San Diego County Sheriff's Department Regional Crime Laboratory

2019 - 17025T&C - Off-site Review

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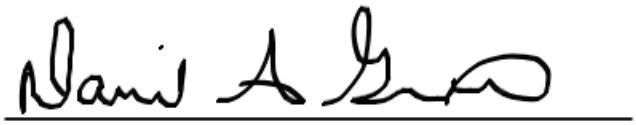

Assessment Checklist for use with AR 3125.11 ISO/IEC 17025:2017 Forensic Science Testing and Calibration Laboratories Accreditation Requirements

CL 3147.8

29April2019

Audit Objective Evidence

4.1 Impartiality

4.1.4 ISO/IEC 17025:2017 — Conforming

Requirement

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

SDCSD Quality Manual 5.3 and 5.3.1

5. Structural requirements

5.4.2 ANAB Accreditation Requirement — Conforming

Requirement

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

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

Objective Evidence

FORENSIC ALCOHOL TECHNICAL PROCEDURES MANUAL Forensic Alcohol Technical Procedures Manual 2.6.2
California Code of Regulations Title 17. Compliance and Department of Motor Vehicles Statements

6.2 Personnel

6.2.6 ISO/IEC 17025:2017 — Conforming

Requirement

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 including, as applicable, the use of equipment.

Objective Evidence

SDCSD Quality Manual 2.4.1
Examples of Work Authorizations

6.5 Metrological traceability

6.5.1.3 ANAB Accreditation Requirement

Conforming

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

Forensic Alcohol Technical Procedures Manual Section 3 Breath Alcohol Calibration Program
Forensic Alcohol Traning Manual 2.4 Module 4: Advanced Breath Alcohol Calibration and Maintenance
Intoximeter Calibration Method Validation
Examiner Work Authorizations

7.1 Review of requests, tenders and contracts

7.1.9 ANAB Accreditation Requirement

Conforming

Requirement

Is the extent of database (e.g., DNA profiles, friction ridge, ballistics, biometrics) searches communicated to customers and updated as needed?

ANAB NOTE 1 “extent” will be specific to the database but may include aspects of the scope or range of the search (e.g., local, state, national, international), the frequency of the search or if the customer is required to make a request to elevate the scope of the search or to have a search performed.

ANAB NOTE 2 This may be communicated on a case-by-case basis, in the report, or in a general customer communication.

Objective Evidence

SDCSD Quality Manual 5.1.22
Forensic Biology Technical Procedures Manual 4.6.7
Firearms Technical Procedures Manual 3.22
Latent Print Technical Procedures Manual
Case File Review

7.2.1 Selection and verification of methods

7.2.1.1.2 ANAB Accreditation Requirement

Conforming

Requirement

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

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

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

Objective Evidence

SDCSD Quality Manual 6.1.4.1
Controlled Substances Technical Procedure Manual
Firearms Technical Procedure Manual
Latent Print Technical Procedure Manual
Questioned Documents Technical Procedure Manual
Trace Evidence Technical Procedure Manual
Example case file.

7.2.2 Validation of methods

7.2.2.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the laboratory have a procedure for method validation that:
a) includes the associated data analysis and interpretation?
b) establishes the data required to report a result, opinion, or interpretation? and
c) identifies limitations of the method, reported results, opinions, and interpretations?

Objective Evidence

SDCSD Quality Manual 9.2.1
Example Validation

7.3 Sampling

7.3.2.b).1 ANAB Accreditation Requirement — Not Applicable

Requirement

Is statistical sampling at a stated level of confidence used if an inference will be made to report on the whole population?

Objective Evidence

Laboratory does not conduct statistical sampling.

7.4 Handling of test or calibration items

7.4.1.1 ANAB Accreditation Requirement — Conforming

Requirement

For all test items received except known origin individual characteristic database samples, does the procedure:
a) 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?
b) address measures to be taken to secure unattended items?
c) 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, trace evidence, DNA extracts)?
d) require chain-of-custody to securely and accurately identify:
1) the individual(s) or location(s) receiving or transferring the item(s)? and
2) the item(s) being transferred? and
3) the chronological order of all transfers, minimally including the date?
e) require communication to the customer regarding the disposition of all items received; and
h) address communication to the customer regarding items collected or created and preserved for future testing?

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

ANAB NOTE 2 d).1) Documentation of internal transfers does not need to include use of personal storage locations.

Objective Evidence

SDCSD Quality Manual 5.1 and 6.5.1
All Disciplines Accredidated Technical Procedure Manuals.

7.6 Evaluation of measurement uncertainty

7.6.1.1 ANAB Accreditation Requirement — Conforming

Requirement

Does the method of analysis for evaluation of measurement uncertainty:
a) 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?
b) include the process of rounding the expanded uncertainty?
c) require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%)? and
d) specify the schedule to review and/or recalculate the measurement uncertainty?

Objective Evidence

SDCSD Quality Manual 9.23
Firearms Technical Procedures Manual 4.10
Forensic Alcohol Technical Procedures Manual 2.7.6 and 3.7.4,
Controlled Substances Technical Procedure Manual Section 13

7.6.3.1 ANAB Accreditation Requirement — Resolved Nonconformity

Requirement

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

ANAB 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

SDCSD Quality Manual 9.23
Example Report
Interview

Nonconformity Resolution Workflow

It was revealed during interview and case file review that the firearms discipline is reporting trigger pull and distance determination values without having estimated a measurement uncertainty for both of these reported test results.

Completion note: The laboratory calculated the measurement uncertainty for trigger pull in the firearms section. The laboratory also removed distance determination from their scope of accreditation. This non-conformity is resolved.

7.7 Ensuring the validity of results

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? and
c) was the resolution of any discrepancy recorded?

ANAB NOTE 1 a) See requirements of 6.2.6 in ISO/IEC 17025:2017.

ANAB NOTE 2 b) Verification may be recorded for each result verified or as a summary for all results verified.

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 to perform the testing or calibration work that is being reviewed?

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 frequency may vary for different disciplines.

Objective Evidence

DSCSD Quality Manual 6.8 and 9.6
Firearms Technical Procedures Manual 4.8.1
Latent Print Technical Procedures Manual 5.5
Example Work Authorizations
Example Testimony Review
Example Trace Evidence Verification
Example Latent Print Verification
Example Firearms Verification

7.7.6 ANAB Accreditation Requirement — Conforming

Requirement

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 and equipment/technologies within each discipline listed on the scope of accreditation?

Objective Evidence

SDCSD Quality Manual 9.4.1 and 9.4.3
Proficiency Test Schedule
Proficiency Test Results Summary

7.8.1 General

7.8.1.2.2 ANAB Accreditation Requirement — Conforming

Requirement

Is there a procedure for reporting of results that:
a) 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 partial work performed?
b) requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement?
c) requires communicating the reason(s) in the report when the reported results are inconclusive? and
d) requires reporting of the initial database entry (e.g., DNA profiles, friction ridge, ballistics, biometrics)?

ANAB NOTE 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

SDCSD Quality Manual 6.5.1
Example Reports

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 ISO/IEC 17025:2017 — Resolved Nonconformity

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 test or calibration.

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

SDCSD Quality Manual 6.4.1 and 6.5
Example Report
Interview

Nonconformity Resolution Workflow

It was revealed during interview and document review that an agreement for simplified reports was drafted, however, was not sent to customers.

Completion note: The laboratory informed all customers, via letter, that simplified reports will be issue for calibration and laboratory services. The letter included exactly what items will not be included in the reports. This nonconformity is resolved.

7.8.5 Reporting sampling - specific requirements

7.8.5.d).1 ANAB Accreditation Requirement — Not Applicable

Requirement

If statistical sampling is used, does the report contain the confidence level and corresponding inference regarding the population?

Objective Evidence

The laboratory does not utilize statistical sampling.

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

SDCSD Quality Manual 9.5, 9.8, 9.9 and 9.13

7.10 Nonconforming work

7.10.2 ISO/IEC 17025:2017 — Conforming

Requirement

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

Objective Evidence

SDCSDS Quality Manual 9.5.2 and 9.20
Example Corrective Action

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

SDCSD Quality Manual 9.5
Example Corrective Action

8.5 Actions to address risks and opportunities (Option A)

8.5.2 ISO/IEC 17025:2017 — Conforming

Requirement

Does the laboratory plan:
a) actions to address these risks and opportunities?
b) 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

SDCSD Quality Manual 9.2.2, 9.5.1, 9.5.2, 9.11.4, and 9.13
Example Risk Assessment

8.7 Corrective actions (Option A)

8.7.1.g) ANAB Accreditation Requirement — Conforming

Requirement

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

Objective Evidence

SDCSD Quality Manual 9.5.3
Example Corrective Action

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

SDCSD Quality Manual 9.5.2 and 9.20
Example Corrective Action

8.8 Internal audits (Option A)

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

SDCSD Quality Manual 9.11
Internal Audit Examples

8.8.2.b).1 ANAB Accreditation Requirement — Conforming

Requirement

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

Objective Evidence

SDCSD Quality Manual 9.11.2
Example Internal Audits

8.9 Management reviews (Option A)

8.9.3 ISO/IEC 17025:2017 — Conforming

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