

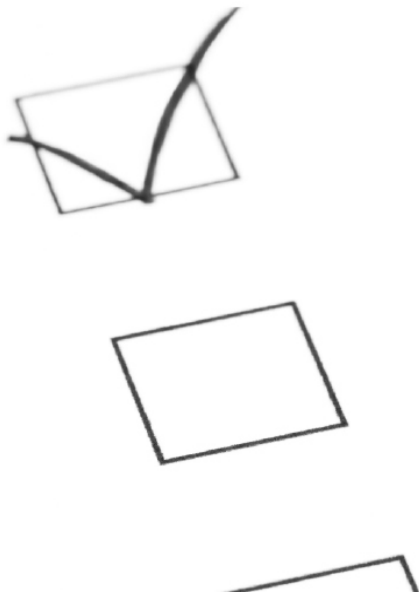
2011 CALA BIENNIAL ASSESSOR TRAINING

So You Think it's a Finding

Session 5

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Building Laboratory
Excellence

Vers l'excellence
dans les laboratoires



OBJECTIVES

- To look critically at the wording of findings.
- Distinguish between opinion and non-conformance.
- Distinguish between observation and suggestion.

DEFINITIONS

Non-Conformance: Any deviation from ISO/IEC 17025 requirements, CALA policy, or laboratory policies and procedures that the assessor has clear evidence of. Always documented as an A or B finding.

Concern: A condition that the assessor believes has a high risk of causing a nonconformance in the future but is not currently non-conforming (i.e, potential source of a non-conformance). Should be rarely documented but, if it is, it can only be a C finding.

Non-conformances can be written against:

- Requirements of ISO/IEC 17025;
- CALA requirements;
- Laboratory policies and procedures.

Non-conformances (Type A and B) are NEVER written against:

- Assessor opinion;
- Potential non-conformances; or,
- Opportunities for improvement.

Structure of a Finding

A finding contains the following:

1. Requirement from the standard, CALA policy, or lab policy/procedure, including specific references whenever possible;
2. Specific observation of the assessor, including reference to records or documents if applicable.

Nothing More.

Structure of a Finding

A finding shall never contain:

1. Direction on how to address the finding (e.g., “modify procedure”, “increase frequency”, “add a low level standard”);
2. Personal opinion;
3. What information to provide to CALA (e.g., “Submit documentary evidence”). These instructions are provided at the closing meeting.

Structure of a Finding

Example 1:

ISO/IEC 17025 4.3.1:

Type A

REQUIREMENT: The laboratory shall have and maintain a procedure for controlling internal and external documents.

OBSERVATION: Procedure *XXX rev xx.xx-Document Control*, does not include information on how external documents are controlled.

Structure of a Finding

Example 1:

ISO/IEC 17025 4.3.1:

Type A

REQUIREMENT: The laboratory shall have and maintain a procedure for controlling internal and external documents.

OBSERVATION: Procedure XXX rev xx.xx-*Document Control*, does not include information on how external documents are controlled.

Text in red is from assessor software. You may modify the text to provide clarification as long as the requirement is not being changed.

Structure of a Finding

Example 1:

ISO/IEC 17025 4.3.1:

Type **A**

REQUIREMENT: The laboratory shall have and maintain a procedure for controlling internal and external documents.

OBSERVATION: **Procedure XXX rev xx.xx-Documents Control, does not include information on how external documents are controlled.**

Text in green is written by the assessor. Be sure to include reference numbers for documents or records that are relevant to the observation.

Group Exercise Rules of Engagement

- 1) You will be provided with a simple scenario.
- 2) Assuming that all associated procedures and records were OK:
 - a) Decide whether or not it is a non-conformance.
 - b) Draft a finding if you determine that it is a NC.
- 3) Assuming that you have not yet reviewed all associated procedures and records:
 - a) What would you look at next?

Group Exercise Scenario 1

Lab SOP XXX.X rev xx. *Receipt of Supplies*

6.5 Received chemicals are checked against purchase order specifications and the shipment receipt is initialed if complete and acceptable.

6.6 Chemicals are placed on the shelf with the oldest bottle at the front to facilitate the preferred order of use.

Assessor Observation

- Assessor observed analyst reaching to the back of the shelf to retrieve a chemical.
- When asked why he did not take the bottle at the front he answered that he wanted to make sure he obtained the freshest chemical.

Group Exercise Scenario 1

Was this a non-conformance?

No

Our gut tells us that there is something wrong, but there was no evidence that expired chemicals were being used.

Group Exercise Scenario 1

Let's look at the findings.

Requirement:

Observation:

Group Exercise Scenario 1

What else would you look at?

1.

Group Exercise Scenario 2

6.0 QC Frequencies for Method:

Calibration check - Weekly

Duplicates - 10%

Spiked Samples - 5%

Certified Reference Material - quarterly

Assessor Observations

- 1) Test is being run every day.
- 2) Test hold time is four weeks.
- 3) Documented QC frequencies are being met.
- 4) Assessor observed a calibration check failure and asked what was done about it.
- 5) Analyst responded that all samples after the last OK calibration check were re-analysed. Records agree with this.

Group Exercise Scenario 2

Is this a non-conformance?

No

The lab was following their procedure and there was no evidence that it had a negative impact on the quality of data.

However, what if the test hold time was two days?

Group Exercise Scenario 2

Let's look at the findings.

Requirement:

Observation:

Group Exercise Scenario 2

What else would you look at?

1.

Group Exercise Scenario 3

When reviewing a customer file, assessor notices two reports, an original report and a revised report. The revised report was clearly marked as such.

When asked why the revised report was issued, lab manager stated that the customer had requested that they receive a simplified report that did not include qualifying comments from the laboratory.

When queried whether the revised report contained all of the information necessary for interpretation of the report, the lab manager said that it didn't matter because the original report contained all of the qualifying remarks.

Group Exercise Scenario 3

Is this a non-conformance?

Yes

5.10.1 paragraph one of the standard requires that “The results of each test...shall be reported accurately, clearly, **unambiguously** and objectively...”

Paragraph two states that “The results shall be reported, usually in a test report... and shall include **all the information** requested by the customer and **necessary for the interpretation** of the test...”

Qualifying remarks are included because they are needed for proper interpretation.

Group Exercise Scenario 3

Let's look at the findings.

Requirement:

Observation:

Group Exercise Scenario 3

What else would you look at?

1.

Let's Dissect a Finding

ISO/IEC 17025 5.3.5

Type **A**

REQUIREMENT: Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

OBSERVATION: Carts were observed to be blocking eyewash stations.

Let's Dissect a Finding

ISO/IEC 17025 5.3.5

Type **C**

REQUIREMENT: Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

OBSERVATION: Carts were observed to be blocking eyewash stations **in organics and microbiology laboratories**.

A specific regulation and requirement were not referenced; therefore, this can only be a C item.

Provide a little more detail as to where the carts were observed, if applicable.

Health and Safety and Regulatory Concerns

ISO/IEC 17025 clause 1.5 Compliance with regulatory and safety requirements on the operation of laboratories is **not covered** by this international standard.

CALA P07: Non-conformances **should not normally** be raised against observed or perceived health and safety activities unless they do not conform to laboratory stated policies and procedures.

This does not mean that health and safety and regulatory issues are ignored.

Health and Safety and Regulatory Concerns

ISO/IEC 17025 clause 4.1.2 *It is the responsibility of the laboratory to carry out its testing activities in such a way as to meet the requirements of ..., the **regulatory authorities** or organizations providing recognition.*

Health and Safety and Regulatory Concerns

If you can reference the specific regulation that is being violated, it may be written as a type A finding.

ISO/IEC 17025 4.1.2

Type **A**

Requirement: Laboratories shall meet the requirements of regulatory authorities.

Observation: OSDWA Reg XXX.XX requires that the laboratory immediately report adverse water quality to MOH, SAC and the utility owner. Positive *E.coli* results were recorded on XXXX, but not reported until XXXX.

But if you cannot reference the specific regulation, and the requirement in the regulation, then it can not be written as a non-conformance.

Health and Safety and Regulatory Concerns

If the laboratory does not conform to its own H&S or regulatory policies, it is written as a type A.

ISO/IEC 17025 4.2.1

Type **A**

Requirement: The laboratory shall document policies and procedures, and these procedures shall be implemented by appropriate personnel.

Observation: Laboratory Quality Manual, section XX.X states that all staff must wear safety glasses in the laboratory. It was observed that several staff in the Organics lab were not wearing safety glasses..

Please Note: instructive signs (e.g., “safety glasses must be worn”) and presence of safety equipment (e.g., tie-down clamps for gas cylinders) are considered laboratory policies.

Health and Safety and Regulatory Concerns

What do the following have in common?



These are all laboratory policies. If a laboratory has instructive signs or things like cylinder clamps, they can be considered policy and an A finding can be written against them.

Health and Safety and Regulatory Concerns

If a specific regulation or laboratory policy cannot be referenced, it can only be written as a type C finding against the most appropriate section of the standard.

ISO/IEC 17025 5.3.5

Type **C**

Requirement: Measures shall be taken to ensure good housekeeping in the laboratory.

Observation: Alcohol burners in the microbiology laboratory were placed in a location where they could be knocked off the bench.

Note: Avoid personal opinion when dealing with H&S. For example, it is common for most labs to provide glasses and lab coats but these may not be regulatory requirements.

Health and Safety and Regulatory Concerns

- 4) If you perceive that you or your team are at risk, refuse to continue with assessment and notify lab management and CALA.

In all cases, laboratory management MUST be notified immediately upon observing a H&S concern.

How would you feel if an accident occurred between the time you observed a concern and the closing meeting.

Let's Dissect a Finding

ISO/IEC 17025 5.4.5

Type **A**

REQUIREMENT: The laboratory shall validate methods to the extent necessary to meet needs of the given application,

Observation: It was observed that the MDL was estimated at 1 mg/L and the sample spike used for this calculation was 38 mg/L. This is higher than the maximum ratio of 10 common in procedures for MDL determinations.

Let's Dissect a Finding

ISO/IEC 17025 5.4.5

Type **A**

REQUIREMENT: The laboratory shall validate methods to the extent necessary to meet needs of the given application,

Observation: The quality manual, Section x.x, states that the laboratory calculates its MDL using a spike that is 1-10x the MDL. It was observed that the MDL for this method was estimated at 1 mg/L and sample spike used for this calculation was 38 mg/L.

Neither the standard nor CALA specifies the procedure to be used for MDL estimation. However, the standard does require a procedure for validation.

Let's Dissect a Finding

ISO/IEC 17025 5.4.1

Type **A**

REQUIREMENT: The laboratory shall have instructions on use and operation of equipment, sample handling and preparation where their absence could jeopardize the test results.

Observation: Modify procedure *XXX-Laboratory Quality Control* to include actions to take when there are non-conformances to analytical QC.

Let's Dissect a Finding

ISO/IEC 17025 5.4.1

Type **A**

REQUIREMENT: The laboratory shall have instructions on use and operation of equipment, sample handling/preparation where their absence could jeopardize the test results.

Observation: Procedure *XXX-Laboratory Quality Control* **does not** include actions to take when there are non-conformances to analytical QC. **It was observed that analysts were recording QC failures and the actions that they took.**

Do not provide any instructions in the finding. Where possible, also indicate whether or not the practice followed was acceptable.

Let's Dissect a Finding

ISO/IEC 17025 4.13.2.3

Type **A**

REQUIREMENT: Changes to original records shall be made so that the original record is not obscured, and that alterations are authorized by initials.

Observation: The pipette calibration record was observed to have obscured data and no authorization for the change.

Let's Dissect a Finding

ISO/IEC 17025 4.13.2.3

Type **A**

REQUIREMENT: Changes to original records shall be made so that the original record is not obscured, and that alterations are authorized by initials.

Observation: The pipette calibration record was observed to have obscured data and no authorization for the change (Pipette XXX.xx, Date XXX.XX; Date XXX.XX: Date XXX.XX).

Include specific references to records that were non-conforming. If they are numerous, it is a type A finding. If it is just a couple isolated incidents, it is a type B finding.

Another Scenario

The lab is a wastewater treatment lab. Samples are received every two days from the WWTP and are labeled “Raw Sewage”, “Final Effluent” and “Sludge”. Each sample also includes the date of sampling.

Assessor asks lab if they assign a unique ID to each sample. They say that the combination of sample ID (e.g., Sludge) and sample date constitutes a unique ID.

Analytical bench sheets and instrument sample tables use the sample ID (e.g., Sludge) as the sample identification but do not include the sample date.

Reports of analysis include both the sample ID and the sampling date.

Is this a non-conformance?

A Big Resounding YES

5.8.2: The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents.

Another Scenario

Assessor observed that when microbiology dishes are put in incubator, the time in is written on the top plate.

Assessor asked if the time in and time out was recorded in a permanent fashion. Analyst responded that it wasn't but that dishes were never removed until the correct amount of time was reached. Assessor told analyst that a finding would be cited against 4.13.2.1 of the standard.

During closing meeting lab manager argued that these records were not needed because each set of analysis has a check box that analyst confirms that the test was run as per SOP. She further argues that there are many things that don't need recording (e.g., exact time of filtering) so why do they have to record incubation duration when the check box confirms that the SOP was followed?

Is this a non-Conformance?

Again, a big YES

It is true that we do not expect a lab to record every little aspect of operations, but the standard does require them to record sufficient records to repeat the test under the same conditions.

The actual duration of incubation is a critical aspect of the test.