

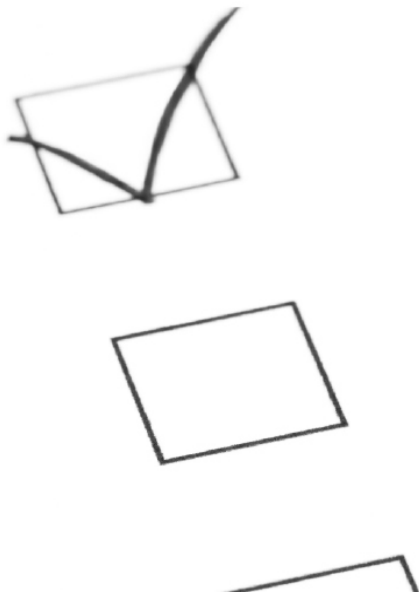
2011 CALA BIENNIAL ASSESSOR TRAINING

Lead Assessor Session

Session 10

Colleen Cotter

March 29, 2011



Building Laboratory
Excellence

Vers l'excellence
dans les laboratoires



Outline

- Administrative Issues
- Review A04-09: The Assessment Report
- Scenarios
- Audit Software
 - Survey results

Pre-assessment

- Expertise on the team
 - List of assessors is on the web site (password protected)
 - Cover sheet of the background package
 - Communication with the team
- New laboratories
 - Leads to look at quality manual
 - Delegate assessors to review method validation

Background Packages

- What seems to be working well:
 - 4 weeks in advance of the assessment
 - Splitting up the checklists between the members
 - Addition of the forms (e.g., meeting attendance, trace of tests, etc.)
- Recognize that staff do not necessarily know who will require the specialized checklists

Audit Software

- Audit software – if you don't have it within a day of receiving the background package, contact Josh Fournier (jfournier@cala.ca)
- Opportunity for input at the end of this session

Proposed Scope Sign-off

- Lead Assessor responsibility to:
 - Ensure that changes to the proposed scope are transferred to one main proposed scope
 - Ensure that a laboratory representative signs-off on the “Proposed Scope Sign-off”

Completion Report

- Only 1 copy of the CD needs to be sent back to the CALA office
- Do not need a hard copy of the quality manual if there is a copy on the CD

Joint Visits

- Draft procedure available with input from SCC and CALA

New Approach to Report Writing

- Refer to A04-09: The Assessment Report
- On-line tool being developed

- Document the observation. Remember that the laboratory staff needs to know exactly what was observed, in order to effectively address the non-conformance. Also, CALA staff needs sufficient information to determine if the laboratory satisfactorily addressed the non-conformance. Document SOP numbers, form numbers, etc...

Example:

- Requirement: The laboratory shall maintain current job descriptions for managerial, technical and key support staff.
- Observation: The laboratory maintained job descriptions, however, the quality assurance responsibilities assigned to the Quality Assurance Manager were not documented.

- One part of a requirement may be met, while another part of it may not. Be very clear as to what was available and what was missing.

Example

- Requirement: The laboratory shall maintain records of management reviews and actions taken.
- Observation: The laboratory maintained records of management reviews but no record of actions that arose from the management review were found.

- A single requirement may have more than one non-conformance. To make the finding clear, you may need to separate the non-conformances.

- If a finding is documented against a requirement in A02-Rating Guide, and it's not systemic, be very specific as to the appendix or method to which it applies. For example:

Example:

- Requirement: A.06.02 The laboratory shall ensure that purchased services and supplies that affect the quality are not used until they have been inspected or verified compliant with specifications, and maintain records.
- Observation: For appendices 17, 19 and 26, SOP xyz requires that ACS grade HCl is used. It was observed that technical grade HCl is actually being used.

- If there is a systemic issue in the appendices, try to tie to an item to a requirement in *A02-Rating Guide*. A general guideline is to do this when one corrective action will resolve the non-conformance.

Example:

- Requirement: If producing water in house and it is used to make media or reagents, check conductivity daily or as-used and verify it is analyzed for parameters as per the most current version of Standard Methods.
- Observation: The records for the reverse osmosis system show that the conductivity has been above the maximum acceptable limit of 2 umhos/cm since March 15, 2011.

- If one piece of evidence cannot address the non-conformance throughout the laboratory, you can repeat the non-conformance against all the applicable appendices OR if it is the exact same finding, can move it up to the Rating Guide and specify exactly which appendices to which the finding applies; don't use words such as "applies to all ICP methods" - specify the appendix numbers

- Example:
- Requirement: B.04.06 If equipment goes outside the direct control of the laboratory, it must be checked and validated before being returned to service.
- Observation: Records indicated that the equipment was off-site for several months and there is no evidence that it was checked and validated prior to being put back into use for client samples. This applies to appendices 1, 5, 8, 12, 29, and 32.

- Do not use the words “applies to” in a finding that applies to requirements in one of the test specific checklists; the audit software has a function to repeat findings in the appendices

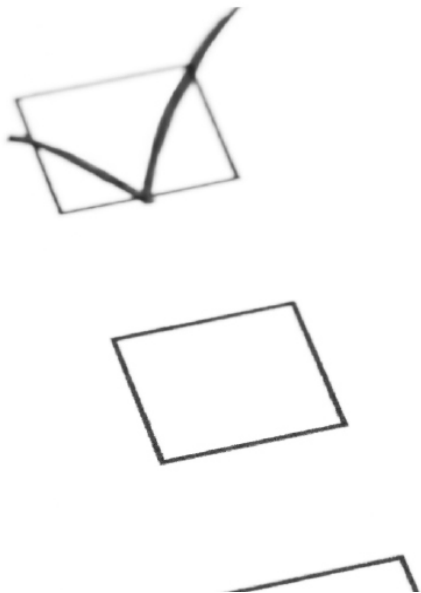
2011 CALA BIENNIAL ASSESSOR TRAINING

Lead Assessor Scenarios

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Scenario #1

- You are leading an assessment where a CALA staff person is on-site in a monitoring role. It seems that every time you ask a question, the laboratory director and/or quality manager look to the CALA staff person for clarification or affirmation, and ask the CALA staff person questions. What do you do?

Scenario #1 (Cont'd)

- Tips:
- Did you go over the role of the monitor during the opening meeting (Laboratory Assessment Binder, A04-02, Section 8.0)?
- Communicate, communicate, communicate (not in front of the laboratory).

Scenario #2

- One of your team members has identified a non-conformance and feels that he/she has the objective evidence to substantiate the finding. You both have very different areas of expertise. The supervisor of the area approaches you (because you are the Lead Assessor) and presents evidence to support the laboratory position.

Scenario #2 (Cont'd)

- Tips:
 - Discussion with your co-assessor.
 - Others?
-
- Where is the dispute process documented?
 - A04-02 (The Opening Meeting) or A04-10 (The Closing Meeting)

Scenario #3

- You ask to see the Training records for an individual. The lab manager indicates that the training records are in the personnel file (which is confidential), and that you cannot see them.

Scenario #3 (Cont'd)

- Tips:
- Could arrangements have been made ahead of time?
- Others?
- If you can't see the records, is there a non-conformance?
- Yes.

Scenario #4

- You're at the Opening Meeting, and already you're picking up bad vibes. According to the lab manager, the last CALA team was too picky and unreasonable in their requests, and the lab manager feels that requirements were imposed on them were subjective. He/she openly states that he/she is considering changing to another accrediting body.

Scenario #4 (Cont'd)

- What are some ways that you can get this assessment back on track?
- Did lab provide feedback to CALA?
- Active listening
- Others?
- Should assessors have to sell the value of accreditation?

Scenario #5

- You have an assessor on your team who is constantly stating his/her opinion in meetings and during the assessment. His/her opinions are not in line with the requirements. He/she then enters a requirement into the assessment report that is not a requirement. What can you do?

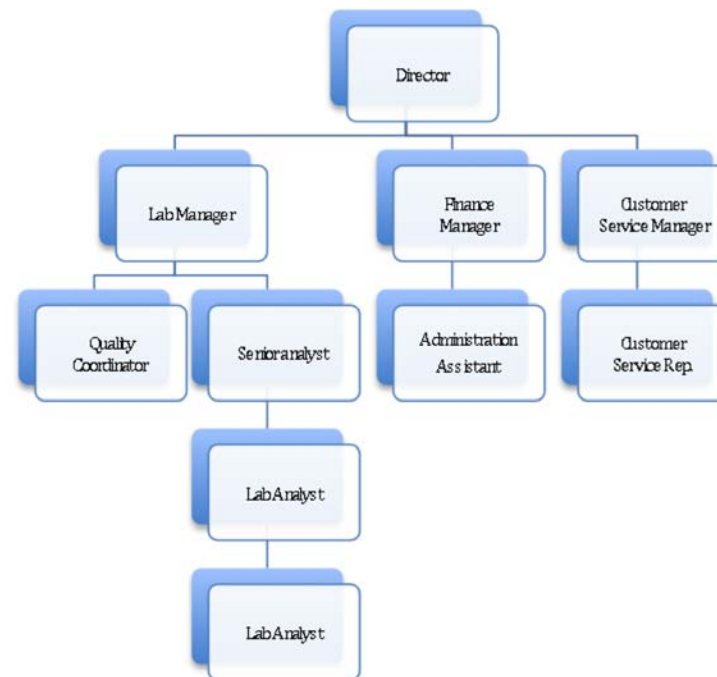
Scenario #5 (Cont'd)

- Tips:
- Back to basics – go over the definitions of Required A and B, and concerns
- Others?

Scenario #6

- You are assessing Section 4.1.5 (e) of ISO/IEC 17025 (i.e., defining organization and management structure). What questions or observations come to mind immediately in each of the following cases? Can you identify any non-conformances and if so, against which clause of the standard?

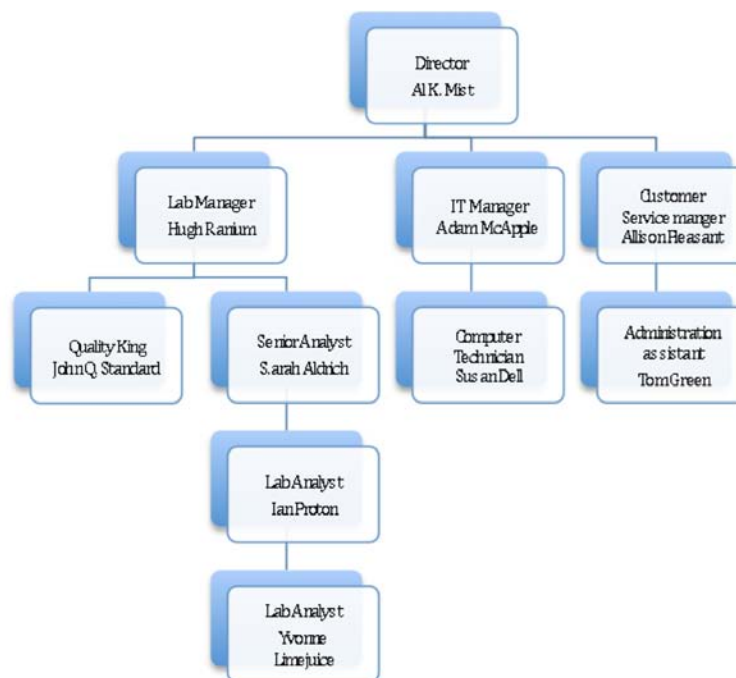
Scenario #6 (a)



Scenario 6 (a)

- Non-conformance?
- **Maybe**
- If the authority and responsibility of the quality manager is not specified (4.1.5.j)
- If quality manager does not have direct access to the highest level of management at which decisions are made (4.1.5.k)
- Others?

Scenario #6 (b)



Scenario 6 (b)

- Is it a non-conformance to have names on the organization chart?
- No - unless there is objective evidence that there has been a change

Scenario #7

- You are assessing a municipal wastewater treatment laboratory, and the laboratory manager is the Environmental Engineer who is responsible for ensuring that some analytes do not exceed provincial discharge levels. You have immediate questions and avenues of inquiry related to the sections of the standard that deal with conflict of interest. What are these sections of the standard that might apply? What questions do you want to ask? What objective evidence do you ask to see?

ISO/IEC 17025, Section 4.1.4

- If the lab is part of an organization performing activities other than testing, the responsibilities of key personnel in the organization that have involvement or influence on the testing shall be defined in order to identify potential conflicts of interest.

ISO/IEC 17025, Section 4.1.5 (b)

- The laboratory shall have arrangements in place to ensure that management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.

ISO/IEC 17025, Section 4.1.5 (d)

- The lab shall have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity.

Scenario #8

- A laboratory does have a list of approved suppliers. The calibration laboratory that performs annual calibrations on the balance is not on the list. Write your finding, using the new approach to writing findings.

Scenario #8 (Cont'd)

- A.06.04 Requirement: Maintain records of investigation of suppliers and a list of all approved suppliers.
- Observation: The laboratory maintains a list of approved suppliers, but only lists suppliers of chemicals and reagents. The calibration laboratory that supplies calibration services is not on this list.

Better?

- A.06.04 Requirement: Maintain records of investigation of suppliers and a list of all approved suppliers.
- Observation: The laboratory maintains a list of approved suppliers (DOC xxx), but only lists suppliers of chemicals and reagents. The calibration laboratory that supplies calibration services is not on this list. The laboratory did maintain a record of investigation of the calibration laboratory.