

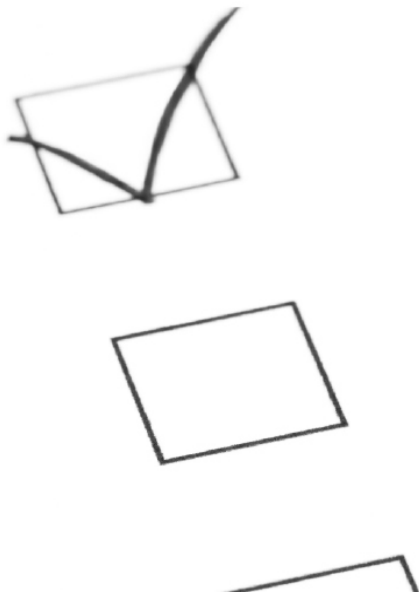
# 2011 CALA BIENNIAL ASSESSOR TRAINING

## Assessment Planning

Session 4

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Building Laboratory  
Excellence

Vers l'excellence  
dans les laboratoires



# Survey Results

- Time
  - Document Review
  - 45 minutes per test
- Project Management
  - Scheduling
  - Common Areas of Review
- Sampling of Records
- Assessing Proficiency Testing

# Document Review

- Critical preparation step
- May not have all of the documents prior to arrival
- Use Doc Review to prepare questions
  - Lab Information on audit software
- Use travel time for Doc Review
- Org chart

# The Schedule

- One full day for QMS by Lead and one Assessor (training for new Lead)
- 1<sup>st</sup> draft schedule - group similar tests together; ask lab to assign analysts.
- 2<sup>nd</sup> draft schedule - Assign tests to Assessors; verify expertise; reorganize schedule.
- Be prepared for staff changes at Lab.
- Flexibility; expect change.

# Assign Common Duties

- Assign an Assessor to review:
  - Balance Records
  - Temperature Monitoring
  - Log-in system, Sample ID scheme
  - Method validation
  - Sample preparation (soil)
  - PT performance
  - Good restaurants in area

# Assessment Visits

- Snapshot in time
- Assess magnitude of Finding
  - Occurrence in single or many tests?
  - If system wide issue, document under Rating Guide and list examples.
- Advise Lab verbally of typos, grammatical errors.

# Lead Assessor

- Project Manager
- Divide all tests by expertise between Assessors.
  - Lead to verify Assessor expertise.
- Minimal tests for Lead, so can fill in if needed.
- Set up computer software (network) so Assessors can enter findings on site.

# Lead Assessor

- Check with Assessors on progress; be prepared to reassign tests.
- Encourage Assessors to:
  - record Findings and Evidence on checklist!
  - record findings on software daily (before dinner).
- Prepare Completion Package on site.
- Ask Lab to ship docs back to CALA

# System Assessment

- Trace of Tests
- Assess function & linkage of Systems
  - Client Feedback, Complaints
  - Nonconformances
  - Corrective/Preventive Actions
  - Internal Audit

# Assessors

- Familiar with reference method
- Assess similar tests together
  - Assess common items once (incubators)
  - ICP metals in water/soil, VOAs in water/soil
  - Different prep, same instrument finish
- 45 minutes; a guideline only
- Speak up if having difficulty

# Value of Findings

- Value Findings – yes
  - Justification – clause number
  - Evidence – document, date, situation
- Trivial Findings – no
- May not have Findings for every test.
- Leave the lab a better lab; not a perfect lab.

# Time Management

- All Assessors are Volunteers. This is not an endurance test.
- Record all findings daily or as found.
- Lead Assessor to review report as findings added. Clarify with Assessors as needed.

# Time Management

- No Lab staff overtime because of Assessment.
- Arrive and leave on time.
- OK to move up time for closing meeting
- Not OK to delay closing meeting.

# Proficiency Testing

- Assessors to confirm demonstrated proficiency.
  - Option i: CALA PT Program or comparable 2x per year
  - Option ii: CALA approved PT, 2x per year
  - Option iii: No longer valid
- Participation of above confirmed by CALA staff

# Proficiency Testing

## Options iv, v &vi

- If Lab chooses Option iv, v or vi:
  - Option iv: one formal study per year from PT provider
  - Option v: one less formal interlab study per year (e.g. multi location labs)
  - Option vi: inter analyst comparison once per year. Examined during site visits.

# Proficiency Testing

## Options iv, v &vi

- Only if Options i and ii not available or suitable.
  - If Assessor knows of possible Option ii, notify CALA staff and Lab.
- Assessors to confirm participation.
- Review CARS for any failures.
- Need program description and acceptance criteria for Option vi (inter analyst comparison).

# Assessment Planning

- Discussion