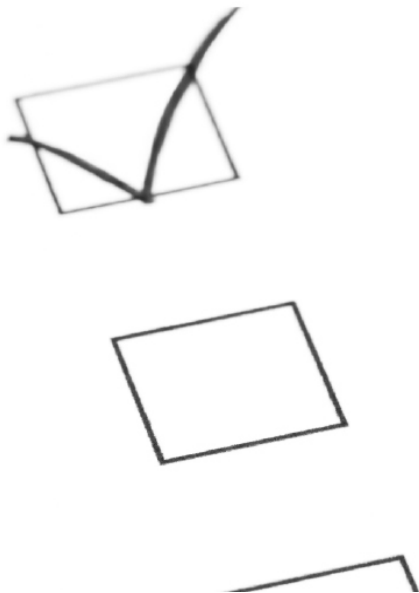


2011 CALA BIENNIAL ASSESSOR TRAINING

Opening Plenary

Colleen Cotter
March 28, 2011



Building Laboratory
Excellence

Vers l'excellence
dans les laboratoires



Outline

- In retrospect...the last 2 years
- On-going Initiatives
- Other Volunteer Opportunities
- Top Challenges
- Biennial Materials
- What's new? Changes for 2011
- Housekeeping

Achievements

- March 2009 - A2LA re-assessment of the CALA PT Program
- May 2009 - APLAC re-evaluation against ISO/IEC 17011
- October 2009 - CALA hosted the ILAC/IAF Conference in Vancouver, B.C.

20 Years!



New Staff



2009 Biennial Output

- Many suggestions implemented
 - Streamlining materials to go to assessors
 - CD's go to all team members
 - Lead Assessors get the forms they need for a specific visit in the background package
 - Leads receive a summary of feedback from team members
 - Final reports now include a notation as to whether a requirement was “changed” from the closing meeting report or “deleted”
 - “Based on” changed to “modified from” on scopes

On-going Initiatives

- One free on-line course for assessors
- IT changes
 - FTP for assessments (Leads will still receive 1 hard copy of the Quality Manual)
 - audit software; survey results posted on the web site
- Exploring risk-based accreditation
 - Definition: *a process whereby a laboratory's past performance is used to determine the rigour of subsequent site visits*
 - Need stakeholder input before any decisions can be made

Other Volunteer Opportunities

- 1 vacancy on the Advisory Panel – public sector, organic expertise
- Program Committee

Top Challenges

- Separation of PT and accreditation
- Consistency – 13% of respondents indicate a lack of consistency between the visit in 2010 and the previous visit
- Objectivity
- Not having evidence documented – items removed at closing meetings or disputed
- Wording of findings – APLAC and ILAC comments

New Fee Structure

- Labs are now paying directly for assessor travel and expenses
 - Will need to get expense claims submitted within 30 days of the assessment

New Approach to Report Writing

- Document the observation; e.g.,
 - 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.
- On-line tool developed

Materials

- Red dot: Need to sign Q21 – Memo regarding conflict of interest and confidentiality
- Green dot: Need a photo for the database
- Schedule for the next 2 days
 - ✓ Indicates registration
- **NEW!** Overall feedback form for the biennial
 - Please take time after each session to complete the form!
- USB



Materials (Cont'd)

- Laboratory Assessment Binder:
 - A04 series of documents needed to perform the assessment
 - 4 key documents: A06, P07, A61, A54
- All presentations can be found at:

http://cala.ca/assessor_training.html

Comments (Type 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.

Comments (Cont'd)

- Requirement: There shall be effective separation between incompatible activities.
- Observation: Ammonium hydroxide was stored below the bench where the ammonia test is performed. A review of the bench sheets shows that there were numerous incidents of the test having to be reanalyzed because of blank contamination.

Pre-assessment Instructions

- Added some instruction around a pre-team meeting
- Clarified that 45 minutes per appendix is a guideline to estimate the overall duration of the visit and that some appendices may take more or less time

Document Changes

- Changes to A02
 - Removed wording that implied some requirements related to calibration were only relevant to calibration labs
- A24 (Microbiology checklist)
 - Removed option to use 36 +/- 1 degree rather than 35.0 +/- 0.5
 - Added A1 media to the table on the last page

Document Changes (Cont'd)

- A03 – Rating Guide Appendix:
 - 02.01: The level and rigour of validation will depend on whether there are modifications from the reference method or if it is an in-house developed method (see CALA Policy A12). As a minimum, the lab shall maintain records of DL, precision, accuracy, and MU
 - Sample history requirements and supporting test methods – need to be documented and available
 - Removed toxicology requirements

Document Changes (Cont'd)

- A126 - Appendix specifically for toxicology appendices
- A61 - Traceability Policy
 - Re-organized
 - Change: if not doing daily or as-used verifications, the laboratory needs to demonstrate how data that has been released to clients is handled if the verification check does not meet acceptance criteria

Document Changes (Cont'd)

- P07
 - Section 4.1.2; if a non-conformance can be referred to a specific regulation, it is a Required “A”
 - Section 5.4.5; guidance around detection limits (DL)
 - has to be done on each instrument if more than one instrument is used for the analysis
 - Report highest DL (not the lowest or average)
 - Spike level used to determine DL dependent on the reference method

Document Changes (Cont'd)

- P07
 - Section 5.5.2; guidance around verifying calibration at the low end
 - Typically use 1 standard $< 10 \times$ DL
 - Exceptions (e.g., in-house samples that are always well into the calibration range)
 - 5.9.1.a; PT samples cannot be used as reference materials

2011 Biennial Schedule

- Topics chosen by
 - Changes to CALA policies and procedures
 - Top challenges
 - Assessor survey (autumn 2010)
- Can't cover everything! e.g., MU raised by 1-2 assessors
- Will look at handouts or job aids (e.g., report writing on-line tool) or ask assessors to contact CALA staff directly
- Trade show!

Monday

Time	Activity	Location
8:30-10:00	Plenary	Ballroom A & B
10:00-10:30	Break	Ballroom A & B
10:30-12:00	Sessions	See schedule
12:00-1:00	Lunch	Ballroom A & B

Monday afternoon

Time	Activity	Location
1:00-2:30	Sessions	See schedule
2:30-3:00	Break	Ballroom A & B
3:00-4:30	Sessions	See schedule
5:30	Reception & Dinner	Ballroom A & B

Tuesday

Time	Activity	Location
8:30-10:00	Sessions	See schedule
10:00-10:30	Break	Ballroom A & B
10:30-12:00	Sessions	See schedule
12:00-1:00	Lunch	Ballroom A & B
1:00-2:30	Sessions	See schedule
2:30-3:00	Break	Ballroom A & B
3:00-4:00	Closing Plenary	Ballroom A & B
4:00	Advisory Panel	Richelieu

- Volunteer facilitators
- Exhibitors at the trade show
- CALA staff

