



Washington State Patrol Breath Test Program

2017-17025C-Off Site Review

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ANSI-ASQ National Accreditation Board

ALI-013-C

United States

Signature

Completed by Melissa Kennedy on 2017-11-27

M Kennedy for Mike Kellett

Audit Objective Evidence

4.1 Organization

4.1.2 ISO/IEC 17025:2005

Conforming

Requirement

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

Objective Evidence

BTP Quality Manual 2.3 Quality Policy Statement
BTP Quality Manual 2.4 Quality Assurance Objectives
BTP Operations Manual 2.5 Quality Assurance Program
Internet – Web Based Discovery Materials Site (Web DMS) located at http://www.wsp.wa.gov/breathtest/wdms_home.htm

4.1.5 ISO/IEC 17025:2005

Conforming

Requirement

- a) Does the laboratory have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures?
- b) Does the laboratory have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work?
- c) Does the laboratory have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?
- d) Does the laboratory have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity?
- e) Does the laboratory define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services?
- f) Does the laboratory specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations?
- g) Does the laboratory provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results?
- h) Does the laboratory have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations?
- i) Does the laboratory have a member of staff who is appointed as quality manager (however named) who, irrespective of other duties and responsibilities, has the defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; does the quality manager have direct access to the highest level of management at which decisions are made on laboratory policy or resources?

NOTE 2 (from 2016 ASCLD/LAB Supplemental Requirement)

The quality manager may be any member of the laboratory staff, including the laboratory director, or may be an individual from and designated by the laboratory's parent agency.

NOTE 3 (from 2016 ASCLD/LAB Supplemental Requirement)

The responsibilities of the quality manager should include the following:

- Maintaining and updating the Quality Manual (however named)
- Monitoring laboratory practices to verify continuing compliance with policies and procedures related to quality
- Evaluating equipment calibration and maintenance records
- Periodically assessing the adequacy of calibration certificate review activities
- Ensuring validation of new technical methods
- Investigating technical problems, propose corrective actions, and verify their implementation
- Administering proficiency testing and evaluating results
- Selecting, training, and evaluating internal auditors
- Scheduling and coordinating management system audits
- Evaluating results of management system audits
- Maintaining training records of laboratory personnel
- Recommending training to improve the quality of laboratory personnel
- Proposing corrections and improvement in the management system

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

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

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

Objective Evidence

For 4.1.5.e and 4.1.5.f only: Organizational charts, Operations Manual (1.5, 1.6 and 1.7)

4.2 Management system

4.2.2.1 ASCLD/LAB Supplemental Requirement

Conforming

Requirement

Does the management system:

- incorporate, or directly reference, the current, published version of the ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists, or equivalent, as part of the laboratory management's commitment to good professional practice (available at www.ascl-d-lab.org)?
- ensure that the current, published version of the ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists, or equivalent, is reviewed annually by all laboratory personnel? and
- maintain a record of the review by all laboratory personnel?

NOTE An equivalent document will cover the same topics and will demonstrate that the relevant aspects are covered.

Objective Evidence

BTP Quality Manual 2.3 Quality Policy Statement
BTP Quality Manual 2.7 Quality System Records: Access, Filing, Storage, Retention and Disposal

4.7 Service to the customer

4.7.2 ISO/IEC 17025:2005

Conforming

Requirement

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

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

Objective Evidence

For procedure see Operations Manual 1.9.3 Customer Surveys
Regarding records see customer survey records and Management Review of December 2916 which has Client Feedback as a component

4.8 Complaints

4.8 ISO/IEC 17025:2005

Conforming

Requirement

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

Objective Evidence

Management Review of December 2016 included consideration of complaints.
For procedure see Operations Manual 1.10 Complaints

4.9 Control of nonconforming testing and/or calibration work

4.9.1 ISO/IEC 17025:2005

Conforming

Requirement

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

Do the policies/procedures ensure that:

- the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified?
- an evaluation of the significance of the nonconforming work is made?
- correction is taken immediately, together with any decision about the acceptability of the nonconforming work?
- where necessary, the customer is notified and work is recalled?
- the responsibility for authorizing the resumption of work is defined?

NOTE Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management system and technical operations. Examples are customer complaints, quality control, instrument

calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

Objective Evidence

4.9.1a
Quality Manual 4.0 Control of Non-Conforming Work
Quality Manual 4.1 Policy
Quality Manual 4.3 Procedure
4.9.1 b
Quality Manual 4.1 Policy
Quality Manual 4.3.4 Evaluation of the Significance of Nonconforming Work
4.9.1 c
Quality Manual 4.2.2 Corrective Action Process
Quality Manual 4.3.4 Evaluation of the Significance of Nonconforming Work
Quality Manual 4.3.5 Corrective Action Plan and Implementation
4.9.1 d
Quality Manual 4.3.9 Notification of Clients
4.9.1 e
Quality Manual 4.3.11 Responsibilities for Authorizing Resumption of Work

4.9.2 ISO/IEC 17025:2005

Conforming

Requirement

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

Objective Evidence

"Quality Variance" and corrective action records

4.11 Corrective action

4.11.3 ISO/IEC 17025:2005

Conforming

Requirement

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

Objective Evidence

Corrective action records

4.11.4 ISO/IEC 17025:2005

Conforming

Requirement

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

Objective Evidence

Corrective action records

4.14 Internal audits

4.14.1 ISO/IEC 17025:2005

Conforming

Requirement

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

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

Objective Evidence

Quality Manual 5.0 for procedure, record of most recent Internal Audit Plan and summary of Internal Audit performed in September 2016.

4.14.1.1 ASCLD/LAB Supplemental Requirement

Conforming

Requirement

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

Objective Evidence

On-site activities for visit in October 2016 included review of 2015 internal audit records. This review is for 2016 internal audit records.

4.14.3 ISO/IEC 17025:2005

Conforming

Requirement

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

Objective Evidence

Summary of internal audit done in September 2016 includes area of activity audited and audit findings. Additional records describe actions taken regarding three nonconformities identified in the audit.

4.15 Management reviews

4.15.1 ISO/IEC 17025:2005

Conforming

Requirement

In accordance with a predetermined schedule and procedure, does the laboratory's top management periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements?

Does the review take account of:

- the suitability of policies and procedures?
- reports from managerial and supervisory personnel?
- the outcome of recent internal audits?
- corrective and preventive actions?
- assessments by external bodies?
- the results of interlaboratory comparisons or proficiency tests?
- changes in the volume and type of the work?
- client feedback?
- complaints?
- recommendations for improvement?
- other relevant factors, such as quality control activities, resources and staff training?

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

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

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

NOTE 4 (from 2016 ASCLD/LAB Supplemental Requirement)
Also see ISO/IEC 17025:2005, Clause 4.2.2.

Objective Evidence

Memorandum summarizing management review meeting of November 29, 2016, contains all elements of this requirement.

4.15.1.1 ASCLD/LAB Supplemental Requirement

Conforming

Requirement

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

Objective Evidence

On-site activities for visit in October 2016 included review of 2015 management review records. This review is for 2016 management review records.

4.15.2 ISO/IEC 17025:2005

Conforming

Requirement

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

Objective Evidence

Memorandum summarizing management review meeting of November 29, 2016, describes findings and planned actions. The November 29, 2016, record and a record dated 11-15-17 titled "Follow Up to 2016 Breath Test Program Management System Review" provide complete information regarding timelines for completion of action items.

5.9 Assuring the quality of test and calibration results

5.9.3 ASCLD/LAB Supplemental Requirement

Conforming

Requirement

Does the laboratory have a program of proficiency testing that is compliant with the current, published version of the ASCLD/LAB Proficiency Testing and Review Program (available at www.ascd-lab.org)?

Objective Evidence

See Quality Manual 9.2 and section 9.2.4 regarding the process.

5.9.3.1 ASCLD/LAB Supplemental Requirement

Conforming

Requirement

Does the laboratory proficiency testing program:

- a) require the laboratory to successfully complete, at least one external proficiency test annually as well as prior to the initial assessment?
- b) require each analyst, technician, and technical support personnel (however named) engaged in calibration work to successfully complete at least one internal or external proficiency test per calendar year?
- c) require the use of an ASCLD/LAB approved proficiency test provider, where available, for external proficiency tests?
- d) require the laboratory's own approved calibration method(s) to be used when performing a proficiency test?
- e) require personnel taking the proficiency test to take the proficiency test using a breath alcohol measuring instrument on which they have performed the job function being tested?
- f) include the establishment of criteria for the evaluation of proficiency tests prior to the proficiency test being taken?
- g) include steps to evaluate potentially inconsistent results? and
- h) require technical and administrative reviews to be performed on external proficiency testing at the same frequency as in regular calibration work?

NOTE 1 Successfully completing a proficiency test means either obtaining the correct response or completing appropriate corrective action.

NOTE 2 The requirement for technician and technical support personnel meeting this proficiency test requirement applies even though they do not furnish results/conclusions.

NOTE 3 A proficiency test may test a specific job related skill or skills, but does not have to test all aspects of an employee's job function. Laboratories should consider varying the design of proficiency tests so that over time an employee is tested on all aspects of the assigned job functions.

Objective Evidence

Quality Manual 9.2 Proficiency Testing

5.9.3.2 ASCLD/LAB Supplemental Requirement

Conforming

Requirement

Does the laboratory proficiency testing program require the following records, at a minimum, to be maintained:

- a) the proficiency test set identifier;
- b) how proficiency test samples were obtained or created;
- c) identity of the person taking the proficiency test;
- d) date of completion;
- e) originals or copies of all data and notes supporting the conclusions;
- f) the proficiency test expected results;
- g) any discrepancies noted;
- h) an indication that performance has been reviewed and feedback provided to the person taking the proficiency test; and
- i) details of the corrective actions taken (when necessary)?

Objective Evidence

Quality Manual 9.2.4 - Proficiency Testing Process