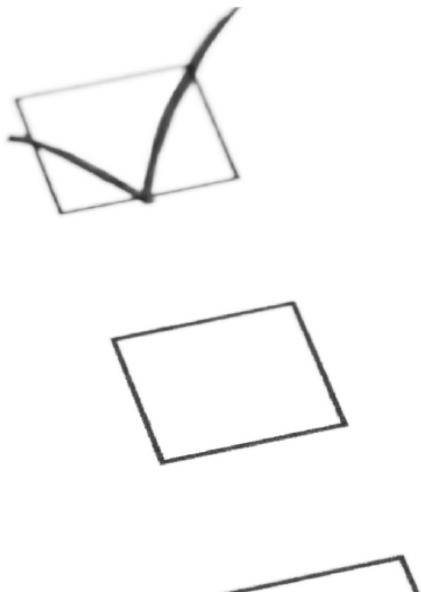


# Accreditation Forum

Colleen M. Cotter,  
Accreditation Manager



Building Laboratory  
Excellence

Vers l'excellence  
dans les laboratoires



# Objective

- Provide stakeholders the opportunity to discuss issues related to the accreditation program

# Topics

- Recent changes to the Accreditation Program
  - Fee Structure
  - Reference Methods
  - Documentation of Findings
- Expansion of the Accreditation Program
- Exploring a New Model of Accreditation
- Others?

# Previous Fee Structure

- Historically, accreditation program was subsidized by the Proficiency Testing (PT) program



# Driving Forces

- International pressure to separate PT and Accreditation
  - Accreditation body cannot perform the activities that are accredited
- PT prices need to be competitive
- Accreditation needs to become self-sustaining

# New Fee Structure

- Membership (\$450) and Accreditation fees (\$450) are due in January each year
- Do you need to be a member to be accredited?
- No

# Accreditation Maintenance Fees

- Accreditation maintenance fees are based on the expenses incurred at CALA to maintain accreditation services
- Due on the anniversary of the assessment
- This fee does not differentiate between small and large laboratories

# Accreditation Maintenance Fees

- Modified schedule for 2011:
  - Reassessment in 2011: \$5065 + \$90 per appendix
  - Reassessment in 2012: \$1825 + \$45 per appendix

# Assessor Expenses

- Assessor expenses are billed separately
  - Deposit of \$1000 for each assessor
  - 60 days following the assessment:  
laboratories receive a final invoice/credit

# Reference Methods

- Background: Feedback from regulators and assessors on methods that were changed significantly from the reference method
- Results:
  - Scopes of testing refer to “modified from [reference method]”
  - *A12 - CALA Policy on Reference Methods*

# A12 - CALA Policy on Reference Methods

- Policy: CALA accredited laboratories will ensure that scopes of testing accurately reflect the reference method.
- Options:
  - List the reference method without qualifiers if there are no changes to **critical** elements of a reference method
  - List “modified from [reference method]”
  - List the reference as “developed in-house”

# Modified from [reference method]

- Laboratories must be able to demonstrate how the testing method deviates from the reference method
- Method validation must incorporate all the changes
  - ISO/IEC 17025, Section 5.4.1
- The testing method must still be the same basis and principle as the reference method
- The laboratory must report the methodology as “modified”

# Significant Changes

- If changes are significant
  - e.g., a reference method for detection of phosphorus using a colorimetric method is not appropriate as a reference method for detection of phosphorus by ICP
- Options
  - Find a more appropriate reference method
  - List as “developed in-house”

# Documentation of Findings

- Background: APLAC and ILAC comments on how CALA documents findings, during the 2009 re-evaluation of CALA
- Result: Documentation of the observation; this approach is in alignment with what other accrediting bodies are doing

# 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.

# Expansion into other areas of testing and/or accreditation

- 2 mineral laboratories
- 2 petroleum laboratories
  - Separate checklist (A120) and guidance (A123) for petroleum-testing labs
- 1 coal laboratory
- Laboratories performing testing under the Canadian Shellfish Sanitation Program (CSSP)

# Potential Areas

- Draft agreement with CFIA for accreditation of food-testing
- Accreditation of Reference Material Producers
- Sampling
- Medical testing laboratories
- Inspection bodies
  
- Note: Cannot accredit Proficiency Testing Providers

# Why explore a new model of accreditation?

- CALA Strategic Plan (2010/11-2015/16) calls for “strategies to improve accreditation services”
- Examine the feasibility of:
  - a risk-based accreditation model
  - building a qualified assessor pool to do representative sampling

# Current

- Year 0: full assessment that covers all requirements in ISO/IEC 17025 and 100% of the scope is assessed
- Year 1: full assessment that covers all requirements in ISO/IEC 17025 and 100% of the scope is assessed
- Year 3: full assessment that covers all requirements in ISO/IEC 17025 and 100% of the scope is assessed

# Representative Sampling

- Simply put, assessing a 'sample' of the proposed scope of testing
- All technologies are covered
- Used by most, if not all, accrediting bodies

# Comparison of Processes

	Current Process	Representative Sampling
ISO/IEC 17025 Requirements	All	All
Scope of Testing Assessed	100%	<100%
Frequency of Reassessment	1 year after initial visit then every 2 years	1 year after initial visit then every 2 years

# Pros and Cons

- More comprehensive assessment of fewer tests
- Might reduce the cost – but it may not and it might actually increase the cost due to staff effort required prior to the visit
- Increases risk

# What does “risk-based” mean?

- A process whereby a laboratory’s past performance is used to determine the rigour of subsequent site visits

# Limitations of 'Risk-Based'

- ISO/IEC 17011, Section 4.3.3: policies and procedures shall be administered in a 'non-discriminatory' way
- ISO/IEC 17011, Section 7.11.3
  - Reassessment alone (intervals shall not exceed 2 years)
  - Some level visit should be done every 2 years

# Limitations (Cont'd)

- Survey of other accrediting bodies that are signatory to APLAC indicates that the norm is every 2 years laboratories undergo the same level of rigour at required intervals and do more oversight as required
- Regulator acceptance

# Objectively determining past performance

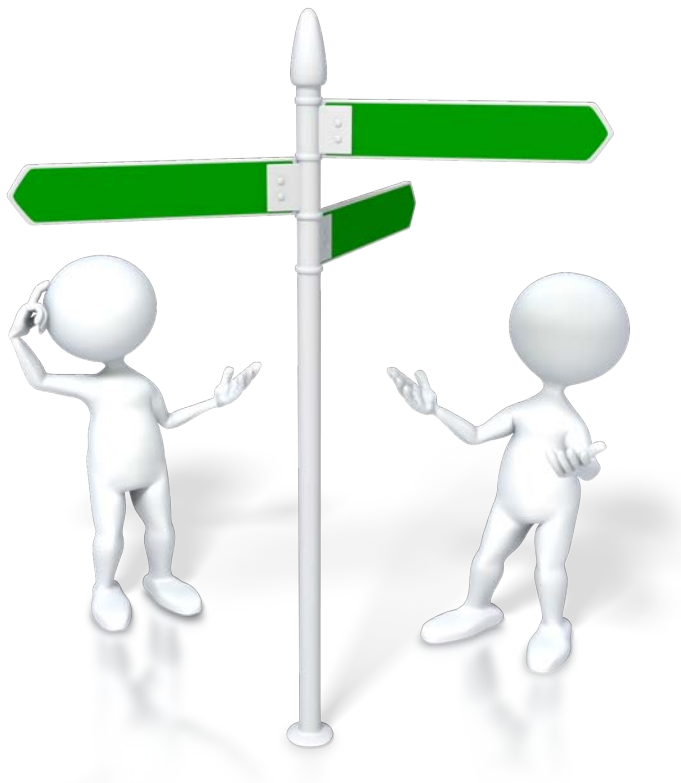
- PT performance?
- Number of assessments?
- Previous assessment reports?



# Comparison of Processes

	Current	Risk-Based
ISO/IEC 17025 Requirements	All	Variable
Scope of Testing Assessed	100%	<100%
Frequency of Reassessment	1 year after initial visit then every 2 years	1 year after initial Some level of visit every 2 years + reassessment

# Next steps



- Best option - representative sampling
- Other options?

# Questions?

