San Diego County Sheriff's Department Regional Crime Laboratory

2018 - 17025C - Initial Assessment

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Data collected on 2018-11-27

ANSI National Accreditation Board

United States

Signature

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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

San Diego County Sheriff's Regional Crime Laboratory is a publicly funded government laboratory.

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

Document and record review, onsite review and interviews

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

Document and record review

4.1.4 ISO/IEC 17025:2005 — Conforming

Requirement

If the laboratory is part of an organization performing activities other than testing and/or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on testing and/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 and organizational chart

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?

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?

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

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

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

Quality Manual organizational chart, job descriptions and records

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?

Objective Evidence

Quality Manual, organizational chart and job descriptions

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 and communication records

4.1.7 ANAB Accreditation Requirement — Conforming

Requirement

Are key managerial personnel and top management designated?

Objective Evidence

Quality Manual and organizational chart

4.2 Management system

4.2.1 ISO/IEC 17025:2005 — Conforming

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 calibration 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 calibration results" includes analysis to arrive at a calibration result or opinion.

Objective Evidence

Quality Manual 9 Quality Assurance
Section Technical Manuals
Section Training Manuals

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 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

Quality Manual and records

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 review

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 and management system review

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

Document and record review

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

QM document review and master document lists

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 and job descriptions

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 and management system review

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 personnel are not required to follow specific procedures or instructions contained in the equipment or software manual.

Objective Evidence

Quality Manual and master document lists

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 director. One or more authorized persons may be identified based on the types of documents for review and approval.

Objective Evidence

Quality Manual and master document lists
Onsite document review

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

Document review and onsite review, Qualtrax system

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

Document and record review

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

Document review and interviews

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

Onsite review and interviews

4.3.3.3 ISO/IEC 17025:2005 — Not Applicable

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

The Laboratory does not allow for amendment of documents by hand pending re-issue.

4.3.3.4 ISO/IEC 17025:2005 — Not Applicable

Requirement

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

Objective Evidence

Documents are not maintained on computerized system

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 and Forensic Alcohol Technical Manual

4.4.1.1 ANAB Accreditation Requirement — Conforming

Requirement

If the breath alcohol calibration laboratory performs calibrations of breath alcohol measuring instruments under the authority of a statute, regulation or other legal requirement, is that statute/regulation/requirement readily available?

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

Objective Evidence

Title 17 , Division 1, Chapter 2, Article 6 (Requirements for Breath Alcohol Testing)

4.4.2 ISO/IEC 17025:2005 — Not Applicable

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

Does not apply to calibration services

4.4.3 ISO/IEC 17025:2005 — Not Applicable

Requirement

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

Objective Evidence

No aspect of Calibration work is subcontracted by the laboratory.

4.4.4 ISO/IEC 17025:2005 — Not Applicable

Requirement

Is the customer informed of any deviation from the contract?

Objective Evidence

Does not apply to calibration services

4.4.5 ISO/IEC 17025:2005 — Not Applicable

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

Does not apply to calibration services

4.5 Subcontracting of tests and calibrations

4.5.1 ISO/IEC 17025:2005 — Not Applicable

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 calibration from one location to another location within a system operating under the same management system is not considered subcontracting.

Objective Evidence

The San Diego County Sheriff's Regional Crime Laboratory does not subcontract calibrations.

4.5.1.2 ANAB Accreditation Requirement — Not Applicable

Requirement

If available, does the laboratory use a subcontractor accredited to ISO/IEC 17025:2005 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 or a National Metrology Institute (NMI) that is a signatory to the BIPM-CIPM Mutual Recognition Arrangement with the required calibration listed in Appendix C of the BIPM key comparison database (KCDB)?

Objective Evidence

The San Diego County Sheriff's Regional Crime Laboratory does not subcontract calibrations.

4.5.2 ISO/IEC 17025:2005 — Not Applicable

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

The San Diego County Sheriff's Regional Crime Laboratory does not subcontract calibrations.

4.5.3 ISO/IEC 17025:2005 — Not Applicable

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

The San Diego County Sheriff's Regional Crime Laboratory does not subcontract calibrations.

4.5.4 ISO/IEC 17025:2005 — Not Applicable

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

The San Diego County Sheriff's Regional Crime Laboratory does not subcontract calibrations.

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 and record review

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

Onsite review, interviews

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

Onsite record review, interviews

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

Record review, interviews

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

Forensic Alcohol Technical Procedures Manual

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, procedure manual and customer survey

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

Customer survey records

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 and corrective action records

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

4.9.2 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 and corrective action records

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 and management system review records

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 documentation

4.11.1.1 ANAB Accreditation Requirement — Conforming

Requirement

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

Objective Evidence

Quality Manual documentation

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 documentation and Corrective action worksheet

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

Document and record review

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

Corrective action records and management system review

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

Internal audit records and management system review

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, corrective action records
and management system review

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

Document and record review

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 and Record review

4.13.1.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Do the procedures for records:
a) specify what technical and administrative record(s) will be in a calibration record if all related technical and administrative records are not maintained?
b) if applicable, address preservation of calibration data printed on thermal paper that will be effected by time or environmental condition?

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

Objective Evidence

Quality Manual Calibration Records

4.13.1.1.2 ANAB Accreditation Requirement — Conforming

Requirement

Are administrative records identifiable to a specific calibration record?

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

Objective Evidence

Document review and onsite 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 6.12 Calibration Records
Onsite record review and interviews

4.13.1.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the retention policy consider applicable legal requirements?

Objective Evidence

Quality Manual and interview

4.13.1.2.2 ANAB Accreditation Requirement — Not Applicable

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

N/A, the lab does not destroy any records

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

Onsite and record review

4.13.1.3 ISO/IEC 17025:2005 Conforming

Requirement

Are all records held secure and in confidence?

Objective Evidence

Onsite review, interview, witnessing

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

San Diego County Sheriff's Department Policy and Procedure Manual and Quality Manual

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.

Objective Evidence

Document review, calibration records, audit trail, witnessing, interview

4.13.2.1.1 ANAB Accreditation Requirement Conforming

Requirement

Are technical records to support a calibration certificate such that, another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data?

Objective Evidence

Document review, calibration records, audit trail, witnessing, interview

4.13.2.1.2 ANAB Accreditation Requirement Conforming

Requirement

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

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

Objective Evidence

Document review, calibration records, audit trail, witnessing, interview

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

Document review, calibration records, audit trail, witnessing, interview

4.13.2.2.1 ANAB Accreditation Requirement — Conforming

Requirement

If data or a calibration 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

Document review, calibration records, audit trail, witnessing, interview

4.13.2.2.2 ANAB Accreditation Requirement — Conforming

Requirement

Once started, if the calibration is not successfully completed, is the date, the reason for not completing the calibration, and the identity of who authorized this action recorded?

Objective Evidence

Document review, calibration records, audit trail, witnessing, interview

4.13.2.2.3 ANAB Accreditation Requirement — Conforming

Requirement

If an adjustment is performed due to a failed calibration procedure, is the pre and post adjustment data retained?

NOTE See related clause ISO/IEC 17025:2005, 5.10.4.3

Objective Evidence

Document review, calibration records, audit trail, witnessing, interview

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

Calibration records, audit trail, witnessing, interview

4.13.2.3.1 ANAB Accreditation Requirement — Resolved Nonconformity

Requirement

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

Objective Evidence

Technical records, calibration certificates, and interview
Forensic Alcohol Technical Procedures Manual Revision 7 and communications with Quality Manager

Nonconformity Resolution Workflow

Changes made to technical records due to the technical review process are not tracked. Practice is to verbally communicate possible discrepancies and perform an additional technical review prior to issuing calibration certificates.

Completion note: The laboratory extensively revised the Forensic Alcohol Technical Procedures manual (V7) to include the policy and procedure for tracking changes to calibration certificates and calibration records as a result of technical review. A Forensic Alcohol section meeting was held to review the new
policies and procedures outlined in the revision.
This non-conformance is resolved.

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

Internal audit records and interview

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

Internal audit records

4.14.1.2 ANAB Accreditation Requirement Conforming

Requirement

Do internal audits include direct observation of a sampling of calibration?

Objective Evidence

Quality Manual review and interview

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

Internal audit records and management system review

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

Internal audit records

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

Document and record review, interview

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 and management system review

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

Management review report and records

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

Management review report and records

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

Onsite review, records, interviews

5.1.3 ANAB Accreditation Requirement — Not Applicable

Requirement

Are reagents prepared in the laboratory labeled with, at a minimum, the identity of the reagent, 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

The laboratory does not prepare reagents for Calibration in house.

5.1.4 ANAB Accreditation Requirement — Not Applicable

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 the calibration?

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

Objective Evidence

The laboratory does not prepare reagents for Calibration in house.

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

Training records and authorizations

5.2.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Do personnel who issue a certificate that includes the results of a calibration meet the minimum education requirements below?

Discipline: Toxicology
Minimum Education Requirements: A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.

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

Objective Evidence

Personnel records

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 calibration (see ISO/IEC 17025 2005, clause 5.2.5)?

Objective Evidence

Job descriptions and work authorizations

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 2.4.1, 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

Forensic Alcohol training program

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 calibration on an item submitted for calibration? 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 calibration certificate 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

Training and competency 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

Personnel and training records

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

Crime Laboratory Personnel Human Resources 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

Personnel authorization records

5.2.5.1 ANAB Accreditation Requirement — Conforming

Requirement

As applicable, does the authorization also address personnel that perform the technical review of a calibration record and related calibration certificate?

Objective Evidence

Qualtrax authorization records

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

Onsite review and technical procedure

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

Onsite review and records

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

Onsite review

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 and onsite review

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 calibration 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 calibration 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

Quality manual documentation and security records

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

Onsite review

5.4 Test and calibration methods and method validation

5.4.1 ISO/IEC 17025:2005 — Conforming

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

Quality manual, technical procedure, onsite review and interviews

5.4.1.3 ANAB Accreditation Requirement — Conforming

Requirement

Does the breath alcohol measuring instrument calibration method assess accuracy (bias and precision) of the instrument across a range of ethanol values that meets the needs of the customer?

Objective Evidence

Document review, calibration records, witnessing

5.4.1.4 ANAB Accreditation Requirement — Conforming

Requirement

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

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

Objective Evidence

Calibration technical procedure, onsite review and calibration records

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 and Technical manual review, audit trail, witnessing

5.4.3 ISO/IEC 17025:2005 — Not Applicable

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

N/A, No lab developed methods

5.4.4 ISO/IEC 17025:2005 — Not Applicable

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

The laboratory does not use non standard methods for calibration

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

The laboratory does not use non standard methods for calibration

5.4.5.2.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a procedure for method validation that:
a) Not applicable to Forensic Science Calibration Laboratories;
b) establishes the data required to report a calibration certificate?
c) identifies limitations of the calibration method?
d) specifies when a currently validated method 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 documentation

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

Technical Procedure, Calibration records, audit trail, witnessing

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

Document review, records and interviews

5.4.6.1 ISO/IEC 17025:2005 — Conforming

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

Quality Manual 9.23 Uncertainty Of Measurement
Records and onsite review

5.4.6.1.1 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 calibration result to have been included in or evaluated against the estimation of measurement uncertainty for that calibration 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 and technical procedure manual
Measurement Uncertainty records

5.4.6.2 ISO/IEC 17025:2005 — Not Applicable

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

N/A, Calibration laboratory

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

Technical procedures manual and measurement uncertainty records, interviews

5.4.6.4 ANAB Accreditation Requirement — Conforming

Requirement

Do laboratories 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

Measurement Uncertainty records

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

Calibration record review, audit trail, witnessing, technical procedure

5.4.7.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the calibration 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 can be part of a technical review.

Objective Evidence

Calibration record review

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 4.3 and QM interview

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

Requirement

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

Objective Evidence

The laboratory does not use computer software developed by the lab

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

Onsite review and calibration records

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? (see 5.6)

Objective Evidence

Onsite review and calibration records

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 laboratory personnel?

Objective Evidence

Authorization records and onsite review

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

Onsite review

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

Calibration records

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 documentation

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

Onsite review and interviews

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

Onsite review

5.5.9 ISO/IEC 17025:2005 — Not Applicable

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

N/A, equipment does not go outside the direct control of the laboratory

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 method specifications, and risk associated with a failed check.

Objective Evidence

Quality Manual 9.3 Calibration And Maintenance Of Equipment And Instrumentation

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

Technical procedure manual

5.5.10.2 ANAB Accreditation Requirement — Not Applicable

Requirement

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

Objective Evidence

No changes are made to intervals of intermediate checks, as one is required by state regulations.

5.5.11 ISO/IEC 17025:2005 — Not Applicable

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

Correction factors are not employed in breath alcohol calibration at the laboratory.

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

Onsite review, witnessing

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

Onsite review and 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

Technical procedure manual

5.6.1.1.1 ANAB Accreditation Requirement — Not Applicable

Requirement

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

Objective Evidence

No changes are made to intervals of equipment calibrations.

5.6.2.1.1 ISO/IEC 17025:2005 — Conforming

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

The calibration is measured in grams per 210 liters of breath, which is not traceable to International SI Units.

5.6.2.1.1.1 ANAB Accreditation Requirement — Not Applicable

Requirement

In situations where the calibration of equipment does not have a significant effect on the calibration results, does the laboratory have objective evidence to demonstrate the insignificant contribution?

Objective Evidence

The laboratory does not use any equipment that does not have a significant effect on the calibration results.

5.6.2.1.1.2 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 the calibration, 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

Calibration service records

5.6.2.1.1.3 ANAB Accreditation Requirement — Not Applicable

Requirement

In situations where a supplier of external calibration services that meets 5.6.2.1.1.2 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

The laboratory uses a supplier that meets 5.6.2.1.1.2.

5.6.2.1.1.4 ANAB Accreditation Requirement — Not Applicable

Requirement

For the purpose of establishing traceability of a measurement, does a laboratory accredited for measuring instrument calibrations 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 equipment calibration and any check of the calibration status shall be carried out by appropriately trained, competency tested, and authorized personnel?
b) the equipment calibration method shall be validated or verified prior to use?
c) certified reference materials or measuring instruments used in the equipment calibration method shall be traceable with appropriate measurement uncertainties?
d) the equipment calibration shall be carried out in an appropriate environment?
e) technical records of the equipment 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

The laboratory does not calibrate its own equipment or measuring instruments.

5.6.2.1.2 ISO/IEC 17025:2005 — Conforming

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

Technical method review, audit trail, certified reference material records

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

Technical procedure manual and onsite record review

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?

Objective Evidence

Certified reference material records

5.6.3.2.1 ANAB Accreditation Requirement — Resolved Nonconformity

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

Certified reference material records, Quality Manual, Forensic Alcohol Technical Procedures Manual, Interview

Nonconformity Resolution Workflow

While the reference material used to establish measurement traceability for the calibrations provides traceability through an accredited ISO/IEC 17025 accredited provider; it does not meet requirement {(a) NMI} or {(b)ISO 17034 or Guide 34}.

Completion note: 1) The laboratory contacted the reference material provider and determined their measurement traceability. 2) The laboratory requested the vendor to provide revised certificates in the future, showing ISO 17034 compliance (email communications with vendor). 3) The laboratory requested the vendor to provide revised certificates showing ISO 17034 compliance for the current lot numbers in use (email communications with vendor). 4) Revised the Forensic Alcohol Technical Procedures Manual sections 2.2.2 and 3.2.1. ("Reference materials used for Calibration and Adjustment of breath instruments shall be purchased from a reference material producer who is accredited to ISO 17034"). 5) Conducted a Forensic Alcohol section meeting to review the new changes to the requirement for vendor calibration certificates to indicate ISO 17034 accreditation. 6) Provided copies of dry gas calibration certificates showing the vendor is ISO 17034:2016 A2LA accredited. This non-conformance is resolved.

5.6.3.2.2 ANAB Accreditation Requirement — Not Applicable

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

The laboratory only uses reference materials that meet 5.6.3.2.1.

5.6.3.2.3 ANAB Accreditation Requirement — Not Applicable

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

N/A, CRMs are not changed.

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

Document review, records and interviews

5.6.3.3.1 ANAB Accreditation Requirement — Not Applicable

Requirement

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

Objective Evidence

The laboratory does not change the interval of intermediate checks.

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 documentation

5.7 Sampling

5.7.1 ISO/IEC 17025:2005 — Not Applicable

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

The laboratory does not perform sampling of substances for calibration.

5.7.2 ISO/IEC 17025:2005 — Not Applicable

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

The laboratory does not perform sampling of substances for calibration.

5.7.3 ISO/IEC 17025:2005 — Not Applicable

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

The laboratory does not perform sampling of substances for calibration.

5.8 Handling of test and calibration items

5.8.1 ISO/IEC 17025:2005 — Conforming

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

Technical procedure manual

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

Technical procedure manual and calibration records

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

Document review and onsite records and interviews

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

Document review and onsite review

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 9.1 Quality Control Procedures and Technical Procedure Manual, onsite review, witnessing

5.9.1.1 ANAB Accreditation Requirement — Conforming

Requirement

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

Objective Evidence

Quality manual and technical procedure

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 9.1.5 Acceptable Tolerances
Forensic Alcohol Technical Manual 3.7.3.4 Performance Check of Breath Instrumentation
Onsite review, witnessing

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 (calibration)?
e) requires proficiency tests to be conducted on a breath alcohol measuring instrument that has been calibrated using an approved method

by the person taking the proficiency test?
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. Laboratories 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) and 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, 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 acting as a certificate issuer is considered calibration work.

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

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

Objective Evidence

Quality Manual documentation

5.9.3.1 ANAB Accreditation Requirement — Conforming

Requirement

Do laboratories have a plan for proficiency testing that will demonstrate conformance with the proficiency testing requirements stated in clause 5.9.3 c) and d)?

Objective Evidence

Quality Manual documentation

5.9.3.2 ANAB Accreditation Requirement — Conforming

Requirement

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

Objective Evidence

Proficiency test records

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

NA/Initial accreditation review

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) discipline 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

Proficiency testing record review

5.9.4 ANAB Accreditation Requirement — Conforming

Requirement

Has the laboratory established a procedure for the technical review of technical records, including calibration certificates, 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 all technical records and calibration certificates 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 are accurate, properly qualified and supported by the technical record?
g) ensure conformance with calibration method(s) and applicable policies and procedures?
h) describe a course of action to be taken if a discrepancy is found?

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

Objective Evidence

Quality Manual documentation

5.10 Reporting the results

5.10.1 ISO/IEC 17025:2005 — Conforming

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 calibration certificate shall be provided to the customer.

Objective Evidence

Quality manual and calibration records

5.10.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a policy and procedure for the reporting of calibration results? Does the procedure:
a) identify what information will be reported in the calibration certificate?
b) if applicable, specify the content for simplified reports or an annex to the report?
c) require the certificate issuer to review the calibration record and document the review, if the issuer is not the person that performed the work?
d) Not applicable to Forensic Science Calibration Laboratories;
e) Not applicable to Forensic Science Calibration Laboratories;
f) Not applicable to Forensic Science Calibration Laboratories;
g) Not applicable to Forensic Science Calibration Laboratories;
h) require the issuance of an endorsed calibration certificate if requested by the customer?

Objective Evidence

Quality Manual documentation

5.10.1.2 ANAB Accreditation Requirement — Conforming

Requirement

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

Objective Evidence

Onsite review, witnessing

5.10.2 ISO/IEC 17025:2005 — Conforming

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 test reports and 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 test report or 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 calibration certificate or a written agreement with the customer for a simplified certificate (see ISO/IEC 17025:2005, clause 5.10.1).

Objective Evidence

Calibration record review

5.10.4.1 ISO/IEC 17025:2005 — Conforming

Requirement

In addition to the requirements listed in 5.10.2, do calibration certificates include the following, where necessary for the interpretation of calibration results:
a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results?
b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof?
c) evidence that the measurements are traceable? (see Note 2 in 5.6.2.1.1)

Objective Evidence

Calibration record review

5.10.4.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a policy and procedure to implement clause 5.10.4.1 (b) of ISO/IEC 17025:2005? Does the procedure:
a) require the estimated uncertainty to be contained in the calibration certificate?
b) require the reported uncertainty statement to include the measured quantity value, y, along with the associated expanded uncertainty, U, the coverage factor, 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 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 2 c) When the measurement is expressed as a fraction, the uncertainty may be reported as a fraction.

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

Objective Evidence

5.10.4.1.2 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 calibration result or prohibits including measurement uncertainty in the calibration certificate, 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 calibration result?

Objective Evidence

No regulatory body, statute, case law, or other legal requirement pertaining to calibrations certificates.

5.10.4.2 ISO/IEC 17025:2005 — Conforming

Requirement

Does the calibration certificate relate only to quantities and the results of functional tests? If a statement of compliance with a specification is made, does this identify which clauses of the specification are met or not met?

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, does the laboratory record those results and maintain them for possible future reference?

When statements of compliance are made, has the uncertainty of measurement been taken into account?

Objective Evidence

Calibration records reviewed

5.10.4.3 ISO/IEC 17025:2005 — Conforming

Requirement

When an instrument for calibration has been adjusted or repaired, were the calibration results before and after adjustment or repair, if available, reported?

Objective Evidence

Calibration record review

5.10.4.4 ISO/IEC 17025:2005 — Conforming

Requirement

Does a calibration certificate (or calibration label) not contain any recommendation on the calibration interval except where this has been agreed with the customer? This requirement may be superseded by legal regulations.

Objective Evidence

Calibration record review

5.10.6 ISO/IEC 17025:2005 — Not Applicable

Requirement

When a calibration has been subcontracted, does the laboratory performing the work issue the calibration certificate to the contracting laboratory?

Objective Evidence

The laboratory does not subcontract calibration work.

5.10.6.1 ANAB Accreditation Requirement — Not Applicable

Requirement

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

Objective Evidence

The laboratory does not subcontract calibration work.

5.10.7 ISO/IEC 17025:2005 — Not Applicable

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

N/A, Calibration results are not transmitted by telephone, telex, facsimile, or other electronic or electromagnetic means

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

Calibration record review

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

Calibration record review

5.10.10.1 ANAB Accreditation Requirement — Not Applicable

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 Calibration accreditation program?
c) non-accredited calibration 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 calibration results?
f) no implication that a product, process, system or person is approved by the accreditation body?

Objective Evidence

The laboratory is not currently accredited and does not use the accreditation symbol for breath alcohol calibration related communications.

5.10.10.2 ANAB Accreditation Requirement — Not Applicable

Requirement

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

NOTE This is applicable to subcontractor results included in a calibration certificate.

Objective Evidence

The laboratory is not currently accredited and does not use the accreditation symbol for breath alcohol calibration related communications.

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

The ILAC mark is not used by the laboratory.