Re: Potential Impeachment Disclosure (PID) of WSP Toxicology Laboratory

Date: August 7, 2020

We have received information from the WSP Toxicology Laboratory that is potential impeachment information ("PII"). This PID (potential impeachment disclosure) relates environmental contamination of portions of the WSP Toxicology Laboratory of methamphetamine. By environmental contamination, we mean that the methamphetamine level found in various areas exceeded the levels specified in WAC 246-205-541. The environmental contamination ***possibly*** contaminated some blood samples during the extraction process.

In March of 2018, the toxicology laboratory took over laboratory and office space from the crime lab. The toxicology laboratory moved one ethanol instrument into that space. In addition, extractions of evidence were to be conducted in that space. Prior to becoming toxicology laboratory space, the crime lab used one of the lab areas to house a methamphetamine production laboratory for training purposes; this information was not known to the Toxicology laboratory at the time. It is hypothesized that this use resulted in environmental contamination of the area.

During the extraction process performed in the contaminated area, analysts observed that some preliminary tests were positive for methamphetamine, while confirmation tests were negative for methamphetamine. There is a possibility that these "false presumptive positives" were due to the environmental contamination. The environmental methamphetamine contamination did not affect any results reported by the toxicology laboratory for two reasons:

First, the one ethanol instrument in the room cannot read/detect methamphetamine. The ethanol instruments can only detect volatiles not drugs.

Second, as to the drug cases, the toxicology laboratory discovered this environmental contamination due to the drug testing process. They noticed in three separate cases that the initial testing indicated there was methamphetamine present. As a quality measure, all cases receive two tests prior to reporting the final result. When the secondary test was performed, methamphetamine was not detected.

The discrepancy between the initial and secondary testing led the toxicology laboratory to conduct environmental testing on that area of the crime lab turned toxicology lab, which showed that the environmental contamination of that room was above state level thresholds found at WAC 246-205-541. Once the toxicology laboratory was aware of the scope of the problem, all personnel ceased testing in the labs and relocated out of the office areas. The areas were then professionally cleaned. The formerly contaminated space has not been used for forensic testing by the toxicology laboratory since June 19, 2019.

Contained herein are the emails between the toxicology laboratory and the accreditation entity as well as the final report issued by the accreditation entity, taking into account the environmental contamination of portions of the toxicology laboratory.

More information will be disclosed as we receive it from the WSP Toxicology Laboratory.

Miriam Norman
Traffic Safety Resource Prosecutor

Pam Loginsky
Staff Attorney at WAPA

Black, Amanda (WSP)

From: Yoder, Anna <ayoder@anab.org>
Sent: Friday, July 26, 2019 6:05 AM
To: Black, Amanda (WSP)
Subject: 190726-WSP-Tox-Possible Meth Exposure-notif_ack

RE: Acknowledgment for Receipt of Disclosed 2019 Event: Possible Meth Exposure
Certificate Number #: ALI-406-T

Dear Ms. Black,
Thank you for the email submitted to "Quality Matters" on July 25, 2019, in which you notified ANAB of the above referenced event whereby possible environmental methamphetamine exposure of testing work and personnel was identified by the laboratory. Kindly accept this email as formal acknowledgment of receipt of the forensic service provider's notification by ANAB.

In accordance with the current version of *ANAB Accreditation Manual for Forensic Service Providers*, Section 4.6 - Disclosure of Significant Changes, Events, and Nonconformities; this matter is subject to review during your laboratory's next regularly scheduled assessment activity. Therefore, no follow-up report for this self-reported disclosure is being requested at this time.

Questions regarding ANAB's approach to self-reported disclosures of significant events and nonconformities may be directed to me at ayoder@anab.org or 919-592-1554.
Thank you very much for your ongoing compliance with the obligations of an accredited forensic service provider.

Sincerely,
Anna

Anna T. Yoder
Compliance Investigator
ANSI National Accreditation Board (ANAB)
ayoder@anab.org
Cell Phone: 919.592.1554
Alternate Desk Phone: 414.501.5370

QualityMatters@anab.org
Quality Matters ®

From: Black, Amanda (WSP) <Amanda.Black@wsp.wa.gov>
Sent: Thursday, July 25, 2019 3:55 PM
To: QualityMatters <qualitymatters@anab.org>
Subject: WSP TLD Notification - ALI-406-T

Good afternoon,

I am contacting ANAB on behalf of the Washington State Patrol Toxicology Laboratory Division (WSP TLD, certificate ALI-406-T) with the following notification regarding possible environmental methamphetamine exposure of testing work and personnel.

As of June 2019, three separate instances were identified where specimens with confirmation (quantitative) results for methamphetamine were not comparable to those from initial (screen) testing. Further quantitative testing confirmed negative methamphetamine results in these three cases. Initial investigation of each isolated occurrence found no root cause for the discrepancy however, one or more analyses of the specimens had been performed in the same sample preparation (laboratory) area. The sample preparation area was previously utilized for chemical/materials analysis work, and was recently converted for use in toxicological analysis work. As a precautionary measure, TLD personnel discontinued work in this sample preparation area and the affected specimens were reanalyzed.

A review of testing work was done to determine if analysis of other specimens may have been affected. TLD policy/procedure requires two independent samplings from a specimen with valid, comparable results in order to report. Review of testing work involved comparison of screening and confirmation results to ensure agreement between test results. The presence of amphetamine was also used to support reporting, as specimens with methamphetamine often contain amphetamine at an expected ratio. While this review was underway, methamphetamine was identified in five specimens analyzed in one drug screening batch (no amphetamine) however, confirmation testing and repeated screening confirmed these to be negative. At that time, TLD personnel discontinued work in the sample preparation area used for the screening batch, as well as a section of office space adjacent to and/or used by personnel performing the sample preparation.

In order to further assess the lab and office environment, TLD Management employed the services of *BioClean* to perform environmental (swab) testing. Test results were received June 25th and, after review of the report and the overall impact of possible environmental exposure on TLD personnel and testing work, this was determined to be a significant event which required additional action and notification to ANAB.

The TLD is in the process of further environmental evaluation, working with *BioClean*, or a similar company, to create a plan of action for cleaning/remediation of the affected areas. No TLD personnel are working in, and no testing work or evidence is being performed/handled in, the affected areas. To date, review of casework has not found any instances where reported results were affected by this event. TLD policies/procedures, including comparison of individual test results and 100% technical review of testing batches and test reports/case files, identified this issue and continue to ensure quality of the reported results.

At your request, I will provide updates on this process as more information is gathered and external work is scheduled. Documentation of this incident and response will be available for review by the ANAB Lead Assessor at our on-site full re-assessment in October 2019.

Please contact me with any questions/concerns.

Thank you.

Amanda Black
Quality Assurance Manager
Washington State Patrol
Toxicology Laboratory Division
Airport Way South, Suite 360
Seattle, WA 98134

From: Black, Amanda (WSP) <Amanda.Black@wsp.wa.gov>
Sent: Friday, August 7, 2020 10:04 AM
To: Couper, Fiona (WSP); Peterson, Brianna (WSP)
Subject: FW: 190726-WSP-Tox-Possible Meth Exposure-notif_ack

Fiona and Brianna,

The full, on-site re-assessment of the TLD by ANAB was done October 8-10, 2019. As described in the email from ANAB below, I can confirm that the Lead Assessor, during the assessment visit, asked me to confirm work was not being performed in the office or laboratory areas in question. I explained the area was restricted, and no work had been performed in the areas since they were vacated by tox personnel. The Lead Assessor observed signage indicating the areas were restricted and work was not being performed in the areas. There was no additional follow-up or documentation requested by the assessor and this was not noted in writing in the final assessment report.

Amanda Black
Quality Assurance Manager
Washington State Patrol
Toxicology Laboratory Division
Airport Way South, Suite 360
Seattle, WA 98134

From: Black, Amanda (WSP)
Sent: Friday, July 26, 2019 9:15 AM
To: Couper, Fiona (WSP) <Fiona.Couper@wsp.wa.gov>
Subject: FW: 190726-WSP-Tox-Possible Meth Exposure-notif_ack

Amanda Black
Quality Assurance Manager
Washington State Patrol
Toxicology Laboratory Division
Airport Way South, Suite 360
Seattle, WA 98134

From: Yoder, Anna <ayoder@anab.org>
Sent: Friday, July 26, 2019 6:05 AM
To: Black, Amanda (WSP) <Amanda.Black@wsp.wa.gov>
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Thank you.

Amanda Black
Quality Assurance Manager
Washington State Patrol
Toxicology Laboratory Division
Airport Way South, Suite 360
Seattle, WA 98134

Washington State Patrol - Toxicology Laboratory Division

2019 - 17025T - Reassessment

Prepared by Jami St. Clair

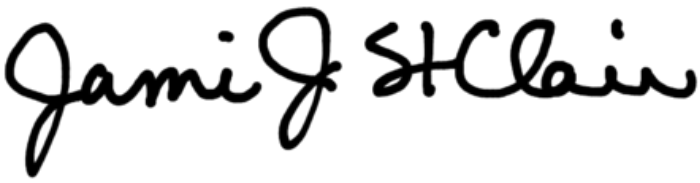
Data collected on 2019-10-08

ANSI National Accreditation Board

United States

Signature

Completed by Jami St. Clair on 2019-12-19



Audit Objective Evidence

4.1 Impartiality

4.1.1 ISO/IEC 17025:2017 — Conforming

Requirement

Are laboratory activities undertaken impartially and structured and managed so as to safeguard impartiality?

Objective Evidence

Operations Manual 1.12: Undue Influence on Analysis
Operations Manual Chapter 5: Courtroom Testimony

4.1.2 ISO/IEC 17025:2017 — Conforming

Requirement

Is the laboratory management committed to impartiality?

Objective Evidence

Operations Manual 1.12: Undue Influence on Analysis
Operations Manual Chapter 5: Courtroom Testimony
Interviews

4.1.3 ISO/IEC 17025:2017 — Conforming

Requirement

Is the laboratory responsible for the impartiality of its laboratory activities and not allow commercial, financial or other pressures to compromise impartiality?

Objective Evidence

Operations Manual 1.12: Undue Influence on Analysis
Washington State Patrol Regulation Manual 8.00.240: Code of Ethics - Employees

4.1.3.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the management system:
a) have a code of ethics as part of the management's commitment to good professional practice? and
b) ensure annual review of the document by all personnel and maintain a record of the review? and
c) ensure appropriate actions are taken when necessary?

Objective Evidence

Operations Manual 1.11 Ethics and Professional Responsibility
Records of Code of Ethics review
Interviews

4.1.4 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory identify risks to its impartiality on an on-going basis? Does this include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel? However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

Objective Evidence

Operations Manual 1.12: Undue Influence on Analysis
Washington State Patrol Regulation Manual 8.00.270: Off-Duty Employment Regulations
Management Review records

4.1.5 ISO/IEC 17025:2017 — Conforming

Requirement

If a risk to impartiality is identified, is the laboratory able to demonstrate how it eliminates or minimizes such risk?

Objective Evidence

Operations Manual 1.12: Undue Influence on Analysis
Complaint records
Interviews

4.2 Confidentiality

4.2.1 ISO/IEC 17025:2017 — Conforming

Requirement

Is the laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities? Does the laboratory inform the customer in advance, of the information it intends to place in the public domain? Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), is all other information considered proprietary information and regarded as confidential?

Objective Evidence

Operations Manual 4.2: Release of Results
Operations Manual 4.4: Procedure for Public Disclosure.
Quality Assurance Manual 12.6.9.3: Release of Reports
Washington State Patrol Regulations Manual 8.00.240: Code of Ethics: Employees

4.2.2 ISO/IEC 17025:2017 — Conforming

Requirement

When the laboratory is required by law or authorized by contractual arrangements to release confidential information, is the customer or individual concerned, unless prohibited by law, notified of the information provided?

Objective Evidence

Operations Manual 4.4: Procedure for Public Disclosure
Washington State Police Public Disclosure Manual

4.2.3 ISO/IEC 17025:2017 — Conforming

Requirement

Is information about the customer obtained from sources other than the customer (e.g. complainant, regulators) confidential between the customer and the laboratory? Is the provider (source) of this information confidential to the laboratory and not shared with the customer, unless agreed by the source?

Objective Evidence

Operations Manual 4.4: Procedure for Public Disclosure
Washington State Police Public Disclosure Manual

4.2.4 ISO/IEC 17025:2017 — Conforming

Requirement

Do personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities, except as required by law?

Objective Evidence

Operations Manual 1.9: Communications
Operations Manual 4.2: Release of Results
Operations Manual 4.4: Public Disclosure

5. Structural requirements

5.1 ISO/IEC 17025:2017 — Conforming

Requirement

Is the laboratory a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities?

NOTE For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

Objective Evidence

The laboratory is a public governmental laboratory.

5.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory identify management that has overall responsibility for the laboratory?

Objective Evidence

Operations Manual 1.6: Organizational Structure;
Operations Manual 1.7: Chain of Command/Personnel Responsibilities
Quality Assurance Manual: 1.2 Definitions (Quality Management System)
Revised Code of Washington
Organizational Chart

5.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Is there a director, whose duties are defined?

Objective Evidence

Operations Manual 1.7.1: TLD Commander/State Toxicologist
Revised Code of Washington (RCW): 68.50.107 State Toxicologist

5.3 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory define and document the range of laboratory activities for which it conforms with this document? Does the laboratory only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis?

Objective Evidence

Laboratory draft scope document

5.4 ISO/IEC 17025:2017 — Conforming

Requirement

Are laboratory activities carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition? Does this include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility?

ANAB NOTE: An example of a regulatory authority is the Federal Bureau of Investigation for laboratories participating in the National DNA Index System (NDIS).

Objective Evidence

Operations Manual Introduction

5.4.1 ANAB Accreditation Requirement — Conforming

Requirement

Does an accredited laboratory conform to requirements in PR 1018 ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status?

Objective Evidence

Washington State Patrol website
Laboratory reports

5.4.2 ANAB Accreditation Requirement — Conforming

Requirement

If a laboratory performs testing or calibration under the authority of a statute, regulation or other legal requirement, does the laboratory make this readily available?

NOTE A legal requirement is created, imposed and enforced by a third-party external to the laboratory.

Objective Evidence

Washington Administrative Code (WAC): Chapter 448-14
Revised Code of Washington (RCW): 43.43.670, 46.61.506

5.5 ISO/IEC 17025:2017 — Conforming

Requirement

a) Does the laboratory define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services?
b) Does the laboratory specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities?
c) Does the laboratory document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results?

ANAB NOTE c) Documenting procedures to the extent necessary to ensure the consistent application of testing and calibration and the validity of the results includes analysis and data interpretation to arrive at a result, opinion or interpretation.

Objective Evidence

Operations Manual 1.7: Chain of Command/Personnel Responsibilities
Organizational Chart
Management System documents

5.6 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:
a) implementation, maintenance and improvement of the management system?
b) identification of deviations from the management system or from the procedures for performing laboratory activities?
c) initiation of actions to prevent or minimize such deviations?
d) reporting to laboratory management on the performance of the management system and any need for improvement?
e) ensuring the effectiveness of laboratory activities?

Objective Evidence

Onsite observations
Interviews

5.7 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory management ensure that:
a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements?
b) the integrity of the management system is maintained when changes to the management system are planned and implemented?

Objective Evidence

Operations Manual 1.9: Communications
Quality Assurance Manual 2.3.3: Review of Controlled Documents

6.1 General

6.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities?

Objective Evidence

Organizational Chart
Management System Documents
Onsite Observations

6.2 Personnel

6.2.1 ISO/IEC 17025:2017 — Conforming

Requirement

Do all personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially, are competent and work in accordance with the laboratory's management system?

Objective Evidence

Operations Manual 1.12.1: Undue Influence on Analysis
Quality Assurance Manual 5: Personnel Qualifications and Training
Interviews

6.2.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience?

ANAB NOTE: See GD 3152 for guidance on the phrase “influence the result of laboratory activities”.

Objective Evidence

Quality Assurance Manual 5.3: Qualifications of Personnel;
Quality Assurance Manual 5.5: Competency Testing
Training modules/program
Position descriptions
Educational records
Training records
Competency records

6.2.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Do personnel who authorize results, opinions and/or interpretations meet the minimum educational requirements established in the country in which the laboratory operates (see Annex A)?

Objective Evidence

Position descriptions
Educational records

6.2.2.2 ANAB Accreditation Requirement — Conforming

Requirement

Does the training program, to the extent necessary based on job function, 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?

NOTE 1 Past work experience and training may be substituted for portions of the training program to the extent that it has been demonstrated to be relevant and sufficient.

NOTE 2 ISO/IEC 17025:2017, section 7.3 may be applicable to training programs

Objective Evidence

Quality Assurance Manual 5.4: Training
Quality Assurance Manual 5.5: Competency Testing
Quality Assurance Manual 5.6: Job Performance
Quality Assurance Manual 5.7: Professional Development Program
Training program
Training records
Competency records

6.2.3 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations?

Objective Evidence

Quality Assurance Manual 5.5: Competency Testing
Quality Assurance Manual 5.6: Job Performance
Training records
Competency testing records

6.2.3.1 ANAB Accreditation Requirement — Conforming

Requirement

Are all personnel who perform testing or calibration activities competency tested? Does the competency test include practical examination(s) that cover the spectrum of anticipated tasks related to the test or calibration? Are the competency test intended results achieved prior to performing the tasks on evidence or a calibration item?

NOTE Competency testing can be conducted for an individual task or a group of tasks covered by a module of a training program.

Objective Evidence

Quality Assurance Manual 5.5: Competency Testing and Authorizations
Competency records
Authorizations to perform work

6.2.3.2 ANAB Accreditation Requirement — Conforming

Requirement

Do personnel who review and authorize results (7.8.1.1), an opinion or an interpretation or perform technical review of results or testimony (7.7.1.l), meet the competency requirements as specified in 6.2.3.1?

Objective Evidence

Quality Assurance Manual 5.5.3: Competency Testing and Authorizations
Competency records
Authorizations to perform work
Authorizations to perform testimony technical review

6.2.4 ISO/IEC 17025:2017 — Conforming

Requirement

Does the management of the laboratory communicate to personnel their duties, responsibilities and authorities?

Objective Evidence

Operations Manual 1.7: Chain of Command/Personnel Responsibilities
Authorizations to perform casework

6.2.5 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have procedure(s) and retain records for:
a) determining the competence requirements?
b) selection of personnel?
c) training of personnel?
d) supervision of personnel?
e) authorization of personnel?
f) monitoring competence of personnel?

Objective Evidence

Quality Assurance Manual 5: Personnel Qualifications and Training
Quality Assurance Manual 11: Proficiency Testing
Operations Manual 1.7: Chain of Command/Personnel Responsibilities
Training records
Competency testing records
Proficiency testing records
Courtroom testimony monitoring records

6.2.6 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory authorize personnel to perform specific laboratory activities, including but not limited to, the following:
a) development, modification, verification and validation of methods?
b) analysis of results, including statements of conformity or opinions and interpretations?
c) report, review and authorization of results?

ANAB NOTE Authorization of personnel includes all aspects of testing or calibration including, as applicable, the use of equipment.

Objective Evidence

Quality Assurance Manual 5.5: Competency Testing and Authorizations
Authorizations to perform work

6.3 Facilities and environmental conditions

6.3.1 ISO/IEC 17025:2017 — Conforming

Requirement

Are facilities and environmental conditions suitable for the laboratory activities and not adversely affect the validity of results?

NOTE Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

Objective Evidence

Quality Assurance Manual 10.5 Environmental Conditions
Operations Manual 7.9: Storage of Evidence
Onsite observations

6.3.2 ISO/IEC 17025:2017 — Conforming

Requirement

Are the requirements for facilities and environmental conditions necessary for the performance of the laboratory activities documented?

Objective Evidence

Quality Assurance Manual 6.14: Refrigerators and Freezers

6.3.3 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results?

Objective Evidence

Quality Assurance Manual 6.14: Refrigerators and Freezers
Temperature records

6.3.4 ISO/IEC 17025:2017 — Conforming

Requirement

Are measures to control facilities implemented, monitored and periodically reviewed and include, but not be limited to:
a) access to and use of areas affecting laboratory activities?
b) prevention of contamination, interference or adverse influences on laboratory activities?
c) effective separation between areas with incompatible laboratory activities?

Objective Evidence

Operations Manual 2: Laboratory Space, Security and Safety
Onsite Observations
Proximity card records

6.3.4.1 ANAB Accreditation Requirement — Conforming

Requirement

Is there a procedure that addresses security and access to areas where testing and calibration occur?

NOTE Topics to consider may include, but are not limited to: access to building, access by personnel, access by visitors, security during operational hours and non-operational hours, and devices that grant access.

Objective Evidence

Operations Manual 2: Laboratory Space, Security, and Safety

6.3.5 ISO/IEC 17025:2017 — Not Applicable

Requirement

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

Objective Evidence

The laboratory does not perform laboratory activities at sites outside its permanent control.

6.4 Equipment

6.4.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results?

NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.

NOTE 2 ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.

Objective Evidence

Quality Assurance Manual 6: Equipment Maintenance
Onsite observations

6.4.2 ISO/IEC 17025:2017 — Not Applicable

Requirement

When the laboratory uses equipment outside its permanent control, does it ensure that the requirements for equipment of this document are met?

Objective Evidence

The laboratory does not use equipment outside its permanent control.

6.4.3 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration?

Objective Evidence

Quality Assurance Manual 6: Equipment Maintenance
Quality Assurance Manual 8: Reagents and Consumable Supplies
Quality Assurance Manual 13: Traceability and Quality Control

6.4.3.1 ANAB Accreditation Requirement — Conforming

Requirement

In addition to the procedural requirements in ISO/IEC 17025:2017, clause 6.4.3, are reagents prepared labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number? Are records maintained identifying who made the reagent and the components used in preparation?

Objective Evidence

Quality Assurance Manual 8.2.8: Reagents
Reagent Preparation Log
Onsite observations

6.4.3.2 ANAB Accreditation Requirement — Conforming

Requirement

Do reference collections have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest?

Objective Evidence

Quality Assurance Manual 9.7: Reference Collections
Reference collection records

6.4.4 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory verify that equipment conforms to specified requirements before being placed or returned into service?

Objective Evidence

Quality Assurance Manual 6: Equipment Maintenance
Quality Assurance Manual 8.2: Reagents
Quality Assurance Manual 9: Reference Materials
Quality Assurance Manual 13.3: Validation/verification of Equipment and Instrumentation
Equipment records

6.4.5 ISO/IEC 17025:2017 — Conforming

Requirement

Is the equipment used for measurement capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result?

Objective Evidence

Quality Assurance Manual 10.10: Uncertainty of Measurement
PQ12706: Estimation and Reporting of Measurement Uncertainty
Measurement uncertainty records
Equipment records

6.4.6 ISO/IEC 17025:2017 — Conforming

Requirement

Is measuring equipment calibrated when:
- the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or
- calibration of the equipment is required to establish the metrological traceability of the reported results?

NOTE Types of equipment having an effect on the validity of the reported results can include:
- those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;
- those used to make corrections to the measured value, e.g. temperature measurements;
- those used to obtain a measurement result calculated from multiple quantities.

Objective Evidence

Quality Assurance Manual 6.3: Calibration of Equipment
Calibration records

6.4.7 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory establish a calibration program, which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration?

Objective Evidence

Quality Assurance Manual 6.3 Calibration of Equipment
Quality Assurance Manual 13.3.6: Equipment Calibration
Calibration program records

6.4.7.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the program for the calibration of equipment include:
a) a list of the equipment requiring calibration;
b) specifications for the calibration laboratory:
c) specified requirements for the calibration; and
d) the interval of calibration?

Objective Evidence

Quality Assurance Manual 6: Equipment Maintenance
Equipment calibration records

6.4.8 ISO/IEC 17025:2017 — Conforming

Requirement

Is all equipment requiring calibration or which has a defined period of validity labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity?

Objective Evidence

Quality Assurance Manual 6.3: Calibration of Equipment
Onsite observations

6.4.9 ISO/IEC 17025:2017 — Conforming

Requirement

Is equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, taken out of service? Is it isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly? Does the laboratory examine the effect of the defect or deviation from specified requirements and initiate the management of nonconforming work procedure (see 7.10)?

Objective Evidence

Quality Assurance Manual 13.3.5: Equipment/Instrument Performance Verification
Pipette calibration/verification records
Nonconforming work records
Onsite observations

6.4.10 ISO/IEC 17025:2017 — Conforming

Requirement

When intermediate checks are necessary to maintain confidence in the performance of the equipment, are these checks carried out according to a procedure?

ANAB NOTE When evaluating the need for intermediate checks, topics to consider include, but are not limited to: the calibration interval, the use of the equipment, the stability of the equipment, the method specifications, and risk associated with a failed check.

Objective Evidence

Quality Assurance Manual 6: Equipment Maintenance
Quality Assurance Manual 8: Reagents and Consumable Supplies
Quality Assurance Manual 10.9.4: Intermediate Checks
PQ12700: Procedure for the Gravitmetric Certification of Hamilton Microlab Diluter-Dispensers
PQ12701: Procedure for the Gravimetric Performance Verification of Adjustable-Volume Piston Pipettes
Equipment records

6.4.11 ISO/IEC 17025:2017 — Not Applicable

Requirement

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

Objective Evidence

The laboratory does not utilize reference values or correction factor.

6.4.12 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory take practicable measures to prevent unintended adjustments of equipment from invalidating results?

Objective Evidence

Quality Assurance Manual 6.3.1: Calibration of Equipment
Onsite observations

6.4.13 ISO/IEC 17025:2017 — Conforming

Requirement

Are records retained for equipment which can influence laboratory activities?

Do the records 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?

Objective Evidence

Quality Assurance Manual 13.3.3.1: Procedure (Validation/Verification of Equipment and Software)
Equipment records

6.5 Metrological traceability

6.5.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference?

NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the “property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty”.

NOTE 2 See Annex A for additional information on metrological traceability.

Objective Evidence

Quality Assurance Manual 13.5.1: Policy (Traceability of Measurement Standards)
Measurement uncertainty records
Equipment calibration records
Reference material records

6.5.1.1 ANAB Accreditation Requirement — Conforming

Requirement

If available, are the suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials used to establish or maintain metrological traceability either:
a) a National Metrology Institute that is a signatory to the BIPM - CIPM Mutual Recognition Arrangement with the calibration of measuring equipment and/or reference standard to be performed or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB)? or
b) a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be performed listed in a scope of accreditation? or
c) an accredited reference material producer that is 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?

Objective Evidence

Quality Assurance Manual 6.3: Calibration of Equipment;
Quality Assurance Manual 13.2.3: Traceability and Quality Control of Reagents
Quality Assurance Manual 13.5.3: Traceability of Measurement Standards
Equipment calibration records
Vendor evaluation records
Reference material records

6.5.1.2 ANAB Accreditation Requirement — Conforming

Requirement

In situations where a supplier that meets 6.5.1.1 is not available, were the competence, capability, and metrological traceability for the supplier and the external product or service being purchased confirmed? Was objective evidence of the confirmation available for review?

Objective Evidence

Quality Assurance Manual 6.3: Calibration of Equipment;
Quality Assurance Manual 13.2.3: Traceability and Quality Control of Reagents
Quality Assurance Manual 13.5.3: Traceability of Measurement Standards

6.5.1.3 ANAB Accreditation Requirement — Not Applicable

Requirement

For the purpose of establishing traceability of a measurement, did an accredited laboratory that may calibrate its own equipment that supports an accredited parameter on the scope meet the related requirements in ISO/IEC 17025 and this document:
a) was the calibration and any check of the calibration status carried out by appropriately trained, competency tested, and authorized personnel?
b) was the calibration method validated or verified prior to use?
c) were certified reference materials or measuring instruments used in the calibration method traceable with appropriate measurement uncertainties?
d) was the calibration carried out in an appropriate environment?
e) were technical records of the calibration established and maintained?
f) did the laboratory have and apply a procedure for calculating the measurement uncertainty for each equipment calibration it conducts? and
g) was a technical review of the technical records including any data transfers and calculations completed by an individual other than the person(s) who performed the work?

Objective Evidence

The laboratory does not calibrate its own equipment.

6.5.1.4 ANAB Accreditation Requirement — Conforming

Requirement

If a certified reference material is changed in a way that alters the traceable measurement value, then is the equipment used to alter the certified reference material evaluated for applicability of measurement traceability accreditation requirements?

Objective Evidence

Quality Assurance Manual 13.3.6: Equipment Calibration
Calibration records
Measurement uncertainty records

6.5.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory ensure that measurement results are traceable to the International System of Units (SI) through:
a) calibration provided by a competent laboratory? or
b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI? or
c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards?

NOTE 1 a) Laboratories fulfilling the requirements of this document are considered to be competent.

NOTE 2 b) Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

NOTE 3 c) Details of practical realization of the definitions of some important units are given in the SI brochure.

Objective Evidence

Equipment calibration records
Reference material records
Vendor evaluation records

6.5.3 ISO/IEC 17025:2017 — Not Applicable

Requirement

When metrological traceability to the SI units is not technically possible, does the laboratory demonstrate metrological traceability to an appropriate reference, e.g.:
a) certified values of certified reference materials provided by a competent producer?
b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison?

Objective Evidence

The laboratory establishes metrological traceability to SI units.

6.6 Externally provided products and services

6.6.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:
a) are intended for incorporation into the laboratory's own activities?
b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider?
c) are used to support the operation of the laboratory?

NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

Objective Evidence

Quality Assurance Manual 7.2.6: Vendor Evaluation
Quality Assurance Manual 10.8: Subcontractors
Vendor evaluation records
Subcontractor evaluation records

6.6.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have a procedure and retain records for:
a) defining, reviewing and approving the laboratory's requirements for externally provided products and services?
b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers?
c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer?
d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers?

Objective Evidence

Quality Assurance Manual 7: Purchasing Services and Supplies
Quality Assurance Manual 10.8: Subcontractors
Purchasing records
Interviews

6.6.3 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory communicate its requirements 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?

Objective Evidence

Quality Assurance Manual 7: Purchasing Services and Supplies
Quality Assurance Manual 10.8: Subcontractors
Purchasing records

7.1 Review of requests, tenders and contracts

7.1.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have a procedure for the review of requests, tenders and contracts? Does the procedure ensure that:
a) the requirements are adequately defined, documented and understood?
b) the laboratory has the capability and resources to meet the requirements?
c) where external providers are used, the requirements of 6,6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval?
d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements?

NOTE 1 c) It is recognized that externally provided laboratory activities can occur when:
- the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;
- the laboratory does not have the resources or competence to perform the activities.

NOTE 2 d) For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.

Objective Evidence

Operations Manual 6.1.4 Customer Requests for Analysis
Quality Assurance Manual 10.8: Subcontractors
Quality Assurance Manual 10.3: Technical Procedures and Methods
Case files

7.1.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory inform the customer when the method requested by the customer is considered to be inappropriate or out of date?

Objective Evidence

Operations Manual 6.1: Customer Requests for Analysis
Case files

7.1.3 ISO/IEC 17025:2017 — Not Applicable

Requirement

When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), was the specification or standard and the decision rule clearly defined? Unless inherent in the requested specification or standard, was the decision rule selected communicated to, and agreed with, the customer?

NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4.

Objective Evidence

Customers do not request statements of conformity for testing performed by the laboratory.

7.1.4 ISO/IEC 17025:2017 — Conforming

Requirement

Are any differences between the request or tender and the contract resolved before laboratory activities commence? Is each contract acceptable both to the laboratory and the customer? Do deviations requested by the customer not impact the integrity of the laboratory or the validity of the results?

Objective Evidence

Operations Manual 6.1: Customer Requests for Analysis
Case files

7.1.5 ISO/IEC 17025:2017 — Conforming

Requirement

Is the customer informed of any deviation from the contract?

Objective Evidence

Operations Manual 6.1: Customer Requests for Analysis
Case files

7.1.6 ISO/IEC 17025:2017 — Conforming

Requirement

If a contract is amended after work has commenced, is the contract review repeated and are any amendments communicated to all affected personnel?

Objective Evidence

Operations Manual 6.1: Customer Requests for Analysis
Case files

7.1.7 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed?

NOTE Such cooperation can include:
a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;

b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.

Objective Evidence

Operations Manual 6.1: Customer Requests for Analysis
Case files

7.1.8 ISO/IEC 17025:2017 — Conforming

Requirement

Are records of reviews, including any significant changes retained? Are records retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities?

Objective Evidence

Operations Manual 6.1: Customer Requests for Analysis
Case files

7.1.9 ANAB Accreditation Requirement — Not Applicable

Requirement

Is the extent of database (e.g., DNA profiles, friction ridge, ballistics, biometrics) searches communicated to customers and updated as needed?

NOTE This may be communicated on a case-by-case basis, in the report, or in a general customer communication.

Objective Evidence

The laboratory does not perform database searches.

7.2.1 Selection and verification of methods

7.2.1.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data?

NOTE “Method” as used in this document can be considered synonymous with the term “measurement procedure” as defined in ISO/IEC Guide 99.

Objective Evidence

Quality Assurance Manual 10.3: Technical Procedures and Methods
PQ12704: Validation Procedure for Confirmatory Methods
PQ12705: Validation Procedure for Screening and Qualitative Methods
Method validation records
Measurement Uncertainty records
Technical Records

7.2.1.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Do all test methods that involve the comparison of an unknown to a known require the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations, prior to comparison to one or more known item(s)?

NOTE 1 Characteristics include, but are not limited to, alleles in a DNA profile, friction ridge detail in a latent print, striation detail on a bullet, features of handwriting, or criteria for evaluation of mass spectrometry fragments and ratios in a seized drug sample or a toxicology sample extract.

NOTE 2 This requirement is not focused on the process of assessing an unknown in order to identify evidence that will be the subject of further comparison. In these circumstances, it may be appropriate to perform a preliminary characterization of the known sample prior to the assessment of the unknown.

Objective Evidence

PQ12707: General Requirements for Chromatographic Test Method Batch Analysis and Acceptance
Technical Records

7.2.1.1.2 ANAB Accreditation Requirement — Not Applicable

Requirement

For laboratories whose scope of accreditation includes calibration:

Do calibration methods assess accuracy (bias and precision) of the instrument across a range of values that meets the needs of the customer? and

Was the source of material(s) used to calibrate a measuring instrument different from that used to adjust a measuring instrument and that used to verify calibration status?

NOTE Preference should be given to material(s) from different manufacturers, followed by different lot numbers of material from the same manufacturer.

Objective Evidence

The laboratory does not perform calibrations.

7.2.1.2 ISO/IEC 17025:2017 — Conforming

Requirement

Are all methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, kept up to date and made readily available to personnel (see 8.3)?

Objective Evidence

Quality Assurance Manual 2.1: Policy (Document Control)
Quality Assurance Manual10.3: Technical Procedures and Methods
Management System documents
Onsite observations

7.2.1.3 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so? When necessary, is the application of the method supplemented with additional details to ensure consistent application?

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.

Objective Evidence

Quality Assurance Manual 10.3.5: Developing Analytical Methods and Procedures
Technical Methods
Technical Records

7.2.1.4 ISO/IEC 17025:2017 — Conforming

Requirement

When the customer does not specify the method to be used, does the laboratory select an appropriate method and inform the customer of the method chosen?
Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.

Objective Evidence

Operations Manual 6.1: Customer Requests for Analysis
Quality Assurance Manual 10.3: Technical Procedures and Methods
Case files
Technical Records

7.2.1.5 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance? Are records of the verification retained? If the method is revised by issuing body, is the verification repeated to the extent necessary?

Objective Evidence

Quality Assurance Manual 10.3.6: Method Validation
Method validation and verification records

7.2.1.6 ISO/IEC 17025:2017 Conforming

Requirement

When method development is required, is this a planned activity and assigned to competent personnel equipped with adequate resources? As method development proceeds, is periodic review carried out to confirm that the needs of the customer are still being fulfilled? Are any modifications to the development plan approved and authorized?

Objective Evidence

Quality Assurance Manual 10.3.6 Method Validation
PQ12704: Validation Procedure for Confirmatory Methods
PQ12705: Validation Procedure for Screening and Qualitative Methods
Method validation records

7.2.1.7 ISO/IEC 17025:2017 Conforming

Requirement

Do deviations from methods for all laboratory activities occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer?

NOTE Customer acceptance of deviations can be agreed in advance in the contract.

Objective Evidence

Operations Manual 6.1.5: Customer Requests for Analysis
Quality Assurance Manual 10.3.4: Technical Procedures and Methods
Case files (communications, correspondence logs)
Technical Records

7.2.2 Validation of methods

7.2.2.1 ISO/IEC 17025:2017 Conforming

Requirement

Does the laboratory validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified? Is the validation as extensive as is necessary to meet the needs of the given application or field of application?

NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items.

NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:
a) calibration or evaluation of bias and precision using reference standards or reference materials;
b) systematic assessment of the factors influencing the result;
c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
d) comparison of results achieved with other validated methods;
e) interlaboratory comparisons;
f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

Objective Evidence

Quality Assurance Manual 10.3.6: Method Validation
PQ12704: Validation Procedure for Confirmatory Methods
PQ12705: Validation Procedure for Screening and Qualitative Methods
Method validation records

7.2.2.1.1 ANAB Accreditation Requirement Conforming

Requirement

Does the laboratory have a procedure for method validation that:
a) includes the associated data interpretation?
b) establishes the data required to report a result, opinion, or interpretation? and
c) identifies limitations of the method, reported results, opinions, and interpretations?

Objective Evidence

Quality Assurance Manual 10.3.6: Method Validation
PQ12704: Validation Procedure for Confirmatory Methods
PQ12705: Validation Procedure for Screening and Qualitative Methods
Method validation records

7.2.2.2 ISO/IEC 17025:2017 Conforming

Requirement

When changes are made to a validated method, is the influence of such changes determined and where they are found to affect the original validation, is a new method validation performed?

Objective Evidence

PQ12704: Validation Procedure for Confirmatory Methods
PQ12705: Validation Procedure for Screening and Qualitative Methods
Method validation records

7.2.2.2.1 ANAB Accreditation Requirement — Conforming

Requirement

The associated data interpretation is considered part of a validated method. When changes are made, was ISO/IEC 17025:2017, 7.2.2.2 applied?

Objective Evidence

PQ12704: Validation Procedure for Confirmatory Methods
PQ12705: Validation Procedure for Screening and Qualitative Methods
Method validation records

7.2.2.3 ISO/IEC 17025:2017 — Conforming

Requirement

Are the performance characteristics of validated methods, as assessed for the intended use, relevant to the customers' needs and consistent with specified requirements?

NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.

Objective Evidence

PQ12704: Validation Procedure for Confirmatory Methods
PQ12705: Validation Procedure for Screening and Qualitative Methods
Method validation records

7.2.2.4 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory retain the following records of validation:
a) the validation procedure used?
b) specification of the requirements?
c) determination of the performance characteristics of the method?
d) results obtained?
e) a statement on the validity of the method, detailing its fitness for the intended use?

Objective Evidence

Quality Assurance Manual 10.3.6: Method Validation
Method validation records

7.3 Sampling

7.3.1 ISO/IEC 17025:2017 — Not Applicable

Requirement

Does the laboratory have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration? Does the sampling method address the factors to be controlled to ensure the validity of subsequent testing or calibration results? Is the sampling plan and method available at the site where sampling is undertaken? Are sampling plans, whenever reasonable, based on appropriate statistical methods?

Objective Evidence

The laboratory does not perform sampling.

7.3.2 ISO/IEC 17025:2017 — Not Applicable

Requirement

Does the sampling method describe:
a) the selection of samples or sites?

b) the sampling plan?
c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration?

NOTE When received into the laboratory, further handling can be required as specified in 7.4.

Objective Evidence

The laboratory does not perform sampling.

7.3.2.1 ANAB Accreditation Requirement — Not Applicable

Requirement

Does the sampling method:
a) require an evaluation of the selected population for homogeneity?
b) require the population to have a reasonable expectation of homogeneity to use a sampling plan?
c) require that the sampling plan makes use of probability and provides an opinion or interpretation with a minimum confidence level of 95.45% (often referred to as approximately 95%)?
d) require each item selected to meet the sampling plan level of confidence to be tested completely? and
e) provide instruction regarding the course of action to take if one or more selected items demonstrate a lack of homogeneity?

Objective Evidence

The laboratory does not perform sampling.

7.3.3 ISO/IEC 17025:2017 — Not Applicable

Requirement

Does the laboratory retain records of sampling data that forms part of the testing or calibration that is undertaken? Did the records include, where relevant:
a) reference to the sampling method used?
b) date and time of sampling?
c) data to identify and describe the sample (e.g. number, amount, name)?
d) identification of the personnel performing sampling?
e) identification of the equipment used?
f) environmental or transport conditions?
g) diagrams or other equivalent means to identify the sampling location, when appropriate?
h) deviations, additions to or exclusions from the sampling method and sampling plan?

Objective Evidence

The laboratory does not perform sampling.

7.4 Handling of test or calibration items

7.4.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer? Are precautions taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration? Are handling instructions provided with the item followed?

Objective Evidence

Operations Manual 7: Evidence Management
LIMS transaction records
Onsite observations

7.4.1.1 ANAB Accreditation Requirement — Conforming

Requirement

When an item is considered to be evidence, does the procedure:
a) address all items received?
b) address requirements for storage, packaging, and sealing of items to:
1) protect the integrity of all items? and
2) require items to be re-sealed as soon as practicable?
c) address measures to be taken to secure unattended items?
d) require chain-of-custody for:
1) all items received? and
2) items that are collected or created and preserved for future testing (e.g., ESDA lifts, test-fired ammunition, latent print lifts, photos, trace evidence, DNA extracts)?
e) require chain-of-custody to securely and accurately identify:
1) the individual(s) or location(s) receiving or transferring the item(s)? and
2) the item(s) being transferred? and

3) the chronological order of all transfers, minimally including the date?
f) address requirements for individual characteristic database samples? and
g) require communication to the customer regarding the disposition of all items received; and
h) address communication to the customer regarding items collected or created and preserved for future testing?

NOTE 1 d) An item being tracked could contain multiple components and be tracked as one item.

NOTE 2 e).1) Documentation of internal transfers does not need to include use of personal storage locations.

Objective Evidence

(d) 2 and (f) do not apply.

Operations Manual 7: Evidence Management
LIMS transaction records
Onsite observations

7.4.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Did the system used to identify items cover all items received?

Objective Evidence

LIMS transaction records
Onsite observations

7.4.3 ISO/IEC 17025:2017 — Conforming

Requirement

Upon receipt of the test or calibration item, are deviations from specified conditions recorded? When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, does the laboratory consult the customer for further instructions before proceeding and record the results of this consultation? When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, does the laboratory include a disclaimer in the report indicating which results may be affected by the deviation?

Objective Evidence

Operations Manual 7: Evidence Management
LIMS transaction records
Case records
Test reports

7.4.4 ISO/IEC 17025:2017 — Conforming

Requirement

When items need to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded?

Objective Evidence

Operations Manual 7.9: Storage of Evidence
Quality Assurance Manual 6.14: Refrigerators and Freezers
Refrigerator temperature logs
Onsite observations

7.4 Handling of test and calibration items

7.4.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have a system for the unambiguous identification of test or calibration items? Is the identification retained while the item is under the responsibility of the laboratory? Does the system ensure that items will not be confused physically or when referred to in records or other documents? Does the system, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items?

Objective Evidence

Operations Manual 7: Evidence Management
Laboratory Information System (LIMS) records
Case records
Test Reports

7.5 Technical records

7.5.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original? Do the technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results? Are original observations, data and calculations recorded at the time they are made and identifiable with the specific task?

ANAB NOTE Options for recording observations include, but are not limited to: written notes, photography, drawing, photocopying, or scanning.

Objective Evidence

Quality Assurance Manual 12: Records, Reviews and Reports
Technical records
Test Reports
Onsite observations

7.5.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory define the technical record(s) to be retained if all related technical records are not maintained?

Objective Evidence

Quality Assurance Manual 12: Records, Reviews and Reports
Technical records
Test Reports
Onsite observations

7.5.1.2 ANAB Accreditation Requirement — Conforming

Requirement

Where abbreviations or symbols specific to the forensic service provider are used, is the meaning of the abbreviations or symbols defined?

Objective Evidence

Quality Assurance Manual 12.3.3.5: General Documentation Requirements
TLDAAD: Acronym/Abbreviation Dictionary
Technical Records

7.5.1.3 ANAB Accreditation Requirement — Conforming

Requirement

Are technical records to support a report (including results, opinions, and interpretations) such that, another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data?

Objective Evidence

Quality Assurance Manual 12.3.3.16: General Documentation Requirements
Technical records
Test Reports

7.5.1.4 ANAB Accreditation Requirement — Conforming

Requirement

Are records created or maintained in a permanent manner?

ANAB NOTE For example, technical records originally captured in pencil (e.g., a rough sketch) can be maintained in a permanent manner by photocopying, scanning, or taking a photo.

Objective Evidence

Quality Assurance Manual 12.3: Testing Documentation
Technical records
Test Reports

7.5.1.5 ANAB Accreditation Requirement — Conforming

Requirement

If an observation, data, or calculation is rejected, is the reason, the identity of the individual(s) taking the action and the date recorded in the technical record?

Objective Evidence

Quality Assurance Manual 12.4: Review of Records
Technical records
Test Reports

7.5.1.6 ANAB Accreditation Requirement — Not Applicable

Requirement

If an adjustment or repair is performed due to a calibration that does not meet specifications, are pre and post adjustment/repair data retained?

NOTE See related clause ISO/IEC 17025:2017, 7.8.4.1.d)

Objective Evidence

The laboratory does not perform calibrations.

7.5.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory ensure that amendments to technical records can be tracked to previous versions or to original observations? Are both the original and amended data and files retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations?

ANAB NOTE Contemporaneous revisions are not considered amendments.

Objective Evidence

Quality Assurance Manual 12.3.3.16: General Documentation Requirements
Technical records
Test Reports

7.6 Evaluation of measurement uncertainty

7.6.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory identify the contributions to measurement uncertainty? When evaluating measurement uncertainty, are all contributions that are of significance, including those arising from sampling, taken into account using appropriate methods of analysis?

Objective Evidence

Quality Assurance Manual 10.10: Uncertainty of Measurement
PQ12706: Estimation and Reporting of Measurement Uncertainty
Measurement uncertainty records

7.6.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the method of analysis for evaluation of measurement uncertainty:
a) require the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method?
b) include the process of rounding the expanded uncertainty?
c) require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%)? and
d) specify the schedule to review and/or recalculate the measurement uncertainty?

Objective Evidence

Quality Assurance Manual 10.10: Uncertainty of Measurement
PQ12706: Estimation and Reporting of Measurement Uncertainty
Measurement uncertainty records

7.6.2 ISO/IEC 17025:2017 — Not Applicable

Requirement

Does a laboratory performing calibrations, including of its own equipment, evaluate the measurement uncertainty for all calibrations?

Objective Evidence

Calibrations of equipment is performed by an external calibration laboratory.

7.6.3 ISO/IEC 17025:2017 — Conforming

Requirement

Does a laboratory performing testing evaluate measurement uncertainty? Where the test method precludes rigorous evaluation of measurement uncertainty, is an estimation made based on an understanding of the theoretical principles or practical experience of the performance of the method?

NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.

NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.

Objective Evidence

Measurement uncertainty records

7.6.3.1 ANAB Accreditation Requirement — Conforming

Requirement

Was the measurement uncertainty evaluated, or estimated when applicable, for all reported quantitative results?

NOTE An item descriptor that includes a number is not considered a result. This difference should be clear to the reader of the report.

Objective Evidence

Measurement uncertainty records
Case records
Test reports

7.6.4 ANAB Accreditation Requirement — Conforming

Requirement

Were the following records maintained for each evaluation and estimation of measurement uncertainty:
a) statement defining the measurand?
b) statement of how traceability is established for the measurement?
c) the equipment (e.g., measuring device[s] or instrument[s]) used?
d) all uncertainty components considered?
e) all uncertainty components of significance and how they were evaluated?
f) data used to estimate repeatability, intermediate precision, and/or reproducibility?
g) all calculations performed? and
h) the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty?

Objective Evidence

Quality Assurance Manual 10.10: Uncertainty of Measurement
PQ12706: Estimation and Reporting of Measurement Uncertainty
Measurement uncertainty records

7.7 Ensuring the validity of results

7.7.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have a procedure for monitoring the validity of results? Is the resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results? Is the monitoring planned and reviewed and include, where appropriate, but not be limited to:
a) use of reference materials or quality control materials?
b) use of alternative instrumentation that has been calibrated to provide traceable results?
c) functional check(s) of measuring and testing equipment?
d) use of check or working standards with control charts, where applicable?
e) intermediate checks on measuring equipment?

f) replicate tests or calibrations using the same or different methods?
g) retesting or recalibration of retained items?
h) correlation of results for different characteristics of an item?
i) review of reported results?
j) intralaboratory comparisons?
k) testing of blind sample(s)?

Objective Evidence

(B), (g), (h), and (k) are not applicable for this laboratory.

Quality Assurance Manual 10: Assuring the Quality of Test Results
Quality Assurance Manual 12.4: Review of Records
Quality Assurance Manual 13.3: Validation/verification of Equipment and Instrumentation
PQ12703: Quality Assurance Principles
Technical Records
Test Reports

7.7.1 ANAB Accreditation Requirement — Conforming

Requirement

g).1 When a verification of a result is carried out:
a) was it conducted by an individual who is currently authorized to perform the testing?
b) was a record of the verification made and did the record identify who performed the verification, when it was performed, and the result of the verification? and
c) was the resolution of any discrepancy recorded?

ANAB NOTE 1 a) See requirements of 6.2.6 in ISO/IEC 17025:2017.

ANAB NOTE 2 b) Verification may be recorded for each result verified or as a summary for all results verified.

l) Is there a procedure for the technical review of technical records, including reports, and testimony? Does the procedure:
1. require that a technical review be performed by an individual that has been competency tested in the task(s) that the review is encompassing?
2. preclude an individual from technically reviewing their own work?
3. define the method to be used to ensure a representative sample of technical records and reports in each discipline are subjected to technical review?
4. define the method to be used to ensure testimony in each discipline is reviewed?
5. define the method to be used to conduct and record the review?
6. ensure that the results, opinions and interpretations are accurate, properly qualified and supported by the technical record?
7. ensure conformance with methods and applicable management system documents? and
8. describe a course of action to be taken if a discrepancy is found?

ANAB NOTE 1 An individual conducting the technical review need not be an employee of the forensic service provider, currently proficiency tested or currently performing the work.

ANAB NOTE 2 An individual who performs a verification can also perform a technical review.

ANAB NOTE 3 The frequency may vary for different disciplines.

Objective Evidence

(g) is not applicable. Laboratory does not perform verifications.

(l) Quality Assurance Manual 12: Records, Reviews, Reports
Operations Manual 5.1: Court Testimony Monitoring
Technical records
Test Reports

7.7.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory monitor its performance by comparison with results of other laboratories, where available and appropriate? Is the monitoring planned and reviewed and include, but not be limited to, either or both of the following:
a) participation in proficiency testing?

NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing?

Objective Evidence

Quality Assurance Manual 11: Proficiency Testing
Proficiency testing records

7.7.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the process for monitoring performance by comparison with results of other forensic service providers at a minimum:
a) ensure successful completion of at least one proficiency test for each discipline prior to accreditation being granted in that discipline? and

b) ensure each location on the scope of accreditation successfully completes, per calendar year, at least one proficiency test for each discipline in which accredited services are provided, with authorized release of the test results to ANAB from the test provider?

NOTE 1 Accreditation occurs in the discipline of Toxicology in both Calibration and Testing. The above requirements apply to the Testing scope of accreditation and Calibration scope of accreditation separately.

NOTE 2 For proficiency tests taken at the end of one calendar year, evaluation of successful completion can occur in the subsequent calendar year.

Objective Evidence

Quality Assurance Manual 11.3: Frequency
Proficiency testing schedule
Proficiency testing records

7.7.3 ISO/IEC 17025:2017 — Conforming

Requirement

Is data from monitoring activities analyzed, used to control and, if applicable, improve the laboratory's activities? If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, is appropriate action taken to prevent incorrect results from being reported?

Objective Evidence

Quality Assurance Manual 10.9.3: Quality Control
Positive control tracking records
Proficiency testing records

7.7.4 ANAB Accreditation Requirement — Conforming

Requirement

Is the performance of personnel monitored? Does monitoring ensure that all personnel who perform testing or calibration successfully complete at least one intralaboratory comparison, interlaboratory comparison or proficiency test per calendar year in each discipline on the scope of accreditation in which the individual conducts work? In the event that the preceding options are not available or appropriate, observation-based performance monitoring is acceptable.

NOTE 1 The monitoring should be varied over time to cover all aspects of assigned job functions but does not have to include all aspects of the work performed each time.

NOTE 2 Solely performing verifications (7.7.1.f).1) or solely reviewing and authorizing results (7.8.1.1) are considered to be testing or calibration and are subject to these requirements.

NOTE 3 Accreditation occurs in the discipline of Toxicology in both Calibration and Testing. The above requirements apply to the Testing scope of accreditation and Calibration scope of accreditation separately.

NOTE 4 For performance monitoring conducted at the end of one calendar year, evaluation of successful completion can occur in the subsequent calendar year.

Objective Evidence

Quality Assurance Manual 11: Proficiency Testing
Proficiency testing schedule
Proficiency testing records

7.7.5 ANAB Accreditation Requirement — Conforming

Requirement

Does the process for monitoring of performance by intralaboratory comparison, interlaboratory comparison, proficiency testing or observation-based testing at a minimum:
a) ensure that results are not known or readily available to the participant being monitored?
b) ensure use of approved methods?
c) ensure appropriate technical records are retained?
d) establish criteria for determining successful completion prior to the monitoring activity?
e) require a mechanism to ensure the quality of intralaboratory comparisons, interlaboratory comparisons and observation-based monitoring prior to the monitoring activity? and
f) for calibration laboratories, require intralaboratory comparisons, interlaboratory comparisons and proficiency tests to be performed using an item that was calibrated by the person performing the comparison or test?

NOTE c) See requirements of 7.5 in ISO/IEC 17025:2017 and this document.

Objective Evidence

Quality Assurance Manual 11: Proficiency Testing
Proficiency testing records

7.7.6 ANAB Accreditation Requirement — Conforming

Requirement

Is there a plan that will:
a) demonstrate conformance with the requirements stated in clause 7.7.2.1.b) and 7.7.4? and
b) ensure inclusion of a representative sample of the components/parameters, methods, and key equipment/technologies within each discipline listed on the scope of accreditation?

Objective Evidence

Quality Assurance Manual 11.6: Assignment and Scheduling (Proficiency Tests)
Proficiency testing schedule
Proficiency testing records

7.7.7 ANAB Accreditation Requirement — Conforming

Requirement

To satisfy the proficiency test requirements in clauses 7.7.2.1.a) and b), did the forensic service provider:
a) where available and appropriate for the work conducted, use a proficiency test provider that is accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the APLAC MRA or IAAC MLA and has the applicable proficiency test(s) on its scope of accreditation? or
b) where not available or not appropriate for the work conducted, gain approval from ANAB for alternative means by which the laboratory's performance can be assessed? and
c) submit results to the proficiency test provider, if applicable, on or before the agreed upon due date?

Objective Evidence

Proficiency testing records Quality Assurance Manual 11: Proficiency Testing
Proficiency testing records

7.7.8 ANAB Accreditation Requirement — Conforming

Requirement

Were the following records maintained for all intralaboratory comparisons, interlaboratory comparisons, proficiency tests and observation-based monitoring:
a) discipline(s) monitored?
b) design of the monitoring activity?
c) expected results?
d) location, when more than one location is associated with a single accreditation certificate?
e) records submitted to a proficiency test provider, when applicable?
f) evaluation of results and action taken for unexpected results? and
g) feedback on individual performance provided to the participant?

Objective Evidence

Quality Assurance Manual 11: Proficiency Testing
Proficiency testing records

7.8.1 General

7.8.1.1 ISO/IEC 17025:2017 — Conforming

Requirement

Are results reviewed and authorized prior to release?

Objective Evidence

Quality Assurance Manual 12.4.2.2: Analyst Review of Test Report and Case File
Technical Records

7.8.1.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Did the authorizer of results review the technical record and document the review?

Objective Evidence

Quality Assurance Manual 12.4.2.2: Analyst Review of Test Report and Case File
Technical Records

7.8.1.2 ISO/IEC 17025:2017 — Conforming

Requirement

Are results provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or

report of sampling), and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used? Are all issued reports retained as technical records?

NOTE 1 For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.

NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

Objective Evidence

Quality Assurance Manual 12.6: Toxicology Test Reports
Quality Assurance Manual 12.3.2: Technical Records
Technical Records
Test Reports

7.8.1.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Are the results provided in a written report or through electronic access?

Objective Evidence

Quality Assurance Manual 12.6: Toxicology Test Reports
Test Reports

7.8.1.2.2 ANAB Accreditation Requirement — Conforming

Requirement

Is there a procedure for reporting of results that:
a) identifies what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for all (partial and complete) work performed?
b) requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement?
c) requires communicating the reason(s) in the report when the reported results are inconclusive? and
d) requires reporting of the initial database entry (e.g., DNA profiles, friction ridge, ballistics, biometrics)?

NOTE 1 a) The reporting of results does not include work performed for the purpose of constructing an individual characteristic database or maintaining the quality and/or effectiveness of information in such a database.

NOTE 2 b) Associations for multiple results may be qualified by a single statistic or qualitative statement if the statistics are identical or, where applicable, meet or exceed a defined minimum threshold.

Objective Evidence

The laboratory does not perform associations (b) or perform database entries (d).

Quality Assurance Manual 12.6: Toxicology Test Reports
Technical Records
Test Reports

7.8.1.2.3 ANAB Accreditation Requirement — Not Applicable

Requirement

Does the documented process for reporting of results of calibration:
a) identify what information will be reported in the calibration certificate? and
b) require the issuance of an endorsed calibration certificate if requested by the customer?

Objective Evidence

The laboratory does not perform calibrations.

7.8.1.3 ISO/IEC 17025:2017 — Resolved Nonconformity

Requirement

When agreed with the customer, the results may be reported in a simplified way. Is any information listed in 7.8.2 to 7.8.7 that is not reported to the customer readily available?

Objective Evidence

Quality Assurance Manual 12.6: Toxicology Test Reports
Technical Records
Laboratory Reports
Review of agency website

Nonconformity Resolution Workflow (ANAB Use)

For classes of drugs which test positive with EMIT but for which a drug is not confirmed by a second test, the laboratory reports the negative confirmation but the report does not include the performance or positive results of the EMIT test for that class of drugs. The laboratory does not have agreements with customers to report in this simplified way.

Completion note: The laboratory established agreements with customers to report results in a simplified way through their website. The laboratory sent notifications to their customers directing them to review the revised information. This nonconformity is resolved.

7.8.1.3.1 ANAB Accreditation Requirement — Conforming

Requirement

When results are reported in a simplified way, does the agreement specify which information in 7.8.2 to 7.8.7 will not be included a written report or through electronic access?

Objective Evidence

Quality Assurance Manual 12.6: Toxicology Test Reports
Presentation records
Review of agency website
Interviews

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does each report include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:
a) a title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”)?
b) the name and address of the laboratory?
c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities?
d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end?
e) the name and contact information of the customer?
f) identification of the method used?
g) a description, unambiguous identification, and, when necessary, the condition of the item?
h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results?
i) the date(s) of performance of the laboratory activity?
j) the date of issue of the report?
k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results?
l) a statement to the effect that the results relate only to the items tested, calibrated or sampled?
m) the results with, where appropriate, the units of measurement?
n) additions to, deviations, or exclusions from the method?
o) identification of the person(s) authorizing the report?
p) clear identification when results are from external providers?

NOTE Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.

ANAB NOTE 2 A legal requirement that dictates the information to be included in a report is a valid reason to not include one or more listed report elements.

ANAB NOTE 3 i) Date(s) may be reflected as a range of dates or the date of each test or calibration.

ANAB NOTE 4 o) Authorization of the report does not have to be performed by the same person(s) who authorized the results. (see ISO/IEC 17025:2017 7.8.1.1).

Objective Evidence

Quality Assurance Manual 12.6: Toxicology Test Reports
Technical Records
Test Reports

7.8.2.2 ISO/IEC 17025:2017 — Conforming

Requirement

Is the laboratory responsible for all the information provided in the report, except when information is provided by the customer? Is data provided by a customer clearly identified? In addition, is a disclaimer put on the report when the information is supplied by the customer and can affect the validity of results? Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), is it stated in the report that the results apply to the sample as received?

Objective Evidence

Quality Assurance Manual 12.6.2: Toxicology Test Reports

7.8.3 Specific requirements for test reports

7.8.3.1 ISO/IEC 17025:2017 — Conforming

Requirement

In addition to the requirements listed in 7.8.2, do the test reports, where necessary for the interpretation of the test results, include the following:
a) information on specific test conditions, such as environmental conditions?
b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6)?
c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:
- it is relevant to the validity or application of the test results?
- a customer's instruction so requires? or
- the measurement uncertainty affects conformity to a specification limit?
d) where appropriate, opinions and interpretations (see 7.8.7)?
e) additional information that may be required by specific methods, authorities, customers or groups of customers?

Objective Evidence

Quality Assurance Manual 10.10.3: Reporting (Uncertainty of Measurement)
Test Reports

7.8.3.1.c).1 ANAB Accreditation Requirement — Conforming

Requirement

Was/Did the measurement uncertainty:
a) included in the report or an annex to the report when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement?
b) include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability?
c) in the format of y ± U?
d) limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits? and
e) reported to the same level of significance as the measurement result?

ANAB NOTE 1 a) A legal requirement is created, imposed, and enforced by a third-party external to the laboratory agency.

ANAB NOTE 2 c) For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentations other than y ± U may be needed.

ANAB NOTE 3 e) Reducing or simplifying a fraction is not a change in level of significance.

Objective Evidence

Quality Assurance Manual 10.10.3: Reporting (Uncertainty of Measurement)
P46-1: Policy on Reporting of Blood Alcohol Results (P46-1)
TCc12727: Confirmation of Cannabinoids by Liquid Chromatography - Tandem Mass Spectrometry
PQ12706: Estimation and Reporting of Measurement Uncertainty
Test Reports

7.8.3.1.1 ANAB Accreditation Requirement — Not Applicable

Requirement

If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a result or prohibits including measurement uncertainty in the report, did the forensic service provider:
a) have objective evidence of the regulation, statute, case law or other legal requirement? and
b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result?

Objective Evidence

No legal requirement exists regarding measurement uncertainty.

7.8.3.2 ISO/IEC 17025:2017 — Not Applicable

Requirement

Where the laboratory is responsible for the sampling activity, do test reports meet the requirements listed in 7.8.5 where necessary for the interpretation of test results?

Objective Evidence

The laboratory does not perform sampling.

7.8.4 Specific requirements for calibration certificates

7.8.4.1 ISO/IEC 17025:2017 — Not Applicable

Requirement

In addition to the requirements listed in 7.8.2, do calibration certificates shall include the following:
a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent)?

NOTE According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.

b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results?
c) a statement identifying how the measurements are metrologically traceable (see Annex A)?
d) the results before and after any adjustment or repair, if available?
e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6)?
f) where appropriate, opinions and interpretations (see 7.8.7)?

Objective Evidence

The laboratory does not perform calibrations.

7.8.4.1.a).1 ANAB Accreditation Requirement — Not Applicable

Requirement

Did/Was the measurement uncertainty:
a) include the measured quantity value, y, along with the associated expanded uncertainty, U, the coverage factor, and the coverage probability?
b) in the format of y ± U?
c) limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits? and
d) reported to the same level of significance as the measurement result?

ANAB NOTE c) For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentations other than y ± U may be needed.

Objective Evidence

The laboratory does not perform calibrations.

7.8.4.1.1 ANAB Accreditation Requirement — Not Applicable

Requirement

If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a calibration result or prohibits including measurement uncertainty in the calibration certificate, did the forensic service provider:
a) have objective evidence of the regulation, statute, case law or other legal requirement? and
b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the calibration result?

Objective Evidence

The laboratory does not perform calibrations.

7.8.4.2 ISO/IEC 17025:2017 — Not Applicable

Requirement

Where the laboratory is responsible for the sampling activity, do calibration certificates meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results?

Objective Evidence

The laboratory does not perform calibrations.

7.8.4.3 ISO/IEC 17025:2017 — Not Applicable

Requirement

Does a calibration certificate or calibration label not contain any recommendation on the calibration interval, except where this has been agreed with the customer?

Objective Evidence

The laboratory does not perform calibrations.

7.8.4.4 ANAB Accreditation Requirement — Not Applicable

Requirement

If applicable, does a label (in addition to the calibration certificate) attached to a calibrated item not give the impression that the item itself is approved and include:
a) the name of the accredited calibration laboratory or its accreditation certificate number?
b) the unambiguous identification of the item calibrated?
c) the date of the current calibration? and
d) cross reference to the calibration certificate issued in respect to the calibration?

Objective Evidence

The laboratory does not perform calibrations.

7.8.5 Reporting sampling - specific requirements

7.8.5 ISO/IEC 17025:2017 — Not Applicable

Requirement

Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, do reports include the following, where necessary for the interpretation of results:
a) the date of sampling?
b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate)?
c) the location of sampling, including any diagrams, sketches or photographs?
d) a reference to the sampling plan and sampling method?
e) details of any environmental conditions during sampling that affect the interpretation of the results?
f) information required to evaluate measurement uncertainty for subsequent testing or calibration?

Objective Evidence

The laboratory does not perform sampling.

7.8.5.d).1 ANAB Accreditation Requirement — Not Applicable

Requirement

d).1 If a sampling plan is used, does the report contain information about the sampling plan, including confidence levels and corresponding inference(s) regarding the population?

Objective Evidence

The laboratory does not perform sampling.

7.8.6 Reporting statements of conformity

7.8.6.1 ISO/IEC 17025:2017 — Not Applicable

Requirement

When a statement of conformity to a specification or standard is provided, does the laboratory document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule?

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

Objective Evidence

The laboratory does not provide statements of conformity.

7.8.6.2 ISO/IEC 17025:2017 — Not Applicable

Requirement

Does the laboratory report on the statement of conformity, such that the statement clearly identifies:
a) to which results the statement of conformity applies?
b) which specifications, standards or parts thereof are met or not met?
c) the decision rule applied (unless it is inherent in the requested specification or standard)?

NOTE For further information, see ISO/IEC Guide 98-4.

Objective Evidence

The laboratory does not provide statements of conformity.

7.8.7 Reporting opinions and interpretations

7.8.7.1 ISO/IEC 17025:2017 — Conforming

Requirement

When opinions and interpretations are expressed, does the laboratory ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement? Does the laboratory document the basis upon which the opinions and interpretations have been made?

NOTE It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.

Objective Evidence

Quality Assurance Manual 5.5: Competency Testing and Authorizations
Communication records

7.8.7.2 ISO/IEC 17025:2017 — Not Applicable

Requirement

Are the opinions and interpretations expressed in reports based on the results obtained from the tested or calibrated item and clearly identified as such?

Objective Evidence

The laboratory does not include opinions or interpretations in the Test Reports.

7.8.7.3 ISO/IEC 17025:2017 — Conforming

Requirement

When opinions and interpretations are directly communicated by dialogue with the customer, is a record of the dialogue retained?

Objective Evidence

Quality Assurance Manual 12: Records, Reviews, and Reports
Communication records

7.8.8 Amendments to reports

7.8.8.1 ISO/IEC 17025:2017 — Conforming

Requirement

When an issued report needs to be changed, amended or re-issued, is any change of information clearly identified and, where appropriate, is the reason for the change included in the report?

Objective Evidence

Quality Assurance Manual 12.8: Amended Test Reports
Test Reports

7.8.8.2 ISO/IEC 17025:2017 — Conforming

Requirement

Are amendments to a report after issue made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number... [or as otherwise identified)", or an equivalent form of wording?

Do such amendments meet all the requirements of this document?

Objective Evidence

Quality Assurance Manual 12.8.1: Amended Test Reports
Test Reports

7.8.8.3 ISO/IEC 17025:2017 — Conforming

Requirement

When it is necessary to issue a complete new report, is this uniquely identified and contain a reference to the original that it replaces?

Objective Evidence

Quality Assurance Manual 12.8: Amended Test Reports
Test Reports

7.9 Complaints

7.9.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have a documented process to receive, evaluate and make decisions on complaints?

Objective Evidence

Operations Manual 1.10: Complaints
WSP Regulations Manual Chapter 12: Complaint and Disciplinary Procedures
WSP Administrative Investigation Manual Chapter 1: Administrative Investigations

7.9.2 ISO/IEC 17025:2017 — Conforming

Requirement

Is a description of the handling process for complaints available to any interested party on request? Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, deal with it? Is the laboratory responsible for all decisions at all levels of the handling process for complaints?

Objective Evidence

Operations Manual 1.10: Complaints
Complaint records
Interviews

7.9.3 ISO/IEC 17025:2017 — Conforming

Requirement

Does the process for handling complaints include at least the following elements and methods:
a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it?
b) tracking and recording complaints, including actions undertaken to resolve them?
c) ensuring that any appropriate action is taken?

Objective Evidence

Operations Manual 1.10: Complaints
Complaint records

7.9.4 ISO/IEC 17025:2017 — Conforming

Requirement

Is the laboratory receiving the complaint responsible for gathering and verifying all necessary information to validate the complaint?

Objective Evidence

Operations Manual 1.10: Complaints
Complaint records

7.9.5 ISO/IEC 17025:2017 — Conforming

Requirement

Whenever possible, does the laboratory acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome?

Objective Evidence

Operations Manual 1.10: Complaints
Complaint records

7.9.6 ISO/IEC 17025:2017 — Conforming

Requirement

Are the outcomes communicated to the complainant made by, or reviewed and approved by, individuals not involved in the original laboratory activities in question?

NOTE This can be performed by external personnel.

Objective Evidence

Operations Manual 1.10: Complaints
Complaint records

7.9.7 ISO/IEC 17025:2017 — Conforming

Requirement

Whenever possible, does the laboratory give formal notice of the end of the complaint handling to the complainant?

Objective Evidence

Operations Manual 1.10: Complaints
Complaint records

7.10 Nonconforming work

7.10.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have a procedure that is implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria)? Does the procedure ensure that:
a) the responsibilities and authorities for the management of nonconforming work are defined?
b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory?
c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results?
d) a decision is taken on the acceptability of the nonconforming work?
e) where necessary, the customer is notified and work is recalled?
f) the responsibility for authorizing the resumption of work is defined?

Objective Evidence

Quality Assurance Manual 4: Control of Nonconforming Work
Corrective action records

7.10.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f)?

Objective Evidence

Quality Assurance Manual 4.3.1.2: Evaluation of Significance
Nonconforming work records

7.10.3 ISO/IEC 17025:2017 — Conforming

Requirement

Where 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, does the laboratory implement corrective action?

Objective Evidence

Quality Assurance Manual 4: Control of Nonconforming Work
Corrective action records

7.11 Control of data and information management

7.11.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory have access to the data and information needed to perform laboratory activities?

Objective Evidence

Management System documents
Onsite observations

7.11.2 ISO/IEC 17025:2017 — Conforming

Requirement

Is the laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction? Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, are they authorized, documented and validated before implementation?

NOTE 1 In this document “laboratory information management system(s)” includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.

NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

Objective Evidence

LIMS records
Interviews

7.11.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Was there a plan for validation of computer software developed by the user and were records of the validation maintained?

Objective Evidence

Software validation records

7.11.3 ISO/IEC 17025:2017 — Conforming

Requirement

Is the laboratory information management system(s):
a) protected from unauthorized access?
b) safeguarded against tampering and loss?
c) operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription?
d) maintained in a manner that ensures the integrity of the data and information?
e) include recording system failures and the appropriate immediate and corrective actions?

Objective Evidence

Quality Assurance Manual 13.4: Electronic Data and Computer Software
Interviews
LIMS records

7.11.4 ISO/IEC 17025:2017 — Not Applicable

Requirement

When a laboratory information management system is managed and maintained off-site or through an external provider, does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of this document?

Objective Evidence

The laboratory information management system is not managed off-site.

7.11.5 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel?

Objective Evidence

LIMS Manual

7.11.6 ISO/IEC 17025:2017 — Conforming

Requirement

Are calculations and data transfers checked in an appropriate and systematic manner?

ANAB NOTE This requirement does not apply if the calculation or data transfer is secure and not subject to human error.

Objective Evidence

Quality Assurance Manual 13.4: Electronic Data and Computer Software
Technical records

7.11.6.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the technical record indicate the check was performed and who performed the check? When possible, is this check not conducted by the person who performed the calculation(s) or the data transfers?

NOTE This check may be part of a technical review.

Objective Evidence

Quality Assurance Manual 13.4: Electronic Data and Computer Software
Technical records

8.1.1 General

8.1.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results? In addition to meeting the requirements of Clauses 4 to 7, does the laboratory implement a management system in accordance with Option A or Option B?

NOTE See Annex B for more information.

Objective Evidence

Quality Assurance Manual 1.4: Quality Assurance Program
Management System documents

The laboratory implements a management system in accordance with Option A.

8.1.2 ISO/IEC 17025:2017 — Conforming

Requirement

Option A
As a minimum, does the management system of the laboratory address the following:
- management system documentation (see 8.2)?
- control of management system documents (see 8.3)?
- control of records (see 8.4)?
- actions to address risks and opportunities (see 8.5)?
- improvement (see 8.6)?
- corrective actions (see 8.7)?
- internal audits (see 8.8)?
- management reviews (see 8.9)?

Objective Evidence

Operations Manual
Quality Assurance Manual

8.1.3 ISO/IEC 17025:2017 — Not Applicable

Requirement

Option B
Does a laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfil at least the intent of the requirements in 8.2 to 8.9?

Objective Evidence

Laboratory conforms to Option A.

8.1.3.1 ANAB Accreditation Requirement — Not Applicable

Requirement

In order for Option B to be available to a forensic service provider, the provider must maintain an accredited ISO 9001 certification. Was the certification body, which certified the provider to ISO 9001, accredited for ISO 9001 by an IAF MLA signatory accreditation body for management systems? Did any forensic service provider that does not meet this criteria choose Option A?

Objective Evidence

Laboratory conforms to Option A.

8.1.3.2 ANAB Accreditation Requirement — Not Applicable

Requirement

Have the Option A requirements under 8.2 through 8.9 in this document are also applied to forensic service providers who choose Option B?

Objective Evidence

Laboratory conforms to Option A.

8.2 Management system documentation (Option A)

8.2.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory management establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization?

Objective Evidence

Management System documents

8.2.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Has the laboratory required the following words (to include forms of the same word) used in ISO/IEC 17025:2017 or in this document to be addressed in writing?
agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify

Objective Evidence

Quality Assurance Manual 1.1: Quality Management System Policy Management System documents

8.2.2 ISO/IEC 17025:2017 — Conforming

Requirement

Do the policies and objectives address the competence, impartiality and consistent operation of the laboratory?

Objective Evidence

Management System documents

8.2.3 ISO/IEC 17025:2017 — Conforming

Requirement

Does laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?

Objective Evidence

Quality Assurance Manual 1.3: Quality Policy Statement
Quality Assurance Manual 1.4: Quality Assurance Program
Meeting minutes
Internal audit records

Management review records

8.2.4 ISO/IEC 17025:2017 — Conforming

Requirement

Are all documentation, processes, systems, records, related to the fulfilment of the requirements of this document included in, referenced from, or linked to the management system?

Objective Evidence

Quality Assurance Manual 1.4: Quality Assurance Program;
Quality Assurance Manual 2: Document Control
SharePoint portal
Onsite observations

8.2.5 ISO/IEC 17025:2017 — Conforming

Requirement

Do all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities?

Objective Evidence

Quality Assurance Manual 2.3.7 Official Controlled Documents
Onsite observations

8.3 Control of management system documents (Option A)

8.3.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory control the documents (internal and external) that relate to the fulfilment of this document?

NOTE In this context, “documents” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

Objective Evidence

Quality Assurance Manual 2: Document Control
Controlled document listing

8.3.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory ensure that:
a) documents are approved for adequacy prior to issue by authorized personnel?
b) documents are periodically reviewed, and updated as necessary?
c) changes and the current revision status of documents are identified?
d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled?
e) documents are uniquely identified?
f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose?

Objective Evidence

Quality Assurance Manual 2 Document Control
Management System documents
Onsite observations

8.4 Control of records (Option A)

8.4.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory establish and retain legible records to demonstrate fulfilment of the requirements in this document?

Objective Evidence

Operations Manual 3: Records Management
Quality Assurance Manual 12.3: Testing Documentation

Onsite observations

8.4.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records? Does the laboratory retain records for a period consistent with its contractual obligations? Is access to these records consistent with the confidentiality commitments, and records readily available?

NOTE Additional requirements regarding technical records are given in 7.5.

ANAB NOTE 2 Contractual obligations for records retention include legal requirements and customer expectations.

Objective Evidence

Operations Manual 3: Records Management
Quality Assurance Manual 1.5: Quality System Records
Quality Assurance Manual 12.3: Testing Documentation
WSP Regulation Manual 6.01.010 Records Retention (Page 106)
Onsite observations

8.5 Actions to address risks and opportunities (Option A)

8.5.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory consider the risks and opportunities associated with the laboratory activities in order to:
a) give assurance that the management system achieves its intended results?
b) enhance opportunities to achieve the purpose and objectives of the laboratory?
c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities?
d) achieve improvement?

Objective Evidence

Quality Assurance Manual 3.3.4.3 Procedure (Management System Review)
2019 Management Review records

8.5.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Have risks and opportunities related to health and safety been considered?

Objective Evidence

Quality Assurance Manual 3.3.4.3 Procedure (Management System Review)
Operations Manual 2.2: Safety
TLD Safety Plan

8.5.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory plan:
a) actions to address these risks and opportunities?
b) how to:
- integrate and implement these actions into its management system?
- evaluate the effectiveness of these actions?

NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.

Objective Evidence

Quality Assurance Manual 3.3.4.3 Procedure (Management System Review)
2019 Management Review records

8.5.3 ISO/IEC 17025:2017 — Conforming

Requirement

Are actions taken to address risks and opportunities proportional to the potential impact on the validity of laboratory results?

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the

risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

Objective Evidence

Quality Assurance Manual 3.3.4.3 Procedure (Management System Review)

8.6 Improvement (Option A)

8.6.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory identify and select opportunities for improvement and implement any necessary actions?

NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

Objective Evidence

Quality Assurance Manual 3.3.4: Management System Review
Quality Assurance Manual 4.4: Preventive Actions;
Quality Assurance Manual 5.6: Job Performance;
Quality Assurance Manual 5.7: Professional Development Program
Management Review records
Preventive action / improvement records

8.6.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory seek feedback, both positive and negative, from its customers? Is the feedback analyzed and used to improve the management system, laboratory activities and customer service?

NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

Objective Evidence

Operations Manual 1.9.3: Service to the Customer/Feedback
Customer feedback records (email communications, correspondence logs, surveys)
Management Review records

8.7 Corrective actions (Option A)

8.7.1 ISO/IEC 17025:2017 — Conforming

Requirement

When a nonconformity occurs, does the laboratory:
a) react to the nonconformity and, as applicable:
- take action to control and correct it?
- address the consequences?
b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
- reviewing and analysing the nonconformity?
- determining the causes of the nonconformity?
- determining if similar nonconformities exist, or could potentially occur?
c) implement any action needed?
d) review the effectiveness of any corrective action taken?
e) update risks and opportunities determined during planning, if necessary?
f) make changes to the management system, if necessary?

Objective Evidence

Quality Assurance Manual 4.3.2: Corrective Action Process
Corrective action records

8.7.1.g) ANAB Accreditation Requirement — Conforming

Requirement

g) Does the process for corrective action establish a reasonable timeframe for completion for each corrective action?

Objective Evidence

Quality Assurance Manual 4.3.2.2.1: Corrective Action Process
Quality Assurance Manual 4.3.2.7.2: Evaluation of Implemented Corrective Actions
Corrective action records

8.7.2 ISO/IEC 17025:2017 — Conforming

Requirement

Are corrective actions appropriate to the effects of the nonconformities encountered?

Objective Evidence

Quality Assurance Manual 4.3.2: Corrective Action Process
Corrective action records

8.7.3 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory retain records as evidence of:
a) the nature of the nonconformities, cause(s) and any subsequent actions taken?
b) the results of any corrective action?

Objective Evidence

Quality Assurance Manual 4.3.2.5: Corrective Action Report (CAR)
Corrective action records

8.8 Internal audits (Option A)

8.8.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory conduct internal audits at planned intervals to provide information on whether the management system:
a) conforms to:
- the laboratory's own requirements for its management system, including the laboratory activities?
- the requirements of this document?
b) is effectively implemented and maintained?

Objective Evidence

Quality Assurance Manual 3: Internal Audits and Management Reviews
Internal audit records

8.8.1.a).1 ANAB Accreditation Requirement — Conforming

Requirement

a).1 Do internal audits provide information on whether the management system conforms to the requirements of this document?

Objective Evidence

Quality Assurance Manual 3: Internal Audits and Management Reviews
Internal audit records

8.8.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Are internal audits conducted at least annually, as well as prior to the initial accreditation assessment?

Objective Evidence

Quality Assurance Manual 3: Internal Audits and Management Reviews
Internal audit records

8.8.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory:
a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements

and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits?
b) define the audit criteria and scope for each audit?
c) ensure that the results of the audits are reported to relevant management?
d) implement appropriate correction and corrective actions without undue delay?
e) retain records as evidence of the implementation of the audit programme and the audit results?

NOTE ISO 19011 provides guidance for internal audits.

Objective Evidence

Quality Assurance Manual 3: Internal Audits and Management Reviews
Internal audit records

8.8.2.b).1 ANAB Accreditation Requirement — Conforming

Requirement

b).1 Do internal audits include direct observation of a sample of accredited services within each discipline?

Objective Evidence

Quality Assurance Manual 3: Internal Audits and Management Reviews
Internal audit records

8.9 Management reviews (Option A)

8.9.1 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory management review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document?

Objective Evidence

Quality Assurance Manual 3: Internal Audits and Management System Reviews
Management Review records

8.9.1.1.ANAB Accreditation Requirement — Conforming

Requirement

Are management reviews conducted at least annually, as well as prior to the initial accreditation assessment?

Objective Evidence

Quality Assurance Manual 3: Internal Audits and Management System Reviews
Management Review records

8.9.2 ISO/IEC 17025:2017 — Conforming

Requirement

Are the inputs to management review recorded and 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?
n) outcomes of the assurance of the validity of results?
o) other relevant factors, such as monitoring activities and training?

Objective Evidence

Quality Assurance Manual 3: Internal Audits and Management System Reviews
Management Review records

8.9.3 ISO/IEC 17025:2017 — Conforming

Requirement

Do the outputs from the management review 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?

Objective Evidence

Quality Assurance Manual 3: Internal Audits and Management System Reviews
Management Review records

Washington State Patrol - Toxicology Laboratory Division

2019 - ABFT Checklist

Prepared by Matt Stillwell

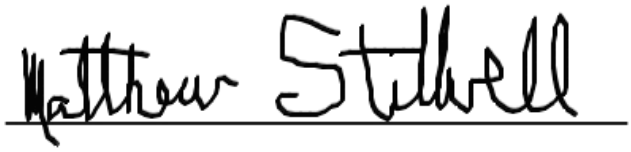
Data collected on 2019-10-08

ANSI National Accreditation Board

United States

Signature

Completed by Matt Stillwell on 2019-12-20



Audit Objective Evidence

Program Document

Proficiency Testing — Conforming

Requirement

Does the laboratory participate in the College of American Pathologists (CAP) proficiency test series AL1, T-series and FTC?

NOTE: Regarding the CAP T-series, laboratories are expected to complete all qualitative challenges, plus those quantitative tests that the lab offers and would ordinarily perform within the reported period for the T-series shipment.

Objective Evidence

CAP FTC-A 2018, FTC-B 2018
T-A, T-B and T-C 2018
CAP FTC-A 2019, T-A 2019

Section A: MANAGEMENT AND ADMINISTRATION

A-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a written statement of its mission or objectives?

NOTE The laboratory must have a brief statement in the SOP manual, outlining their primary activities. For example, this may be to provide a medical examiner or coroner system with comprehensive toxicology services that will assist in determining the cause and manner of death. Some laboratories may also provide support services for law enforcement agencies by providing analyses for alcohol or other drugs in biological fluids seized from motor vehicle drivers, other transportation operators, or from victims of drug facilitated sexual assault.

Objective Evidence

TLD Operations Manual 1.1 Mission Statement - pg. 5
TLD Operations Manual 1.2 Goals and Objectives - pg. 5
TLD Operations Manual 1.5 Services and Functions - pg. 5

A-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does laboratory staff have reasonable access to the forensic, medical and other scientific literature?

NOTE Toxicology staff must have reasonable access to the current forensic literature. Commonly used texts must be available within the laboratory. This should include a compendium of analytical data for common drugs, basic pharmacology and toxicology texts and a compendium of prescription drug monographs. Examples might include Disposition of Toxic Drugs and Chemicals in Man (Baselt), Clarke's Analysis of Drugs and Poisons, The Pharmacological Basis of Therapeutics (Goodman & Gilman), Clinical Toxicology of Commercial Products, and the Physicians' Desk Reference (PDR). Staff must have reasonable access to the common forensic and analytical toxicology journals through subscription, university affiliation or electronic means. That access may be direct, through an institutional or university library, or could be via a colleague.

Objective Evidence

Quality Assurance Manual - 5.7.3 Laboratory Library

Observed first floor library

A-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a procedure to communicate to staff changes to methods or procedures?

NOTE It is important that there is effective and regular documented communication between the laboratory director and all other laboratory staff. In some laboratories this may be accomplished by holding regular (e.g., weekly, monthly) meetings. However, this may be difficult to arrange in busy laboratories, especially where more than one shift is in operation, or where staff are frequently away at court. Alternate acceptable means are via personal or posted memorandum.

Objective Evidence

Testing Quality Assurance Manual 2.3.4 Approval/Issue of Controlled Documents;
Testing Quality Assurance Manual 2.4.8 Approved/Adopted (document revisions)

Email notifications of revised/new approved documents
Official documents posted on portal (SharePoint)

A-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is an organizational chart of the laboratory included in the SOP manual delineating reporting responsibility with regard to QA/QC issues?

NOTE It is important for the laboratory to have an organizational chart or other means to clearly define the reporting structure of the laboratory, including to whom QA/QC staff is responsible.

Objective Evidence

Quality Assurance Manual 1.4.1 Laboratory Quality Management

A-5 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a written policy that addresses the confidentiality of client information and results?

NOTE A written policy must exist which addresses the confidentiality of laboratory data. This must include both the storage and release of information to third parties. While releasing results by telephone is not necessarily forbidden, reasonable precautions must be taken to prevent release by and to unauthorized persons. The exact precautions taken will depend on the jurisdiction and, for example, how well staff knows the police or other requesting agencies. Guidelines must also be given as to the extent of interpretation which may be given with the results and who is authorized to give that interpretation.

Objective Evidence

Operations Manual 1.9.1 Policy (Communications)
Quality Assurance Manual 12.6.9.3 (Release of Test Reports)

A-6 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is there a procedure that addresses the resolution of complaints against the laboratory?

NOTE From time to time, complaints may be received against a laboratory, covering everything from slow turnaround times, questioned accuracy or inability to conduct certain tests. A policy must be in place that requires an appropriate, documented response to all complaints received in writing. When necessary, corrective action must be taken and documented.

Objective Evidence

TLD Operations Manual 1.10 Complaints
Customer feedback (surveys, email)
Complaint records

A-7 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is there a procedure for notifying clients of analytical and other deficiencies that have affected the forensic reliability of reported results?

NOTE Occasionally, errors or deficiencies may be uncovered that may have affected the reliability of toxicology results that have been reported. A written procedure must be in place that addresses this issue and causes clients to be notified when such errors or deficiencies are judged to be forensically significant. If the error or deficiency uncovered is sufficiently serious for the client to be notified, ABFT must be notified at the same time.

Objective Evidence

TLD Quality Assurance Manual 4.3.1.2.2,
TLD Quality Assurance Manual 4.3.1.3 Evaluation of Significance (Nonconforming Work)
TLD Quality Assurance Manual 4.3.2.4 Notification of Clients.

Section B: PERSONNEL

B-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a Director with the required experience and qualifications?

NOTE The forensic toxicology laboratory shall be directed by a person who has the appropriate education and experience to assume the required professional, organizational, educational and administrative responsibilities. The director's experience and qualifications must to be comparable to those certified in “forensic toxicology” by the American Board of Forensic Toxicology.

The director must be qualified as a forensic toxicologist to direct the laboratory, but does not necessarily have the experience to interpret all results generated by that laboratory, providing that the laboratory also employs or contracts other people with the required expertise. For example, a laboratory director may be very experienced in the field of impaired driving by drugs, but have limited experience in postmortem toxicology. That is generally acceptable, providing that the laboratory also has another toxicologist with adequate experience in postmortem toxicology.

Examples of alternative acceptable qualifications:
- Doctoral degree in a chemical or biological discipline and at least three years of full-time laboratory experience in forensic toxicology
- Master's degree in a chemical or biological discipline and at least five years of full-time laboratory experience in forensic toxicology
- Bachelor's degree in a chemical or biological discipline and at least seven years of full-time laboratory experience in forensic toxicology.

Objective Evidence

Dr. Fiona Couper is the WSP TLD Laboratory Director is TLD Commander/State Toxicologist and she meets the criteria specified above.

B-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have one or more forensic toxicologists with sufficient experience and qualifications to interpret, as necessary, the results generated by the laboratory?

NOTE It is acknowledged that a perfectly competent and experienced laboratory director may not have the time or specific experience required to interpret all forensic toxicology results. However, the laboratory must employ or contract sufficient qualified forensic toxicologists with the required experience to assist clients with interpretation of the results generated by the laboratory.

Objective Evidence

TLD Operations Manual 4.3 Interpretation of Results - Only Forensic Scientists and TLD Management shall provide interpretation of results and laboratory data.

B-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is a record of the director's education and experience maintained?

NOTE Examples of acceptable supporting documentation of director's experience and qualifications include: an up-to-date curriculum vitae; up-to-date list of professional publications and presentations; job description listing duties and responsibilities; copies of diplomas, certificates and licenses; court testimony; research; participation in continuing education programs.

Objective Evidence

Records of Dr. Couper education and experience are maintained by the Laboratory, and can be reviewed on-site.

B-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is the director responsible for:
a) daily management of the laboratory?
b) preparation and revision of the standard operating procedure manual?
c) establishing procedures for validating new assays?
d) maintaining a quality assurance program?
e) training laboratory staff?

NOTE The director has to be familiar with all aspects of the laboratory's operations. The director must be responsible for the management of the laboratory, and for the development of a complete, up-to-date procedure manual that is available to, and followed by, all personnel performing toxicological testing. The director must establish a procedure for validating new drug assays and will also be responsible for maintaining a quality assurance program to ensure the proper performance and reporting of all test results. The director must be responsible for (1) ensuring that the laboratory personnel are adequately trained and experienced to conduct the work of the laboratory and (2) maintaining the competency of laboratory personnel by monitoring their work performance and verifying their skills. Authority can be delegated commensurate with assigned responsibilities.

Objective Evidence

TLD Operations Manual - 1.7 Chain of Command/Personnel Responsibilities - Outlined in 1.7.1 through 1.7.11

B-5 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have qualified personnel who can substitute for the director in his/her absence, or an alternate contingency plan in the event of an extended absence of the laboratory director?

NOTE The range and type of duties of laboratory personnel will vary according to the size and the scope of the laboratory. It is important that

laboratories have a person or persons who has (or together have) sufficient training and experience to substitute for the director in case of his or her absence.

Objective Evidence

TLD Operations Manual 1.7.12 Temporary Designation of Responsibility/Authority (Chain of Command/Personnel Responsibilities)

B-6 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are laboratory personnel trained appropriately?

NOTE Training and development of personnel is essential in order to increase productivity, improve performance and enable them to assume greater responsibilities. A training program to develop technical skills of an employee is important in each area of expertise. Personnel have to be familiar with all areas of toxicologic testing within their responsibility and understand how their responsibilities relate to the operation of the laboratory as a whole. Training must include, but not be limited to, theory and practice of methods and procedures that the individual performs, understanding quality control practices and procedures, maintenance of chain of custody, laboratory safety, etc. The director is responsible for providing adequate training of personnel and for maintaining the competency of laboratory personnel by monitoring their work performance and verifying their skills. Records must be maintained to support the current qualifications, experience and training of all personnel. These records may either be maintained in an individual's personnel file or in separate training files. Analysts must have demonstrated competency for the work for which they are approved to perform.

Objective Evidence

Quality Assurance Manual 5.4 Training; 5.5 Competency Testing and Authorizations

B-7 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is personnel experience and training documented and current?

Does documentation, as appropriate, include:
- Training checklists/summaries (mandatory for technical staff)
- Resume
- Job description
- Copies of certificates
- Copies of diplomas
- Copies of licenses
- Testimony experience
- Other

NOTE It is the responsibility of the employer to verify the authenticity of academic or other required qualifications.

Objective Evidence

TLD Quality Assurance Manual 5.3 Qualifications of Personnel
TLD Quality Assurance Manual 5.4 Training
TLD Quality Assurance Manual 5.5 Competency Testing and Authorizations

B-8 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

For the laboratory personnel that testify, is their experience and training commensurate with the testimony

NOTE Many laboratory personnel rarely, if ever testify. When they do, it is frequently only to give factual testimony regarding the handling of evidence and performance of tests. Training for testimony may be limited, and given between receipt of the subpoena and the date the testimony is expected. However, the testimony of more senior toxicology personnel, especially those expected to give opinion evidence will need more extensive training. Formal training for more senior and experienced staff may be minimal, although experience must be documented as part of their curriculum vitae or training file.

Objective Evidence

Operations Manual Chapter 5 Courtroom Testimony
Quality Assurance Manual 5.7.4 Courtroom Testimony Training

B-9 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory maintain a record of occasions when staff testify?

NOTE For staff that testify, a record of the date of testimony and case caption must be maintained as part of their general training record and professional experience.

Objective Evidence

B-10 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have sufficient technical personnel to handle the workload?

NOTE There must be sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory. The Accreditation Committee and Board will carefully evaluate negative response to this question. A negative response to this question will generally only result in punitive action if it is clear that the laboratory does not have the necessary personnel to fulfill their mandate. Long turnaround times alone will not normally be sufficient to result in failure to award accreditation or suspension of accreditation. Under-staffing sufficient to warrant withholding accreditation or to cause suspension of accreditation will normally also result in a failure to meet other critical standards of the ABFT Accreditation Program.

Objective Evidence

Organizational Chart - August 2019

B-11 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a written policy for the continuing education of technical personnel?

NOTE Management of the laboratory must recognize the importance of the continued training of the technical staff, commensurate with their job function. Supervisory or lead technical personnel may require periodic specialist training, which may or may not be available from within the institution. The training of more junior technical personnel might typically be by supervisory personnel. Forensic toxicologists who testify or provide interpretation must be encouraged to review the forensic literature on a regular basis and at least periodically attend relevant local or other forensic conferences. Educational programs such as lunchtime seminars etc., are encouraged.

Objective Evidence

Quality Assurance Manual 5.7 Professional Development Program

B-12 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Do all staff review, agree to, and adhere to, ethical guidelines for performance of their job?

NOTE The ethical guidelines may be those drafted by the employer (e.g., government or corporate entity), a professional organization (e.g., AAFS, SOFT), other professional standard (e.g., SWGTOX) or other suitable professional standard drafted by laboratory management.

Objective Evidence

TLD Operations Manual 1.11.1

Section C: STANDARD OPERATING PROCEDURE MANUAL

C-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a Standard Operating Procedure (SOP) manual which covers the laboratory's general operations and all of the current analytical methods?

NOTE Laboratories must have a complete and current Standard Operating Procedure (SOP) manual that describes all the routinely used analytical and administrative procedures.

Objective Evidence

Verified the Standard Operating Procedures (SOP)
Operations Manual TLD_OP_Operations Manual_Rev7_20190819
Quality Assurance Manual TLDTestQM_Testing QA Manual_Rev2_20170710
Quality Assurance Principles PQ12703_Qual Assur Principles_Rev 1_20170724
Individual Test Method SOPs

C-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a documented procedure for SOP change control?

NOTE There must be a requirement for document control to ensure the current version of an SOP is in use. Revision histories to an SOP must be tracked; changes to SOPs in a new revision must include a record of what changed from the previous version.

Objective Evidence

Quality Assurance Manual - 2.3 Procedure and Revisions to Procedures and Technical Documents - 2.4

C-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is the scope of the analytical screening or detection methods in the SOP consistent with the laboratory's stated mission?

NOTE The list of the analytes commonly screened for by the laboratory must be consistent with the laboratory's stated mission. The goals of a medical examiner's laboratory would include assisting the medical examiner in determining the cause and manner of death through the analysis of postmortem specimens and through the interpretation of the analytical results, if necessary in a court of law. In this case the list of routine analytes must include alcohol, drugs of abuse, over the counter drugs, other therapeutic agents and toxic chemicals.

It is recognized that for some smaller laboratories the range of drugs or other analytes quantified may be limited. However, while no laboratory can be expected to detect every substance of potential forensic importance, for postmortem toxicology, the capability of the screening tests must go well beyond what routine immunoassay testing will detect and must include at a minimum GC/MS[MS] and/or LC/MS[MS] technology.

For a laboratory involved in human performance toxicology the mission statement would be different and reflect its goal of assisting law enforcement agencies in the detection of the "impaired driver". This goal would require the analysis of body fluids (primarily blood, serum or urine) and the interpretation of the results, if necessary, in a court of law. In this case the list of routine analytes must include those substances that may modify human performance or behavior.

The judgment of the inspector is important in assessing the effectiveness of the screening tests performed. However, there are two considerations in answering this question. First, what is the mission of the laboratory and what does the client (e.g., police, pathologist) require. A "drug screen" may be inherently limited, but the client is aware of and willing to accept those limitations. For example, for DUI work, some jurisdictions may only require an immunoassay screen for drugs of abuse with appropriate confirmation of "positives". The second consideration is whether the laboratory is conducting a "limited screen", but implying from the wording of the report that a reasonably comprehensive drug screen has been performed.

Objective Evidence

TLD Operations Manual - 1.1 Mission
The laboratory provides objective evidence for screening major illicit drugs and drugs of abuse, with the capability to confirm and/or quantify the most common compounds. For novel or rarely-identified compounds, the laboratory may send specimens to an external subcontractor laboratory for testing.

C-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

If the laboratory relies solely on targeted screening methods, is there a documented policy to periodically update the list of drugs screened for?

NOTE Some laboratories rely exclusively on one or more screening tests that target specific groups or panels of drugs (e.g., immunoassay, LC/MS[MS], LC/TOF[MS]). While those panels may serve the laboratory and its clients very well, the overall effectiveness of the laboratory to detect new or emerging drugs is diminished over time unless there is a policy to periodically review and update the list of drugs screened for. Where full-scan methods such as GC/MS are used and the mass spectral libraries periodically updated, the ability to detect a broad range of drugs is maintained within the limitation of the technology.

Objective Evidence

The laboratory does not rely solely on targeted screening methods.

C-5 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the SOP contain guidelines as to which tests are to be performed on different types of cases, consistent with the laboratory's stated mission?

NOTE It is recognized that different clients may request different tests for the same type of case. It is also recognized that reference laboratories in particular may have a limited ability to select specific tests unless the client selects or authorizes that. However, where the laboratory partially directs the specific tests to be performed (e.g., broad screen GC/MS or LC/MS or LC/TOF for medical examiner/coroner or crime laboratory), the tests run must be of sufficient scope and sensitivity to meet the needs of the case.

Objective Evidence

Reviewed TLD_OP_Operations Manual_Rev7_20190819; Operations Manual 6.3 Testing Guidelines

The guidelines provide general information based on case type. Actual testing performed is dictated by case type, case history (request for analysis form, incident/death investigation report, customer information) and preliminary screening results.

C-6 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory director or appropriate designee review, date and sign each procedure?

NOTE Individual procedures or methods can be approved by notation on the first page of the document, or other suitable means. While each page may be signed by the laboratory director, it is not essential. Software programs that control documents and apply electronic signatures in an appropriate manner are acceptable.

Objective Evidence

TLDTestQM_Testing QA Manual_Rev2_20170710 Quality Assurance Manual 2.3.4 Approval/Issue of Controlled Documents
The review/approval process for procedures includes signature/date of the Laboratory Director (TLD Commander/State Toxicologist), Quality Assurance Manager or Laboratory Manager.
Document Review and Approval (DRA) forms - for new SOPs or revisions to SOPs

C-7 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory director or his/her designee date and initial all changes to individual procedures or SOPs?

Objective Evidence

TLDTestQM_Testing QA Manual_Rev2_20170710; Verified Quality Assurance Manual 2.4 Revisions to Procedures and Technical Documents' 2.4.8 Approved/Adopted.

C-8 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is there documented evidence of review of the administrative (non-analytical) SOP(s) by the director at least annually?

NOTE It is desirable that the director review, sign and date each change made to the SOP. These changes may result from suggestions of the laboratory staff or from modifications made to the procedure by the director. The director may delegate this responsibility to an individual with supervisory responsibility for the scientific aspects of the laboratory. If the director has delegated this responsibility, there must still be evidence that the director has authorized continued use of the non-analytical procedure, at least annually. The review may be documented by signature on a summary sheet.

Objective Evidence

TLD Quality Assurance Manual 2.3.6 Annual Review of Controlled Documents
All procedures are reviewed annually.
Spoke with Amanda Black on the review of control documents.

C-9 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory director ensure that all current analytical methods are accurate and appropriate for the mission of the laboratory?

NOTE It is not necessary for the laboratory director to personally review and re-approve the details of each analytical method annually. In a large laboratory, annual review and approval of the analytical methods may be delegated to a senior supervisory individual. The purpose of the review is to ensure that the analytical SOPs available to staff are appropriate, current, accurate and adequately validated. However, the laboratory director must be aware of all important changes made to SOPs and general laboratory operation.

Objective Evidence

TLD Quality Assurance Manual 2.4 Revisions to Procedures and Technical Document

Reviewed validation TCb12744 Basic LCMSMS Validation_2018 1915pg
Reviewed Validation of blood ethanol procedure HSCG7 1355pg
Reviewed policy TCb12744 Basic LCMSMS_Original_20180807

Observed records showing review of SOPs and document review and approval forms (DRA).

C-10 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is the laboratory SOP, or the appropriate sections of the SOP, readily available to analysts in the laboratory?
NOTE All laboratory staff must have easy access to the SOP. In some laboratories abbreviated SOPs will be available at the bench. These must be consistent with the approved manual.

Objective Evidence

TLD Quality Assurance Manual 2.1 Policy
TLD Quality Assurance Manual 2.2.8 Master Document File
TLD Quality Assurance Manual 2.3.4 Approval/Issue of Controlled Documents

C-11 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

If the laboratory uses abbreviated procedures (e.g. index cards) at the bench, are they consistent with the approved SOP?

Objective Evidence

Abbreviated procedures are not used at the bench. Scientists have access to SharePoint in the laboratory, where the official SOPs can be printed for use at the bench.

C-12 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

At a minimum does the SOP Manual contain sections on:
a) specimen receiving, accessioning, aliquoting and storage?
b) procedures for recording the transfer of specimens?
c) procedures for retention and disposal of specimens?
d) procedures for the set-up and normal operation of instruments?
e) description of the quality assurance and quality control program?
f) criteria for the acceptance of analytical data?
g) protocols for recording, reviewing and reporting results?

Objective Evidence

a) Specimen receiving, accessioning, aliquoting and storage
Operations Manual 7.5 Receipt of Evidence
Operations Manual 7.6 Accessioning/Examination of Evidence
Operations Manual 7.9 Storage of Evidence
Individual test method SOPs address specimen aliquoting
b) Procedures for recording the transfer of specimens
Operations Manual 7.10 Retrieving/Returning Evidence from the Evidence Vault
c)Procedures for retention and disposal of specimens
Operations Manual 7.13 Extended Retention of Evidence
Operations Manual 7.12 Return of Evidence to Submitting Agency
Operations Manual 7.15 Evidence Disposal
d)Procedures for the set-up and normal operation of instruments
Addressed in individual SOPs i.e., TCb12714 Basic Drug
e)Description of the quality assurance and quality control program
Quality Assurance Manual Chapter 1 Quality Management System
Quality Assurance Manual Chapter 10 Assuring the Quality of Test Results
f)criteria for the acceptance of analytical data
Quality Assurance Principles
General Requirements for Chromatographic Test Method Batch Analysis and Acceptance
g) Protocols for recording, reviewing and reporting results
Quality Assurance Manual Chapter 12 Records, Reviews and Reports

C-13 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Do the assay protocols in the SOP contain sufficient detail to allow analysts to perform the assay, including, but not limited to the following:
a) the principle of each analytical procedure?
b) details for the preparation of reagents, standards, calibrators and controls?
c) specimen requirements?
d) calibration procedure and parameters?
e) assay acceptance and reporting criteria?
f) potential interferences (where likely or known)?
g) references?

NOTE The written procedures must contain sufficient detail to enable the routinely performed assays to be carried out without reference to supplementary information sheets or cards which are not part of the SOP. Some of these criteria may be included in more general documents (e.g., QA/QC)

Objective Evidence

Sections covering each of the above can be found in each analytical SOP.

C-14 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a written procedure for the set-up and operation of all analytical instruments?

NOTE The SOP must contain sufficient information and directions to enable the operator to set up and adjust each instrument for the required assay. This may include the normal operating conditions for the assay, any adjustments that need to be made (e.g., GC-NPD bead current offset, gas or mobile phase flows) or criteria met (e.g., minimum response for a designated analyte). It may also include a description of the settings for any software used for the acquisition and/or processing of analytical data. Settings and descriptions that are critical to or necessary for the individual assays must be described in the method. However, more general descriptions of instrument set-up and operation may be described in a separate section of the SOP. Preventive maintenance that must be performed (e.g., for GCs, replace septum, cut front of column) may be listed in the individual assays, especially if it is critical to the assay (e.g., replacing the injection port liner prior to each run may be important for some assays). Routine preventive maintenance may often be described in a separate section of the SOP, or in a logbook or chart that stays with the respective instrument.

Objective Evidence

Procedure for Instrument Maintenance and Performance Verification (PTmp12504)
Procedure for the Tune and Evaluation of Mass Spectrometers (PTms12503)
Individual test method SOPs (the respective instrument conditions are given)
Training modules for instrumentation and specific test methods
Instrument maintenance checklists

C-15 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory maintain copies of the outdated SOPs and the dates they were in effect?

NOTE Copies of outdated SOPs are required to be kept so that the laboratory has an accurate record of the analytical procedures and analytical protocols that were in effect when particular results were generated, in case of legal challenge.

Objective Evidence

Obsolete/retired SOPs are watermarked with the date of retirement, posted on SharePoint.
TLD Quality Assurance Manual 2.3.5 Archiving Controlled Documents

Observed TLD_OP_Operations_Manual Rev6_20161128

C-16 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is there a protocol for approving or handling deviations from the written procedure?

NOTE The unique nature of forensic work means that on occasion it may be necessary to deviate from or modify written procedures, in order to accommodate an unusual sample type or condition, multiple or unusual analytes, or small sample volume. The laboratory must have a protocol for documenting these and other deviations from normal practice. The laboratory director or designee must approve all deviations.

Objective Evidence

TLD Operations Manual - Introduction
Quality Assurance Manual 10.6 Deviation from Policy or Procedure
Quality Assurance Manual 12.4.2.3.3 (Technical Review of Test Report and Examination Records)

reviewed case ST-18-14800

Section D: SPECIMENS, SECURITY AND CHAIN OF CUSTODY

D-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory make instructions available to user agencies, including the types and amounts of specimens required?

NOTE The proper selection, collection, submission and storage of specimens for toxicologic analysis are important if analytical results are to be accurate and their subsequent interpretation is to be scientifically sound. The laboratory must develop and provide detailed guidelines and instructions to all user agencies and parties the laboratory serves. These instructions must include recommendations regarding:
-types and minimum amounts of specimens needed for and analysis and subsequent interpretation
-specific requirements for the type and size of specimen containers
-type and amount of preservative to be added, if appropriate
-instructions for proper labeling of individual specimen containers
-acceptable conditions for packing and transportation
-instructions how to properly fill out all chain of custody documentation

Objective Evidence

Forensic Services Guide (http://www.wsp.wa.gov/forensics/docs/toxicology/other_docs/forensic_services_guide.pdf)
Request for Analysis form (http://www.wsp.wa.gov/forensics/toxicology.htm#toxforms)
Notification emails for changes (e.g., switching from lab-supplied kits to agencies ordering directly from supplier)

D-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory compare the information on the specimen labels against that on the requisition and document any discrepancies?

NOTE Specimens must be labeled with appropriate identifying information and accompanied by a request form containing the same information. The document can also serve as the external chain of custody form. At the time of specimen receipt, it must ensure that the information on the labels matches that on the request documentation. Any discrepancies must be documented, for example, in case files or in separate log books.

Objective Evidence

TLD Operations Manual 7.6.5.6 Evidence Description

Interviewed Tyler Orrell, property and evidence custodian.
Observed accessioning of ST-19-11877

D-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory assign unique identification number(s) to each container of specimen received?

NOTE The manner in which individual specimens are identified within a laboratory may vary. It is a common procedure for individual specimens to each be given a unique “accession number” upon receipt in the laboratory. Alternative procedures may be acceptable, providing that each individual container of specimen is uniquely identified in some way. For example, some medical examiner laboratories use the ME case number, plus a “specimen designator” (e.g., “Bl” for blood). This is acceptable providing that multiple specimens of the same type (e.g., multiple vials of blood from the same case) are uniquely identified.

Objective Evidence

TLD Operations Manual 7.6.5.1 ST (State Toxicology) Number

Witness files ST-18-12418, ST-18-13200, ST-18-01641, ST-18-05594

D-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory document the condition of specimens that appear abnormal?

NOTE It is important to maintain a document regarding the condition of specimens at the time of receipt. This document may either be maintained in individual case files or in separate log books and must contain information such as: deficiencies in the integrity of external packaging, integrity of seals, amount of specimen and degree of decomposition. Other deficiencies may include the unusual appearance of a specimen (e.g., “watery” blood, bloody urine, etc.).

Objective Evidence

Operations Manual 7.6.1 - 7.6.5 Accessioning/Examination of Evidence - "Request for Analysis forms"

Interview with Property and Evidence Custodian, Tyler Orrell

D-5 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is entry into the laboratory controlled during working hours?
NOTE Access to the forensic toxicology laboratory must be limited to authorized personnel. Unauthorized persons must be escorted and must sign a logbook upon entry and departure, indicating the time, date and purpose of the visit. The physical layout of the laboratory must be such that unauthorized persons cannot enter without detection. All exterior ingress/egress points require proper locks. All keys and access cards (or equivalent) must be accounted for and their distribution limited. Where the forensic toxicology laboratory is located within a larger multidisciplinary laboratory that has a secure perimeter (e.g., open plan government or similar facility) records or exhibits must be secured whenever authorized toxicology staff is not present. Where the toxicology laboratory does not have a secure perimeter of its own and it is impractical to build one, access must be recorded by a suitable means such as closed-circuit security camera.

Objective Evidence

TLD Operations Manual Chapter 2 Laboratory Space, Security and Safety
TLD Operations Manual 7.3 Evidence Vault Access

D-6 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is the laboratory secure during non-working hours?

NOTE The laboratory must be secured by locks during non-working hours to prevent unauthorized access. Additional security precautions may sometimes include monitoring devices (e.g. motion detectors) and security personnel in the building where the laboratory is located.

Objective Evidence

TLD Operations Manual Chapter 2 Laboratory Space, Security and Safety
TLD Operations Manual 2.4.3 Opening and Closing Procedures

D-7 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory secure short and long-term specimen storage areas when not in use?

NOTE Specimens must be stored in a secure manner at all times to maintain integrity. Proper security can be achieved by storing specimens in locked cabinets, refrigerators or rooms. It is acceptable to leave storage rooms unlocked when authorized personnel are present.

Objective Evidence

TLD Operations Manual 7.9 Storage of Evidence

It was observed that the laboratory has secure short and long-term specimen storage areas

D-8 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory secure record storage areas?

NOTE Records have the same evidentiary importance as the specimens and therefore must be stored in a secure manner. Records can be stored in a secured room, area, or file cabinet. Access must be restricted to authorized personnel (e.g., personnel assigned to records management, appropriate supervisory and laboratory personnel). “In use” records (e.g., incomplete files or those pending reporting or filing) may be, as a matter of convenience, temporarily stored at different locations prior to final disposition. Temporary storage of such files outside of a locked cabinet or storage room is acceptable, providing the laboratory is secured and access is controlled by authorized laboratory personnel.

Objective Evidence

TLD Operations Manual 3.2 Storage of Records (Records Management)

Records are retained in a secured file room with controlled access. Some records are maintained in the LIMS system.

D-9 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory maintain the available external chain of custody, requisition and/or shipping information?

Objective Evidence

The Request for Analysis form submitted with specimens by user agencies has COC information. Internal COC is maintained in LIMS.

TLD Operations Manual 7.4.2 Evidence Request for Analysis Forms
TLD Operations Manual 7.5 Receipt of Evidence

Reviewed case file ST-18-12418 chain of custody

D-10 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory document all persons handling the specimens?

NOTE Transfer and handling of specimens must be clearly documented as part of the permanent laboratory records and must indicate, at a minimum, the date and identity of the individuals involved in the specimen transfer, and laboratory identification number. This document may be a logbook, worksheet or other suitable means of recording the information and does not necessarily have to be a strict chronological “z-style” chain of custody document. Batch forms are acceptable if transfer involves multiple specimens.

Objective Evidence

All internal transactions (and transactions for send-outs to external laboratories) are documented in LIMS, with security (PIN required).

TLD Operations Manual 7.10 Retrieving/Returning Evidence from the Evidence Vault
TLD Operations Manual 7.11 Transfer of Evidence to a Subcontracted or Reference Laboratory
TLD Operations Manual7.12 Return of Evidence to Submitting Agency

Handling of specimens is documented on the toxicology laboratory chain of custody report (ST-18-12418)

D-11 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are specimens maintained in such a manner as to, as far as practical, preserve the analytical and toxicological integrity of the specimen?

NOTE Specimens received in the laboratory must, as appropriate, be refrigerated as soon as possible after arrival, to preserve them in the condition in which they were received.

Objective Evidence

TLD Operations Manual 7.5 Receipt of Evidence
TLD Operations Manual 7.9 Storage of Evidence

D-12 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a specimen retention policy and have corresponding adequate space for the short and long-term storage of specimens?

NOTE The specimen retention policy must meet any local regulatory requirements and satisfy the needs of the laboratory's clients.

Objective Evidence

TLD Operations Manual 7.12 Return of Evidence to Submitting Agency
TLD Operations Manual 7.13 Extended Retention of Evidence
TLD Operations Manual 7.15 Evidence Disposal

Section E: QUALITY ASSURANCE , QUALITY CONTROL and REPORTING

E-Introduction — Conforming

Requirement

Quality assurance encompasses all aspects of the analytical process, from specimen collection and receiving through analysis, data review and reporting of results. A quality assurance program must obviously include a quality control program that is used to evaluate whether the analysis is operating within defined tolerance limits. An effective program must detect both random and systematic errors in a timely manner and allow the laboratory to take corrective action, including investigation of the root cause of the problem.

Objective Evidence

The laboratory implements a Quality Assurance Program which addresses those topics listed above.

E-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is a suitably qualified individual assigned day-to-day responsibility for QA?

NOTE A specific individual must be assigned to the day-to-day responsibility for QA. In a smaller laboratory that individual might be the laboratory director. However, in most laboratories, although the director will retain overall responsibility for QA, day-to-day responsibility will be delegated to a deputy, supervisor or other responsible technical person. Suitability should be judged in the context of academic qualifications, experience, knowledge and job function, but does not necessarily require formal training in QA.

Objective Evidence

Quality Assurance is assigned to the Quality Assurance Manager (Amanda Black). Additional assistance is provided by Brianne O'Reilly (Technical Leader).
TLD Operations Manual 1.7.3 Quality Assurance (QA) Manager
TLD Quality Assurance Manual 1.4.1 Laboratory Quality Management

E-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is the quality assurance program of the laboratory reviewed annually?

NOTE Annual review of the entire Quality Assurance Program of the laboratory is required, to ensure that it is up-to-date and is effective. That review will normally be documented as a signed and dated review (or revision) of the QA section of the laboratory's SOP Manual. It should be noted that the annual review is of the program as a whole, and does not just apply to QC or other analytical data, which must be reviewed on a considerably more frequent basis. In particular, the review must address whether proper corrective action has been taken where deficiencies exist. The review should include randomly selected casework. The annual review may be conducted by the laboratory director or a qualified designee (e.g., deputy director, QA supervisor or equivalent), but must undergo final review by the laboratory director.

Objective Evidence

Quality Assurance Manual 3.1 Policy (Internal Audits and Management System Reviews)
Quality Assurance Manual 3.3.4 Eleven Elements of the Management System Review
Quality Assurance Manual 3.4 Documentation

Annual Supervisor/management meeting minutes
Review of MSR 2018 Summary and Supplemental Information to Date
Internal audit records 2018
Positive control tracking records
Proficiency testing records

E-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

For qualitative immunoassays does the laboratory include appropriate positive and negative controls with each batch of specimens for

analysis?

NOTE With each analytical run of specimens, whether a single specimen or a batch, controls must be carried through the procedure with the unknowns. Each batch of specimens must include at least 10% controls, including at a minimum, one positive and one negative, dispersed throughout the batch. Where multiple positive controls are analyzed, the run must conclude with at least one positive control. Inclusion of a positive and negative control mid-way through long immunoassay runs (e.g., 96-well ELISA plate) is a good practice to determine if “drift” has occurred. All screening batches must end with a positive control.

Although there is no need to monitor the concentration of a positive control in a qualitative assay, the target concentration must challenge the assay. For example, it would be unacceptable to select a positive control for a benzoylecgonine immunoassay at 4000 ng/mL if the decision point is 300 ng/mL; an acceptable concentration might be 400-600 ng/mL. On the other hand, for a chromatographic assay, the concentration must be such that it is routinely detectable by the chromatographic system.

Unless the assay is validated for alternate matrices, matrix matched controls may be prepared by fortifying analyte free matrices such as tissue homogenates, expired blood bank blood or plasma or other appropriate matrix.

Open controls (controls whose identity and concentration is known to the analyst) can be purchased commercially, prepared in the laboratory or saved and pooled from previous cases. Regardless of the source, the concentration of the analyte in controls used for quantitative analysis must be validated. There is no requirement to analyze blind controls (controls whose identity is unknown to the analyst) because of the difficulty of doing this effectively.

Objective Evidence

Quality Assurance Manual 10.9 Quality Control
Screening of Biological Specimens by Enzyme Multiplied Immunoassay Technique (TSe12718)

EMIT testing has at least one negative control and two levels of positive controls. Samples are bracketed with positive controls with a total number to make up 10% of the batch.

E-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have appropriate written criteria for the acceptance of the qualitative immunoassay and other non-chromatographic controls?

NOTE Criteria for the acceptance of qualitative controls used by the laboratory must be included in the SOP. It is acceptable to indicate simply that the positive control must test positive and the negative control must test negative.

Objective Evidence

Quality Assurance Manual 10.9.3 (Quality Control)
TSe12718-Screening of Biological Specimens by Enzyme Multiplied Immunoassay Technique (EMIT) 18.8.1 Controls (Criteria)

E-5 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have appropriate written criteria for the acceptance of qualitative controls for chromatography-based assays?

NOTE Criteria for the acceptance of qualitative controls used by the laboratory must be included in the SOP. The criteria must include some means of assessing minimum sensitivity of the assay, e.g., detection of drugs contained in the control at a concentration approaching the LOD of the screen, or other criteria such as minimum peak height or peak area.

Objective Evidence

Quality Assurance Manual 10.9.3 (Quality Control)

PQ12707 General Requirements for Chromatographic Test Method Batch Data Analysis and Acceptance 7.3.2.1.1, 7.3.2.2.1 (Basic drug screen by GC-MS/NPD)

E-6 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

For quantitative assays, does the laboratory include appropriate controls with each batch of specimens for analysis?

NOTE To the extent practical, every analyte within an assay must have a same-substance matched control.

For quantitative assays, controls are used to verify the calibration and to monitor its stability. In this case the controls used must include, at a minimum, a negative and a positive control that realistically monitors the performance of the assay. Each batch of specimens must include at least 10% controls, including at a minimum, one positive and one negative. Additional controls may be necessary to challenge the linearity of the procedure and ensure reliable quantitative values along the entire curve. The number and concentrations of acceptable controls will be determined by the extent and nature of the calibration and method validation, and the extent to which case results are reported quantitatively outside the range of the (multi-point) calibration. It is good laboratory practice to reinject a control or calibrator during long analytical runs, and to end an analytical run with a control or calibrator to demonstrate stability of the calibration.

Objective Evidence

Quantitative test methods include positive controls for each target compound reported from the testing batch. Controls must make up at least 10% of the extracted batch (Determined by the number of specimens).

Individual quantitative test method SOPs i.e., TCb12714

E-7 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

For frequently run assays, are the quantitative control results listed or plotted in a manner that facilitates review by the laboratory director or designee?

NOTE For frequently performed quantitative assays (e.g., monthly), the laboratory must list or plot the results using one of a variety of techniques. Most commonly Levy-Jennings charts will be used. Some laboratories may use cumulative sum (cusum) charts or mean/range charts. Acceptable results are those where the determined concentrations are within the mean plus or minus a valid statistical measure, for example +/-20%, or if there is adequate data,+/-2 standard deviations.

Signing and dating the QC record constitutes evidence of review. In some cases the director may designate this review to a laboratory manager or quality control supervisor.

Objective Evidence

Testing QA Manual 10.9.3 (Quality Control)
Testing QA Manual 10.9.3.1 Positive control tracking charts

Assessor reviewed spreadsheets and levy-Jennings chart for controls for Methamphetamine, Amphetamine, MDA, MDMA and Pseudoephedrine

E-8 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have appropriate written criteria for the acceptance of quantitative controls?

NOTE Criteria used by the laboratory must be included in the SOP Manual.

The appropriateness of acceptable criteria is to some extent based on the assay. The use of two standard deviations for all quantitative assays is an accepted practice, providing that the absolute deviation from target is not unreasonable (e.g., +/- 30 - 40% would normally be considered unacceptable) and providing there is an adequate number of data points. Other acceptable criteria include use of the mean or target value +/-20%, or less, depending on the intended purpose of the assay. Whatever criteria are used, the laboratory must clearly demonstrate that they are appropriate for the assay by monitoring precision over time. However, it is understood that for some assays insufficient data is generated to make an analysis of control precision meaningful. It may sometimes be appropriate to set less stringent quantitative criteria for a control which is close to the LOQ of the assay, compared with a mid-range control, especially where concentrations approaching the LOQ are of little toxicological or forensic significance.

Objective Evidence

PQ12703 Quality Assurance Principles
PQ12707 General Requirements for Chromatographic Test Method Batch Data Analysis and Acceptance

E-9 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are repeated QC failures thoroughly investigated to determine the root cause?

NOTE Occasional QC or calibration failures may be due to occasional random errors and not necessarily due to an easily identifiable problem. However, repeated failures beyond that statistically expected, indicates a problem that must be thoroughly investigated. Causes may include a poor assay design, poor technique, bad or deteriorated reagents, deteriorated calibration standards or QC samples. The investigation and any corrective action must be documented.

Objective Evidence

Quality Assurance Manual 4.3.2 Corrective Action Process
Quality Assurance Manual 4.3.2.3 Root Cause Analysis
Quality Assurance Manual 4.3.2.5 Corrective Action Report (CAR)
Quality Assurance Manual 10.9.3 Quality Control

Assessor reviewed Corrective Action Report for basic drug screen sample switching dated January 14, 2019 which contained a root cause analysis.

E-10 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Where corrective action has been taken to correct a QC or other failure, is that assay or test closely monitored over an appropriate period of time to ensure that the corrective action has appropriately addressed the deficiency?

NOTE The duration of monitoring will depend on the frequency with which the assay is performed and to some extent on the nature of the issue (e.g., random failure or persistent issue).

Objective Evidence

Quality Assurance Manual 4.3.2 Corrective Action Process

Reviewed Corrective Action-Zolpidem Concentration Discrepancies report
Interview with Amanda Black

E-11 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

If the laboratory prepares its own calibrators and controls, are these made using independently prepared stock solutions?

NOTE Calibrators and controls must be independently prepared from a separate weighing or initial dilution or obtained/derived from other sources. If both the calibrator and control(s) are derived from the same source, the laboratory may introduce an undetectable bias into its results, since controls are used to verify the calibration. Preparation of calibrator and control solutions must be properly documented as to the source of the materials, how much was used, the identity of the preparer and the date of preparation. In some laboratories this may be done by a separate QA section or an individual assigned QA responsibilities.

Objective Evidence

PQ 12702-Standard Solution Preparation

Where possible, different suppliers are used for calibrators and controls preparation as are used in working standard preparation.

Document review of preparation and verification records for new ethanol internal standard (P0818).
Document review of preparation of synthetic opioid qualitative working solution NSO180816-W

E-12 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

To extent feasible, does the laboratory independently verify the identity and concentration of analytical standards that are not supplied with a certificate of analysis?

NOTE Generally, high quality reference materials and stock solutions obtained from a supplier are provided with a certificate that describes the identity, quality and concentration of the material. Where certification is not provided, the laboratory must verify the identity of the material. The verification may involve obtaining a full spectrum GC/MS analysis with comparison to library spectra and absence of additional/ interfering chromatographic peaks, measurement of a physical constant (e.g., melting point, refractive index), or use other analytical techniques (e.g., HPLC, IR, UV/VIS). This verification may need to be repeated if the reference material is used beyond its expiration date.

Objective Evidence

Quality Assurance Manual 9.3 Purchase (Reference Materials)
Quality Assurance Manual 9.5 Verification

Review of Ibuprophen powder verification of the identity (found on WSP drive: W)
Review of ethanol verification of the identity.

E-13 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory take appropriate, documented corrective action when control results exceed specified limits?

NOTE It is important that the laboratory recognize when results for a control are unacceptable. In this case, the laboratory must have a procedure in its SOP to describe the corrective action and how it will be documented. The appropriateness of the corrective action is dependent on the assay. For qualitative immunoassays it may be necessary to repeat all specimens in a batch, for example if the negative control tests positive. On the other hand, in quantitative assays the SOP must clearly define the acceptance criteria for controls and what corrective action to be taken if they fail.

Corrective action may be documented as an annotation on the analytical record, as a separate memorandum attached to the data, or referenced to a separately filed package of material.

Objective Evidence

PQ12703 Quality Assurance Principles
PQ12707 General Requirements for Chromatographic Test Method Batch Data Analysis and Acceptance

Documentation was observed on each worklist (batch). When control results from the batch precludes limited reporting, or yields no reportable results this is documented on the QC form and/or batch worklist and included in each case file for specimens tested in the batch (observe documentation of the GC-NPD/MS).

E-14 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

To the extent possible and reasonable, are proficiency test (PT) samples handled in the same manner as client samples?

NOTE It is recognized that PT samples generally look different from client samples and the manner of reporting results may be very different from client samples. As far as possible, the same range of testing must be performed as would be on client samples and the same criteria used for evaluation and acceptance of analytical results.

If a particular test is not routinely performed by the laboratory and where ordinarily that test would be referred to a reference laboratory, the results must not be reported back to the PT provider.

All technical staff must participate in the handling and analysis of proficiency test samples appropriate for their area of responsibility at the time the samples are received in the laboratory and processed. No staff member shall be deliberately excluded from testing proficiency test samples who would otherwise be handling routine case samples for the same tests.

Proficiency findings must never be shared or discussed with another laboratory until after the results are reported to the PT provider and the PT provider's report is received by both laboratories.

Objective Evidence

Quality Assurance Manual 11.5.6 - 11.5.8 Proficiency Tests

Proficiency testing records reviewed demonstrated that the analysis was consistent with the same manner as a client sample.

The assessor reviewed AChandler CAP T-04 2019 and Gingras A CAP FTC-01 2019

E-15 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Do proficiency test scores received from the PT provider undergo documented review by the laboratory director?

NOTE At a minimum the director must review and sign-off on all proficiency test results received from the PT provider after results are submitted and scoring is complete, and where necessary after appropriate corrective action has been taken.

Objective Evidence

Quality Assurance Manual 11.8 Review of Performance (Proficiency Testing)

The assessor witnessed the initial and date of the laboratory director on the memo attached to each PT reviewed (Chandler, Johnston, Gingras and Daniel).

E-16 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

If unacceptable results occurred in PT programs does the laboratory take appropriate, documented corrective action including, as appropriate, a root-cause investigation?

NOTE Corrective action may include repeat analysis of the proficiency testing specimen, preparation of new calibrators, or a complete re-validation of the analytical procedure. If the laboratory reports a false negative, it is important that this review, and if necessary corrective action, is taken promptly.

False positive results require the most rigorous investigation. Extensive and thorough investigation is expected. However, the error may be considered less serious if it is clerical in nature and unique to the way results are reported for the particular PT program (e.g., use of an incorrect analyte code). The extent of investigation and corrective action required for a false negative will depend of whether the analyte might ordinarily be expected to be detected by the laboratory at the spiked concentration, or whether detection is judged to be unimportant for the mission of the laboratory.

The laboratory director should make his or her decision as to whether performance has been satisfactory, where practical, based on the following: no false positives; ethanol within +/-2 S.D. of the participant mean or +/-10% weighed-in target; for drugs, the challenges should be within +/-2 S.D. of the participant mean or +/-20% weighed-in target for drugs. Corrective action or investigation (if only limited to an audit of the raw data) is sometimes appropriate, even if the results are within +/-2 S.D. For example, the proficiency test S.D. range for some analytes is so large that +/-2 S.D. can represent from near zero to at least double the weighed-in target or participant mean.

It is not sufficient to only reanalyze the PT sample and accept the new result if it is within the acceptable range. It is important to investigate the reason for the initial failure and take appropriate documented corrective action. See the separate document: Guidelines for Performing Corrective Action for Deviations in Proficiency Test Results for further information. Where the error is determined to be forensically significant, a review of potentially affected casework must be conducted.

Objective Evidence

Quality Assurance Manual 11.8.5 Proficiency Test Discrepancies

No objective evidence was found to support the practice of the laboratory taking appropriate, documented corrective action for unacceptable PT results. However, If a discrepancy occurs between the analyst's test results and the provider's results, the QA Manager will immediately notify the analyst who performed the test and their Supervisor. The QA Manager and the Supervisor then determines a course of action.

E-17 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory properly label reagents as to identity, date of preparation, expiration date (where appropriate) and identity of the preparer?

NOTE It is good laboratory practice for the date of preparation, expiration date and identity of the preparer to be included on the label of in-house prepared reagents. For purchased reagents, the date received and/or opened must be labeled. Chemicals and solvents that are known to be stable do not require an expiry date.

Objective Evidence

Quality Assurance Manual 8.2.8 (Reagents)

A review of randomly selected prepared reagents where appropriately labeled with the identity, date of preparation and expiration (when appropriate) and initials of the analyst that prepared the reagent.

E-18 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory validate new or freshly prepared reagents?

NOTE There are two primary ways to check new reagents. A laboratory can prepare separate validation batches containing only controls prepared with the new and current reagents. Alternatively, a laboratory can prepare routine batches of specimens, including controls, with the new reagents and compare the results of controls from preceding batches, prepared with the current reagents.

The most critical reagents requiring such checks are:
- immunoassay kits
- derivatizing reagents
- organic solvents and mixtures for chromatography and extraction
- pH-specific reagents and buffers
- hydrolysis reagents
- solid phase extraction reagents

Objective Evidence

Quality Assurance Manual 8.2.7 (Reagents)
Individual test method SOPs (for pH specific buffers)

Reagent verifications are filed in the reagent preparation logs located on a table near the lab coats

Verification of reagents or checking the reliability of reagents occurs concurrent with casework unless specified otherwise. If a reagent has been defined as a critical supply then the verification or reliability testing will occur before it is employed for evidence testing.

E-19 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory periodically check the accuracy of fluid dispensing devices (e.g. pipettes) used for critical volume application?

NOTE The laboratory must periodically check the accuracy of pipettes used for quantitative measurements at least annually. Typically gravimetric or colorimetric methods are used. Where a pipette is not calibrated because it is intended solely to qualitatively dispense reagents, it must be labeled as such (e.g., “qualitative only”).

Objective Evidence

Pipettes and automatic diluters used to measure critical volumes are calibrated annually, with intermediate checks of performance performed between calibrations.

Quality Assurance Manual 6.1 (Policy)
Quality Assurance Manual 6.3 Calibration of Equipment; 6.6 Diluters; 6.12 Pipettes
Quality Assurance Manual 13.3.4 Equipment/Instrument Maintenance
Quality Assurance Manual 13.3.5 Equipment/Instrument Performance Verification
Procedure for Gravimetric Performance Verification of Adjustable Volume Piston Pipettes (PQ12701)
Procedure for the Gravimetric Certification of Hamilton Microlab Diluter Dispensers (PQ12700)

Reviewed pipette calibration records and the Hamilton automatic diluter calibration records performed by Quality Control Services (QCS) .

E-20 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a preventive maintenance schedule and service logs for all instruments in routine use and ensure these records are readily available to the staff operating the instruments?

NOTE Most instruments require some type of routine maintenance. This can usually be divided into routine service that the operator performs (e.g., for GC, liner and septum changing, cutting columns etc.), service that is performed less frequently (e.g., changing rough pump oil; MS source cleaning), in addition to ad hoc work performed by qualified service personnel. Records of scheduled service may be included as an integral part of the service log, or as part of a separate maintenance schedule for the laboratory, such that it is readily evident to users of the equipment and QA staff. However, all service work must be documented and that documentation readily available to operators of the equipment.

Records of service or maintenance must be accessible near the instrument it pertains to, or failing that, in a location known and readily accessible to the operators of the instrument.

Objective Evidence

Quality Assurance Manual 6.1 (Policy)
Quality Assurance Manual 13.3.4 Equipment/Instrument Maintenance
Quality Assurance Manual13.3.5 Equipment/Instrument Performance Verification
PTmp12504 - Procedure for Instrument Maintenance and Performance Verification

The laboratory does have a preventive maintenance schedule and service logs

E-21 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Where appropriate, is equipment which is uncalibrated, broken, or otherwise out of service, clearly marked as such?

NOTE It is a requirement that equipment that is broken or out-of-service pending calibration be clearly marked as such unless it is such a condition or location that its status is obvious. For example, adjustable pipettes that require cleaning or recalibration must not be left such that they are apparently available for use. Larger equipment, such as centrifuges, must be clearly tagged as out-of-service if they are unsafe or require maintenance (e.g., due to fractured, corroded or unbalanced rotors of a centrifuge).

Objective Evidence

Quality Assurance Manual 13.3.5.5, 13.3.5.6 Equipment/Instrument Performance Verification Pipette calibration/verification records

The laboratory uses red tags to indicate an instrument or piece of equipment is out of service.

E-22 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory regularly monitor, and as necessary record, temperatures on all equipment where temperature control is critical for the application?

NOTE For some equipment (e.g., refrigerators, freezers) it is important to regularly monitor and to record critical temperatures (for example, where specimens are stored). At a minimum, temperatures and corrective action must be recorded where set limits have been exceeded. For some devices (e.g., heating blocks, water baths), temperature may be monitored and adjusted at the time of use.

Objective Evidence

6.8 Heating Blocks, Sand Baths, Incubators, Ovens
6.14 Refrigerators and Freezers
6.15 Thermometers

Reviewed refrigerator 14 temperature record log (Lot # A185137).

E-23 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are analytical balances cleaned, serviced and checked periodically by qualified service personnel?

NOTE Balances used for critical weighing (e.g., preparation of calibrations solutions or QC material) must be checked, and as necessary calibrated, by qualified personnel at least annually. Documentation of such service must be maintained.

Objective Evidence

The laboratory uses one analytical balance, which is serviced and calibrated annually by the approved, external calibration provider.

Quality Assurance Manual 6.4 Balances

Balance calibration records
Quarterly balance checks (internal)

Analytical balance appeared clean and serviced by an outside vendor and balance checks are up-to-date.

E-24 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory use standard weights for checking the accuracy of balances when critical weighing is performed?

NOTE Documentation of the checks must be maintained.

Objective Evidence

13.5.3 Procedure (Traceability of Measurement Standards)

A set of calibrated mass standards are used for evaluating the analytical balance prior to preparation of weighed powder standard solutions or performance verification of automatic diluters.

Diluter certification record for Hamilton ML600JE12962 # Dil 6
Solution preparation record for Ibuprophen.

E-25 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are in-house computer programs, spreadsheets and macros which are used to calculate or report analytical results being adequately validated?

NOTE In-house computer programs, spreadsheets or macros used to calculate or report analytical results must be validated prior to routine use and periodically checked thereafter (e.g., annually, or as appropriate for intended use). Backup copies of validated files must be kept secure from general use (e.g., physically secure, via password protection or read-only status). Spreadsheets in particular can easily have formulas in cells changed without it necessarily being obvious to the user. The extent of monitoring some macros or programs may simply be to ensure that it appears to do what it was written for, without any special checks (e.g., draw a set of 3 overlaid chromatograms). Validation of commercial software is not required.

Objective Evidence

Quality Assurance Manual 13.4 Electronic Data and Computer Software

All software used in calculating and reporting analytical results is "off the shelf" commercial (instrument software for quantitative analysis of specimens).

E-26 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have written criteria for corrective action for unacceptable instrument performance?

NOTE The SOP must contain some basic guidance on how to troubleshoot problems. In most instances this will be described as part of a section on the set-up and operation of the particular instrument and may be general in nature (e.g., no GC or LC peaks, peaks too small, retention times irreproducible, etc.). More extensive troubleshooting may be referenced to the appropriate manufacturer's manual. However, this must not replace the laboratory's own basic guide which must be in the SOP. Sometimes, corrective action may also be described as part of the individual analytical method, especially where a problem is commonly associated with a particular analyte (e.g., one prone to tailing and adsorption).

Objective Evidence

Procedure for Instrument Maintenance and Performance Verification 5.7 Troubleshooting

E-27 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is a record kept documenting when analytical chromatography columns are replaced?

NOTE This record will normally be kept in the maintenance log for the appropriate instrument. That record may also include a performance check using an extracted or unextracted calibrator, control or test mixture. Some laboratories may choose to evaluate columns using a cocktail of drugs, some of which are known to be susceptible to adsorption and tailing on columns with active sites. Documentation of column performance may form part of the analytical record, or may be kept as a separate log.

Objective Evidence

Assessor observed analytical column change, and subsequent performance check, is documented in the maintenance log for each chromatographic instrument (GC-MS/NPD 9).

E-28 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is there evidence that, prior to issuing the final report, the following have been reviewed by a qualified individual, and that the review was documented:
- chain of custody documentation?
- validity of the analytical data?
- quality control?
- final report?

NOTE No matter how good are the abilities of the laboratory to conduct accurate and precise analytical work, those efforts will be defeated unless the appropriate records are carefully reviewed for accuracy and completeness before the final report is issued. The SOP Manual must include a procedure for the final review of toxicology results prior to issuing the toxicology report. This must include chain of custody documentation, all qualitative and quantitative data, including relevant quality control, in addition to a clerical check of the final report. In most instances, the individual who signs the toxicology report will conduct the final review. However, in some circumstances, particularly in larger laboratories, responsibility for part of the review may be delegated to quality assurance or other qualified personnel. Different aspects of the review may be conducted by different people. A "qualified" person is defined as someone with sufficient training and experience to perform the stated review. If the laboratory uses a LIMS for data collection, processing and reporting, the system must be designed so that data review by appropriate personnel is required before a report can be released.

Case data from failed runs must be maintained (paper or electronic), as it forms part of the record of testing performed on any given specimen/case and may be important in the overall context of case review.

Objective Evidence

Quality Assurance Manual 12.4.2.1 Testing Batch Review
Quality Assurance Manual 12.4.2.3 Technical Review of Test Report and Examination Records
Quality Assurance Manual 12.4.2.4 Administrative Review of Test Report and Case File

Review of Case files ST-18-00963, ST-18-14800, ST-18-07074, ST-18-02796, ST-18-05594

E-29 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Was a review of all analytical data undertaken by at least one qualified person other than the analyst?

NOTE It is expected that the person who conducted an analysis will perform the initial technical review of the data. All data must undergo at least one additional documented technical review by a qualified person. That person must be sufficiently experienced to adequately understand the data they are reviewing.

Objective Evidence

Quality Assurance Manual 12.4.2.3 Technical Review of Test Report and Examination Records

The Test Report and associated analytical data is included in the technical review of case file ST-18-00963, ST-18-14800, ST-18-07074, ST-18-02796, ST-18-05594.

E-30 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Where possible, was the final report reviewed in the light of information provided with the specimen?

NOTE Wherever possible, analytical results must be reviewed with reference to whatever case history or other information is available. This can be a valuable quality assurance check. For example, if a fatal concentration of a drug were found in an individual who appeared to be the innocent victim of an industrial accident, further review of the analytical data would be warranted. At the very least, review of the case history must ensure that the appropriate toxicants were tested for. However, it is also recognized that such review may be very limited if a specimen is provided to perform a specific test with little or no additional information provided. If the laboratory is unable to test for certain drugs which were either requested, or that were available and which could be relevant to the death or incident, this must be stated on the report.

Objective Evidence

Quality Assurance Manual 12.4.2.4 Administrative Review of Test Report and Case File

The Request for Analysis form and any other information submitted with the specimen can be found in the case file and is reviewed with the testing data and Test Report.

Case files ST-18-00963, ST-18-14800, ST-18-07074, ST-18-02796, ST-18-05594

E-31 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Was the information provided in the report supported by the available data and consistent with good laboratory practice?

NOTE Data must be available to fully support the results contained in the report (e.g., identification for reported analytes, valid calibration for quantitative results). Vague terms used to report the possible presence of an analyte, such as “indicated”, must be avoided unless properly defined as part of the report. Where presumptive, unconfirmed results are reported (e.g., positive cannabinoids immunoassay screen where the finding has little or no forensic importance), the fact that the result is presumptive and unconfirmed must be clearly stated.

Objective Evidence

Quality Assurance Manual 12.4.2.3 Technical Review of Test Report and Examination Records

Review of Case files ST-18-00963, ST-18-14800, ST-18-07074, ST-18-02796, ST-18-05594

E-32 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Where test results obtained from another laboratory are included in the report, was the name of the reference laboratory clearly stated?

NOTE If a test is referred out to another laboratory, the result received maybe incorporated into the report of the referring laboratory. Alternatively, the report of the reference laboratory may simply be attached or forwarded separately.

Objective Evidence

Quality Assurance Manual 12.6.7 Results from Subcontractors

The Test Report, ST-18-01641 refers to the report from the subcontractor (NMS), which is included.

E-33 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are records of testing data including laboratory accession numbers, specimen type, analyst and date of analysis being maintained for a minimum of 5 years or as otherwise mandated by local, state or federal authority, whichever is longer?

NOTE Before results are reported, each batch of analytical data shall be reviewed by scientific personnel with experience in the analytical procedures used in the laboratory. At a minimum this must include: chain of custody documentation, analytical data and calculations, and quality control data. This data must be retained for a minimum of 5 years in a manner that it can be easily retrieved if requested.

Objective Evidence

Operations Manual Chapter 3 Records Management; 3.1 Retention Time of Records (WSP retention schedule);

Case files and Test Reports are retained offsite after two years and maintained for 50 years.

Section F: IMMUNOASSAYS

F-Introduction — Conforming

Requirement

A number of immunoassays are used to screen for drugs and their metabolites, particularly the drugs of abuse. These immunoassays include, for example, enzyme immunoassay (EIA), kinetic interaction of micro particles in solution (KIMS), fluorescence polarization immunoassay (FPIA), and enzyme linked immunosorbent assay (ELISA).

Although these applications are suitable for the screening of urine specimens by commercial drug testing laboratories, they may not be of much use to the forensic toxicologist. Very often he/she needs to screen specimens other than urine and to use different cut-offs. It is certainly acceptable for them to do so provided that the modified assay has been validated by the laboratory and that this validation has been documented.

As with all qualitative assays it is necessary to analyze negative and positive controls with each batch of specimens. Positive controls must be targeted at a realistic concentration that appropriately challenges the assay (e.g., 125 - 200% of the cut-off). Negative controls may be spiked with analyte at an appropriate concentration below the cut-off (e.g., 50 - 80%), or may contain no analyte. The actual concentrations, frequency and position of controls will depend on the matrix and application. In many laboratories, immunoassay results are individually reported, and therefore accuracy and precision around the cut-off is important.

Objective Evidence

The Toxicology laboratory currently uses enzyme immunoassay (EMIT TSe12718).

F-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is the laboratory's instrumentation maintained and serviced regularly, according to the manufacturer's recommended protocol or as appropriate for the intended use? Are those records readily available to the technical staff operating the instrument?

NOTE In addition to containing instrument specifications and routine testing procedures, the instrument operator's manual contains recommended maintenance procedures to be performed daily, weekly, monthly, etc.; troubleshooting diagrams or flow charts and directions for equipment servicing that can be performed by the operator. Many operator manuals contain service log sheets and maintenance checklists that can be copied and used in the laboratory. Proper maintenance will increase the life span of the instrument and decrease the likelihood of instrument malfunction. These records must be readily available to the operator of the instrument and supervisory personnel responsible for data review. They are indicators that the instrument is operating properly.

Objective Evidence

PThd12506 Procedure for the Maintenance of Hamilton Microlab® Diluter-Dispensers
PThs12505 Procedure for the Maintenance of Headspace Gas Chromatograph Instruments
PTmp12504

All maintenance and service information is retained in the instrument maintenance binder.

F-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

If the immunoassay is being used to test specimens for which the assay is not approved by the manufacturer, or if the test method recommended by the kit manufacturer has been modified, has the laboratory validated those changes?

NOTE It is necessary for the laboratory to validate any modification to a commercially available immunoassay. There are three common situations under which this may occur. Following are suggested validation protocols:

1) Use of a different specimen from that recommended: the most common example of this situation is the analysis of blood rather than urine using assays designed and marketed for urine. In this case the laboratory has to document, for example, that there is adequate separation between negative specimens and the cut-off.

2) Use of a different cut-off from that recommended: the most common example of this situation is the lowering of the cut-off to detect any drug present. In this case the laboratory has to document that there remains adequate separation between a negative specimen and a positive one. If this is the case the laboratory must also document that there is adequate separation between negative specimens and the cut-off. For laboratories that have lowered the manufacturer's cut-offs, it is recommended that the response of the negative plus two standard deviations does not overlap the response of the cut-off.

3) Modification of the reagents: similar validation studies to those described for 1 and 2 are necessary, but in addition it may be necessary to confirm the cross-reactivities quoted by the manufacturer, particularly if the laboratory is using the kit to detect a drug grouping, for example the benzodiazepines. For qualitative assays it is required that the laboratory analyze replicate calibrators at the cut-off of the assay. The best example of the use of replicate calibrators is the calibration of an immunoassay using a cut-off calibrator. The SOP must clearly define the number of calibrators to be used, the criteria for acceptance of the calibrators and corrective action to be taken. At the very least, the laboratory must run the calibrators in duplicate and take the mean as the cut-off reading.

To verify that the immunoassay retains its specificity when used with an alternate matrix (e.g. liver homogenate in a blood-based assay) the laboratory must analyze a randomly selected set of specimens as part of method validation and confirm all immunoassay positives by a reference procedure, such as GC/MS[MS] or LC/MS[MS].

Objective Evidence

Review comparison study between Au400e to new Au400e to include matrix study. Tissue Homgenates are not performed.

F-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

If the laboratory routinely analyzes specimens other than those which the manufacturer recommends, were matrix matched controls being included?

NOTE This situation is most commonly encountered when the laboratory is using an immunoassay designed for urine and applying it to blood. In this case the laboratory must use calibrators and/or controls in a similar matrix. If the assay is being used for quantitation, it is also necessary that the concentrations of drugs in the controls have been verified by a separate reference procedure.

Objective Evidence

TSe12718 Screening of Biological Specimens by Enzyme Multiplied Immunoassay Technique (EMIT)

inteview with Amanda Black advised blood controls are used with blood samples. Review of case files ST-18-00963 and ST-18-14800

F-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory validate automatic pipetting /diluting equipment for potential carryover?

NOTE Very often the larger laboratories will use automatic pipetting/diluting equipment or automated analyzers. Because these instruments are used to analyze specimens that can contain large concentrations of analyte, it is important that the laboratory has validated this potential for carryover and taken corrective action if it occurs. An example of appropriate corrective action is reanalyzing consecutive positives with a negative control between them, when the first positive urine has a higher concentration than the carryover limit.

Objective Evidence

The method validation included use of all aspects of the Au400e automatic analyzer.

EMIT Validation and Comparison Study was performed to include evaluating for possible carryover.

Section G: CHROMATOGRAPHY AND MASS SPECTROMETRY – GENERAL QUESTIONS

G-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are quantitative calibrators or controls prepared in a matched matrix for the samples being analyzed or the equivalency of non-matched matrices demonstrated through validation studies?

NOTE It is important that an appropriate matrix be used to prepare calibrator and control samples, since the extraction efficiency of analytes may be matrix-dependent. For some forensic toxicology procedures, providing an appropriate matrix is no more difficult than for any other test. Typical examples include tissue homogenates, expired blood bank blood or plasma or urine. For others the matrix may be unique (e.g., decomposed tissues, bone, hair or nails) and providing a matrix blank can be very difficult. In such cases the laboratory must select the one that is closest to the specimen being analyzed. For example when hair is analyzed the digestion medium would be acceptable as a matrix blank.

It may be acceptable to analyze specimens of differing matrixes against a common calibration, if matrix-matched controls are run at the same time, or if it has been documented, that the assay is not significantly matrix-sensitive.

The use of standard addition is another acceptable approach to demonstrating that there is not a significant matrix affect with a particular specimen (i.e., running the specimen “as is” and with the addition of known amounts of analyte). Recovery of the “addition” must be within pre-defined limits (e.g., target +/-20%).

The use of stable-isotope (e.g., deuterated) internal standards can partially or wholly compensate for matrix effects. This must be confirmed as part of assay validation.

Objective Evidence

Quality Assurance Principles 4.2.2 Batch Analysis
Quality Assurance Principles 4.4.5 Calibrators
SOPs i.e., TCb12714 Basic Drug

Review of Validation Report for Basic Drug Confirmatory Method Using LC-MSMS (08-03-18)

G-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory only report quantitative results that are within a valid calibration range?

NOTE Normally, reporting results outside of the established calibration range is not valid. However, it is accepted that the laboratory director or designate may authorize reporting in a semi-quantitative manner, where doing so would provide the client with useful information (e.g.,

“less than X mg/L”, or “greater than the X mg/L” – where X is the lowest or highest calibrator).

Objective Evidence

Quality Assurance Manual 10.3 Technical Procedures and Methods
PQ12704 Validation Procedure for Confirmatory Methods
PQ12705 Validation Procedure for Screening and Qualitative Methods
Quality Assurance Principles 4.4 Calibrators; 4.16 Reporting

Values will lie within the limits of the LLOQ and ULOQ Values. Otherwise a dilution or increase in specimen may be required.

G-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

For qualitative and quantitative assays does the laboratory analyze positive and negative controls concurrently with each batch of specimens?

NOTE Case specimens must never be assayed in isolation. For example, a sample that tests negative must be supported by a positive control that is extracted and run simultaneously to demonstrate that there were no analytical deficiencies.

At least one positive control or calibrator must be included at the end of the run. For runs longer than 20 test samples, a calibrator or control must be injected mid-run. The mid-run and end-of-run calibrator or control can be a reinjection of extracts run earlier in that same run, or may be additional extracts. (Re)injection of calibrators and/or controls is a valid way of demonstrating stability of analytical instrumentation (e.g., GC/MS).

Objective Evidence

Quality Assurance Principles 4.2 Batch Analysis

Testing batch records for Amines by LC/MS/MS Worklist with test date 10-22-18; analyst Asa Louis
Case file ST-18-12418. Positive and negative controls are analyzed in every batch.

G-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are calibrators and controls analyzed in the same manner as unknowns?

NOTE All calibrators and controls have to be analyzed in the same manner as the specimens, where this is possible. One of the most common faults is that calibrators and controls are not subject to hydrolysis, or some other pre-treatment.

Objective Evidence

Quality Assurance Principles 4.3.1 Quality control samples will be processed in the same way as case specimens during testing.

TOX SOPs do not contain any provisions for separate treatment of calibrators, controls, or unknowns; they are processed the same. (i.e., Basic Drug Identification/Confirmation by Gas Chromatography-Mass Spectrometry/Nitrogen Phosphorus).

G-5 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is a valid calibration for each quantitative assay established using appropriate criteria for acceptance of that calibration?

NOTE Linearity of the procedure must be verified by using at least three positive calibrators. The concentration range of the calibrators should be such that they bracket the anticipated concentration range of the specimens (or dilutions). If the concentration of the specimen exceeds the concentration of the highest calibrator, the specimen must be diluted and re-extracted if accurate quantitation is required. Otherwise the specimen must be reported as having a concentration greater than the highest calibrator. A negative control must also be run to ensure that no significant analyte signal is contributed by the reagents or sample matrix. The “blank” sample is not considered a calibrator.

There are a variety of procedures for establishing the acceptability of calibration data, and these are often listed as options within data reduction software included with modern analytical instruments. Laboratories may use linear regression and define acceptability in part based on the “r2” value. Typically, values of greater than 0.98 are acceptable with non-deuterated internal standards and, for mass spectrometry, greater than 0.99 with stable isotope internal standards. For frequently run assays with a linear response, it may be valuable to monitor variables such as the slope of the calibration line. A significant deviation from historical values indicates a problem with the assay.

If the laboratory uses more than three calibration points, the SOP must clearly indicate how many points can be deleted and under what circumstances. The SOP must also address which results can be reported after calibrators are deleted.

Objective Evidence

Quality Assurance Principles 4.4 Calibrators
Quality Assurance Principles 4.5 Calibration Curve or Standard Curve

Validation Report for Volatiles by Headspace Gas Chromatography and Validation of HSGC Inst. 7, Limits of quantitation/linearity (date: Jan. 25, 2019).

G-6 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

For multi-point calibrations, are criteria established for acceptability of calibrations, and for individual calibrators when read back against the final calibration?

NOTE Generally calibrators should read-back values that are within +/-20% of their nominal value. A slightly wider acceptance value (e.g., +/-25% or +/-30%) may be acceptable for calibrators that approach the LOQ of the assay.

Objective Evidence

Quality Assurance Principles 4.4 Calibrators; 4.5 Calibration Curve or Standard Curve
General Requirements for Chromatographic Test Method Batch Data Analysis and Acceptance 7.3.1 Calibrators and Calibration Curves

Calibrators will be back-calculated against the contemporary calibration curve. The LLOQ is acceptable if its value is within ± 25% of the target and all other calibrators are acceptable if their values are within ± 20% of their targets, unless otherwise described in the SOP.

Calibrators for ethanol analysis will be deemed acceptable if their values are within ± 10% of their targets.

G-7 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

If the laboratory uses historical calibration, are controls run with each batch of specimens to verify validity of the calibration at or close to the reporting limits?

NOTE It is acceptable for laboratories to use historical calibration curves if they have demonstrated and documented the linearity and precision of the curve over time. If they do use historical curves, then they must validate the calibration by using controls with each batch of specimens. These controls must be such that they validate the calibration over the entire range of the curve.

Objective Evidence

Amanda Black, Quality Manager, advised the laboratory does not use historical calibrations.

G-8 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is an internal standard included in qualitative assays?

NOTE Laboratories must use at least one internal standard for qualitative chromatographic assays. By doing so the laboratory can monitor recovery of the batch and also determine whether a dilution is necessary for the quantitative assay. An internal standard will also assist in identifying the unknown analyte, if the laboratory uses relative retention times for this purpose.

The internal standard must have chemical and physical properties as similar to the analyte as possible. If the analyte is derivatized, the internal standard must form an analogous derivative. For mass spectrometric assays, isotopically labeled (e.g., deuterated) internal standards are recommended where available. Adequate method validation will allow for assessment of the adequacy of an internal standard. Some screening methods, such as LC/TOF, may require the use of multiple isotopically labeled internal standards.

Objective Evidence

Individual toxicology SOPs, examples below include:
TCa12717 Identification and Confirmation of Select Acidic and Neutral Drugs by Gas Chromatography
TCb12714 Basic Drug Ident/Confirmation by Gas Chromatography - Mass Spectrometry/Nitrogen Phosphorus Detection
TCb12744

G-9 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is an internal standard used for quantitative assays?

NOTE The laboratory must use an internal standard for quantitation using chromatographic procedures. It is not acceptable for the laboratory to add a “marker” after the extraction (and if done, derivatization) is completed. This is regarded as an external standard procedure.

The internal standard must have chemical and physical properties as similar to the analyte as possible. If the analyte is derivatized, the internal standard must form an analogous derivative. For mass spectrometric assays, isotopically labeled (e.g., deuterated) internal standards are recommended where available. Adequate method validation will allow for assessment of the adequacy of an internal standard. Many quantitative methods, such as LC/MS/MS, benefit from the use of multiple isotopically labeled internal standards.

Objective Evidence

Quality Assurance Principles 4.9 Internal Standard
Individual test method SOPs

The presence of internal standard was observed in data packets in case files.

G-10 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Is internal standard recovery monitored and action taken for unusually poor recovery?

NOTE The laboratory must monitor internal standard recovery in chromatographically based quantitative assays and investigate instances where the internal standard recovery is substantially reduced. Generally, internal standard recoveries less than 50% or greater than 200% relative to the calibrators or controls must be investigated. Where internal standard recovery is substantially reduced, it may or may not indicate possible quantitative inaccuracy depending on the appropriateness of the internal standard. Method validation will provide information on how sensitive the assay is to reduced internal standard recovery. This will usually depend on the appropriateness of the internal standard (e.g., isotopically labeled analogue of the target analyte or not). Standard addition to an aliquot of that specimen may be used to determine whether or not the low internal standard recovery has had a significant effect on the quantitation of the target analytes(s) and therefore whether reporting a quantitative result is appropriate.

Objective Evidence

Quality Assurance Principles 4.9.10 (Internal Standard)

SOP states that If a specimen's internal standard response, measured by peak area or height, is less than 50%, or greater than 200%, of that measured for calibrators and QC samples, this will be investigated.

G-11 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a documented policy and procedure for determining whether carry-over or contamination may have occurred in qualitative and quantitative assays?

NOTE Laboratories often use automated injection systems. Because these instruments are used to analyze specimens that can contain large concentrations of analyte, it is important that the laboratory has validated this potential for carryover and taken corrective action if it occurs. Other possible sources of contamination include homogenizers, inadequately cleaned glassware (e.g., micro-vials) and transfer pipettes. Appropriate corrective action might include analyzing solvent or matrix-based blanks between specimens.

The policy or procedure must include cross-checks to, for example, determine that if an analyte is detected in one screening procedure or assay that it is detected in all other procedures of comparable sensitivity capable of detecting the analyte. Other examples may be to review screening results carefully to ensure that where a high concentration of analyte is present in one specimen, that the extract injected or sampled that follows it is examined for the possibility of carry-over.

Detection of carry-over or contamination may sometimes require a careful review of the analytical results against the case history, and may require the reanalysis of specimens, or analysis of multiple specimens. Where a laboratory routinely quantifies analytes in separate assays from that used to detect the substance, carry-over or contamination (within the laboratory) may be easy to detect. However, extreme caution is warranted where a drug is simultaneously detected and quantitated in a single specimen analyzed in a single assay. Analysis of a second aliquot for qualitative confirmation is strongly encouraged to preclude the possibility of sample mix-up, especially where the initial finding does not appear to be consistent with the circumstances of the case or medical record.

Objective Evidence

Quality Assurance Principles 4.11 Carryover

G-12 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are new assays appropriately validated before implementation?

NOTE It is important that each analytical procedure is adequately validated before it is implemented. The extent of the validation data will depend on the assay and its application. For qualitative assays it must include data on sensitivity and interferences. For quantitative assays it must include LOD, LOQ, calibration model, matrix effects, accuracy and precision.

Infrequently run quantitative assays (e.g., less than 5 times annually) may be regarded as "self-validating" if sufficient calibrators and controls are run to demonstrate linearity, precision and sensitivity. For example, if a multi-point matrix-matched calibration is run, if each calibrator when read against the graph is acceptable (e.g., +/-20% of nominal value), and case results are only to be reported out within the calibrator range, and if an independently prepared control is run and acceptable (e.g., +/-20% of target), the assay may be regarded as "valid". For such assays, and subject to sample availability, it is good practice to include a "standard addition" tube where a known amount of standard has been added to the unknown in order to assess recovery and linearity.

Objective Evidence

Quality Assurance Manual 10.3.6 Method Validation
PQ12703 Validation Procedure for Screening and Qualitative Methods
PQ12704 Validation Procedure for Confirmatory Methods

Review of Validation Report for Basic Drug Confirmatory Method Using LCMSMS

G-13 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Do validation of quantitative LC-based mass spectrometric quantitative assays include adequate ion suppression studies?

NOTE For LC-based mass spectrometric assays (e.g., LC/MS and LC/MS/MS), the validation studies must include an evaluation of ion suppression.

Objective Evidence

Validation Procedure for Confirmatory Methods 5.14 Evaluation of Ionization Suppression/Enhancement

Reviewed "Validation Report for Basic Drug Confirmatory Method Using LC-MSMS" to include ion suppression studies.

G-14 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are validation records summarized and the data maintained?

NOTE Validation data must be retained for at least 10 years. Validation records must be recorded and summarized in such a manner that they can readily be reviewed and understood by another toxicologist without reference to the individual who performed the validation. The validation package must clearly summarize what was done, what results were obtained, and what the conclusions were. Laboratories will not be unduly penalized for failure to have available documentation of validation that occurred prior to their initial accreditation. However, the ABFT Accreditation Program reserves the right to request assay validation, or re-validations of an assay, where performance issues are evident. Analysis of proficiency test samples can serve to demonstrate ongoing validation of a method, especially where those analyses are performed frequently (e.g., ethanol).

Objective Evidence

Quality Assurance Manual 10.3.6.3 (Method Validation)
Validation Procedure for Confirmatory Methods 5.17 Validation Summary/Report
Validation Procedure for Screening and Qualitative Methods 6.10 Validation/Summary Report

Method validation records are retained on a computer and a review of "Validation Report for Basic Drug Confirmatory Method Using LC-MSMS" cosisted of a summary report with data.

G-15 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

For assays that have been in use for several years, is data available in a summarized format that substantiates validity and reliability?

NOTE For older, established assays, the laboratory must have data available that demonstrates the validity and reliability of the assay. Where the assay is for multiple analytes, the data must be available for all analytes covered by the assay. For quantitative assays, the data may include information on the linearity of calibrations and the performance of calibrators and/or controls over a specified period of time.

Objective Evidence

Data is available and summarized in a format that substantiates validity and reliability per conversation with Amanda Black and witnessing a spreadsheet containing summarized data.

G-16 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have documented criteria or guidance for designating a positive qualitative result?

NOTE The SOP Manual must clearly define the criteria for designating and reporting a positive analytical result. Definition of a positive analytical result by chromatography may be based on retention time, relative retention time, or retention index. For LC-spectrophotometry or GC-mass spectrometry it may be based on comparison with reference library data and a statistically based “fit”. In gas chromatography-mass spectrometry it may be based on a combination of retention time and “fit”, or if selected ion monitoring is used a comparison of ion ratios with those in the calibrator.

Definition of a “positive identification” may require a combination of positive analytical results, for example a positive immunoassay and a positive GC/MS result. It is important that the laboratory recognizes the distinction between a positive analytical result and a positive specimen. Reporting of a positive specimen based on a single positive analytical result is strongly discouraged unless the result can be corroborated by additional information such as contained in a pharmacy, medical or investigative record. However, it is recognized that in some circumstances, performance of a second or replicate test may not be possible due to limited sample volume, in which case this must be stated in the toxicology report. Alternatively some laboratories may report certain results as “unconfirmed”. Note: The guidance contained within this paragraph is not intended to apply to isolated, referred, tests performed by a reference laboratory where a toxicologist or other forensic professional in another jurisdiction is responsible for overall management and reporting of toxicology findings for the case.

Objective Evidence

General Requirements for Chromatographic Test Method Batch Data Analysis and Acceptance
7.4.4.1 Identification (Screening)

Screening of Biological Specimens by Enzyme Multiplied Immunoassay Technique (EMIT)
Section 18.8 Batch Acceptance
Section 18.10 Reporting

Cannabinoid Screening by Liquid Chromatography - Tandem Mass Spectrometry
Section 42.7 Reporting

G-17 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are positive results from non-specific screening tests confirmed by another, more specific method, such as mass spectrometry?

NOTE Confirmation of the identity of an analyte in a different specimen from that used for the first test (e.g., urine and blood) is acceptable, as is confirmation in a second aliquot of the same specimen. However, confirmation of a drug or toxicant in the same original extract would not normally be regarded as acceptable, since that would not rule out the possibility that the vial or extraction tube used was contaminated.

The quantitation of an analyte may serve as acceptable confirmation of its identity if it was initially detected by a significantly different method

(e.g., GC or HPLC quantitation of a drug detected by immunoassay).

Use of one immunoassay test to confirm the results of another immunoassay test is not acceptable.

Notwithstanding the above, it is recognized that in some circumstances a suitable second test procedure is not available, or is unnecessary. For example, the probability that a 75% carboxyhemoglobin result obtained by a properly conducted spectrophotometric assay is incorrect in a well documented suicide is exceedingly low, whereas the unexpected finding of a 30% carboxyhemoglobin by a similar determination in blood from a motor vehicle accident victim holds a lower degree of certainty. However, at the very least the presence of a drug or toxicant must be verified in more than one specimen, or if only one specimen is available by replicate analyses on different occasions and with adequate positive and negative controls in the same matrix.

Nonetheless, use of a second confirmatory technique is encouraged for all analytes, including ethanol (e.g., GC dual-column analysis, enzymatic, or colorimetric) and carbon monoxide (e.g., visible spectrophotometry, palladium chloride or GC).

If only a single specimen (e.g. blood) is available on a specific case, a separate repeat analysis must be performed for confirmation of a positive result.

Effective January 1, 2014 ethanol must be determined using a 2-column GC method or alternate method of equivalent or greater forensic strength.
Reporting the possible presence of drugs of abuse or other drugs in forensically significant circumstances, based on immunoassay screening results, is discouraged, but may be acceptable in some circumstances and if reported an appropriate comment is made. For example, a positive cannabinoid screening result in a person known to be a chronic cannabis user may be acceptable if the result is not forensically significant (e.g., unrelated suicide) and the report states that the result has not been confirmed by a more specific method. Alternatively, reporting a positive cannabinoid result for a motor vehicle driver based on only an immunoassay test is not acceptable.

Objective Evidence

Quality Assurance Principles
4.1 Confirmation of Positive Results; 4.13 Mass Spectrometry

Samples are confirmed in a second sample/second sampling.

Section H: GAS CHROMATOGRAPHY-MASS SPECTROMETRY (GC/MS[MS]) and LIQUID CHROMATOGRAPHY-MASS SPECTROMETRY (LC/MS[MS]) and TOF

H-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have written procedures for the set-up, tuning and operation of the mass spectrometer(s)?

NOTE The SOP must contain sufficient information and directions to enable the operator to set up and adjust each instrument for the required assay. As a minimum, this must include the normal operating conditions for the gas chromatographic portion of the assay, other routine MS tuning and checks that need to be made (e.g., PFTBA tuning, ion source pressure, air and water checks). This must include a description of the settings for any software used for the acquisition and/or processing of analytical data. Settings and descriptions that are critical to or necessary for the individual assays must be described in the method. However, more general descriptions of instrument set-up and operation may be described in a separate section of the SOP. Preventive maintenance that must be performed may be listed in the individual assays, especially if it is critical to the assay. Routine preventive maintenance such as ion source or ion trap cleaning (GC/MS) or spray chamber cleaning (LC/MS) may often be described in a separate section of the SOP, or in a log-book or chart which stays with the respective instrument.

Records of MS tuning must be maintained for at least as long as the analytical records. Hard copies of all MS tuning records are typically kept in chronological order in a folder or binder for easy review if a problem subsequently developed. However, an electronic record is also satisfactory, particularly if the records are in a database format so that they may be searched or graphically displayed. LC/MS instruments are usually more stable than GC/MS instruments and therefore full tuning each day is usually not necessary.

The laboratory must have predetermined MS tuning criteria for routine operation, as determined by the manufacturer. However, if the laboratory is performing selected ion monitoring assays, selected tuning may be performed (e.g., to favor the high mass region). Criteria must normally be set to monitor the amount of air and water in the system (i.e., as a measure of whether the system is “leaking”). Typically, nitrogen (as m/z 28) is <10% and water (m/z 18) is <5%, relative to m/z 69 of PFTBA.

The manufacturer usually identifies LC/MS[MS] tuning criteria. Some manufacturers provide commercial tuning solutions, whereas others recommend procedures based on target analytes or other chemicals.

If the tuning parameters are outside the acceptable values set by the laboratory, there must be evidence of corrective action. Sometimes this is indicated directly on the MS tuning records. Often, the corrective action is recorded in a logbook or service record.

Objective Evidence

Procedure for the Tune and Evaluation of Mass Spectrometers PTms12503
MS Perameters can be found in the individual SOPs

H-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

If the laboratory uses GC/MS full scan for mass spectral identification, is there adequate written criteria or guidance for identifying a positive spectral match?

NOTE This is a difficult area to define, particularly in terms of a mathematical fit or “quality match”. However, as a minimum, operators must ensure that all of the diagnostic ions present in the reference spectra are present in the unknown. There may be additional ions in the ‘unknown’ spectrum due to minor interferences that cannot be removed by background subtraction, but all of the diagnostic ions present in the reference spectrum much be present in the ‘unknown’ unless absent due to low absolute abundance. Relative abundances of the diagnostic ions, as well as relative retention times must always be considered in designating a “positive” match.

Objective Evidence

General Requirements for Chromatographic Test Method Batch Data Analysis and Acceptance
7.4.4.1 Identification (screening, basic drug by GC-Ms/NPD)

Documented spectrum agreement should be 75 or greater wherever possible and A reference spectrum for the compound found in a published article, research paper, other reference material or electronic library match

H-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

If the laboratory uses LC/MS 'full' scan or related methods scan for mass spectral identification, is there adequate written criteria or guidance for identifying a positive match?

NOTE LC/MS spectra (or first stage LC/MS/MS) tend to be relatively simple and often consist mainly of an M+1 or M-1 base peak, plus isotope and/or adduct ions. While such spectra may be useful for indicating the molecular weight of the analyte, the relative lack of spectra information limits the certainty of identifying the substance specifically. Additional use of retention time can increase the confidence of identification. Running scans at 4 – 6 different cone voltages can further improve the accuracy of identification if additional fragments can be generated. However, LC/MS scans are often only useful as a screen for tentative identification of analyte or perhaps for confirmation together with another mass spectra method.

Objective Evidence

The laboratory does not use LC-MS full scan methods.

H-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

If the laboratory uses LC/TOF* data for mass spectral identification, is there adequate written criteria or guidance for identifying a positive match?
NOTE Like LC/MS spectra LC/TOF spectra tend to be relatively simple and often consistent mainly of a M+1 or M-1 base peak, plus isotope and/or adduct ions. However, TOF data provides the additional information of mass accuracy to 3 or 4 decimal places, thereby considerably improving the chances of identifying the molecular formula of the analyte. Additional use of retention time can increase the confidence of identification significantly. However, LC/TOF scans are useful as a screen for tentative identification of analyte or perhaps for confirmation together with another mass spectra method. Criteria for acceptable retention time deviation and mass deviation must be used as part of the criteria for evaluating LC/TOF data (e.g., minimum mass accuracy of +/-5 millimass units). *Also applies to high resolution data not derived using TOF technology.

Objective Evidence

The laboratory is in the process of finalizing an LC/TOF/MS screening method. Criteria in the validation study for acceptance has been determined.

Documented validation study for LC/TOF/MS was made available while onsite.

H-5 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

If the laboratory uses commercial software to assist in mass spectral identification (e.g., GC/MS[MS], LC/MS[MS], LC/TOF applications), is there adequate written criteria or guidance for identifying a positive match that includes review of the underlying mass spectral data?

NOTE Laboratories must not solely use algorithms or "match factors" built into commercial software for identification of analytes. While such factors may be a very useful guide, the user must understand the underlying basis for software-aided identification and must be able to review the underlying data in order to visually confirm the general basis for the software match.

Objective Evidence

Interview with Amanda Black affirmed that the laboratory does not currently use "match factors" for identification. The forthcoming LC-TOF-MS screening method does use a total score factor however, identification will include evaluation of other components: retention time deviation, mass deviation and isotope abundance/spacing.

H-6 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

If the laboratory uses GC/MS selected ion monitoring for identification, does the laboratory compare ion ratios and retention times between calibrators, controls and unknowns?

NOTE If the laboratory uses selected ion monitoring to simultaneously identify and quantitate certain analytes, whenever possible, three ions must be monitored for the analyte and two ions for the internal standard. For GC/MS, the qualifying ions must be +/-20% of the target ion, relative to a calibrator. Typically, retention times must be +/-2% relative to a calibrator included in the same run. Identification and measurement of suitable secondary ions may be more difficult with LC/MS, and ion ratios may be less stable or be more concentration-dependent. C-13 isotope ions are not suitable for use as qualifier ions (e.g., M+1 vs. M+2).

If selected ion monitoring is being carried out for quantitation only, and the analyte has already been identified separately, the above criteria may be considered desirable rather than mandatory. It is realized that for some methods (e.g., GC/NCI, GC/PCI) it may be difficult to choose multiple ions. Even with EI ionization, some spectra may contain only one or two ions that are >5% relative abundance. Therefore, additional or complimentary methods of identification become important. However, measurement of ion ratios is encouraged where possible. Although

LC/MS spectra tend to give simpler spectra than with EI ionization, it is often possible to alter the “fragmentor voltage” or “cone voltage” in order to induce fragmentation, and therefore production of secondary ions.

Objective Evidence

General Requirements for Chromatographic Test Method Batch Data Analysis and Acceptance
7.3.1.2 Criteria for Batch Acceptance; 7.4.1 Criteria for Case Specimen Acceptance

Criteria for acceptance of calibrators, controls and case specimens within a GC-MS SIM testing batch includes comparison of ion ratios and retention times.

H-7 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Where practical, is the confirmation of analyte identity by LC/MS/MS (screening OR quantitation) where possible based on at least 2 transitions in addition to retention time criteria?

NOTE The transition relative abundances must be +/-20% of target, relative to a calibrator. Typically, retention times must be within +/-3% relative to a calibrator included in the same run.

Objective Evidence

Confirmation methods for amines, opiates, cannabinoids, buprenorphine, fentanyl, select basic drugs, tricyclic antidepressants and benzodiazepines utilize LC-MS/MS with two transitions monitored for each target compound.

The following Individual SOPs:
TCa12739 Amines
TCb12744 Basic Drug
TCc12727 THC

Section I: OTHER ANALYTICAL TECHNIQUES

I-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

If used, are spectrophotometers, including CO-Oximeters, appropriately calibrated and maintained?

NOTE In addition to containing instrument specifications and suggested testing procedures, the instrument operator's manual contains recommended maintenance procedures to be performed daily, weekly, monthly, etc.; troubleshooting diagrams or flow charts and directions for servicing the equipment that can be performed by the operator. Many operator manuals contain service log sheets and maintenance checklists that can be copied and used in the laboratory. Proper maintenance will increase the life span of the instrument and decrease the likelihood of instrument malfunction. These records must be readily available to the operator of the instrument and supervisory personnel responsible for data review. They are indicators that the instrument is operating properly. In all spectrophotometers, spectral resolution is proportional to light energy. The ability of the system to transmit light energy through windows, cuvettes and pellets depends upon their freedom from scratches, deposits, moisture, etc.

Objective Evidence

Not in the scope of accreditation.

I-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

If used, is capillary electrophoresis equipment appropriately calibrated, maintained, and performed in a manner that is appropriate for the application?

NOTE Fundamentally, operation and maintenance of CE equipment is similar to the principles applied to other analytical equipment such as GC/MS or LC/MS[MS]. The same principles apply to performing a calibration, as well as the evaluation of calibrators and QC samples.

Objective Evidence

Not in the scope of accreditation.

I-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

If used, is thin layer chromatography performed in a manner that is appropriate for the application?

NOTE Appropriate standards or calibrators (as applicable) must be included with each TLC plate. The standards must include drugs/compounds that test the chromatographic range of the TLC plate, and that test all phases of the staining/development system.

Negative and appropriate positive controls must be extracted and run through the entire procedure and which include drugs/compounds that test the chromatographic range of the TLC plate and the staining/development system.

Solvent mixtures must be prepared fresh, as required for the chromatographic system. If a mixture of solvents is used, certain components

will evaporate with time faster than others, leading to poor extraction efficiency or irreproducible migration rates. If a commercial kit is used, the manufacturer's instructions should be followed.

Objective Evidence

Not in the scope of accreditation

I-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

If used, are atomic absorption, graphite furnace spectrophotometry or ICP-MS techniques performed in a manner that is appropriate for the application?

Objective Evidence

The laboratory does not use these techniques.

Section J: BIOCHEMISTRY

J-Introduction — Not Applicable

Requirement

Some toxicology laboratories are periodically asked to perform certain biochemistry tests on postmortem specimens such as vitreous humor or partially hemolyzed blood. Examples include glucose, sodium, chloride, urea and creatinine. Results of such testing may assist forensic pathologists in the determination of cause of death. It is also recognized that performance of biochemistry tests on postmortem specimens may not be practical in all clinical laboratories.

The equipment used to perform such tests in forensic laboratories is generally designed and validated to perform such tests on unhemolyzed serum or plasma, or urine. If the methodology is used to test postmortem samples, the methods must be appropriately validated for forensic specimens. The components of a good validation may be similar to that for other tests, such as chromatography based tests. However, the scope and nature of the validation should be considered fit for purpose.

Objective Evidence

Not in the scope of accreditation.

J-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

Is the laboratory instrumentation maintained and serviced regularly, according to the manufacturer's recommended protocol?

NOTE In addition to containing instrument specifications and routine testing procedures, the instrument operator's manual contains recommended maintenance procedures to be performed daily, weekly, monthly, etc.; troubleshooting diagrams or flow charts and directions for equipment servicing that can be performed by the operator. Many operator manuals contain service log sheets and maintenance checklists that can be copied and used in the laboratory. Proper maintenance will increase the life span of the instrument and decrease the likelihood of instrument malfunction. These records must be readily available to the operator of the instrument and supervisory personnel responsible for data review. They are indicators that the instrument is operating properly. Changes in instrument and reagent performance with time can be noted.

Objective Evidence

Not in the scope of accreditation.

J-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

Are maintenance records readily available to the technical staff operating the equipment?

Objective Evidence

The laboratory does not perform biochemical testing.

J-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

If a commercial methodology is applied to specimens that have not been approved by the manufacturer is the application validated by the laboratory?

NOTE The vast majority of biochemical analyses are sodium, potassium, chloride, urea, creatinine and glucose in vitreous humor, performed using commercial equipment and reagents designed for clinical testing of serum or plasma. It is necessary for the laboratory to validate any modification to a commercially-available assay such as running a different specimen for which the commercial assay was designed (e.g.,

vitreous instead of serum or plasma), or running a specimen of a very different condition (e.g., badly hemolyzed blood versus serum or plasma).

When these tests are performed in a forensic toxicology laboratory, staff is responsible for ensuring that the equipment is properly maintained and serviced, and that adequate matrix-matched positive controls are run. Preparing a positive vitreous electrolyte control may be as simple as pooling multiple specimens to obtain an adequate volume. The control material may be tested multiple times in order to establish an acceptable QC range. As necessary, such a pool may be augmented with additional analyte such as glucose to establish a useful QC range.

Objective Evidence

Not in the scope of accreditation.

Section K: OTHER EXHIBITS

K-Introduction — Not Applicable

Requirement

Forensic toxicology laboratories may periodically be asked to qualitatively, and occasionally quantitatively, analyze non-biological exhibits for the presence of drugs and other toxicants. Such exhibits include drug abuse paraphernalia such as syringes, spoons, pipes etc., as well as powders, pills, capsule contents, possible drug residues (e.g., dry residue or fluid in drinking vessels). Analysis of such exhibits is generally well within the capability of any competent forensic toxicology laboratory and the findings may assist forensic pathologists in determining the cause or manner death.

Objective Evidence

Not in the scope of accreditation

K-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

Is analysis of drugs in non-biological samples performed in a manner that prevents cross-contamination with assays used to perform testing on non-biological samples?

NOTE Analysis of high-concentration exhibits such as pills, powder and drug paraphernalia should ideally be performed in an area that is separate for that used for biological exhibits such as blood and urine, and ideally using different analytical equipment. Where it is not practical to do so, care must be taken to avoid any cross-contamination or carry-over. Use of disposable glassware to minimize cross-contamination is important. Also the use of post-analysis checks such as the analysis of negative control material can demonstrate the absence of contamination once the analysis is complete.

Objective Evidence

Not in the scope of accreditation

K-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

Is determination of the identity of a drug or other toxicant performed in an acceptable, scientifically sound manner, as for forensic toxicology testing on biological samples?

Objective Evidence

Not under the Scope of Accreditation

K-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

Is determination of the concentration of a drug or other toxicant performed in an acceptable, scientifically sound manner, as for forensic toxicology testing on biological samples?

Objective Evidence

Not included under scope of accreditation

K-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Not Applicable

Requirement

Where a laboratory chooses to perform testing on non-biological samples, are the procedures used clearly outlined in an SOP, or as necessary, supplemented by bench notes that are retained with the analytical record or case file?

Objective Evidence

Not under the scope of accreditation

Section L: SAFETY

L-1 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory follow good laboratory safety practices?

NOTE It is essential that the laboratory personnel work in a safe and healthy environment. In the event of an accident, proper equipment must be available to render first aid to the victim and prevent harm to others. Safety must be both the individual and collective responsibilities of all laboratory personnel. The safety manual must, at a minimum, address the following:
- specimen handling, including infectious material and the disposal of biological specimens
- handling and disposal of solvents, reagents, and other chemicals
- handling and disposal of radioactive materials
- handling and disposal of laboratory glassware
- responses to personal injuries
- responses to spillage of biological specimens, chemicals, solvents, reagents or radioactive materials
- evacuation procedures
- regulations governing protective clothing, eating, drinking, or smoking in the laboratory.

Objective Evidence

TLD Safety Plan (TLDSafety_Rev 3)
The laboratory has two designated Safety Officers; Kelly Daniel and Darlene Valencia

Handling and disposal of radioactive materials not applicable

L-2 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have a safety manual which clearly defines all safety policies and which is readily available to all laboratory staff?

NOTE Laboratory personnel must be familiar with the contents of the safety manual and must have easy access to it. The manual may be owned and controlled by the institution that the forensic toxicology is a part of (e.g., larger laboratory system or hospital).

Each laboratory must be aware of and abide by local, state and federal regulations that may exceed minimum standards established on the basis of the above considerations.

Objective Evidence

Operations Manual 2.2 Safety

The laboratory follows a strict chemical hygiene, waste disposal and general laboratory safety program that is documented in the TLD Safety Plan.

L-3 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Are the laboratory's work areas clean and free of clutter?

NOTE General cleanliness and good housekeeping must be apparent. The laboratory must have proper general ventilation and adequate heating, cooling and humidity control. Adequate and proper lighting must be provided for personnel to carry out assigned tasks.

Objective Evidence

Operations Manual 2.1 Space

The technical assessor performed a walk through of the lab area.

L-4 ABFT 2013 Forensic Toxicology Laboratory Requirements — Conforming

Requirement

Does the laboratory have adequate room to accommodate all technical work and safe storage of laboratory and supplies?

NOTE Inadequate space reduces the efficiency of laboratory operations and increases the risk of mishandling or contaminating evidence. Inadequate space also reduces personnel morale and thus adversely affects productivity. The physical design of the laboratory should enhance the flow of work from the time of specimen receipt to final disposal. Interrelationship of functional areas must be laid out in a manner that will facilitate the use of equipment and instruments. Each employee must have enough space to accomplish assigned tasks. Sufficient space must be provided for each instrument to facilitate its use and operation. Personnel must have space available for writing reports and other official communications. An area for general supplies and materials intended for immediate use must be available. An area must be provided for laboratory and clerical supplies that are in excess of short-term use.

Objective Evidence

Operations Manual 2.1 Space
Operations Manual 2.2 Safety
Operations Manual 2.5 Security of Volatile Chemicals

A walk through was performed and observed adequate space to accommodate technical work and storage of supplies.