



# *Florida Department of Environmental Protection*

## ***DEP QA System QA Directive QA Rule***

*Aquatic Ecology & Quality Assurance Section*



# *Quality Assurance (QA)*

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- 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?*

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- ✓ 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*

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- 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
- Approved procedures
- Prevent contamination
- Proper preservation

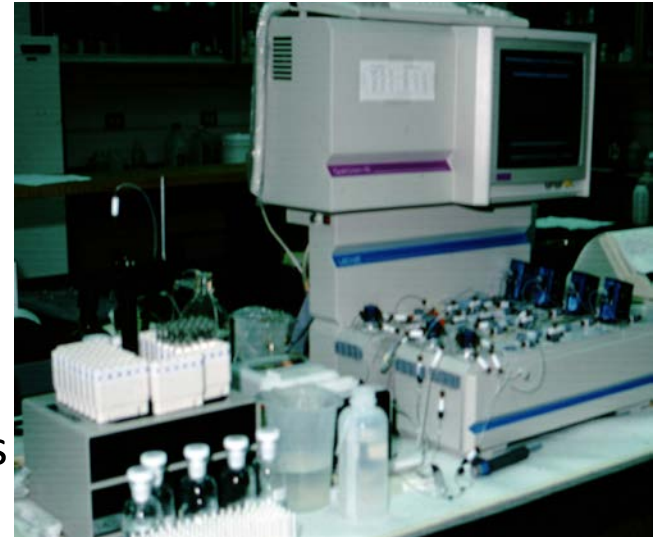




# *Analysis Issues*

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- 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*

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- **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**

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- 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*

# **QMP**

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- “...Quality Management Plan (QMP), which documents the organization’s quality policy, describes its quality system, identifies the environmental programs to which the quality system applies, and which is implemented following approval by the organization’s executive leadership...”.\*
- This is the basis for the ***Quality Management Plan*** (QMP) for DEP required by EPA and cited in the QA Directive.

(\*EPA Order CIO 2105.0, *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, U.S. Environmental Protection Agency, Washington, D.C. (May 5, 2000).





## ***What is the QA Directive?***

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- **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? (cont.)*

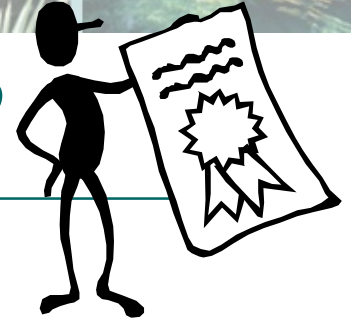
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- Establishes internal DEP QA Policy
  - Foundation is statute, QA rule and QMP
- Distributes QA responsibility throughout DEP
  - District & Division Directors
  - Program & Section Administrators
  - Quality Assurance Officers
  - Program Technical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





# Why is the QA Directive 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***

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- 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*

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- 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***

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- Evaluate the effectiveness of program 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 Aquatic Ecology and Quality Assurance Section assistance as necessary.





## *QA Officer Responsibilities*

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- 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, corrective actions, review of data or report deliverables.
- Coordinate QA activities within the program.
- Provide information to and coordinate with AEQAS.





## *All Staff Will:*

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- 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.



## ***Aquatic Ecology and Quality Assurance Section will assist with:***

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- Administration and guidance
  - DEP QA program (except air)
  - DEP Quality Management Plan
  - DEP QA Rule (62-160 FAC)
  - DEP SOPs (sampling, field testing, bioassessment 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
  - QA Report to Secretary





## *What's the “Short Story”*

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- You need a Quality Plan
- Everyone should know and follow the plan
- Staff need QA training to do their job
- QA Officer coordinates with AEQAS
- AEQAS will provide training and assistance



## ***DQOs and DQIs***

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**Data Quality Objective:** Specifications (descriptive and/or prescriptive) 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***

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- 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, approved lab methods
- Use calibrated test instrumentation
- Use quality control samples to measure DQIs
- Meet water quality standards detection levels





## *DQI Examples*

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- Specific test methods and DEP SOPs used
- Sensitivity levels reported (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*

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- Samplers need to know the SOPs.
- Data users need to know how to interpret the data and determine if data are usable for the specified purpose.
- Everyone needs to know what their responsibilities are.



# ***Auditing and Corrective Action***

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- **Evaluating and ensuring data quality:**
  - There needs to be some type of data checking (i.e. various types of ***auditing***):
    - Field performance
    - Lab accountability
    - Databases and reports
  - If an issue arises, there needs to be a procedure to fix it (i.e. ***corrective actions*** based on findings from auditing)



# Quality Plan

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- A description of your Quality System, Data Quality Objectives and how your routine operations help achieve them
- Quality Plan template is available
  - Template not required
  - Example formats and contents
    - See DEP Quality Plans webpage





## *Quality Plan - Example Contents*

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- 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*

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- Sampling & field-testing (meter) 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*

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- 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*

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- 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

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- 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*

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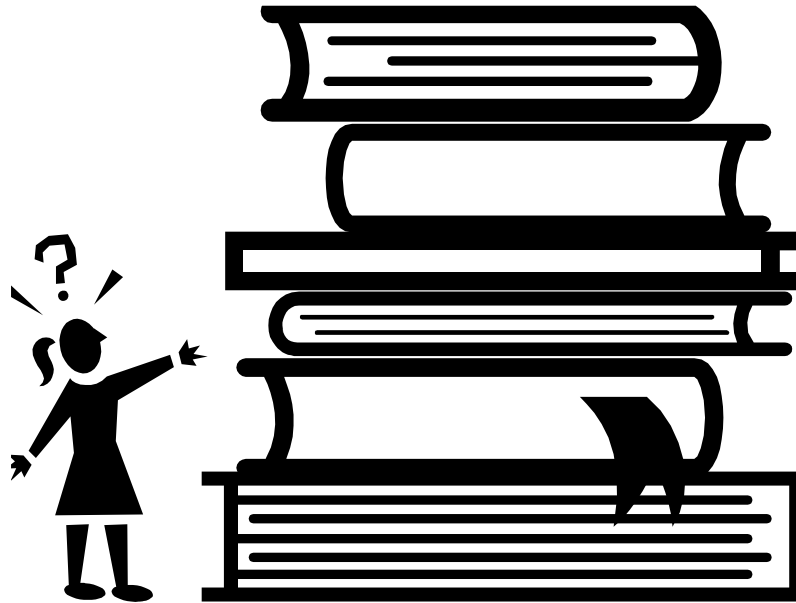
- Annual QA report to Secretary
  - Procedures & criteria for compilation & summary
- Internal QA Management Procedures
  - Review of overall Quality System
  - Evaluation of DQOs & DQIs
  - Evaluation of staff QA activities
  - Review of audit results
  - Evaluation of corrective actions
  - Review 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?*

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# *Annual QA Report to the DEP Secretary*

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- Systematic assessment of program or work unit QA activity
  - Lead or coordination by unit QA Officer
    - AEQAS will provide instructions and guidance for report content
  - Report of program or work unit QA assessment findings
  - Submitted to Aquatic Ecology and Quality Assurance Section
    - AEQAS will compile QA Report to Secretary





## *Annual QA Report – Example Topics for Work Unit Reports*

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- Assessment of QA activity in DEP programs and organizational units for the calendar year
  - Audits performed or received and outcomes
    - Corrective actions implemented
  - QA review of compliance data, reports and contract deliverables
  - Training performed and received
  - Quality system problems and improvements
  - QA Coordination activities
    - QA Communications including development of guidance, SOPs and other QA information
- Future QA Goals





## ***Potential Content for a QA Report*** *(Some Example Details for Trainings and Audits)*

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- Trainings
  - Number of staff:
    - Attending DEP SOP training
    - Attending this basic QA training
    - Receiving SCI and Stream Habitat Assessment bioassessment training
- Audits
  - Number of staff passing initial SCI sampling audits and/or refresher audit testing
  - Results of QA officer audit of work unit sampling team
    - Summary of findings, corrective action
  - Number of PAI audits conducted by wastewater compliance staff
    - Summary of findings, corrective action





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

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- 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

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- 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

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- 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

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- 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?*

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