

**QUALITY ASSURANCE MANUAL
TOXICOLOGY LABORATORY
LABORATORY SERVICES DIVISION (LSD)
COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT (CDPHE)**

Purpose

This Quality Assurance Manual (QAM) describes the Quality Assurance (QA) system used by the CDPHE Toxicology Laboratory (Lab) to comply with the following requirements:

State Board of Health Rules Pertaining To Testing For Alcohol and Other Drugs, 5 CCR 1005-2
CDPHE Laboratory Services Division's Quality Assurance Manual
American Board of Forensic Toxicology (ABFT) requirements

The purpose of this QAM is to provide the necessary framework within which all Toxicology Laboratory work will be performed in order to ensure all Lab QA requirements are met. The analyses performed by the Lab include the analysis of alcohol and drugs in human blood and urine. The Lab's standard of quality requires that all analyses are scientifically valid, accurate within the method's capability, consistent, and reliable in order to support any forensic conclusions supported by these analyses.

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I. Mission Statement

II. Quality Policy

The Toxicology Laboratory QAM ensures the accuracy, precision and reliability of laboratory results by meeting the following objectives.

Develop and maintain analytical methods capable of meeting accuracy, precision, sensitivity, and specificity requirements for each analysis performed by this Lab.

Ensure Lab personnel receive adequate and sufficient training to enable them to perform required analyses and tasks according to the QAM requirements.

Monitor Lab performance through participation in appropriate proficiency testing programs in accordance with accrediting agencies and provide corrective actions and recurrence controls as necessary.

Meet appropriate accreditation requirements.

2. Management Review of this quality system

2.1 Management review of the Lab's quality system and analytical work will be conducted annually. This review will be conducted by the LSD Quality Assurance Officer, the Toxicology Lab Quality Assurance Officer, and/or the Toxicology Supervisor. Additional personnel may be added. The LSD Director shall have final approval authority for responses to any and all findings or recommendations. The review will include, but not be limited to, the following items.

- Policy and procedure accuracy and appropriateness
- Audit results from the previous year
- Proficiency results from the previous year
- Personnel training records
- Quality Assurance charts and records
- Corrective actions and recurrence controls implemented in the past year

2.2 The Toxicology Supervisor will maintain records of the above items for a period of not less than five (5) years.

3. Internal Complaints

3.1 Lab personnel complaints regarding the Lab's quality system may be submitted orally, by e-mail, or in written hard copy form.

3.2 Complaints will be evaluated by the Toxicology Supervisor, Chemistry Laboratory Program Manager, or the LSD Director. The LSD QA Officer and/or the Toxicology QA Officer may be required by management to assist.

3.3 Corrective Actions and/or Recurrence Controls shall be implemented as necessary and documentation shall be maintained for a period of not less than five (5) years.

4. External Complaints

4.1 CDPHE LSD has a complaint tracking system. All customer complaints shall be handled and tracked in accordance with this system.

4.2 Toxicology employees will respond to all customer complaints coming directly to the Lab. Every effort will be made by Toxicology employees to resolve complaints in a manner that is both timely and satisfactory to the customer and Lab as much as is within their means. Complaints requiring action beyond Toxicology personnel's means will be passed immediately to the proper management and/or complaint tracking group.

III. Organization

The Toxicology Laboratory is a section of the Chemistry Laboratory which is a Program in the CDPHE Laboratory Services Division.

1. Organization Chart

1.1 The organization chart for CDPHE LSD, including the Toxicology Lab, is included as Attachment I.

2. Job Descriptions and Qualifications

2.1 Job descriptions for all Lab personnel are maintained by the Toxicology Supervisor.

2.2 Detailed records of individual educational qualifications are maintained by the Human Resources Department.

2.3 Qualifications and/or experience requirements for each job/position description are determined and maintained by the CDPHE Human Resources Department.

3. LSD Director - Responsibilities

The LSD Director is responsible for all personnel, activities, and work performed in the LSD. The Director provides direction and leadership for LSD and monitors the LSD QA Program.

4. Chemistry Program Manager - Responsibilities

The Chemistry Program Manager is responsible for all personnel, activities, and work performed in the Chemistry Laboratory and reports directly to the LSD Director. Duties include management oversight of the Toxicology Lab and membership on the LSD QA Committee.

5. Toxicology Laboratory Supervisor – Responsibilities

The Toxicology Lab Supervisor is responsible for all personnel, activities, and work performed in the Toxicology Lab and reports directly to the Chemistry Program Manager.

5.1 Duties and responsibilities include the following.

- Daily Lab operations, including staff assignments and training (This can be delegated to a Work Leader.)
- QA of Lab analyses and reports
- Review and approve SOPs
- Perform staff evaluations
- Provide expert testimony as a toxicologist
- Maintain document and record storage
- Monitor the Lab's budget and obtain financial grants

6. Toxicology Laboratory Quality Assurance Office - Responsibilities

6.1 The Toxicology Lab's QA Officer is either the Toxicology Supervisor or a Toxicology employee appointed by the Toxicology Supervisor.

6.2 The Toxicology QA Officer's responsibilities include but are not limited to the following activities.

- Development and maintain the Toxicology QA Manual
- Ensure validation of analytical procedures
- Evaluate and maintain proficiency testing records
- Monitor QA charts to verify compliance with policies and procedures
- Member of LSD QA Committee
- Ensure compliance with training and competency requirements
- Prepare for and assist in inspections of accrediting agencies

7. Personnel Code of Ethics and Conduct

7.1 Lab personnel must meet background check requirements in accordance with CDPHE and LSD policy.

7.2 Lab personnel must comply with CDPHE and LSD policies regarding patient confidentiality and other applicable rules.

8. Personnel Evaluations

8.1 Every Lab employee will receive a personal evaluation every fiscal year in accordance with applicable CDPHE requirements.

8.2 Evaluation records shall be maintained in accordance with CDPHE Human Resources requirements.

8.3 The Toxicology Laboratory Supervisor is responsible for giving evaluations to Lab employees.

IV. Management of Manuals and Documentation

All Lab work must be performed to strict QA standards to ensure the accuracy and reliability of the tests performed. Manuals, SOPs and documents are a primary means of accomplishing this. Therefore, manuals and documents shall be maintained and managed in such a way as to protect and ensure the integrity of these documents. Documents and the control of them shall comply with LSD policies.

1. LSD Quality Assurance Manual

1.1 The LSD QAM shall be managed in accordance with LSD policies.

1.2 The Toxicology QAM will comply with all applicable requirements of the LSD QAM.

2. Toxicology Quality Assurance Manual

2.1 There shall be one official copy of the Toxicology QA Manual. It shall be a hard copy under the control of the Toxicology Lab Supervisor.

2.2 The Toxicology QA Manual must be reviewed, approved, and signed and dated by the Toxicology Lab Supervisor, Chemistry Lab Program Manager, LSD QA Officer, and the LSD Director.

2.3 An electronic copy may be posted on the Lab's web site. This copy shall be updated annually.

2.4 All changes to the QA Manual must be approved by the Toxicology Supervisor and/or the Toxicology QA Officer.

2.5 The Toxicology QA Manual shall be reviewed annually for accuracy and adequacy. This review shall be performed by the Toxicology Supervisor or the Toxicology QA Officer.

2.6 Upon completion of the annual review, Toxicology personnel will read the QA Manual and sign signifying their annual review.

3. Controlled Documents

3.1 Control of documents will be in accordance with LSD Policies.

3.2 Documents directly impacting the Lab's QA policy must be controlled. This includes, but is not limited to, the following.

- Toxicology QA Manual

- Standard Operating Procedures

- Instructions and Policies regarding the Lab's security, chain-of custody, and general operating procedures

3.3 Controlled documents shall have the following identifying information.

- Appropriate title identifying the documents use, application, or purpose

- Effective date

- Number of pages

- Header for each page

- SOPs will include the analysis and instrument

- Appropriate approval signatures

- Revision number, if applicable

3.4 Controlled copies will be in hard form. There shall be one controlled copy per document.

3.5 The Toxicology Lab Supervisor is responsible for maintaining controlled documents.

3.6 Uncontrolled copies of controlled documents must be clearly marked "copy" and must be dated.

3.7 Controlled documents shall be removed from use when no longer in effect.

3.8 The Toxicology Lab Supervisor is responsible for maintaining these documents in storage.

V. Procurement of Supplies and Services

Procurement of services and supplies shall comply with CDPHE policies applicable to procurement and budgetary constraints.

1. Procurement of Supplies

1.1 The use of Purchase Orders (PO) shall be in accordance with LSD policies. Appropriate signature must be obtained before the PO is submitted to a vendor.

1.2 Supplies obtained from the LSD Storeroom will comply with LSD policies and will include the use of the storeroom form.

1.3 Upon receipt of supplies, packing slips and container contents will be checked to verify all items are present.

2. Procurement of Services

2.1 Contracts and POs for preventive maintenance of instruments and equipment must indicate specific services to be rendered.

2.2 1 Use of Purchase Orders (PO) shall be in accordance with LSD policies. Appropriate signature must be obtained before the PO is submitted to a vendor.

2.3 Records of performed maintenance shall be maintained for a minimum of five (5) years.

3. Quality of Reagents, Standards and Controls

3.1 Materials used in the Lab will meet quality requirements for the particular use of the material.

3.2 The Lab will comply with requirements for procured reagents as given in the LSD Quality Manual.

3.3 As much as possible, all standards used as calibrators or controls will be traceable to NIST or ASTM.

3.4 If procurement of the standard cannot meet this requirement, the Toxicology Supervisor and/or Toxicology QA Officer can approve use of an adequate substitute from a competent vendor.

3.5 The vendor's quality statement for standards and controls shall be on file for five (5) years after the standard has been used.

4. Quality of Supplies and Services

4.1 The quality of materials used in the Lab will meet the requirements for their use in the Lab.

5. Subcontracting

5.1 It is the policy of the Toxicology Lab to minimize subcontracting of analytical work and to use only competent subcontracts as necessary.

5.2 Subcontractors should be ABFT or ASCLD accredited. If not, the subcontractor must provide other evidence of their QA reliability. The Toxicology Supervisor and/or Toxicology QA Officer must approve use of these subcontractors.

VI. Handling of Evidence/Samples

The receipt, handling, analysis, storage, and disposal of samples/evidence shall be performed in a manner that will ensure they are protected from loss, contamination, or other detrimental change. The LSD computer system, LITS+ is used to maintain identity and record analytical results.

1. Sample Receipt

1.1 The analyses to be performed are determined by the customer (normally law enforcement agencies). Any changes or additions are determined by that customer.

1.2 Samples are received through several means including, but not limited to, the following.

- US Mail

- Delivery services (UPS, FedEx, and others)

- Couriers (law enforcement officers and others)

- Drop box for after hours deliveries

1.3 Lab personnel obtain samples from Receiving and check the samples and their associated paperwork for sample identity and chain-of custody.

2. Sample Verification

2.1 Lab personnel verify sample identity and chain-of-custody. Discrepancies and/or concerns are resolved per SOP.

2.2 Paperwork is given to Central Accessioning so the sample can be entered in LITS+ and labels generated.

2.3 Lab personnel affix appropriate labels to the samples.

3. Sample Handling and Analysis

3.1 Chain-of-custody will be maintained at all times and will be recorded per Lab policy and procedures.

3.2 Analyses will be performed per appropriate Lab SOP.

4. Sample Storage

4.1 Samples will be stored in a manner to preserve the sample's identity, integrity, and security.

4.2 Storage of samples will be in access controlled rooms or have a lock on the storage refrigerator or freezer.

5. Sample Disposal

5.1 Samples will be disposed of in accordance with 5 CCR 1005-2 and Lab procedures.

6. Records and Documents

6.1 Unless otherwise stated specifically for a sample(s) records and documents shall be stored for five (5) years.

6.2 Records and documents will be stored in controlled access rooms or in locked files.

6.3 The Toxicology Laboratory Supervisor is responsible for the storage of these records.

7. Disposal of records and documents

7.1 Disposal of hard copies and electronic media will comply with LSD policies and will be performed in a manner that will protect subject identification.

VII. Operating Procedures

1. Method Validation

1.1 Prior to placing new analytical methods into use for analysis of customer samples, validations shall be performed to ensure accurate and reliable results from their use. Validations shall be performed in accordance with the Chemistry Lab's validation SOP.

1.2 References will be provided when applicable.

1.3 Potential sources of interference and/or variation will be considered and preventive measures taken.

1.4 Method limitations potentially impacting quality of results will be noted.

1.5 Validations shall have proper approval and signatures before being accepted for use.

2. Instrument Validation, Calibration, and Maintenance

2.1 Prior to placing new instrumentation into use for customer samples, validations shall be performed to ensure accurate and reliable results from their use. Validation can be performed by the vendor upon installing the instrument or by Toxicology personnel.

2.2 When replacing older instrument models and when instrumentation methodology remains the same, the Toxicology Supervisor or Toxicology QA Officer may determine what validation, if any, is required. Validation or lack of the need for validation shall be documented and the record maintained for the life of the "new" instrument.

2.3 Normal Preventative Maintenance Operations and routine repairs do not require new validation studies. The analysis of appropriate calibrators and controls resulting in accurate values will suffice.

2.4 Analytical balances used to weigh standards, controls and samples that result in weights being used to report sample results shall be calibrated annually. Calibration checks will be monitored and results recorded on a monthly basis.

2.5 Pipettes used for analytical purposes shall be calibrated twice per year. Results shall be recorded and be kept on file.

2.6 Calibration dates and the next calibration due date shall be recorded on the balance or pipette and documentation of the calibrations shall be kept on file for five (5) years.

2.7 Balances and pipettes not calibrated shall be clearly labeled as such and use limitations shall be stated in the balance or pipette.

3. Manufacturer's Manuals

3.1 Manufacturer's manuals shall be kept and available for use for the life of the instrument/equipment.

4. Maintenance Logs

4.1 Maintenance logs shall be kept near the instruments.

4.2 Lab personnel are responsible for completing daily logs.

4.3 The Toxicology Supervisor or the Work Lead will review and initial and date these logs monthly.

4.4 The Toxicology Supervisor is responsible for maintaining these records for five (5) years.

5. Instrument Software

5.1 Software, records, and documentation shall be maintained for the life of the instrument plus five (5) years.

6. Standard Operating Procedures (SOP)

6.1 All Lab analytical work shall be performed in accordance with applicable requirements of 5 CCR 1005-2, the LSD QAM, and ABFT.

6.2 SOPs are managed as controlled documents.

VIII. Laboratory Testing Control

Quality control samples shall be analyzed and monitored to ensure analytical methods are operating properly. Technical and administrative reviews of documents, analytical reports and position papers will be performed to ensure accuracy of these documents and reports.

1. Quality Control

1.1 All analytical SOPs will list requirements for standard calibrators, quality control samples, and any other controls (e.g., instrument controls) necessary for reliable analytical work.

1.2 All procured standards and control materials shall meet quality requirements for their intended use.

1.3 Quality records for all procured standards, calibrators, and controls shall be maintained for five (5) years after their use.

1.4 All reagents/standards prepared by Lab personnel will be labeled with the following information.

- Name of reagent/standard
- Date of preparation
- Initials of person who prepared the reagent
- Expiration date
- Lot number of source material, if applicable

1.5 Analysis of specific quality controls and their frequency of analysis will be included in analytical SOPs.

1.6 Quality control data will be recorded and charts will be generated where applicable. These charts will be generated at least quarterly. Data will be reviewed and initialed monthly by the Toxicology Supervisor or Toxicology QA Officer.

2. Technical Reviews

2.1 Analytical data will be reviewed by the analyst, Toxicology QA Officer and/or the Toxicology Supervisor. In addition, peer reviews may be performed. Reviews will be initialed and dated.

2.2 Reviews shall include the following.

- Calibration data
- Control data
- Sample data
- Accuracy of any information/data transcribed from original data to work sheets and reports

3. Administrative Reviews

3.1 All analytical reports generated will receive administrative reviews.

3.2 Reviews shall include the following information.

- All information taken from the Request for Analysis and entered into LITS+
- Possible typographical errors
- Date(s) of analysis
- Name of the analyst(s)
- Results match analytical data

4. Court Testimony Reviews

4.1 All Toxicology personnel testifying in court will be subject to annual reviews where possible.

4.2 The reviews will include the following items.

- Knowledge of subject matter
- Communication skills
- Physical appearance (neat, clean)
- Neutrality

4.3 The Toxicology Supervisor is responsible for maintaining these reviews for at least one (1) year.

4.4 Reviews may be performed using a standard form sent to the Prosecuting Attorney or by direct observation by an experienced Toxicology employee using the same form.

5. Technical Problems

5.1 If technical problems occur that could impact the validity and reliability of the test, that method shall not be used to analyze customers' samples until the issue has been resolved or mitigated.

5.2 Experienced Lab personnel will investigate the problem, and when possible determine the root cause and implement preventive action(s). The Toxicology Supervisor, Work Lead, or Toxicology QA Officer will assist with this and approve implementation of these actions and monitor the results to ensure the problem has been resolved.

6. Nonconformities

6.1 Nonconformance with this QAM and/or Lab SOPs will be investigated by Lab personnel and the Toxicology Supervisor or Work Lead. Outside assistance will be obtained when the Chemistry Program Manager or LSD Director deems it desirable.

6.2 The Toxicology Supervisor or Toxicology QA Officer will work with the analyst to determine if any sample results were significantly impacted, what action(s) are necessary to resolve the issue, and will initiate this action(s).

6.3 If sample results have been significantly impacted, the customer will be notified in a timely manner.

6.4 Generation of an amended report will be in accordance with the QA requirements of this QAM.

IX. Proficiency Testing

Proficiency testing shall meet the requirements of 5 CCR 1005-2 and requirements of any applicable additional accrediting agency, such as ABFT.

1. Testing Proficiency Samples

1.1 Proficiency tests shall be performed for each type of sample analyzed by the Lab, namely: blood alcohol, blood drugs, and urine drugs.

1.2 Testing shall be in accordance with the Lab's SOPs and in like manner to actual law enforcement agency samples.

1.3 Testing shall comply with the submitting agency's rules governing their proficiency tests.

1.4 All analysts will be involved in at least one proficiency test in their area(s) of work assignments(s).

2. Reports and Records

2.1 Reports will be submitted in accordance with the requirements of the submitting agency

3. Corrective Actions

3.1 Corrective actions will comply with LSD's QA policies regarding proficiency tests.

4. Records

4.1 Proficiency test data, results, reports, and corrective actions will be maintained for five (5) years.

X. Reports

Reports include analytical results from LITS+, litigation packets, and reports such as position papers that are generated by Lab personnel.

1. Reviewing Reports

1.1 All reports will be reviewed for technical and administrative accuracy.

1.2 All reports shall be accurate, clearly stated, and unbiased.

1.3 Amended reports will be labeled as such. Amended reports include corrected reports and reports where additional testing was performed.

2. Oral Reports

2.1 Results provided orally, including phone conversations, will include any qualifiers such as, "pending final QA review."

3. Litigation Packets

3.1 Requests for litigation packets must be received via fax, mail, or email. Phone requests are not sufficient.

3.2 Litigation packet data shall be reviewed by qualified personnel to ensure accuracy and completeness.

3.3 Litigation packets may be picked up by the requester of requester's agent or may be sent by fax or certified mail.

XI. Facility Requirements

The Lab is located at 8100 Lowry Blvd, Denver, CO. All facility requirements listed herein are applicable to that facility. Any significant facility changes or relocation of the Lab will require a new Facility assessment and plan.

1. Security

1.1 The LSD Security Plan provides the Lab's primary security basis and the Lab will comply with that Plan. The Lab will have a Lab Security Plan subject to the LSD Plan and specific to the Lab's needs, including sample security and chain-of-custody.

1.2 Lab personnel will comply with training requirements for LSD security and Lab security.

1.3 Access to the Lab is controlled by access card as specified in the Plan.

- 1.4 Access to analytical lab rooms is controlled by card. Only employees with the necessary background check and a need to be in these rooms will be granted access.
- 1.5 Access to Lab sample storage and record file rooms are card controlled.
- 1.6 All individuals not having card access must be escorted by Lab employees when allowed in these rooms.
- 1.7 Lost/missing access cards will be reported immediately to the LSD Security Officer and Lab supervision.

2. Safety

The LSD Director is responsible for safety at the LSD facility. Managers and supervisors are responsible for safety in their respective areas. All LSD employees, including Toxicology personnel, are responsible for their own safety.

2.1 Safety requirements are governed by the LSD Safety Manual.

2.2 All Lab employees shall receive safety training upon being hired or transferred into the Lab and will receive annual training thereafter.

2.3 Training will comply with the LSD Safety Manual and will include, but is not limited to, the following topics.

- Fire safety

- Chemical safety

- Biohazard safety

- Electrical safety

- Slip, Trip and Fall safety hazards

2.4 All training for, use of, and checking of safety equipment is governed by the LSD Safety Manual.

2.5 The availability of, training for, and use of Personal Protective Equipment (PPE) shall be in compliance with the LSD Safety Manual.

2.6 Drills for response to safety alarms shall comply with the LSD Safety Manual.

2.7 Checking of safety equipment, including alarms, eye washes, and safety showers will comply with the LSD Safety Manual.

2.8 Accidents will be handled and reported in accordance with the LSD Safety Manual.

2.9 The LSD Safety Committee meets regularly to address safety issues in the LSD facility. Lab personnel should contact supervision and/or safety committee members with safety concerns.

XII. Personnel Qualifications and Training

All Toxicology Laboratory personnel must meet the qualification and training requirements before being permitted to perform Lab work.

1. Qualifications

1.1 Individuals must pass a criminal background check before hiring or assignment to the Lab.

1.2 Lab employees must meet minimal educational and/or experience requirements for the specific job in accordance with CDPHE Human Resources requirements for the specific position.

2. Training

2.1 Lab employees must receive and remain current with LSD training requirements, including but not limited to the following subjects.

- CDPHE orientation training

- LSD annual safety training

- LSD security training

2.2 Lab employees must be trained in specific assignment and/or analyses prior to handling Lab samples and documents.

2.3 Training shall be in accordance with LSD and Lab requirements.

2.4 The trainer shall be qualified to perform both the work and the training duties.

2.5 Training shall be documented in the Training Log.

2.6 Competency assessments will comply with LSD requirements and shall be documented in the Training Log and with the LSD QA Officer.

- 2.7 An annual review of Lab personnel training and competency assessments records shall be performed to ensure training is adequate and timely.
- 2.8 On-going education and off site training are encouraged and will be in accordance with CDPHE LSD policies.
- 2.9 Corrective actions for cases involving elapsed time between assessments/training reviews will be handled through the LSD QA Team.

XIII. Quality Audits

1. CHPHE Certification Audits

- 1.1 The CDPHE Certification Group will perform certification audits in accordance with 5 CCR 1005-2.
- 1.2 Corrective actions will comply with 5 CCR 1005-2.
- 1.3 Accrediting agency audits will be performed in accordance with that agency's specifications.

2. LSD QA Audits

- 2.1 LSD QA audits shall be performed in accordance with the LSD QA Manual. Audits shall be performed at least annually.
- 2.2 Corrective actions will comply with the LSD QA Manual requirements.

3. Additional Certification Audits

- 3.1 Audits from external certification groups, such as ABFT, will be conducted in accordance of that group's requirements.
- 3.2 Corrective actions will comply with that group's requirements.

4. Audit Responses

- 4.1 The Toxicology QA Officer is responsible for all audit responses with necessary Lab and/or LSD approvals being obtained during this process.
- 4.2 Audit documents and responses shall be kept on file for five (5) years or as required by the auditing agency whichever is longer.
- 4.3 The Toxicology Supervisor is responsible for maintaining these records.

XIV. Forms

Organization chart
Lab requisitions
LITS+ reports
Litigation packet forms
Chain-of-custody forms
Fax forms