

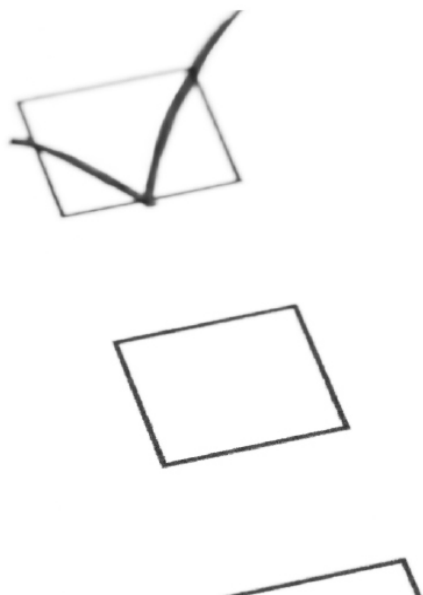
# 2011 CALA BIENNIAL ASSESSOR TRAINING

## Practice Makes Perfect

Session 14

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Building Laboratory  
Excellence

Vers l'excellence  
dans les laboratoires



# YOU ALWAYS PERFORM AT THE LEVEL YOU PRACTICE



# Session Goals

- **Categories of Findings**
- **New structure of Findings**
- **Practicing how to write Findings**
- **Introducing CALA's newest on-line tool**

## 4 Categories of Findings

- **Type A:** Non-conformance against the standard, CALA requirements, the lab's own procedures or a condition that affects validity of the test result
- **Type B:** Non-conformance that is random or infrequent, or a condition whereby the lab has minimal evidence to support full implementation of the requirement
- **Type C:** Comments to document concerns or highlight areas where the lab excels
- **Serious Non-conformances:** If non-conformities seriously call accredited test results into question, grade it as type A and notify CALA

# New Structure of Findings

- **Requirement:**  
(Rating Guide, Checklists, ISO/IEC 17025)
- **Observation:**  
(document exactly what was observed)

# Examples of Findings

- **Requirement:** Method quality control is adequate and either included or referenced in the test method; specifically, use a control culture to monitor biological response.
- **Observation:** Procedure xxx did not include recovery of positive control organisms on selective versus non-selective media. However, appropriate records were observed.

# Examples of Findings

- **Requirement:** When a laboratory subcontracts work, this work shall be placed with a competent subcontractor. The laboratory shall maintain a register of all subcontractors that it uses for tests as well as a record of the evidence of compliance with the International Standard for the work in question.
- **Observation:** A list of subcontracted laboratories is maintained; however, the method of approval is not defined, nor is the requirement to subcontract tests to a laboratory that is accredited for those same tests. As well, no records were observed to demonstrate that the subcontractors were accredited for those tests at the time of subcontracting.

# Examples of Findings

- **Requirement:** The laboratory shall ensure that all purchased supplies required for the test are available and meet requisite specification.
- **Observation:** The desiccant is checked monthly as scheduled in the Preventive Maintenance (PM) System. The assessment occurred two weeks after the last scheduled check where the record stated no maintenance was needed. Although it was observed that the desiccant was turning colour, there was no plan to take action until the next scheduled PM notification.

# Examples of Findings

- **Requirement:** The procedures on hand-written amendments to documents shall be defined and shall include requirements to clearly mark, initial and date amendments, and formally re-issue the documents as soon as practicable.
- **Observation:** The Quality Manual did not indicate the instances where hand-written amendments are allowed. Several hand-written amendments were observed on controlled documents (in SOP xxx, SOP yyy and SOP zzz).

# Examples of Findings

- **Requirement:** Analyst worksheets (notebooks) contain adequate information.
- **Observation:** The balance used during the conduct of testing could not be traced because the balance identification was not recorded on Form xyz.

# Examples of Findings

- **Requirement:** The laboratory shall record the audit findings and the corrective actions that arise from them.
- **Observation:** During the review of the 2010 internal audit file, only the checklists used to perform the audits were available. Records of findings and actions taken were not available.

# Examples of Findings

- **Requirement:** The laboratory must have polices and procedures related to the management system and ensure that they are communicated, understood and implemented.
- **Observation:** Section 18.1 of the Quality Manual states that all new hires read the QM within 90 days and records be retained. Records show that one new hire read the QM approximately seven months after hire and another over one year.

# Are the Findings written correctly?

## Example 1

**Requirement:** The laboratory shall subcontract with competent subcontractors and maintain records of competent subcontractors used.

**Observation:** It is documented that if a laboratory is subcontracting to a laboratory that is not accredited, a reference sample is sent for confirmation.



# Are the Findings written correctly?

## Example 2

**Requirement:** The laboratory shall maintain sufficient records to enable the test to be repeated under conditions as close as possible to the original.

**Observation:** The soil sample weights, reagent volume, etc. were not recorded.



# Are the Findings written correctly?

## Example 3

**Requirement:** Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared as necessary.

**Observation:** A full 4 liter bottle of iso-octane was near the edge of a desk and adjacent to a door opening, presenting a significant safety hazard since it would be very easy to knock the container onto the floor, creating a fire hazard.



# Are the Findings written correctly?

## Example 4

**Requirement:** The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation where their absence could jeopardize the results of tests.

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



# Correctly written Findings

## Example 1

**Requirement:** The laboratory shall subcontract with competent subcontractors and maintain records of competent subcontractors used.

**Observation:** The laboratory procedure SOP xxx, section 8.7 states that if a laboratory is not accredited, a reference sample may be sent for confirmation. Actual practice supports the use of accredited laboratories only.

# Correctly written Findings

## Example 2

**Requirement:** The laboratory shall maintain sufficient records to enable the test to be repeated under conditions as close as possible to the original.

**Observation:** The soil sample weights, reagent volumes and preparation dates were not recorded on the worksheet for method xxx.

# Correctly written Findings

## Example 3

**Requirement:** Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared as necessary.

**Observation:** It was observed that a full 4 litre bottle of iso-octane was near the edge of a desk and adjacent to a door opening.

# Correctly written Findings

## Example 4

**Requirement:** The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation where their absence could jeopardize the results of tests.

**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.

# Documenting Findings

## Scenario 1

The laboratory conducts internal audits on an annual basis. Audits are performed by qualified personnel, independent of the activity to be audited, each element of the quality system is checked at least once a year as well as testing activities.

The audit findings, corrective actions and follow-up audit activities that verify the implementation and effectiveness of the corrective actions taken are extremely well documented.

# Documenting Findings

## Scenario 2

The assessors noted that for appendices 5, 15, 22 and 41, SOP xyz requires that expiry of prepared mixed standard solutions shall not exceed the expiry of the stocks used in preparation. The expiry of all mixed solutions exceeded the expiry of stocks by six months.

# Documenting Findings

## Scenario 3

The new laboratory has a documented procedure for the resolution of complaints from customers, but at the time of the assessment there were no customer complaint records on file.

# Documenting Findings

## Scenario 4

The laboratory's SOPxyz, section 11 states that the final results of analysis are to be corrected for dilution. This is due to the fact that all samples for arsenic are diluted by 10% as compared to the standards. These dilutions are not being accounted for and as a result data is being reported that is lower than the actual value.

# Finding Scenario 1

**Requirement:** The laboratory shall periodically conduct internal audits to verify that its operations comply with all elements of the quality system and requirements of ISO/IEC 17025:2005.

**Observation:** Laboratory staff are to be commended for their approach to internal audits. The processes were very well documented.

## Finding Scenario 2

**Requirement:** The intermediate checks are carried out to maintain confidence in the calibration status of reference materials according to defined procedures.

**Observation:** For appendices 5, 15, 22 and 41, SOP xyz requires that expiry of prepared mixed standard solutions shall not exceed the expiry of the stocks used in preparation. It was observed that expiry of prepared mixed standard solutions exceeded the expiry of the stocks by six months.

## Finding Scenario 3

**Requirement:** Document a policy and procedure for the resolution of complaints from customers and maintain records of complaints, investigations and corrective actions taken by the laboratory.

**Observation:** The laboratory has a documented procedure and at the time of the assessment there were no customer complaint records available.

## Finding Scenario 4

**Requirement:** The laboratory test procedure and all supporting work instructions are performed as documented.

**Observation:** The procedure SOPxyz, section 11 states that the final results are to be corrected for dilution, however it was observed that all samples for arsenic are diluted by 10%, but these dilutions are not being accounted for and As data is being reported that is 10% lower than the actual value.

# CONGRATULATION and



# CALA's newest on-line tool coming soon!