Houston Forensic Science Center

2018 - 17025T - Reassessment

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ANSI-ASQ National Accreditation Board

United States

Signature

Completed by Mike Healy on 2018-10-07

Audit Objective Evidence

4.1 Organization

4.1.1 ISO/IEC 17025:2005 — Conforming

Requirement

Is the laboratory or the organization of which it is part of, an entity that can be held legally responsible?

NOTE (from ANAB Accreditation Requirement)
Publicly funded government laboratories are recognized as meeting 4.1.1.

Objective Evidence

Yes, HFSC is a publicly funded laboratory.
Reviewed "Governing Documents" link on hfsc website.

4.1.2 ISO/IEC 17025:2005 — Conforming

Requirement

Is the laboratory carrying out testing/calibration activities to meet the requirements of the International Standard and satisfying the needs of customers, regulatory authorities, or organizations providing recognition?

Objective Evidence

Quality Manual clause 4.1.2 and Reference 3. in the Quality Manual.

4.1.2.1 ANAB Accreditation Requirement — Conforming

Requirement

If an National DNA Index System (NDIS) participating laboratory, is there conformance to requirements in the NDIS Operational Procedures Manual and in applicable FBI Quality Assurance Standards?

Objective Evidence

Quality Manual clause 4.1.2.1 , DNA Standard Operating Procedures and a previously submitted FBI QAS report from 2016.

4.1.3 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory’s management system cover work carried out in the laboratory’s permanent facilities, at sites away from its permanent facilities, or in associated temporary/mobile facilities?

Objective Evidence

Quality Manual clause 4.1.3 and observations at the Fannin and Travis facilities.

4.1.4 ISO/IEC 17025:2005 — Conforming

Requirement

If the laboratory is part of an organization performing activities other than testing or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on testing or calibration activities defined in order to identify potential conflicts of interest?

NOTE 1 Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard.

NOTE 2 If the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.

Objective Evidence

Quality Manual clause 4.1.4; HFSC is not part of a larger organization even though it is partially housed in the Houston Police Dept.
Note 2 is applicable based on "Governing Documents" found on their website.

4.1.5 ISO/IEC 17025:2005 — Conforming

Requirement

a) Does the laboratory have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures? (see also 5.2)

b) Does the laboratory have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work?

c) Does the laboratory have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?

d) Does the laboratory have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity?

e) Does the laboratory define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services?

f) Does the laboratory specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and or calibrations?

g) Does the laboratory provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results?

h) Does the laboratory have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations?

i) Does the laboratory have a member of staff who is appointed as quality manager (however named) who, irrespective of other duties and responsibilities, has the defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; does the quality manager have direct access to the highest level of management at which decisions are made on laboratory policy or resources?

NOTE 1 Individuals may have more than one function and it may be impractical to appoint deputies for every function.

j) Does the laboratory have deputies appointed for key managerial personnel?

k) Does the laboratory ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system?

Objective Evidence

a) Quality Manual 4.1.4
b) Quality Manual 4.1.5
c) Quality Manual 4.1.5.2 and 4.13.1.3
d) Conflict of Interest policy.
e) Organizational charts.
f) Quality Manual 4.1.4.2
g) h) and i) Quality Manual 4.1.5.2. See 4.2.6, 4.1.5.1 and HFSC organizational chart for additional information.
j & k) Quality Manual 4.1.5.

4.1.5 ANAB Accreditation Requirement — Conforming

Requirement

a).1 Does the laboratory have a laboratory director whose duties are defined?

h).1 Does the laboratory have designated individual(s) responsible for technical management for each discipline?

NOTE 2 (from ANAB Accreditation Requirement)
A person may have technical management responsibility for more than one discipline.

Objective Evidence

Quality Manual 4.1.5, organizational chart and review of Job descriptions for lab director and technical leaders.

4.1.6 ISO/IEC 17025:2005 — Conforming

Requirement

Does top management ensure that appropriate communication processes are established in the laboratory and that communication occurs regarding the effectiveness of the management system?

Objective Evidence

Quality Manual 4.1.6 , review of company meetings and observation of HFSC intranet usage.

4.1.7 ANAB Accreditation Requirement — Conforming

Requirement

Are key managerial personnel and top management designated?

Objective Evidence

Quality Manual 4.1.4-4.1.4.2, 4.1.5-4.1.5.2.and review of the organizational charts.

4.2 Management system

4.2.1 ISO/IEC 17025:2005 — Resolved Nonconformity

Requirement

Has the laboratory established, implemented, and maintained a management system appropriate to the scope of its activities? Has the lab documented its policies, systems, programs, procedures, and instructions to the extent necessary to assure the quality of the test/calibration results? Is the system's documentation communicated to, understood by, available to, and implemented by appropriate personnel?

NOTE 1 (from ANAB Accreditation Requirement)
When the testing laboratory is part of a larger organization, some management system elements may be contained in organization documents.

NOTE 2 (from ANAB Accreditation Requirement)
"…document … to the extent necessary to assure the quality of test results" includes analysis and data interpretation to arrive at a test result, opinion or interpretation.

Objective Evidence

Review of Technical Records, quality documents and interviews of staff were conducted. Review of technical records in the Forensic Biology Discipline revealed that individuals who performed another interpretation on data that had been previously interpreted a few years earlier and who performed the required technical reviews were not in conformance with HFSC DNA SOP policy 4.9.1.2 that states: If an analyst has not been proficiency tested on a legacy test kit within the last two calendar years, then the Technical Leader must document and approve the completion of the analyst's review of the validation data and standard operating procedures of the legacy test kit.

Nonconformity Resolution

Review of technical records in the Forensic Biology Discipline revealed that individuals who performed another interpretation on data that had been previously interpreted a few years earlier and who performed the required technical reviews were not in conformance with HFSC DNA SOP policy 4.9.1.2 that states: If an analyst has not been proficiency tested on a legacy test kit within the last two calendar years, then the Technical Leader must document and approve the completion of the analyst's review of the validation data and standard operating procedures of the legacy test kit.

Completion note: The Corrective Action report submitted, along with the September 10, 2018 edits to the DNA General SOP section 4.9.1.2 have resolved this non-conformity.

4.2.2 ISO/IEC 17025:2005 — Conforming

Requirement

Are the laboratory's management system policies defined in a quality manual (however named), including a quality policy statement? Are overall objectives established in the management system and reviewed during management review? Is the quality policy statement issued under the authority of top management?

Does the quality policy statement include at least the following:
a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers?
b) the management's statement of the laboratory's standard of service?
c) the purpose of the management system related to quality?
d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work?
e) the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system?

NOTE 1 The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

Objective Evidence

HFSC Quality Manual 4.2.2 Quality Policy Statement.

4.2.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the management system:
a) incorporate, or directly reference, the current, published version of the Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel, or equivalent document, as part of the laboratory management's commitment to good professional practice?
b) ensure annual review of the document by all laboratory personnel and maintain a record of the review?
c) ensure appropriate actions are taken when necessary?

NOTE An equivalent document is one that covers the same topics and demonstrates that the relevant aspects are covered.

Objective Evidence

Quality Manual 4.2.2.1 and 4.2.2.2

4.2.3 ISO/IEC 17025:2005 — Conforming

Requirement

Does evidence exists showing top management is committed to the development and implementation of the management system and to continually improving its effectiveness?

Objective Evidence

Quality Manual 4.2.3 and observation of management reviews.

4.2.4 ISO/IEC 17025:2005 — Conforming

Requirement

Does top management communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements?

Objective Evidence

Quality Manual clause 4.2.4 and Company meetings.

4.2.5 ISO/IEC 17025:2005 — Conforming

Requirement

Does the quality manual include or make reference to supporting procedures including technical procedures? Does the quality manual outline the structure of documentation used in the management system?

Objective Evidence

Quality Manual clause 4.2.5

4.2.6 ISO/IEC 17025:2005 — Conforming

Requirement

Are the roles/responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with the International Standard, defined in the quality manual?

Objective Evidence

Quality Manual 4.2.6 and 4.1.4.

4.2.7 ISO/IEC 17025:2005 — Conforming

Requirement

Does top management ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented?

Objective Evidence

Quality Manual 4.2.7 and review of the Qualtrax system.

4.3 Document control

4.3.1 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test/calibration methods, as well as drawings, software, specifications, instructions, and manuals?

NOTE 1 In this context “document” could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

NOTE 2 The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.

NOTE 3 (from ANAB Accreditation Requirement)
Equipment and software manuals maintained only for general reference purposes are not subject to document control requirements. In this context, “general reference purposes” means that laboratory personnel are not required by the laboratory to follow specific procedures or instructions contained in the equipment or software manual.

Objective Evidence

Quality Manual 4.3.1 and review of the Qualtrax system.

4.3.2.1 ISO/IEC 17025:2005 — Conforming

Requirement

Are all documents issued to personnel in the lab as part of the management system reviewed and approved for use by authorized personnel prior to issue? Is a master list or an equivalent document control procedure identifying current revision status and distribution of documents in the management system established and readily available to preclude use of invalid and/or obsolete documents?

NOTE (from ANAB Accreditation Requirement)
“Authorized personnel” is not limited to the laboratory director. One or more authorized persons may be identified based on the types of documents for review and approval.

Objective Evidence

Quality Manual 4.3.2.1
Qualtrax files were observed by Lead Assessor and approvals were documented.

4.3.2.2 ISO/IEC 17025:2005 — Conforming

Requirement

Do(es) the procedure(s) adopted ensure that:

a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed?
b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirement?
c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use?
d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked?

Objective Evidence

Quality Manual clause 4.3.2.2
Review of Qualtrax program found corrective action for an obsolete drug standard form.
Qualtrax program tracks current version of forms and references when the previous versions became obsolete.

4.3.2.3 ISO/IEC 17025:2005 — Conforming

Requirement

Are management system documents generated by the lab uniquely identified? Does such identification include the date of issue and/or revision identification, page numbering, total number of pages or a mark to signify the end of the document, and issuing authority(ies)?

Objective Evidence

Quality Manual clause 4.3.2.3
New version of Quality Manual was issued prior to the on site assessment.
Qualtrax files were reviewed to show changes from previous version.

4.3.3.1 ISO/IEC 17025:2005 — Conforming

Requirement

Are changes to documents reviewed and approved by the same function that performed the original review unless specifically designated otherwise? Do designated personnel have access to pertinent background information upon which to base their review and approval?

Objective Evidence

Quality Manual clause 4.3.3.1
Document histories were observed in Qualtrax.

4.3.3.2 ISO/IEC 17025:2005 — Conforming

Requirement

Is (where practicable) the altered or new text identified in the document or appropriate attachments?

Objective Evidence

Quality Manual clause 4.3.3.2
Document histories were reviewed in Qualtrax and new text for changes shown in red font.

4.3.3.3 ISO/IEC 17025:2005 — Conforming

Requirement

If the lab's document control system allows for amendment of documents by hand pending re-issue of documents, are procedures and authorities for such amendments defined? Are amendments clearly marked, initialed, and dated? Is a revised document formally re-issued as soon as practicable?

Objective Evidence

Quality Manual 4.3.3.3 specifies the hand amendment of documents is not allowed and was not observed on site.
Amendments are reflected as changes to the document and tracked in Qualtrax software program.

4.3.3.4 ISO/IEC 17025:2005 — Conforming

Requirement

Are procedures established to describe how changes in documents maintained in computerized systems are made and controlled?

Objective Evidence

Quality Manual clause 4.3.3.4
Qualtrax administrator is a Quality Specialist and Qualtrax permissions are managed by the Quality Division.
The security for access to the laboratory's Qualtrax system was observed on site.

4.4 Review of requests, tenders and contracts

4.4.1 ISO/IEC 17025:2005 — Conforming

Requirement

Has the laboratory established and maintained procedures for the review of requests, tenders, and contracts? Do the policies and procedures for these reviews leading to a contract for testing and/or calibration ensure that:
a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2)?
b) the laboratory has the capability and resources to meet the requirements?
c) the appropriate test and/or calibration method is selected and capable of meeting the customers' requirements (see 5.4.2)?
Were any differences between the request or tender and the contract resolved before any work commenced? Was each contract acceptable both to the laboratory and the customer?

NOTE 1 The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way.

NOTE 2 The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programmes using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

NOTE 3 A contract may be any written or oral agreement to provide a customer with testing and/or calibration services.

Objective Evidence

Quality Manual 4.4.1 and observations of client services/case management personnel intake procedures.

4.4.1.a).1 ANAB Accreditation Requirement — Conforming

Requirement

Is the extent of database (e.g., CODIS, AFIS, NIBIN) searches communicated to customers and updated as needed?

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

Objective Evidence

Review of a sampling of applicable reports from Biology, Latent Prints and Firearms.
Quality Manual 4.4.2

4.4.2 ISO/IEC 17025:2005 — Conforming

Requirement

Are records of review, including any significant changes, maintained? Are records maintained of pertinent discussions with a customer relating to the customer's requirements or results of the work during the period of execution of the contract?

NOTE For review of routine and other simple tasks, the date and the identification (e.g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

Objective Evidence

Quality Manual clause 4.4.2 and 4.4.3 . Communications Logs were observed in sampling of case records.

4.4.3 ISO/IEC 17025:2005 — Conforming

Requirement

Does the review also cover any work that is subcontracted by the lab?

Objective Evidence

Quality Manual 4.4.4

4.4.4 ISO/IEC 17025:2005 — Conforming

Requirement

Is the customer informed of any deviation from the contract?

Objective Evidence

Quality Manual clause 4.4.5

4.4.5 ISO/IEC 17025:2005 — Conforming

Requirement

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

Objective Evidence

Quality Manual 4.4.6

4.5 Subcontracting of tests and calibrations

4.5.1 ISO/IEC 17025:2005 — Conforming

Requirement

When a laboratory subcontracts work whether because of unforeseen reasons (e.g. workload, need for further expertise, or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency, or franchising arrangements), is work placed with a competent subcontractor? A competent subcontractor is one that, for example, complies with the International Standard for the work in question.

NOTE (from ANAB Accreditation Requirement)
Transferring an item for testing from one location to another location within a system operating under the same management system is not considered subcontracting.

Objective Evidence

Quality Manual 4.5.1 and observation of approved subcontractor list.

4.5.1.1 ANAB Accreditation Requirement — Conforming

Requirement

If available, does the laboratory use a subcontractor accredited to an appropriate international standard by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement with a scope of accreditation that covers the services being subcontracted?

NOTE Determining an “appropriate international standard” is the responsibility of the laboratory.

Objective Evidence

Quality Manual clause 4.5.1 and mandatory Texas Forensic Science Commission accreditation.

4.5.2 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer (preferably in writing)?

Objective Evidence

Quality Manual 4.5.2

4.5.3 ISO/IEC 17025:2005 — Conforming

Requirement

Is the laboratory responsible to the customer for the subcontractor’s work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used?

Objective Evidence

Quality Manual 4.5.3

4.5.4 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question?

Objective Evidence

Quality Manual 4.5.4 and review of Subcontractor List

4.6 Purchasing services and supplies

4.6.1 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory have a policy and procedure for the selection and purchasing of services and supplies it uses that affect the quality of tests and/or calibrations? Do procedures exist for purchase, reception, and storage of reagents and laboratory consumable materials relevant for tests and calibrations?

Objective Evidence

Quality Manual 4.6.1 and 4.6.2. Observations of supply storage areas.

4.6.2 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory ensure purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for test and/or calibrations concerned? Do services and supplies used comply with specified requirements? Are records of actions taken to check compliance maintained?

Objective Evidence

Quality Manual 4.6.2 Review of sectional Quality Control records and SOPs.

4.6.3 ISO/IEC 17025:2005 — Conforming

Requirement

Do purchasing documents for items affecting the quality of laboratory output contain data describing services and supplies ordered? Are these purchasing documents reviewed and approved for technical content prior to release?

NOTE The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the management system standard under which they were made.

Objective Evidence

Quality Manual 4.6.3 Review of sectional SOPs.

4.6.4 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory evaluate suppliers of critical consumables, supplies, and services which affect the quality of testing and calibration, and maintain records of these evaluations and a list of those approved?

Objective Evidence

Quality Manual clause 4.6.4 Review of Approved Vendor list.

4.6.4.1 ANAB Accreditation Requirement — Conforming

Requirement

Are the reference standards, reference materials, and calibrations of equipment/reference standards used to establish and/or maintain measurement traceability viewed as critical?

Objective Evidence

Quality Manual 4.6.4 and 5.6.3. Observations in discipline sections.

4.7 Service to the customer

4.7.1 ISO/IEC 17025:2005 — Conforming

Requirement

Is the laboratory willing to cooperate with customers or their representatives in clarifying the customer's request to monitor the laboratory's performance in relation to work performed, provided the laboratory ensures confidentiality to other customers?

NOTE 1 Such cooperation may include: a) providing the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer; b) preparation, packaging, and dispatch of test and/or calibration items needed by the customer for verification purposes.

NOTE 2 Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, should be maintained throughout the work. The laboratory should inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.

Objective Evidence

Quality Manual 4.7.1
Houston FSC puts out a quarterly newsletter, maintains a public website with SOP's posted on it and has regular meetings with its largest contributor (HPD).

4.7.2 ISO/IEC 17025:2005 — Conforming

Requirement

Does evidence exist that the laboratory encourages feedback, both positive and negative, from customers or other parties? Is the feedback used to improve the management system, testing/calibration activities, and customer service?

NOTE Examples of the types of feedback include customer satisfaction surveys and review of test or calibration reports with customers.

Objective Evidence

Quality Manual 4.7.2 and inspection of management reviews and sampling of customer feedback.

4.8 Complaints

4.8 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory have a policy and procedure for resolution of complaints received from customers or other parties? Are records maintained of all complaints and of investigations and corrective actions taken by the laboratory? (see also 4.11)

Objective Evidence

Quality Manual 4.8 and review of completed Complaint Forms in Qualtrax.

4.9 Control of nonconforming testing and/or calibration work

4.9.1 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory have a policy and procedures that shall be implemented when any aspect of its testing/calibration work, or results of this work, do not conform to its own procedures or the agreed requirements of the customer?

Do the policies/procedures ensure that:
a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified?
b) an evaluation of the significance of the nonconforming work is made?
c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work?
d) where necessary, the customer is notified and work is recalled?
e) the responsibility for authorizing the resumption of work is defined?

NOTE Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

Objective Evidence

Quality Manual 4.10.2 and review of completed Quality Incident and Corrective Action workflows in Qualtrax.

4.9.2 ISO/IEC 17025:2005 — Conforming

Requirement

Where the evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, are corrective action procedures given in 4.11 promptly followed?

Objective Evidence

Quality Manual 4.10 and 4.11 and review of corrective actions in Qualtrax.

4.10 Improvement

4.10 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?

Objective Evidence

Quality Manual 4.10 Review of Management reviews, internal audits, improvement ideas and corrective actions in Qualtrax.

4.11 Corrective action

4.11.1 ISO/IEC 17025:2005 — Conforming

Requirement

Has the laboratory established a policy and a procedure and designated appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified?

NOTE A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers and from staff observations.

Objective Evidence

Quality Manual 4.11 and 4.11.1
Review of nonconformance workflows in Qualtrax.

4.11.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the procedure for corrective action require establishment of a reasonable timeframe for completion for each corrective action?

Objective Evidence

Quality Manual clause 4.11
Qualtrax workflows reviewed target completion in 30 working days from quality division notification.
The Quality Division acknowledges there may be instances where this timeframe is not reasonable.

4.11.2 ISO/IEC 17025:2005 — Conforming

Requirement

Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem?

NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

Objective Evidence

Quality Manual 4.11.2
Observed in Qualtrax incident/corrective action workflows reviewed.

4.11.3 ISO/IEC 17025:2005 — Conforming

Requirement

Selection and implementation of corrective actions: Where corrective action is needed, does the laboratory identify potential corrective actions? Does it select and implement the action(s) most likely to eliminate the problem and to prevent recurrence? Are corrective actions to a degree appropriate to the magnitude and risk of the problem? Does the laboratory document and implement any required changes resulting from corrective action investigations?

Objective Evidence

Quality Manual 4.11.3
Review of Qualtrax corrective action workflows.
Review of closed incident and corrective actions report posted to HFSC public website.

4.11.4 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory monitor the results to ensure that the corrective actions taken have been effective?

Objective Evidence

Quality Manual 4.11.5
Review of follow-up audits done in Biology.

4.11.5 ISO/IEC 17025:2005 — Conforming

Requirement

Where identification of non-conformances or departures casts doubts on the laboratory's compliance with its own policies and procedures or on its compliance with the International Standard, does the lab ensure the appropriate areas of activity are audited in accordance with 4.14 as soon as possible?

NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

Objective Evidence

Quality Manual 4.11.5
Review of follow-up audits done in Biology.

4.12 Preventive action

4.12.1 ISO/IEC 17025:2005 Conforming

Requirement

Are needed improvements and potential sources of non-conformances, either technical or concerning the management system, identified? If preventive action is required, are action plans developed, implemented, and monitored to reduce the likelihood of occurrence of such non-conformances and to take advantage of opportunities for improvement? If improvements opportunities are identified, are action plans developed, implemented, and monitored to take advantage of opportunities for improvement?

Objective Evidence

Quality Manual 4.12
Review of Preventative Action Reports.

4.12.2 ISO/IEC 17025:2005 Conforming

Requirement

Do procedures for preventive actions include initiation of such actions and application of controls to ensure that they are effective?

NOTE 1 Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

NOTE 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

Objective Evidence

Quality Manual clause 4.12.
Review of Preventive Action workflows in Qualtrax.

4.13 Control of records

4.13.1.1 ISO/IEC 17025:2005 Conforming

Requirement

Does the laboratory establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records? Do the quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions?

Objective Evidence

Quality Manual clause 4.13.1.1
Review of case records scanned into LIMS and management reviews in Qualtrax.

4.13.1.1.1 ANAB Accreditation Requirement Conforming

Requirement

Do the procedures for records specify what technical and administrative record(s) will be in a test record if all related technical and administrative records are not maintained?

NOTE The components of a test record are not required to exist in a single location.

Objective Evidence

Quality Manual clause 4.13.1.1.1 and review of a sampling of case records, training records and proficiency tests.

4.13.1.1.2 ANAB Accreditation Requirement Conforming

Requirement

Are administrative records identifiable to the specific test record(s)?

NOTE Multi-paged administrative records which are bound together in some manner may be identified by the test record identifier one time.

Objective Evidence

Quality Manual 4.13.2.4 and review of a sampling of case records.

4.13.1.2 ISO/IEC 17025:2005 Conforming

Requirement

Are all records legible and stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss? Are retention times of records established?

NOTE Records may be in any media, such as hard copy or electronic media.

Objective Evidence

Quality Manual 4.13.1.2.
Review of case files in LIMS system.

4.13.1.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the retention policy consider applicable legal requirements?

Objective Evidence

Quality Manual 4.13.1.2
Review of a sampling of case reports in records retention system.

4.13.1.2.2 ANAB Accreditation Requirement — Conforming

Requirement

If an original record, paper or other media, is captured as an electronic record, and the original record will be destroyed, does the laboratory ensure that the electronic record is complete prior to destruction of the original record?

Objective Evidence

Quality Manual 4.13.1.2
Review of a sampling of case reports in records retention system.

4.13.1.2.3 ANAB Accreditation Requirement — Conforming

Requirement

If abbreviations or symbols specific to the laboratory are used, is the meaning of the abbreviations or symbols defined by the laboratory?

Objective Evidence

Quality Manual clause 4.13.2.6 and review of sectional SOPs for abbreviation lists.

4.13.1.3 ISO/IEC 17025:2005 — Conforming

Requirement

Are all records held secure and in confidence?

Objective Evidence

Quality Manual 4.13.1.3
Security observed on access to laboratory facilities and computerized systems.

4.13.1.4 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory have procedures to protect/back-up records stored electronically and to prevent unauthorized access to or amendment of these records?

Objective Evidence

Quality Manual 4.13.1.4
Secured access to LIMS system observed.

4.13.2.1 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory retain records of original observations, derived data, and sufficient information to establish an audit trail, calibration records, staff records, and a copy of each test report/calibration certificate issued, for a defined period? Do records for each test/calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test/calibration to be repeated under conditions as close as possible to the original? Do records include the identity of personnel responsible for the performance

of the sampling, test/calibration and checking of results?

NOTE 1 In certain fields it may be impossible or impractical to retain records of all original observations.

NOTE 2 Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.

NOTE 3 (from ANAB Accreditation Requirement)
The phrase “original observations” includes electronic media such as audio or video recordings.

Objective Evidence

Quality Manual 4.13.2.1
Review of a sampling of case records.

4.13.2.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Are technical records to support a test report (including test 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 Manual 4.13.2.5 and review of a sampling of case records.

4.13.2.1.2 ANAB Accreditation Requirement — Conforming

Requirement

Is each technical record:
a)be traceable to a unique test record identifier?
b) reflect the date(s) that testing was performed?
c) of a permanent nature?

NOTE b) Testing date(s) may be reflected as a range of dates or the date of individual test performance.

Objective Evidence

Quality Manual 4.13.2.2 and review of a sampling of case records.

4.13.2.2 ISO/IEC 17025:2005 — Conforming

Requirement

Are observations, data, and calculations recorded at the time they are made and identifiable to the specific task?

Objective Evidence

Quality Manual 4.13.2.2, review of a sampling of case records and observations of analysts performing case work.

4.13.2.2.1 ANAB Accreditation Requirement — Conforming

Requirement

If an observation, data, or a test result 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 Manual 4.13.2.2

4.13.2.3 ISO/IEC 17025:2005 — Conforming

Requirement

When mistakes occur in records, is each mistake crossed out (not erased, made illegible, or deleted) and the correct value entered alongside? Are all such alterations to records signed or initialed by the person making the correction? In the case of records stored electronically, are equivalent measures taken to avoid loss or change of original data?

Objective Evidence

Quality Manual 4.13.2.3
Review of a sampling of case records.

4.13.2.3.1 ANAB Accreditation Requirement — Conforming

Requirement

Are all changes made to technical records as a result of verification or technical review tracked?

Objective Evidence

Quality Manual 4.13.2.3 and review of a sampling of technical and administrative reviews associated with case records.

4.14 Internal audits

4.14.1 ISO/IEC 17025:2005 — Conforming

Requirement

Does the lab periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with requirements of the management system and the International Standard? Does the internal audit program address all elements of the management system, including the testing/calibration activities? Does the quality manager have the responsibility to plan and organize audits as required by the schedule and requested by management? Are such audits carried out by trained/qualified personnel who are, wherever resources permit, independent of the activity to be audited?

NOTE The cycle for internal auditing should normally be completed in one year.

Objective Evidence

Quality Manual 4.14.1
Review of audit reports in Qualtrax.

4.14.1.1 ANAB Accreditation Requirement — Conforming

Requirement

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

Objective Evidence

Quality Manual 4.14.1.1
Review of audit reports.

4.14.1.2 ANAB Accreditation Requirement — Conforming

Requirement

Do internal audits include direct observation of a sampling of testing within each discipline?

Objective Evidence

Quality Manual 4.14.3 and review of internal audits.

4.14.2 ISO/IEC 17025:2005 — Conforming

Requirement

If audit findings cast doubt on the effectiveness of operations or on the correctness or validity of the laboratory's test/calibration results, does the laboratory take timely corrective action and notify customers in writing if investigations show that the lab results may have been affected?

Objective Evidence

Quality Manual 4.14.2 and review of Corrective Action Reports.

4.14.3 ISO/IEC 17025:2005 — Conforming

Requirement

Are the areas of activity audited, the audit findings, and corrective actions that arise from them recorded?

Objective Evidence

Quality Manual 4.14.3
Review of audit reports and associated corrective action workflows in Qualtrax.

4.14.4 ISO/IEC 17025:2005 Conforming

Requirement

Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?

Objective Evidence

Quality Manual 4.14.4
Reivew of a follow up audit conducted in Biology.

4.15 Management reviews

4.15.1 ISO/IEC 17025:2005 Conforming

Requirement

In accordance with a predetermined schedule and procedure, does the laboratory's top management periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements?
Does the review take account of:
• the suitability of policies and procedures?
• reports from managerial and supervisory personnel?
• the outcome of recent internal audits?
• corrective and preventive actions?
• assessments by external bodies?
• the results of interlaboratory comparisons or proficiency tests?
• changes in the volume and type of the work?
• client feedback?
• complaints?
• recommendations for improvement?
• other relevant factors, such as quality control activities, resources and staff training?

NOTE 1 A typical period for conducting a management review is once every 12 months.

NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

NOTE 4 (from ANAB Accreditation Requirement)
Also see ISO/IEC 17025:2005, Clause 4.2.2.

Objective Evidence

Quality Manual 4.15.1
Reviewed Management Review reports in Qualtrax.

4.15.2 ISO/IEC 17025:2005 Conforming

Requirement

Are findings from management reviews and actions that arise from them recorded? Does management ensure that those actions are carried out within an appropriate/agreed timescale?

Objective Evidence

Quality Manual 4.15.2
Reviewed last Management Review in Qualtrax.

4.15 Management reviews

4.15.1.1 ANAB Accreditation Requirement Conforming

Requirement

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

Objective Evidence

Quality Manual 4.15.1
Review of last Management Review posted in Qualtrax August 2017.
Next one is scheduled for after assessment. (August 2018)

5.1 General

5.1.2 ISO/IEC 17025:2005 — Conforming

Requirement

The extent to which factors contribute to the total uncertainty of measurement differs considerably between types of tests/calibrations. Does the laboratory take into account these factors in developing test/calibration methods and procedures, in training and qualification of personnel, and in selection and calibration of the equipment it uses?

Objective Evidence

Quality Manual 5.1.1 and 5.1.2
Review of a sampling of case records and analyst training records in Seized Drugs and Toxicology.

5.1.3 ANAB Accreditation Requirement — Conforming

Requirement

Are reagents prepared in the laboratory labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number, and, as applicable, storage requirements? Are records maintained identifying who made the reagent and the components used in preparation?

Objective Evidence

Quality Manual 5.1.3
Review of sectional Reagent Logs and records.

5.1.4 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a procedure for routinely checking the reliability of its reagents? Does the reliability testing occur before use or, if appropriate, concurrent with testing?

NOTE The routine recorded use of appropriate quality control procedures is a suitable method to ensure the continued reliability of reagents.

Objective Evidence

Quality Manual 5.1.4 and review of sectional SOP's.

5.2 Personnel

5.2.1 ISO/IEC 17025:2005 — Conforming

Requirement

Does management ensure the competence of all who operate specific equipment, perform tests/calibrations, evaluate results, and sign test reports/calibration certificates? When using staff which are undergoing training, is appropriate supervision provided? Are personnel performing specific tasks qualified on the basis of appropriate education, training, experience, and/or demonstrated skills, as required?

NOTE 1 In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the customer.

NOTE 2 The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have: relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service; knowledge of the general requirements expressed in the legislation and standards; and an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.

Objective Evidence

Quality Manual 5.2.1
Review of authorization memos, training binders, and competency tests results.

5.2.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Do personnel who issue a report that includes the result of a test, a series of tests, an opinion, or an interpretation meet the minimum education requirements below?

Disciplines:
Biology
Wildlife Forensics
Fire Debris and Explosives
Geological Materials
Gunshot Residue
Materials (Trace)

Seized Drugs
Toxicology
Minimum Educational Requirements: A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.

Disciplines:
Bloodstain Pattern Analysis
Firearms/Toolmarks
Footwear and Tire
Document Examination
Friction Ridge
Digital Evidence
Video/Imaging Technology and Analysis
Crime Scene Investigation
Fire and Explosion Investigation
Minimum Educational Requirements: The educational requirement(s) specified in the job description

Disciplines:
Anthropology
Disaster Victim Identification
Odontology
Minimum Educational Requirements: An advanced degree in anthropology, dentistry, or medicine

NOTE Minimum educational requirements apply to personnel working in any discipline of testing for which training begins after the date of initial accreditation in that discipline under these requirements.

Objective Evidence

Quality Manual 5.2.6.1
Review of Qualtrax shows transcripts and/or diplomas for analysts.

5.2.1.2 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory management define the minimum education and experience requirements that must be met for ensuring competence of personnel:
a) designated as laboratory director (see clause 4.1.5.a).1)?
b) designated as technical management (see ISO/IEC 17025 2005, clause 4.1.5.h)?
c) performing specific tasks related to testing (see ISO/IEC 17025 2005, clause 5.2.5)?
d) performing specific tasks that create items (e.g., test-fired ammunition, photos, trace evidence collection, DNA swabs, etc.) that could be used for testing?

Objective Evidence

Quality Manual 5.2.6.1 and reviw of job descriptions.

5.2.2 ISO/IEC 17025:2005 — Conforming

Requirement

Does management formulate goals with respect to the education, training, and skills of laboratory personnel? Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel? Is the training programme relevant to the present and anticipated tasks of the laboratory? Is the effectiveness of the training actions evaluated?

Objective Evidence

Quality Manual 5.2.2 and review of discipline Training Programs. Review of a sampling of analysts training records.

5.2.2.1 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, civil law and testimony?
e) provisions for retraining?
f) provisions for maintenance of skills and expertise?
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 17025:2005, sub-section 5.7 may be applicable to training programs.

Objective Evidence

Quality Manual 5.2 and sectional training manuals.
Sectional Training Manuals were reviewed.

5.2.2.2 ANAB Accreditation Requirement — Conforming

Requirement

Do all personnel regardless of academic qualifications or past work experience, complete a competency test(s) and achieve the intended result(s) prior to performing testing on a test item or performing specific tasks that create items that could be used for testing? Does the competency test(s), at a minimum, include practical examination(s) that cover the spectrum of anticipated work to be performed and, if applicable, issuing a test report and providing testimony?

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 Manual 5.2.6.2 and review of staff members training records.

5.2.3 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory use personnel who are employed by, or under contract to, the lab? Where contracted and additional technical and key support personnel are used, does the laboratory ensure such personnel are supervised and competent and that they work in accordance with the laboratory's management system?

Objective Evidence

Quality Manual 5.2.3
Interviews with Lieutenant over security and Digital Examiners who are employees of the Houston Police Department assigned to Houston Forensic Science Center.

5.2.4 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory maintain current job descriptions for managerial, technical, and key support personnel involved in tests/calibrations?

NOTE Job descriptions can be defined in many ways. As a minimum, the following should be defined: the responsibilities with respect to performing tests and/or calibrations; the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results; the responsibilities for reporting opinions and interpretations; the responsibilities with respect to method modification and development and validation of new methods; expertise and experience required; qualifications and training programmes; managerial duties.

Objective Evidence

Quality Manual 5.2.4
Review of several job descriptions.

5.2.5 ISO/IEC 17025:2005 — Conforming

Requirement

Does management authorize specific personnel to perform particular types of sampling, tests/calibrations, to issue test reports/calibration certificates, to give opinions and interpretations, and to operate particular types of equipment? Does the laboratory maintain records of relevant authorizations, competence, educational and professional qualifications, training, skills, and experience of all technical personnel, including contracted personnel? Is this information readily available and does it include the date on which authorization and/or competence is confirmed?

Objective Evidence

Quality Manual 5.2.5
Review of Authorization Memos in Qualtrax.

5.2.5.1 ANAB Accreditation Requirement — Conforming

Requirement

As applicable, does the authorization also address:
a) personnel that perform the technical review of a test record and related test report(s)?
b) personnel that perform specific tasks that create items that could be used for testing?

Objective Evidence

Quality Manual 5.2.6.2, 4th paragraph.

5.3 Accommodation and environmental conditions

5.3.1 ISO/IEC 17025:2005 — Conforming

Requirement

Do laboratory facilities for testing/calibration (including but not limited to energy sources, lighting, and environmental conditions), facilitate correct performance of tests/calibrations?

Does the laboratory ensure environmental conditions do not invalidate results or adversely affect the required quality of any measurement? Is particular care taken when tests/calibrations are undertaken at sites other than a permanent lab facility? Are the technical requirements for accommodation and environmental conditions that can affect the results of tests/calibrations documented?

Objective Evidence

Quality Manual 5.3.1 and observations of laboratory's facilities at Travis and Fannin.

5.3.2 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory monitor, control, and record environmental conditions as required by relevant specifications, methods, and procedures or where they influence the quality of the results? Is due attention paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned? Are tests/calibrations stopped when the environmental conditions jeopardize the results of the tests/calibrations?

Objective Evidence

Quality Manual 5.3.2 and review of temperature logs in discipline areas.

5.3.3 ISO/IEC 17025:2005 — Conforming

Requirement

Is there effective separation between neighboring areas in which there are incompatible activities? Are measures taken to prevent cross-contamination?

Objective Evidence

Quality Manual 5.3.3 , sectional SOPs and observations of the faciity.

5.3.4 ISO/IEC 17025:2005 — Conforming

Requirement

Is access to and use of areas affecting the quality of the tests/calibrations controlled? Does the laboratory determine the extent of control based on its particular circumstances?

Objective Evidence

Quality Manual 5.3.4, review of HFSC Security Manual and interview with LT in charge of facility security.

5.3.4.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a policy and procedure that addresses laboratory security and access to areas where testing activities occur? (also see ISO/IEC 17025:2005, clause 5.8.4).

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

Objective Evidence

Review of HFSC Security Manual and interview with LT in charge of facility security.

5.3.5 ISO/IEC 17025:2005 — Conforming

Requirement

Are measures taken to ensure good housekeeping in the lab? Are special procedures prepared where necessary?

Objective Evidence

Quality Manual 5.3.5 and observations of the laboratory's facilities.

5.4 Test and calibration methods and method validation

5.4.1 ISO/IEC 17025:2005 — Resolved Nonconformity

Requirement

Does the laboratory use appropriate methods and procedures for all tests/calibrations within its scope? Do these include sampling, handling, transport, storage, and preparation of items to be tested or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test/calibration data?

Does the laboratory have instructions on use and operation of all relevant equipment, and on handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests/calibrations? Are all instructions, standards, manuals, and reference data relevant to the work of the laboratory kept up to date and made readily available to personnel? (see 4.3) Do deviations from test/calibration methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer?

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

Objective Evidence

A review of sample of technical records, quality documents and interviews were conducted.
The FBI Quality Assurance Standard for Testing Laboratories - 2011 was completed.
A four person mixture that was interpreted by the Forensic Biology discipline was identified. This type of sample is a rare occurrence and interpretation requires approval from the DNA Technical Leader (DNA SOP, 13.1.5.5.7.1). In this instance the deviation was authorized and documented In the technical record file. Technical justification for the deviation is not supported by the current validation data.

Nonconformity Resolution

Related to QAS 8.3.2
A four person mixture that was interpreted by the Forensic Biology discipline was identified. This type of sample is a rare occurrence and interpretation requires approval from the DNA Technical Leader (DNA SOP, 13.1.5.5.7.1). In this instance the deviation was authorized and documented In the technical record file. Technical justification for the deviation is not supported by the current validation data.

Completion note: This Corrective Action report along with the edits made to the DNA Interpetation SOP on September 10, 2018, especially in Section 1.1.6.5.7 have resolved this non-conformity.

5.4.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory use appropriate procedures for test data interpretation?

Objective Evidence

Quality Manual 5.4.1.1 , review of sectional SOPs, and observations of analysts working cases.

5.4.1.2 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, 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

The SOP's for Latent Prints, Firearms and DNA analysis all address this standard.
This was verified by the Technical Assessors.

5.4.2 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory use test/calibration methods, including methods for sampling, which meet the needs of the customer and which are appropriate for the tests/calibrations it undertakes? Are the preferred methods published in international, regional, or national standards used? Does the laboratory ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so? When necessary, is the standard supplemented with additional details to ensure consistent application?

When the customer does not specify the method to be used, does the laboratory select appropriate methods that have been 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 lab-developed methods or methods adopted by the lab appropriate for the intended use and validated? Is the customer informed as to the method chosen? Does the laboratory confirm it can properly operate standard methods before introducing the tests/calibrations? If the standard method changes, is the confirmation repeated? Does the laboratory inform the customer when the method proposed by the customer is considered to be inappropriate or out of date?

Objective Evidence

Quality Manual 5.4.2 and review of a sampling of case records.

5.4.3 ISO/IEC 17025:2005 — Conforming

Requirement

Is introduction of test/calibration methods developed by laboratory for its own use a planned activity and assigned to qualified personnel equipped with adequate resources? Are plans updated as development proceeds and is effective communication among all personnel involved ensured?

Objective Evidence

Quality Manual 5.4.3 and review of validation studies.

5.4.4 ISO/IEC 17025:2005 — Conforming

Requirement

When it is necessary to use methods not covered by standard methods, are these subject to agreement with the customer and do they include a clear specification of the customer's requirements and the purpose of the test/calibration? Is the method developed validated appropriately before use?

NOTE For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:
a) appropriate identification;
b) scope;
c) description of the type of item to be tested or calibrated;
d) parameters or quantities and ranges to be determined;
e) apparatus and equipment, including technical performance requirements;
f) reference standards and reference materials required;
g) environmental conditions required and any stabilization period needed;
h) description of the procedure, including affixing of identification marks, handling, transporting, storing and preparation of items, checks to be made before the work is started, checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use, the method of recording the observations and results, any safety measures to be observed;
i) criteria and/or requirements for approval/rejection;
j) data to be recorded and method of analysis and presentation;
k) the uncertainty or the procedure for estimating uncertainty.

Objective Evidence

Quality Manual 5.4.4 and Digital and Multimedia Evidence sectional SOPs for exceptions.

5.4.5.2 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use? Is validation as extensive as is necessary to meet the needs of the given application or field of application? Does the laboratory record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use?

NOTE 1 Validation may include procedures for sampling, handling and transportation.

NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:
•calibration using reference standards or reference materials;
•comparison of results achieved with other methods;
•interlaboratory comparisons;
•systematic assessment of the factors influencing the result;
•assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

NOTE 3 When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

NOTE 4 (from ANAB Accreditation Requirement)
Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the laboratory itself (as in the case of laboratory developed methods or where significant modifications are made to previously validated methods).

Objective Evidence

Quality Manual 5.4.5.1-3 and review of validation studies.

5.4.5.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a procedure for method validation that:
a) encompasses the test process to include data interpretation?
b) establishes the data required to report a test result, opinion, or interpretation?
c) identifies limitations of the test method, reported test results, opinions, and interpretations?
d) specifies when a currently validated method, including associated data interpretation, needs additional validation?
e) requires a validation plan providing direction for parameter evaluation and parameter acceptance criteria to determine if the method is fit-for-purpose prior to starting a method validation?

NOTE Modifications to a validated method require evaluation to confirm that the changes do not have an adverse effect on the method's performance. The decision regarding which performance characteristics require additional validation is based on logical consideration of the specific parameters likely to be affected by the change(s).

Objective Evidence

Quality Manual 5.4.5.1
Review of method validation in Biology.

5.4.5.3 ISO/IEC 17025:2005 — Conforming

Requirement

Are the range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, relevant to the customers' needs?

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

Objective Evidence

Quality Manual 5.4.5.2.
Review of Validation methods in Toxicology.

5.4.5.4 ANAB Accreditation Requirement — Conforming

Requirement

Prior to implementation of a validated method that is new to the laboratory, was the reliability of the method demonstrated in-house against all documented performance characteristics of that method? Are the records of performance verification maintained for reference?

Objective Evidence

Quality Manual 5.4.5.3 and review of validation methods.

5.4.6.1 ISO/IEC 17025:2005 — Not Applicable

Requirement

Does the calibration laboratory or a testing laboratory performing its own calibrations, have and apply a procedure to estimate the uncertainty of measurement for all calibrations/types of calibrations?

Objective Evidence

Lab does not do calibrations.

5.4.6.2 ISO/IEC 17025:2005 — Conforming

Requirement

Do testing labs have and apply procedures for estimating uncertainty of measurement?
In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases, does the lab at least attempt to identify all the components of uncertainty and make a reasonable estimation, and ensure that the form of reporting of the result does not give a wrong impression of the uncertainty? Is the reasonable estimation based on knowledge of the performance of the method and on the measurement scope and does it make use of, for example, previous experience and validation data?

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:
•the requirements of the test method;
•the requirements of the customer;
•the existence of narrow limits on which decisions on conformity to a specification are based.

NOTE 2 In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

Objective Evidence

Quality Manual 5.4.6.2 and review of applicable sectional SOPs.

5.4.6.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Do testing laboratories have and apply a procedure to estimate the uncertainty of measurement for quantitative test results?

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

Objective Evidence

Quality Manual 5.4.6.2 and review of applicable sectional SOPs.

5.4.6.2.2 ANAB Accreditation Requirement — Conforming

Requirement

Does the procedure for estimation of measurement uncertainty:
a) require the specific measuring device or instrument used for a reported test result to have been included in or evaluated against the estimation of measurement uncertainty for that test 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%)?
d) specify the schedule to review and/or recalculate the measurement uncertainty?

Objective Evidence

Quality Manual 5.4.6.2
Sampling of case records in Seized Drugs and Toxicology.

5.4.6.3 ISO/IEC 17025:2005 — Conforming

Requirement

When estimating the uncertainty of measurement, are all uncertainty components which are of importance in the given situation taken into account using appropriate methods of analysis?

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

NOTE 2 The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

NOTE 3 For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see Bibliography).

Objective Evidence

Quality Manual 5.4.6.3 and review of sectional uncertainty documents.

5.4.6.4 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory maintain the following records for each 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?
h) the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty?

NOTE Records are not required to exist in a single location.

Objective Evidence

Quality Manual 5.4.6.4 and review of uncertainty records in different laboratory disciplines.

5.4.7.1 ISO/IEC 17025:2005 — Conforming

Requirement

Are calculations and data transfers subject to appropriate checks in a systematic manner?

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

Objective Evidence

Quality Manual 5.4.7.1 and review of sectional SOP's.

5.4.7.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the test record indicate the check was performed and who performed the check? When possible, was 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 Manual 5.4.7.1
Review of a sampling of case records.

5.4.7.2 ISO/IEC 17025:2005 — Conforming

Requirement

When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, does the laboratory ensure that:

a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use?
b) procedures are established and implemented for protecting the data and such procedures include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing?
c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data?

NOTE Commercial off-the-shelf software (e.g. wordprocessing, database and statistical programmes) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2 a).

Objective Evidence

Quality Manual 5.4.7.2 and observations of laboratory instrumentation with autosamplers,

5.4.7.2.a).1 ANAB Accreditation Requirement — Conforming

Requirement

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

Objective Evidence

Quality Manual 5.4.7.2

5.5 Equipment

5.5.1 ISO/IEC 17025:2005 — Conforming

Requirement

Is the laboratory furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests/calibrations (including sampling, preparation of test/calibration items and processing and analysis of test/calibration data)? In those cases where the laboratory needs to use equipment outside its permanent control, does it ensure that the requirements of the International Standard are met?

Objective Evidence

Quality Manual 5.5.1 and observations of the laboratory's facilities.

5.5.2 ISO/IEC 17025:2005 — Conforming

Requirement

Is equipment/software used for testing, calibration, and sampling capable of achieving the accuracy required and does it comply with the specifications relevant to tests/calibrations concerned? Are calibration programs established for key quantities or values of the instruments where these properties have a significant effect on the results? Before being placed into service, is equipment (including that used for sampling) calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications?
Is it checked or calibrated before use?

Objective Evidence

Quality Manual 5.5.2 and observations of the equipment in the laboratory.

5.5.3 ISO/IEC 17025:2005 — Conforming

Requirement

Is equipment operated by authorized personnel? Are up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) readily available for use by the appropriate lab personnel?

Objective Evidence

Quality Manual 5.5.3, review of Authorization Memos and observations of equipment manuals in the laboratory.

5.5.4 ISO/IEC 17025:2005 — Conforming

Requirement

Is each item of equipment and its software used for testing/calibration and significant to the result, when practicable, uniquely identified?

Objective Evidence

Quality Manual 5.5.4 and observations in the sections of the laboratory.

5.5.5 ISO/IEC 17025:2005 — Conforming

Requirement

Are records maintained of each item of equipment and its software significant to the tests/calibrations performed? Do the records include at least the following:

a) the identity of the item of equipment and its software?
b) the manufacturer's name, type of identification, and serial number or other unique identification?
c) checks that equipment complies with the specification (see 5.5.2)?
d) the current location, where appropriate?
e) the manufacturer's instructions, if available, or reference to their location?
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration?
g) the maintenance plan, where appropriate, and maintenance carried out to date?
h) any damage, malfunction, modification or repair to the equipment?

Objective Evidence

Quality Manual 5.5.5 and review of equipment records maintained by disciplines in the laboratory.

5.5.6 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory have procedures for safe handling, transport, storage, use, and planned maintenance of measuring equipment to ensure proper functioning and to prevent contamination or deterioration?

NOTE Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.

Objective Evidence

Quality Manual 5.5.6

5.5.7 ISO/IEC 17025:2005 — Conforming

Requirement

Is equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, taken out of service? Is it isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration/test to perform correctly? Does the laboratory examine the effect of the defect or departure from specified limits on previous tests/calibrations and institute the "Control of nonconforming work" procedure? (see 4.9).

Objective Evidence

Quality Manual 5.5.7
Observed out of service equipment stored in a specified area.

5.5.8 ISO/IEC 17025:2005 — Conforming

Requirement

Whenever practicable, is all equipment under the control of the laboratory and requiring calibration labeled, coded, or otherwise identified to indicate the status of calibration, including the date of the last calibration and the date or expiration criteria when re-calibration is due?

Objective Evidence

Quality Manual 5.5.8 and observations of balances in the laboratory.

5.5.9 ISO/IEC 17025:2005 — Conforming

Requirement

When, for whatever reason, equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service?

NOTE (from ANAB Accreditation Requirement)
The focus of this requirement is the use of equipment by non-laboratory personnel. The focus is not on equipment sent to an external calibration service supplier (e.g., thermometer, barometer) although, the laboratory should evaluate if the equipment could have been damaged during shipping. If damage is suspected, then a check of the calibration status (ISO/IEC 17025:2005, clause 5.5.10) should be performed.

Objective Evidence

Quality Manual 5.5.9

5.5.10 ISO/IEC 17025:2005 — Conforming

Requirement

When intermediate checks are needed to maintain confidence in the calibration status of the equipment, are these checks carried out according to a defined procedure?

NOTE (from ANAB Accreditation Requirement)
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 test method specifications, and risk associated with a failed check.

Objective Evidence

Quality Manual 5.5.10

5.5.10.1 ANAB Accreditation Requirement — Conforming

Requirement

If a laboratory determines that intermediate checks of the calibration status are needed, does the procedure define the frequency of the checks?

Objective Evidence

Quality Manual 5.5.10, 5.5.10.1 and review of applicable sectional SOP's.

5.5.10.2 ANAB Accreditation Requirement — Conforming

Requirement

Once established, is any extension in the interval of intermediate checks based on empirical data and an evaluation of risk?

Objective Evidence

Quality Manual 5.5.10.1

5.5.11 ISO/IEC 17025:2005 — Conforming

Requirement

Where calibrations give rise to a set of correction factors, does the laboratory have procedures to ensure that copies (e.g. in computer

software) are correctly updated?

NOTE (from ANAB Accreditation Requirement)
The evaluation of the impact of correction factors resulting from the calibration of equipment may be a one-time evaluation or may occur each time the equipment is used.

Objective Evidence

Quality Manual 5.5.11

5.5.12 ISO/IEC 17025:2005 — Conforming

Requirement

Is test/calibration equipment, including both hardware and software, safeguarded from adjustments which would invalidate the test/calibration results?

Objective Evidence

Quality Manual 5.5.12

5.6 Measurement traceability

5.6.1 ISO/IEC 17025:2005 — Conforming

Requirement

Is all equipment used for test/calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration, or sampling, calibrated before being put into service? Does the laboratory have an established program and procedure for the calibration of its equipment?

NOTE Such a programme should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

Objective Evidence

Quality Manual 5.6.1.1 and review of calibration records.

5.6.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does a program and procedure for the calibration of laboratory equipment include a list of the equipment requiring calibration, specifications for the calibration laboratory, specified requirements for the calibration, and the interval of calibration?

Objective Evidence

Quality Manual 5.6.1.1 and review of applicable sectional SOP's.
Balances, pipets, gauge blocks, steel rulers, standard reference weights.

5.6.1.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Once established, is any extension in the interval of calibration based on empirical data and an evaluation of risk?

Objective Evidence

Quality Manual 5.6.1.2

5.6.2.1.1 ISO/IEC 17025:2005 — Not Applicable

Requirement

For calibration laboratories, is the program for calibration of equipment designed and operated so as to ensure that calibrations and measurements made by the lab are traceable to the International System of Units (SI) (Systeme international d'unites)? A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, is traceability of measurement assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability, and traceability? Do the calibration certificates issued by these laboratories contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification? (See also 5.10.4.2).

NOTE 1 Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

NOTE 2 Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

NOTE 3 Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

NOTE 4 The term “identified metrological specification” means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

NOTE 5 When the terms “international standard” or “national standard” are used in connection with traceability, it is assumed that these standards fulfil the properties of primary standards for the realization of SI units.

NOTE 6 Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located.

NOTE 7 If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

NOTE 8 The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.

Objective Evidence

HFSC does not do calibrations.

5.6.2.1.2 ISO/IEC 17025:2005 — Not Applicable

Requirement

There are certain calibrations that currently cannot be strictly made in SI units. In these cases, does the calibration provide confidence in measurements by establishing traceability to appropriate measurement standards such as:
•the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material?
•the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned?
Where possible, is participation in a suitable programme of interlaboratory comparisons required?

Objective Evidence

HFSC does not do calibrations.

5.6.2.2.1 ISO/IEC 17025:2005 — Conforming

Requirement

Has the testing laboratory applied the requirements given in 5.6.2.1 for measuring and test equipment with measuring functions used, unless it has established that the associated contribution from the calibration contributes little to the total uncertainty of the test result? When this situation arises, does the laboratory ensure that the equipment used can provide the uncertainty of measurement needed?

NOTE The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.

Objective Evidence

Quality Manual 5.6.2.2

5.6.2.2.1.1 ANAB Accreditation Requirement — Conforming

Requirement

In situations where the calibration of equipment does not have a significant effect on sampling, the test result, or the total uncertainty of the test result, does the laboratory have objective evidence to demonstrate the insignificant contribution?

Objective Evidence

Quality Manual 5.6.1.3

5.6.2.2.1.2 ANAB Accreditation Requirement — Conforming

Requirement

If available, are suppliers of external calibration services for reference standards requiring calibration and equipment where the calibration of the equipment has a significant effect on the accuracy or validity of sampling or a test result; or the total uncertainty of the test result; either:
a) a National Metrology Institute that is a signatory to the BIPM - CIPM Mutual Recognition Arrangement with the calibration to be performed

listed in Appendix C of the BIPM key comparison database (KCDB)? or
b) a service supplier accredited to ISO/IEC 17025:2005 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration to be performed listed in a scope of accreditation?

Objective Evidence

Quality Manual 5.6.1.4 and review of calibration certifications issued by these vendors.

5.6.2.2.1.3 ANAB Accreditation Requirement — Conforming

Requirement

In situations where a supplier of external calibration services that meets 5.6.2.2.1.2 is not available, does the laboratory confirm competence, measurement capability, and measurement traceability for the supplier and the service being purchased? Is objective evidence of the confirmation available for review?

Objective Evidence

Quality Manual 5.6.1.5

5.6.2.2.1.4 ANAB Accreditation Requirement — Not Applicable

Requirement

For the purpose of establishing traceability of a measurement, does an accredited testing laboratory which calibrates its own equipment that supports an accredited parameter on the scope meet the related requirements in ISO/IEC 17025:2005 and this document:
a) the calibration and any check of the calibration status shall be carried out by appropriately trained, competency tested, and authorized personnel?
b) the calibration method shall be validated or verified prior to use?
c) certified reference materials or measuring instruments used in the calibration method shall be traceable with appropriate measurement uncertainties?
d) the calibration shall be carried out in an appropriate environment?
e) technical records of the calibration shall be established and maintained?
f) the laboratory shall have and apply a procedure for calculating the measurement uncertainty for each equipment calibration it conducts?
g) a technical review of the technical records including any data transfers and calculations shall be completed by an individual other than the person(s) who performed the work?

Objective Evidence

HFSC does not do calibrations.

5.6.2.2.2 ISO/IEC 17025:2005 — Conforming

Requirement

Where traceability of measurements to SI units is not possible and/or not relevant, are the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, required as for calibration labs (see 5.6.2.1.2)?

Objective Evidence

Quality Manual 5.6.2.2.

5.6.3.1 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory have a program and procedure for the calibration of its reference standards? Are reference standards calibrated by a body that can provide traceability as described in 5.6.2.1? Are such reference standards of measurement held by the lab used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated? Are reference standards calibrated before and after any adjustment?

Objective Evidence

Quality Manual 5.6.3.1 and review of standard weights.

5.6.3.2 ISO/IEC 17025:2005 — Conforming

Requirement

Are reference materials, where possible, traceable to SI units of measurement, or to certified reference materials? Are internal reference materials checked as far as is technically and economically practicable?

NOTE (from ANAB Accreditation Requirement)
When certified reference material is used in conjunction with a measuring system for establishing measurement traceability, the measuring system itself will not be subject to the requirements for measurement traceability.

Objective Evidence

Quality Manual 5.6.3.2 and observations of reference materials at laboratory.

5.6.3.2.1 ANAB Accreditation Requirement — Conforming

Requirement

If available, are suppliers of certified reference material used to establish or maintain measurement traceability either:
a) a National Metrology Institute that is a signatory to the BIPM - CIPM Mutual Recognition Arrangement with the certified reference material listed in the BIPM key comparison database (KCDB)? or
b) an accredited reference material producer that is accredited to ISO 17034:2016 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 Manual 5.6.3.2

5.6.3.2.2 ANAB Accreditation Requirement — Conforming

Requirement

In situations where a reference material producer that meets 5.6.3.2.1 is not available, does the laboratory confirm competence, measurement capability, and measurement traceability for the supplier and product being purchased? Is objective evidence of the confirmation available for review?

Objective Evidence

Quality Manual 5.6.3.2.

5.6.3.2.3 ANAB Accreditation Requirement — Conforming

Requirement

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

Objective Evidence

Quality Manual 5.6.3.2

5.6.3.3 ISO/IEC 17025:2005 — Conforming

Requirement

Are checks needed to maintain confidence in the calibration status of reference, primary, transfer, or working standards and reference materials carried out according to defined procedures and schedules?

Objective Evidence

Quality Manual 5.6.3.3 and review of sectional SOP's.

5.6.3.3.1 ANAB Accreditation Requirement — Conforming

Requirement

Once established, is any extension in the interval of intermediate checks based on empirical data and an evaluation of risk?

Objective Evidence

Quality Manual 5.6.3.3.

5.6.3.4 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory have procedures for safe handling, transport, storage, and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity?

NOTE Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.

Objective Evidence

Quality Manual 5.6.3.4 and observations of storage areas for reference standards and reference materials.

5.7 Sampling

5.7.1 ISO/IEC 17025:2005 — Conforming

Requirement

Does the lab have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing/calibration? Is the sampling plan as well as the sampling procedure available at the location where sampling is undertaken? Are sampling plans, whenever reasonable, based on appropriate statistical methods? Does the sampling process address the factors to be controlled to ensure the validity of the test and calibration results?

NOTE 1 Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g. forensic analysis), the sample may not be representative but is determined by availability.

NOTE 2 Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.

Objective Evidence

Quality Manual 5.7.1 with reference to Seized Drugs section and applicable sectional SOPs.

5.7.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the sampling plan and procedure(s):
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?
e) provide instruction regarding the course of action to take if one or more selected items demonstrate a lack of homogeneity?

Objective Evidence

Quality Manual 5.7.1

5.7.2 ISO/IEC 17025:2005 — Conforming

Requirement

Where the customer requires deviations, additions or exclusions from the documented sampling procedure, are these recorded in detail with the appropriate sampling data and included in all documents containing test and/or calibration results, and communicated to the appropriate personnel?

Objective Evidence

Quality Manual 5.7.2 and review of applicable sectional SOPs.

5.7.3 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken? Do these records include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon?

Objective Evidence

Quality Manual 5.7.3 and review of applicable sectional SOPs.

5.8 Handling of test and calibration items

5.8.1 ISO/IEC 17025:2005 — Conforming with Comment : 0

Requirement

Does the laboratory have procedures for the transportation, receipt, handling, protection, storage, retention, and/or disposal of test/calibration

items, including all provisions necessary to protect the integrity of the test/calibration item, and to protect the interests of the laboratory and the customer?

Objective Evidence

Quality Manual 5.8.1 and interviews.

COMMENT; It may be advantageous to the laboratory to reference their VEHICLE USE POLICY administrative document to this section of their Quality Manual. This is based on the observation of the CS/CM units involvement with the transportation of evidence to and from a major stakeholder's property room.
It may also be advantageous to the Crime Scene Unit to delineate how photos are returned to outside agencies.

5.8.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Do the procedures address:
a) all items (evidence) received and handled by the laboratory and not only those tested?
b) requirements for storage, packaging, and sealing items to:
1) protect the integrity of all items while in possession of the laboratory?
2) require the item to be re-sealed as soon as practicable after the requested testing is completed?
c) measures to be taken to secure unattended items which are in the process of being tested?
d) requirements for tracking (chain-of-custody) of:
1) all items received and not only those tested?
2) items that are created and used or could be used for testing (e.g., ESDA lifts, test-fired ammunition, latent print lifts, photos, trace evidence, DNA extracts)?
3) all internal transfers?
e) requirements for tracking (chain-of-custody) to securely and accurately identify:
1) the individual(s) or location(s) receiving or transferring the item(s)?
2) the item(s) being transferred?
3) the chronological order of transfers, minimally including the date?
f) requirements for individual characteristic database samples?
g) requirements for communicating to the customer the disposition of all items received?

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

NOTE 2 d) Samples of test items that are not preserved for future testing do not require tracking.

NOTE 3 d) Documentation of internal transfers do not need to include use of personal storage locations.

Objective Evidence

Quality Manual 5.8.1 and 5.8.1.1 through 5.8.1.4. Observations of evidence handling were also made.

5.8.2 ISO/IEC 17025:2005 — Conforming

Requirement

Does the laboratory have a system for identifying test/calibration items? Is the identification retained throughout the life of the item in the laboratory? Is the system designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents? Does the system, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory?

Objective Evidence

Quality Manual 5.8.2 and review of a sampling of evidence items and their chains of custody.

5.8.2.1 ANAB Accreditation Requirement — Conforming

Requirement

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

Objective Evidence

Quality Manual 5.8.2

5.8.3 ISO/IEC 17025:2005 — Conforming

Requirement

Upon receipt of the test/calibration items, are abnormalities or departures from normal or specified conditions, as described in the test or calibration method, recorded? When there is doubt as to the suitability of an item for test/calibration, or when an item does not conform to the description provided, or the test/calibration required is not specified in sufficient detail, does the laboratory consult the customer for further instructions before proceeding and is the discussion recorded?

Objective Evidence

Quality Manual 5.8.3 and 5.10.1.

5.8.4 ISO/IEC 17025:2005 Conforming

Requirement

Does the laboratory have procedures and appropriate facilities for avoiding deterioration, loss, or damage to the test/calibration item during storage, handling, and preparation? Are handling instructions provided with the item followed? When items have to be stored under specified environmental conditions, are these conditions maintained, monitored, and recorded? Where a test/calibration item or a portion of an item is to be held secure, does the laboratory have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned?

NOTE 1 Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

NOTE 2 A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples.

NOTE 3 Reasons for keeping a test or calibration item secure can be for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.

Objective Evidence

Quality Manual 5.8.4 through 5.8.4.5 and observations of evidence storage areas.

5.9 Assuring the quality of test and calibration results

5.9.1 ISO/IEC 17025:2005 Conforming

Requirement

Does the laboratory have quality control procedures for monitoring the validity of tests/calibrations undertaken? Is the resulting data recorded in such a way that trends are detectable and, where practicable, are statistical techniques applied to the reviewing of the results? Is the monitoring planned/reviewed? The monitoring may include, but is not limited to, the following:

a) regular use of certified reference materials and/or internal quality control using secondary reference materials.
b) participation in inter-laboratory comparison or proficiency-testing programs.
c) replicating tests/calibrations using the same or different methods.
d) retesting or recalibration of retained items.
e) correlation of results for different characteristics of an item.

NOTE The selected methods should be appropriate for the type and volume of the work undertaken.

Objective Evidence

Quality Manual 5.9 and review of sectional SOPs.

5.9.1.1 ANAB Accreditation Requirement Conforming

Requirement

Are quality control procedures to ensure the validity of tests undertaken specified in the test method and is the result of each quality control activity recorded?

Objective Evidence

Quality Manual 5.9, 5.9.1 and 5.9.2 and sectional SOPs.

5.9.1.2 ANAB Accreditation Requirement Conforming

Requirement

Do reference collections of data or materials which are maintained for identification, comparison, or interpretation purposes (e.g., mass spectra, motor vehicle paints or headlamp lenses, drug samples, wood fragments, bullets, cartridges, DNA profiles, laboratory developed population databases) have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest?

Objective Evidence

Quality Manual 5.6.3.2 and observation of reference collections.

5.9.1.3 ANAB Accreditation Requirement Conforming

Requirement

When a verification of a test result is carried out:
a) is it conducted by an individual who is currently authorized to perform the testing?
b) is a record of the verification made and does the record identify who performed the verification, when it was performed, and the results of the verification?

c) is planned action taken to deal with situations where the verification does not agree with the original test result?
d) is the resolution of any discrepancy recorded?

Objective Evidence

Quality Manual 5.9.1 and review of firearm and latent print case records.

5.9.2 ISO/IEC 17025:2005 — Conforming

Requirement

Is quality control data analyzed? If the data analyzed is found outside pre-defined criteria, is planned action taken to correct the problem and to prevent incorrect results from being reported?

Objective Evidence

Quality Manual 5.9.2

5.9.3 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a proficiency test procedure which at a minimum:
a) requires that expected proficiency test results are not known or readily available to the test taker?
b) requires each applicant laboratory to successfully complete at least one external proficiency test for each discipline in which application for accreditation has been made?
c) requires each location on the scope of accreditation to successfully complete, per calendar year, at least one external proficiency test for each discipline in which accredited services are provided, with authorized release of the test results to ANAB from the test provider?
d) requires all personnel to successfully complete at least one internal or external proficiency test per calendar year in each discipline on the scope of accreditation in which the individual conducts testing?
e) requires proficiency tests to be conducted using approved test methods?
f) requires appropriate technical records to be retained?
g) establishes criteria for determining successful completion of proficiency tests prior to the proficiency tests being taken?
h) requires results to be evaluated and appropriate action to be taken for unexpected results?
i) requires feedback to be provided to test participants and specifies the mechanism for recording the feedback?
j) requires a mechanism to ensure the quality of internally created or previously used proficiency tests prior to issuing the test?

NOTE 1 A proficiency test may test a specific job related skill or skills, but does not have to test all aspects of an employee's job function. The laboratory should consider varying the design of proficiency tests so that over time an employee is tested on all aspects of the assigned job functions.

NOTE 2 c) - d) For proficiency tests taken at the end of one calendar year, evaluation of these tests can occur in the subsequent calendar year.

NOTE 3 d) Internal proficiency tests may include internally created practical tests, previously worked or older unworked commercially provided practical tests, testing reanalysis, external tests whose results are not submitted to the test provider or not authorized for release to ANAB and when appropriate, observation based tests.

NOTE 4 d) Solely performing verifications or solely acting as a report issuer are both considered performing testing work.

NOTE 5 d) Proficiency testing is applicable to personnel who perform testing but do not issue a report.

NOTE 6 f) See requirements of 4.13.2 in ISO/IEC 17025:2005 and this document.

Objective Evidence

Quality Manual 5.9.3 and review of proficiency testing records

5.9.3.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a plan for proficiency testing that will:
a) demonstrate conformance with the proficiency testing requirements stated in clause 5.9.3c) and d)?
b) ensure inclusion of a representative sample of the types of tests within each discipline listed on the scope of accreditation?

Objective Evidence

Quality Manual 5.9.3 and review of proficiency test records, completed and planned.

5.9.3.2 ANAB Accreditation Requirement — Conforming

Requirement

To satisfy the external proficiency test requirements in clauses 5.9.3.b) - c), does the laboratory:
a) where available and appropriate for the testing 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 testing conducted, gain approval from ANAB for alternative means by which the laboratory's performance can be assessed?

Objective Evidence

Quality Manual 5.9.3.2 and 5.9.3.4 and review of proficiency test records including ANAB alternate approval.

5.9.3.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Are external proficiency test results used to satisfy clause 5.9.3.2.a) submitted to the external test provider on or before the agreed upon due date?

Objective Evidence

Quality Manual 5.9.3.4 and review of proficiency testing records.

5.9.3.3 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory maintain the following records for all proficiency testing conducted:
a) test set identifier?
b) disciplines tested?
c) how test was created?
d) expected proficiency test results?
e) location where the proficiency test was taken when more than one location is associated with a single accreditation certificate?
f) records submitted to an external proficiency test provider?
g) evaluation of results and action taken for unexpected results?
h) feedback provided to the participants?

Objective Evidence

Quality Manual 5.9.3.5 and review of Proficiency test records stored in Qualtrax.

5.9.4 ANAB Accreditation Requirement — Conforming

Requirement

Has the laboratory established a procedure for the technical review of technical records, including test reports, and testimony? Does the procedure:
a) require that a technical review be performed by an individual that has been competency tested in the task(s) that the review is encompassing?
b) preclude an individual from technically reviewing their own work?
c) define the method to be used to ensure a representative sample of technical records and test reports in each discipline are subjected to technical review?
d) define the method to be used to ensure testimony in each discipline is reviewed?
e) define the method to be used to conduct and record the review?
f) ensure that the results, opinions and interpretations are accurate, properly qualified and supported by the technical record?
g) ensure conformance with test methods and applicable policies and procedures?
h) describe a course of action to be taken if a discrepancy is found?

NOTE 1 a) An individual conducting the technical review need not be an employee of the laboratory, currently proficiency tested or currently performing testing.

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

NOTE 3 c) The sampling rate may vary for different disciplines.

Objective Evidence

Quality Manual 5.9.6 , 5.9.4 through 5.9.4.3 and review of a sampling of case files.

5.10 Reporting the results

5.10.1 ISO/IEC 17025:2005 — Conforming with Comment : 0

Requirement

Are results of each test/calibration or series of tests/calibrations carried out by the laboratory reported accurately, clearly, unambiguously, objectively, and in accordance with any specific instructions in the test/calibration methods?

Are the results reported, usually in a test report/calibration certificate (see note 1), and do they include all the information requested by the customer and necessary for the interpretation of the test/calibration results and all information required by the method used? This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. If applicable, have written agreements been obtained? If any information listed in 5.10.2 to 5.10.4 is not reported to the customer, is it readily available in the laboratory which carried out the tests/calibrations?

NOTE 1 Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.

NOTE 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.

NOTE 3 (from ANAB Accreditation Requirement)
"The results shall be reported…" means that the test report shall be provided to the customer.

Objective Evidence

Quality Manual 5.10.1 and sample of laboratory reports reviewed.

COMMENT: It would be advantageous to the laboratory to revisit their administrative and technical review program to reduce the number of typographical errors that originate in the Latent Prints discipline.

5.10.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a policy and procedure for the reporting of test results? Does the procedure:
a) identify what will be reported for all items received, including items not tested, items created that were or could be tested, and for all testing performed (partial and complete)?
b) if applicable, specify the content for simplified reports or an annex to the report?
c) require the report issuer to review the test record and document the review if the issuer is not the person that performed the work?
d) address how to properly qualify the significance of associations whether by a statistic or a qualitative statement?
e) describe how to clearly communicate the reason(s) when the reported results indicate that no definitive conclusion can be reached?
f) require reporting of the initial database entry (e.g., CODIS, AFIS, NIBIN)?
g) require reporting of an association resulting from a database search (e.g., CODIS, AFIS, NIBIN)?

NOTE 1 a) Testing and the requirement to report test results does not include activities undertaken for the purpose of constructing an individual characteristic database or maintaining the quality and/or effectiveness of information in such a database.

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

Objective Evidence

Quality Manual 5.10.2 and review of a sampling of case records.

5.10.2 ISO/IEC 17025:2005 — Resolved Nonconformity

Requirement

Does each test report/calibration certificate include at least the following information, unless the lab has valid reasons for not doing so?

a) a title (e.g. “Test Report” or “Calibration Certificate”)?
b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory?
c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate?
d) the name and address of the customer?
e) identification of the method use?
f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated?
g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration?
h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results?
i) the test or calibration results with, where appropriate, the units of measurement?
j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate?
k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated?

NOTE 1 Hard copies of calibration certificates should also include the page number and total number of pages.

NOTE 2 It is recommended that laboratories include a statement specifying that the calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

NOTE 3 (from ANAB Accreditation Requirement)
A valid reason includes, but is not limited to, a legal requirement that dictates information to be included in a test report or a written agreement with the customer for a simplified report (see ISO/IEC 17025:2005, clause 5.10.1).

Objective Evidence

A sample of technical records and reports, along with quality documents were reviewed from Seized Drugs.
Reports in the Seized Drug discipline include information on test method capability, but are not specific to the methods utilized for the testing of the reported item(s). An example of the current report statement wording is; " All reported items were individually identified by at least two tests including "GC/MS or FTIR."

Nonconformity Resolution

Reports in the Seized Drug discipline include information on test method capability, but are not specific to the methods utilized for the testing of the reported item(s).
An example of the current report statement wording is;
" All reported items were individually identified by at least two tests including "GC/MS or FTIR."

Completion note: This Corrective Action report along with the review of a sampling of seized drug reports that use this new reporting format has resolved this non-conformity.

5.10.3.1 ISO/IEC 17025:2005 — Conforming

Requirement

In addition to the requirements listed in 5.10.2, do the test reports, where necessary for the interpretation of the test results, include the following:
a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions?
b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications?
c) where applicable, a statement on the estimated uncertainty of measurement? Information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit?
d) where appropriate and needed, opinions and interpretations (see 5.10.5)?
e) additional information which may be required by specific methods, customers or groups of customers?

Objective Evidence

Quality Manual 5.10.3.1 and a review of a sampling of case records.

5.10.3.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a policy and procedure to implement clause 5.10.3.1 (c) of ISO/IEC 17025:2005? Does the procedure:
a) require the estimated uncertainty to be included in the test report or an annex to the test report when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement?
b) require the reported uncertainty statement to include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability?
c) require the uncertainty statement to be in the format of y ± U and the units of y and U to be consistent?
d) limit the rounded expanded uncertainty to at most two significant digits, unless the laboratory has a documented rationale for reporting additional significant digits?
e) require the rounded expanded uncertainty to be reported to the same level of significance as the measurement result?

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

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.

NOTE 3 c) When the measurement is expressed as a fraction, the uncertainty may be reported as a fraction.

NOTE 4 e) Reducing or simplifying a fraction is not a change in level of significance.

Objective Evidence

Quality Manual 5.10.2

5.10.3.1.2 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 test result or prohibits including measurement uncertainty in the test report, does the laboratory :
a) have objective evidence of the regulation, statute, case law or other legal requirement?
b) have a policy and procedure for applying the estimated uncertainty at the laboratory’s established level of confidence prior to reporting the test result?

Objective Evidence

No legal requirement for a specific format.

5.10.3.2 ISO/IEC 17025:2005 — Conforming

Requirement

In addition to the requirements listed in 5.10.2 and 5.10.3.1, do test reports containing the results of sampling include the following, where necessary for the interpretation of test results:
a) the date of sampling?
b) unambiguous identification of the substance, material or product 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 procedures used?
e) details of any environmental conditions during sampling that may affect the interpretation of the test results?
f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned?

Objective Evidence

Quality Manual 5.10.3.2
Observation during witnessing of a Seized Drug case being worked.

5.10.3.2.1 ANAB Accreditation Requirement — Conforming

Requirement

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

Quality Manual 5.7.1 and 5.10.3.2 along with review of a sampling of case records.

5.10.5 ISO/IEC 17025:2005 — Conforming

Requirement

When opinions and interpretations are included, did the laboratory document the basis upon which the opinions and interpretations have been made? Were opinions and interpretations clearly marked as such in a test report?

NOTE 1 Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

NOTE 2 Opinions and interpretations included in a test report may comprise, but not be limited to, the following:
• an opinion on the statement of compliance/noncompliance of the results with requirements;
• fulfilment of contractual requirements;
• recommendations on how to use the results;
• guidance to be used for improvements.

NOTE 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue should be written down.

Objective Evidence

Quality Manual 5.10.5 and review of a sampling of case records.

5.10.6 ISO/IEC 17025:2005 — Conforming

Requirement

When the test report contains results of tests performed by subcontractors, were the results clearly identified? Did the subcontractor report the results in writing or electronically?

Objective Evidence

Quality Manual 5.10.6
Review of a sampling of case records in Biology.

5.10.6.1 ANAB Accreditation Requirement — Conforming

Requirement

If results of subcontracted tests are included in a test report that makes reference to accreditation:
a) was approval obtained from the subcontractor to include excerpts from the subcontractor's report or certificate?
b) was the accreditation symbol of the subcontractor not used on the report if the subcontractor is not accredited by ANAB?

Objective Evidence

Quality Manual 5.10.6

5.10.7 ISO/IEC 17025:2005 — Conforming

Requirement

In the case of transmission of test/calibration results by telephone, telex, facsimile, or other electronic or electromagnetic means, are the requirements of the International Standard met? (see also 5.4.7).

Objective Evidence

Quality Manual 5.10.7 and 5.4.7.

5.10.8 ISO/IEC 17025:2005 — Conforming

Requirement

Is the format designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse?

NOTE 1 Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

NOTE 2 The headings should be standardized as far as possible.

Objective Evidence

Quality Manual 5.10.8 and review of a sampling of case reports.

5.10.9 ISO/IEC 17025:2005 — Conforming

Requirement

Are material amendments to a test report or calibration certificate after issue made only in the form of a further document, or data transfer, which includes the statement:
“Supplement to Test Report [or Calibration Certificate], serial number...[or as otherwise identified]”,
or an equivalent form of wording?

Do such amendments meet all requirements of the International Standard?

When it is necessary to issue a complete new test report or calibration certificate, is it uniquely identified and does it contain a reference to the original that it replaces?

Objective Evidence

Quality Manual 5.10.9 and review of a sampling of amended reports.

5.10.10.1 ANAB Accreditation Requirement — Conforming

Requirement

If a laboratory makes reference to accreditation in any communication (e.g., report, internet, documents, brochures, or advertising) by use of an accreditation symbol (alone or in combination with the ILAC mark), business name or business acronym, does the laboratory ensure:
a) use only by the legal entity accredited and as named on the certificate of accreditation?
b) the accreditation symbol or statement used is specific to the ANAB or ASCLD/LAB Forensic Testing accreditation program?
c) non-accredited testing is clearly identified as such by a disclaimer?
d) no misleading or unauthorized representation of accreditation status?
e) no implication that the accreditation body accepts responsibility for test results?
f) no implication that a product, process, system or person is approved by the accreditation body?

Objective Evidence

Quality Manual 5.10.10.1. Also reviewed website and a sampling of case records.

5.10.10.2 ANAB Accreditation Requirement — Conforming

Requirement

In addition to the requirements of 5.10.10.1 for reports, does the laboratory ensure:
a) no reference is made to accreditation when none of the testing included in a report is within the scope of accreditation?
b) in reports that make reference to accreditation:
1) opinions or interpretations included are based on those test results for which accreditation is held?
2) opinions or interpretations outside the scope of accreditation, but based on those test results for which accreditation is held, are clearly identified as such by a disclaimer?

NOTE This is applicable to subcontractor results included in a test report.

Objective Evidence

Quality Manual 5.4.5.2, 5.10.1 and 5.10.10.2.
A review of a sampling of case reports also documented this.

5.10.10.3 ANAB Accreditation Requirement — Not Applicable

Requirement

When the ILAC mark is used:
a) has permission for use of the ILAC mark been obtained from ANAB?
b) is the mark used in conjunction with the ANAB accreditation symbol and in accordance with the conditions for use set forth by ANAB?

Objective Evidence

Do not use ILAC mark
Quality Manual 5.10.10.3