San Diego Co. Sheriff's Dept - Regional Crime Laboratory

2017-17025T-Off-Site Review

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Data collected on 2017-11-01

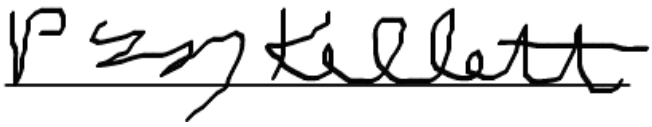
ANSI-ASQ National Accreditation Board

ALI-333-T

United States

Signature

Completed by Mike Kellett on 2017-12-27



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

Appropriate use of the accreditation symbol was verified on a sampling of test reports.

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?

NOTE (From 2011 ASCLD/LAB Supplemental Requirement)
The laboratory director should have a minimum of a baccalaureate degree in a natural science, criminalistics or a closely related field and at least five years of forensic science experience performing casework in one of the ASCLD/LAB-International accredited disciplines. If the director lacks a scientific background, then there should be support within management by personnel with appropriate scientific background. Additional education in management or business administration by college course work or short training courses (or both) is recommended and the laboratory director should have at least two years of experience in management.

NOTE 2 (From 2011 ASCLD/LAB Supplemental Requirement)
The laboratory or its parent agency should have a formal written budget. The budget should be adequate to meet the objectives of the laboratory.

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 (From 2011 ASCLD/LAB Supplemental Requirement)
A laboratory director should recognize the impact a quality manager can have on the successful implementation of a management system and of continuously improving its effectiveness. Appropriate personnel selection for this position should address an ability to communicate well and work effectively with all levels of laboratory personnel. The laboratory director may serve as quality manager. The responsibilities of the quality manager should include the following:
• Maintaining and updating the Quality Manual
• Monitoring laboratory practices to verify continuing compliance with policies and procedures related to quality
• Evaluating instrument calibration and maintenance records
• Periodically assessing the adequacy of test report review activities
• Ensuring validation of new technical procedures
• 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

4.1.5(e and f only))
Crime Laboratory Organizational Chart
Law Enforcement Services Bureau Organizational Chart
Quality Manual - Appendix B

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 Quality Manual – Section 9.22: Customer Feedback
Records for 2016 Customer Satisfaction Survey
Customer survey summary in 2016 Management Review Report

4.8 Complaints

4.8 ISO/IEC 17025:2005 — Conforming

Requirement

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

Objective Evidence

Quality Manual – Section 9.8: Complaints Against Crime Laboratory Employees
Quality Manual – Section 9.9: Complaints Against the Quality System

4.9 Control of nonconforming testing and/or calibration work

4.9.1 ISO/IEC 17025:2005 — Conforming

Requirement

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

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

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

Objective Evidence

Quality Manual 9.5
Quality Concerns and Corrective Action Logs

4.9.2 ISO/IEC 17025:2005 — Conforming

Requirement

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

Objective Evidence

Quality Manual – Section 9.5 and sampling of 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

A sampling of corrective action records was reviewed.

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

A sampling of corrective action records provide evidence of monitoring corrective actions to ensure effectiveness.

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.

ASCLD/LAB Program Application
"Trained and qualified personnel" in this instance means trained and qualified to conduct audits. Objective evidence of audit training and qualification must be maintained by the laboratory.

Objective Evidence

For procedure see Quality Manual – Section 9.11: Annual Audits and Section 9.12: Quality System Review
2017 Internal Audit Schedule provided as well as summary of results of internal audits

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

2017 Internal Section Audit Reports and Supervisor Responses

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.

Objective Evidence

See QM 9.13 for procedure
2016 Management Review Report (Jan 11, 2017) includes all elements of 4.15.1

4.15.1.1 ASCLD/LAB Supplemental Requirement — Conforming

Requirement

Are management reviews conducted at least annually?

Objective Evidence

Quality Manual – Section 9.13: Annual Management Review
2016 Management Review Report

4.15.2 ISO/IEC 17025:2005 — Conforming

Requirement

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

Objective Evidence

Quality Manual – Section 9.13: Annual Management Review
2016 Management Review Report

5.9 Assuring the quality of test and calibration results

5.9.3.3 ASCLD/LAB Supplemental Requirement — Conforming

Requirement

Did each analyst (however named) and technical support personnel engaged in testing activities successfully complete at least one internal or external proficiency test per calendar year in his/her forensic science discipline(s)?

NOTE 1 Successfully completing a proficiency test means either obtaining the correct response or completing corrective actions pursuant to laboratory policy and/or directives from an ASCLD/LAB Proficiency Review Committee (PRC).

NOTE 2 Proficiency testing using reexamination/reanalysis or blind techniques are acceptable forms of internal proficiency testing.

NOTE 3 The requirement for technical support personnel meeting this proficiency test requirement applies even though the technical support person may not furnish results/conclusions.

ASCLD/LAB Program Application
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

A sampling of names from the organizational chart was compared to available proficiency testing records for personnel. This comparison provided evidence of conformance.

5.9.3.3.2 ASCLD/LAB Supplemental Requirement — Conforming with Comment : 0

Requirement

Did each analyst (however named) and technical support personnel (however named) engaged in testing activities successfully complete at least one proficiency test during each five-year accreditation cycle, in each category of testing appearing on the laboratory's Scope of Accreditation, in which the individual performs testing? To satisfy this requirement, did the laboratory have a documented schedule for proficiency testing which is being followed by each analyst and technical support person?

NOTE The requirement for technical support personnel meeting this proficiency test requirement applies even though the technical support person may not furnish results/conclusions.

ASCLD/LAB Program Application
Where creating and/or maintaining an individual characteristic database is a primary job function, proficiency testing is required for anyone working in that category of testing.

All accredited laboratories are required to have and follow a proficiency testing plan to meet 5.9.3.3.2 of the ASCLD/LAB-International Supplemental Requirements for Testing Laboratories. When developing that plan, a separate individual characteristic database proficiency test is not required for an analyst when the use of a database is an extension of the duties in another category of testing.

Objective Evidence

Proficiency test schedule; records of completed proficiency tests

Sampling of proficiency testing records verifies the laboratory has completed within the accreditation cycle proficiency tests for each category of testing appearing on its accreditation certificate.
The laboratory would benefit by verifying that each analyst authorized to perform General Chemical Testing in the Drug Chemistry discipline has completed or is scheduled to complete (includes reporting) a General Chemical Testing proficiency test.

5.9.3.4 ASCLD/LAB Supplemental Requirement — Conforming

Requirement

Did the laboratory participate annually in, and successfully complete, at least one external proficiency test for each discipline of forensic science in which it provides services? Were ASCLD/LAB approved test providers used where available? Whenever there is not an ASCLD/LAB approved test provider available, did the laboratory locate and use a source of an external test in the discipline?

ASCLD/LAB Program Application
Due to challenges in designing and administering proficiency tests for the Crime Scene discipline and the Latent Print Processing category of testing to meet the external proficiency requirement, observation based proficiency tests will be allowed in these two areas as long as the following elements are met (with objective evidence): (1) The observer is approved by the tested laboratory's management based on training and casework experience; (2) The observer has knowledge of the laboratory's technical procedures; and (3) All applicable proficiency test documentation shall be maintained in accordance with 5.9.3.5 of the 2011 Supplemental Requirements for Testing Laboratories.

Objective Evidence

A sampling of 2016 and 2017 proficiency test records provides evidence of conformance.