Field and Lab Audits

What is an Audit?

- Check that data and processes are of sufficient quality for environmental decision-making
  - Data Quality Objectives (DQOs) met?
  - SOPs, methods and project-specific requirements followed?
- Documentation sufficient to recreate event?
- Opportunity for learning and tweaking processes

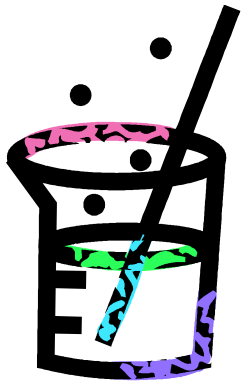
Audit Overview

- Program and project DQOs and Data Quality Indicators (DQIs) as audit criteria
  - QA rule requirements (62-160 FAC)
  - Program rules and requirements
  - DEP SOP requirements (DEP-SOP-001/01, DEP-SOP-002/01 and DEP-SOP-003/11)
  - Project QA plan requirements, if applicable (contracts and grants)
  - Analytical method requirements for labs
  - NELAC (or TNI) requirements for labs
  - DEP data usability criteria (DEP-EA-001/07)

Audit Overview - Field

- Field audits
  - System (evaluation of procedures, equipment and documentation)
  - Performance (evaluation of sampler's technique, knowledge of DEP SOPs and record-keeping)
  - Project (tracking specific sample results through field records for data validation and usability assessment)

Audit Overview - Laboratory



- Laboratory audits
  - System (evaluation of procedures, equipment and documentation)
    - Usually performed by DOH ELCP
  - Project (tracking specific sample results through lab records for data validation and usability assessment)

Lab Audits - DoH vs. DEP

- DoH looks at the Big Picture –
  - Is there a Quality System?
  - Do processes and procedures meet NELAC (TNI) Requirements?
  - Lab certification sets the minimum bar
- DEP looks at specific data-
  - How effective are the system and processes in generating data for a specific purpose?
  - Typically tracks selected data through documents
    - *Are data usable for a specific purpose?*

Audit Overview - Project

- **Project audits** including data review
  - Tiered approach determines depth or degree of evaluation
  - Routine data review for compliance with permits and rules can incorporate lower level tiers of audit criteria
    - Examples:
      - Date checks for holding times
      - Method number checks for approved methods
      - Result checks for applicable “reversals”
      - Data qualifier code checks for QC problems
      - MDL and PQL value checks for DQO attainment

Audit Overview – Internal vs external

- Internal audits
  - Required for all sampling organizations (FA 4200)
  - System, performance and project audits recommended
  - Coordinated by your QA Officer
    - Assistance with audits offered by AEQAS
    - Internal "Quality of Science" reviews conducted by AEQAS for DEP internal program quality system evaluation, if requested
- External audits (*conducted by DEP*)
  - Authorized by QA rule
  - Applicable to any person or organization involved in data generation or support activities

Records to reconstruct history of each sample

- **Documentation** is critical to assessing data usability
- Can an independent auditor **reconstruct** how the sample was collected, received in lab, processed and analyzed, test results evaluated, reported, etc.
  - Can the calibration condition of field-testing instruments used to measure sample characteristics be verified?

Audit Checklists

- Generic sampling checklists in FA 1000 (DEP SOPs) and on QA Officer Resources page:
  - http://www.dep.state.fl.us/water/sas/qa/officer.htm
    - Lab checklists for selected analytes on QAO webpage
- Other checklist versions available from AEQAS
- Serve as on-site reminders of audit criteria
- Provide detailed feedback as part of audit report
- May need project-specific checklist
  - Derive from project DQOs and DQIs

Field Checklists

- DEP SOPs are basis for typical audit
  - Sampling collection
  - Sampling equipment
  - Sample preservation
  - Field testing calibrations
  - Documentation of field-related activities
- Audits of project-specific data records will track the selected samples or data points
  - Documentation per QA rule must be available

Lab checklists

- Analytical methods, NELAC (TNI) standards, DEP-EA-001/07, Program-specific DQOs, contract requirements, etc. are basis for checklists
  - Checklists require tailoring to the above for given audit and data selected
  - Data records audits track individual data or samples through the lab records
    - "Systems" audits may also inspect available equipment & supplies, record-keeping structure, and conduct analyst interviews
  - Documentation per QA rule requirements must be available for audits

Data Review And Audits

Checklists

TMDL Data Evaluation Checklists - Use these checklists as guidance to evaluate the usability of your data for the TMDL Program:

- Field Performance Audit Checklist
- Data Evaluation Checklist

Field Audit Checklists - Use these example checklists as guidance for conducting internal audits.

- Documentation Checklist
- Field Quality Control Checklist
- Field Testing Checklist
- General Sampling Checklist
- Aqueous Sampling Checklist
- Groundwater Sampling Checklist
- Surface Water Sampling Checklist
- Stream Condition Index (SCI) Sampling Checklist
- Qualitative Periphyton Sampling Checklist

Lab Audit Checklists (MSExcel file)

Data Usability Document

Department of Health Environmental Laboratory Certification Program (DOH ELCP) Checklists and Other Information

Common Problems Seen During Audits

- Common TMDL Audit Deficiencies - List of common field and laboratory audit deficiencies from TMDL or RCRA audits.
- Groundwater Sampling Audit Issues

Audits

Performance Audit Inspection (PAI) Typical Records Request List (Sampling and Analyses) (

http://www.dep.state.fl.us/water/sas/qa/dr-audits.htm

Audit Report

- Complete relevant checklists
- Send preliminary report of audit findings which clearly outlines major and minor deficiencies and recommendations
  - Include checklists (if appropriate)
  - Send to audited and/or responding entity
  - Copy to associated DEP staff
- Ask for response and strategy for addressing issues
  - Indicate mandatory corrective actions
- Consider responses and prepare final audit report
  - Note acceptable corrective actions
- Document any data usability recommendations

Corrective Action

- Work with the audited party to develop corrective actions. Examples:
  - Additional staff training
  - Procedure changes
  - Record-keeping changes
- Auditor and audited party should agree to actions (detailed in audit report)
- Follow up with audited party to ensure compliance and understanding
  - Additional audit may be required

Usability Recommendation Process

- Evaluate each sample-analyte combination per applicable criteria
  - Assess criticality of any failures
  - Identify mitigating data and facts
  - Determine qualification status of analytical result
- Tally number and percentage of qualified sample results for analyte
- Characterize analyte (field and) laboratory system with respect to selected audit data

Usability Recommendation Process (cont'd.)

- Evaluate response from audited entity
  - Usually documented in final audit report
- Audit more data records as necessary
  - Repeat evaluation process for additional data
- Recommend qualified or unqualified use of analyte data for the audited calendar ranges or project, permit, etc.
  - Document usability recommendation for individual sample results or for larger set of data
- Resolve data management issues – database records

Data Records Selection Criteria

- Driven by program, project or site, permit, contract, problem, etc.
- What is purpose of audit? Examples:
  - Assess overall usability for a dataset?
  - Determine usability for specific data points?
  - Evaluate compliance data for a permit?
  - Investigate a known problem with the data?
  - Respond to fraud allegation or other complaint?
  - Follow-up to verify corrective actions?

Data Records Selection Criteria - Example

- Identify “major” data generators or other category of generators of ambient monitoring data used for surface water impairment assessment
- Choose relevant analytes specific to audited entity
- Pick sample records for low-med-hi concentrations for each audit year, including non-detects
- Include data records for 5-year range or other date span
- Target minimum of 15 audit samples

General Audit Topics & Problems Encountered During Audits

Field Records Audit Topics

- Sample collection information
  - Location, date, time, analytes, preservation, matrices, collection equipment & procedures
  - Groundwater purging information
- Field testing information
  - Measurement results
  - Calibration verification
- DEP SOPs are audit criteria
  - Basis for checklists for performance and documentation

Lab Records Audit Topics

- Sample preservation & holding time
- Instrument calibration & verification
- Analytical sensitivity (MDL & PQL)
- Analytical precision & accuracy
- Blank contamination control
- Sample concentration bracketing
- Method-specific procedures
- Data reduction, reporting & transcription

Holding Times

- Criteria established in DEP SOP tables per DEP QA rule & 40 CFR Part 136
- Field record is audited to verify collection date and time
- Lab analytical record is used to verify sample prep and analysis date and time, as applicable

Evaluation of Sample Preservation

- Criteria established in DEP SOP tables per DEP QA rule & 40 CFR Part 136
- Field records should indicate type(s) of preservation for each sample container
  - Includes field check of required preservation pH
  - Field info transmitted to lab should also indicate any other specific preservations

Evaluation of Sample Preservation (cont'd.)

- Lab records are evaluated independently of field records
  - pH preservation and chilling is not verified upon laboratory sample receipt
    - Records are checked for any indication of verification of sample pH and temperature
      - Check with pH paper (pH value recorded or noted within specified range)
      - "Received in ice" OK only for same-day delivery

Calibration Evaluation - Examples

- Minimum number of standards used
- Corr. Coeff. ≥ 0.995 where applicable
- “Second-source” standard used to verify initial calibration
- All verifications within specified range (method or other criterion)
- Sample and QC results “bracketed” between acceptable calibration verifications

Spike Evaluation

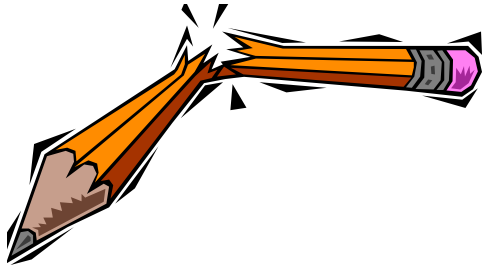
- LCS usually takes precedence over matrix spike
  - Matrix spike evaluated where required by method or other criterion
  - Matrix spike evaluated for parent sample
- Recovery calculations verified by auditor using raw data
  - Example default recovery targets:
    - 90% - 110% for nutrients
    - 85% - 115% for metals (LCS)
    - 70% - 130% for metals (Matrix Spike)

Auditing of Data Reduction & Reporting

- Final results are verified according to method-specified calculation formulas
- Raw sample responses from the instrumentation are compared to standard responses
- Specific QC evaluations are applied to the analyses, for example:
  - Metals, microbiology and BOD QC per method requirements
- Reports or databases are compared to audit results

Field Issues - Field Sampling Performance

- Not having proper, functioning equipment out in the field
- Not following DEP SOPs
- “Sloppy” contamination control and sample handling (e.g., cross-contamination of equipment between samples, agitation/aeration of VOCs)
- Not documenting required information



Field Issues - Field Testing

- DEP SOP calibration verification protocols for test instruments were not followed.
- Pre-deployment checks on field test and sampling equipment were not conducted.
  - Equipment does not work during sampling event
- Standards used for calibrating field measurements did not bracket sample concentrations.
- Field meter calibration criteria not met
  - Calibration acceptance criteria were not being assessed (at all)

Field Issues - Documentation

- Various calibration records incomplete
  - Including linkage between meter calibration records and sample measurement data
  - Sources for field calibration standards were not documented
  - Calibration verifications not documented

Field Issues- General Documentation

- Sample preservation and verification (including filtration) not recorded
- Groundwater purging records incomplete
- Lack of clear, unique identification of samples
- No documentation of sampling equipment used to collect samples

Lab Issues – Procedure and documentation

- **Lab Procedural & Documentation Issues**
  - Lab doesn't check received field samples for proper preservation (i.e. doesn't document the check)
  - Lab QC data generated at concentrations not relevant to the project sample concentrations (spikes and duplicates)
  - Lab doesn't evaluate the results of analytical blanks for impact on sample results
  - Critical aspects of sample preparation are not recorded (e.g., filtration times for chlorophyll, method-required processing steps for other tests)

Lab Issues – data reporting

- **Lab data reporting**
  - Reported MDLs and PQLs not low enough to meet project or program DQOs
  - Lab QC data is “selectively” used to report unqualified sample results
  - Sample results are reported without qualification whose concentrations are outside of the calibration range
  - Sample results reported with missing or inappropriate data qualifier codes

Problems With Calibration Range

- Samples outside of calibration range reported without qualification
  - Standards used for the calibration curve define the calibration range
  - PQL (LOQ) concentration should be bracketed by curve
    - Lowest calibration standard may be at the lab PQL (LOQ)
  - Results above highest standard are estimated values
- QC samples are evaluated per above
  - Blanks, spikes and duplicates outside of range are estimated results

Blank Contamination

- Blanks not adequately evaluated
  - Sample results reported without qualification
  - Blank results selectively used or ignored
- Blanks are evaluated based on chronology and batching
  - Before and after sample result (relative to analytical run times)
  - Prepared blanks in prep batch
- “10%” criterion applied to contamination level
- Sample results are evaluated against any applicable field-QC blank results

MDL & PQL Problems

- Lab MDL or PQL is too high for indicated use
  - Data not usable for non-detect samples
  - Estimated values for sample results <PQL *may* be problematic
  - Elevated MDL/PQL from unnecessary sample dilutions not usable

Spiking Problems

- LCS analyzed concentration too high relative to sample concentration range or desired PQL
  - Applicable for non-detect results
    - Evaluation of recovery near PQL (if appropriate QC check used)
  - Spike concentration not appropriate to samples
- Matrix spike analyzed concentration too high or too low relative to unspiked parent samples
  - Evaluated on case-by-case basis for the parent sample and analytical run
- Spike not digested or processed with samples

Precision Evaluation & Problems

- When lab controls precision using duplicate results <PQL
  - RPD or %RSD may not be representative
- LCS duplicates take precedence over MS duplicates and sample duplicates
  - Sample duplicates evaluated for parent sample

Selective Use of Calibration & QC Results

- Blanks, spikes, duplicates and standards are audited against the run-time and batch relationships to samples
  - Lab ignores failed results; uses good results to pass verifications or QC measures
  - Lab selectively uses chronologically related data to pass verifications or QC measures
  - Lab selectively uses batch-related QC results
  - Lab uses data NOT justifiably related to samples to pass verifications or QC measures; e.g., re-runs on different days

Qualified Data Reporting

- Laboratory fails to report results with appropriate qualifiers
  - DEP QA rule data qualifier codes
- Sample results are independently qualified by auditors based on audit results
  - Audit qualified results are compared to reported data or database records

Audits – Examples and Resources

- DEP Audit reports page
  - http://www.dep.state.fl.us/labs/cgi-bin/reports/search.asp
- QAO Resources page – Data Review & Audits
- DOH certification inspection checklists
  - http://www.dep.state.fl.us/labs/dohforms.htm
- Additional checklists from AEQAS