Florida Department of Environmental Protection

Quality Assurance, QA Directive, QA Rule

QA Training

Spring 2011

Quality Assurance (QA)

- Integrated system of management activities involving:
  - Planning
  - Implementation
  - Documentation
  - Assessment
  - Reporting
  - Quality improvement
- Ensures that process, item, or service is of type and quality needed and expected by client (ANSI/ASQC E-4, 1994)

Why should I care about QA?

✓Environmental Measurement is a Messy Business

✓DEP's Ability to Use Data is Dependent on How Well the Process Works

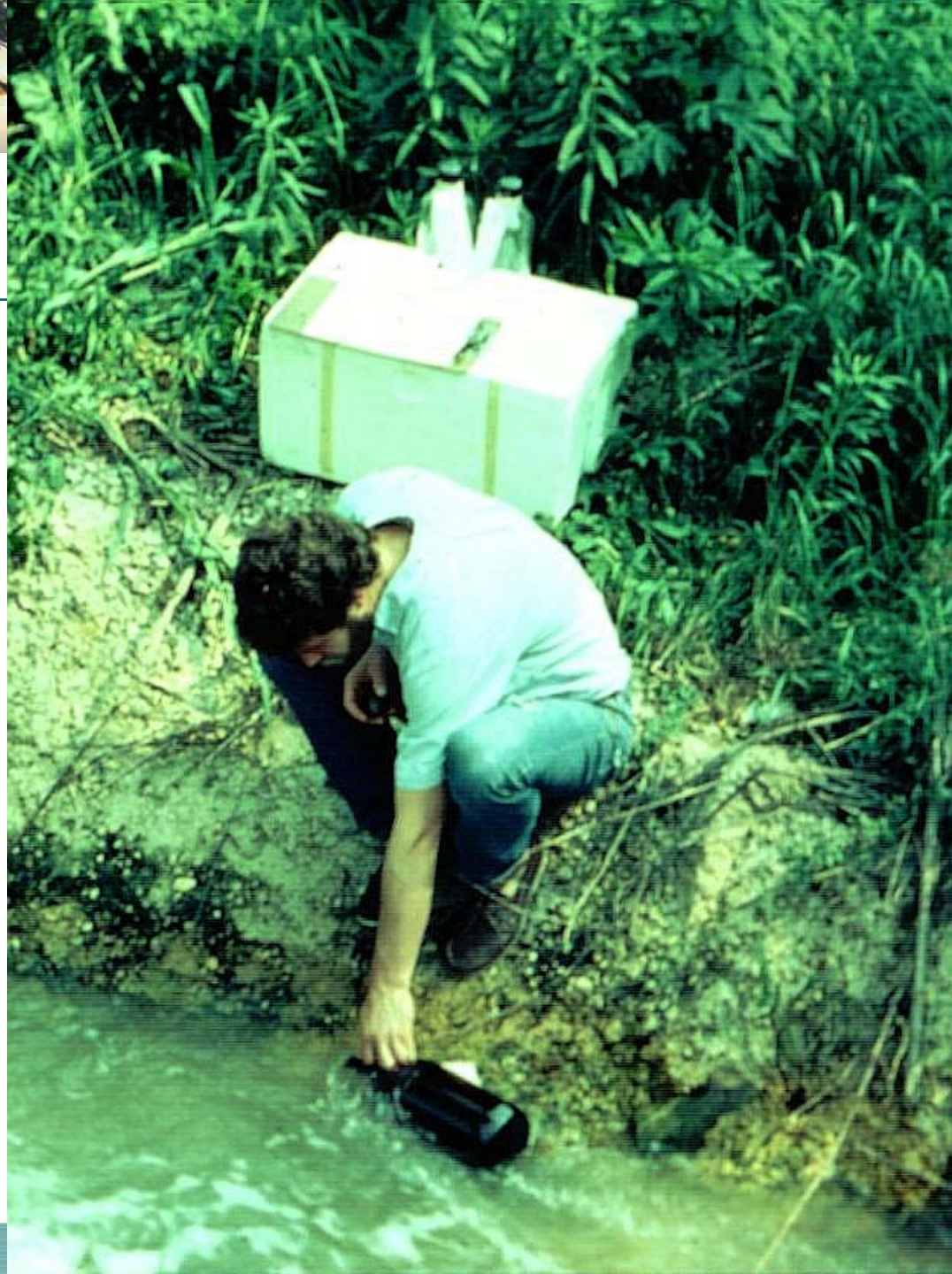
- Scientific validity
- Legal defensibility

Data Quality & DEP

- If “real” result is higher than reported
  - Environment is not protected
- If “real” result is lower than reported
  - Costly, unneeded treatment requirements
- In either case:
  - Legal challenges
  - Adverse publicity
- Ultimately Results in More Staff Time and $$

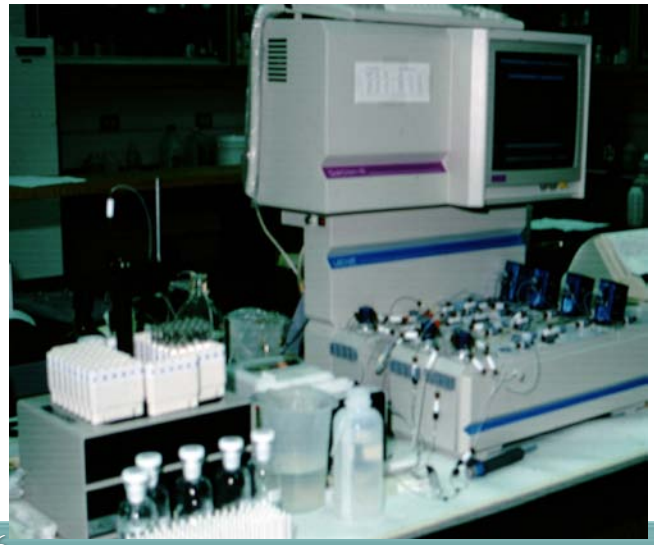
Sampling Issues

- Proper location
- Correct equipment or bottles
- Prevent contamination
- Proper preservation



Analysis Issues

- Sample log-in & tracking
- Preparation steps
- Holding times
- Calibration & maintenance
- Blank contamination
- Spike recovery
- Pairing sample with result and QC elements
- Detection limits



Authority and Obligations

Florida Statute

- **Chapter 403.0623**, Florida Statutes directs DEP to:
  - "establish, by rule, appropriate quality assurance requirements for environmental data submitted to the department and the criteria by which environmental data may be rejected by the department, and
  - to adopt and enforce rules to establish data quality objectives and specify requirements for training of laboratory and field staff, sample collection methodology, proficiency testing, and audits of laboratory and field sampling activities".

Authority and Obligations

Quality Assurance Rule

- By legislative mandate (Chapter 403.0623, Florida Statutes) DEP adopted the Quality Assurance Rule, 62-160 F.A.C., which "…defines the minimum field and laboratory quality assurance, methodology and reporting requirements of the Department."

- The QA rule is an additional authority for the QA Directive

Authority and Obligations

QAMP

- "It is the policy of the U. S. Environmental Protection Agency (EPA) that all environmental programs conducted by, or on behalf of, the EPA, shall establish and implement effective quality systems to support the scientific and legal defensibility of those programs".*
- This is the basis for the Quality Assurance Management Plan (QAMP) for DEP required by EPA and cited in the QA Directive.

(*EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, U.S. Environmental Protection Agency, Washington, D.C. (May 5, 2002).

What is the QA Directive?

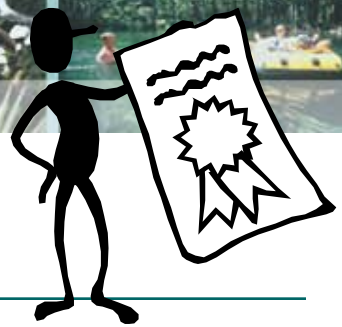
DEP Directive 972:

"Quality Assurance Directive for the Collection, Analysis and Interpretation of Environmental Data for the FDEP Water, Waste and Natural Resources Programs"

Outlines DEP QA authority, policy and staff responsibilities for *distributed* QA function

What is the QA Directive?

- Establishes internal DEP QA Policy
  - Foundation is statute, QA rule and QAMP
- Distributes QA responsibility throughout DEP
  - District & Division Directors
  - Program & Section Administrators
  - Quality Assurance Officers
  - Program Technical Staff
  - Standards & Assessment Section QA Staff
- Annual QA Report to the Secretary



Why is it important?

- Established processes and procedures
  - Defined Data Quality Objectives (DQO) and Indicators (DQI)
- Accountability for data quality
  - Distributed responsibilities for quality assurance
- Organized and formalized via quality planning
  - Quality plans, manuals, project plans, etc.
- Assessment of Data Usability
  - Are DQOs achieved for specified data use?
  - DEP-EA-001/07

Distributed QA Function

- Department-wide culture of competence and responsibility of effort for quality assurance management of scientific data
- No single person or work unit can manage all QA functions for DEP
- Consistent implementation of DEP QA Policy across programs and work units
- Tiered application of responsibilities for QA

Director Responsibilities

- Develop a quality system.
- Provide resources for its implementation.
- Designate Quality Assurance Officers.
- Develop and implement procedures to review, assess and improve the quality system.
- Delegate authority for implementation of quality assurance corrective actions to the program Quality Assurance Officers.

Program Admin. Responsibilities

- Publish and evaluate the effectiveness of Data Quality Objectives and Data Quality Indicators.
- Develop corrective action policies.
- Develop QA procedures for data management and data archiving.
- Determine % data evaluated for usability.
- Request Standards and Assessment Section assistance as necessary.

QA Officer Responsibilities

- Implement corrective actions as needed.
- Conduct systems audits of data generators (lab and field).
- Conduct sampling performance audits.
- Document all program QA activities including training, audits and corrective actions.
- Coordinate QA activities within the program.
- Provide information to and coordinate with the Standards and Assessment Section.

All Staff Will:

- Evaluate program data using program Data Quality Objectives and Data Quality Indicators.
- Provide feedback for improving the program quality system to the program Quality Assurance Officer.

Standards and Assessment will:

- Administration and guidance
  - DEP QA program (except air)
  - DEP Quality Management Plan
  - DEP QA Rule (62-160 FAC)
  - DEP SOPs (sampling, field testing, lab)
- Service and Training
  - Sampling using DEP SOPs
  - Field Auditing (sampling performance)
  - Data evaluation (field and laboratory)
- Liaison
  - Lab certification (DOH ELCP)
  - Approved analytical methods
  - DEP program-specific QA support
  - Report to Secretary

What's the "Short Story"

- You need a plan.
- Folks need to know and follow the plan.
- Employees need the training to do their job.
- QA Officer coordinates with us.
- SAS will provide training and assistance.

DQOs and DQIs

Data Quality Objective: Specifications established for an intended use of a set of data. A target or goal describing a level of expected data quality.

Data Quality Indicator: A specified, numerical or qualitative criterion used to evaluate data for conformance with a Data Quality Objective

DQO Examples

- Use DEP SOPs for sampling
  - Sampler training & performance for SCI and HA
  - DEP SOP sampling training
- Use certified lab for analyses (DOH/ELCP)
- Use standardized lab methods
- Use calibrated test instrumentation
- Use quality control samples to measure DQIs
- Meet water quality standards

DQI Examples

- Sensitivity (MDL and PQL)
- Precision (field and lab duplicates/replicates)
- Accuracy (spikes and other positive controls)
- Contamination controls (field and lab blanks)

QC samples measure DQIs

(MDL studies, PQL checks, duplicates, spikes, blanks)

Training

- Samplers need to know the SOPs.
- Data interpreters need to know how to determine the data are usable.
- Everyone needs to know what their responsibilities are.
- Discussion

Auditing and Corrective Action

- There needs to be some type of data checking:
  - Field performance
  - Lab accountability
  - Data bases and reports
- If an issue arises, there needs to be a procedure to fix it.
- Discussion

Quality Plan

- Simply a description of your Data Quality Objectives and how your routine operations help achieve them.
- Quality Plan template is available
  - Example format and contents
    - Limited scope of examples
    - Not all examples apply to each program or unit
  - Template not required
  - See website

Quality Plan - Example Contents

- Function & organization of work unit or program
  - Responsibilities for staff positions
  - QA officer/coordinator responsibilities
- Description of program/work unit activities related to quality assurance

Quality Plan - Example Contents

- Sampling & field-testing (meters) procedures
- Procedures for lab analyses
- Data review, evaluation & interpretation for applied uses
  - Data use decision processes – conformance with establish DQOs, Usability for compliance, monitoring, research, etc
  - Reviews per required procedures, analytical methods, planning documents, other requirements
  - Calculation & document checks for errors

Quality Plan - Example Contents

- Audit procedures – internal & external – coordination with program/unit QAO
  - Field sampling performance
  - Field and lab data records
  - Internal QA procedures for ensuring data integrity & defensibility
    - Feedback from data users about data quality
  - Implementation & documentation of corrective actions
  - Audit reporting procedures

Quality Plan - Example Contents

- Training – coordination with QA Officer
  - Internal training (routine procedures & criteria – including corrective actions)
    - Internally published training materials
    - New staff and refresher training
  - External training received
  - Training provided to external parties such as consultants, facilities, permittees, etc.
  - Procedures for evaluating training effectiveness
- Standard Operating Procedures – internal & external
  - For relevant activities as described in the Quality Plan
  - Includes procedures for handling external and public inquiries about data quality & interpretation, technical assistance, etc.

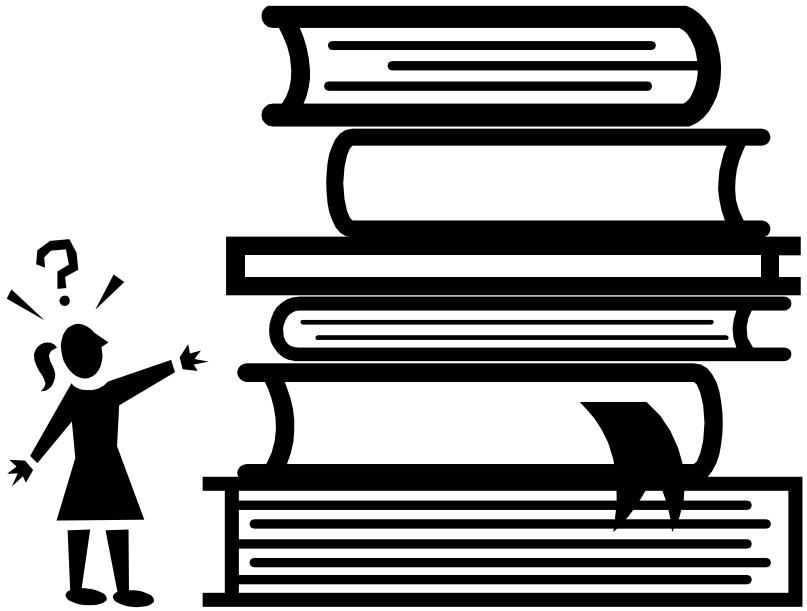
Quality Plan - Example Contents

- Database and Paper Archive Management
  - Quality control procedures for database entries, extractions, manipulations, etc.
- Contract Management – Process and Criteria
  - Development of contract QA language & planning documents
  - Review of work product per contracted QA requirements
- Sampling Project Design
  - Preparation of sampling plans, QA plans, etc.
  - Review of work product per sampling plan

Quality Plan - Example Contents

- Annual QA report to Secretary
  - Procedures & criteria for compilation & summary
- Internal QA Management Procedures
  - Review of overall Quality System
  - Evaluation of DQOs & DQIs
  - Evaluation of staff QA activities
  - Review of audit results
  - Evaluation of corrective actions
  - Review of components for annual report to Secretary
- Internal Documentation Procedures
  - How are all of the QA activities above documented?

What is the state of your quality plan?



Annual QA Report to the DEP Secretary

- Systematic assessment of program or work unit QA activity
  - Lead or coordination by unit QA Officer
  - Report of assessment findings
    - Includes trainings, issues, audits, corrective actions
    - Submitted to Standards & Assessment Section (DEP QA Coordinator)

Annual QA Report – Procedure and Content

- First annual report will be “learning curve” for everyone
  - Standards & Assessment Section (SAS) will develop additional guidance in 2011 as needed
- Example report will be provided for format and content
- Provide specific details as needed in full report
- Provide abstract or executive summary of highlights
  - SAS will organize abstracts for report
  - Detailed reports for each program/work unit included as appendices

Annual QA Report – Example Topics

- Assessment of QA activity for each program and district
- Audits performed and outcomes
- Corrective actions implemented
- Quality system problems and improvements
- Training performed and received

Potential Content for District *(include names and dates)*

- Trainings
  - 4 staff attended DEP SOP training (October 2010)
  - 2 staff conducted SCI and Stream Habitat Assessment training for 3 new staff (include names).
- Audits
  - 2 staff members passed their initial SCI sampling audits
  - 3 staff passed SCI re-audit testing (October 2010)
  - QA officer conducted a field audit on sampling team (dates)
    - Summary of findings, corrective action
  - Wastewater compliance staff conducted 2 PAI audits
    - Summary of findings, corrective action

QA Rule, 62-160, F.A.C. - Contents

- Scope & Applicability
- Definitions & Standards
- Approved Field & Lab Procedures & Methods
  - Approval of New & Alternative Field & Lab Procedures
- Reporting & Documentation Requirements for Field & Lab Procedures
- Lab Certification
- Sample Preservation & Holding Times
- Electronic Signatures
- Research Field & Lab Procedures
- Field & Lab Audits
- Data Validation
- Data Qualifier Codes
- Incorporated document references

QA Rule

- The **QA rule applies to** all entities involved with sampling, field testing, lab analysis, data review & presentation and vending services for sampling supplies (kits) or instrument calibration
- **More stringent requirements** can be imposed by contracts, orders, permits or other DEP rules
- Most sampling and field testing is routine and must follow the **DEP SOPs**
- There are **minimum documentation and reporting requirements** for both field & lab records
  - DEP can ask for any required records at any time
  - DEP can specify the format of data reports submitted to the Department
- Most lab analyses must be performed by **certified labs**

QA Rule

- Most **lab methods** are routine, are "recognized" as approved by DEP and may be specified in DEP rules, contracts, orders or permits, where required
- **Alternative field & lab procedures & methods** must be pre-approved by DEP
- Most **sample preservation & holding time procedures** are standard and are required as listed in the DEP SOPs (FS 1000 tables)
- **Research** field & lab procedures must be pre-approved via work plans, sampling & analysis plans or contracts that provide required minimum information

QA Rule

- DEP can **audit** samplers, field records and lab records at any time
  - Can include on-site audits by DEP auditors
- There are **minimum criteria for validating data** submitted to (or generated by) DEP
  - There is a **Data Usability document (DEP-EA-001/07)** to help explain the process of determining whether data is usable for a specific purpose
- Specific **Data Qualifier Codes** must be used for reported data associated with quality control failures (Table 1 in the QA Rule)

Questions?