



## Colorado Bureau of Investigation

2019 - 17025T - Reassessment

Prepared by Lucy Davis

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ANSI National Accreditation Board

6000 W. 54th Avenue, Arvada, 80002

Colorado, United States

**Signature**

Completed by Lucy Davis on 2019-06-19

A handwritten signature in black ink, appearing to read 'Lucy Davis', is written over a horizontal line.

## Audit Objective Evidence

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### 4.1 Impartiality

#### 4.1.1 ISO/IEC 17025:2017

**Conforming**

##### Requirement

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

##### Objective Evidence

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Quality Manual Section 4  
Interviews with staff

#### 4.1.2 ISO/IEC 17025:2017

**Conforming**

##### Requirement

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Is the laboratory management committed to impartiality?

##### Objective Evidence

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Quality Manual Section 4  
CBI Department of Public Safety - Code of Conduct Directive  
CBI Guiding Principles, Vision, and Mission Statements  
Interviews with Quality Manager and staff

#### 4.1.3 ISO/IEC 17025:2017

**Conforming**

##### Requirement

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

##### Objective Evidence

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Quality Manual Section 4  
CBI Directive 2.2  
Conditions of Employment  
CBI Department of Public Safety - Code of Conduct Directive

#### 4.1.3.1 ANAB Accreditation Requirement

**Conforming**

##### Requirement

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Does the management system:

- 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 management's commitment to good professional practice?
- ensure annual review of the document by all personnel and maintain a record of the review? and
- 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

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QP4 Management System Review  
CBI Department of Public Safety - Code of Conduct Directive  
CBI Guiding Principles, Vision, and Mission Statements  
Review of Guiding Principles Laboratory Review report  
Interview with Quality Manager

#### 4.1.4 ISO/IEC 17025:2017

**Conforming**

##### Requirement

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

impartiality.

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

**Objective Evidence**

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Quality Manual 4.3  
Interview with Quality Manager

**4.1.5 ISO/IEC 17025:2017**

**Conforming**

**Requirement**

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

**Objective Evidence**

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Quality Manual 4.4.b  
Interview with Quality Manager

**4.2 Confidentiality**

**4.2 ISO/IEC 17025:2017**

**Conforming**

**Requirement**

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Confidentiality

**Objective Evidence**

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QP10 Responsibility to the Customer, Section G  
CBI Department of Public Safety - Code of Conduct Directive

**4.2.1 ISO/IEC 17025:2017**

**Conforming**

**Requirement**

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

**Objective Evidence**

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QP10 Responsibility to the Customer, Section G  
General Notice to Customers  
Interview with Quality Manager

**4.2.2 ISO/IEC 17025:2017**

**Conforming**

**Requirement**

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

**Objective Evidence**

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QP10 Responsibility to the Customer, Section G  
Forensic Services Submission and Analysis of Evidence Notice to Customer  
Interview with Quality Manager

**4.2.3 ISO/IEC 17025:2017**

**Conforming**

**Requirement**

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

**Objective Evidence**

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QP10 Responsibility to the Customer  
CBI Department of Public Safety - Code of Conduct Directive

**4.2.4 ISO/IEC 17025:2017**

**Conforming**

**Requirement**

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

**Objective Evidence**

QP10 Responsibility to the Customer  
CBI Department of Public Safety - Code of Conduct Directive  
Memorandum of Understanding Quality System - Northern Colorado Laboratory Group and Colorado Bureau of Investigation  
Interview with Quality Manager

**5. Structural requirements**

**5.1 ISO/IEC 17025:2017**

**Conforming**

**Requirement**

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

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

ANAB NOTE 2 Publicly funded government laboratories are recognized as meeting 5.1

**Objective Evidence**

Quality Manual 4.1.  
Colorado Title 24-33.5-412  
Memorandum of Understanding Quality System - Northern Colorado Laboratory Group and Colorado Bureau of Investigation

**5.2 ISO/IEC 17025:2017**

**Conforming**

**Requirement**

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

**Objective Evidence**

Quality Manual Section 5.4  
QP2 Responsibilities, Authority and Management Continuity  
Organization Chart

**5.2.1 ANAB Accreditation Requirement**

**Conforming**

**Requirement**

Is there a director, whose duties are defined?

**Objective Evidence**

Quality Manual Section 5.4  
QP2 Responsibilities, Authority and Management Continuity  
Organization Charts

**5.3 ISO/IEC 17025:2017**

**Conforming**

**Requirement**

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

**Objective Evidence**

Quality Manual 1.2.1  
CBI website (<https://www.colorado.gov/pacific/cbi/forensic-services>)  
Review of technical reports

**5.4 ISO/IEC 17025:2017**

**Conforming**

## Requirement

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

## Objective Evidence

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Quality Manual 4.2.  
Review of Management Review and Internal Audits  
Interviews with staff

### 5.4.1 ANAB Accreditation Requirement

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**Conforming**

## Requirement

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Does an National DNA Index System (NDIS) participating laboratory conform to requirements in the NDIS Operational Procedures Manual and in applicable FBI Quality Assurance Standards?

## Objective Evidence

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Externally Controlled document list  
Review of annual FBI Quality Assurance Standards Audit documentation and notification to FBI  
Interviews with DNA Technical Leader and CODIS State Administrator

### 5.4.2 ANAB Accreditation Requirement

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**Conforming**

## Requirement

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

## Objective Evidence

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Quality Manual 1.2.1.  
Review of technical reports  
Review of CBI Forensic Services website: <https://www.colorado.gov/pacific/cbi/forensic-accreditation>

### 5.4.3 ANAB Accreditation Requirement

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**Conforming**

## Requirement

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

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

## Objective Evidence

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QP2 Responsibilities, Authority and Management Continuity  
QP1 Commitment to Quality  
CBI website

### 5.5 ISO/IEC 17025:2017

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**Conforming**

## Requirement

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

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

## Objective Evidence

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Quality Manual 5.1  
QP2 Responsibilities, Authority and Management Continuity  
CBI Laboratories Organization Charts  
Discipline specific procedure manuals

### 5.6 ISO/IEC 17025:2017

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**Conforming**

## Requirement

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Does the laboratory have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

- a) implementation, maintenance and improvement of the management system?
- b) identification of deviations from the management system or from the procedures for performing laboratory activities?
- c) initiation of actions to prevent or minimize such deviations?
- d) reporting to laboratory management on the performance of the management system and any need for improvement?
- e) ensuring the effectiveness of laboratory activities?

## Objective Evidence

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Quality Manual 5.4  
QP2 Responsibilities, Authority and Management Continuity  
QP11 Quality Incident Review  
Interviews with Quality Manager, Deputy Laboratory Director, and staff

## 5.7 ISO/IEC 17025:2017

**Conforming**

## Requirement

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Does the laboratory management ensure that:

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

## Objective Evidence

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Quality Manual 4.5  
Review of monthly meetings and agendas  
Interview with Laboratory Deputy Director

## 6.1 General

### 6.1 ISO/IEC 17025:2017

**Conforming**

## Requirement

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

## Objective Evidence

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Review of Management System and discipline specific documents  
On-site inspection of facilities and equipment  
Interviews with staff

## 6.2 Personnel

### 6.2.1 ISO/IEC 17025:2017

**Conforming**

## Requirement

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

## Objective Evidence

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Quality Manual 9.1.  
QP16 Training  
Review of personnel competency and authorization records  
On-site witnessing of analysis  
Interviews with staff

### 6.2.2 ISO/IEC 17025:2017

**Conforming**

## Requirement

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

## Objective Evidence

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Quality Manual 9.4  
QP16 Training  
Discipline specific training plans (manuals)

### 6.2.2.1 ANAB Accreditation Requirement

Conforming

#### Requirement

Do personnel who authorize results, opinions, and/or interpretations in the following disciplines meet the minimum educational requirements below?

Discipline Minimum Education Requirements

Biology A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.

Wildlife Forensics

Fire Debris and Explosives

Geological Materials

Gunshot Residue

Materials (Trace)

Seized Drugs

Toxicology

Bloodstain Pattern Analysis Meet the educational requirement(s) specified for competence (see ISO/IEC 17025:2017 6.2.2).

Firearms/Toolmarks

Footwear and Tire

Document Examination

Friction Ridge

Digital Evidence

Video/Imaging Technology and Analysis

Crime Scene Investigation

Fire and Explosion Investigation

Anthropology An advanced degree in anthropology, dentistry, or medicine.

Disaster Victim Identification

Odontology

Medicolegal Death Investigation

NOTE 1 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.

NOTE 2 This table is not exhaustive and additional disciplines may be added as appropriate.

#### Objective Evidence

Quality Manual 9.4.

Review of Employee Records

Review of job descriptions

Interviews with Quality Manager and staff

### 6.2.3 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

QP16 Training

Review of personnel education, training, and competency records

Interviews with staff

### 6.2.3.1 ANAB Accreditation Requirement

Conforming

#### Requirement

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

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

#### Objective Evidence

QP16 Training Section F

Discipline specific training plans (manuals)

Review of personnel competency records

Interviews with technical leaders

### 6.2.3.2 ANAB Accreditation Requirement

Conforming

#### Requirement

Do personnel who review and authorize results (7.8.1.1), an opinion or an interpretation or perform technical review of results or testimony (7.7.1.1), meet the competency requirements as specified in 6.2.3.1?

#### Objective Evidence

QP16 Training  
Discipline specific training plans (manuals)  
Review of personnel competency and authorization records  
Review of case records

#### 6.2.4 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

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Quality Manual 9.2  
CBI Department of Public Safety Conditions of Employment 2.2 directive  
Job descriptions  
Interviews with staff

#### 6.2.5 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

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QP16 Training  
CBI Department of Public Safety Human Resources Records  
QP25 Proficiency Testing  
QP2 Responsibilities, Authority and Management Continuity  
Review of personnel competency and authorization records

#### 6.2.6 ISO/IEC 17025:2017

Conforming

##### Requirement

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

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

##### Objective Evidence

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Quality Manual 9.3  
QP16 Training  
Review of personnel authorization records

##### Other

#### 6.2.2.2 ANAB Accreditation Requirement

Conforming

##### Requirement

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Does the training program, to the extent necessary based on job function, include:  
a) the knowledge, skills, and abilities needed to perform work?  
b) general knowledge of forensic science?  
c) the application of ethical practices in forensic science?  
d) criminal law, civil law, and testimony?  
e) provisions for retraining?  
f) provisions for maintenance of skills and expertise? and  
g) criteria for acceptable performance?

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

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

##### Objective Evidence

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QP16 Training  
Discipline specific training plans (manuals)

Review of personnel training records

### 7.5.1.5 ANAB Accreditation Requirement

Conforming with Comment : 0

#### Requirement

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

#### Objective Evidence

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QP14 Control of Records, Section B  
Review of case records  
Interviews with staff

#### Comment

The laboratory would benefit by clearly identifying in the technical records the date of data rejection.

## 6.3 Facilities and environmental conditions

### 6.3.1 ISO/IEC 17025:2017

Conforming

#### Requirement

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

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

#### Objective Evidence

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Quality Manual Section 10  
QP29 Temperature Monitoring  
Discipline specific procedure manuals Section 3  
On-site inspection of facilities  
Interviews with staff

### 6.3.2 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

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Quality Manual Section 10.  
QP29 Temperature Monitoring  
Discipline specific procedure manuals Section 3  
On-site inspection of facilities

### 6.3.3 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

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Quality Manual Section 10  
QP29 Temperature Monitoring  
Discipline specific procedure manuals Section 3  
On-site inspection of facilities  
Review of temperature logs  
Interviews with staff

### 6.3.4 ISO/IEC 17025:2017

Conforming

#### Requirement

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Are measures to control facilities implemented, monitored and periodically reviewed and include, but not be limited to:

- access to and use of areas affecting laboratory activities?
- prevention of contamination, interference or adverse influences on laboratory activities?
- effective separation between areas with incompatible laboratory activities?

## Objective Evidence

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Discipline specific procedure manuals Section 3  
QP17 Security  
Facilities Operations Manual  
Review of Security Quality Incident Reports  
Interview with Quality Manager

### 6.3.4.1 ANAB Accreditation Requirement

**Conforming**

#### Requirement

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

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

#### Objective Evidence

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QP17 Security  
Facilities Operations Manual  
Discipline specific procedure manuals Section 3  
Review of Security Quality Incident Reports

### 6.3.5 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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

#### Objective Evidence

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QP17 Security  
Crime Scene Operations Manual Section 3  
Interviews with staff

## 6.4 Equipment

### 6.4.1 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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

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

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

#### Objective Evidence

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QP21 Equipment, instrumentation  
Discipline specific procedure manuals Section 5  
Review of reagent and equipment logs  
On-site witnessing of analysis and inspection of equipment  
Interviews with staff

### 6.4.2 ISO/IEC 17025:2017

**Not Applicable**

#### Requirement

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

#### Objective Evidence

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CBI does not use equipment that is out of their permanent control

### 6.4.3 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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

#### Objective Evidence

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QP21 Equipment, instrumentation  
Discipline specific procedure manuals Section 5  
Interviews with Quality Manager and staff

#### 6.4.3.1 ANAB Accreditation Requirement

**Conforming**

#### Requirement

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

#### Objective Evidence

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QP8 Reagents, chemicals and supplies Section III.F  
Discipline specific procedure manuals Section 6  
Review of reagent logs  
On-site inspection of facilities

#### 6.4.3.2 ANAB Accreditation Requirement

**Conforming**

#### Requirement

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

#### Objective Evidence

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Quality Manual 12.3.  
DNA Database operations manual  
Firearms operations manual Section 10.18  
DNA operations manual Section 11  
On-site review  
Interviews with staff

#### 6.4.4 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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

#### Objective Evidence

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QP21 Equipment  
Discipline specific procedure manuals Section 5  
Review of maintenance records  
Interview with staff

#### 6.4.5 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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

#### Objective Evidence

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QP21 Equipment  
Discipline specific procedure manuals Section 5  
Review of maintenance logs  
Review of calibration logs and certificates

#### 6.4.6 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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Is measuring equipment calibrated when:

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

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

#### Objective Evidence

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QP21 Equipment  
Discipline specific procedure manuals Section 5  
Review of maintenance logs  
Review of calibration logs and certificates

### 6.4.7 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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

#### Objective Evidence

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QP21 Equipment  
Discipline specific procedure manuals Section 5  
Review of calibration logs and certificates  
Interview with Quality Manager

### 6.4.7.1 ANAB Accreditation Requirement

**Conforming**

#### Requirement

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Does the program for the calibration of 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

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QP21 Equipment  
Discipline specific procedure manuals Section 5  
Review of calibration logs and certificates

### 6.4.8 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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

#### Objective Evidence

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QP21 Equipment  
Discipline specific procedure manuals Section 5  
Review of equipment logs  
On-site inspection of equipment

### 6.4.9 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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

#### Objective Evidence

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QP21 Equipment  
Discipline specific procedure manuals Section 5  
Review of maintenance logs  
On-site inspection of equipment  
Quality Incident Reports  
Interviews with Quality Manager and staff

### 6.4.10 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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

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

#### Objective Evidence

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QP21 Equipment  
Discipline specific procedure manuals Section 5  
Review of equipment logs

### 6.4.11 ISO/IEC 17025:2017

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**Conforming**

#### Requirement

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

#### Objective Evidence

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QP21 Equipment  
Discipline specific procedure manuals Section 5  
Review of reference material logs  
Interviews with Quality Manager and staff

### 6.4.12 ISO/IEC 17025:2017

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**Conforming**

#### Requirement

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

#### Objective Evidence

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QP21 Equipment  
QP17 Security  
Discipline specific procedure manuals Section 5  
Interviews with Quality Manager and staff

### 6.4.13 ISO/IEC 17025:2017

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**Conforming**

#### Requirement

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Are records retained for equipment which can influence laboratory activities?

Do the records include the following, where applicable:

- a) the identity of equipment, including software and firmware version?
- b) the manufacturer's name, type identification, and serial number or other unique identification?
- c) evidence of verification that equipment conforms with specified requirements?
- d) the current location?
- e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval?
- f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity?
- g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment?
- h) details of any damage, malfunction, modification to, or repair of, the equipment?

#### Objective Evidence

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QP21 Equipment  
Review of equipment records in LIMS Resource Manager  
Interviews with Quality Manager and staff

## 6.5 Metrological traceability

### 6.5.1 ISO/IEC 17025:2017

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**Conforming**

#### Requirement

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

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

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

#### Objective Evidence

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QP22 Traceability  
Review of calibration records and certificates  
Review of Measurement Uncertainties and Budgets

### 6.5.1.1 ANAB Accreditation Requirement

Conforming

#### Requirement

If available, are the suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials used to establish or maintain metrological traceability either:  
a) a National Metrology Institute that is a signatory to the BIPM - CIPM Mutual Recognition Arrangement with the calibration of measuring equipment and/or reference standard to be performed or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB)? or  
b) a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be performed listed in a scope of accreditation? or  
c) an accredited reference material producer that is accredited to ISO 17034, by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material?

#### Objective Evidence

QP22 Traceability  
Review of approved Vendor List  
Review of calibration records and certificates  
Interview with Quality Manager

### 6.5.1.2 ANAB Accreditation Requirement

Conforming

#### Requirement

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

#### Objective Evidence

QP22 Measurement Traceability Section E  
Interview with Quality Manager  
No situations were identified that a supplier was not available

### 6.5.1.3 ANAB Accreditation Requirement

Not Applicable

#### Requirement

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

#### Objective Evidence

CBI does not calibrate its own equipment although they address it in their procedures.  
QP22 Measurement Traceability

### 6.5.1.4 ANAB Accreditation Requirement

Conforming

#### Requirement

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

#### Objective Evidence

QP24 Reference Materials Section C  
Drug Chemistry procedure manual 10.10  
Toxicology procedure manual Section 6  
Review of reference material logs  
Interviews with staff

### 6.5.2 ISO/IEC 17025:2017

Conforming

## Requirement

---

Does the laboratory ensure that measurement results are traceable to the International System of Units (SI) through:

- calibration provided by a competent laboratory? or
- certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI? or
- direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards?

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

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

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

## Objective Evidence

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QP22 Traceability  
Review of approved vendors list  
Review of calibration records and certificates  
Interview with Quality Manager

### 6.5.3 ISO/IEC 17025:2017

**Conforming**

## Requirement

---

When metrological traceability to the SI units is not technically possible, does the laboratory demonstrate metrological traceability to an appropriate reference, e.g.:

- certified values of certified reference materials provided by a competent producer?
- results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison?

## Objective Evidence

---

QP22 Traceability  
Review of calibration records and certificates  
Interview with Quality Manager

## 6.6 Externally provided products and services

### 6.6.1 ISO/IEC 17025:2017

**Conforming**

## Requirement

---

Does the laboratory ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

- are intended for incorporation into the laboratory's own activities?
- are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider?
- are used to support the operation of the laboratory?

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

## Objective Evidence

---

QP07--Subcontracting, Outsourcing  
QP08--Reagents, Chemicals and Supplies  
QP09--Evaluation of Suppliers  
Review of approved vendor list  
Interview with Quality Manager

### 6.6.2 ISO/IEC 17025:2017

**Conforming**

## Requirement

---

Does the laboratory have a procedure and retain records for:

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

## Objective Evidence

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QP07--Subcontracting, Outsourcing  
QP08--Reagents, Chemicals and Supplies  
QP09--Evaluation of Suppliers  
Review of Purchase Request  
CBI Department of Public Safety Directive, Chapter 3.4, Operating Expenses and Procurement  
Interview with Quality Manager

### 6.6.3 ISO/IEC 17025:2017

Conforming

#### Requirement

Does the laboratory communicate its requirements to external providers for:

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

#### Objective Evidence

QP07--Subcontracting, Outsourcing  
QP08--Reagents, Chemicals and Supplies  
QP09--Evaluation of Suppliers  
CBI Department of Public Safety Directive, Chapter 3.4, Operating Expenses and Procurement  
Purchase Order Terms and Conditions  
Review of approved vendor list  
Interview with Quality manager

## 7.1 Review of requests, tenders and contracts

### 7.1.1 ISO/IEC 17025:2017

Conforming

#### Requirement

Does the laboratory have a procedure for the review of requests, tenders and contracts? Does the procedure ensure that:

- the requirements are adequately defined, documented and understood?
- the laboratory has the capability and resources to meet the requirements?
- where external providers are used, the requirements of 6,6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval?
- the appropriate methods or procedures are selected and are capable of meeting the customers' requirements?

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

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

#### Objective Evidence

QP06--Review of Requests, Tenders and Contracts  
Evidence Submission forms  
Forensic Services Submission and Analysis of Evidence Notice to Customer  
Review of case records  
Interviews with staff

### 7.1.2 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

QP06--Review of Requests, Tenders and Contracts  
Evidence Submission forms  
Forensic Services Submission and Analysis of Evidence Notice to Customer  
Review of case records  
Interviews with staff

### 7.1.3 ISO/IEC 17025:2017

Not Applicable

#### Requirement

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

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

#### Objective Evidence

CBI does not issue conformity statements

#### 7.1.4 ISO/IEC 17025:2017

**Conforming**

##### Requirement

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

##### Objective Evidence

QP06--Review of Requests, Tenders and Contracts  
Review of case records  
Interviews with staff

#### 7.1.5 ISO/IEC 17025:2017

**Conforming**

##### Requirement

Is the customer informed of any deviation from the contract?

##### Objective Evidence

QP06--Review of Requests, Tenders and Contracts  
Forensic Services Submission and Analysis of Evidence Notice to Customer  
Review of case records  
Interviews with staff

#### 7.1.6 ISO/IEC 17025:2017

**Conforming**

##### Requirement

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

##### Objective Evidence

QP06--Review of Requests, Tenders and Contracts  
Review of case records  
Interviews with staff

#### 7.1.7 ISO/IEC 17025:2017

**Conforming**

##### Requirement

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

NOTE Such cooperation can include:

- a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;
- b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.

##### Objective Evidence

QP06--Review of Requests, Tenders and Contracts  
Forensic Services Submission and Analysis of Evidence Notice to Customer  
Review of case records  
Interviews with staff

#### 7.1.8 ISO/IEC 17025:2017

**Conforming**

##### Requirement

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

##### Objective Evidence

QP06--Review of Requests, Tenders and Contracts  
Review of case records  
Interviews with staff

#### 7.1.9 ANAB Accreditation Requirement

**Conforming**

##### Requirement

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

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

**Objective Evidence**

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Review of case records and associated reports  
Interviews with staff

**7.2.1 Selection and verification of methods**

**7.2.1.1 ISO/IEC 17025:2017**

**Conforming**

**Requirement**

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

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

**Objective Evidence**

---

Quality Manual 11.1  
Discipline specific procedure manuals  
Review of case records  
On-site witnessing of analysis  
Interviews with staff

**7.2.1.1.1 ANAB Accreditation Requirement**

**Conforming**

**Requirement**

---

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

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

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

**Objective Evidence**

---

Quality Manual 11.2  
Discipline specific procedure manuals  
Review of case records  
Interviews with staff

**7.2.1.1.2 ANAB Accreditation Requirement**

**Not Applicable**

**Requirement**

---

Does a 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**

---

CBI does not conduct breath alcohol measuring instrument calibrations.

**7.2.1.1.3 ANAB Accreditation Requirement**

**Not Applicable**

**Requirement**

---

Was the 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**

---

CBI does not conduct breath alcohol measuring instrument calibrations.

**7.2.1.2 ISO/IEC 17025:2017**

**Conforming**

## Requirement

---

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

## Objective Evidence

---

Quality Manual 11.1  
Discipline specific procedure manuals  
Review of documents in Qualtrax  
Interview with Quality Manager

### 7.2.1.3 ISO/IEC 17025:2017

**Conforming**

## Requirement

---

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

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

## Objective Evidence

---

Quality Manual 11.1  
Discipline specific procedure manuals  
Review of documents in Qualtrax  
Interview with Quality Manager

### 7.2.1.4 ISO/IEC 17025:2017

**Conforming**

## Requirement

---

When the customer does not specify the method to be used, does the laboratory select an appropriate method and inform the customer of the method chosen?

Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.

## Objective Evidence

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Quality Manual 11.2  
Forensic Services Submission and Analysis of Evidence Notice to Customer  
Discipline specific procedure manuals  
Review of case records

### 7.2.1.5 ISO/IEC 17025:2017

**Conforming**

## Requirement

---

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

## Objective Evidence

---

Quality Manual 11.2  
QP19 Validations  
Review of validation and performance check records  
Interviews with technical managers

### 7.2.1.6 ISO/IEC 17025:2017

**Conforming**

## Requirement

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

## Objective Evidence

---

QP19 Validations  
Review of validation records  
Interviews with technical managers

### 7.2.1.7 ISO/IEC 17025:2017

Conforming

#### Requirement

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

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

#### Objective Evidence

QP18 Deviations  
Review of Deviation Request  
Review of case records  
Interview with Quality Manager

### 7.2.2 Validation of methods

#### 7.2.2.1 ISO/IEC 17025:2017

Conforming

#### Requirement

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

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

NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:

- calibration or evaluation of bias and precision using reference standards or reference materials;
- systematic assessment of the factors influencing the result;
- testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
- comparison of results achieved with other validated methods;
- interlaboratory comparisons;
- evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

#### Objective Evidence

QP19 Validations  
Review of validation records  
Interviews with technical managers

#### 7.2.2.1.1 ANAB Accreditation Requirement

Conforming

#### Requirement

Does the laboratory have a procedure for method validation that:

- includes the associated data interpretation?
- establishes the data required to report a result, opinion, or interpretation?
- identifies limitations of the method, reported results, opinions, and interpretations?

#### Objective Evidence

QP19 Validations  
Review of validation records  
Interviews with technical managers

#### 7.2.2.2 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

QP19 Validations  
Review of validation records  
Interviews with technical managers

#### 7.2.2.2.1 ANAB Accreditation Requirement

Conforming

#### Requirement

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

## Objective Evidence

---

QP19 Validations  
Review of validation records  
Interviews with technical managers

### 7.2.2.3 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

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

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

## Objective Evidence

---

Quality Manual 11.3.2  
Review of validation records  
Interviews with technical managers

### 7.2.2.4 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

Does the laboratory retain the following records of validation:

- the validation procedure used?
- specification of the requirements?
- determination of the performance characteristics of the method?
- results obtained?
- a statement on the validity of the method, detailing its fitness for the intended use?

## Objective Evidence

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QP19 Validations  
Review of validation records  
Interviews with technical managers

## 7.3 Sampling

### 7.3.1 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

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

## Objective Evidence

---

Quality Manual Section 13  
CHE 08 Sampling

### 7.3.2 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

Does the sampling method describe:

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

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

## Objective Evidence

---

Quality Manual Section 13  
CHE 08 Sampling

### 7.3.2.1 ANAB Accreditation Requirement

**Conforming**

#### Requirement

---

Does the sampling method:

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

#### Objective Evidence

---

Quality Manual Section 13  
CHE 08 Sampling

### 7.3.3 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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Does the laboratory retain records of sampling data that forms part of the testing or calibration that is undertaken? Did the records include, where relevant:

- a) reference to the sampling method used?
- b) date and time of sampling?
- c) data to identify and describe the sample (e.g. number, amount, name)?
- d) identification of the personnel performing sampling?
- e) identification of the equipment used?
- f) environmental or transport conditions?
- g) diagrams or other equivalent means to identify the sampling location, when appropriate?
- h) deviations, additions to or exclusions from the sampling method and sampling plan?

#### Objective Evidence

---

Quality Manual Section 13  
CHE 08 Sampling  
Review of case records  
Interviews with staff

### 7.4 Handling of test or calibration items

#### 7.4.1 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

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

#### Objective Evidence

---

Quality Manual Section 14  
Evidence Operations Manual EP1  
Discipline specific procedure manuals Section 4  
On-site inspection of evidence storage locations

#### 7.4.1.1 ANAB Accreditation Requirement

**Conforming**

#### Requirement

---

When an item is considered to be evidence, does the procedure:

- a) address all items received?
- b) address requirements for storage, packaging, and sealing of items to:
  - 1) protect the integrity of all items? and
  - 2) require items to be re-sealed as soon as practicable?
- c) address measures to be taken to secure unattended items?
- d) require chain-of-custody for:
  - 1) all items received? and
  - 2) items that are collected or created and preserved for future testing (e.g., ESDA lifts, test-fired ammunition, latent print lifts, photos, trace evidence, DNA extracts)?
- e) require chain-of-custody to securely and accurately identify:
  - 1) the individual(s) or location(s) receiving or transferring the item(s)?
  - 2) the item(s) being transferred? and
  - 3) the chronological order of all transfers, minimally including the date?
- f) address requirements for individual characteristic database samples? and
- g) require communication to the customer regarding the disposition of all items received and address communication to the customer regarding items collected or created and preserved for future testing?

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

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

#### Objective Evidence

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Quality Manual Section 14  
Evidence Operations Manual EP1  
Discipline specific procedure manuals Section 4  
Forensic Services Submission and Analysis of Evidence Notice to Customer  
Review of case records and reports

#### 7.4.2.1 ANAB Accreditation Requirement

Conforming

##### Requirement

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

##### Objective Evidence

Quality Manual Section 14  
Evidence Operations Manual EP1  
Discipline specific procedure manuals Section 4

#### 7.4.3 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

Quality Manual Section 14  
Evidence Operations Manual EP1  
Discipline specific procedure manuals Section 4  
Review of case records and reports

#### 7.4.4 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

Quality Manual Section 14  
Evidence Operations Manual EP1  
Discipline specific procedure manuals Section 4  
QP29 Temperature Monitoring  
On-site inspection of facilities and review of records

### 7.4 Handling of test and calibration items

#### 7.4.2 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

Quality Manual Section 14  
Evidence Operations Manual EP1  
Discipline specific procedure manuals Section 4 and 10

### 7.5 Technical records

#### 7.5.1 ISO/IEC 17025:2017

Resolved Nonconformity

##### Requirement

Does the laboratory ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original? Do the technical records include the date and the identity of

personnel responsible for each laboratory activity and for checking data and results? Are original observations, data and calculations recorded at the time they are made and identifiable with the specific task?

#### Objective Evidence

---

QP14--Control of Records  
Technical records and reports  
Interviews with staff  
Instrument records

#### Nonconformity Resolution Workflow

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In Crime Scene, multiple options exist for determining projectile path and the vertical (elevation) and horizontal (azimuth) components of the path. Technical records do not document which mechanism was used.

Completion note: CBI laboratory updated the Discipline Operation Manual CRS 10-17 to require the use of photographs when using the protractor method. The updated procedure was provided. The case records will be monitored for 3 months to confirm compliance. This nonconformity is resolved.

#### 7.5.1.1 ANAB Accreditation Requirement

**Conforming**

##### Requirement

---

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

##### Objective Evidence

---

QP14--Control of Records  
Review of case records

#### 7.5.1.2 ANAB Accreditation Requirement

**Conforming**

##### Requirement

---

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

##### Objective Evidence

---

QP14--Control of Records  
Discipline Operations Manuals Abbreviation List  
Review of case records

#### 7.5.1.3 ANAB Accreditation Requirement

**Conforming with Comment : 0**

##### Requirement

---

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

##### Objective Evidence

---

QP14--Control of Records  
Discipline operating procedures  
Review of technical (case) records  
Interviews with staff

##### Comment

The Denver laboratory would benefit from increasing the detail maintained in Firearms technical records (examiner notes) when documenting significant agreement or association.

#### 7.5.1.4 ANAB Accreditation Requirement

**Conforming**

##### Requirement

---

Are records created or maintained in a permanent manner?

##### Objective Evidence

---

QP14--Control of Records  
Discipline specific procedure manuals  
Review of case records

#### 7.5.1.6 ANAB Accreditation Requirement

**Not Applicable**

## Requirement

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

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

## Objective Evidence

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CBI does not do calibrations

## 7.5.2 ISO/IEC 17025:2017

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**Conforming**

### Requirement

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

### Objective Evidence

---

QP14--Control of Records  
Review of case records  
Review of amended reports

## 7.6 Evaluation of measurement uncertainty

### 7.6.1 ISO/IEC 17025:2017

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**Conforming**

#### Requirement

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

#### Objective Evidence

---

QP20--Estimating Uncertainty of Measurement  
Discipline specific procedure manuals Section 9  
Review of Chemistry, Toxicology, and Firearms UOM Budgets

#### 7.6.1.1 ANAB Accreditation Requirement

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**Conforming**

##### Requirement

---

Does the method of analysis for evaluation of measurement uncertainty:

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

##### Objective Evidence

---

QP20--Estimating Uncertainty of Measurement  
Discipline specific procedure manuals Section 9  
Review of Chemistry, Toxicology, and Firearms UOM Budgets

### 7.6.2 ISO/IEC 17025:2017

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**Not Applicable**

#### Requirement

---

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

#### Objective Evidence

---

CBI does not perform calibrations.

### 7.6.3 ISO/IEC 17025:2017

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**Conforming**

#### Requirement

---

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

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

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

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

#### Objective Evidence

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QP20--Estimating Uncertainty of Measurement  
Discipline specific procedure manuals Section 9  
Review of Chemistry, Toxicology, and Firearms UOM Budgets  
Interviews with technical managers

### 7.6.3.1 ANAB Accreditation Requirement

**Conforming**

#### Requirement

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

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

#### Objective Evidence

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QP20--Estimating Uncertainty of Measurement  
Discipline specific procedure manuals Section 9  
Review of Chemistry, Toxicology, and Firearms UOM Budgets  
Review of case records and associated reports

### 7.6.4 ANAB Accreditation Requirement

**Conforming**

#### Requirement

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Were the following records maintained for each evaluation and estimation of measurement uncertainty:

- statement defining the measurand?
- statement of how traceability is established for the measurement?
- the equipment (e.g., measuring device[s] or instrument[s]) used?
- all uncertainty components considered?
- all uncertainty components of significance and how they were evaluated?
- data used to estimate repeatability, intermediate precision, and/or reproducibility?
- all calculations performed? and
- the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty?

#### Objective Evidence

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QP20--Estimating Uncertainty of Measurement  
Discipline specific procedure manuals Section 9  
Review of Chemistry, Toxicology, and Firearms UOM Budgets  
Interviews with staff

## 7.7 Ensuring the validity of results

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### 7.7.1 ISO/IEC 17025:2017

**Conforming**

#### Requirement

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Does the laboratory have a procedure for monitoring the validity of results? Is the resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results? Is the monitoring planned and reviewed and include, where appropriate, but not be limited to:

- use of reference materials or quality control materials?
- use of alternative instrumentation that has been calibrated to provide traceable results?
- functional check(s) of measuring and testing equipment?
- use of check or working standards with control charts, where applicable?
- intermediate checks on measuring equipment?
- replicate tests or calibrations using the same or different methods?
- retesting or recalibration of retained items?
- correlation of results for different characteristics of an item?
- review of reported results?
- intralaboratory comparisons?
- testing of blind sample(s)?

#### Objective Evidence

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Quality Manual Section 15  
QP21--Equipment, Instrumentation  
QP23--Reference Standards  
QP24--Reference Materials  
QP25--Proficiency Testing

**7.7.1 ANAB Accreditation Requirement****Conforming****Requirement**

g).1 When a verification of a result is carried out:

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

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

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

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

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

ANAB NOTE 3 The sampling rate may vary for different disciplines.

**Objective Evidence**

QP26--Reviews  
 QP27--Testimony  
 Discipline specific procedure manuals  
 Review of case and testimony review records  
 Interviews with Quality Manager and staff

**7.7.2 ISO/IEC 17025:2017****Conforming****Requirement**

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

- a) participation in proficiency testing?

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

- b) participation in interlaboratory comparisons other than proficiency testing?

**Objective Evidence**

QP25--Proficiency Testing  
 Discipline specific procedure manuals  
 Review of proficiency test records and plan

**7.7.2.1 ANAB Accreditation Requirement****Conforming****Requirement**

Does the process for monitoring performance by comparison with results of other forensic service providers at a minimum:

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

NOTE 1 Calibration and Testing scopes of accreditation are separate within the Toxicology discipline. The above requirements apply to each scope of accreditation.

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

**Objective Evidence**

QP25--Proficiency Testing  
 Review of proficiency testing records and plan  
 Interview with Quality Manager

**7.7.3 ISO/IEC 17025:2017****Conforming**

## Requirement

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

## Objective Evidence

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Quality Manual Section 15.2  
QP11 Quality Incident Review  
Review of Quality Incident reports  
Review of proficiency testing records  
Interview with Quality Manager

## 7.7.4 ANAB Accreditation Requirement

**Resolved Nonconformity**

### Requirement

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

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

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

NOTE 3 Calibration and Testing scopes of accreditation are separate within the Toxicology discipline. The above requirements apply to each scope of accreditation.

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

### Objective Evidence

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QP25--Proficiency Testing  
Proficiency Test Schedules and records  
Interview with Quality Manager

### Nonconformity Resolution Workflow

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Secondary Crime Scene Analysts have not completed annual intralaboratory comparisons, interlaboratory comparisons, proficiency tests or observation-based performance monitoring in the Crime Scene discipline.

**Completion note:** CBI laboratory gave 5 secondary Crime Scene Analysts an internal proficiency test. Documentation of the proficiency test created and successful completion by the analysts was provided. They updated their proficiency testing plan to include documentation of proficiency tests provided to secondary Crime Scene Analysts covered both their primary and secondary CSI duties and added the 5 other analysts to their proficiency test plan. This nonconformity is resolved.

## 7.7.5 ANAB Accreditation Requirement

**Conforming**

### Requirement

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Does the process for monitoring of performance by intralaboratory comparison, interlaboratory comparison, proficiency testing or observation-based testing at a minimum:

- ensure that results are not known or readily available to the participant being monitored?
- ensure use of approved methods?
- ensure appropriate technical records are retained?
- establish criteria for determining successful completion prior to the monitoring activity?
- require a mechanism to ensure the quality of intralaboratory comparisons, interlaboratory comparisons and observation-based monitoring prior to the monitoring activity? and
- for calibration laboratories, require intralaboratory comparisons, interlaboratory comparisons and proficiency tests to be performed using a breath alcohol measuring instrument that was calibrated by the person performing the comparison or test?

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

### Objective Evidence

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QP25--Proficiency Testing  
Review of proficiency testing records  
Interview with Quality Manager

## 7.7.6 ANAB Accreditation Requirement

**Conforming**

### Requirement

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Is there a plan that will:

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

**Objective Evidence**

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QP25--Proficiency Testing  
Review of proficiency testing records and plan  
Interview with Quality Manager

**7.7.7 ANAB Accreditation Requirement**

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**Conforming**

**Requirement**

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

**Objective Evidence**

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QP25--Proficiency Testing  
Review of approved vendors including proficiency testing provider's accreditation  
Review of proficiency testing records  
Interview with Quality Manager

**7.7.8 ANAB Accreditation Requirement**

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**Conforming**

**Requirement**

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

**Objective Evidence**

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QP25--Proficiency Testing  
Review of proficiency testing records  
Interview with Quality Manager

**7.8.1 General**

**7.8.1.1 ISO/IEC 17025:2017**

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**Conforming**

**Requirement**

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Are results reviewed and authorized prior to release?

**Objective Evidence**

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QP28--Reporting of Results  
Discipline specific procedure manuals  
Review of case records and associated reports

**7.8.1.1.1 ANAB Accreditation Requirement**

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**Conforming**

**Requirement**

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

**Objective Evidence**

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QP28--Reporting of Results section A.3  
Review of case records and associated reports

**7.8.1.2 ISO/IEC 17025:2017**

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**Resolved Nonconformity**

## Requirement

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Are results provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used? Are all issued reports retained as technical records?

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

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

## Objective Evidence

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QP28--Reporting of Results Section III  
Discipline specific reporting procedures  
Technical records and associated reports  
Interviews with staff

## Nonconformity Resolution Workflow

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Crime Scene procedure CRS 10-07 Sections H3 and I2 requires that trajectory angle descriptions be reported as estimates. Case reviews revealed that trajectory angle descriptions are not being reported as estimates.

Completion note: CBI laboratory updated the Discipline Operation Manual CRS 10-17 to require the trajectory angle descriptions to be reported as "approximate" rather than as estimates. The updated procedure was provided. The case records will be monitored for 3 months to confirm compliance. This nonconformity is resolved.

### 7.8.1.2.1 ANAB Accreditation Requirement

**Conforming**

#### Requirement

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Are the results provided in a written report?

#### Objective Evidence

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QP28--Reporting of Results  
Discipline specific procedure manuals  
Review of case records and associated reports

### 7.8.1.2.2 ANAB Accreditation Requirement

**Conforming**

#### Requirement

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Is there a procedure for reporting of results that:

- identifies what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for all (partial and complete) work performed?
- requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement?
- requires communicating the reason(s) in the report when the reported results are inconclusive?
- requires reporting of the initial database entry (e.g., CODIS, AFIS, NIBIN)? and
- requires reporting of an association resulting from a database search (e.g., CODIS, AFIS, NIBIN)?

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

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

#### Objective Evidence

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QP28--Reporting of Results  
Discipline specific procedure manuals  
Review of case records and associated reports

### 7.8.1.2.3 ANAB Accreditation Requirement

**Not Applicable**

#### Requirement

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Does the documented process for reporting of results of calibration:

- identify what information will be reported in the calibration certificate? and
- require the issuance of an endorsed calibration certificate if requested by the customer?

#### Objective Evidence

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CBI does not perform calibrations

**Requirement**

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

**Objective Evidence**

The agency does not have agreements with their customers for reporting results in a simplified way.

**7.8.1.3.1 ANAB Accreditation Requirement****Requirement**

When results are reported in a simplified way, does the agreement with the customer specify the content of a simplified report?

**Objective Evidence**

The agency does not have agreements with their customers for reporting results in a simplified way.

**7.8.2 Common requirements for reports (test, calibration or sampling)****7.8.2.1 ISO/IEC 17025:2017****Requirement**

Does each report include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

- a) a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling")?
- b) the name and address of the laboratory?
- c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities?
- d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end?
- e) the name and contact information of the customer?
- f) identification of the method used?
- g) a description, unambiguous identification, and, when necessary, the condition of the item?
- h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results?
- i) the date(s) of performance of the laboratory activity?
- j) the date of issue of the report?
- k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results?
- l) a statement to the effect that the results relate only to the items tested, calibrated or sampled?
- m) the results with, where appropriate, the units of measurement?
- n) additions to, deviations, or exclusions from the method?
- o) identification of the person(s) authorizing the report?
- p) clear identification when results are from external providers?

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

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

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

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

**Objective Evidence**

QP28--Reporting of Results  
Reports  
Interview with Quality Manager

**Nonconformity Resolution Workflow**

The reports issued by the laboratory do not always contain the following information:

- d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end,
- f) identification of the method used,
- i) the date(s) of performance of the laboratory activity,
- l) a statement to the effect that the results relate only to the items tested, calibrated or sampled, and
- n) additions to, deviations, or exclusions from the method.

Completion note: CBI laboratory updated their Forensic Services Submission and Analysis of Evidence General Notice to Customer to state the elements required in criteria 7.8.2.1 both included and not included in the simplified reports issued. The CBI Request for Laboratory Examination form was revised to include the statement, "By submitting evidence for testing, you agree to our posted Notice to Customer that can be found at the CBI Website" above the Investigating Officer signature line. Both documents were provided. This nonconformity is resolved.

### 7.8.2.2 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

QP28--Reporting of Results  
Review of case records and associated reports  
Interviews with Quality Manager and staff

### 7.8.3 Specific requirements for test reports

#### 7.8.3.1 ISO/IEC 17025:2017

Conforming

#### Requirement

In addition to the requirements listed in 7.8.2, do the test reports, where necessary for the interpretation of the test results, include the following:

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

#### Objective Evidence

QP28--Reporting of Results  
Review of case records and associated reports  
Interviews with staff

#### 7.8.3.1.c).1 ANAB Accreditation Requirement

Conforming

#### Requirement

Was/Did the measurement uncertainty:

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

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

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

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

#### Objective Evidence

QP28--Reporting of Results  
Review of case records and associated reports  
Interviews with staff

#### 7.8.3.1.1 ANAB Accreditation Requirement

Not Applicable

#### Requirement

If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a result or prohibits including measurement uncertainty in the report, did the forensic service provider:

- have objective evidence of the regulation, statute, case law or other legal requirement? and
- have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result?

#### Objective Evidence

CBI does not have a regulatory body, statute, case law or other legal requirement that specifies the format for the reporting of a result.

**Requirement**

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

**Objective Evidence**

QP28--Reporting of Results  
Review of case records and associated reports  
Interviews with staff

**7.8.4 Specific requirements for calibration certificates****7.8.4.1 ISO/IEC 17025:2017****Not Applicable****Requirement**

In addition to the requirements listed in 7.8.2, do calibration certificates shall include the following:

a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent)?

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

b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results?

c) a statement identifying how the measurements are metrologically traceable (see Annex A)?

d) the results before and after any adjustment or repair, if available?

e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6)?

f) where appropriate, opinions and interpretations (see 7.8.7)?

**Objective Evidence**

CBI does not issue calibration certificates.

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

Did/Was the measurement uncertainty:

a) include the measured quantity value,  $y$ , along with the associated expanded uncertainty,  $U$ , the coverage factor, and the coverage probability?

b) in the format of  $y \pm U$ ?

c) limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits? and

d) reported to the same level of significance as the measurement result?

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

**Objective Evidence**

CBI does not issue calibration certificates.

**7.8.4.1.1 ANAB Accreditation Requirement****Not Applicable****Requirement**

If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a calibration result or prohibits including measurement uncertainty in the calibration certificate, did the forensic service provider:

a) have objective evidence of the regulation, statute, case law or other legal requirement? and

b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the calibration result?

**Objective Evidence**

CBI does not issue calibration certificates.

**7.8.4.2 ISO/IEC 17025:2017****Not Applicable****Requirement**

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

**Objective Evidence**

CBI does not issue calibration certificates.

#### 7.8.4.3 ISO/IEC 17025:2017

Not Applicable

##### Requirement

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

##### Objective Evidence

CBI does not issue calibration certificates.

#### 7.8.4.4 ANAB Accreditation Requirement

Not Applicable

##### Requirement

If applicable, does a label (in addition to the calibration certificate) attached to a calibrated 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? and
- d) cross reference to the calibration certificate issued in respect to the calibration?

##### Objective Evidence

CBI does not issue calibration certificates.

#### 7.8.5 Reporting sampling - specific requirements

##### 7.8.5 ISO/IEC 17025:2017

Conforming

##### Requirement

Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, do reports include the following, where necessary for the interpretation of results:

- a) the date of sampling?
- b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate)?
- c) the location of sampling, including any diagrams, sketches or photographs?
- d) a reference to the sampling plan and sampling method?
- e) details of any environmental conditions during sampling that affect the interpretation of the results?
- f) information required to evaluate measurement uncertainty for subsequent testing or calibration?

##### Objective Evidence

QP28--Reporting of Results Section D.3  
Review of case records and associated reports  
Interviews with staff

##### 7.8.5.d).1 ANAB Accreditation Requirement

Conforming

##### Requirement

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

##### Objective Evidence

QP28--Reporting of Results  
Review of case records and associated reports  
Interviews with staff

#### 7.8.6 Reporting statements of conformity

##### 7.8.6.1 ISO/IEC 17025:2017

Not Applicable

##### Requirement

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

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

##### Objective Evidence

CBI does not issue statements of conformity

#### 7.8.6.2 ISO/IEC 17025:2017

Not Applicable

##### Requirement

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

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

##### Objective Evidence

CBI does not issue statements of conformity

#### 7.8.7 Reporting opinions and interpretations

##### 7.8.7.1 ISO/IEC 17025:2017

Conforming

##### Requirement

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

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

##### Objective Evidence

QP28--Reporting of Results Section III.A  
QP16-Training  
Review of personnel authorization records  
Review of case records and associated reports  
Interviews with staff

##### 7.8.7.2 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

QP28--Reporting of Results  
Discipline specific procedure manuals  
Review of case records and associated reports  
Interviews with staff

##### 7.8.7.3 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

QP28--Reporting of Results  
Review of case records  
Interviews with staff

#### 7.8.8 Amendments to reports

##### 7.8.8.1 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

QP28--Reporting of Results  
Review of case records and amended reports  
Interviews with staff

### 7.8.8.2 ISO/IEC 17025:2017

Conforming

#### Requirement

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

Do such amendments meet all the requirements of this document?

#### Objective Evidence

QP28--Reporting of Results  
Review of case records and amended reports  
Interviews with staff

### 7.8.8.3 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

QP28--Reporting of Results  
Review of case records and amended reports  
Interviews with staff

## 7.9 Complaints

### 7.9.1 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

Quality Manual Section 7  
QP10--Responsibilities to the Customer  
Website - <https://www.colorado.gov/pacific/cbi/form/compliments-complaints>  
Review of Complaint and Quality Incident Reports  
Interview with Quality Manager

### 7.9.2 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

Quality Manual Section 7  
QP10--Responsibilities to the Customer  
QP11-Quality Incident Review  
Review of Complaint and Quality Incident Reports  
Interview with Quality Manager

### 7.9.3 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

Quality Manual Section 7

QP10--Responsibilities to the Customer  
QP11-Quality Incident Review  
Review of Complaint and Quality Incident Reports  
Interview with Quality Manager

#### 7.9.4 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

QP10--Responsibilities to the Customer  
QP11-Quality Incident Review  
Review of Complaint and Quality Incident Reports  
Interview with Quality Manager

#### 7.9.5 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

QP10--Responsibilities to the Customer  
QP11-Quality Incident Review  
Review of Complaint and Quality Incident Reports  
Interview with Quality Manager

#### 7.9.6 ISO/IEC 17025:2017

Conforming

##### Requirement

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

NOTE This can be performed by external personnel.

##### Objective Evidence

QP10--Responsibilities to the Customer  
QP11-Quality Incident Review  
Review of Complaint and Quality Incident Reports  
Interview with Quality Manager

#### 7.9.7 ISO/IEC 17025:2017

Conforming

##### Requirement

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

##### Objective Evidence

QP10--Responsibilities to the  
QP11-Quality Incident Review  
Review of Complaint and Quality Incident Reports  
Interview with Quality Manager

### 7.10 Nonconforming work

#### 7.10.1 ISO/IEC 17025:2017

Conforming

##### Requirement

Does the laboratory have a procedure that is implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria)? Does the procedure ensure that:

- a) the responsibilities and authorities for the management of nonconforming work are defined?
- b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory?
- c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results?
- d) a decision is taken on the acceptability of the nonconforming work?
- e) where necessary, the customer is notified and work is recalled?
- f) the responsibility for authorizing the resumption of work is defined?

## Objective Evidence

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QP11--Quality Incident Review  
QP12--Corrective Action  
Review of Quality Incident Reports  
Interview with Quality Manager

### 7.10.2 ISO/IEC 17025:2017

---

**Conforming**

#### Requirement

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

## Objective Evidence

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QP11--Quality Incident Review  
QP12--Corrective Action  
Review of Quality Incident Reports  
Interview with Quality Manager

### 7.10.3 ISO/IEC 17025:2017

---

**Conforming**

#### Requirement

---

Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, does the laboratory implement corrective action?

## Objective Evidence

---

QP11--Quality Incident Review  
QP12--Corrective Action  
Review of Quality Incident and Corrective Action Reports  
Interview with Quality Manager

## 7.11 Control of data and information management

### 7.11.1 ISO/IEC 17025:2017

---

**Conforming**

#### Requirement

---

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

## Objective Evidence

---

Quality Manual Section 12.2  
QP03--Electronic Quality Management System  
Review of Qualtrax software  
Review of the LIMS software  
Interviews with Quality Manager and staff

### 7.11.2 ISO/IEC 17025:2017

---

**Conforming**

#### Requirement

---

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

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

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

## Objective Evidence

---

Quality Manual Section 12.2  
QP03--Electronic Quality Management System  
Review of Qualtrax software  
Review of the LIMS software  
Interviews with Quality Manager and staff

### 7.11.2.1 ANAB Accreditation Requirement

---

**Conforming**

## Requirement

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

## Objective Evidence

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Quality Manual Section 12.2  
QP19 Validations

CBI has no user developed software

## 7.11.3 ISO/IEC 17025:2017

---

**Conforming**

## Requirement

---

Is the laboratory information management system(s):

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

## Objective Evidence

---

Quality Manual Section 12.2  
QP03--Electronic Quality Management System  
Interviews with Quality Manager and staff

## 7.11.4 ISO/IEC 17025:2017

---

**Conforming**

## Requirement

---

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

## Objective Evidence

---

Quality Manual Section 12.2  
QP03--Electronic Quality Management System  
Interview with Quality Manager

LIMS is managed by the Department.

## 7.11.5 ISO/IEC 17025:2017

---

**Conforming**

## Requirement

---

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

## Objective Evidence

---

Quality Manual Section 12.2  
QP03--Electronic Quality Management System  
Interviews with Quality Manager and staff.

## 7.11.6 ISO/IEC 17025:2017

---

**Conforming**

## Requirement

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

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

## Objective Evidence

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Quality Manual 12.2.  
QP26-Reviews  
Review of case records  
Interviews with staff

## 7.11.6.1 ANAB Accreditation Requirement

---

**Conforming**

## Requirement

---

Does the technical record indicate the check was performed and who performed the check? When possible, is this check not conducted by

the person who performed the calculation(s) or the data transfers?

NOTE This check may be part of a technical review.

#### Objective Evidence

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Quality Manual Section 12.1  
QP26-Reviews  
Review of case records  
Interviews with staff

### 8.1.1 General

#### 8.1.1 ISO/IEC 17025:2017

**Conforming**

##### Requirement

---

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

NOTE See Annex B for more information.

#### Objective Evidence

---

Quality Manual Section 5.1  
Review of Management Reviews, Internal Audit reports, and quality documents  
Interviews with Laboratory Deputy Director and Quality Manager

#### 8.1.2 ISO/IEC 17025:2017

**Conforming**

##### Requirement

---

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

#### Objective Evidence

---

Quality Manual 5.1  
Quality Policies

#### 8.1.3 ISO/IEC 17025:2017

**Not Applicable**

##### Requirement

---

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

#### Objective Evidence

---

CBI uses Option A

#### 8.1.3.1 ANAB Accreditation Requirement

**Not Applicable**

##### Requirement

---

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

#### Objective Evidence

---

CBI uses Option A

#### 8.1.3.2 ANAB Accreditation Requirement

**Not Applicable**

## Requirement

---

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

## Objective Evidence

---

CBI uses Option A

## 8.2 Management system documentation (Option A)

### 8.2.1 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

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

#### Objective Evidence

---

Quality Manual Section 5.1  
QP1 Commitment to Quality  
Colorado Bureau of Investigation Guiding Principles, Vision, and Mission Statements  
Interviews with Laboratory Deputy Director and Quality Manager

#### 8.2.1.1 ANAB Accreditation Requirement

**Conforming**

#### Requirement

---

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

#### Objective Evidence

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Quality Manual Section 3.1

### 8.2.2 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

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

#### Objective Evidence

---

Quality Manual  
QP1 Commitment to Quality  
Colorado Bureau of Investigation Guiding Principles, Vision, and Mission Statements

### 8.2.3 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

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

#### Objective Evidence

---

Quality Manual  
QP1 Commitment to Quality  
QP04--Management System Review  
Review of Management Reviews, Internal Audit reports, and quality documents  
Interviews with Laboratory Deputy Director, Quality Manager and staff

### 8.2.4 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

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

#### Objective Evidence

---

Quality Manual Section 5.3  
Discipline specific procedure manuals

## 8.2.5 ISO/IEC 17025:2017

Conforming

### Requirement

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

### Objective Evidence

Quality Manual Section 5.1  
Review of Qualtrax  
Interviews with staff

## 8.3 Control of management system documents (Option A)

### 8.3.1 ISO/IEC 17025:2017

Conforming

### Requirement

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

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

### Objective Evidence

QP05--Document Control  
Externally Controlled Document List  
Review of documents in Qualtrax System  
Interview with Quality Manager

### 8.3.2 ISO/IEC 17025:2017

Conforming

### Requirement

Does the laboratory ensure that:

- documents are approved for adequacy prior to issue by authorized personnel?
- documents are periodically reviewed, and updated as necessary?
- changes and the current revision status of documents are identified?
- relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled?
- documents are uniquely identified?
- the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose?

### Objective Evidence

QP05--Document Control  
QP04--Management System Review  
Review of documents in Qualtrax System  
Interview with Quality Manager

## 8.4 Control of records (Option A)

### 8.4.1 ISO/IEC 17025:2017

Conforming

### Requirement

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

### Objective Evidence

QP14--Control of Records  
Review of Management Reviews, Internal Audit reports, and quality documents  
Review of case records  
Interview with Quality Manager

### 8.4.2 ISO/IEC 17025:2017

Conforming

### Requirement

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

NOTE Additional requirements regarding technical records are given in 7.5.

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

#### Objective Evidence

---

QP14--Control of Records  
On-site inspection of facilities and records storage  
Review of case records  
Interview with Quality Manager

### 8.5 Actions to address risks and opportunities (Option A)

#### 8.5.1 ISO/IEC 17025:2017

**Conforming**

##### Requirement

---

Does the laboratory consider the risks and opportunities associated with the laboratory activities in order to:

- give assurance that the management system achieves its intended results?
- enhance opportunities to achieve the purpose and objectives of the laboratory?
- prevent, or reduce, undesired impacts and potential failures in the laboratory activities?
- achieve improvement?

#### Objective Evidence

---

Quality Manual Section 8  
QP13--Preventive Action  
Review of risks and opportunities review  
Interview with Quality Manager

#### 8.5.2 ISO/IEC 17025:2017

**Conforming**

##### Requirement

---

Does the laboratory plan:

- actions to address these risks and opportunities?
- how to:
  - integrate and implement these actions into its management system?
  - evaluate the effectiveness of these actions?

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

#### Objective Evidence

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Quality Manual Section 8  
Review of risks and opportunities review  
Interview with Quality Manager

#### 8.5.3 ISO/IEC 17025:2017

**Conforming**

##### Requirement

---

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

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

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

#### Objective Evidence

---

Quality Manual Section 8  
Review of risks and opportunities review  
Interview with Quality Manager

### 8.6 Improvement (Option A)

#### 8.6.1 ISO/IEC 17025:2017

**Conforming**

##### Requirement

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

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

## Objective Evidence

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Quality Manual Section 8  
QP11--Quality Incident Review  
QP13--Preventive Action  
Review of Quality Incident Reports  
Interview with Quality Manager

### 8.6.2 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

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

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

#### Objective Evidence

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QP10--Responsibilities to the Customer  
Website - <https://www.colorado.gov/pacific/cbi/form/compliments-complaints>  
Website - <https://www.surveymonkey.com/r/CBI-FS-2minute>  
Review of Customer Feedback report  
Review of Management Review  
Interview with Quality Manager

## 8.7 Corrective actions (Option A)

### 8.7.1 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

When a nonconformity occurs, does the laboratory:

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

#### Objective Evidence

---

QP11--Quality Incident Review  
QP12--Corrective Action  
Review of Quality Incident Review Reports  
Review of Corrective Action Reports  
Interview with Quality Manager

### 8.7.1.g) ANAB Accreditation Requirement

**Conforming**

#### Requirement

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

#### Objective Evidence

---

QP11--Quality Incident Review  
QP12--Corrective Action  
Review of Corrective Action Reports  
Interview with Quality Managers

### 8.7.2 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

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

#### Objective Evidence

---

QP11--Quality Incident Review  
QP12--Corrective Action  
Review of Quality Incident Review Reports  
Review of Corrective Action Reports

### 8.7.3 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

QP11--Quality Incident Review  
QP12--Corrective Action  
Review of Quality Incident Review Reports  
Review of Corrective Action Reports

## 8.8 Internal audits (Option A)

### 8.8.1 ISO/IEC 17025:2017

Conforming

#### Requirement

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

#### Objective Evidence

QP15--Audits  
Review of Internal Audit Summary and supporting checklists  
Denver/Boulder - 12/3-4/2018  
Grand Junction - 11/15-16/2018  
Pueblo - 12/5/2018  
NCRFL - 11/27-28/2018  
Interview with Quality Manager

#### 8.8.1.a).1 ANAB Accreditation Requirement

Conforming

#### Requirement

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

#### Objective Evidence

QP15--Audits  
Review of Internal Audit Summary and supporting checklists  
Interview with Quality Manager

#### 8.8.1.1 ANAB Accreditation Requirement

Conforming

#### Requirement

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

#### Objective Evidence

QP15--Audits  
Review of Internal Audit Summary and supporting checklists  
Denver/Boulder - 12/3-4/2018  
Grand Junction - 11/15-16/2018  
Pueblo - 12/5/2018  
NCRFL - 11/27-28/2018  
Interview with Quality Manager

### 8.8.2 ISO/IEC 17025:2017

Conforming

#### Requirement

Does the laboratory:  
a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits?  
b) define the audit criteria and scope for each audit?  
c) ensure that the results of the audits are reported to relevant management?

- d) implement appropriate correction and corrective actions without undue delay?
- e) retain records as evidence of the implementation of the audit programme and the audit results?

NOTE ISO 19011 provides guidance for internal audits.

#### Objective Evidence

---

QP15--Audits  
Review of Internal Audit Summary and supporting checklists  
Review of Quality Incident and Corrective Action Reports  
Interview with Quality Manager

### 8.8.2.b).1 ANAB Accreditation Requirement

**Conforming**

#### Requirement

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

#### Objective Evidence

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QP15--Audits  
CBI has not performed an internal audit since going on-line with ISO/IEC 17025:2017.

## 8.9 Management reviews (Option A)

### 8.9.1 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

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

#### Objective Evidence

---

QP04--Management System Review  
Review of Management Review Meeting Minutes 8/2018 and 11/2018

#### 8.9.1.1.ANAB Accreditation Requirement

**Conforming**

#### Requirement

---

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

#### Objective Evidence

---

QP04--Management System Review  
Review of Management Review Meeting minutes

### 8.9.2 ISO/IEC 17025:2017

**Conforming**

#### Requirement

---

Are the inputs to management review recorded and include information related to the following:

- a) changes in internal and external issues that are relevant to the laboratory?
- b) fulfilment of objectives?
- c) suitability of policies and procedures?
- d) status of actions from previous management reviews?
- e) outcome of recent internal audits?
- f) corrective actions?
- g) assessments by external bodies?
- h) changes in the volume and type of the work or in the range of laboratory activities?
- i) customer and personnel feedback?
- j) complaints?
- k) effectiveness of any implemented improvements?
- l) adequacy of resources?
- m) results of risk identification?
- n) outcomes of the assurance of the validity of results?
- o) other relevant factors, such as monitoring activities and training?

#### Objective Evidence

---

QP04--Management System Review  
Review of Management Review Meeting minutes  
Interview with Quality Manager

---

**Requirement**

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

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

---

**Objective Evidence**

QP04--Management System Review  
Review of Management Review Meeting minutes  
Interview with Laboratory Deputy Director and Quality Manager