

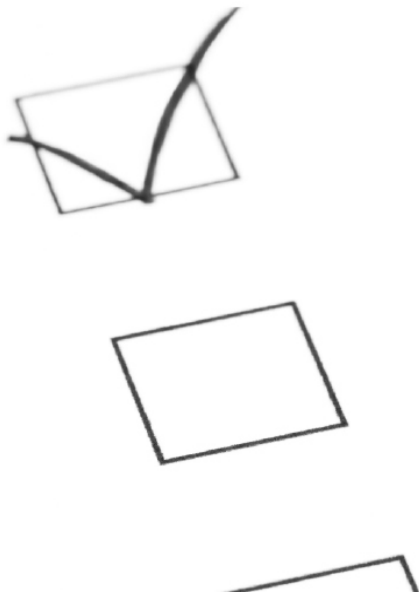
# 2011 CALA BIENNIAL ASSESSOR TRAINING

## Assessment Scenarios

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Building Laboratory  
Excellence

Vers l'excellence  
dans les laboratoires



# SCENARIO 1

You are assessing your assigned appendices, and have interviewed 2-3 different analysts. You are encountering resistance from all analysts because all have the same comment - your findings differ from the previous assessment. How do you respond to this comment?

## SCENARIO 2

You are assessing a lab that analyzes water under the Ontario *Safe Drinking Water Act* (OSDWA). It turns out that the lab reported an adverse drinking water sample 2 days before the assessment team arrived. The MOE inspectors are onsite during the assessment and the laboratory staff is highly stressed. What could you do in this scenario? What other important lesson is in this scenario?

## SCENARIO 3

The laboratory is performing weekly verification of balances. In reviewing the records, it was observed that one of the weekly verification checks did not meet the acceptance criteria. Is this a non-conformance? If no, why? If yes, why?

## SCENARIO 4

In the course of assessing an appendix, it is noted that limits are established but there are no control charts. Is this a non-conformance? If yes, what did you determine before deciding that this was a non-conformance? What is the relevant clause of the standard?

## SCENARIO 5

During the assessment of an appendix, you note that there is no evidence of Proficiency Testing. Upon further investigation, you determine that there is absolutely no formal PT available for this test. When you ask the lab how they met proficiency requirements, the QA Manager presents inter-analyst data for you. Reviewing the inter-analyst data, you note that one analyst reported a result of 0.95 mg/L and the other analyst reported a result of 1.13 mg/L. What's your next question? Under what circumstances might there be a non-conformance?

## SCENARIO 6

You note that the QC limits are relatively bigger than the statistically calculated number, but are still “fit for use”. Is this a non-conformance?

## SCENARIO 7

During the document review, you note that the laboratory uses “should” throughout its documentation. When you are on-site, you find that the analyst is following the method correctly, and do not identify any gaps between the documented procedure and what the analyst is actually doing on a day-to-day basis. Still, you know that the steps in the method are critical and thus, feel that they need to be documented as “shall” and not “should”. In the review of the management requirements, it was noted that historically there is not a high level of staff turnover. Is this a non-conformance? If not, when might a non-conformance be identified?

## SCENARIO 8

During the document review, you do not see a reference to the glassware cleaning SOP in the test method. The analyst is also responsible for cleaning the glassware for this particular appendix, and you ask to see the glass cleaning SOP.

Scenario 8a: The analyst deftly waltzes across the floor, grabs another binder, finds the current authorized copy of the glassware cleaning SOP, and shows it to you. Is this a non-conformance? If so, what clause of the standard?

## SCENARIO 8

During the document review, you do not see a reference to the glassware cleaning SOP in the test method. The analyst is also responsible for cleaning the glassware for this particular appendix, and you ask to see the glass cleaning SOP.

Scenario 8b: The analyst fumbles about, leafs through binders upon binders and cannot find the glassware cleaning SOP anywhere. Is this a non-conformance? If so, what clause of the standard?

## SCENARIO 9

Requirement: The laboratory shall have a calibration program that is traceable to SI units.

Observation: The laboratory is using a traceable liquid in glass thermometer calibrated at 100 degrees C in a 35 degree C incubator.

Is this a non-conformance?

## SCENARIO 10

Requirement: The laboratory shall have quality control procedures for monitoring the validity of tests undertaken.

Observation: The laboratory is performing an analysis on a field duplicate for a specific matrix, but is not performing a replicate analytical measurement on a sample in a run.

Is this a non-conformance?