Quality Assurance for Environmental Laboratories

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Session Objectives

This Session will discuss:

• Concept of Quality for Environmental Labs
• Overview of Available Standards and Tools
• Application of QA to Environmental Labs
• Lessons Learned
Concept of Quality for Environmental Labs

• Environmental labs are an integral element of the PDCA decision process:
  – Need for environmental data -> Planning
  – Data objectives -> Planning documents
  – Field Samples -> Labs for analysis
  – Lab results -> Evaluation of results
  – Make decision -> Take action
Concept of Quality for Environmental Labs

• Quality of decisions depends on:
  – Sufficient data
  – Adequate quality (not “best”)  
  – Satisfying technical and quality objectives

• Quality is best applied as a system of management and technical practices.
Concept of Quality for Environmental Labs

• Quality – Why Critical to Labs
  – Ensure that correct methods are used (QA)
  – Ensure that methods are applied correctly (QC)
  – Ensure that results meet needs and expectations (QA)
Available Tools and Standards

- Available Standards:
  - Management Systems Standards:
    - ISO 9001
    - ISO/IEC 17025
    - NELAC Standards
  - Technical Standards:
    - Reference Methods (e.g., ASTM)
    - Instrument Standards
    - Method Standards
Available Tools and Standards

• Available Tools:
  – Quality Management Plans
  – Quality Assurance Project Plans
  – Standard Operating Procedures
  – Technical and Performance Audits
  – Statistical Methods for Evaluation
  – Laboratory Information Management Systems
Application of QA

• Who’s in the Audience?
  – Engineers using Analysis Laboratories?
  – Analysis Laboratories?
  – QA Staff interested in Laboratories
Application Side Bar

• Is Sampling and Sample Collection Quality Important?
  – The need to include Sampling in the Quality Planning for Specific Projects
“Quality is best applied as a system of management and technical practices”

- Quality Systems Include (at a minimum)
  - The Big Picture - Quality Management Plans
  - The Middle Game - Laboratory Quality Plans – for a specific site or if the Laboratory is part of a bigger organization.
  - The Fine Details - Standard Operating Procedures
Developing a Quality System

• Available Tools:
  – Quality Management Plans (e.g. QA/R-2)
    • It’s a requirement!
  – Quality Assurance Project Plans (e.g. QA/R-5)
    • It’s also a requirement!
  – Should we mention NELAC (2003)
Background - Application of QA to Laboratories

• What Good is a Quality System Requirements and Guidance
  – Laboratories must think and work through the details of what quality practices to implement
  – Laboratories get guidance others have found important to include in their quality system.
    • (The Mentor/Coach Dilemma for QA/QC)
Application of QA

• How does a Laboratory use the Guidance and Tools to develop a system and practices?
  – Front End Issues
  – Implementation Issues
  – Back End Issues
Quality System Foundation

- Required practices for a QA system?
  - Quality Management Plan
  - Laboratory Specific Quality Plan
    - Needed if Laboratory is part of a larger company or organization
  - Standard Operating Procedures

- Is a QAPP required if a Lab Quality Plan exists?
Quality System Foundation

• Real Benefits of Having a Quality Management Plan
  – It orients employees to the Company its practice(s)
    • How the company see’s itself?
    • What is it’s commitment to quality?
    • How is it organized?
    • What’s important to the company?
    • Who’s in the management chain?
    • What people are responsible for management, staff, and quality?
    • How people are trained?
Front End Issues
Application of QA

• Front End Issues with the Client
  – Ensure correct methods are used (QA/PM) – Client/Lab Interface
    • How is this done?
    • Who Makes these decisions?
    • What’s the “Contract” with the Client?
Quality Decisions
Pick the Right Method

• Identify the Question (Requirements)
  – Is the method suited for the matrix?
  – How sensitive does the method need to be?
  – Is the measurement different from the blank at this sensitivity?
    • (Condensable Particulate Matter example)
  – How precise (reproducible) does the method need to be?
  – Is this the least expensive method to generate an acceptable result?
    • (Source Vent Air Example)
  – Are there multiple analytes to consider?
Front End Issues
Application of QA

• Front End Issues for the Laboratory
  – Ensure that methods are applied correctly
    (QC) Lab Management/Staff Interface
    • Who is responsible for communicating client
      needs to the staff?
    • Who is responsible for correct
      implementation of methods?
    • Who checks methods are correctly
      implemented?
Implementing the System Practical Lessons?

• What are the critical elements for a successful System?
  – Training
    • System doesn’t work unless the staff read and understand the vision.
    • System doesn’t work unless the staff take ownership and can improve the system.
    • So Who trains new staff, investing them in the Quality System?
Training Training Training

• **Systematic Training is important**
  – Training by experienced staff not as a “hand-me-down” from new staff
  – Keep the Training Pure by having experience staff train.
Implementing the System Practical Lessons

– Updates and Revisions
  • Some of the boiler plate isn’t important?
  • Who has the time or responsibility to review and revise?
  • what’s the incentive for those who implement the system?
Implementing of the System -2

• What’s Required to Implement the System
  – Sample Prep/Analysis Method Setup
    • Which comes first the setup or the SOP?
Implementing of the System - 3

• What’s Required to Implement the System
  – Method Demonstration Tools
    • Detection limits are Laboratory Specific
    • Initial Precision and Recovery/Accuracy
    • Ongoing Precision and Recovery/Accuracy
    • Secondary Source Check Samples
Detection Limit Example

• Detection Limits are often based on uncertainty (imprecision) in a method
  – How to do it … right or wrong?
    • Detection limits are a function of concentration!
    • What makes it good?
      – Control sources of variability.
    • Good MDLs promote good analysis
      – Practice controlling variability
Implementation of the System -4

- Data Reporting Demonstration
  - Initial Report Data Verification
    - Back to the Client Requirements
      - What level of detail? – Data
      - What level of detail? – Narrative
      - What Level of detail? – QC Report
      - Ongoing Report Validation
    - Who Validates the Data/Report?
    - How often is the QA Staff Involved?
Quality System Upsets

-Major Staff Changes

- Do we care about staff training files?
- Retraining is critical?
- What about for new training
  - How is retraining done
  - Who does it Example
    » New Staff Pass Down
    » Experienced Staff following Training Procedure
Quality System Upsets

- **SOP Changes** –
  - Who owns the SOP
    - Who initiates the SOP change
    - When are SOP’s changed
    - Who initiates the SOP training
  - New SOPs
    - New Methods
    - Variations of Methods
  - Tracking and Archiving SOPs
    - What Quality System applies to which Samples??
Quality System Improvements

–Major QA System Changes
  • Who communicates the change
  • QA Oversight vs. Project Management Oversight
    – Example, how to track samples/due dates/Hold Times)
      » LIMS an be messy!
      (A LIMS/QA/Project Manager issue)
Application of QA

• Quality – Why it is Critical to Labs
  – Back End Issues
    • Ensure that results meet Client and Data User needs and expectations (QA)
    • Ensure the report meets the clients requirements (QC)
    • Results that meet clients needs promote return clients
Back End QA System Issues

• Evaluation Tools
  – What they are
    • Periodic Evaluation – Technical Systems Audits
    • Data Review and Data Quality Audits
    • Performance Evaluation Samples (Audit samples)
    • Round Robin (real matrix) comparisons.
  – How are tools used
    • What tools are used when
    • Are we are missing tools?
    • What else do you need to know? (QA is a living system!)
Back End QA System Issues

- Accreditation and Audits
  - Makes a laboratory follow through with preparation of its quality plan
  - Requires verification that everyone who works for the laboratory has read the QMP and the appropriate SOPs (training)
  - Gives Outside Credibility
Back End QA System Issues

• What are significant outcomes of QA Evaluation?
  – When things don’t work you got to figure out why and make adjustments and not just report the data as invalid.

• How are these outcomes communicated to the staff.
  – How do you define continuous improvement?
Questions?