director, Medical Examiner, or the Director. All priority requests for individual cases will be documented in the LIMS under the "Request" tab with a brief description of the prioritization request. Case-type prioritization documentation will be maintained by the Discipline.

The ASCL has adequate personnel for supervising testing, including trainees, by individuals familiar with the methods and procedures, the purpose of each test, and with the assessment of the test results.

Each discipline has a section chief with overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations. Each Section Chief or designee has appropriate technical training and experience in the discipline. In addition, the Assistant Director oversees each Section Chief and their discipline.

The laboratory has a Quality Assurance Manager with defined responsibilities and the authority to ensure that the quality management system is implemented and followed at all times. The Quality

Assurance Manager has direct access to the highest level of management at which decisions are made on laboratory policy or resources.

When key management personnel plan to be absent for three days or longer, a deputy is appointed and all affected personnel are notified.

4.1.2 PERSONNEL

The laboratory management is committed to impartiality.

The ASCL prepares, in accordance with State of Arkansas personnel policy, performance expectations for each employee outlining the job expectations for the coming year. Managers evaluate each employee on their individual performance as compared with their individual expectations.

Managers have the responsibility and authority to receive and take action on employee concerns within their discipline. Section 2.4 of the *ASCL Personnel Handbook* contains provisions for employee grievances that cannot be resolved at the manager level.

The laboratory strives to ensure that employees are aware of the relevance and importance of their activities, and how they contribute to the achievement of the objectives of the management system. This is accomplished through effective communication from management to all employees.

4.1.3 FISCAL

The ASCL is responsible for the impartiality of its activities. Financial, commercial, and other pressures are mitigated by the following policies/arrangements.

The Arkansas State Legislature sets the annual budget for the laboratory. This budget is apportioned to each section based on laboratory needs.

Section 2.1 of the *ASCL Personnel Handbook* (ASCL-DOC-02) contains specific guidelines on the acceptance of gifts or gratuities.

4.1.3.1 ETHICAL PRACTICE

The ASCL is committed to ethical practice, including adherence to its *Code of Ethics Policy* (ASCL-DOC-06) and the *ASCLD/LAB Guiding Principles for Professional Responsibility for Crime Laboratories and Forensic Scientists* (ASCL-DOC-11), which must be read annually by all personnel.

A record of this review is maintained in Qualtrax.

When a departure (or apparent departure) from ethical practice is identified, a *Quality Assurance Concern* (QAC) is started.

4.1.4 RISKS TO IMPARTIALITY

The ASCL reviews risks to its impartiality on an ongoing basis. Risks are reviewed as part of the quarterly Management Review process. Risks are also evaluated whenever necessitated by a change to lab policy or by external actions/situations.

The ASCL is an independent state agency. The Governor of Arkansas is responsible for approving our biennial budget and providing funding accordingly.

4.1.5 ACTIONS TAKEN IN RESPONSE TO RISK

If a risk to the impartiality of the ASCL is identified, the actions taken to minimize or eliminate the risk will be recorded.

4.2 CONFIDENTIALITY

4.2.1 STATUTE

Case information at the ASCL is controlled by state statute (§ 12-12-312). This includes all case information obtained or created during the performance of laboratory activities. Policies related to A.C.A. § 12-12-312 are found in the Personnel Handbook.

Customer agencies that have made the necessary arrangements with the ASCL are granted secure access to JusticeTrax iResults, where they may check on the status of their laboratory requests and view completed reports for their agency. JusticeTrax access is secured by username/password.

Investigative information may not be released until after a technical review has been completed, unless a Discipline Quality Manual allows release after an independent verification. Final results, conclusions, or reports will be released only after a technical and administrative review of the case file has been completed and documented.

4.2.2 THIRD-PARTY RELEASE

If the ASCL is required[2] to release case information to a third party, the submitting agency (or agencies) will be notified. This requirement is not triggered by the release of information to a party to a case (e.g., defendant, involved attorney, involved law enforcement agency, or judge).

4.2.3 THIRD-PARTY SOURCE

Information obtained from a third-party is also privileged and confidential. The source of the information will not be disclosed unless agreed to by the source.

4.2.4 SCOPE OF CONFIDENTIALITY

ASCL confidentiality requirements apply to laboratory personnel, board members, contractors, and any other party acting on the laboratory's behalf.

[2] For example, in response to a valid court order or at the direction of a Prosecuting Attorney

5 STRUCTURAL REQUIREMENTS

5.1 ESTABLISHMENT

Act 517 of 1977 established the Arkansas State Crime Laboratory (ASCL) via A. C. A. § 12-12-301.

5.2 MANAGEMENT

The Arkansas State Crime Laboratory is managed by the Director, who has overall responsibility for the laboratory.

5.2.1 DIRECTOR

QUALIFICATION

The Governor of the State appoints the Director. The ASCL Board shall prescribe the duties, responsibilities, compensation, and qualifications for the Director.

AUTHORITIES AND RESPONSIBILITIES

The ASCL Director is responsible for the overall functioning of the Arkansas State Crime Laboratory, and has the overall authority and responsibility to make and enforce decisions.

The Director:

- Oversees the operation of the laboratory, through executive and legislative direction
- Monitors the financial status of the biennial budget
- Liaises between the Criminal Justice System and the laboratory
- Maintains a professional relationship with statewide media
- Approves all new hiring
- Serves on the Alcohol and Drug Abuse Coordinating Council
- Appoints the Chief Forensic Pathologist
- Supervises the Section Chief for Forensic Toxicology

5.2.2 ASSISTANT DIRECTOR (AD)

QUALIFICATION

The position requires a minimum of a baccalaureate degree in one of the physical sciences, with a minimum of five years' experience in a forensic laboratory. A master's degree can substitute for two years of experience in a forensic laboratory.

AUTHORITIES AND RESPONSIBILITIES

- Oversees the analytical sections of the laboratory
- Assists with purchasing equipment and supplies for the laboratory
- Assists with the inventory of supplies and equipment
- Oversees new hires for the analytical sections of the laboratory

- Provides administrative assistance to the Director with regard to budgeting for laboratory personnel, equipment, and supplies
- Writes or assists with grant proposals, and maintains the budget, payouts, and equipment purchases for such grants
- Supervises the Section Chiefs for Forensic DNA, CODIS, Forensic Chemistry, Physical Evidence, Latent Prints, Firearms/Toolmarks, and Digital Evidence
- Reviews job applications
- Reviews Performance Evaluations for accuracy and consistency
- Coordinates new employee and random drug testing program
- Oversees all construction, renovation, and remodeling of the laboratory
- Liaises between the laboratory and other state agencies for contract services (e.g., janitorial, security, waste hauling)

5.2.3 QUALITY ASSURANCE MANAGER (QAM)

QUALIFICATION

The position requires a minimum of a baccalaureate degree in one of the physical sciences, with a minimum of five years' experience in a forensic laboratory. A master's degree can substitute for two years of experience in a forensic laboratory.

AUTHORITIES AND RESPONSIBILITIES

- Maintains and updates the labwide quality manual
- Monitors laboratory practices to verify continuing compliance with policies and procedures
- Periodically assesses the adequacy of report review activities
- Ensures the validation of new technical procedures
- Investigates technical problems, proposes remedial action, and verifies implementation
- Administers proficiency tests and evaluates results
- Selects, trains, and evaluates internal auditors
- Schedules and coordinates quality system audits
- Ensures that laboratory personnel training records are maintained
- Recommends training to improve the quality of laboratory staff
- Proposes corrections and improvements to the quality system
- Ensures compliance with the ANAB accreditation standard
- Assumes Assistant Director's authorities and responsibilities in his or her absence

5.2.4 HEALTH AND SAFETY MANAGER (HSM)

QUALIFICATION

The position requires a minimum of a baccalaureate degree in one of the physical sciences, with a minimum of five years' experience in a forensic laboratory. A master's degree can substitute for two years of experience in a forensic laboratory.

AUTHORITIES AND RESPONSIBILITIES

- Effects a standardized safety program within the laboratory

- Provides health- and safety-related educational materials
- Assists supervisors in teaching safety rules regulations and procedures to their employees
- Conducts safety surveys and ensures that proper practices and procedures are being followed
- Reviews and evaluates the effectiveness of the safety manual, in concert with Section Safety Officers
- Recommends changes in safety policies and procedures to the Director and implements approved changes
- Assists supervisors in resolving safety incidents and maintaining records of such incidents
- Coordinates with a registered nurse for the administration of employee immunizations and maintenance of inoculation records for employees
- Monitors the procurement, use, and disposal of chemicals used in the lab
- Maintains safety auditing procedures
- Helps project directors develop precautions and maintain adequate facilities
- Maintains a current copy of all Safety Data Sheets (SDSs)
- Provides regular, documented formal chemical hygiene and housekeeping inspections, including routine inspections of emergency equipment
- Keeps abreast of current legal requirements regarding regulated substances
- Seeks ways to improve the safety program

5.2.5 CHIEF FORENSIC PATHOLOGIST (STATE MEDICAL EXAMINER)

QUALIFICATION

The Director, with the approval of the State Crime Laboratory Board, shall appoint and employ the Chief Forensic Pathologist. A. C. A. § 12-12-307 lists the qualifications for this position. The State Crime Laboratory Board has further required the following qualifications:

- Must obtain a license to practice medicine in the State of Arkansas
- Must have a minimum of five years' experience in the field of forensic pathology
- Must be board certified in Forensic Pathology by the American Board of Pathology

AUTHORITIES AND RESPONSIBILITIES

- Plans and oversees the day-to-day operations of forensic pathology, involving medico-legal investigations using laboratory and medical procedures to determine the cause, manner, and mechanism of death as prescribed by Arkansas Code
- Performs thorough postmortem examinations, with certifications of the cause, manner, and mechanism of death
- Consults with toxicologists, analysts, examiners, physicians, and law enforcement officers to establish medical evidence and to obtain expert opinions regarding unexplained deaths
- Testifies as an expert witness to provide information concerning findings, evaluations, and autopsy results in accordance with state and federal law
- Develops and supervises in-service training for Medical Examiner staff and other laboratory personnel to ensure qualify performance within the Medical Examiner Section and the laboratory

- Provides consultation and recommendations to the Director for administrative or legislative changes needed to improve the delivery of services provided to the public
- Responsible for maintaining the necessary records required for the Medical Examiner Section

5.2.6 OTHER STAFF

Qualifications, authorities, and responsibilities for Section Chiefs, analysts, technicians, and other staff are included in each discipline's Quality Manual.

Technical Support staff may perform duties in a discipline even if they do not have the educational qualifications to be an analyst in the discipline. Technical support job descriptions and duties performed will be in agreement with one another. Job descriptions are documented in the appropriate quality manual. Technical Support must have adequate knowledge of the techniques and methods used in their assigned tasks. Any data generated by technical support must be interpreted by a case-qualified analyst.

5.3 SCOPE OF LABORATORY ACTIVITIES

The Arkansas State Crime Laboratory carries out testing activities defined by its Scope of Accreditation, issued by ANAB. The Arkansas State Crime Laboratory does not claim conformity for any laboratory activities not listed on its scope document.

5.4 NORMATIVE DOCUMENTS

It is the responsibility of the ASCL to carry out all activities in a manner that meets the requirements of the ANAB Accreditation Program and satisfies the needs of the customer, criminal justice community, and others as authorized by law. This includes conformance to:

- Arkansas Code Annotated (A.C.A.) §§ 12-12-301 through 12-12-326
- ISO/IEC 17025:2017 (*General requirements for the competence of testing and calibration laboratories*)
- ANAB AR 3125 (*ISO/IEC 17025:2017 Forensic Testing and Calibration Laboratories Accreditation Requirements*)
- Labwide and Section Quality Manuals
- Labwide and Section Training Manuals

The management system covers all work carried out by the ASCL, including the Little Rock laboratory, the Hope laboratory, the Lowell Laboratory, and sites away from these facilities (including the Digital and Multimedia Evidence co-location at the ASP Headquarters in Little Rock).

5.4.1 USE OF ACCREDITATION SYMBOLS

The Arkansas State Crime Laboratory conforms to the requirements in *PR 108 ANAB Policy on Use of Accreditation Symbols and Claims of Accreditation Status*, available at ANAB.org.

The ANAB accreditation symbol is used on reports of laboratory analysis, accompanied by our certificate number (ALI-351-T) and a statement such as: "An ASCLD/LAB Accredited Laboratory (Since December 13, 2004)" or "An ANAB Accredited Laboratory (Since December 13, 2004)".

The ANAB accreditation symbol appears on our website, where it is used to link directly to our scope of accreditation.

5.4.2 STATUTORY AUTHORITY

The Arkansas State Crime Laboratory operates under the authority of A.C.A. § § 12-12-301 through 12-12-326, available in their most current form in Qualtrax.

5.5 LABORATORY OPERATIONS

5.5.1 GENERAL

The Arkansas State Crime Laboratory is a division of the Department of Public Safety of the State of Arkansas, reporting to the Secretary of the Department of Public Safety.

5.5.2 AUTHORITIES AND INTERRELATIONSHIPS

Intralaboratory authorities and relationships are defined by the laboratory's organizational charts, located in Qualtrax. Responsibilities are detailed in each position's job descriptions.

Each subordinate shall be accountable to only one immediate supervisor for each laboratory activity.

5.5.3 QUALITY MANUAL

The *ASCL Quality Manual* (ASCL-DOC-01) is a compilation of policies and procedures governing ASCL operations. The Quality Manual is readily available on Qualtrax to all ASCL personnel. ASCL personnel are responsible for knowing and using these policies and procedures. The quality manual is reviewed annually by the Quality Assurance Manager, Assistant Director, and Director. It is updated as needed to reflect changing organizational, technical, and procedural information.

Unforeseen circumstances may require immediate deviations from the policies and procedures of this manual. In such situations, a written request for an exception to policy will be submitted to the Assistant Director (or designee). This written request shall include:

1) an adequate description of the circumstance requiring the action,
2) a statement of the proposed alternative policy and/or procedure, and
3) the expected duration of the exception.

The Assistant Director will maintain documentation of the approved policy exception.

Each discipline of the laboratory has a Discipline Quality Manual and Discipline Training Manual(s). The purpose of these manuals is to:

- Promote the efficient and effective operation of the ASCL
- Assist the laboratory staff in performing their assigned duties and tasks
- Document the policies and procedures established for each discipline, in sufficient detail to ensure the consistent application of laboratory activities and the validity of results, including analysis and data interpretation to arrive at a result, opinion, or interpretation

All personnel are responsible for knowing and using the policies and procedures in their Discipline Quality Manual. Each Discipline Quality Manual and Discipline Training Manual are reviewed annually by the appropriate Section Chief and updated as needed.

5.6 QUALITY MANAGEMENT

The ASCL has a Quality Assurance Manager with the authority and resources needed to:

- Implement, maintain, and improve the management system
- Identify deviations from the management system or from laboratory policies and procedures
- Initiate actions to prevent or minimize such deviations, including stopping work
- Report directly to the Director and/or Assistant Director on the performance of the management system, and any need for improvement, and
- Ensure the effectiveness of laboratory activities

The Quality Assurance Manager's authority is derived from that of the Director, to whom they have direct access.

5.7 MANAGEMENT SYSTEM COMMUNICATION AND INTEGRITY

ASCL methods of communication include regular Section Chief meetings, Discipline meetings, email, telephone, and personal meetings.

ASCL management communicates the importance of meeting customer, statutory, and regulatory requirements during regular Section Chief and labwide meetings. Pertinent items from the Section Chief meeting minutes are emailed to laboratory personnel. Managers review this information with their employees, and document both what was reviewed and who received the information.

ASCL management will assess the effect of planned policy and procedural changes prior to implementation to evaluate the risks associated with the change, and to ensure that it does not contradict or conflict with other policies or procedures.

6 RESOURCE REQUIREMENTS

6.1 GENERAL

The ASCL has the personnel, facilities, equipment, systems, and support services necessary to manage and perform its laboratory activities. These are provided through an annual budget, set by the Arkansas Legislature and approved by the Governor.

6.2 PERSONNEL

6.2.1 GENERAL

All analysts and technicians are employed by the ASCL. All staff who could influence the activities of the laboratory will act impartially, be competent, and work in accordance with the ASCL management system, regardless of location. The laboratory sets requirements for the performance of certain duties in concordance with ANAB GD 3152 (*ISO/IEC 17025:2017 and ANAB AR 3125 Matrix of Laboratory Tasks*), as summarized in the following table:

Task	Authorization	Training	Education Requirements	Competency Testing	Monitoring Competence of Personnel
Development, modification, verification, and validation of methods	×	×	×		
Performance of laboratory activities[3]	×	×	×	×	×
Analysis of results[4]	×	×	×	×	×
Review of results	×	×	×	×	×
Authorization of results[5]	×	×	×	×	×
Verification of a result[6]	×	×	×	×	×
Technical review[7]				×	
Expression of an opinion or interpretation	×	×	×	×	
Reporting of a result[8]	×				
Authorizing a Report[9]	×				

[3] Such as testing or sampling. These tasks may be performed by an analyst/examiner or a technician.
[4] Generating an analytical result from the results of a test or examination. This task may only be performed by an analyst/examiner.
[5] Authorizing a result to be reported, in our case by marking the request as "Draft Complete")
[6] By a second qualified analyst/examiner.
[7] By a second person—the technical reviewer cannot review their own work.
[8] Adding a result to a request, in our case by entering those findings into JusticeTrax.
[9] Authorizing the release of a report to the customer, in our case by marking the request as "Admin Reviewed"

6.2.2 COMPETENCE REQUIREMENTS

The competence requirements for all personnel are found in the appropriate job description and the training program for that position (if any). These requirements include:

- Education (job description)
- Qualification (job description)
- Training (training program)
- Technical knowledge (job description and/or training program)
- Skills (job description and/or training program)
- Experience (job description)

6.2.2.1 ANALYST/EXAMINER EDUCATIONAL REQUIREMENTS

Personnel who authorize results, opinions and/or interpretations shall meet the minimum educational requirements listed in § 9.1.

6.2.2.2 TRAINING PROGRAM

Section Chiefs shall ensure the competence of personnel who operate specific equipment, perform tests, evaluate results, or sign test reports. Personnel in training shall have appropriate supervision. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience, and/or demonstrated skills, as required.

The training program covers all aspects of training, to the extent necessary, based on the job function. The topics to be covered (when necessary) include:

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

Where applicable, training will cover:

- Method development, modification, verification, and validation
- Laboratory activities (testing and/or sampling)
- Analysis of results
- Review of results
- Authorization of results
- Verification of results
- Expression of an opinion or interpretation

Past work experience and training may be substituted for the training program (to the extent that they have been demonstrated to be relevant and sufficient) with the approval of the Section Chief and Assistant Director.

At the conclusion of training, the Section Chief shall document (e.g., by memorandum) that the individual has been properly trained and that their ability to perform the specified testing has been assessed. This record shall be kept in the individual's Training Binder. In addition, the *Analyst and Technician Competency Authorization Documentation* form (ASCL-FORM-62) must be completed (or updated) and recorded in the Personnel tab of Qualtrax.

6.2.2.2.1 LABWIDE TRAINING PROGRAM

The *ASCL New Analyst/Technician Training Manual* (ASCL-DOC-03) must be completed by all new analysts and technicians. The purpose of this training program is to provide an introduction to laboratory policies, forensic science, and criminal court proceedings. Among the topics covered in this program are:

- Establishment of the ASCL
- Confidentiality of Records
- Ethics in Forensic Science
- General Knowledge of Forensic Science
- Criminal Law Procedures and Expert Testimony
- Quality Assurance/Quality Control

This training occurs concurrently with the discipline training program.

6.2.2.2.2 DISCIPLINE TRAINING PROGRAM

Each discipline shall have a training manual to facilitate training in the knowledge, skills, and abilities needed to perform the appropriate testing. Discipline Training Manuals shall have stated objectives and may specify required readings, tasks, and practical exercises. Each employee will be trained under the direction of an experienced analyst in each aspect of the duties they are expected to perform. Training records shall contain sufficient detail to confirm that individuals performing particular tasks have been properly trained and that their ability to perform these tasks has been assessed. Criteria for successful completion of the training program are contained in each Discipline Training Manual.

Past work experience and training may be substituted for the training program (to the extent that they have been demonstrated to be relevant and sufficient) with the approval of the Section Chief and Assistant Director.

Below are areas that shall be covered in the Discipline Training Manuals (when applicable):

- Evidence handling
- Sampling
- Test methods
- Equipment

- Controls, reagents, and chemicals
- Result interpretations
- Case records (technical and administrative record requirements)
- Report writing
- Technical and administrative reviews, independent verifications
- Moot court

The effectiveness of both the training received and the technical competence of analysts are monitored by the following mechanisms:

- 100% technical and administrative review[10]
- Proficiency testing
- Monitoring of court testimony
- Annual internal audits and/or external assessments

Discipline-specific training programs can be modified to provide refresher or remedial training, as needed, for previously-experienced employees (e.g., if an analyst has been away from the bench for a period of time, or if an analyst has an inconsistency in a proficiency test or casework). The Section Chief (or designee) will design the appropriately modified program. This modified training shall be documented.

When applicable, the training program shall include training in the presentation of analytical results in court.

6.2.2.2.3 EMPLOYEE DEVELOPMENT PROGRAM

The laboratory prioritizes the continuing education of laboratory personnel. The ASCL encourages and supports employees to improve their knowledge and skills in order to grow as individuals and to fully develop their potential. The ASCL affords employees the opportunity to attend annual training and participate in professional forensic organizations. This training may include professional meetings, staff development seminars, technical training courses, in-house technical meetings, courses, seminars, and ASCL sponsored seminars and conferences. Travel procedures are detailed in § 3.21 of the *ASCL Personnel Handbook* (ASCL-DOC-02). This training shall be documented in Qualtrax.

The effectiveness of training events will be discussed in Discipline meetings.

6.2.2.2.4 LITERATURE

The ASCL maintains and provides access to literature resources such as relevant books, journals, and other literature dealing with each discipline. Each discipline shall have a system in place to encourage individuals to review appropriate new literature.

[10] This serves as a continuous mechanism of assessing the competence of the analyst/examiner

6.2.3 COMPETENCE OF STAFF

The ASCL ensures the competence of all personnel to perform the tasks for which they are responsible, and to evaluate the significance of any deviations from policy and/or procedure.

6.2.3.1 COMPETENCY TESTING

All personnel who perform testing[11] are competency tested. This competency test includes practical examination(s) that cover the spectrum of anticipated testing tasks. Competency testing may be conducted on a single task or a group of tasks, as appropriate.

For laboratory personnel whose job responsibility includes report writing, a competency test shall include, at a minimum:

- Practical examination of sufficient unknown samples to cover the anticipated spectrum of assigned testing tasks, to evaluate the individual's ability to properly perform analysis
- A written report to demonstrate the individual's ability to properly convey results and/or conclusions and the significance of those results and/or conclusions
- A written or oral examination to assess the individual's knowledge of the discipline, laboratory activity, or task being performed, and
- Moot court[12] to demonstrate the individual's ability to properly convey and present results of evidence in court

The intended result(s) of the competency test shall be achieved and documented prior to performing the covered task(s) on actual items of evidence. This may be achieved in several ways, including:

- Observed testing on a surrogate item[13]
- Written examination
- Oral examination

The risk involved will be considered when determining the extent of the competency test.

6.2.3.2 COMPETENCY-TESTED ACTIVITIES

Competency testing for the following activities will be conducted and documented prior to these actions being performed on evidence:

- Laboratory activities (testing and/or sampling)
- Analysis of results
- Review of results
- Authorization of results
- Verification of results
- Technical review

[11] i.e., laboratory activities (analysis/examination of evidence) and/or analysis of results
[12] The requirement for moot court may be waived for employees receiving training in additional categories of testing within the same discipline
[13] Such as a secondary standard or old proficiency test material

- Expressing an opinion or interpretation

6.2.4 DUTIES, RESPONSIBILITIES, AND AUTHORITIES

The duties, responsibilities, and authorities of each position are contained in its job description.

Job descriptions shall include the following (as applicable):

- responsibilities with respect to performing tests
- responsibilities with respect to the planning of tests and evaluation of results
- responsibilities for reporting opinions and interpretations
- responsibilities with respect to method modification and development and validation of new methods
- expertise and experience required
- qualifications and training programs
- managerial duties, if applicable

6.2.5 PERSONNEL REQUIREMENTS

The ASCL has procedures and retains records for:

- Determining competence requirements
  - The discipline training programs contain the specific elements which determine competence in that discipline
- Selection of personnel
  - Job descriptions include requirements for education, skills, and abilities
- Training of personnel
  - See § 6.2.2.2, above
- Supervision of personnel
- Authorization of personnel
  - See § 6.2.6, below
- Monitoring the competence of personnel

6.2.6 AUTHORIZATIONS

The Section Chief (or the DNA Technical Leader for DNA and CODIS) authorizes personnel to perform certain duties. Personnel may not perform these duties without authorization, except during supervised training. These duties include:

- Performing testing activities
  - Use of equipment (as applicable)
- Method development, modification, verification, and/or validation
- Analysis of results, including:
  - Statements of conformity
  - Opinions/interpretations
- Reporting results

- Reviewing Results
- Authorizing results

Authorization is documented on the *Analyst and Technician Competency Authorization Documentation* form (ASCL-FORM-62), signed by the Section Chief, and maintained in the Personnel tab of Qualtrax. Qualtrax shall also contain a curriculum vitæ or résumé that includes educational and professional qualifications, training, skills, and experience. The individual's Training Binder will contain all completed training records.

6.3 FACILITIES AND ENVIRONMENTAL CONDITIONS

6.3.1 GENERAL

Facilities and environmental conditions shall be suitable for laboratory activities whenever and wherever work is carried out. This includes microbial contamination, humidity, temperature, and other conditions.

If these conditions may adversely affect the validity of results, then testing is halted until the situation can be corrected.

The ASCL performs laboratory activities at four locations:

- Main Laboratory[14]: 3 Natural Resources Drive, Little Rock AR 72205
- Hope Regional Laboratory[15]: 2500 South Main Street, Hope AR 71802
- Arkansas State Police Headquarters[16]: 1 State Police Plaza Drive, Little Rock AR 72209
- Lowell Regional Laboratory[17]: 1120 West Monroe Avenue, Lowell AR 72745

6.3.2 DOCUMENTATION

Disciplines will document in their quality manuals any conditions (facilities or environmental conditions) that are necessary to ensure the validity of results.

6.3.3 MONITORING RECORDS

Disciplines will monitor and record environmental conditions if:

- These conditions are specified in a method or procedure, or
- The conditions influence the validity of results

6.3.4 CONTROL OF FACILITIES

The ASCL controls access to its facilities. The measures taken to achieve this are monitored and reviewed during the annual review of policies and procedures contained in quality manuals.

[14] Building administered by State Building Services
[15] Building administered by the University of Arkansas Community College at Hope
[16] Building administered by Arkansas State Police Troop A
[17] Building administered by Arkansas State Police Troop L

6.3.4.1 ACCESS

GENERAL

Unescorted access to all laboratory areas (at all premises) is restricted to those personnel authorized by the Director. A key fob or physical key is required to access these areas.

Forensic DNA, CODIS and Physical Evidence laboratory areas are locked at all times and require a key fob, a physical key, or an escort to enter the section. Only the following are allowed unescorted access to the section:

- Management Personnel:
  - Director
  - Assistant Director
  - Quality Assurance Manager
  - Health and Safety Manager
- Technical Personnel:
  - CODIS Personnel
  - Forensic DNA Personnel
  - Physical Evidence Personnel
- Other personnel deemed necessary by the Director

All employees are required to provide a DNA sample for the ASCL contamination database. Any person who enters the secure areas of the ASCL may be required to provide a DNA sample for the ASCL contamination database.

Issuance of key fobs to authorized personnel requires approval by the Director. Newly-hired personnel are automatically authorized by the Director to have both basic key fob access (e.g., exterior doors, elevators, stairs, west Administration door, 2nd floor atrium doors) and standard key fob permissions for the section into which they have been hired. All issuance of physical keys, as well as any additional key fob permissions for new or existing employees, requires specific authorization by the Director. A Qualtrax workflow is typically used to record this authorization.

FOB/KEY LOSS

If a fob or key is misplaced by a staff member, their supervisor will be notified immediately if the fob/key location is completely unknown, or within 48 hours if the fob/key is expected to be recovered (e.g., it has been misplaced in their home).

EVIDENCE STORAGE AREAS

Evidence storage conditions prevent loss, deterioration, or contamination, and maintain the integrity and identity of the evidence. Proper security is achieved by storing evidence in locked cabinets, refrigerators, vaults, or rooms. Evidence storage space may be shared by laboratory personnel. It is not necessary to place locks on refrigerators and freezers which are maintained in rooms and/or areas which are secure and restricted. Each Discipline Quality Manual shall address evidence storage procedures.

The Evidence Receiving Section has limited access. Access requires a security fob and/or key. The following people have access to the evidence storage area:

- Evidence Receiving Section Chief
- Evidence Technicians

The following individuals have access to the evidence storage area, but only during regular work-hours. They must sign the log when entering and leaving the evidence storage area, but do not need to be escorted.

- Director
- Assistant Director
- Quality Assurance Manager
- Health and Safety Manager
- Information Technology Support
- Other personnel as deemed necessary by the Director

Access to individual characteristic database samples is restricted to those employees authorized by the Director. The *Individual Characteristic Database Authorization* workflow in Qualtrax is used to authorize employees and to maintain the record of authorizations and deauthorizations.

6.3.4.1.1 MAIN LABORATORY

Access to the laboratory is controlled by magnetic locks at each exterior door, accessed by key fob. Access to elevators and stairwells on the basement and first floor levels requires a key fob. Access to laboratory sections is controlled by either key fob or physical key.

Visitors are required to sign in at the foyer. Law enforcement officers are required to show their badge/identification before being allowed entry. All other visitors must be escorted, except in the atrium area.

The laboratory has a security camera system which covers all exterior entrances and some interior locations.

The main laboratory has a Master Key Box containing master door keys, extra door keys, section key box keys, and/or section master cabinet keys. A Master Key Log is kept and an inventory conducted as needed. Keys removed or added to the Master Key Box are recorded on a logs maintained by the Quality Assurance Manager. Keys given out on a temporary basis (e.g., to make a new copy) will be recorded on a log attached to the Master Key Box. Door keys are issued to authorized personnel in order to access certain areas of the laboratory complex. Issuance to authorized personnel requires approval by the Director using a Qualtrax® workflow. This must be completed prior to giving a key from the Master Key Box to an employee (except for temporary transfers).

Firearms, Forensic Biology, Forensic Chemistry, and Physical Evidence sections have a key box containing cabinet keys and section door keys. The key to the section key box is kept by the

appropriate Section Chief. Logs are maintained to document when keys are added or removed from the section key box.

A security company provides continuous monitoring of the fire alarm system, and notifies the fire department and DBA of alarms.

6.3.4.1.2 HOPE REGIONAL LABORATORY

Access to the laboratory is controlled by magnetic and physical locks at each exterior door, accessed by key fob and physical key. Access to the testing area is controlled by key fob. Access to the evidence storage area is controlled by key fob and physical key.

All visitors must be escorted while in the laboratory testing area.

A security company provides continuous monitoring of the fire alarm system and notifies the fire department and University of Arkansas Community College at Hope of alarms.

6.3.4.1.3 ARKANSAS STATE POLICE HEADQUARTERS

Building security is controlled by the Arkansas State Police. Access to the Digital Evidence area is controlled by magnetic locks, accessed by key fob. Access to the laboratory areas and offices is controlled by physical keys, except for the server room, which is controlled by a magnetic lock.

All visitors must be escorted while in the Digital Evidence area.

The ASP maintains a security camera system which covers exterior entrances and some interior locations.

6.3.4.1.4 LOWELL REGIONAL LABORATORY

Access to the laboratory is controlled by magnetic and physical locks at each exterior door, accessed by key fob and/or physical key. Access to interior areas is controlled by key fob.

All visitors must be escorted while in the laboratory testing area.

Cameras cover both entrances and the evidence area.

6.3.4.2 PREVENTION OF ADVERSE INFLUENCES

Disciplines are responsible for taking the necessary measures to prevent contamination, cross-contamination, interference, or adverse influences on laboratory activities.

6.3.4.3 SEPARATION

MAIN LABORATORY

ASCL laboratory areas are designed to ensure effective separation between neighboring areas in which there are incompatible activities (e.g., Forensic Chemistry and Toxicology).

HOPE REGIONAL LABORATORY

Only Forensic Chemistry is available at this premise.

ARKANSAS STATE POLICE HEADQUARTERS

Only Digital Evidence is available at this premise.

LOWELL REGIONAL LABORATORY

Forensic Chemistry and Toxicology laboratory areas are physically separated.

6.3.5 EXTERNAL ACTIVITIES

When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

6.4 EQUIPMENT

6.4.1 ACCESS

The ASCL has adequate equipment to perform all necessary testing. Details of specific quality control measures on equipment that has a significant effect on the quality of test results will be outlined in the appropriate Discipline Quality Manual.

6.4.2 OUTSIDE EQUIPMENT

If the ASCL must use equipment outside of its permanent control, the laboratory shall ensure that the equipment meets the requirements of this section.

A successful performance verification is required for any equipment that has gone outside of the direct control of the laboratory (e.g., for repair or preventive maintenance) before that equipment may be returned to service. Documentation of these verifications will be maintained.

6.4.3 PROPER FUNCTIONING

Disciplines will have procedures for equipment to ensure proper functioning and prevent contamination or deterioration, including:

- Handling
- Transport
- Storage
- Use
- Planned maintenance

All equipment will be maintained in a clean, orderly, and safe condition. Laboratory equipment shall be handled responsibly to ensure optimal performance and to avoid contamination and premature wear and damage. It is the Section Chief's responsibility to ensure that proper planning and care is taken when equipment is initially placed or is subsequently moved. Care shall be taken to minimize the possibility of shipping damage if equipment is shipped outside of the laboratory's

control for calibration or maintenance. Equipment that is infrequently used shall be stored per manufacturer's recommendations, if available (e.g., covered, powered-down).

Each discipline has maintenance policies and procedures for equipment having a significant effect on the results. The Discipline Quality Manual will document preventative maintenance steps designed to maintain optimum performance from the equipment.

New employees shall be trained on the appropriate equipment during their training program, as detailed in each Discipline Training Manual. Section Chiefs shall authorize personnel to operate equipment (documented on *Analyst & Technician Competency Authorization Documentation*, ASCL-FORM-62). This authorization documentation is maintained in Qualtrax. Only individuals who have been trained in the proper use of the equipment shall operate it.

When new equipment requires a validation, appropriate personnel will be trained in its use. This training will be documented and maintained in Qualtrax.

Up-to-date instructions on the use and maintenance of the equipment shall be readily available for use.

REAGENTS/CHEMICALS/CONTROLS

Reagents, chemicals and controls used by the disciplines of the Arkansas State Crime Laboratory are maintained and quality controlled by each discipline. The Discipline Quality Manuals, when applicable, shall have a procedure for ensuring the reliability of reagents. In addition, the following rules shall be followed:

- Items with a manufacturer-specified expiration date may not be used after that date without documentation to support continued reliability
- For items without a manufacturer-specified expiration date, expiration dates will be based on experience, industry standard, or scientific consensus
- Appropriate logs must be maintained within each discipline for reagents and standards used
- Each analyst must ensure that the controls, reagents and/or chemicals used in their analysis are of satisfactory quality
- Controls, reagents, or chemicals which are determined not to be reliable must be immediately removed from use

6.4.3.1 REAGENT RECORDS AND LABELING

Reagents may be purchased or prepared. Minimum requirements for quality control of reagents are outlined below.

PURCHASED REAGENTS/CHEMICALS

Containers must be labeled with the following:

- Lot number
- Date opened
- Expiration date (if applicable)
- Initials (upon opening)

- Date received and initials

PREPARED REAGENTS/CHEMICALS

Containers must be labeled with the following:

- Identity
- Date of preparation
- Date of expiration

PREPARED REAGENTS

Logbooks must include the following[18]:

- Identity
- Date of preparation
- Date of expiration
- Instructions on preparation of reagent
- Lot numbers of solvents and/or chemicals used in preparation of reagent
- A method to verify the reagent's reliability (if applicable)[19]
- Initials of the person preparing reagent
- Initials of the person verifying reagent (if applicable)

PREPARED CHEMICALS

Logbooks must include the following:

- Identity
- Date of preparation
- Date of expiration
- Instructions on preparation of chemical
- Lot numbers of solvents and/or compounds used in preparation of chemical
- Initials of the person preparing chemical

CONTROLS

The specification of appropriate controls is a part of each Discipline Quality Manual. The following characteristics shall be considered when designing controls:

- Similarity to the samples being tested
- Homogeneity
- Stability
- Significant variables in the analysis
- Quantitative controls shall be in the expected range of the assay

An appropriate logbook must be kept for controls, including the following:

- Source
- Lot number, when available

[18] Non-routine reagents prepared for one-time use may be recorded with the above-listed items in the appropriate laboratory case notes, and any excess reagent discarded after use
[19] The reliability verification will occur before use

- Date received and/or prepared
- Expiration date, if appropriate
- Demonstration of quality

6.4.3.2 REFERENCE COLLECTION RECORDS

Reference collections[20] maintained by the ASCL for identification, comparison, or interpretation purposes have each entry in the collection documented, uniquely identified, and handled properly to protect the characteristic(s) of interest.

6.4.4 PERFORMANCE VERIFICATION

Before equipment is placed (or returned) into service, a performance verification will be successfully completed. A performance verification is normally required after instrumentation/equipment maintenance has been performed. This ensures that the equipment meets all specified requirements. The procedures for performance verification of instrumentation/equipment will be detailed in the Discipline Quality Manual.

In general, performance verification intervals shall not be less stringent than the manufacturer's recommendations.

6.4.5 FITNESS FOR SERVICE

All equipment used for measurement will be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.6 CALIBRATION REQUIREMENT

Measuring equipment will be calibrated when:

- The measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or
- Calibration is required to establish metrological traceability of the reported results (i.e., to SI units)

6.4.7 CALIBRATION PROGRAM

The ASCL has a calibration program, which is reviewed and adjusted as necessary to maintain confidence in the status of calibration.

The Discipline Quality Manual will have defined intervals for re-calibration or performance verifications of measurement instrumentation/equipment and reference standards. Section Chiefs (or designees) will be responsible for ensuring that reference standards and measurement instrumentation/equipment meet appropriate specifications.

[20] For example: mass spectral libraries, bullets, cartridge cases, DNA profiles

Reference standards of measurement held by the laboratory shall be used for performance verifications and/or adjustments only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

New equipment used for tests which has a significant effect on the accuracy or validity of the result of that test shall either be received with calibration documentation or an external calibration will be performed before use in casework.

The Arkansas State Crime Laboratory is not a calibration laboratory and uses external calibration services for calibration of equipment.

There are two categories for equipment:

CATEGORY 1: The equipment has a significant effect on the accuracy or validity of sampling or a test result (e.g., measurements that require a measurement uncertainty calculation, reported measurements).

CATEGORY 2: The equipment could have some effect on the overall quality of testing.

When *Category 1* equipment requires a calibration, the ASCL shall use an external calibration laboratory accredited to *ISO/IEC 17025:2005*.

For *Category 2* equipment, the external calibration laboratory does not have to be accredited to *ISO/IEC 17025:2005*, but the unaccredited vendors shall be evaluated by the Quality Assurance Manager using the *Vendor Evaluation Form* (ASCL-FORM-61). The calibration documentation issued by the external calibration lab must confirm competence, measurement capability, and traceability to the appropriate National Metrology Institute (NMI).

If the associated contribution from the calibration of the equipment contributes little to the total uncertainty of the test result, the equipment does not require calibration. This assessment must be documented.

For all equipment that requires calibration, the appropriate Discipline Quality Manual shall indicate which calibration category the equipment falls under and the calibration procedures (e.g., schedule) for the equipment.

6.4.7.1 COMPONENTS

Each discipline will detail the components of the calibration program for their discipline, including:

- A list of all equipment requiring calibration
- Specified requirements for the calibration
- The interval of calibration

External calibration laboratories must meet certain specifications (see § 6.5.1.1). Accreditation certificates for approved calibration laboratories are maintained in Qualtrax.

6.4.8 LABELLING

All equipment[21] that is calibrated, or has a defined period of validity, will be marked so as to indicate either the calibration status or the period of validity.

6.4.9 OUT OF SERVICE

Any equipment which has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service.

It will be labeled as "Out of Service" or isolated from functional equipment to prevent its use. It will only be returned to service after it has been verified and documented to perform correctly.

When equipment is removed from service, a *Quality Assurance Concern* workflow is initiated in Qualtrax, and the ASCL will examine any effect that the deviation may have had on its activities. See section 7.10 for lab policies regarding nonconforming work.

6.4.10 INTERMEDIATE CHECKS

Intermediate checks of equipment may be necessary to maintain confidence in the performance of equipment. When necessary, these checks are conducted according to procedures documented in discipline quality manuals. These procedures are based upon a risk assessment, including such factors as:

- the calibration interval,
- the purpose of the equipment,
- the stability of the equipment,
- the requirements of the method(s), and
- the risk associated with a failed check.

6.4.11 CORRECTION FACTORS

When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

After a performance verification has been performed, it may be necessary to make adjustments to the equipment using certified or traceable reference standards/materials (e.g., balance, pH meter, GC-MS). These adjustments shall be documented in the calibration/performance verification log.

There are types of equipment that cannot be adjusted if they fail calibration specifications (e.g., liquid-in-glass thermometers). Correction factors may be used, but procedures are necessary to ensure that copies (e.g., in computer software) are correctly updated.

[21] Including reagents

6.4.12 EQUIPMENT ADJUSTMENT

If unintended adjustments of equipment may influence testing results, the discipline will take precautions (when practicable) to prevent these unintended adjustments. This may be accomplished by, for example:

- Using positive and negative controls, standards, or known reference material at the beginning and end of instrumental runs/analytical sequences
- Placing tamper-proof seals over the adjustment points
- Specifying dedicated personnel as the only individual(s) authorized to make the adjustments

The Discipline Quality Manual shall indicate any such procedures necessary to safeguard equipment calibrations, when applicable.

6.4.13 EQUIPMENT RECORDS

For all equipment that can influence laboratory activities, records will be retained that include the following (where applicable):

a) the identity of equipment, including software and firmware version;
b) the manufacturer's name, type identification, and serial number or other unique identification;
c) evidence of verification that equipment conforms with specified requirements;
d) the current location;
e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;
h) details of any damage, malfunction, modification to, or repair of, the equipment;
i) the LIMS instrument case number(s), if applicable;
j) the identifier used to identify the instrument in case work, if applicable;
k) the date the equipment was permanently retired from service, if applicable.

When equipment is retired, the records shall be maintained and available for at least one full accreditation cycle.

6.5 METROLOGICAL TRACEABILITY

6.5.1 GENERAL

The laboratory establishes and maintains metrological traceability of its measurement results by means of an unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

Each discipline shall be able to exhibit measurement traceability on measurements that have a significant effect on the accuracy or validity of the result of the test, including all measurements explicitly requiring a measurement uncertainty calculation.

The following table lists examples of equipment used for testing that can be calibrated by external calibration laboratories using traceable reference standards.

Type of Calibration Reference Standard	Type of Equipment
Mass	Balance
Mass-derived	Pipette (volume)
Length	Caliper, ruler
Temperature	Thermometer

Table 1: Calibrated Equipment

6.5.1.1 SUPPLIER REQUIREMENTS

If available, suppliers of external calibration services for measuring equipment and/or reference standards will be 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 a scope of accreditation.

If available, suppliers of certified reference materials (CRMs) used to establish or maintain metrological traceability will be accredited to ISO 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 ALTERNATE SUPPLIER REQUIREMENTS

If no supplier is available that meets the requirements of § 6.5.1.1, then the competence, capability, and metrological traceability of the supplier/product/service will be confirmed by the ASCL and recorded using ASCL-FORM-61 (*Vendor Evaluation Form*). This evaluation will be maintained and available for review.

6.5.1.3 INTERNAL CALIBRATION

The ASCL does not perform calibration of its own equipment.

6.5.1.4 CRM ALTERATION

If a certified reference material is changed in a way that alters its traceable measurement value[22], then the equipment used to alter the material will be evaluated for applicability of measurement traceability requirements[23].

[22] For example, the dilution of a solution with a certified concentration of an analyte
[23] For example, the metrological traceability of a calibrated volumetric flask

6.5.2 TRACEABILITY TO THE INTERNATIONAL SYSTEM OF UNITS

All measurement results at the ASCL are traceable to the International System of Units (SI) through:

- Calibration provided by a competent laboratory, or
- Certified values of CRMs provided by a competent producer (see §§ 6.5.1.1 and 6.5.1.2) with stated metrological traceability to the SI[24]

6.5.3 ALTERNATE TRACEABILITY

If metrological traceability to the SI units is not technically possible, the ASCL will demonstrate metrological traceability to an appropriate reference, e.g.:

a) Certified values of CRMs provided by a competent producer (see §§ 6.5.1.1 and 6.5.1.2)
b) Results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison

6.6 EXTERNALLY-PROVIDED PRODUCTS AND SERVICES

6.6.1 GENERAL

Only suitable externally-provided products and services will be used, when they are:

a) Intended for incorporation of the lab's own activities[25], or
b) Provided directly to the customer as received by the laboratory[26], or
c) Used to support the operation of the laboratory[27]

The ASCL is responsible to the customer for the work of any subcontractor, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

The *ASCL Procurement Policies and Procedures* document (ASCL-DOC-07) specifies policies and procedures for the purchase, receipt, and storage of materials relevant to testing. When the material or service must meet certain specifications in order to perform adequately, then these items and their specifications (e.g., manufacturer, type, grade, or other technical data relevant to the supply or service) must be defined in the Discipline Quality Manual, purchasing documents, or a discipline document.

SUPPLY INSPECTION AND VERIFICATION

Supplies, reagents, and consumable materials that affect the quality of tests are not used until they have been inspected or otherwise verified as being in compliance with specifications defined in the Discipline Quality Manual, purchasing documents, or a discipline document.

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[24] For example, via a Certificate of Analysis from a provider fulfilling the requirements of ISO 17034
[25] For example: outsourced analysis used by an ASCL analyst as the basis of an opinion/interpretation
[26] For example: outsourced analytical report forwarded to a customer without modification
[27] For example: consumable materials, reference materials, equipment maintenance, proficiency testing services, calibration services

The Procurement Section inspects all received materials to ensure agreement with what was ordered. Any inconsistencies are reconciled before materials are distributed to the appropriate section for use in casework. The appropriate Section Chief or designee will verify (if applicable) that the materials meet the required specifications. This approval will be documented in Qualtrax in the External Supply Request workflow.

Chemicals and reagents are to be initialed and dated with a "Received Date" by the Procurement staff. As chemicals and reagents are requested and received, the analysts are responsible for initialing and dating containers with the "Open Date". Supplies, reagents and consumable materials shall be stored in accordance with the manufacturer's recommendations, if any.

PURCHASING DOCUMENTS

The Qualtrax *External Supply Workflow* is used to request the purchase of items. Alternate forms may be used with permission from the Procurement Section. This workflow includes the following information:

- Vendor Name
- Date
- Part Number (if known)
- Description
- Quantity
- Price
- Total
- Justification

The description shall define the specific item being requested, including any required type, class, grade, precise identification, or other technical data, if appropriate. The approval of the Section Chief and Assistant Director are necessary.

VENDOR EVALUATION

Critical consumables, supplies, and services (i.e., those which affect the quality of testing) will be obtained from reliable suppliers. Discipline Quality Manuals shall contain a list of any critical supplies. The following policies will be used to evaluate suppliers to determine the reliability of services and/or supplies they provide:

- Critical consumable materials are obtained from a source that has a minimum of *ISO 9000* accreditation, whenever possible.
- Calibration and testing services and supplies are obtained from vendors accredited to *ISO/IEC 17025* or from vendors who meet nationally certified standards (for calibration services refer to § 5.6.2.1, and for subcontracting of testing refer to § 4.5.1), whenever possible.
- If a source is used that does not meet the above criteria, the source will be evaluated against the intent of ISO/IEC 17025. This may be done by obtaining documentation of the QA program/protocol or by completing a *Vendor Evaluation Form* (ASCL-FORM-61).

A list of approved vendors and sub-contractors is maintained by the Quality Assurance Manager. Supporting documentation (e.g., copy of certification, QA protocol) is maintained in Qualtrax.

6.6.2 RECORDS

If the Arkansas State Crime Laboratory transfers evidence to an outside laboratory[28], an *Inter-Laboratory Evidence Transfer Form* (ASCL-FORM-07) must be completed and entered into the case file. The Inter-Laboratory Evidence Form may be waived for items funded out of a grant and/or items under a contract. Any cost incurred by the laboratory must be approved by the Assistant Director.

All external laboratories performing casework or calibration for the Arkansas State Crime Laboratory must be accredited by an accrediting body recognized by the Arkansas State Crime Laboratory. These laboratories must provide the Arkansas State Crime Laboratory with documentation of accreditation, which is maintained in Qualtrax.

6.6.3 COMMUNICATION

The ASCL will communicate its requirements (if any) to external providers for:

a) the products and services to be provided
b) the acceptance criteria
c) competence, including any required qualification of personnel
d) activities that the laboratory, or its customer, intends to perform at the external provider's premises

[28] For example: FBI, NMS, Bode Technologies

7 PROCESS REQUIREMENTS

7.1 REVIEW OF REQUESTS, TENDERS, AND CONTRACTS

7.1.1 GENERAL

The ASCL reviews all requests, tenders, and contracts to ensure that:

a) The requirements of this process are well-defined, documented, and understood
b) The ASCL has the capability and resources to meet these requirements
c) When external providers are used:
    1) The requirements of § 6.6 are applied
    2) The ASCL advises the customer of the specific laboratory activities to be performed by the external provider, and
    3) Gains the customer's approval
d) The appropriate methods are selected, and that they are capable of meeting the customer's requirements

The ASCL publishes all of its Quality Manuals on its website, which contain the laboratory's policies and procedures regarding this process. In addition, important information is listed on the *ASCL Evidence Submission Forms* (ASCL-FORM-12 and ASCL-FORM-63), including evidence requirements, agreements related to testing, subcontracting, and agreements related to reporting. The ASCL also distributes educational information to its customers through a periodic newsletter, presentations at law enforcement and prosecutor meetings, and training courses provided to law enforcement.

Upon receipt, the Evidence Receiving section reviews each request to determine if it appears to be within the scope of normal laboratory services. If so, the Evidence Technician will accept the evidence and initial and date the *ASCL Evidence Submission Form*. The Evidence Technician will then enter the request into the LIMS and route it to the appropriate discipline. Requests for non-routine work must be reviewed by the appropriate Section Chief. The Section Chief must initial and date the *ASCL Evidence Submission Form* next to the request.

The Medical Examiner section is considered to be an internal customer. Reviews of Medical Examiner requests, tenders, and contracts may be performed in a simplified way (as detailed in the appropriate Discipline Quality manual).

The ASCL may find it necessary to transfer evidence to an outside laboratory for testing. This decision will generally be made by the affected discipline. This decision may occur after a review of the contract or it may be discovered during the testing process. Subcontracting is agreed to by the customer as part of the evidence submission process. Documentation stating the reason for subcontracting will be in the case record. If a cost is incurred by the customer, then the customer must approve of the arrangement, and this approval will be documented in the case record.

A subcontracting report is generated and distributed to the customer advising them of the subcontracted work, including what laboratory activities are being subcontracted. The results of the subcontracted work are distributed separately.

The ASCL uses the methods and procedures documented in its Discipline Quality Manuals, which are capable of meeting the customers' requirements.

7.1.2 INAPPROPRIATE REQUESTS

The ASCL makes all decisions regarding analytical processing and choice of methods, which is agreed to by the customer as part of the submission process. If the customer requests testing which is inappropriate or out-of-date, they are informed as part of the review of the request.

7.1.3 STATEMENTS OF CONFORMITY

The ASCL does not issue reports containing statements of conformity.

7.1.4 RESOLUTION OF DIFFERENCES

Any difference between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the ASCL and the customer.

7.1.5 DEVIATION FROM THE CONTRACT

When the customer agrees to the contract, the customer agrees that the ASCL may make deviations as deemed necessary. However, the customer will be notified (e.g., iResults, phone call, e-mail) if the ASCL goes outside its scope of testing.

7.1.6 AMENDMENT OF THE CONTRACT

If the contract needs to be amended after work has begun, the contract shall be reviewed (as stated above) by the discipline making the amendment, and all affected personnel shall be notified.

7.1.7 COOPERATION WITH CUSTOMERS

The ASCL will cooperate, whenever possible, with customers in clarifying their request(s) and in monitoring the ASCL's performance in relation to the work performed. It does this by maintaining open channels of communication with customers, and cooperating in providing a timely response to concerns and questions regarding requests for services and the status of ongoing work.

However, in order to ensure confidentiality of case information, limit the potential for contamination, ensure the security of evidence and case records, and provide the best service possible to all customers, the ASCL does not routinely permit the customer to be present during the testing process. Any requests for an exception to this policy should be communicated to the Director or Assistant Director. Requests for viewing autopsies will be evaluated by the Chief Medical Examiner. Refer to the *Personnel Handbook* (ASCL-DOC-02, § 3.23) for the policy regarding

court officials viewing and/or photographing evidence. Also refer to the *Personnel Handbook* § 3.24 (Witnessing the Examination of Evidence).

7.1.8 RECORDS OF REVIEW

Upon review of the request, the Evidence Receiving Technician initials and dates the *ASCL Evidence Submission Form*. If a significant change to the request is made, the change will also be initialed and dated.

The laboratory maintains records related to the customer request within the casefile, including the *ASCL Evidence Submission Form* (ASCL-FORM-12_WD or ASCL-FORM-63) and case-related discussions with the customer (which are documented on an *Agency Contact Form* (ASCL-FORM-06), e-mail, or equivalent).

7.1.9 DATABASE SEARCH EXTENT

The extent of database searches is communicated with our customers and updated as needed. Please refer to discipline quality manuals for specific policies and procedures.

7.2 SELECTION, VERIFICATION, AND VALIDATION OF METHODS

7.2.1 SELECTION AND VERIFICATION OF METHODS

7.2.1.1 SELECTION OF METHODS

Only appropriate methods and procedures will be used in casework. These include methods and procedures for sampling, handling, transport, storage and preparation of items to be tested, and where appropriate, an estimation of the measurement uncertainty. Instructions are documented for the use and operation of all relevant equipment, and the handling and preparation of items for testing, where the absence of such instructions could jeopardize the results of tests.

7.2.1.1.1 TEST METHODS

Each discipline within the ASCL will maintain a quality manual containing a "Test Method" section. This section will contain a detailed procedure for each analytical method used in that discipline, available to all analysts who work in that discipline. There are often many acceptable procedures to accomplish a particular examination. The considerable variation that exists in actual casework requires a forensic scientist be free to exercise sound judgment in choosing the method most appropriate to the case at hand. The Section Chief ensures that those procedures which are contained in their Discipline Quality Manual meet acceptable scientific standards and that they are applied appropriately.

Each test method shall include the following, when applicable:

- the scope of the test method
- reagents, standards, chemicals, and controls

- sample preparation
- quality assurance/control measures
- the interpretation of results, which should include:
  - precautions to be taken
  - possible sources of error
  - applicable literature references
  - criteria for positive, negative, and inconclusive results
  - applicable disclaimers
- documentation requirements
- specifications for critical reagents and equipment (if applicable)

Laboratory procedures may specify where specific case record components (e.g., spectra of standards or calibration documentation) are maintained without also referencing the location of these records in the case file.

If it becomes necessary to deviate from a documented method and/or procedure, the deviation must be technically justified and authorized by the appropriate Section Chief. The deviation will be documented in the case record. Each Section Chief will keep a log of method/procedure deviations.

7.2.1.1.2 COMPARISON OF KNOWNS AND UNKNOWNS

When a method includes the comparison of an unknown to a known, the unknown will be evaluated to identify characteristics suitable for comparison and (if applicable) characteristics[29] suitable for statistical rarity calculations, prior to comparison[30] to one or more known items.

7.2.1.1.3 CALIBRATION METHOD SELECTION

The ASCL does not perform calibration.

7.2.1.2 METHOD AVAILABILITY

All methods and procedures are contained in Discipline Quality Manuals, which are controlled and maintained in Qualtrax. Any supporting documentation is readily available to personnel.

7.2.1.3 METHOD VERSION

Only the current approved version of a method may be used in casework.

7.2.1.4 METHOD SELECTION

The ASCL selects the method(s) to be used in casework. Part of the submission agreement between the ASCL and the customer is that the customer agrees that the method(s) used in the case will not be included on the case report, but is available upon request.

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[29] For example: alleles in a DNA profile, friction ridge detail in a latent print, striation detail on a bullet, criteria for evaluation of mass spectrometry fragments/ratios

[30] It may be appropriate to perform a preliminary characterization of a known prior to assessment of the unknown in some situations, such as the selection of test items for comparison

Methods may be:

- Laboratory-developed or modified
- Published either in international, regional or national standards
- Published by reputable technical organizations
- Published in relevant scientific texts or journals
- Specified by the manufacturer of the equipment

7.2.1.5 METHOD VERIFICATION

The ASCL verifies that it can properly perform a method before introducing it by performing method verification. This verification demonstrates that the method is fit for service, and that the laboratory is capable of reliably achieving the intended results. Documentation of method verifications will be retained.

If the method is revised, the method verification must be repeated to the extent necessary to demonstrate that the method is still fit for service.

7.2.1.6 METHOD DEVELOPMENT

When method development is performed, it is a planned activity, assigned to personnel approved to perform method validation. Adequate resources are made available.

During the method development, the process is reviewed to ensure that the needs of the customer are still being fulfilled. If a modification to the plan is required, it will be approved and authorized by a revision of the plan document in Qualtrax.

7.2.1.7 DEVIATION FROM METHOD

If a deviation from a documented method and/or procedure is necessary, it must be technically justified and authorized by the appropriate Section Chief. The deviation will be documented in the case record. Each Section Chief will keep a log of method/procedure deviations.

7.2.2 VALIDATION OF METHODS

Validation is the process used by the scientific community to assess the ability of a procedure to reliably obtain a desired result, to determine the conditions under which such results can be obtained, and to determine the limitations of the procedure. The validation process identifies the critical aspects of the procedure that must be carefully controlled and monitored. All validations must include successful testing of samples that are representative of what would typically be encountered in casework.

Validation studies can be conducted externally by the scientific community (as in the case of standard or published methods) or by the laboratory itself (as in the case of methods developed in-house or where significant modifications are made to previously validated methods).

7.2.2.1 EXTENT OF VALIDATION

Prior to implementing a non-standard method, a laboratory-developed method, a standard method used outside its intended scope, or amplifications and modifications of a standard method, a validation will be performed. The validation will be as extensive as necessary to ensure that the method if fit for service and meets the needs of the given application.

The techniques used for validation can include one or more of:

- Evaluation of bias and precision using reference standards or material
- A systemic assessment of the factors influencing the result
- Testing method robustness by varying controlled parameters
- Comparison of results achieved with other validated methods
- Interlaboratory comparisons
- Evaluation of the measurement uncertainty of the results, based on an understanding of the theoretical principles of the method, and practical experience of the performance of the method

7.2.2.1.1 VALIDATION PROCEDURE

Before the validation begins, a validation plan will be approved by the appropriate Section Chief(s), Quality Assurance Manager, and the DNA Technical Leader (for DNA and CODIS methods). The validation plan should address the expected performance of the method as it relates to the needs of the customer. The validation plan shall be updated as necessary and affected personnel will be notified.

Once the validation plan is approved, the validation may begin. Elements included in the validation will include:

- Associated data analysis/interpretation
- The data required to report a result, opinion, or interpretation
- Any limitations of the method, including reported results, opinions, or interpretations

Whenever practicable, validation shall also involve the use of at least one of the following procedures:

- Split samples
- Blind trials
- Concordance testing

Validation guidelines promulgated by reputable technical organizations may alternately be used to determine the structure and extent of the validation process.

After the validation has been completed, a validation summary will be prepared by the personnel involved in the validation process. This will include the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use. The validation summary will be reviewed and approved by the appropriate Section Chief(s),

Quality Assurance Manager, DNA Technical Leader (when applicable), Assistant Director, and Director. The Discipline Quality Manual shall be updated appropriately.

Following approval of the validation, individuals will be trained by the personnel involved in performing the validation. This training will include the interpretation of results, quality assurance and quality control measures, and documentation requirements. The training will be performed prior to use of the new analytical procedure in casework and must be documented in Qualtrax. All documentation supporting validation must be readily available to each analyst who uses it.

For validations conducted outside of the laboratory, individuals will be trained appropriately prior to use in casework and this training shall be documented in Qualtrax.

7.2.2.2 CHANGES TO VALIDATED METHODS

Any change[31] to a validated method requires an evaluation of the effect of the change. If the change affects the original validation, a new validation will be performed (to the extent necessary to demonstrate method validity).

7.2.2.3 RELEVANCE TO NEEDS

The performance characteristics of successfully-validated methods will be appropriate and relevant to the customer's needs and consistent with any specified requirements.

7.2.2.4 VALIDATION RECORDS

After the validation has been completed, a validation summary will be prepared by the personnel involved in the validation process. This will include:

- The procedure used for the validation
- Specification of the requirements
- Determination of the applicable performance characteristics of the method[32]
- The results obtained
- A statement as to whether the method is fit for the intended use

The validation summary will be reviewed and approved by the appropriate Section Chief(s), Quality Assurance Manager, DNA Technical Leader (when applicable), Assistant Director, and Director. The Discipline Quality Manual shall be updated appropriately.

[31] Including changes to data analysis and interpretation

[32] For example: measurement range, accuracy, measurement uncertainty, limit of detection, limit of quantification, selectivity, linearity, repeatability/reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, dilution integrity, bias

7.3 SAMPLING

7.3.1 GENERAL

The ASCL uses a sampling plan and method whenever it carries out sampling. Sampling is defined here as the "selection of a sample for testing, according to a procedure". Sampling often occurs before submission to the laboratory, but any sampling in the laboratory[33] must be performed in conformance with this section.

The sampling plan describes what kind of sampling will be used (i.e., statistical sampling[34] or non-statistical sampling[35]).

The sampling method describes how the sampling is achieved. This helps ensure that the results of testing are valid by addressing the factors that may affect them. Sampling methods are included in discipline quality manuals.

The sampling plan and method shall be available at the site where sampling occurs.

7.3.2 SAMPLING METHOD

Each sampling method includes:

- The method for selection samples or sites
- The sampling plan
  - If an inference is made to report on the whole population from which a sample is taken, then statistical sampling must be used
- The preparation and treatment of the sample(s) to yield the item for subsequent testing

Sampling methods are located in the discipline quality manuals. Each sampling method will include, as appropriate:

- Homogeneous Materials
  - How to determine if a material is homogeneous
  - How the sample can be made homogeneous by the analyst
  - How to remove a sample from a homogeneous material
- Statistical Sampling: Population Determination Guidelines for Multi-unit Populations[36]
  - The population must be contained in a single item of evidence
  - The population determination shall take into account all typical forms and quantities in which evidence may appear
  - The "sampling unit" is the basic unit into which the sample is divided[37]

[33] For example: selecting a subset of the submitted items for testing, or taking representative samples from a piece of physical evidence
[34] Previously called "sampling"
[35] Previously called "sample selection"
[36] A multiple-unit population consists of items which are similar in relevant visual characteristics
[37] For example: tablet, baggie of powder, piece of glass, fiber, stain, blood sample

- Procedures to statistically determine the number of samples to be tested:
  - Various statistical models are acceptable[38]
  - Samples must be selected at random, without bias
  - The limits of inference that can be made about the population must be documented
- Non-statistical Sampling
  - Sample selection (or portion thereof) may be based on:
    - The training and experience of the examiner
    - Legal limits/charging/statutory guidelines
    - A non-statistically based plan

Each sample/sampling unit will be tested to meet all method requirements for the relevant discipline(s).

Non-statistical sampling is used when a subset of an evidence item is tested, but no inference is made about the whole.

7.3.3 SAMPLING RECORDS

Sampling records will be maintained whenever sampling is performed, including (where relevant):

- Identification of the sampling method used[39]
- The date and time of sampling
- The identification and description of the sample[40]
- Identification of the person performing the sampling
- Identification of any equipment used
- Environmental or transport conditions
- Diagram(s) identifying the sampling location
- Any deviation, addition, or exclusion form the sampling method and plan

Deviations from the sampling plan and procedures may be requested by the customer or deemed appropriate by the analyst. Any deviations shall be approved in writing by the appropriate Section Chief and maintained in the case record.

7.4 HANDLING OF TEST ITEMS

7.4.1 GENERAL

The Arkansas State Crime Laboratory receives, secures, analyzes and documents evidence submitted by duly authorized agencies. The ASCL processes evidence in a timely manner consistent with the need for quality services, preservation of the chain-of-custody, and protection of the

[38] For example: hypergeometric, Bayesian, or other probability-based approaches
[39] If only one sampling process is used in routine casework, then this may be documented in the Discipline Quality Manual instead of individual case notes. Use of any alternate sampling process must then be noted in the case notes.
[40] For example: number, amount, name

integrity of the evidence. It is a system-wide priority to ensure that the necessary precautions are taken to maintain the integrity of the evidence, including proper collection and preservation techniques.

The *Evidence Receiving Quality Manual* (ER-DOC-01) contains policies and procedures for the transportation, receipt, handling, protection, storage, retention, maintenance, control, and disposition of test items, including all provisions necessary to protect the integrity of the test item. Additional policies may be implemented by individual disciplines in their quality manual.

Evidence will be stored in a secure evidence storage area in accordance with the requirements of the Evidence Section's Quality Manual, until transferred to a laboratory analyst or examiner, another laboratory, or the submitting agency. Storage of evidence in individual disciplines is addressed in each Discipline's Quality Manual. Evidence shall be maintained under appropriate conditions to prevent deterioration, loss, or damage to the evidence during storage, handling, or the testing process.

Evidence requiring special consideration because of its potential for contamination, fragility, or hazardous nature shall be handled in accordance with the customer's handling instructions and/or the requirements of the *Evidence Receiving Quality Manual*. If evidence must be stored under special environmental conditions (e.g., refrigeration or freezing), then these conditions shall be maintained, monitored, and recorded.

When evidence, such as latent prints and impressions, can only be recorded or collected by photography and the impression itself is not recoverable, then the photographic image must be treated as evidence.

RESPONSIBILITIES AND PROCEDURES

Those employees assigned to the Evidence Receiving Section will have primary responsibility for the receipt, storage, transfer, and return of evidence. All employees will be trained to recognize the need for taking precautions necessary to ensure the integrity of evidence and the safety of ASCL personnel.

All firearms will be handled as though they are loaded. If it is unclear whether a firearm is loaded, a Firearms Examiner (or an individual with firearms experience) will determine this by inspection. This may occur if the submission form is not properly completed or if the submitter of the evidence is unsure of the status of the firearm and requests the ASCL to inspect it.

All externally-submitted illicit lab evidence is inspected by a forensic chemist or an individual with the appropriate chemistry background and training. The *Illicit Laboratory Safety Form* (ER-FORM-01) is used to certify that the evidence has been inspected. The *Forensic Chemistry Quality Manual* (DRG-DOC-01) contains policies for inspecting this evidence.

Large and/or bulky submissions may be reviewed by an analyst or examiner to determine which items are most likely to be instructive and to eliminate unnecessary examinations or analyses.

Whenever possible, this review will occur in coordination with a representative of the investigating agency (in person or by phone).

If there is evidence in a case involving a laboratory employee or their immediate family, including postmortem examinations, the employee must notify the Director as soon as possible. The Director or designee will determine the specific case management needs.

Evidence for the Digital Evidence section is received at the main ASCL location and transported to and from the ASP location, as necessary.

EVIDENCE INVENTORY

An evidence inventory will be conducted approximately every six months. This inventory will consist of an Evidence Receiving Inventory (all evidence stored in Evidence Receiving) and a Section Inventory (all evidence in the analysts' possession). This inventory will not include those samples retained for future analysis or destruction (e.g., toxicology samples, DNA long term storage).

The Evidence Receiving Section Chief will schedule and coordinate the inventory with the Quality Assurance Manager. The Evidence Receiving Section Chief and Quality Assurance Manager will provide a written report to the Director for the Evidence Receiving Inventory and the Section Inventory, respectively. The Quality Assurance Manager will maintain a copy of these reports.

At the Hope Regional Laboratory, the Forensic Chemistry Supervisor will schedule and conduct the inventory, and provide a written report to the Director. This inventory will include all evidence held at the laboratory. The Quality Assurance Manager will maintain a copy of the report.

EVIDENCE RETENTION

Individual discipline retention policies are found in the appropriate Discipline Quality Manual.

If a private individual requests a sample be retained, a fee may be imposed by the ASCL to cover cost of storage, as determined by the Director or designee.

INDIVIDUAL CHARACTERISTIC DATABASES

The ASCL uses three individual characteristic databases. Employees using these databases must receive proper training and/or clearance through the appropriate organizations, as listed below:

Acronym	Database	Discipline	Approving Body
AFIS	Automated Fingerprint Identification System	Latent Prints	Arkansas State Police
CODIS	Combined DNA Index System	CODIS	CODIS-National Index System guidelines
NIBIN	National Integrated Ballistics Information Network	Firearms/ Toolmarks	NIBIN-Forensic Technologies, Inc., and the Bureau of Alcohol, Tobacco, Firearms, and Explosives

Individual characteristic database samples include ten print cards of known individuals (Latent Prints: AFIS), convicted offender/arrestee known biological samples (CODIS), and test fired ammunition produced at the ASCL (Firearms/Toolmarks: NIBIN). Ten print cards are treated as examination documentation. Test fired ammunition produced by the ASCL and convicted offender/arrestee known biological samples are treated as reference materials[41]. Specific procedures concerning individual characteristic database samples are addressed in the appropriate Discipline Quality Manual.

Database Sample	Discipline	Characterization
Ten print card	Latent Prints (AFIS)	Examination documentation
Convicted offender/arrestee known biological sample	CODIS (CODIS)	Reference material
Test-fired ammunition generated at the ASCL	Firearms/Toolmarks (NIBIN)	Reference material

7.4.1.1 HANDLING PROCEDURES

7.4.1.1.1 STORAGE

All evidence not in the process of examination/analysis shall be maintained in a secured, limited-access storage area under proper seal. This will normally be the evidence storage area in Evidence Receiving or section Secure Storage.

Evidence in the process of examination may be left unattended for limited periods of time (e.g., lunch, short breaks) but must be in a secure, limited-access area. If the analyst needs to be away for a longer period of time, then the evidence shall be secured in a short term storage location, whenever practical. Otherwise, the analyst shall take reasonable precautions to protect the evidence from loss, cross-transfer, contamination, and deleterious change.

Evidence shall not be left unattended if it is not in the process of being examined or there is no expectation of frequent examination. Additional policies may be implemented by individual disciplines in their quality manual.

Individual characteristic database samples controlled by the ASCL must be protected from loss, cross-transfer, contamination, and deleterious change. Specific requirements will be addressed in the appropriate Discipline Quality Manual.

7.4.1.1.2 PACKAGING AND SEALING

Evidence will be sealed so that the contents cannot readily escape, and that opening the container would result in obvious damage or alteration to the container or its tape seal. All evidence must bear a proper seal, including the initials (or other identifier) of the person sealing the evidence across the seal.

[41] Test fires that may be used as evidence for future comparisons must be treated as evidence at all times. Test fires considered to be reference material may not routinely be redesignated as evidence.

Whenever practical, the original seal will be left intact when opening a container. Instead, a new opening will be made to access the evidence. When the analysis (or examination) in complete, this new opening will be properly sealed as outlined above, leaving all original packaging seals intact and clearly marked.

If reusing the original container is impractical, a new evidence container may be used. It shall be marked and sealed according to the above procedures and the original evidence packaging shall be kept inside the second evidence container. If the original packaging cannot be kept, complete documentation and a picture of original packaging must be retained in the case record. (Toxicology samples only need a written description of the packaging.) Documentation of the change in packaging (with full description) must be included in the case record for future reference.

Items with an expectation of frequent or continued analysis may be considered "evidence in the process of examination/analysis" and may be stored unsealed in a limited access area as long as the evidence is protected from loss, cross-transfer, contamination, and deleterious change. Cases no longer in the process of examination shall be closed and the evidence properly sealed until analysis resumes or a new service request is received.

Evidence transported from a crime scene by laboratory personnel shall be protected from loss, cross transfer, contamination, and deleterious change during transportation to the ASCL, whether in a sealed or unsealed container. Where appropriate, further processing to preserve, evaluate, document, or render evidence safe shall be accomplished prior to final packaging. The evidence shall be appropriately identified, packaged, and entered into the LIMS as soon as practical.

7.4.1.1.3 CHAIN OF CUSTODY

Evidence[42] within the laboratory is tracked by the LIMS. All internal transfers are tracked electronically from the time of receipt to the final disposition, providing a printable chain of custody. For each internal electronic transfer, the following information is recorded:

- The person, location, or state relinquishing the item of evidence
- The person, location, or state accepting the item of evidence
- The item(s) being transferred
- An indication of the security of that transfer (i.e., a checkmark indicating if each person used a barcode and PIN)
- The date and time of the transfer

Subitems shall be tracked through the chain of custody to the same extent as original items.

The LIMS database contains electronic signatures and initials for all analysts. In some cases, a combination of written and electronic chain of custody is used.

[42] This includes both items that are received by the laboratory as well as items that are collected/created and preserved for future testing (e.g., test-fired ammunition, latent print lifts, DNA extracts)

INTRA-LABORATORY TRANSFER

Cases may be transferred within the ASCL System as necessary in order to minimize the turn-around time and to provide the best overall service to our customers.

INTER-LABORATORY TRANSFER

If the Arkansas State Crime Laboratory finds it necessary to transfer evidence to an outside laboratory (e.g., FBI, NMS), an *Inter-Laboratory Evidence Transfer Form* (see ASCL-FORM-07) must be completed and entered into the case file. This form may be waived for analysis funded out of a grant and/or under a contract. Any cost incurred by the laboratory must be approved by the Assistant Director.

EVIDENCE RETURN

When evidence is returned to Evidence Receiving after all necessary analyses are completed, the item is retained until it is released to an authorized representative of the submitting agency. Authorized representatives are either employees of the submitting agency, or have written authorization from the submitting agency on file in Evidence Receiving. If the evidence technician does not recognize the representative, then proper identification must be provided. The signature and printed name of the receiving representative is required to document evidence return.

Evidence will only be shipped after receipt of a written request from the submitting agency and the approval of the Director or the Assistant Director. When mailing or shipping evidence, the following requirements apply:

- Controlled substances, currency, or firearms cannot be mailed
- All other evidence may be mailed via U.S. Certified Mail (return receipt requested)
- When shipping any evidence by other than the U.S. Postal Service, the vendors must provide return receipt and be able to track shipment

7.4.1.1.4 CUSTOMER NOTIFICATION

The Evidence Receiving Section will notify[43] submitting agency personnel to pick up completed evidence whenever it is deemed necessary.

The ASCL will communicate to the customer the disposition of all received items.

The ASCL will communicate to the customer if it has collected/created items which are preserved for future testing.

7.4.2 ITEM IDENTIFICATION

A unique case number is assigned to every case when evidence is initially received by the laboratory. Each exterior container is labeled with a unique barcode. Agency evidence numbers will be used to identify the evidence whenever practical.

[43] In writing

If uniquely-identified items must be subdivided, then appropriate subitem identifiers will be assigned and each subitem will be labeled with its identifier. This allows for the tracking of each subitem and the identification of its origin.

All evidence will be marked or identified with the laboratory case number (e.g., YYYY-######) to ensure that it is identifiable and traceable to the corresponding case. When the evidence does not lend itself to marking, then the proximal container must be marked or identified with the laboratory case number.

Individual characteristic database samples controlled by the ASCL must be uniquely identified. The appropriate Discipline Quality Manuals address identification requirements.

7.4.2.1 EXTENT

All items received by the ASCL will be identified as detailed in § 7.4.2.

7.4.3 DEVIATIONS

Evidence submitted to the laboratory must be properly packaged, labeled, and sealed to prevent contamination, loss, or deleterious change. All packaging deficiencies noted at the time of receipt must be corrected, preferably by the submitting customer. If the customer is not available, or if it is not expedient to call the customer back to correct the deficiency, then an Evidence Technician may take steps to correct the problem (e.g., provide a remedial seal). However, if the deficiency is serious enough to bring into question the integrity or identity of the test item, then the appropriate Section Chief and customer agency must be contacted to resolve the issue before the evidence is analyzed.

If a packaging deficiency is not apparent until the case is checked out by an analyst, the analyst may correct the deficiency. If there is any concern that the packaging deficiency has affected the integrity or identity of the test item, the analyst's Section Chief and the customer agency shall be advised and consulted with for further instructions.

If the analyst discovers an inconsistency between the stated and actual contents of a package, or if there is doubt about the suitability of an evidence item for testing, then the analyst shall attempt to contact the customer before proceeding. All contacts will be documented in the case record (e.g., using an *Agency Contact Form* (ASCL-FORM-06), by email). For minor inconsistencies, the analyst shall use their judgment on whether to contact the customer, but must make a note of the discrepancy in the case file.

All remedial actions taken to correct packaging or evidence deficiencies shall be noted in the case record (e.g., on the submission form or in analytical notes).

If the customer requires testing, acknowledging a deviation from specified conditions, a disclaimer will be included in the report indicating which results may be affected by the deviation. Such a deviation must be approved by the Section Chief (see § 7.2.1.1.1).

7.4.4 ENVIRONMENTAL CONDITIONS

If evidence has to be stored or conditioned under special environmental conditions (e.g., refrigerated, frozen), then these conditions shall be maintained, monitored, and recorded.

7.5 TECHNICAL RECORDS

7.5.1 GENERAL

All case records are stored in the JusticeTrax LIMS-plus software program. As a case is created in JusticeTrax, request(s) will be added for disciplines with evidence to be processed. Each request has a set of milestones, including:

- Unassigned
- Assigned
- Findings Entered
- Draft Complete
- Tech. Reviewed
- Admin. Reviewed

In addition, each request has a storage location for images.

Each case record will contain enough information to enable reanalysis to be conducted under conditions as close as possible to the original, and to identify factors affecting uncertainty. The identity of all individuals who sampled evidence, conducted testing, or verified results will be specified in the case record.

Observations, data, and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

Dates shall be recorded to indicate when the work was performed. At a minimum, the starting and ending dates must be recorded. Each discipline's Quality Manual must describe a dating procedure.

Operating parameters used during instrumental analysis shall be recorded in the examination records or another appropriate location. The locations shall be specified in the Discipline Quality Manual.

The unique ASCL case number (e.g., YYYY-######, either handwritten or electronically generated) and the analyst's handwritten initials or signature (or secure electronic equivalent) must be on all examination records in the case file.

When examination records are prepared by an individual other than the issuing examiner, the initials of that individual(s) shall be on each page(s) of examination records representing their work. It shall be clear from the case record who performed each stage of the examination/analysis.

When data from multiple cases are recorded on a single printout, kept in a single file, and referenced for the files for which data was generated, the case number for each case for which data

was generated shall be appropriately recorded on the printout. When the printout is placed in each of the appropriate case records, only the individual case number is required.

When examination records are recorded on both sides of a page, each side shall include both the case number and analyst's initials.

7.5.1.1 TECHNICAL RECORD RETENTION

Examination records are any records generated by the analyst/examiner for a case file (e.g., notes, worksheets, photographs, spectra, printouts, charts, and other data). Examination records that are essential for the evaluation and interpretation of the data must be stored in the appropriate folder within the "Request" folder in the LIMS case file. When it is not feasible to incorporate the examination records in the LIMS case file, these records may be stored external to the LIMS case file. The location of these records must be specified in the Discipline Quality Manual or in the case file.

All other records contained in the case file will be considered administrative records and will normally be stored in the "Case Images" folder in the LIMS case file. It is acceptable to place an administrative memorandum in a "Request" folder after the draft complete milestone if (and only if) it does not serve as an examination record (i.e., it solely helps explain the administrative information contained within the examination record).

7.5.1.2 ABBREVIATIONS

Abbreviations may be used in examination records. Each discipline shall have a master abbreviation legend accessible to appropriate personnel. Commonly understood abbreviations (e.g., etc., mL, pos.) are not required to be included in this legend, but all uncommon or non-standard abbreviations must be included in the appropriate legend to be used in a case record.

7.5.1.3 TECHNICAL RECORD SUFFICIENCY

Technical records to support a report[44] shall be such that, in the absence of the analyst, another competent reviewer could evaluate what was done and interpret the data. Discipline Quality Manuals detail the required record documentation.

7.5.1.4 TECHNICAL RECORD PERMANENCY

Records are created or maintained in a permanent manner. Handwritten notes and observations must be in ink. However, pencil may be appropriate for diagrams or making tracings. No handwritten information will be obliterated or erased.

7.5.1.5 REJECTION

If data, an observation, or a calculation is rejected, the following information will be recorded in the technical record:

[44] Including results, opinions, and interpretations

- The reason for the rejection
- The identity of the person rejecting
- The date of the rejection

This includes both rejection by a reviewer/verifier, and rejection of data by the analyst/examiner.

7.5.1.6 CALIBRATION DATA

If an adjustment/repair is performed because a calibration does not meet specifications, then pre- and post-adjustment/repair data will be retained (i.e., all calibrations will include "as found" data).

7.5.2 AMENDMENTS TO TECHNICAL RECORDS

Amendments[45] to technical records must be trackable to previous versions or to original observations. Both the original and amended data/files will be retained, including:

- The date of alteration
- An indication of the altered aspect(s)
- The personnel who made the alteration(s)

Any corrections made to existing hardcopy technical records will be made by an initialed and dated single strikeout (so that what is stricken can still be read) by the person making the change. All additions will be initialed and dated. Correction fluid or correction tape may not be used.

Changes made to electronic documents must allow the reviewer to track what changes were made to the document, who made the change, and when. If a correction is made, the original version will be maintained[46].

Contemporaneous[47] revisions to technical records are not considered to be amendments.

When the analyst/examiner has completed a request, then they will set the milestone(s) in JusticeTrax to draft complete. Examination records for a request will be considered completed at this time. If a change is subsequently made to the examination record, the original record will remain in the electronic case file and the changed record will be stored with a different name (e.g., amended notes). There shall be sufficient information to determine what was changed.

If a report is changed after it has been draft completed, but before release, the original version will be maintained in the case record.

[45] Including additions, deletions, changes, interlineations, or any other modification to the original information

[46] A second copy of the document is not necessary if it has not yet been placed into JusticeTrax; the correction can be made on the original notes.

[47] Contemporaneous means at the same period of time. Amendments made after moving on to the next case are not considered to be contemporaneous. Amendments made before moving on to the next case, while the matter is still fresh in memory, may be considered contemporaneous.

7.6 EVALUATION OF MEASUREMENT UNCERTAINTY

The ASCL will assess the measurement uncertainty when quantitative values are reported for:

- the quantity (mass or volume) of a controlled substance
- the presence of a controlled substance when it is reported as a percentage (mass or volume fraction) of the whole sample
- values reported for blood alcohol or drug concentration in toxicology samples
- the barrel length of a firearm and/or the overall length of a firearm

The analytical protocols for estimation of the measurement uncertainty for the affected disciplines will be contained either in the Discipline Quality Manual or a location specified in the manual. The Section Chief, or designee, shall be responsible for maintaining documentation of all measurement uncertainty calculations. The estimated measurement uncertainty shall be available to the customer, either by appearing on the report or by request.

7.6.1 UNCERTAINTY COMPONENTS

When constructing the uncertainty budget, all uncertainty components which are of importance in the given situation shall be taken into account. Sources that may contribute to the uncertainty include, but are not limited to, the following:

- reference standards and reference materials
- methods and equipment
- environmental conditions
- properties and condition of the item being tested
- the individual conducting the measurement
- any contribution of the sampling method

Factors that do not impact the measurement uncertainty to any significant degree (based on previous experience) may be dismissed, but must still be documented.

7.6.1.1 METHOD REQUIREMENTS

The specific measuring device or instrument used for a reported result must have been either included in the estimation of measurement uncertainty or evaluated against it. Records of all evaluations will be maintained.

During calculations, the evaluator shall not round any components of the calculation before the final determination of the estimated measurement uncertainty. The estimated measurement uncertainty will be rounded up at the appropriate level of significance, rather than rounded down or truncated.

The coverage probability of the expanded uncertainty will be at least 95.45% (i.e., k=2).

Each discipline that evaluates measurement uncertainty will have a schedule to review and/or recalculate the measurement uncertainty.

7.6.2 CALIBRATION

The ASCL does not perform calibration.

7.6.3 ESTIMATION PROCEDURE

Reasonable estimation of the performance of the method shall be based on previous experience and validation data. It is important to keep in mind that the nature of certain test methods may preclude a rigorous, metrologically- and statistically-valid calculation of the measurement uncertainty. Only those components under the control of the laboratory need to be considered when estimating the measurement uncertainty. The basic procedure for estimating the measurement uncertainty may include, but is not limited to, the following actions:

- Specify the measurand.
- Specify the measurement method, including the equipment or instrument used to take the measurement.
- Construct and document an appropriate uncertainty budget identifying and listing all potential sources of uncertainty, including those not used in the calculation.
- Gather the appropriate measurement data. Sources of measurement data could include method validation, QC data, proficiency tests, replicate testing data, calibration certificates, or scientific literature.
- Estimate the uncertainty of the measurement method in accordance with an appropriate formula.
- Document the estimated uncertainty of the measurement method, and have the results and supporting data readily available in the laboratory.
- Specify calculation and reporting guidelines, including the number of significant figures and/or decimal places in the estimated measurement uncertainty.
- Re-evaluate the estimated measurement uncertainty as scheduled, and as the need arises (e.g., when a significant change occurs in the uncertainty budget). Each Discipline Quality Manual will contain procedures for recalculating the measurement uncertainty, if applicable.

7.6.3.1 EVALUATION REQUIREMENTS

A measurement uncertainty will be evaluated for all reported quantitative results[48]. This will be available to the customer, either by appearing on the report or by request.

7.6.4 REQUIRED RECORDS

The following records will be maintained for each evaluation/estimation of measurement uncertainty:

- A statement defining the measurand
- A statement of how traceability is established for the measurement
- The equipment used
- All uncertainty components considered (whether used in the calculation or not)

[48] Please note that numeric descriptors (e.g., five tablets, two-inch stain) are not considered to be results.

- All uncertainty components of significance, and how they were evaluated
- The data used to estimate repeatability, intermediate precision, and/or reproducibility
- All calculations performed
- The combined standard uncertainty
- The coverage factor (e.g., k=2 or k=3)
- The coverage probability (e.g., 95.45% or 99.73%)
- The resulting expanded uncertainty

7.7 ENSURING THE VALIDITY OF RESULTS

7.7.1 GENERAL

Each discipline within the ASCL maintains a quality manual containing quality control procedures designed to monitor and ensure the validity of test results. Quality control data will be recorded in a way to allow trends to be detected and, whenever practical, statistical techniques will be used to review the data. The records shall be retained to show that all appropriate quality control measures have been taken and are acceptable.

The following is a list of quality control measures used at the ASCL[49]:

- Use of certified reference materials and/or internally-generated secondary reference standards
- Use of alternate instrumentation that has been calibrated to provide traceable results
- Functional checks of measuring and testing equipment
- Where applicable, the use of positive and negative controls and internal standards, with control charts
- Intermediate checks on measuring equipment
- Replicate tests using the same or different methods
- Retesting/verification of retained items
- Correlation of results for different characteristics of an item
- Technical and administrative review of reported results
- Interlaboratory comparisons[50]
- Testing of blind samples
- Competency testing of analysts before beginning casework
- Testimony monitoring (for testifying analysts)

Appropriate controls and standards (e.g., drug reference materials) shall be specified in the methods and their use recorded in the case record.

[49] Procedures for these measures are located in this manual and the Discipline Quality Manuals
[50] For example, external proficiency testing

7.7.1.1 VERIFICATION

Verification is an independent examination of evidence by another currently authorized to perform the casework being verified. Verifications must be documented in the case file, indicating the results of the verification, the identity of the verifier, and when the verification was performed.

If the individual draws a different conclusion from the primary analyst, both analysts shall attempt to come to a resolution. If a resolution cannot be achieved, the issue shall be brought to the attention of the Section Chief. The Section Chief shall consult with the involved parties and resolve the issue. The resolution of any discrepancy or substantive disagreement shall be recorded. (See also § 7.5.1.5)

If verifications are performed in a discipline, the Discipline Quality Manual will detail verification and documentation requirements. Verification is currently performed for all latent print and firearm associations/identifications, eliminations, and sufficiency determinations.

7.7.1.2 CASE REVIEW

All cases will be technically and administratively reviewed prior to the release of the report. The review process must confirm that electronic versions of all necessary documentation are in the imaging module of LIMS. Case review documentation may be recorded on a case review form[51] or in the *Reviewer Notes* field in the related request in JusticeTrax. Disciplines may restrict the required documentation style in their Quality Manual.

All discipline-specific case review forms must include all the fields in the *ASCL Case Review Form*, unless otherwise authorized by the Quality Assurance Manager. The Section Chief may add more information fields or requirements, if appropriate.

If a reviewer discovers an error in the case record, the reviewer must document the error (using a case review form or the *Reviewer Notes* field) and inform the analyst. If the analyst and the reviewer cannot reach consensus, then both the analyst and reviewer must meet with the Section Chief (or designee) for resolution. (See also § 7.5.1.5)

All non-conforming work identified during review will be handled according to § 8.7 (Corrective Action).

The successful completion of technical and administrative review is recorded by the setting of the appropriate milestone(s) in JusticeTrax.

7.7.1.2.1 TECHNICAL REVIEW

The technical review will include a thorough review of the analyst's examination records to ensure that the records support the reported results.

[51] The *ASCL Case Review Form* (ASCL-FORM-05), or a discipline-specific form

At a minimum, the technical review shall include a review of all examination records and the report to ensure that:

- All necessary analyses are performed and documented according to established guidelines
- The case data supports the results and/or conclusions in the report
- The report is accurate
- Associations and results are properly qualified in the report
- The report contains all required information

The technical review includes, but is not necessarily limited to: bench notes, spectra, graphs, external telephone conversation records, investigative reports, sketches, diagrams, and laboratory reports. The records must provide an adequate basis for any reported conclusions.

The technical review does not shift the responsibility for the forensic findings to the reviewer, but the reviewer has the responsibility of ensuring that the case record provides an adequate basis for the conclusion.

It is the responsibility of the technical reviewer to report serious or repetitive deficiencies to the Section Chief. If the technical reviewer discovers a problem that raises an immediate concern regarding the overall quality of the analyst's work, the technical reviewer must promptly notify the Section Chief. The Section Chief will consult with the Quality Assurance Manager and Assistant Director to determine whether a Corrective Action Request is warranted.

Technical reviews must be conducted by individuals competency tested and authorized by the appropriate Section Chief to perform the testing work that is being reviewed. This authorization shall be documented on the *Analyst & Technician Competency Authorization Documentation* form (ASCL-FORM-62).

An individual conducting technical review does not have to be an active examiner or undergo proficiency testing. The reviewer must have sufficient knowledge of the discipline to verify compliance with the laboratory's technical procedures and that the reported conclusions are supported by the examination documentation. For those individuals not currently competent in the reviewed discipline, the Section Chief shall write an authorization memo/letter which will be maintained in Qualtrax. Additional requirements pertaining to Forensic Biology and CODIS are detailed in the appropriate Discipline Quality Manuals.

Technical review of an examination record or report shall not be conducted by the author or co-author.

Verification of a critical finding does not constitute authorship, and does not disqualify the verifier from performing technical review.

7.7.1.2.2 ADMINISTRATIVE REVIEW

Administrative review includes a review of spelling and grammar, markings[52], descriptions of evidence and seals, and other appropriate documentation.

Administrative review may be conducted by any individual qualified to perform technical review. Administrative review shall not be conducted by the author of the report.

At a minimum, the administrative review shall include:

- A review of the report to ensure consistency with laboratory policy and editorial correctness
- A review of all administrative and examination records to ensure that they contain the unique ASCL case number and are stored properly in LIMS
- A review of the examination records to ensure dates are recorded to indicate when the work was performed, and
- A review of examination records to ensure that all corrections in the case file are made consistent with laboratory policy

7.7.1.2.3 TESTIMONY REVIEW

Testimony must also be technically reviewed by a competency-tested and authorized reviewer. This can be achieved in multiple ways, including:

- Direct observation of the testimony
- Review of transcripts of testimony given by an examiner

A *Testimony Evaluation Form* (ASCL-FORM-04 or ASCL-FORM-04_PDF) will be completed by the reviewer, and signed by both the analyst and their supervisor. Feedback shall be given, both positive and in any area needing improvement. If the evaluation is less than satisfactory, the Section Chief will determine whether remedial actions are required, which may include the following:

- Re-training, including a mock trial
- Courtroom monitoring by the Section Chief for a designated period of time

Each discipline will document a schedule and plan for testimony review, based on an evaluation of risk. Elements to define include:

- Who is reviewed, if not all testifying personnel
- Frequency of review

Technical review of testimony must occur annually in each Section, when practicable, although more frequent review is desirable.

Feedback on testimony may also be solicited from court (or other) personnel using a *Testimony Evaluation Form*, but this feedback does not meet the testimony review requirements of this section.

[52] For example, case number, date, and initials on appropriate pages

7.7.2 INTERLABORATORY COMPARISONS

The ASCL monitors its performance by participating in proficiency testing, as a form of interlaboratory comparison. This assists the ASCL in the evaluation of individual technical expertise and the monitoring of training needs and procedural weaknesses for individual analysts and disciplines within the laboratory.

7.7.2.1 EXTERNAL PROFICIENCY TESTING

For each location and calendar year[53], the ASCL participates in at least one external proficiency test for each discipline in which accredited services are provided. The providers of these tests must be authorized to release the test results to ANAB.

DNA analysts and technical support personnel performing DNA analysis participate in two external proficiency tests per year as specified in the current FBI Quality Assurance Standards (documents available at www.fbi.gov).

7.7.3 MONITORING ACTIVITY ANALYSIS

The data from monitoring activities is evaluated as part of the quality control system of the laboratory. When this data is found to be outside acceptable criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. The initiation of the corrective action process may be necessary (see § 8.7).

7.7.4 INDIVIDUAL PROFICIENCY TESTING

Each analyst and technical support personnel engaged in testing activities, verifications, review of results, or the authorization of results shall successfully complete at least one internal or external proficiency test per calendar year[54] in each discipline in which they perform that work.

Proficiency test assignments should be varied so that personnel are evaluated on all aspects of their job function, over time.

Successfully completing a proficiency test means either obtaining the correct response or successfully completing corrective action(s) resulting from an incorrect response (see § 8.7).

7.7.5 PROFICIENCY TESTING REQUIREMENTS

Analysis, verification, technical review, and administrative review policies are employed during proficiency testing as they are normally applied to casework, except: all parts of a proficiency test provided by an approved test provider shall be examined as completely as the discipline's procedures allow.

[53] For proficiency tests conducted at the end of the calendar year, the evaluation may take place in the next calendar year

[54] For proficiency tests conducted at the end of the calendar year, the evaluation may take place in the next calendar year

A case will be created in JusticeTrax LIMS-plus for all proficiency tests. Under the "Offense" tab, "Proficiency Test" shall be selected. For external proficiency tests, the analyst shall complete the test and submit the results by the due date.

Some external proficiency tests (e.g., Firearms/Toolmarks, Latent Prints) may be taken independently by multiple analysts in succession. The first analyst taking the test will submit the results to the external provider before any of the succeeding analysts receive the test. This will be considered an External Proficiency Test. The remaining analysts will independently take the exam by the proficiency due date. These tests will be considered Internal Proficiency Tests. Precautions are taken to prevent the initial results from influencing subsequent examiners (e.g., each proficiency case record is restricted in JusticeTrax so that the other analysts taking the test cannot access it).

The criteria for successful completion of proficiency testing must be defined prior to the evaluation of the results. These criteria are defined in the discipline Quality Manuals, and more specific criteria may be documented in the Proficiency Test workflow.

The laboratory's overall performance in proficiency testing is reviewed annually as part of management review, as well as upon the evaluation of individual testing events.

For intralaboratory monitoring events (i.e., internal proficiency tests), the quality of the comparison will be evaluated prior to the monitoring activity. This is typically achieved by predistribution testing, but other methods may be detailed in the discipline Quality Manuals or proficiency test workflow. Documentation of this evaluation will be maintained.

Nonconformities identified at any point in the testing will be handled in accordance with § 7.10 (Nonconforming Work) and/or § 8.7 (Corrective Action).

Each Section Chief (or supervisor) is responsible for comparing the analytical results to the expected results, determining if the analytical results are acceptable, and reviewing these results with the analyst.

The following criteria shall be used for evaluating proficiency test results:

- No analyst may evaluate their own proficiency test
- All tests are graded as satisfactory or unsatisfactory
  - A satisfactory grade is attained when the experimental results match the expected results
- If there is a discrepancy between the expected results and the experimental results, the Section Chief must notify the Quality Assurance Manager
- Minor discrepancies may be deemed satisfactory, based on the following factors, with approval of the Quality Assurance Manager:
  - Discipline interpretation guidelines
  - Consensus results

If the results are deemed to be unsatisfactory, a Quality Assurance Concern workflow must be initiated.

7.7.6 PROFICIENCY TEST SCHEDULE

Disciplines maintain a documented schedule of proficiency testing. These plans are designed to ensure that:

- For each location and calendar year, the ASCL participates in at least one external proficiency test for each discipline in which accredited services are provided
- Proficiency tests are varied over time to cover all aspects of assigned job functions
- Personnel who solely perform verifications, review of results, or authorization of results are included in the proficiency test schedule
- A representative sample of components/parameters and equipment/technologies are included within each discipline listed on the scope of accreditation

Each individual engaged in testing activities (both analysts and technical support personnel) shall be proficiency tested annually in each discipline in which they perform testing.

Only personnel already competent in the covered testing may be assigned to or participate in an external proficiency test. Each laboratory discipline shall have a documented plan for proficiency testing designed to meet all requirements.

7.7.7 PROFICIENCY TEST SOURCING

The ASCL uses competent proficiency test providers. Whenever possible, providers that meet the requirements of ISO/IEC 17043 are used. If no such provider is available, the ASCL will gain approval from ANAB for alternative means to assess the laboratory's performance[55].

Results will be submitted to the provider on or before the agreed-upon due date.

7.7.8 PROFICIENCY TEST RECORDS

Current proficiency test information is maintained using a Qualtrax workflow, which records:

- Individual's name
- ASCL case number
- Discipline and laboratory activity[56]
- Design of test (i.e., internal, external)
- Expected results[57]
- Location of testing
- Records submitted to the provider (when applicable)
- Evaluation (i.e., satisfactory, unsatisfactory)
- Date the results are communicated to the analyst (however named)
- For internal proficiencies:
  - Preparation records

[55] For example, by using otherwise-competent providers, or collaboration with other laboratories
[56] Also referred to as "category of testing"
[57] For external tests, this is usually the consensus result. For internal tests, it is the intended result or the result of predistribution testing

- For external proficiencies:
  - Proficiency provider and distribution identifier
  - The summary report (or equivalent) from the proficiency provider
- An evaluation of the analyst's results by their supervisor, listing any discrepancies
- Feedback on individual performance given to the participant

Additionally, the JusticeTrax case file will contain:

- All administrative and examination documentation
- Corrective Action Request documentation, when applicable

Historical proficiency test information is maintained in each individual's Employee History Binder and in the appropriate case records.

The proficiency testing record consists of the combination of the individual JusticeTrax case records, the historical log of proficiency testing in each Employee History Binder, and the proficiency records in Qualtrax.

7.8 REPORTING OF RESULTS

7.8.1 GENERAL

7.8.1.1 REVIEW AND AUTHORIZATION OF RESULTS

All results will be reviewed and authorized before release.

7.8.1.1.1 DOCUMENTATION

Both the review of results and the authorization of results are performed by the author of the report, and are documented by the setting of the draft complete milestone.

ASCL analysts issuing a report based on examination records generated by another individual shall complete and document a review of all relevant pages of documentation in the case record (e.g., initialing each page of the examination record, the use of a review checklist or statement).

ASCL analysts offering testimony based on examination records generated by another individual shall complete a *Court Case Review Form* (ASCL-FORM-57) before testifying.

7.8.1.2 REPORTS

When analytical conclusions and/or opinions are generated, a "Report of Laboratory Analysis" will be issued to the investigating agency (including to the ASCL Medical Examiner's Office). The results shall be reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific instructions in the test methods. Each analyst/examiner proofreads and signs their reports to indicate that the report is accurate and error-free. The LIMS allows the analyst to sign their reports electronically.

ASCL reports are generated using the LIMS and are formatted in a manner designed to accommodate the types of tests conducted and to minimize the possibility of misunderstanding or misuse. Section Chiefs shall ensure that discipline report formats are optimized for the clear presentation of test results.

The process of adding the analyst's signature on the laboratory report is electronically secure, requiring two-factor authentication (scanning of an analyst's barcode and entry of their personal PIN number). After the case has been administratively reviewed, the document becomes a static PDF file.

Reports are the same for internal and external customers.

A laboratory report is not required in the following instances:

- Analytical work performed for research activities, training exercises, validation studies, quality assurance studies, or ten print record intercomparisons.
- When a case is adjudicated or the customer cancels the request before the work or report is completed. In this case, any partial work completed will not be reported.
- Activities for the purpose of constructing an individual characteristic database or maintaining the quality and/or effectiveness of information in such a database.
- Retesting which does not result in a different analytical result (e.g., reanalysis in response to a CAR to determine whether corrective action is required, re-examination proficiency testing).

7.8.1.2.1 REPORT DISTRIBUTION

Reports are normally made available to the customer electronically through JusticeTrax iResults. Facsimile or email may be used to transmit results to the customer, but the sender must follow the requirements of A. C. A. § 12-12-312 and the policy on Confidentiality of Records (§ 4.2).

7.8.1.2.2 REPORTING PROCEDURE

Each item received will be addressed on the report, either singly or as part of a group.

When associations are made, the significance of the association shall be communicated clearly and qualified properly in the report.

When comparative examinations result in the elimination of an individual or object, the report shall clearly communicate the elimination.

When results are inconclusive, the reason shall be documented in the laboratory report.

If an initial database entry[58] is made, this shall be communicated on the report.

7.8.1.2.3 CALIBRATION

The ASCL does not perform calibration or issue calibration reports.

[58] For example: DNA profiles, friction ridge, ballistics, biometrics

7.8.1.3 SIMPLIFIED REPORTING

The ASCL, in agreement with its customers, reports in a simplified way. This agreement is documented on the submission form by the customer's signature.

7.8.1.3.1 REPORT ELEMENTS

A list of the specific report elements included and excluded on reports is available to the customer on the ASCL website. A link to where this list is located on the website is included on the *Evidence Submission Form* (ASCL-FORM-12_WD or ASCL-FORM-63). All elements are documented (when applicable) and available upon customer request.

7.8.2 COMMON REQUIREMENTS FOR REPORTS

7.8.2.1 REPORT ELEMENTS

Below are listed the elements which are and aren't included in each report. Elements listed as "excluded" may be included when appropriate. This list is maintained on the ASCL website, and a link to where this list is located on the website is included on the *Evidence Submission Form* (ASCL-FORM-12_WD or ASCL-FORM-63). All elements are documented (when applicable) and available upon customer request.

- Included Elements
  - Report
    - A title (i.e., Report of Laboratory Analysis)
    - The name and address of the laboratory
    - The location of the performance of the activities (i.e., the location listed in the header of the report)
    - The ASCL case number on each page of the report, and page numbering of the form "Page x of y"
    - The name and address of the customer
    - The date of issue of the report
    - A statement that the results only relate to the items tested
  - Evidence item(s)
    - Identification of the received item or material
    - Identification of the sampled item or material sampled, when appropriate
  - Results
    - The results with, where appropriate, the units of measurement
    - Measurement uncertainty[59], where relevant, presented in the same units as the result
    - Clear identification when results are from external providers
    - The signature, function, and name of the reporting analyst/examiner
- Excluded Elements

[59] The measurement uncertainty is not reported for some analyses. Where a numerical measurement (e.g., a drug concentration in blood) is reported without an accompanying measurement uncertainty, the measurement uncertainty is available upon request.

- Report
  - The date the item(s) were received (located on *Evidence Submission Form* (ASCL-FORM-12_WD or ASCL-FORM-63) and chain of custody)
  - The date of sampling, where applicable (located in analytical notes)
  - The date(s) of testing (located in analytical notes)
  - The signature, function, and name of case reviewer(s) (located in JusticeTrax)
- Evidence item(s)
  - Detailed description and condition of the item (located in analytical notes)
- Testing/Sampling/Results
  - An identification of the method(s) used during analysis (located in analytical notes)
  - The specific sampling plan used, where applicable (located in analytical notes)
  - Additions to, deviations, or exclusions from the method (located in analytical notes)
  - Information on test/sampling conditions or environmental conditions (located in analytical notes, when appropriate)
  - Location of sampling, when appropriate (located in analytical notes)

The ASCL does not include results from external providers in its reports. These results are forwarded to the customer, and a communication is generated in iResults informing the customer of this external testing.

Each report will state that the listed results relate only to the items tested, and that it is only an official ASCL report when reproduced in full.

7.8.2.2 RESPONSIBILITIES

The ASCL is responsible for the information contained in each report, except where provided by the customer. Any information provided by the customer and included in the results will be clearly identified on the report. If this information can affect the validity of the results, a disclaimer to that effect will be included.

Where the ASCL has not been responsible for the sampling stage, a statement will be included that the results apply to the sample as received.

7.8.3 SPECIFIC REQUIREMENTS FOR TEST REPORTS

7.8.3.1 ADDITIONAL STATEMENTS

If necessary for the interpretation of test results, the following statements will be included:

- Information of specific test conditions, such as environmental conditions
- Where relevant, a statement of conformity[60] with requirements/specifications
- Where applicable, the measurement uncertainty[61], when:
  - It is relevant to the validity/application of the test results, or

[60] The ASCL does not routinely issue statements of conformity
[61] Presented in the same units as the measurand, or in a term relative to the measurand (e.g., percent)

    - When instructed by the customer, or
    - When the measurement uncertainty affects conformity to a specification limit
- Additional information as required by the method and/or the customer

Measurement uncertainties for toxicology volatiles values are included in the report.

7.8.3.1.1 STATUTORY REPORTING REQUIREMENTS

The ASCL is under no regulatory or statutory requirement for how to report measurement uncertainty.

7.8.3.2 REPORTING SAMPLING

If the laboratory is responsible for a sampling event, the following items will be reported if they are necessary for the interpretation of results:

- The date of sampling
- A unique identification of the sampled item/material
- The location of sampling, including any diagrams, sketches, or photographs
- A reference to the sampling plan and sampling method
    - If statistical sampling is used, the report will contain the confidence level and corresponding inference regarding the population
- Details of any environmental conditions that would affect the interpretation of results
- Information required to evaluate measurement uncertainty for any subsequent testing

7.8.4 SPECIFIC REQUIREMENTS FOR CALIBRATION CERTIFICATES

The ASCL does not perform calibration or issue calibration certificates.

7.8.5 REPORTING SAMPLING—SPECIFIC REQUIREMENTS

Please refer to Section 7.8.3.2.

7.8.6 REPORTING STATEMENTS OF CONFORMITY

The ASCL does not issue statements of conformity.

7.8.7 REPORTING OPINIONS AND INTERPRETATIONS

7.8.7.1 AUTHORIZATION

Only personnel authorized by the ASCL to express opinions and interpretations in reports may do so, and only for the types of testing for which they have been authorized. The case record shall support the basis for any interpretation/opinion.

7.8.7.2 SCOPE OF OPINIONS/INTERPRETATIONS

The following (or equivalent) statement will appear on all laboratory reports:

"The results stated below relate only to the items tested and represent the interpretations/opinions of the undersigned analyst."

7.8.7.3 DIALOGUE

When opinions or interpretations are directly communicated by dialogue to a customer, a record of the communication will be retained[62] in the case record.

7.8.8 AMENDMENTS TO REPORTS

7.8.8.1 IDENTIFYING THE CHANGE(S)

An amended report is necessary if an error is found on the original report (including reports uploaded to iResults). An "amended request" will be created in the LIMS and all administrative and examination records for the amended analysis will be added to the electronic case record. Administrative and technical reviews are required before an amended report is issued. When an amended report is necessitated by a change in analytical results, then the Section Chief or Section Quality Manager will perform the technical review on the amended request. Documentation of this review will be incorporated into the original case file.

The original report and all original records will be kept in the case record.

An amended report is generally not needed when an agency revises or corrects administrative information that they provided at the time of submission[63] after a report has already been issued. Exceptions can be made for individual cases, when appropriate.

When an amended report is issued, any change of information will be clearly identified. Where appropriate, the reason for the change will be included in the report.

7.8.8.2 STYLE OF AMENDMENT

Any amendments to an issued report are made by issuing a complete new report.

7.8.8.3 IDENTIFYING THE AMENDED REPORT

The statement "*AMENDED REPORT TO ORIGINAL* [*TYPE*] *REPORT ON* [*DATE*]" (or equivalent) will appear below the header information and above the listing of the evidence and the results[64]. The amended report will contain all of the items on the original report and any amendments.

The original report must be stored in the JusticeTrax case record.

7.8.9 SUPPLEMENTAL REPORTS

A supplemental report is necessary when additional evidence is received after the original report has been issued, additional requests for analysis are made, or other additional testing is required in

[62] For example, using an *Agency Contact Form* (ASCL-FORM-06) or email
[63] For example, correcting the spelling of a name, or changing an incorrect agency case number
[64] The date of the original report must be entered in the "additional data" tab of the amended request

a case[65]. A "supplemental request" will be created in the LIMS, and all administrative and examination records for the additional evidence will be added to the electronic case record. Administrative and technical reviews are required before a supplemental report is issued. The statement "SUPPLEMENTAL REPORT TO ORIGINAL [TYPE] REPORT ON [DATE]" (or equivalent) will appear below the header information and above the listing of the evidence and the results[66].

All original records will remain in the case record.

7.9 COMPLAINTS

7.9.1 GENERAL

A complaint is an expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected. The ASCL considers complaints to be useful in identifying opportunities for improvement.

Complaints are received by the laboratory in a number of ways:

- Externally-initiated communication
  - Oral communication
  - Phone call
  - Email
  - Letter
- Lab-initiated communication
  - Customer feedback survey
- Internal communication
  - *Quality Assurance Concern* (QAC) workflow

The ASCL processes complaints using the *Quality Assurance Concern* (QAC) workflow in Qualtrax.

Employees are encouraged to notify the laboratory if they have a complaint or concern regarding the quality system. This is done through the *Quality Assurance Concern* workflow in Qualtrax (see § 9.2). This workflow ensures that both supervisory personnel and Top Management are apprised of the concern, and allows the employee to know how their complaint is addressed.

Policies and procedures for internal complaints regarding grievance and sexual harassment are found in the *Personnel Handbook* (ASCL-DOC-02).

7.9.2 TRANSPARENCY OF PROCESS

The process for handling complaints is available to the general public in this document, which is freely available on the ASCL website.

[65] When additional evidence is received on a case that has not been completed, the additional evidence may be analyzed and included in the original report
[66] The date of the original report must be entered in the "additional data" tab of the supplemental request

7.9.3 COMPLAINT PROCESS

Upon receipt of a complaint, a *Quality Assurance Concern* (QAC) workflow is started in Qualtrax (see § 9.2) by the person who received the complaint. The QAC is forwarded to a supervisor for comment, and then forwarded to the Assistant Director and Quality Assurance Manager for validation, evaluation, and classification. Complaints determined invalid or baseless may be closed without further action.

The complaint classification determines which actions are appropriate. These actions may involve any or all of: investigation, cause analysis, preventive action, corrective action, simple correction, and administrative/personnel actions.

Any contact or communication with an outside agency must be documented on an *Agency Contact Form* (ASCL-FORM-06), email, or equivalent document.

7.9.4 RESPONSIBILITY

The ASCL is responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 COMMUNICATION

Whenever possible, the laboratory will acknowledge receipt of the complaint to the complainant and provide progress reports (as appropriate) to the complainant.

7.9.6 INDEPENDENT EVALUATION

The ASCL will have the outcome made by, or reviewed and approved by, person(s) not involved in the original laboratory activities in question.

7.9.7 NOTICE OF COMPLETION

The ASCL will, whenever possible, formally notify the complainant of the end of the complaint handling.

7.10 NONCONFORMING WORK

7.10.1 GENERAL

Nonconforming testing is testing in which ASCL procedures are not followed or the agreed-upon requirements of the customer (e.g., testing of standards and controls, test precision and accuracy, the care and handling of evidence, instrument performance) are not met. All laboratory staff, including analysts and supervisory personnel, must be vigilant for any indication of nonconforming testing.

Nonconformities, deficiencies, or departures from accepted quality standards may be identified or brought to the attention of laboratory management through a variety of means, including the following:

- Technical case review
- Administrative case review
- Quality control checks
- Instrument performance verification or calibration
- Proficiency testing
- Testimony evaluation
- Case re-examination
- Internal audits
- External assessments
- Employee or customer complaints
- Quality System reviews
- Staff observation or supervision

There are three key levels of non-conforming work, each of which may require a different response:

- Simple corrections
- Level 2 nonconformities
- Level 1 nonconformities

7.10.1.1 SIMPLE CORRECTION

The nature of the non-conforming work is limited in scope and significance. The problem identified is easily corrected and does not cast doubt on the overall reliability of results.

If the nonconforming test or work is an isolated incident and easily resolved by a quality control adjustment, the correction can be taken immediately and documented in the case file or the discipline's quality control records, when appropriate.

7.10.1.2 LEVEL 2 NONCONFORMITY

The nature of the non-conforming work does not, to any significant degree, affect the fundamental reliability of the work product of the laboratory or the integrity of evidence, but it may continue to occur without a proper cause analysis and appropriate corrective action. While corrective action is necessary, there is still no doubt regarding the overall reliability of test results.

The Section Chief and Quality Assurance Manager will be notified immediately for consultation and to evaluate the significance of the nonconforming testing or work. A *Quality Assurance Concern* (QAC) workflow will be initiated.

7.10.1.3 LEVEL 1 NONCONFORMITY

The nature of non-conforming work is such that the reliability of test results is questioned. There is potential that erroneous or invalid results have been reported.

The Section Chief and Quality Assurance Manager will be notified immediately for consultation and to evaluate the significance of the nonconforming testing or work, including an impact analysis on previous results.

A *Quality Assurance Concern* workflow (see § 9.2) will be initiated, but it is imperative to first address suspension of work and recall of reports. It may be necessary to notify the customer of any affected cases, including possibly recalling reports.

The Section Chief, DNA Technical Leader (if applicable), and Assistant Director have the responsibility and authority to immediately suspend any observed non-conforming work activity that could result in erroneous reports or unreliable testing data. Resumption of work may only be authorized by agreement between the Section Chief, DNA Technical Leader (if applicable), and Quality Assurance Manager.

7.10.2 RECORDS OF NONCONFORMING WORK

The ASCL will retain records of its response to nonconforming work and actions taken for all Level 1 and 2 nonconformities using the *Quality Assurance Concern* (QAC) workflow. Simple corrections can be documented in the case file or discipline's quality control records, when appropriate.

7.10.3 CORRECTIVE ACTION IMPLEMENTATION

If the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, then the *Quality Assurance Concern* will be classified as a corrective action, and corrective action will be implemented.

A common sense approach must be employed in determining the appropriate response to nonconformity in testing or other work. For example, a minor departure from accepted policy regarding a strikeout on a document would not normally rise to the level of being considered a nonconformity. The error would require correction, but not the initiation of a formal corrective action procedure. Continued non-compliance, however, might result in the need for formal corrective action implementation.

Supervisory discretion must be used in determining the need for corrective action or whether other remediation could be employed. The Quality Assurance Manager should be involved to ensure that standards are applied evenly throughout the laboratory and that any actions taken are both consistent with prior corrective actions and in compliance with quality assurance standards.

7.11 CONTROL OF DATA AND INFORMATION MANAGEMENT

7.11.1 ACCESS TO INFORMATION

The laboratory will have access to the data and information needed to perform laboratory activities.

7.11.2 LIMS VALIDATION

The LIMS used by the ASCL is JusticeTrax, a commercial, off-the-shelf software package.

Commercial software in general use within its designed application range is considered sufficiently validated. However, significant software configuration/modifications shall be authorized, documented, and validated before use.

7.11.2.1 LABORATORY-DEVELOPED SOFTWARE

Any laboratory-developed software will be documented in sufficient detail and suitably verified. The validation will be carried out in accordance with a validation plan, and records of the validation will be maintained.

7.11.3 LIMS REQUIREMENTS

JusticeTrax is protected from unauthorized access by the practice of user authentication by username and password.

The JusticeTrax database is backed up at least weekly, and an off-site storage location is used.

The JusticeTrax server is maintained by the IT department along with the laboratory's other servers, in a climate-controlled area. System failures, and the laboratory's response, are recorded.

7.11.4 OFF-SITE LIMS

The ASCL's LIMS is managed and maintained on the ASCL's main premise.

7.11.5 LIMS DOCUMENTATION

JusticeTrax contains a help file, and maintains a Customer Care help center which contains updated information.

7.11.6 CALCULATIONS AND DATA TRANSFERS

When a request has been draft completed, this indicates that the author has ensured that all calculations and data transfers are accurate and that the calculations conform to written procedures.

By completing the technical review, the technical reviewer is confirming that they have checked the calculation(s) and data transfers for accuracy. If an additional check is required, this requirement shall be included in the appropriate Discipline Quality Manual.

7.11.6.1 CALCULATION AND DATA TRANSFER RECORDS

The Technical Review milestone is the documentation that all necessary checks of calculations and data transfers have been successfully completed. Whenever possible, this review will not be performed by the person who performed the calculation or data transfer.

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 OPTIONS

8.1.1 GENERAL

The ASCL has a management system capable of supporting and demonstrating the consistent achievement of all accreditation requirements and assuring the quality of laboratory results.

8.1.2 OPTION A

The ASCL opts for Option A, and addresses the following topics:

- Management system documentation
- Control of management system documents
- Control of records
- Actions to address risks and opportunities
- Improvement
- Corrective actions
- Internal audits
- Management reviews

8.1.3 OPTION B

The ASCL is not accredited to ISO 9001, and does not opt for Option B.

8.2 MANAGEMENT SYSTEM DOCUMENTATION (OPTION A)

8.2.1 POLICIES AND OBJECTIVES

The *ASCL Quality Manual* (ASCL-DOC-01)is a compilation of policies and procedures governing ASCL operations. The Quality Manual is readily available on Qualtrax to all ASCL personnel. ASCL personnel are responsible for knowing and using these policies and procedures. The quality manual is reviewed annually by the Quality Assurance Manager, Assistant Director, and Director. It is updated as needed to reflect changing organizational, technical, and procedural information.

Unforeseen circumstances may arise which require immediate deviations from the policies and procedures of this manual. In such situations, a written request for an exception to policy will be submitted to the Assistant Director (or designee). This written request shall include:

- an adequate description of the circumstance requiring the action,
- a statement of the proposed alternative policy and/or procedure, and
- the expected duration of the exception.

The Assistant Director will maintain documentation of the approved policy exception.

Each discipline of the laboratory has a Discipline Quality Manual and Discipline Training Manual. The purpose of these manuals is to:

- Promote the efficient and effective operation of the ASCL
- Assist the laboratory staff in performing their assigned duties and tasks
- Document the policies and procedures established for each discipline

All personnel are responsible for knowing and using the policies and procedures in their Discipline Quality Manual. Each Discipline Quality Manual and Discipline Training Manual are reviewed annually by the appropriate Section Chief and updated as needed.

8.2.1.1 REQUIREMENT FOR WRITTEN EVIDENCE

Where a form of one of the following words is used in the accreditation requirements, the requirement will be addressed in writing:

- Agree
- Appoint
- Authorize
- Define
- Instruction
- Method
- Plan
- Procedure
- Program/programme
- Record
- Schedule
- Specify

8.2.2 MISSION AND QUALITY POLICY STATEMENTS

The mission of the Arkansas State Crime Laboratory is to provide the highest quality scientific services to the criminal justice community and the State of Arkansas. This is accomplished through a team of skilled and dedicated employees using scientific equipment and appropriate validated methodologies. The laboratory strives to provide these services in a timeframe amenable to our customers.

The missions for the respective disciplines are:

CODIS

Process all convicted offender samples and felony arrest samples utilizing DNA technology to input into the National DNA Index System (NDIS). Convicted offender samples and casework samples are searched both locally in the State DNA Index System (SDIS) and on the national level to help solve criminal cases.

DIGITAL EVIDENCE

The Digital Evidence section is responsible for analyzing computers, mobile devices, digital storage devices, and video evidence for the criminal justice system. This may include systematic retrieval of digital data that may be of evidentiary value and video enhancement as well as technical support to law enforcement agencies. This analysis is performed in a chain-of-custody environment using validated and appropriate procedures in order to ensure the most accurate and relevant analytical results.

FIREARMS/TOOL MARKS

Perform examinations, which include the following: the comparison of bullets, cartridge cases and shot shells to one another and/or with suspect weapons; the comparison of tool marks to one another and/or with suspect tools; firearm function testing; distance determination; restoration of obliterated serial numbers; image cartridge cases and bullets into the National Integrated Ballistics Information Network (NIBIN).

FORENSIC CHEMISTRY

Utilize various scientific methodologies and instrumentation to perform analyses to identify controlled substances. Included are drugs of abuse controlled under Act 590 of 1971 and addenda thereafter. Illicit laboratory chemists also assist law enforcement agencies to dismantle suspected illicit laboratories, collect representative samples of evidence, submit the samples to evidence receiving on behalf of the law enforcement agency, and analyze evidence associated with illicit laboratories.

FORENSIC DNA

Analyze biological evidence utilizing PCR technology in order to determine its source. This evidence is used to include or exclude individuals from having deposited the evidence in the commission of a criminal act. Samples will be entered into CODIS when appropriate.

FORENSIC TOXICOLOGY

Analyze samples from the State Medical Examiner, law enforcement officers, and county coroners. Use various scientific methodologies and instrumentation to perform analysis on biological specimens to determine the presence and levels of drugs and/or alcohol.

LATENT PRINTS/AFIS

Develop latent fingerprints using a full range of physical, chemical, and alternative light source methods and compare to prints of subjects in order to identify or eliminate. Compare footwear and tire impressions to suspect footwear and tires. Utilize the computer-based Automated Fingerprint Identification System (AFIS) for searching, matching and storing fingerprints and related data.

PHYSICAL EVIDENCE

SEROLOGY

Utilize scientific methodologies and instrumentation to examine physical evidence for the presence of blood, semen and/or transfer DNA. Collect and store tape lifts for possible further testing.

TRACE EVIDENCE

Utilize scientific methodologies and instrumentation to examine physical evidence for the presence of ignitable liquids and primer gunshot residue. Perform hair screening to determine suitability for DNA analysis.

STATE MEDICAL EXAMINER

Perform post mortem examinations and determine the cause and manner of death, in cases subject to the jurisdiction of the State Medical Examiner as set out in A. C. A. § 12-12-315. The Medical Examiner shall include the general application of the medical sciences to assist the criminal justice system in the State of Arkansas.

QUALITY POLICY STATEMENT

The goal of the Arkansas State Crime Laboratory (ASCL) is to provide the highest quality forensic services to our customers. The ASCL has defined its customer base as the Judicial System, which includes law enforcement agencies, prosecutors and defense counsel, and regulatory and other public service government agencies. The ASCL is committed to meet the needs and expectations of our customers through a dedication to quality and service.

The ASCL standard of quality requires that all forensic conclusions, both written and oral, are scientifically valid, accurate, consistent, and reliable. This standard of quality serves as the guiding principle for all technical and strategic decisions involving work undertaken by the ASCL.

This guiding principle is shared by all employees of the ASCL.

The objectives involved in meeting our quality goal are:

- Ensuring the use of validated procedures that are reliable, reproducible, and which serve their intended purpose with respect to precision, accuracy, sensitivity, and specificity
- Providing laboratory reports that are clear, accurate, objective, and readily understood by our customers
- Providing relevant, professional, and impartial testimony in judicial proceedings
- Participating in a proficiency testing program that monitors the capabilities of the analysts/examiners and the reliability of our analytical results
- Participating in annual audits of the quality system
- Providing a system to ensure the integrity and security of evidence from its receipt to its return
- Complying with ANAB Accreditation Standards
- Continually improving the effectiveness of the ASCL Quality Management System
- Identifying opportunities for improvement related to quality in all areas of operation, taking corrective action to remediate non-conforming work, and striving to prevent recurrence
- Providing continuing employee education and training

The entire staff of the ASCL will adhere to the spirit and intent of the quality assurance program, as well as to the directives of this Quality Manual and its supporting documents, which include the Personnel Handbook, the Health and Safety Manual, and the Discipline Quality and Training Manuals. All members of the staff will strive to improve customer satisfaction for every service provided by this laboratory.

We are committed to a strategy of continuous improvement: constantly determining the needs and expectations of our customers and striving to meet them.

I personally affirm these commitments and support the established comprehensive quality assurance system, which will allow our agency to meet all of the requirements of the ANAB Accreditation Standards.

Kermit B. Channell, II

8.2.3 COMMITMENT TO MANAGEMENT SYSTEM

Top Management is committed to developing, implementing, and continually improving the effectiveness of the management system. This is demonstrated by management's involvement in monitoring the quality system through a variety of means, including:

- Annual management review
- Internal audits
- Procedure reviews
- Proficiency testing
- Re-examination of casework
- Corrective action
- Preventive action

The Quality Assurance Manager monitors activities to improve the quality system and recommends actions needed to improve the quality system's effectiveness.

8.2.4 DOCUMENTATION

Laboratory quality policies are included in this quality manual, which generally follows the same outline as the *ISO/IEC 17025:2017* and *ANAB AR 3125 Additional Requirement* documents. Quality policies and technical procedures which apply only to a particular discipline are included in their Discipline Quality Manual. Discipline Quality Manuals shall not contradict this quality manual and will be outlined similarly to this manual. The DNA and CODIS Quality Manuals will be outlined similarly to the FBI Quality Assurance Standards.

Other supporting manuals include:

- *ASCL Personnel Handbook* (ASCL-DOC-02): includes State, Federal and ASCL policies.
- *ASCL Health and Safety Manual* (ASCL-DOC-08): contains safety and environmental compliance policies and information
- *ASCL New Analyst/Technician Training Manual* (ASCL-DOC-03)
- Discipline Training Manuals: contain the training program for each discipline.

8.2.5 ACCESSIBILITY

All personnel involved in laboratory activities have access to ASCL quality manuals at all locations where operations essential to the effective functioning of the laboratory are performed. On-site, management system documentation is available in the Qualtrax document control system. Off-site, quality manuals are available on the ASCL website.

8.3 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS (OPTION A)

8.3.1 CONTROLLED DOCUMENTS

The ASCL's labwide quality manual, administrative procedures, discipline quality manuals, training manuals, and quality assurance documents and forms are controlled using Qualtrax software to

ensure that they are adequate, approved for use, and that only the current versions of the document are in use. This section provides instructions concerning the creation, revision, and distribution of these controlled documents.

CONTROLLED DOCUMENT PREPARATION

Internally generated documents shall be prepared by personnel with adequate expertise in the subject. The level of detail of the document shall be commensurate with the complexity of the activity and the background of the intended user of the document. The document must include enough detail and specificity to ensure that the activity conforms to quality specifications and/or expectations.

8.3.2 CONTROLLED DOCUMENT POLICIES AND PROCEDURES

8.3.2.1 DOCUMENT APPROVAL

Each new or revised internally-generated controlled document is required to be reviewed[67] and approved by appropriate personnel prior to issuance, as detailed in the following table. The current and archived versions of all controlled documents will be maintained on Qualtrax.

	Director	Assistant Director	Quality Assurance Manager	Section Chief	Health and Safety Manager	DNA Technical Leader
Labwide Quality Manual	×	×	×			
Labwide controlled documents		×	×			
Personnel Handbook	×	×	×			
Health and Safety Manual	×	×	×		×	
Health and Safety documents		×	×		×	
Discipline Quality Manuals	×	×	×	×		×[68]
Discipline-specific controlled documents			×	×		×[68]

Table 2: Document Approval Matrix

After the review and approval process is complete, the document is published on Qualtrax. All appropriate personnel will be notified by email and have access to these official electronic documents. Individuals may print hardcopies of internal documents as needed for personal use—however, these copies are unofficial.

[67] Documents are reviewed for adequacy, completeness, editorial correctness, and the like
[68] For the DNA and CODIS sections only

Only the current revision of a document is visible on the document tree in Qualtrax. This precludes the use of invalid and/or obsolete documents. The revision history of controlled documents is maintained in Qualtrax.

CONTROL OF EXTERNAL DOCUMENTS

External documents, software, or any other document in which a particular revision/version is required will be referenced in the appropriate internally-generated controlled document (e.g., Quality Manual, Training Manual) or as an attachment to the appropriate document. The reference shall identify the current revision/version and location of the document. These documents will be available at each location where related work is conducted.

8.3.2.2 DOCUMENT REVIEW

Controlled documents shall be reviewed at least annually (from the initial creation date or last revision date) and revised whenever necessary to ensure that they reflect current policies, practices, and technology. With the exception of quality manuals, the Personnel Handbook, and the Health and Safety Manual, documents that have been edited within the year will not require an additional review. This document review will be performed by appropriate personnel and tracked in Qualtrax.

8.3.2.3 DOCUMENT REVISION

Revised documents are subject to the same review, approval, documentation, and issuance requirements of the original document, as stated above.

When a controlled document is revised, the editor of the document must give a general summary of the changes made in Qualtrax. All substantive changes must be individually listed. Minor and non-substantive changes may be listed *en masse* (e.g., formatting update, spelling corrections).

Any change to a controlled document, even a minor one, requires a revision to the document.

There are two ways to revise documents:

- By checking out a controlled document in Qualtrax, editing this version of the document, and checking it back in to Qualtrax, or
- By creating a new version of a controlled document and replacing the version in Qualtrax.

The original document, the revised document, and a summary of changes will be maintained in Qualtrax. The Qualtrax system tracks who made the revision, the reviewers and approvers, and who was notified of the revision.

RESPONSIBILITIES

The Preparer of the document is responsible for:

- Preparing the document in the proper format
- Addressing or resolving comments from reviewers
- Submitting the document in Qualtrax

The Section Chief (and Technical Leader, if applicable) is responsible for:

- Ensuring that reviews are completed annually on all documents in their section
- Reviewing and approving all discipline-specific controlled documents
- Ensuring that the documents are scientifically suitable for issue
- Ensuring that the documents contain the required quality assurance elements (e.g., controls, measurement uncertainty, traceability)

The Quality Assurance Manager is responsible for:

- Ensuring that all documents meet QA requirements as outlined in the ANAB accreditation standards
- Ensuring the annual review of Quality and Training Manuals by appropriate Section Chiefs (and the Technical Leader, if applicable) to determine if a revision is needed
- Maintaining the official electronic controlled documents on Qualtrax
- Properly issuing and distributing documents through Qualtrax
- Maintaining review documentation in Qualtrax
- Reviewing and approving all controlled documents
- Issuing all controlled documents and ensuring all appropriate employees are notified of new or revised documents
- Updating the uncontrolled version of documents on the ASCL website

The Assistant Director is responsible for:

- Approving all Quality Manuals[69], Health and Safety Manual, Personnel Handbook and Labwide Controlled Documents.

The Director is responsible for:

- Approving all Quality Manuals, Health and Safety Manual and Personnel Handbook.

8.3.2.4 DOCUMENT AVAILABILITY

All documents are available in the Qualtrax document control system. Access to view documents is not controlled. Modification of documents is only possible through the process outlined in § 8.3.2.3.

8.3.2.5 DOCUMENT IDENTIFICATION

Each internally generated controlled document follows these format requirements.

Each controlled document has a footer on each page containing, at a minimum:

- The unique document identifier, in the format: DISCIPLINE – TYPE – INDEX NUMBER
  - Discipline abbreviations are as follows:
    - ASCL ----------Labwide
    - CODIS----------Combined DNA Index System
    - DE ----------Digital Evidence
    - DNA----------Forensic DNA

[69] Except Forensic Toxicology, which is under the supervision of the Director

        - DRG ----------Forensic Chemistry
        - ER ----------Evidence Receiving
        - FA ----------Firearms/Tool Marks
        - HRL_ER----------Hope Regional Laboratory - Evidence Receiving
        - LP ----------Latent Prints
        - SER----------Physical Evidence–Serology
        - TOX ----------Toxicology
        - TR ----------Physical Evidence–Trace
    - Type abbreviations are as follows:
        - DOC ----------Document
        - FORM ----------Form
    - Index numbers will be unique to each document/form, but may be subdivided further as needed[70]
- Revision date
    - The date the document is effective. The effective date will not be prior to the approval date.
- Approval authority (same as issuing authority)
- Page *x* of *y*[71]

8.3.2.6 DOCUMENT OBSOLESCENCE

Employees will destroy outdated documents upon receiving updated documents. It is the employee's responsibility to verify that they are using the current revision of any document.

Retired controlled documents are maintained in Qualtrax, and only the Qualtrax System Administrators have access to view these documents. When archived documents are requested, they will be watermarked appropriately before being released.

8.4 CONTROL OF RECORDS (OPTION A)

8.4.1 RECORDS

All records shall be legible, readily retrievable, and maintained in a manner that prevents damage, deterioration, or loss of the records. The storage location of physical records must be secure and have limited-access.

Records include both quality and technical records. This policy provides procedures and practices for the identification, collection, organization, accessibility, filing, indexing, access, storage, maintenance, and disposal of records.

TECHNICAL RECORDS

Case files will be retained by the Arkansas State Crime Laboratory in either physical or electronic form. The Arkansas State Crime Laboratory uses the JusticeTrax LIMS-plus software program. All

[70] For example: TOX-FORM-09-001, TOX-FORM-09-002, and so on
[71] Unless the document length is always limited to one page, or has a field for manual numbering

case documentation will be stored electronically. Once reviewed, this electronic version is considered the official case record.

Storage for CODIS technical records is detailed in the *CODIS Quality Manual* (CODIS-DOC-01).

Historical non-electronic case files for the Little Rock laboratory are stored in the appropriate section, the evidence storage area in Evidence Receiving, the laboratory annex, or off-site storage. Historical non-electronic case files for the Hope Regional Laboratory are stored onsite. Whenever a case file is removed from an on-site file storage area by an authorized person, an "In-and-Out" card shall be inserted in its space citing the case number, date of removal, initials of the person removing the file, and initials of the person for whom the file is being retrieved.

QUALITY RECORDS

Labwide quality records will be stored as specified by the Quality Assurance Manager. Discipline quality records such as reagent and chemical QC logs, training records, etc., will be stored in a location designated by the Section Chief.

8.4.2 RECORD POLICIES AND PROCEDURES

RECORD RETENTION

Case files will be stored indefinitely. The following items are required to be retained (either electronically or physically) for a period of eight years:

- Corrective Action Documentation
- Audit Records
- Training Records
- Continuing Education Documentation
- Proficiency Testing Records
- Court Testimony Reviews

All other quality records (e.g., Employee History Binders, instrument maintenance logs) will be stored for at least one full ANAB accreditation cycle (four years).

Access to quality and technical records (both electronic and physical) is limited to those ASCL employees who require access to conduct analysis or assist customers. Physical records are kept in limited-access areas (refer to § 6.3.4). Access rights are assigned at the time of hire using the *New Hire IT Information Form* (ASCL-FORM-27), with the approval of the Section Chief. The Assistant Director may review and change security roles at any time.

Access to electronic records is limited by the LIMS through the use of a user name and password, with appropriate permissions. Data is further controlled at a group and individual level so that only those personnel authorized for specific data-access management rights are assigned access to that data. Audit trails are established for LIMS transactions. In addition, access to case files in LIMS may be restricted when deemed necessary.

All electronic records are backed up and stored off-site.

See § 4.2.2 for the laboratory's policies regarding confidentiality.

8.5 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES (OPTION A)

8.5.1 RISKS AND OPPORTUNITIES

The ASCL considers risks and opportunities in several ways:

- Preventive actions identified by the *Quality Assurance Concern* workflow
- Evaluation of risks and opportunities during periodic state-mandated Risk Assessment activities
- Internal audits
- Identification of risks and opportunities during management review
- External comments and complaints
- Internal comments and complaints
- Customer surveys

Preventive action (PA) may be initiated using the *Quality Assurance Concern* workflow in Qualtrax (see § 9.2). This workflow may be initiated by any employee who identifies a potential source of a nonconformity or a way to improve the quality system. The submission will be reviewed by the employee's supervisor and forwarded to the Quality Assurance Manager for an initial review and classification of the submission.

The evaluation of the submission may include:

- Consulting possibly-affected lab employees to determine if the preventive action could have an unforeseen negative impact on the quality of work or operations in other areas of the laboratory
- Consulting with members of top and/or key management to determine whether the preventive action is aligned with laboratory policies and goals
- Determining whether the improvement will require any revisions of ASCL policies and procedures
- Determining if the improvement is in place at other laboratories
- Determining the fiscal impact of the proposed improvement
- Discussing the plan with customers to determine if the preventive action would affect their needs and/or be viewed as a quality improvement

SELECTION AND IMPLEMENTATION OF ACTIONS

After classification, if preventive action is needed, the request goes to the affected Supervisor (and any designee) to finalize the preventive action proposal.

This proposal is then submitted to the Quality Assurance Manager (and for DNA/CODIS matters, the DNA Technical Leader) for review and approval.

Once accepted, the Section Chief (and any designee) initiates preventive actions.

Once these actions have been successfully completed, the Implementation Coordinator and Quality Assurance Manager must approve the completion of the implementation process. If the CAR involves the DNA or CODIS section, the DNA Technical Leader must also approve the completion of the implementation process and evaluate its effectiveness.

MONITORING

The Quality Assurance Manager must then review the effectiveness of the preventive action.

A period of monitoring (to confirm effectiveness) may be necessary before the preventive action process is closed. If so, then that will occur before the Quality Assurance Manager approves the effectiveness review.

Upon a determination that the monitored preventive action was effective, the Assistant Director will conduct a final review of the workflow, and indicate that the process is closed by his or her concurrence with the findings.

The preventive action process is documented and maintained using the Qualtrax system. This record shall include the proposed preventive action(s) and the effectiveness review.

8.5.1.1 HEALTH AND SAFETY

Risks and opportunities related to health and safety are considered in multiple ways:

- Monthly safety surveys are completed and evaluated on a discipline and labwide scope
- Quarterly meeting between the Health and Safety Manager and discipline Safety Managers
- Internal comments and complaints

8.5.2 PLANNING

Preventive actions are submitted and implemented using the *Quality Assurance Concern* workflow.

Any preventive actions that are approved will be put into place, and will be placed into the management system[72] when appropriate. The effectiveness of the preventive action will be evaluated as part of the *Quality Assurance Concern* workflow, and reviewed during management review.

8.5.3 PROPORTIONALITY

The actions taken to address risks and opportunities will be proportional to their potential impact on the validity of laboratory results.

[72] For example, into a quality manual, training manual, or test method

8.6 IMPROVEMENT (OPTION A)

8.6.1 IMPROVEMENT

The laboratory shall strive to continually improve the effectiveness of the Quality Management System. Opportunities for improvement are identified through various means, including:

- *Quality Assurance Concern* submissions
- Corrective and Preventive Action Requests
- Customer surveys
- Annual management reviews
- Internal and external audits
- Employee suggestions

8.6.2 EXTERNAL FEEDBACK

The ASCL seeks feedback from customers in several ways, including personal communications, attendance at meetings, and surveys. A link to the ASCL Survey is located on the *Law Enforcement Login* page of the ASCL website. Surveys may also be sent to customers.

Customers are asked for comments regarding subjects such as examination services, turn-around time, the clarity of the test report, interactions with ASCL employees, overall satisfaction, and suggestions for improvement. Customers (if identified) may be contacted regarding their responses. The results of these surveys are reviewed by ASCL Top Management and communicated with appropriate personnel[73].

8.7 CORRECTIVE ACTIONS (OPTION A)

8.7.1 NONCONFORMITIES

When a nonconformity occurs, the ASCL addresses it appropriately, which may include actions to:

- Control the nonconformity
- Correct the nonconformity
- Address the consequences of the nonconformity

The laboratory corrective action process is used whenever Level 1 or Level 2 nonconformities (as described in § 8.7.1) are indicated. The Quality Assurance Manager is authorized to oversee the corrective action process. The Quality Assurance Manager consults with the Assistant Director, directs the corrective action process, and actively involves the appropriate Section Chief (and, if applicable, the DNA Technical Leader), as necessary and appropriate..

The Corrective Action process is accomplished through the *Quality Assurance Concern* workflow in Qualtrax (see § 9.2).

[73] Typically at a labwide meeting

A *Quality Assurance Concern* (QAC) workflow may be initiated through Qualtrax by any employee. This request will be sent to the immediate supervisor for comment, and is then forwarded to the Quality Assurance Manager for an initial review and classification. If the magnitude of the nonconformity requires a work-stoppage, this is determined at this point.

If corrective action is warranted, the Quality Assurance Manager will forward the workflow to the appropriate supervisor for cause analysis.

CAUSE ANALYSIS

Cause analysis is critical in ensuring that nonconforming work is prevented from reoccurring, and is sometimes the most difficult part in the corrective action procedure. The cause(s) are often not obvious, requiring a careful analysis of all potential causes of the problem. Exercises like creating an Ishikawa diagram or performing a "Five Whys" analysis may be helpful.

Please note that in order to minimize the risk posed by a nonconformity, some initial response may be necessary prior to cause analysis (e.g., instrument repair, removal of an analyst from casework duties). However, a full cause analysis is the primary method of determining the most effective response(s) to a nonconformity.

The Section Chief shall start the investigation to determine the cause(s) of the problem. The cause analysis shall examine all possible sources of the nonconforming work, and may include the evaluation of case records, technical methods, equipment, supplies, training, customer agency needs, work environment, etc.

An evaluation of whether similar nonconformities exist, or could potentially occur, will be a part of this evaluation.

The cause analysis is then submitted to the Quality Assurance Manager for review and evaluation.

SELECTION AND IMPLEMENTATION OF ACTIONS

After acceptance of the cause determination, the supervisor (or designee) will recommend appropriate corrective action(s). This recommendation shall be appropriate to the magnitude and the risk of the problem. A reasonable timeframe for the completion of the corrective action will be established and entered in the workflow.

The proposed actions from the Section Chief will then be reviewed by the Quality Assurance Manager and the Assistant Director (and for DNA/CODIS CARs, the DNA Technical Leader) to determine whether they are appropriate and sufficient to address the nonconformity.

Once accepted, the Section Chief (and any designee) may initiate corrective actions.

Once corrective actions have been successfully completed, the Implementation Coordinator and Quality Assurance Manager must approve the completion of the implementation process. If the CAR involves the DNA or CODIS section, the DNA Technical Leader must also approve the completion of the implementation process and evaluate its effectiveness.

Actions depend on the severity of the nonconformity, and include (but are not limited to) the following:

LEVEL 2 NONCONFORMITY

Corrective/preventive actions:

- Take appropriate corrective action to minimize the chance of a recurrence of the nonconformity
- Casework review, whenever necessary
- Depending on the circumstances of the nonconformity, the examiner may be required to successfully complete a proficiency test or work under supervision for a period of time

LEVEL 1 NONCONFORMITY

Corrective/preventive actions:

- Halt the casework of the individual, procedure, discipline, or laboratory (as appropriate) until the appropriate corrective action is taken, in order to minimize the chance of a recurrence of the nonconformity
- Notify the customer agency (if necessary)
- Review all relevant casework
- If the nonconformity is not systemic, but instead isolated to an individual, then the examiner must successfully complete a proficiency test before resumption of casework
- Remedial training or a period of supervised casework may also be required
- Other actions as deemed necessary

MONITORING

The Quality Assurance Manager must then review the effectiveness of the corrective action. The corrective action will also be reviewed during the internal audit process, for implementation and effectiveness.

One of the goals of the corrective action process is to prevent recurrence of the nonconformity. A period of monitoring (to confirm effectiveness) may be necessary before a CAR is closed. If so, then that will occur before the Quality Assurance Manager approves the effectiveness review.

Upon a determination that the monitored corrective action was effective, the Assistant Director will conduct a final review of the CAR, and indicate that the corrective action process is closed by his or her concurrence with the findings.

Review of corrective actions[74] may result in changes to the management system, or updating of the risks and opportunities determined during planning.

8.7.2 PROPORTIONALITY

Corrective action will be appropriate to the type and severity of the nonconformity and/or its effects.

[74] For example: by the Quality Assurance Manager, during Management Review, or during Internal Audit

A serious nonconformity may necessitate an additional audit of the appropriate area(s), or of the entire quality system, if it brings compliance with established policies and procedures or ANAB accreditation requirements into question. These additional audits may be from an external source or conducted internally.

8.7.3 RECORDS

The corrective action process is documented and maintained using the Qualtrax system. This record shall include a description of the nonconforming work, the effect of the discrepancy, cause findings, the action(s) taken, the results of corrective action, and any after-action monitoring requirements to avoid recurrence.

8.8 INTERNAL AUDITS (OPTION A)

8.8.1 INTERNAL AUDITS

Internal audits of the laboratory will be performed to verify that laboratory operations comply with the requirements of the management system and accreditation requirements. Internal audits typically address all elements of the ASCL Quality Management System, although it may occasionally be necessary to conduct limited-scope internal audits.

8.8.1.1 SCHEDULE

Internal audits shall be conducted each calendar year.

8.8.2 AUDIT POLICIES AND PROCEDURES

The Quality Assurance Manager will schedule and coordinate the audit in each discipline of the laboratory. Such audits will be carried out by trained and qualified personnel who are (if resources permit) independent of the activity to be audited. Each audit team will be selected and led by the Quality Assurance Manager. The selection of auditors for a specific team will be primarily based on the expertise needed for that particular audit. The Quality Assurance Manager will preferentially select auditors who have the ability to relate in a professional, non-threatening, and non-judgmental manner with those whose work is being audited.

The auditors will be tasked with the following:

- Determining whether the ASCL's management system is:
  - Conforming to its own requirements[75]
  - Conforming to its accreditation requirements[76]
  - Effectively implemented and maintained
- Reviewing records to ensure that CVs are current, and that proficiency tests, testimony evaluations, and annual training is documented
- Reviewing case records to assess whether appropriate analytical protocols are being followed

[75] For example: with all quality manuals and other required policies and procedures
[76] In this case: ISO/IEC 17025:2017 and ANAB AR 3125, with QAS requirements for DNA and CODIS

- Observing laboratory areas to review instrument/equipment logs, perform spot checks of reagents/chemicals, and to assess laboratory cleanliness and compliance with health and safety requirements
- Direct observation of a sample of accredited services within their assigned discipline(s)
- Evaluation of other items as assigned, such as:
  - Changes affecting the laboratory
  - Results of previous audits

Additional audit foci may need to be considered, resulting from:

- Changes affecting the laboratory
- The results of previous audits and/or assessments

During and/or after the auditing activities, each team meets with the Quality Assurance Manager to review their observations and any possible nonconformities. This meeting is intended to help clarify issues and correct possible misunderstandings that may have occurred during the audit.

The Quality Assurance Manager collects the written information developed by the auditors and develops an audit summary containing a statement of findings and general observations. The Quality Assurance Manager will provide a copy of each discipline's audit summary to the Section Chief. The Quality Assurance Manager and Section Chief will meet to discuss the audit summary. Each Section Chief receiving a finding must either appeal the finding or complete a Corrective Action Request (CAR) for each finding. These responses, along with supporting documentation, must be returned to the Quality Assurance Manager by the assigned deadline, if applicable.

General observations are considered to be opportunities for improvement and require a response by the Section Chief.

The audit summary will be reviewed by the Quality Assurance Manager, Assistant Director, and the Director.

If audit findings cast doubt on the effectiveness of operations or on the correctness or validity of test results, then timely corrective action shall be taken. The ASCL shall notify customers in writing if an investigation shows that laboratory results have been affected.

The area of activity audited, the audit findings, and any corrective actions that arise from the audit shall be recorded and maintained by the Quality Assurance Manager. Records of internal audits shall be retained for at least two ANAB accreditation cycles (i.e., eight years).

Documentation of the implementation and effectiveness of any corrective action will be recorded in the appropriate CAR.

8.9 MANAGEMENT REVIEWS (OPTION A)

8.9.1 MANAGEMENT REVIEW

The laboratory management holds quarterly management meetings to ensure the management system's continuing suitability, adequacy and effectiveness, including the laboratory's stated policies and objectives related to the fulfilment of its accreditation requirements.

8.9.1.1 TIMEFRAME

During the calendar year, the laboratory will review each required element at least once.

8.9.2 INPUTS

The inputs to management review shall be recorded and shall include information related to the following:

a) changes in internal and external issues that are relevant to the laboratory;
b) fulfilment of objectives;
c) suitability of policies and procedures;
d) status of actions from previous management reviews;
e) outcome of recent internal audits;
f) corrective actions;
g) assessments 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 (including risks to impartiality);
n) outcomes of the assurance of the validity of results; and
o) other relevant factors, such as monitoring activities and training.

8.9.3 OUTPUTS

The outputs from the management review shall record all decisions and actions related to at least:

a) the effectiveness of the management system and its processes;
b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
c) provision of required resources;
d) any need for change.

9 ANNEX A (NORMATIVE)

9.1 EDUCATIONAL REQUIREMENTS

Personnel who authorize results or express opinions/interpretations in the following disciplines will meet the minimum educational requirements listed[77]:

Discipline	Minimum education requirements
Biology[78] Fire debris and explosives Gunshot residue Materials (Trace) Seized drugs Toxicology	A baccalaureate or advanced degree[79] in a chemical, physical, or biological science or forensic science
Digital evidence Firearms/toolmarks Footwear and tire Friction ridge	Meet the requirements of the job description as specified by the appropriate quality manual

Technicians working as technical support in any discipline shall meet the education requirements specified in their job description and Discipline Quality Manual. Additional requirements may also be specified in the appropriate Discipline Quality Manual.

9.2 QUALITY ASSURANCE CONCERN WORKFLOW

The *Quality Assurance Concern* (QAC) workflow is intended to address concerns of any level, including:

- Internal complaints
- External complaints
- Simple corrections
- Administrative/personnel matters
- Preventive actions
- Corrective actions

The person with the concern starts the workflow and details their concern. It is forwarded to their supervisor for comment, and then forwarded to the Quality Assurance Manager for classification,

[77] These requirements do not apply to personnel trained before the date of initial accreditation in that discipline

[78] Personnel performing DNA analysis (and where applicable), shall meet the educational requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories.

[79] Or foreign equivalent

generally in consultation with the Assistant Director and involved personnel. The concern can be classified as a Corrective Action, Preventive Action, Simple Correction, Administrative/Personnel Matter, Complaint, or as something which does not require a formal response.

Wherever the Corrective Action, Preventive Action, or Complaint processes are referred to in Arkansas State Crime Laboratory management system documents, the QAC process should be considered to be a high-level process within which those processes may occur.

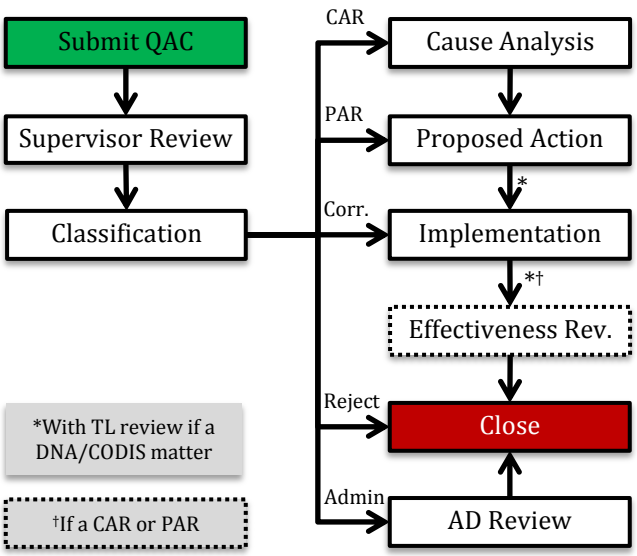

Figure 1: Simplified QAC Flowchart