

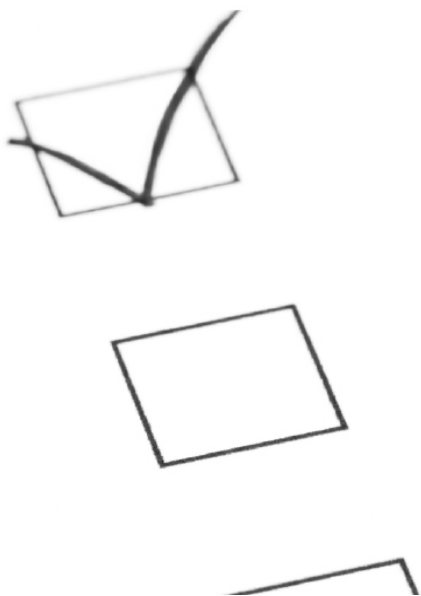
2011 CALA BIENNIAL ASSESSOR TRAINING

Accreditation Requirements

Session 12

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Building Laboratory
Excellence

Vers l'excellence
dans les laboratoires



Session Goals

- By the end of the session participants should be :
 - more familiar with where requirements are documented
 - more comfortable in identifying and grading non-conformances
 - more familiar with CALA Policy requirements vs. ISO/IEC 17025 requirements

In each scenario (below), determine:

- if there is a non-conformance;
- if so, the clause of ISO/IEC 17025 and/or CALA Accreditation Policy that is not being met;
- where the evidence would be documented in the CALA documentation; and,
- how the non-conformance would be graded (Required A or Required B).

Types of Findings

- **Required Actions - A:** A nonconformance against the standard (ISO/IEC 17025), CALA requirements, the laboratory's own procedures, or a condition that affects the validity of the test result.
- **Required Actions - B:** A non-conformance that is random or infrequent (e.g., a few records are missing or are out of date) or has been deemed a phase-in requirement by CALA, or a condition whereby the laboratory has minimal evidence to support full implementation of the requirement.

Types of Findings

- **Comments - C:** Comments may be used to document concerns or highlight areas where the laboratory excels. Use comments judiciously, and always discuss with the laboratory representative. Do not use this option to make suggestions to the laboratory. Comments must link back to ISO/IEC 17025 or CALA policies.
- **Serious Non-conformances:** If any non-conformities seriously call accredited test results being reported to customers into question, document the nonconformity, grade it as Required A item, and immediately notify the CALA office in writing.

Scenario 1:

- You are interviewing an analyst for an appendix where the matrix is “soil”. In the course of the interview, it becomes obvious that there are no procedures related to sub-sampling. The response is that this section of the Appendix is only applicable to laboratories that do their own field sampling and is not applicable to sub-sampling.

Scenario 1:

- N/C: Yes.
- Clause: ISO/IEC 17025, Section 5.7
- CALA Documentation: P07 Section 5.7A03-Appendix, 04.01
- Grade: Required A
- This clause applies when the field sampling is occurring under the direct control of the laboratory, and when the laboratory is performing any sub-sampling
- If a laboratory is sub-sampling from a larger sample of soil, the laboratory must have documented sub-sampling procedures

Scenario 2:

- The appendix you are assessing has not been used for more than one year, and there are little data/records to support the method. Can you assess the method? If so, is there a non-conformance? If yes, against what clause of the standard?

Scenario 2:

- Can you assess the method: Yes
- Rationale: A06, Accreditation Program, Policies and Procedures, Section 3.2.2 – as long as the method has been validated, some “real” samples have been performed, and there is an analyst available, the method can be assessed.

Scenario 2:

- N/C: Yes
- Clause: ISO/IEC 17025, Section 4.1.2; the laboratory must carry out its testing activities to meet the requirements of the accrediting body.
- CALA Documentation: A.01.02. The accreditation requirement is that samples (not just PT samples) must be done every six (6) months (see A06, Section 3.1.2).
- Grade: Required A
- Note: CALA may have further discussions with the lab to determine if the method should remain on the scope.

Scenario 3:

- In reviewing the calibration for the analysis of copper by ICP, you observe that the lab uses 4 calibration standards but none are $< 10 \times$ the detection limit. The analyst indicated that this was not necessary as there is a QC standard $< 10 \times$ MDL.
- Is this a non-conformance?

Scenario 3

- N/C -No
- Clause: ISO/IEC 17025, Section 4.1.2; the laboratory must carry out its testing activities to meet the requirements of the accrediting body
- CALA documentation: P07 5.5.2 Equipment calibration clarifies the use of the low level standard

Scenario 4

- You observe that the thermometer in the oven used for TSS was last calibrated 14 months ago when it was bought from the supplier. The information on the calibration certificate for the thermometer indicates the calibration is valid for 2 years

Scenario: 4

- N/C: yes
- Clause: ISO/IEC 17025, Section 4.1.2; the laboratory must carry out its testing activities to meet the requirements of the accrediting body
- CALA Documentation: A61 4.1 Laboratories that calibrate their measurement equipment on an annual basis are deemed to be compliant with this policy. Decreasing the frequency of calibration will save the laboratory some calibration costs, but this can only be done if the laboratory has solid evidence in hand about how each instrument contributes to the overall uncertainties of all measurements made with it (see A.3.1 Significance Test in appendix A for an example).
- Grade: A

Scenario: 4

- Additionally 5.10.4.4 A calibration certificate shall not contain any recommendation on the calibration interval except where this has been agreed with the customer.
- In most cases the calibration lab required no input from the customer.

Scenario: 5

- In the sample preparation area the analyst performing digestion of fat samples for pesticides analysis was using a copy of an AOAC method for fat digestion. When asked for the laboratory procedure specific to the laboratory, the analyst replied that the AOAC method was all that he had.

Scenario: 5

- N/C: No, assuming everything else is Ok.
- Clause: ISO/IEC 17025, 5.4.2 The lab shall ensure that it uses the latest valid edition of the standard unless its not appropriate or possible to do so. When necessary the standard shall be supplemented with additional details to ensure consistent application.
- CALA Documentation: P07
- Grade: NA
- Rationale: If the reference standard is written in such a way that it can be followed directly with no additional inputs then it can be used as is.

Scenario: 6

- SOP 76A rev. 3 was observed being used by the analyst in the inorganic chemistry section. Upon review the assessor noticed that the procedure was based on the 16th Edition of Standard methods. Section 4.3 of the QM states “Obsolete documents may be used to meet customer requirements if specified by contract”.

Scenario: 6

- N/C: NA.
- Clause: ISO/IEC 17025, 5.4.2 The lab shall ensure that it uses the latest valid edition of the standard unless its not appropriate or possible to do so.
- CALA Documentation: P07 5.4.1
- Grade: NA
- Rationale: CALA requires that the latest edition of a standard or test method is used unless otherwise specified under regulation or contract.

Scenario: 7

- While reviewing the records for VOCs in soil you request that the analyst turn on the equipment to look at some chromatograms. The analyst remarked that this was unnecessary and a waste of time as the records contained the same information and refused.

Scenario: 7

- N/C: Yes.
- Clause: : ISO/IEC 17025, Section 5.5 Equipment, Section 4.1.2;
- CALA Documentation: A06 section 3.2.3, Equipment should be operational at the time of the assessment, and an assessor can ask for the equipment to be turned on and operated, or ask that all or part of a method be demonstrated.
- Grade: A
- If it is a case that equipment has recently broken down, the assessor will need to take this into consideration. Lab will to provide evidence appropriate check are done prior to return to service.

Scenario: 8

- During an assessment the assessor noted that a simplified test report doesn't include a note that information is available for any of the items listed in section 5.10.2 of ISO/IEC 17025:2005.

The laboratory stated that they don't have the external customers, only internal, which has the same company name and the same address as the laboratory. In addition the ISO/IEC 17025:2005, clause 5.10.2 states that this information must be on the report unless the laboratory has a valid reason for not doing so.

Scenario: 8

- N/C: NA.
- Clause: ISO/IEC 17025, 5.10.2 Each test report shall include at least the following standard unless the lab has a valid reason for not doing so.
- 5.10.1 – In the case of tests or calibration for internal customers.....the results may be reported in a simplified way.
- CALA Documentation: P07 5.10
- Grade: NA
- Assessor would expect to see some agreement with the customer.

Scenario: 9

- During the reassessment of an accredited laboratory, the assessor requests to see the method validation for several methods. The laboratory cannot provide the assessor with an estimate of precision or recovery, but demonstrates that it has years of duplicate data and the results of control standards, and that it monitors the results of these quality control samples. The assessor requires that the laboratory provide evidence of method validation.

Scenario: 9

- N/C: Yes.
- Clause: : ISO/IEC 17025, Section 5.4.5.2 “The laboratory shall validate.....The lab shall record the results obtained, procedure used for the validation, and a statement as to whether the method is fit for intended use”.
- CALA Documentation: P07 5.4.5
- Grade: A
- The lab may have collected a lot of data but had done nothing with it to demonstrate the method is fit for purpose.