POLICY MAINTENANCE ADMINISTRATOR: Division of Environmental Assessment and Restoration

PURPOSE AND SCOPE: This Directive outlines procedures and staff responsibilities for the comprehensive implementation of DEP’s Quality Management Plan for DEP’s Regulatory, Ecosystem Restoration, and Land and Recreation Programs. This Directive instructs those DEP Programs responsible for the generation and use of environmental, scientific data to implement a management system (involving planning, reviewing, training, and assessment) that will ensure that data collection, generation, interpretation, reporting, evaluation and archival storage will be of sufficient quality to support DEP decisions. This directive is applicable to all DEP Regulatory, Ecosystem Restoration, and Land & Recreation Programs (except the Division of Air Resources Management).

AUTHORITY
The authority for DEP’s Quality Assurance (QA) Program is provided by:

a. Section 403.0623, Florida Statutes (F.S.), which requires DEP to “establish, by rule, appropriate quality assurance requirements for environmental data submitted to DEP and the criteria by which environmental data may be rejected by DEP. Such rules may be in addition to any laboratory certification provisions under ss. 403.0625 and 403.863.” DEP has promulgated the Quality Assurance Rule under authority of this legislative mandate.

b. Chapter 62-160, Florida Administrative Code (F.A.C.), Quality Assurance, which is the DEP rule that specifies the minimum field and laboratory quality assurance, methodology, reporting, auditing and data usability requirements for environmental data measurements for DEP programs, excluding those administered by the Division of Air Resources Management.

c. The Quality Management Plan for the Department of Environmental Protection (QMP), which is DEP’s documented “strategy to establish and implement effective quality systems.” The scope of the QMP is applicable to all DEP regulatory programs for water, waste and ecosystem restoration participating in funding agreements with the United States Environmental Protection Agency (EPA) or discharging responsibilities associated with EPA rules or any other EPA agreements with DEP, such as those delegating specific authorities to DEP. The QMP is submitted to the EPA as a prerequisite for obtaining federal funding through EPA for DEP programs, and is required by EPA as documentation of DEP’s quality management system.

PROCEDURES
Standards and procedures for this policy are accessible via DEP’s intranet.
Policy

It is the Secretary's intent that the quality assurance requirements and activities outlined in Section 403.0623, F.S., Chapter 62-160, F.A.C., and the EPA Quality Management Plan be implemented throughout the agency. It is DEP's policy to:

a. Use scientifically valid and legally defensible data for programmatic decisions affecting protection of the environment.

b. Have each District and Program implement a Quality System, and develop and maintain Quality Plans describing organizational responsibilities and performance criteria for managing, assessing and improving the Quality System.

c. Adaptively manage the Quality Systems for applicable Programs to be consistent with provisions of the DEP Quality Management Plan and this Directive.

d. Ensure that each individual who is involved with the process of data generation, data receipt, data assessment, data storage, and data interpretation is properly trained to execute their assigned functions.

e. Develop Data Quality Objectives and Data Quality Indicators for the data generated by each applicable DEP program or submitted to the program by other entities.

f. Implement procedures to evaluate the quality of the data used by each program using Data Quality Objectives and Data Quality Indicators, and develop corrective action policies and procedures to be implemented when data do not meet the program's Data Quality Objectives.

g. Develop procedures to audit the performance and record-keeping practices of data generators within and outside DEP.

h. Implement quality assurance procedures for the management of DEP's data repositories.

i. Perform a yearly systematic assessment of DEP's quality assurance activities, including any corrective actions, with the findings submitted to the Secretary.

Areas of Responsibility

Implementation of the DEP Quality Management Plan and this Directive requires active participation throughout all levels of DEP. To ensure this participation:

a) Division Directors and District Directors will:

(1) Ensure that each program develops and carries out a Quality System, develops and maintains a quality plan, designates Quality Assurance Officers, and provides resources and staff training for implementation of the Quality System.

(2) Evaluate internal and public feedback related to DEP data quality issues.

(3) Review each program's annual Quality Assurance Report(s) submitted for the compilation of the Annual QA Report to the Secretary.

b) Program and Section Administrators will:

(1) Ensure that a Quality System that conforms to the DEP Quality Management Plan and this Directive is fully operational in their program.
(2) Designate Quality Assurance Officers, and provide general oversight.
(3) Evaluate proposed Data Quality Objectives and Data Quality Indicators to ensure they meet program needs.
(4) Periodically evaluate the effectiveness of the quality assurance activities performed by program staff, including review of audit results.
(5) Evaluate corrective action policies and procedures to be implemented when data do not meet program Data Quality Objectives.
(6) Request Quality of Science reviews and/or training from the DEP Aquatic Ecology and Quality Assurance Section as necessary, and review audit results with the designated program QA Officer.
(7) Review the annual Quality Assurance Report to the Secretary, and discuss findings with the program QA Officer.

c) Quality Assurance Officers will:
(1) Be familiar with and maintain and/or coordinate the maintenance of the quality documents and quality assurance requirements of their program, which includes updating the Program or work unit Quality Plan as needed.
(2) Coordinate and participate in the quality evaluation of program data, and provide oversight to ensure that staff perform their QA functions.
(3) Coordinate and/or perform audits of internal and external data generators (lab and field) including sampling performance audits, as applicable.
(4) Ensure that corrective actions are implemented for data non-conformance incidents as determined by evaluation of the data against program Data Quality Objectives.
(5) Assist program managers in developing the Quality System and logistical aspects of its implementation, such as coordinating associated training needs.
(6) Document all program QA activities, including training, audits and corrective actions and provide this information in the program’s QA report(s) to the DEP Aquatic Ecology and Quality Assurance Section for the compilation of the annual Quality Assurance Report to the Secretary.

d) Program Staff will:
(1) Be familiar with the Program Quality Plan and the DEP Quality Assurance requirements that affect their program.
(2) Routinely carry out duties involving data collection, data usability evaluation, data interpretation, and the generation of DEP work products in a manner that ensures scientific defensibility.
(3) Ensure that all activities are implemented according to the relevant program Quality Plan and applicable DEP rules and policies.
(4) Evaluate program data using program Data Quality Objectives and Data Quality Indicators.
(5) Implement corrective actions as directed by the Quality Assurance Officer.
(6) Provide feedback to the program Quality Assurance Officer for improving the program Quality System.

e) Aquatic Ecology and Quality Assurance Section Staff will:

(1) Facilitate communication between all DEP QA Officers.

(2) Provide technical resources for developing Quality Systems to all DEP staff and other stakeholders, including training, tools and materials on topics such as laboratory certification, laboratory methodology, use of the DEP Standard Operating Procedures, development of Data Quality Objectives and Data Quality Indicators, data quality assessment, conducting audits, collection and interpretation of physical, chemical, and biological data, etc.

(3) Develop and maintain DEP’s Standard Operating Procedures for sample collection, field testing, bioassessments and taxonomic identifications.

(4) Perform data validation and data usability audits, systems audits and field sampling performance audits of both external and internal data generators.

(5) Administer the QA Rule, Chapter 62-160, F.A.C., and revise it as necessary.

(6) Review and update the DEP Quality Management Plan as necessary.

(7) Perform Quality of Science reviews and training activities at the request of DEP program administrators.

(8) Serve as a liaison with The NELAC Institute and the Florida Department of Health Environmental Laboratory Certification Program.

(9) Assemble and submit the annual Quality Assurance Report to the Secretary.

(10) Assist applicable DEP program staff with the compilation of documentation for the annual Demonstration of QA Competency required by EPA.

Overall Administrative Infrastructure

a. The central administrative function for DEP’s Quality Assurance Program is located in the Water Quality Standards Program, Aquatic Ecology and Quality Assurance Section.

b. A division, district, program or section office may implement, at its discretion, supplemental policies and procedures for additional management and control of environmental measurements or other work products, provided they are consistent with DEP policies and procedures as described in this Directive and in other quality assurance documents cited in this Directive.

Definitions

a. Data - factual information, especially values derived from scientific measurements organized for analysis or used to make decisions.

b. Data Quality Indicator – a specified numerical or qualitative criterion used to evaluate data for conformance with a Data Quality Objective. Example Data Quality Indicators include specific method numbers to be used for lab analyses; specified spike recovery and duplicate precision
numerical targets; specified Method Detection Limit and Practical Quantitation Limit numerical targets for reported non-detect and estimated sample concentrations; laboratory analyses certified by the Department of Health; maintaining a 95% performance level of correct identifications in biological assessments; and correctly executing a sampling plan.

c. Data Quality Objective - a target or goal describing a level of expected data quality. Example Data Quality Objectives include using specified, approved laboratory methods; monitoring and reporting precision and accuracy for laboratory analyses; developing a detailed sampling plan that controls for confounding variables; meeting specified Method Detection Limits and Practical Quantitation Limits for permit compliance; following specified DEP Standard Operating Procedures for sample collection and field-testing; using environmental laboratories certified by the Florida Department of Health; and maintaining laboratory quality control for taxonomic identification.

d. Data Usability Audit – a type of audit in which data for a project or group of projects are evaluated against specified Data Quality Objectives and Data Quality Indicators to determine the usability of the data for a specific application.

e. Data Validation – a detailed evaluation of individual data points for conformance with numerical calibration and quality control targets and other Data Quality Indicators.

f. Department of Health Environmental Laboratory Certification Program (DOH ELCP) – the state agency responsible for certifying environmental laboratories per the Department of Health certification rule, Chapter 64E-1, F.A.C.

g. Quality Plan – a quality assurance document, prepared and maintained by a DEP program or other designated DEP organizational work unit or group of work units, that describes staff responsibilities, internal procedures and performance assessment criteria comprising the program or work unit quality system developed to implement this Directive. The quality plan should be utilized as a reference QA document by all program or work unit staff, and as a QA training document for new staff. Past versions of the quality plan serve as an archival record of historical quality system documentation for the program or work unit. The quality plan should cite other QA documents, such as this Directive, the QA Rule (Chapter 62-160, F.A.C.), the DEP SOPs, the DEP QMP, and other internal SOPs or requirements as necessary to describe the work unit quality system. The Quality Plan is a living document that must be routinely reviewed and updated as necessary to describe current staff organization and responsibilities, work unit procedures and QA assessment criteria. DEP programs or work units performing sampling or field-testing activities must include the required quality system elements described in DEP SOP FA 1000 (subpart FA 3300, Quality Manual) in the quality plan.

h. Quality of Science Review – a comprehensive review of the quality system for a program or group of programs to evaluate the effectiveness of the quality system and its implementation, with recommendations for improvement.

i. Quality System - a structured and documented management system describing the process of planning, review, training, and assessment to ensure that the collection, generation, evaluation,
interpretation, reporting and storage of data are sufficient to support the use of the data for DEP decisions.

j. Sampling Performance Audit – a type of audit in which a sampler or sampling team is observed while conducting a sampling event. The sampler(s) are evaluated against program requirements such as the use of specific DEP Standard Operating Procedures for sample collection and the ability to meet numerical calibration acceptance criteria for field-meter testing.

k. System Audit – a type of audit in which an entity is evaluated for the capability to perform a laboratory method or field procedure. The entity must be able to demonstrate the implementation of all of the documentation, procedural steps and quality control functions necessary for the audited capability, and must possess the equipment or instrumentation, and, where necessary, the supporting infrastructure required to execute the method or procedure using an established, operational quality system that meets DEP’s quality assurance requirements.

l. The NELAC Institute (TNI) – the nationally recognized body for standards development for the accreditation of environmental laboratories.

m. Work Product – Any physical product or any service produced or reviewed by DEP staff and subject to the provisions and requirements of this directive. Examples include reports, memos, letters, databases, listings, rules, recommendations, presentations, audits, consulting, training, etc.