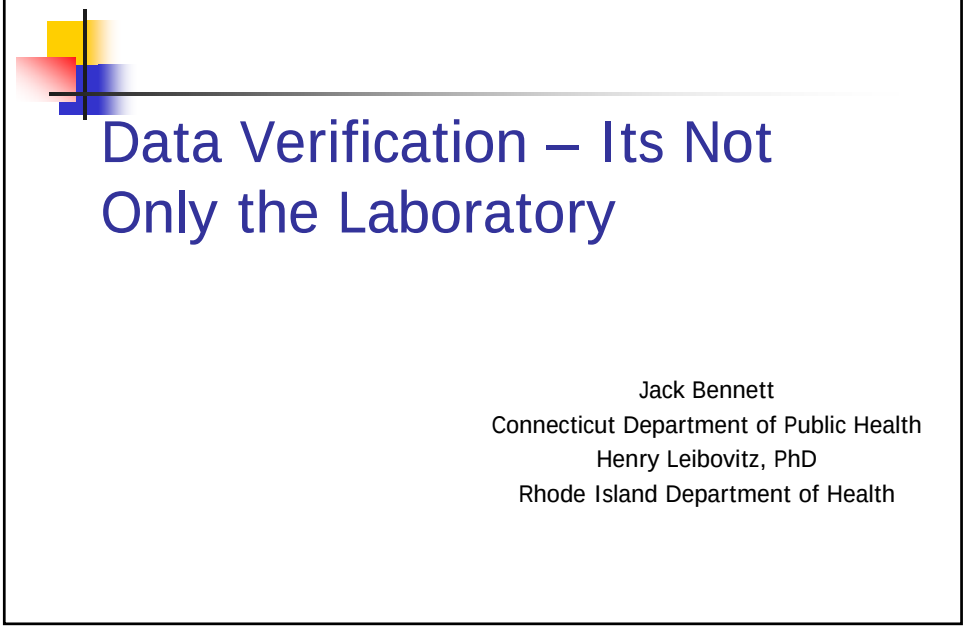

Data Verification – Its Not Only the Laboratory

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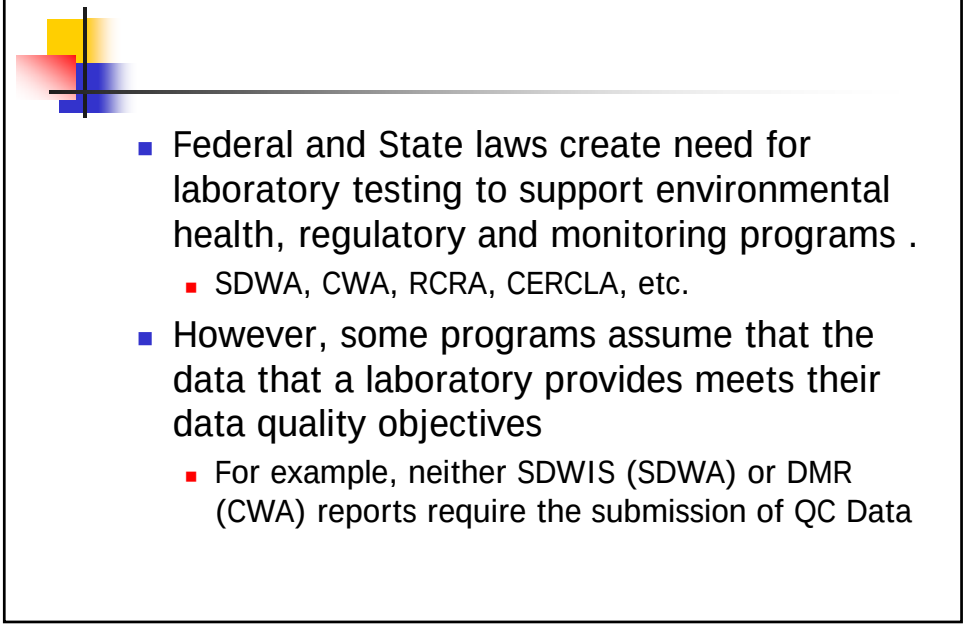

- Federal and State laws create need for laboratory testing to support environmental health, regulatory and monitoring programs .
  - SDWA, CWA, RCRA, CERCLA, etc.
- However, some programs assume that the data that a laboratory provides meets their data quality objectives
  - For example, neither SDWIS (SDWA) or DMR (CWA) reports require the submission of QC Data

Reasons Environmental Laboratory QC Data Is Not Used

- Assumption - if laboratory is certified then no need to verify data.
- Poorly defined in program Quality Plan
- Programs choose not to use QC data.

Laboratory Certification

Most States and Federal environmental programs require support laboratories to become certified by a recognized Accreditation Authority.

But the lab is certified...

- Many organizations assume that because a lab is certified that every bit of data that comes out of a lab is good
  - Lab certification just captures a “snapshot” of the labs operations
  - Different certification programs vary in the depth of examination of the laboratory operations

Laboratory Certification Assures Capability

- Quality Assurance Plan
- Method Detection Limit (MDL) studies
- Initial Demonstration of Capability
- Standard Operating Procedures
- Analysts receive training
- On-site assessments every 2-3 years

Laboratory Certification Does Not Assure Accountability

- Are sample testing Quality Controls met?
- Are test results and reports reviewed?
- Is compliance and monitoring data acceptable?
- Are program Data Quality Controls met?

Are Laboratory Results Acceptable - Who Decides ?

- Laboratories decide
- Programs give up their responsibility of assuring that data is acceptable for decision making.

The OIG Report

- On Sept 21, 2006 EPA's Office of Inspector General released the "Promising Techniques Identified to Improve Drinking Water Laboratory Integrity and Reduce Public Health Risks" report

The OIG Report

- Since laboratory integrity is crucial to EPA's strategy for providing the public with safe drinking water, the OIG performed a study to identify:
  - Vulnerabilities in the drinking water sample analysis process
  - Techniques to mitigate those vulnerabilities
  - Opportunities to further safeguard public health

Key findings

- Over the past 6 years, the number of laboratory fraud cases has increased steadily
  - In FY2002 there were 12 cases and in FY2005 there were 58 cases.
    - About 30 to 35 percent of the cases in FY2004 and FY2005 involved laboratories responsible for analyzing drinking water

Areas of Concern

- Inappropriate procedure
- Laboratory fraud
- Data quality
- Laboratory integrity

Examples of types of problems

- Pencil whipping
- Juicing
- Peak dialing
- Time traveling
- Drylabbing
- Sample collection

Why the problems can occur

- Economic pressures
- Time pressures
- Client pressures
- Lack of technical expertise by auditors to detect fraud
- Lack of internal controls
- Clients do not ask for QC data

Improper Laboratory Practices

- Concerns may be addressed by data review and verification or validation
- Programs need to identify options and resources available to assure the laboratory they use are certified and the sample results they submit are acceptable.

Data Review, Verify or Validate?

Environmental Programs may:

- Verify or validate sample results
- Accept or reject sample results based on QC results.

Data Verification

The process of evaluating the completeness, correctness and the conformance of a data set to method and/or contractual requirements

- Should be done by both the organization producing the data as well as the organization using the data
- One of the outputs from the verification process should be a case narrative detailing any problems or stating that there were no problems.

Data Validation

- Is an analyte and sample specific process that determines the analytical quality of a data set and is usually done by an independent party.
  - It can involve going back to the raw data and reconstructing the data set
- We are not suggesting that every data set go through full validation

Data Quality Objectives (DQO)

Program Quality Plans should:

- Define how laboratory QC data will be used to meet DQO,
- Describe level of review necessary to assess acceptability of laboratory data (verify or validate?)

What can be done? - Program Training and Data Review

- Develop data review training workshops
- Use Laboratory and Certification Officer expertise as a resource
- Utilize new electronic data review software to verify or validate electronic reporting

What Level of Data Review?

Programs must decide and define the level of data review required in its Quality Plan prior to the onset of the project.

Level of Data Review

1. Review QC Sample results associated with samples.
2. Review and verify sample results by examining original QC and sample data.
3. Validate the entire analysis including calibration, QC and sample data.

Standardized Laboratory QA/QC includes:

- Statements of data quality from the laboratory director
- Detection, quantitation and reporting limits
- Calibration verification
- Traceability of standards
- Initial / Ongoing Precision and Recovery (IPR/OPR)

Standardized Laboratory QC (cont'd)

- Analysis of blanks (Method Blank)
- Recovery of analytes spiked into a laboratory reagent blank (LFB, LCS)
- Recovery of analytes spiked into the sample matrix (MS, LFM)

Submitting QA/QC Data with the Analytical Results

- Quality of the data evaluated directly
- Program decides to accept or reject data
- Supporting data becomes property of program
- Program can defend data used to support decisions by verifying it first.

"Solutions to Analytical Chemistry Problems with Clean Water Act Methods"

("Pumpkin Book" EPA 821-R-07-002) March 2007

Strongly recommends that the supporting QA/QC data be submitted along with the analytical results

Retrieving data on request

Data provided by laboratories may have been compliant . . .

. . . if QC data becomes misplaced there is no way to prove the data was compliant.

The Problems with Retrieving QC Data Only When Questions Arise

- Programs rely upon laboratories to keep QA/QC records unless requested.
- QA/QC data may be components of analytical results for a variety of clients.
- Resolving questions of compliance is time consuming and confusing for the program

What OIG Recommends

- Training of lab certification officers in fraud investigation techniques and procedures
- Use the following techniques to detect fraud
  - Enhanced audits
  - Use data validation and verification techniques
  - Require analyst notation and sign off on manual integrations
  - Review raw electronic data and use electronic data analysis
  - And more….

Limited Program Resources

Many programs do not have the resources or the training necessary to help themselves review, verify or validate laboratory data.

What can Programs do now??

- Require submission of "basic" QC data
  - Require electronic submission of QC data along with sample data
    - EPA recently promulgated a final rule about electronic reporting of data under the Clean Water Act
    - **http://www.epa.gov/fedrgstr/EPA-GENERAL/2005/October/Day-13/g19601.htm**

What can Programs do now??

- Require that a statement signed by the lab director attesting that samples were analyzed properly
- Review the QC data when it is submitted
  - Program staff are not expected to be chemists, but data review checklists that define "basic" QC data and acceptance criteria can be useful

What can Programs do now??

Programs may randomly request entire data set including original QC, calibration and sample data for assessment.

Validation may be performed by Program or third party data validators.

- EPA recently stressed the importance of programs having the final say in the FAQ to the March 2007 methods update rule.
- “These amendments... clarify that the regulatory authority decides whether to reject or accept data that have failed QC specifications in the method, or when problems have occurred during sample collection.”

- Implementing routine reporting of QC data will not only help ensure that routine monitoring data is of known quality but will also prove valuable in case of the need to respond to a radiation, chemical or biological incident

In Summary

- The laboratory and the program are partners in ensuring that the data generated is of acceptable quality for its intended use.
- Each partner has a role in ensuring the quality of the data
- The end user of the data bears the responsibility of ensuring data is suitable for its intended us

In Summary

- EPA should provide an incentive for State Programs to submit QC data
  - Support improvements in data verification requirements
  - Work with all partners to develop requirements
  - Stepwise approach will be necessary

- Questions??