



Biennial Assessor Training - Day 2

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Canadian Association for Environmental Analytical
Laboratories
(CAEAL)

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Required vs Recommended

- Required: non-conformance is deemed to compromise the quality of the results
- Recommended: non-conformance is deemed to not compromise the quality of results
- Suggestion: observation is not a non-conformance

Recurring “B” Items



- If a “B” item recurs at the next site assessment, it does become an “A”
- Severity is no longer the issue - the issue is that the item must be addressed as it is a non-conformance to the standard

Appendix 02.01



- Ensure the test method is validated based on performance history or documented validation data*
 - *includes detection limit, precision, accuracy and recovery, as appropriate



Method Validation

- Resources
 - Eurachem Document
 - Test method Development and Evaluation
 - In-House Validation Checklist
- One standard less than or equal to 10X the detection limit may be part of the initial validation and/or calibration, but not necessarily required every run



Exercise (15-20 min)

Objective: consistent approach as to how method validation requirement is assessed

List 5 items that assessors need to check for method validation for:

- A) chemistry
- B) microbiology
- C) toxicology

NQI



- See what Jennifer is covering, so that we don't overlap

Future Developments



- Representative Sampling
- Assessor Training
- Environmental Working Group



Representative Sampling

- Direction and Timeline
 - » Assessing a representative sample of the scope
 - » Pilot project: 2001?
 - » Implementation: 2002?
- Guidelines
 - » Guidelines to be developed to ensure consistency
 - » Assess 100% of scope on an initial assessment



Assessor Training

- Biennial vs annual?
- Chance for all assessors to partake in same discussions
- Specialized training for disciplines

Environmental Working Group



- Goal: Produce guidelines for the accreditation of environmental laboratories

When to NOT assess a test?



- Assessment = objective evidence gathered to demonstrate that a lab has the following to produce competent results:
 - People (with skills and knowledge)
 - Environment (with facilities and equipment)
 - Quality Assurance
 - Procedures

Conformance to the Standard



- Assessment: comparison of the requirement to the actual conditions that exist
- When the actual conditions that exist **DO NOT MEET** the requirement, a requirement or recommendation results
- Be specific enough to ensure requirement is met (and can even give examples) **BUT** don't give the lab the only solution

Appendix 06.02



Ensure all supplies are stored under appropriate conditions (e.g., 1-4 degrees C) and in a manner which satisfies requirements for safety, security, separation of incompatible materials, and ease of retrieval

Question: How does this requirement apply to storage of standards and samples?



Field Tests

- What we know so far:
 - » Will only look at the test as another method
 - » NOT looking at the sampling component of the test (i.e., field testing vs field sampling)
- Question: Are all the components of the Appendix applicable to HACH kits?



Audit Planning

- Contact team members 3-4 weeks in advance
- Obtaining SOPs
 - » Language in application has been strengthened
 - » Communicate, communicate, communicate!
- Account for time when there are different instruments in the same appendix

Responses



- Please advise laboratories to not send responses to required actions via e-mail

Appendix



- Definition: A unique matrix - test method combination that may contain more than one parameter
- Please initial appendix cover sheets
- Transfer changes to the main scope

Microbiology Scope



- Appendix: Coliforms
 - » Parameters: Total coliforms, fecal coliforms and E. coli
- Methods
 - » Presence-Absence
 - » Membrane Filtration
 - » Most Probable Number (e.g., Colilert, Quantitray)

Reporting Actions Already Resolved



- When a client completes a corrective action to a requirement or recommendation before you are off-site:
- on the assessment report, note that objective evidence was provided before the end of the assessment
 - advise the laboratory that the requirement and associated corrective action will appear on the assessment report

Confidentiality



- Signed confidentiality agreement

Trace of Tests



- Choose 1 Proficiency Testing (PT) sample
- Verify that the PT is being treated as routine, as per Section 5.0 of the Application (i.e., Terms and Conditions of Accreditation)
- If not, make it a recommended action (?)

Publicity Guidelines



- The CAEAL logo is a registered trademark and may not be used by laboratories (Section 5.0 of Program Description - Tab 10)
- Notify CAEAL office via completion report

Types of Assessments



- Abbreviated
- Verification
 - » To verify implementation of required actions
 - » As the result of move