UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4

Science and Ecosystem Support Division
980 College Station Road
Athens, Georgia 30605-2720

July 3, 2018

Myra C. Reece
Director of Environmental Affairs
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, S.C. 29201

Dear Ms. Reece:

Thank you for the Quality Management Plan for the South Carolina Department of Health and Environmental Control (SCDHEC). This Plan was submitted in response to the QMP grant condition specified in 40 CFR Part 31.45 and EPA CIO 2105.0 (formerly Executive Order 5360.1, Revision A2), for environmental data and is part of the terms and conditions placed by Region 4 on all grants awarded to SCDHEC.

The QMP meets the agency's requirements and I have signed the document to indicate Region 4 approval. The QMP is valid for five (5) years unless a significant reorganization of SCDHEC occurs which would require revision of the document. If you have any questions or need additional information, please contact me at (404) 562-9235.

Sincerely,

Liza I. Montalvo
Quality Assurance Manager

Enclosure

Quality Management Plan

Environmental Affairs

2600 Bull St.
Columbia, SC 29201

February 2018

S.C. Department of Health and Environmental Control

Strategic Plan

Vision

Healthy people living in healthy communities

Mission

To improve the quality of life for all South Carolinians by protecting and promoting the health of the public and the environment

Core Values

Non-negotiables of our Agency character, defining how we interact with others, shaping our decision processes, and guiding our organizational beliefs about how we achieve our mission

- **Pursuing Excellence – We are steadfast in our commitment to the highest achievable standards of quality and professionalism in our pursuit of healthy people living in healthy communities.**
- **Inspiring Innovation – We encourage and empower our teams to find creative solutions to promote and protect the health of the public and the environment.**
- **Promoting Teamwork – We foster an inclusive and collaborative environment, valuing diversity of thoughts, experience and expertise of every team member, our stakeholders and communities.**
- **Embracing Service – We embrace our responsibility to reliably serve our communities, our customers and each other in a respectful manner, relying upon clear and uncompromised commitments to integrity, trust, dependability and responsiveness.**

Agency Strategies

Five strategic focus areas, the imperatives that unite our teams, align our work, and enable our Agency to move forward in our ambitious mission.

- **Education and Engagement**
- **Science in Action**
- **Leadership and Contribution**
- **Service and Accessibility**
- **Operational Excellence**

Acronyms and Definitions

-A-

ABC Assistant Bureau Chief
ARESD Analytical Radiological Environmental Services Division

-B-

BAQ Bureau of Air Quality
BEHS Bureau of Environmental Health Services
BBM Bureau of Business Management
BIS Bureau of Information Services
BLWM Bureau of Land and Waste Management
BOW Bureau of Water
Bureau Project Officer – individual responsible for writing or coordinating efforts to write QAPPs.

-C-

CIO Chief Information Officer

-D-

DAQA Division of Air Quality Analysis
DQI Data Quality Indicator, examples would be precision, accuracy, sensitivity, comparability, and representativeness.
DQO Data Quality Objective – A systematic planning system designed to produce qualitative and quantitative statements that clarify project objectives and define the appropriate type of environmental data and specify tolerable levels of decision error.

-E-

EA Environmental Affairs
EFIS Environmental Facilities Information System - the computer database that houses facility/lab information (addresses, contacts, owners), permit, and certification information.
EISOP Environmental Investigations SOP and QA Manual

-I-

IT Information Technology – computers - hardware, software

-L-

LCO Laboratory Certification Officer
LIMS Laboratory Information Management System- this is the computer system that tracks samples and houses their analytical results and provides lab reports.

-M-

MDL Method Detection Limit - this is a measurement of sensitivity of the instrument/method used

-O-

OCRM Ocean and Coastal Resource Management

-P-

PT (Proficiency Testing) – Blind study samples obtained from an external vendor. These are needed by a laboratory to show proficiency for an analysis and to maintain certification. These are annual assessments that are part of the national proficiency testing programs such as the Water Supply PT Studies, Water Pollution PT Studies, DMR QA Studies, Radiological PT Studies, etc.

Program Manager – One who manages projects and staff to ensure that goals are met, project deadlines are achieved, and overall program effectiveness is assessed and retooled as necessary.

-Q-

QAM Quality Assurance Manager or their designee
QAPP Quality Assurance Project Plan
QMP Quality Management Plan

-S-

SCDHEC South Carolina Department of Health or Environmental Control (the Department)
SOPs Standard Operating Procedure

-T-

TSA Technical Systems Assessment - TSAs are internal and external on-site assessments of environmental data gathering activities.

Contents

1.0 Program Plan Identification Form and Approvals

Document Title:	Quality Management Plan
Organization Title:	South Carolina Department of Health and Environmental Control
Address:	2600 Bull St. Columbia, SC 29201
Responsible Official:	Myra C. Reece, Director of Environmental Affairs
Quality Assurance Manager:	Sandra A. Flemming, Assistant Bureau Chief Bureau of Environmental Health Services

1.1. Approvals

Myra C. Reece
Director of Environmental Affairs

Signature: Myra C Reece Date: 3/5/2018

Liza Montalvo
EPA Region 4 Quality Assurance Manager

Signature: L. Montalvo Date: 6/28/18

1.2. Concurrences

Rhonda Thompson
Chief, Bureau of Air Quality

Signature: Rhonda Thompson Date: 03/5/2018

Renee Shealy
Chief, Bureau of Environmental Health Services

Signature: Renee Shealy Date: 3/5/2018

Daphne Neel
Chief, Bureau of Land and Waste Management

Signature: Daphne G. Neel Date: 3/5/18

Elizabeth B. von Kolnitz
Chief, Division of Ocean and Coastal Resource Management

Signature: Elizabeth B. von Kolnitz Date: 3/6/18

Mark Hollis
Chief, Bureau of Water

Signature: Mark R Clark Date: 3/5/18

Sandra A. Flemming
Assistant Bureau Chief, Bureau of Environmental Health Services
Quality Assurance Manager

Signature: Sandra A Flemming Date: 03/02/18

2.0 Introduction

The South Carolina Department of Health and Environmental Control (DHEC or Department) is the state regulatory agency charged with promoting and protecting the state's public health and its land, air, coastal resources and water quality as authorized by federal and state law. The Agency provides a wide range of resources and services that support a vision of healthy people living in healthy communities (refer to the Agency's Strategic Plan on page 2 of this document). DHEC's quality system is the means by which the Department implements the quality management process. The quality system encompasses a variety of technical and administrative elements, such as: organizational structure, policies and procedures, responsibilities, authorities, required documents, and guidance documents. This Quality Management Plan (QMP) describes a management system established by the Department to ensure that the collection, analysis and quality of its environmental data are sufficient for its intended purpose. The QMP defines DHEC's Quality Assurance (QA) policies and procedures; the criteria and areas of QA application; and the different QA related roles, responsibilities, and authorities of personnel.

3.0 DHEC Quality Assurance Practice and Objectives

3.1. DHEC Quality Assurance (QA) Practice

Environmental data are critical to decision making. Making the correct decision based on the data is important in the protection of the public and the environment. The Department's quality assurance practice is that there be sufficient QA activities conducted to demonstrate that all environmental data generated, processed, or used will be scientifically valid, legally defensible, and of known and acceptable precision and accuracy. Data shall be complete, representative, and comparable. The quality of all data generated by and for DHEC shall meet or exceed all Department and EPA requirements. Data of the appropriate type and quality shall be used by the Department in all of its environmental programs and decision making processes. In addition, all employees are responsible for adhering to this practice and other policies, procedures and guidance of the quality system.

3.2. Objectives

The following are DHEC objectives which support the implementation of Quality Assurance in environmental data collection and use:

- The Data Quality Objective (DQO) process shall be used to plan project goals and objectives as they relate to needed environmental data quality prior to the initiation of data collection activities for non-routine (excluding emergency response) sample collection. Non-routine work includes those processes not specified by regulation, permit, work plan, or programmatic QAPP.
- The DQOs or similar outputs from a systematic planning process shall be documented in a Quality Assurance Project Plan (QAPP) or equivalent project planning document.
- Routine work mandated by regulation or the needs of a specific program are addressed in programmatic QAPPs or work plans.

- Special studies or sampling involving a potential public health threat or a criminal investigation may not have an approved QAPP due to a limited time frame for obtaining samples. Whenever possible, sample collection, documentation, and analysis will be conducted consistent with established procedures and protocols used for routine work, including adherence to applicable Standard Operating Procedures (SOPs).
- QAPPs or the equivalent planning documents shall be developed by the staff responsible for designing, implementing and potentially using the data collected during projects, studies, or tasks that include the collection or use of environmental data. QAPPs shall be approved by the Quality Assurance Manager (QAM) and/or designee. EPA Region 4 must approve QAPPs when EPA funding is used. In addition, any laboratory that will be relied on to support the project/study shall be consulted during the development of the QAPP to determine if the laboratory's analytical capabilities and staff resources are commensurate with the project/study needs.
- All laboratories that will be responsible for the analysis of environmental samples intended to fulfill regulatory requirements or to demonstrate compliance with regulatory or permit requirements shall be certified, where such certification exists (by either EPA or the DHEC Office of Environmental Laboratory Certification Program), for all project applicable methods.
- Any methods used to monitor or measure environmental conditions, characteristics or contaminants for activities and regulatory requirements not related to compliance will have demonstrated precision and accuracy appropriate for the intended purpose and a written Standard Operating Procedure incorporating QA/QC procedures adequate to control data quality.
- Quality staff, technical staff, and management shall receive QA training appropriate for their job responsibilities.
- Both external and internal assessments shall be performed to determine the effectiveness of the DHEC quality system. External assessments are those that are performed by organizations external to the Agency such as the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). Internal assessments are those that are performed by staff within the Agency.
- QA processes shall be designed in the most cost-effective manner without compromising data quality.
- Continuous improvement shall be emphasized in the quality management system.
- DHEC staff shall conduct all business with integrity and in an ethical manner.

4.0 Organization and Management of DHEC

DHEC operations are overseen by the S.C. Board of Health and Environmental Control. The Board is empowered to make, adopt, disseminate, and enforce reasonable rules and regulations for the promotion of public health and the prevention, reduction, and control of pollution. The Agency Director is appointed by the Board with the approval of the State Senate. The Office of the Director, in addition to oversight of Environmental Affairs (EA) includes finances, operations, communications, information technology, general counsel, and human resources supporting Environmental Affairs activities. Environmental Affairs includes the following environmental program areas:

- Division of Ocean and Coastal Resource Management,
- Bureau of Air Quality,
- Bureau of Environmental Health Services,
- Bureau of Water, and
- Bureau of Land and Waste Management.

An organizational chart depicting the Department's organizational structure is included as Appendix A.

Internal coordination of QA/QC activities among the various programs, bureaus and divisions located within DHEC is provided through several means:

- Use of standard operating procedures (SOPs) for routine work: SOPs are approved by program management staff. In the case of analytical or sample collection activities, SOPs are also approved by the QAM or designee.
- Use of QAPPs for non-routine work: All QAPPs must be approved by the QAM or designee. QAPPs must also be approved by EPA Region 4 when EPA funding is used.
- Periodic training for continuous quality system improvement.

4.1. Organization of Environmental Affairs (EA)

The Director of Environmental Affairs oversees the five program areas listed above under section 4.0. An organizational chart depicting the EA's organizational structure is included in Appendix B. Responsibility for Quality Assurance Management resides in the EA Bureau of Environmental Health Services. An organizational chart depicting the EA Bureau of Environmental Health Services organizational structure is included in Appendix C. The quality assurance responsibilities of each EA bureau include the preparation of QAPPs for special studies and programmatic plans for all routine activities; the monitoring and overview of external environmental programs; and the preparation, review, and revision of SOPs.

4.1.1. EA Division of Ocean and Coastal Resource Management (OCRM)

OCRM is responsible for protecting the quality of the coastal environment while also promoting the sustainable economic development of the eight-county coastal zone for the benefit of all citizens of the state. To achieve these goals, OCRM implements a robust coastal zone management program that regulates the development and limited use of coastal resources and engages stakeholders in long-term planning and coastal policy development initiatives. In addition to issuing project-specific permits, OCRM reviews and certifies other state and federal permits within the coastal zone through a comprehensive coastal zone consistency process. This effort strives to ensure that permitted activities have given full consideration to the protection of ecological, cultural, and historic values as well as the need for economic development. OCRM also provides tools and technical assistance to coastal municipalities and fosters collaborative resource management strategies through local comprehensive beachfront management plans.

4.1.2. EA Bureau of Environmental Health Services (BEHS)

BEHS consists of the Regional Offices and Laboratories (Upstate, Midlands, Pee Dee and Low Country) and the EA BEHS Laboratories in Columbia. The organization of BEHS is provided in Appendix C. EA BEHS Laboratories include the Division of Air Quality Analysis (DAQA), Analytical and Radiological Environmental Services Division (ARESD), and the Office of Environmental Laboratory Certification. Quality Assurance Management is overseen by the State's Quality Assurance Manager (QAM) and designated staff.

BEHS Regional Offices and Laboratories

BEHS Regional Offices and Laboratories are responsible for implementing the various Environmental Affairs Programs (Air, Water, and Land and Waste Management) throughout the state. Activities include inspection and sampling of drinking water systems; inspection of hazardous waste generation, treatment and storage facilities; approval of water and wastewater systems for operation; ambient sampling of the state's waters and air; inspection and sampling of wastewater treatment systems; inspection of domestic landfill operations; inspection of industrial air pollution facilities; inspection and approval of septic tanks; inspection of public swimming pools and bathing areas; inspection of construction sites for proper storm water and sediment control; sampling and classification of shellfish harvesting areas and inspection of processing facilities; sampling, inspection, and permitting of milk and dairy facilities; inspections and permitting of food facilities; investigation and sampling for potential rabies cases; response to oil chemical spills, radiological emergencies, or other environmental emergencies; and investigation of complaints concerning the environment, including laboratory support. The regional offices and laboratories are listed below.

Upstate EA Region

Anderson, Greenville, Greenwood, and Spartanburg Offices: The Greenville laboratory performs laboratory and field analyses, while the Anderson, Greenwood, and Spartanburg laboratories perform only field analyses.

Midlands EA Region

Aiken, Columbia, and Lancaster Offices: The Aiken and Lancaster laboratories perform laboratory and field analyses, while the Columbia laboratory performs only field analyses. The Columbia area laboratory is separate from ARESD.

Pee Dee EA Region

Florence, Myrtle Beach, and Sumter Offices: The Florence and Myrtle Beach laboratories perform laboratory and field analyses, while the Sumter laboratory performs only field analyses.

Low Country EA Region

Beaufort, Charleston, and Orangeburg Offices: The Charleston and Beaufort laboratories perform laboratory and field analyses while the Orangeburg laboratory performs only field analyses.

EA Laboratories

EA Laboratories is composed of three entities: Analytical Radiological Environmental Services Division (ARESD), the Division of Air Quality Analysis (DAQA), and the Office of Environmental Laboratory Certification. Sample analyses include milk and dairy products, water, sediment, ambient air, and radiological environmental monitoring. The testing and analyses conducted complement and support all EA programs. DAQA in partnership with the Bureau of Air Quality (BAQ) maintains responsibility for the implementation of the ambient air monitoring program for the BAQ, analyzes the ambient air samples that are collected and submits ambient data to the national database. The ARESD and regional laboratories perform laboratory testing and analysis of water, sediment, and biological samples to determine if chemical and microbiological properties are consistent with quality standards. Also, ARESD analyzes milk and dairy products. ARESD supports activities in the regional laboratories by establishing the SOPs used by the regional laboratories and providing technical consultation when necessary.

Office of Environmental Laboratory Certification

The Office of Environmental Laboratory Certification is located organizationally within EA Laboratories. This Office has the responsibility for administering the Environmental Laboratory Certification Program as required by Regulation 61-81(R. 61-81). Certification of laboratories is required before the Department will accept analytical data for any parameter required by the following:

- State Safe Drinking Water Act and Regulation
- State Pollution Control Act and Regulations
- State Solid Waste Management Regulation
- State Hazardous Waste Act and Regulations.

The Office of Environmental Laboratory Certification certifies private, industrial, municipal, commercial, federal, and state laboratories (except those certified by EPA Region 4) that produce data required by DHEC or that will be officially submitted to the Department. Certification is offered for the parameters and methods that fall under the Safe Drinking Water Act, the Clean Water Act, and the Resource Conservation and Recovery Act (RCRA), as well as other parameters as requested by the program areas. The Office of Environmental Laboratory Certification also certifies laboratories performing shellfish analyses for waters and meats under the Food and Drug Administration (FDA) certification requirements.

The responsibilities of the Office of Environmental Laboratory Certification include:

- Conducting technical system assessments at least every three years of the in-state laboratories and reviewing technical system assessments of out-of-state laboratories certified under an equivalent state certification program at least every three years. The assessments are qualitative assessments of personnel, equipment, facilities, procedures, and QA activities.
- Providing quality assessments of laboratories generating data to the affected project managers and other interested parties upon request.
- Performing data quality assessments in which data are reviewed and evaluated to determine the quality and usability of the data. These are performed at the request of the program area(s) of the Department.
- Maintaining a database of certified laboratories that documents the certification status of all laboratories certified by the state's program. The database will include the certification status of parameters and test methods employed by the laboratory.
- Informing the program areas and the public (upon request) of the certification status of laboratories generating environmental data.
- Oversight of the annual performance audits using the Water Supply Proficiency Testing (PT) Studies and Water Pollution PT Studies. The results for required performance audit testing are reviewed and follow-up assessments/audits or decertification actions are taken as required by regulation. Results of the PT studies are tracked in a database for all laboratories certified by the office.
- Informing the EA program areas, QAM, and laboratories of changes in regulations that affect certification methods and requirements.

4.1.3 EA Bureau of Air Quality (BAQ)

The BAQ is responsible for the implementation of the S.C. Pollution Control Act, the Asbestos Abatement License Act, and the Federal Clean Air Act for the maintenance of standards and improvement of the air quality in South Carolina. The BAQ maintains the State Air Quality Implementation Plan that conforms to state and federal mandates. Activities of the BAQ include regulation development; air quality monitoring data analysis and data reporting; mobile source modeling for transportation conformity; compliance inspections of emission sources; enforcement actions taken to attain compliance with emission standards and permit requirements; licensing and oversight of asbestos removal and demolition projects, contractors and workers; permit issuance for emission sources; testing and evaluation of emissions; modeling of emissions prior to construction to ensure compliance with national air quality standards; accidental release prevention; and emission inventory. BAQ is supported by the Division of Air Quality Analysis, which includes the monitoring support staff and laboratory, and Regional Air staff. Both are housed in the EA BEHS. The BAQ works in close partnership with DAQA who assist with network design support and site evaluations to ensure that the monitoring sites meet EPA exposure requirements. DAQA is responsible for the analysis of air quality samples, the operation of the ambient air monitoring network, and data management. Regional personnel collect ambient air samples for DAQA, perform compliance inspections, and provide local response.

4.1.4 EA Bureau of Water (BOW)

The BOW is responsible for ensuring that waters of the state are in compliance with state water quality standards for the protection of aquatic life and human health. The BOW ensures that public drinking water supplies are safe; public swimming pools and natural swimming areas are clean and safe; and restores and maintains the chemical, physical, and biological integrity of the state's waters to the degree that these water resources may be used to the maximum extent possible. Activities of the BOW include reviewing plans and/or permit issuance for the construction and discharge of all proposed water, wastewater, stormwater, and agricultural wastewater systems; inspection of such facilities under construction and in operation; reviewing applications for permits to construct/repair/alter/remove any dam regulated under the S.C. Dams and Reservoirs Safety Act and conducting on-going inspection programs for the dams; conducting routine monitoring for bacteriological, organic and inorganic chemical and radiological contamination; conducting biological assessments of natural waters of the state; coordinating activities to prevent the contamination of existing and potential underground sources of drinking water and improving the quality where health or environmental impact exists; establishing specific classifications for all streams and tributaries throughout the state and effluent standards and guidelines for wastewater discharges; developing and promulgating rules and regulations for pollution abatement and for public health regarding sanitation, processing and handling of shellfish, fish, crab meat, lobster and shrimp; initiating enforcement actions to abate any violations including assessment of appropriate civil penalties with reference to the State Safe

Drinking Water Act, the State Primary Drinking Water Regulations, the S.C. Pollution Control Act, and the Water Pollution Control Permits Regulation.

The ARESD laboratory and the regional environmental laboratories located within the BEHS work in partnership with the BOW. These laboratories are responsible for analyzing the water samples that are collected by BEHS field staff located in the respective regions.

4.1.5 EA Bureau of Land and Waste Management (BLWM)

The BLWM is responsible for ensuring the regulated management of all solid and hazardous waste in the state to protect the health and safety of the public and to protect the environment. Activities of the BLWM include hazardous and infectious waste regulation, storage, transportation, treatment and disposal to ensure the safe and adequate management of these wastes.

The BLWM maintains a fund to ensure financing for contingencies (including appropriate staff oversight of clean-up activities) arising from hazardous waste spills or accidents at permitted facilities or at pre-existing abandoned sites. The bureau also maintains reasonable enforcement standards to abate control and prevent pollution; regulates the methods of disposition of garbage and any like refuse matter; administers and implements the requirements of the S.C. Mining Act, which involves permitting all mining activities to ensure the environmental protection, public safety and reclamation of all lands and waters involved in mining within the State.

The BLWM activities include enforcement actions, inspections, and permitting; promoting voluntary waste reduction through source reduction and recycling of industrial wastes; radioactive waste management; and technical assistance to the Emergency Preparedness Division and the Governor in case of radiological emergencies. The sound use and protection of groundwater; waste assessment; and supervision of cleanup activities are responsibilities of the BLWM. As part of this responsibility, the Underground Storage Tank (UST) Program has been designated as responsible for statewide compliance and corrective action programs related to underground storage tanks. Exact responsibilities are outlined in the State Underground Petroleum Environmental Response Bank (SUPERB) Act and Regulations 61-92 and 61-98. Specific compliance related services include: review and issuance of underground storage tank permit applications to install and operate; verification of tank owner's financial responsibility for corrective action and third party liability; maintenance of up to date information for all tank systems state wide; annual registration fee collection and decal issuance; oversight of installations, system upgrades, and abandonments; geotechnical services; and statewide inspection and outreach efforts.

The BLWM utilizes BEHS regional staff to perform compliance inspections. The BLWM may utilize third party contractors to perform environmental sample collection, sample analysis, and data handling. The BLWM uses commercial laboratories as well as internal laboratories for the analysis of regulatory samples.

4.2 Quality Assurance Program Management

4.2.1 The Quality Assurance Manager (QAM)

The EA BEHS Assistant Bureau Chief (ABC) of EA BEHS Laboratories serves as the Quality Assurance Manager (QAM). The QAM is assisted by designated staff members to perform many of the duties related to environmental quality management practices. Because of the diverse subject matter covered by the EA program areas, the QAM also relies on the QA Liaisons (See Section 4.2.2) as designees for the review of matters related to specific programs and functions within those programs.

The QAM or designee shall:

- Be informed of each special environmental monitoring study.
- Be provided with a written QAPP for special studies
- Maintain a list of both internal and external QAPPs submitted to the QAM with the date the QAPP was approved.
- Identify and respond to QA needs, resolve problems, and answer requests for guidance and assistance to groups both internal and external to the Department. Provide guidance to staff to develop and maintain an acceptable QA program.
- Communicate and disseminate QA related information to all program areas, QA Liaisons, Project Managers, Bureau Chiefs, ABCs, and the EPA Regional Quality Assurance Manager.
- Serve as the environmental measurements clearinghouse in the preparation, approval, implementation, and revision of all QAPPs and SOPs.
- Delegate peer reviews and other bureau specific QA tasks to the QA Liaisons.
- Resolve disputes regarding quality assurance issues within the Department and also with external data producers.
- Report QA concerns to the EA Bureau Chiefs, EA Assistant Bureau Chiefs, and/or the Director of Environmental Affairs.
- Perform internal data quality assessments of internal laboratories and recommend corrective actions when necessary.
- Perform assessments of field procedures.

4.2.2 QA Liaison

In order to coordinate quality assurance activities throughout EA, each bureau shall designate one or more QA Liaisons. The QA Liaison assists in the coordination of bureau QA activities, and helps the QAM ensure understanding and implementation of the quality system. The QA Liaisons shall:

- Work with the QAM and other QA Liaisons to coordinate QA/QC activities.
- Identify and respond to QA needs, resolve problems, and answer requests for guidance or assistance.
- Work with the bureau's staff to develop and maintain an acceptable QA program.
- Work as a peer reviewer for QAPPs generated by their bureau. However,

in the case where there would be a conflict of interest (for example, the Liaison is developing a QAPP or is the Project Manager), an alternate peer reviewer for the QAPP must be chosen. The Liaison may delegate QAPP review to a colleague in his/her bureau that has greater expertise in the subject matter, but this delegation must not cause a conflict of interest.

- Work with the Environmental Laboratory Certification Program to ensure that laboratories generating data are certified for the applicable parameters and methods employed for the analysis (where certification exists) and ensure consistency for sample preparation, quality control practices, and laboratory reporting requirements.
- Disseminate information regarding QA issues to their respective bureaus.
- Attend QA training provided by the QAM or other appropriate external training as funding is available.

4.2.3 Project Manager

The program area shall designate a Project Manager for each data collection, pollution control or waste remediation activity. Each Project Manager is responsible for assigned internal environmental data collection projects and is accountable for the management of the external data collection projects. The Project Manager has the principal responsibility for ensuring that project data quality objectives are met.

Key responsibilities of the Project Manager are to:

- Prepare and/or direct the preparation of QAPPs for special projects and submit the plans to the QAM or designee for review and approval. Prepare or direct the preparation of QAPP updates and the distribution of the updates.
- Prepare and/or approve the data quality objectives, specifications, and acceptance criteria for all special projects.
- Oversee the quality of the data generated from external projects funded through financial assistance agreements as required.
- Informally assess the adherence of all parties to the QAPP.
- Participate in conducting QA system/performance assessments of projects as requested by the QAM or designee.
- Take corrective actions that may be required by assessment findings and document the corrective actions.
- Report data quality problems to the QA Liaison and QAM or designee (if needed).
- Attend QA training provided by the QAM or other appropriate external training as funding is available.

4.2.4 EA Staff

EA program management and technical staff are responsible for the daily implementation of the QMP. This includes organizing and planning activities to consistently meet quality requirements; coordinating work performance for specific projects; and training personnel through SOPs. All program area technical staff will assist the QAM or designee in their area of expertise as requested.

Program management and technical staff assistance may include, but is not limited to, the following:

- Assist the QAM or designee with the technical aspects of QA as related to his/her expertise in air, water, chemical toxicity, toxic substances, hazardous waste, engineering, chemistry, biology, microbiology, field operations, and data operations.
- Identify QA needs, resolve problems, and answer requests for guidance or assistance in his/her specific area of expertise.
- Attend QA training provided by the Department, QAM, or other applicable external training as funding is available.
- Internal coordination of QA/QC activities among the various programs, divisions, and bureaus located within DHEC is provided through several means:
- Use of standard operating procedures for routine work: These are approved by the QAM and/or management. In the case of analytical or sample collection activities these are approved by the QAM and/or designee.
- Use of QAPPs for non-routine work: All QAPPs must be approved by the QAM or designee. EPA Region 4 must approve QAPPs when EPA funding is used.

5.0 Quality System Components

DHEC's quality system is a structured and documented management system that describes how quality is ensured in the environmental data used by DHEC. Environmental data quality is the responsibility of all EA staff directly or indirectly involved in sample collection, generation of data, and evaluation of data used to support Department decisions. The quality system elements include the activities associated with planning, implementation, and assessment. The planning process is addressed by using programmatic or project specific QAPPs; implementation is performed and overseen by the data user and/or project manager; and assessment of the data is conducted as specified in the associated QAPP. Activity includes, but is not limited to, project design, sample analysis, remedial design, grant administration, procurement, and business practices. The quality system encompasses a variety of technical and administrative elements such as: organizational structure, policies and procedures, responsibilities, authorities, standard operating procedures, and guidance documents. Responsibilities for each quality system component are discussed in Section 4. The components/tools of DHEC's Quality System are listed below:

5.1. Quality System Documentation

5.1.1. Quality Management Plan

The Quality Management Plan is the primary tool used to describe the quality system of the Department. The purpose of the QMP is to describe the overall quality system that is used to ensure the environmental data collected, evaluated, and used to support Department decisions are of adequate quality and usability for their intended purpose. In addition, the plan supports processes that ensure environmental technology used for pollution control or waste remediation is designed, constructed, and operated according to defined specifications and protocols. This QMP also includes descriptions of activities that support environmental data collection such as general requirements for hiring and training qualified staff, planning documents needed such as QAPPs or work plans, and required assessments, etc.

5.1.2. Quality Assurance Project Plans (QAPPs)

Quality Assurance Project Plans (QAPPs) are used for non-routine or external studies and may include or reference the Standard Operating Procedures which describe routine processes. QAPPs are discussed in detail under Project-Specific Documentation in Section 5.6.1.

5.1.3. Standard Operating Procedures (SOPs)

SOPs are written instructions that document a routine or repetitive activity performed by an organization. The development and use of SOPs are an integral part of a successful quality system and provides staff with the necessary information to perform their job properly and facilitate consistency. SOPs can describe both technical and administrative programmatic operations used within an organization. The SOPs must address the general elements described in EPA Guidance for the Preparation of Standard Operating Procedures, QA/G-6, April 2007.

The objectives of SOPs are:

- To establish appropriate traceability of standards, reference materials, reagents, and instrumentation, the calibration and quality control practices required, and the QC/QA of sample calculations, and results;
- To ensure that methods are performed correctly and uniformly by all analysts;
- To establish consistency with sound scientific/engineering principles;
- To establish consistency with EPA regulations, guidelines, and methods;
- To establish consistency in the operation of associated instruments and software.

SOPs are prepared by the various program areas to facilitate consistent conformance to technical and quality system requirements and to support adequate and consistent data quality. SOPs are reviewed for accuracy by appropriate senior staff and by technical specialists in the applicable work area(s). SOPs are dynamic documents, requiring revision due to changes in regulation, in equipment, and/or protocol. Staff are expected to follow procedures in all applicable SOPs while conducting technical procedures and operations. Staff may only depart from existing written procedures on a project specific basis with approval from the project or program management. In the case of laboratory SOPs, the QAM or QAM designee should provide approval. Such departures must be clearly and consistently documented so that data users are aware of the departures.

EA BEHS maintains SOPs for field and laboratory procedures. The *Bureau of Environmental Health Services Field Quality Plan* incorporates both the field QA plan and the field SOPs to be followed by staff. The EA BEHS Laboratory's SOPs are entitled *ARESD Procedures and Quality Control Manual for Chemistry Laboratories*; *ARESD Laboratory Procedures Manual for Microbiology*; *ARESD Laboratory Procedures Manual for Radiochemistry Laboratory*; and DAQA *Procedures and Quality Control Manual.* For each approved method used, an SOP must be available. SOPs are periodically evaluated for necessary revisions due to changes in regulation, guidance, procedures, equipment, reagents, etc. In the event of an SOP change, the SOP must be updated prior to implementation of the applicable change. When SOPs are updated, the revised SOP must be distributed to all affected staff. The revised SOP must be reviewed by staff familiar with the procedure and program requirements. After review the SOP must be signed and dated to document the approval of the revised SOP.

A document control system is used for laboratory SOPs. Obsolete SOPs are physically removed from the staff; however, they are retained for historical reference. Actual changes in the SOP will be indicated by the document control information, which will include the revision date and number. The revision history of the SOP will document all changes. Field analysis SOPs are developed by each bureau performing field analysis. SOP review and approval is the responsibility of bureau management. If the SOPs are revised, the revised SOPs are distributed to staff with a summary of the changes in the revision history. Training will be conducted as necessary to ensure that the revised SOP will be consistently followed by all staff.

Although SOPs are usually written for field and laboratory procedures, the value of a SOP is not limited to these work environments. Other functional areas within the Department may also use written administrative and technical SOPs to ensure consistency in performing critical procedures. For example, the Office of Environmental Laboratory Certification has administrative SOPs that address primarily administrative activities such as processing applications, billing procedures, evaluation of laboratories, issuing certifications, evaluating proficiency testing samples, etc. These administrative SOPs ensure that these procedures are performed consistently and correctly. Administrative and technical SOPs are a valuable training tool for new staff.

5.2. Annual Reviews and Planning

Annual reviews and planning tools include bureau meetings, program specific workgroups, SOP and record reviews, request for proposals (RFPs), and QAPP development and reviews. Many quality issues are assessed during monthly bureau meetings and workgroup meetings. Workgroup meetings include drinking water and wastewater committee meetings attended by technical field staff. Appropriate corrective action is determined and then applied by updating SOPs and/or other documentation, notifying staff of the revision, and providing training, if necessary.

Planning includes the use of work plans and QAPPs in which key staff members must determine needs, what will be performed for specific projects, and how a project or routine study will be implemented. Routine processes and/or procedures are described in SOPs.

Planning may also include requests for proposals (RFPs). Project managers shall ensure all RFPs for environmental sampling or analytical services contain a clear description of the QA requirements necessary to meet project objectives. The QA procedures must be included and clearly described in the proposals. Any laboratory producing analytical data for a program's utilization must have SOPs available for review. The SOPs must contain the general elements as given in *EPA Guidance for the Preparation of Standard Operating Procedures, QA/G-6* April 2007. The laboratory organization, structure, and areas of responsibility must be available for review by the program accepting the data. The laboratory must have certification from the Office of Environmental Laboratory Certification for the parameters to be analyzed if such certification exists. Methods used to monitor or measure environmental conditions, characteristics or contaminants for activities and regulatory requirements not related to compliance will have demonstrated precision and accuracy appropriate for the intended purpose and written SOPs incorporating QA/QC procedures adequate to control data quality. If certification does not exist for a specific parameter, then a demonstration of capability for the specific method/parameter may be required of any external company or laboratory performing an analysis and submitting environmental data.

5.3. Management Assessments

Management assessments are performed by, or at the direction of, upper management using tools such as program compliance meetings, data verification and validation, data assessments, and quality system assessments. In cases where data quality issues are discovered, an investigation will be conducted to determine the scope of the issue. Compliance meetings are used to determine appropriate corrective action. Corrective actions are implemented and communicated by the appropriate manager to the affected staff.

Quality system assessments are covered at length in Section 12. The Office of Environmental Laboratory Certification Program performs evaluations (assessments) on all external certified environmental laboratories. ARESD and DAQA are assessed by EPA Region 4. Sections within ARESD are certified by EPA Region 4 and FDA. The DHEC regional labs are evaluated and certified by the Office of Environmental Laboratory Certification at least

every 3 years. EPA Region 4 periodically performs on-site evaluations on these regional laboratories for drinking water analyses. Any laboratory generating data that are reported to the Department must have an established quality program appropriate for the expected data use.

5.4. Training

Training is an integral part of maintaining the department's quality system. Initial training for new employees as well as on-going training for all staff is required for implementation of the quality system. Additionally, ethics training is based on the EA Laboratory Ethics Policy is included in laboratory staff training. Training plans are specifically developed for employees of EA BEHS to ensure that employees are trained to perform their applicable job duties related to data quality measurements. On the job training is part of the overall training plan along with external sources of training for specific job duties. Annual training is also required for revised SOPs and safety. DHEC's Office of Staff Training and Development provides Department required training for all DHEC employees. Employee training is documented in the South Carolina Enterprise Information System (SCEIS) training module. Training is further discussed in Section 6.

5.5. Systematic Planning of Projects

Systematic planning of projects is necessary to clearly define study objectives and establish performance and acceptance criteria for the collection, evaluation, or use of project data. The use of systematic planning is a key component of DHEC's quality system. The Department uses the Data Quality Objectives (DQO) Process for systematic planning when data are to be used to support a decision or provide an estimate. This systematic planning process includes the identification and involvement of all participants and data users - project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts etc. Systematic planning is discussed in Section 10.

5.6. Project-Specific Quality Documentation

The QMP is the primary tool used to describe the quality system of the Department. This document describes basic requirements for hiring and training staff, for the planning needed, for assessments required, etc. Other quality system documentation tools include Quality Assurance Project Plans (QAPPs), Waste Analysis Plans (WAPs), Sampling and Analysis Plans (SAPs), and Standard Operating Procedures (SOPs).

5.6.1. QAPPs

Project QAPPs are required for non-routine work or special projects. Several program areas may be required to maintain programmatic QAPPs that describe routine processes for the specific program [e.g. Underground Storage Tank (UST) Program]. Although an external activity may originate outside the Department, an approved QAPP is necessary for the collection and data generation activities that are the responsibility of the Department. The scope of QAPPs prepared for EPA Region 4 under cooperative agreements will be dictated by the individual program requirements. The QAPPs should be consistent with the requirements specified in DHEC's QAPP Guide which closely follows the *EPA's Requirements for Quality Assurance Project Plan, QA/R-5*, March 2002.

The goal is to have an approved QAPP in place prior to any data generation. This may require not only the QAM approval, but also EPA approval if the project uses EPA funding. However, with authorization from the QAM or designee, preliminary data may be generated to inform possible sampling sites or collect other information needed to support the QAPP development. Preliminary data generation supporting sampling plan or QAPP development are expected to be limited to of only one or two sampling events and must be documented in the project planning documentation. The results of this sampling and how the results affected the study design (sampling site locations, etc) must be discussed in the QAPP.

Special studies or sampling involving an immediate public health threat or a criminal investigation may not have an approved QAPP due to a limited time frame for obtaining samples. Sample collection, documentation and analysis, wherever possible, will be conducted consistent with established procedures and protocols used for routine work, requiring adherence to applicable SOPs. Projects involving environmentally-related measurement activities conducted by or for EA shall be performed with the approval of QAM or designee. Routine work such as, but not limited to, data reported in accordance with the National Pollutant Discharge Elimination System, shall be conducted using existing, approved SOPs. Refer to DHEC's website for a detailed list of regulations utilized for the routine compliance work performed by or for the Department.

http://www.scdhec.gov/Agency/RegulationsAndUpdates/LawsAndRegulations/

The QAM or designee will ensure that the necessary data quality will be determined and documented before the data generation effort begins. The project manager will ensure the data generated will be of the quality and integrity specified by the QAPP and/or SOPs; including oversight of the sample collection and processing. Each environmental monitoring organization shall develop and implement SOPs, reviewed by the QAM or designee, for all routine monitoring activities. When the Department enters into a cooperative agreement with another agency, the lead entity will be responsible for generation and maintenance of the project QAPP, unless otherwise agreed upon.

The project QAPP, coupled with related SOPs, define specific project QA/QC requirements. This approach identifies the parameters to be measured and discusses the QA activities to be conducted during sampling, analysis, and data validation stages of the project. The document entitled EPA Requirements for Quality Assurance Project Plans, QA/R-5, Final; March 2001 provides detailed instructions for the preparation of QA project plans. Additional information is provided in the EPA's Guidance for Quality Assurance Project Plans, QA/G-5, December 2002.

In order to support planning and implementation of a project, the QAPP must specify the level or degree of QA/QC needed for each environmental data operation. DHEC will evaluate the QA/QC applied to a project based on the purpose of the environmental data collection, the type of work performed, and the intended use of the data. The QAPP shall include procedures for assessing the quality and suitability of environmental data generated for accuracy, precision, completeness, comparability, and representativeness.

For more information regarding format and requirements for writing a QAPP, a document entitled The Guidance Document for Preparing Quality Assurance Project Plans (QAPPs) For Environmental Monitoring Projects/Studies is available on the DHEC website at the following URL.

https://www.scdhec.gov/HomeAndEnvironment/Docs/OAPP_Guide%20Sept_2008_Finalflags.pdf

All of the Department's QAPPs must be approved by the QAM or designee prior to the beginning of data collection. EPA Region 4 must approve QAPPs when EPA funding is used. The QAM or designee shall review all plans, provide input, recommend changes, and approve final plans. Upon request, the QA Liaisons or designated technical staff shall serve as peer reviewers for QAPPs with regard to their area of expertise. QA activities are to be tracked by the Project Manager.

The environmental data collection work addressed by the QAPP may not be started until the initial QAPP has been approved by the DHEC sponsoring program and the QAM or designee (except as discussed in the beginning of this section). In some cases, DHEC may grant conditional or partial approval to permit some of the work to begin while non-critical deficiencies are being resolved. The QAM or designee should be consulted to determine the nature of the work that may continue and the type of work that may be performed under a conditionally approved QAPP.

The review of a QAPP may result in:

- Full Approval: All identified deficiencies in the QAPP have been corrected and the project may commence.
- Partial Approval: Some activities identified in the QAPP still contain critical deficiencies while other activities are acceptable. If the acceptable activities are not contingent upon the completion of the activities with deficiencies, a partial approval is granted for those activities to proceed. Staff should continue to resolve the portions of the QAPP that are deficient. The QAM or designee will ensure that all deficiencies are addressed and final approval is granted.

- Conditional Approval: Approval of the QAPP or portions thereof will be granted upon agreement by the project manager to implement specific conditions, add specific language, or correct deficiencies required for approval to allow the initiation of field work. In most situations, the conditional approval is upgraded to final approval upon receipt, review, and sign off by all parties of the revised/additional QAPP pages.

Once approved, the project manager and organization performing the work is responsible for maintaining and implementing the QAPP. This responsibility includes ensuring all personnel involved in the work have copies of or access to the approved QAPP along with all other necessary planning documents. Section A9 of a QAPP specifies how the approved QAPP will be disseminated to those on the distribution list in Section A3 of the document. Personnel should understand their responsibilities prior to the start of data generation activities.

Organizations are responsible for keeping the QAPP current when any technical aspects of the project change. QAPPs must be revised to incorporate such changes. Any revisions or additions to the QAPP must be re-approved by the program and the QAM or designee and distributed to all participants in the project. EPA Region 4 must approve QAPPs when EPA funding is used. (See The Guidance Document for Preparing Quality Assurance Project Plans (QAPPs) For Environmental Monitoring Projects/Studies).

5.6.2. Waste Analysis Plans (WAPs) and Sampling and Analysis Plans (SAPs)

In certain cases, WAPs and SAPs are required by RCRA regulation. When plans are required by regulation, the applicable regulation is reviewed to ensure that the content and format requirements are understood. The EPA has prepared various guidance documents that the Department uses to assist in preparing WAPs and SAPs to meet the program regulatory requirements.

5.6.3. SOPs

SOPs are discussed in detail in Section 5.1.1.

5.6.4. Project and Data Assessments

Data used within EA include internal analytical data generated by the Department's laboratories, field activities, and/or private laboratories as part of a QAPP or contract; external analytical data generated in support of program grants, cooperative and interagency agreements, and by facilities in fulfillment of permit or regulatory requirements; and data such as meteorological information, emissions profile, or standards recognized by national or regional organizations for specific purposes, such as air modeling. National inventories of emissions and discharge recognized by the EPA or improved datasets based on those inventories, may be used in DHEC projects or data analysis. Statistical analysis is performed as needed by the programs or data users. The types of statistical analysis performed are specified in the SOPs and/or QAPPs.

Project and data assessments are performed by conducting data verification and validation. For internal work, the section manager of the laboratory verifies the data. For routine work based on external data, the Department verifies the data for completeness and determines if the data meets the requirement of having been generated by a certified laboratory (where such certification exists). For

non-routine work, requirements for verification and validation are defined in the associated QAPP. All analytical data, including field measurements, requiring use of a certified laboratory must be generated in a laboratory that is certified by the Environmental Laboratory Certification Program or by the EPA for all parameters, where such certification exists. Analytical data from a laboratory not certified for the specific analysis, but determined to be of appropriate quality for project objectives will be used only as specified in the associated QAPP.

Data assessments are performed on all laboratories certified by the Office of Environmental Certification as a part of the on-site evaluation performed every three years. The certification program evaluates all certified parameters performed under the Safe Drinking Water Act (SDWA), Clean Water Act (CWA), and the Solid and Hazardous Waste (SHW) programs. If deficiencies are noted in the data received by the department, the Office of Environmental Certification will perform a data validation on the raw data.

6.0 Personnel Qualifications and Training

6.1. Training

It is DHEC's practice that each program area will ensure that all personnel performing tasks and functions related to data quality will have the necessary qualifications, including education, training, and experience. Minimum personnel qualifications are established by the Office of Personnel Services. Any preferred qualifications are determined by the hiring authority. Ensuring that personnel qualification requirements have been met is the responsibility of the hiring authority. Documentation of training is maintained in MySCCentral database.

6.2. Training Requirements for EA Staff

Once hired, every employee attends orientation and Department required training. Additional training necessary to perform job duties is determined by the employee's required job description. Training plans are developed for staff to ensure that each employee acquires the necessary knowledge and skills to perform their job duties. For example, a laboratory staff member must have Hazard Communication Training; while a staff member performing field duties may be required to take Confined Space Training. Some job duties require training that is only offered outside of DHEC. For example, staff in the Environmental Laboratory Certification Program are required to successfully complete the Chemistry and Microbiology Drinking Water Certification Courses given by EPA. Within EA, program managers, sometimes jointly with the QAM, shall determine the need for staff to attend QA related training. Elements of the QMP and the Quality System are embedded in the field and laboratory SOPs, Staff are required to read and document they have read these SOPs before they are allowed to perform the work. Additional training may be part of a corrective action for issues identified in the laboratory or to communicate new requirements.

The new employee is scheduled to attend most required training classes as soon as possible. However, there are situations in which the employee must obtain experience on the job prior to completing required training classes. Immediate supervisors, along with the division directors, determine what job-related training

classes are needed for specific personnel. The section manager is responsible for ensuring that their staff have obtained the required training.

For continuous education/training, staff are required to periodically review the SOPs that are applicable to their work and sign a form for each SOP documenting that they have read, understood and will abide by the requirements of that SOP. If an SOP is updated, staff are required to review the updated SOP. Once per year, regional laboratory staff are required to attend an update conference given by ARESD and the QAM or designee.

6.3. Professional Licenses and Certifications for DHEC Personnel

Positions which require professional licenses, certifications, or other formal qualifications in order to be compliant with specifications stipulated in state or federal statutes/regulations are specified in the position description for the employee's job. Some examples are as follows:

- Environmental Laboratory Certification Program: Laboratory Certification Officers (LCOs) are required to successfully complete the EPA's Laboratory Certification courses for microbiology and chemistry. These certification courses are completed after on the job training. Certification officers should attend refresher training at least every five years to keep their knowledge of the methods and drinking water program current.
- The Shellfish Program: The Shellfish Program requires staff to be certified by the SC Criminal Justice Academy as Class I law enforcement officers for the patrol and enforcement components of the program. The law (SC Code of Law Section 44-1-151) makes violation of shellfish laws and regulations criminal acts. Enforcement for criminal acts (tickets, arrests, etc.) can only be performed by a certified law enforcement officer.

The Underground Storage Tank (UST) Program: The DHEC UST Program is a Class I Certified Site Rehabilitation Contractor (#UCC-0116) as required by R. 61-98. This regulation stipulates a requirement of a Professional Engineer (P.E.) or Professional Geologist (P.G.) as registered in South Carolina. Several UST staff members holding professional licenses are listed in the Contractor Certification File to meet this regulatory requirement due to involvement in State led investigations and Brownfields initiatives. For these projects, UST requires licensing for drillers. This requirement is specified in the UST programmatic QAPP. The documentation is submitted with the site specific QAPP. The position descriptions for these staff members do not specifically require this certification, but the UST Program must retain registered professionals on staff to maintain certification so that any necessary work can be accomplished.

6.4. The QAM Qualifications and Training

Besides the qualifications required for technical staff, the QAM and their designated staff must meet the following qualifications at a minimum:

- Knowledge gained through a combination of training and experience in a scientific discipline and knowledge of statistics.
- Knowledge of applicable federal laws, EPA regulations and guidelines for environmental monitoring, and related EPA requirements.

Excellent written and oral communication skills in meeting and dealing with the general public, private industry, and officials of federal, state, and local governments.

7.0 Procurement of Items and Services

The DHEC Bureau of Business Management (BBM) is responsible for providing the Department with administrative support in the following areas: procurement of goods and services; facility management; asset accounting and property management; central supply, mail and courier operations; motor vehicle management/maintenance; facility maintenance; printing, photography and graphics; and security services. BBM maintains a continuous review of state and federal laws, policies and procedures to assist in the management process of the Department. In addition, BBM procures quality goods and services to meet program specifications and requirements for all Department entities in accordance with established rules and guidelines for procurement. The person/program initiating the purchase and receiving the items is responsible for inspecting the items to ensure they meet quality requirements. If items are rejected, the vendor is contacted to obtain a replacement or to address the issue prior to payment for goods.

Within the bureaus, the process for ensuring that the procurement documents contain clear descriptions of the items and services required and for specifying the technical and QA/QC requirements for items and services is performed or assigned at the division director level. The division director or their designee(s) determines specifications, writes a full description of the items or services required, and ensures that the procurement documents contain the appropriate technical and QA/QC requirements prior to sending them through the procurement process.

For situations involving grants, agreements, and contracts with external parties the review process ensures that:

- All documents associated with the grant/agreement/contract are complete and accurate;
- The agreement between the vendor and Environmental Affairs clearly describes the item or service needed with a level of detail sufficient to ensure that it will meet all requirements of the Department;
- The agreement describes all technical and quality specifications necessary to meet the requirements of the Department;
- The agreement specifies the quality system elements for which the supplier is responsible;
- And the agreement includes a requirement for verifying the supplier's conformance.

When reviewing and approving solicitations from vendors for items or services, the review process includes experts who can determine whether responses satisfy all technical and quality requirements. This review process examines each solicitation for evidence of the supplier's capability to satisfy Environmental Affairs and EPA quality requirements. The review process also ensures procured items and services are acceptable.

8.0 Documents and Records

Records created or received in the course of the Department's business, including information maintained in paper or electronic format, are public records. Public records must be maintained and disposed of in accordance with the S.C. Public Records Act S.C. Code Ann. §§ 30-1-10 *et*

seq. and DHEC policy and procedures. DHEC will make public records reasonably accessible to the public unless restricted by law.

The Act delegates authority to the S.C. Department of Archives and History (State Archives) to create and maintain an efficient and economical records management program. The Act requires the establishment and development of standards, procedures, techniques, and schedules for effective management of public records, including compliance with retention schedules and document destruction guidelines. Records should be destroyed or purged once the retention requirement has been met and approval has been received from the DHEC Records Officer and/or State Archives.

As the legal custodian of DHEC's records, the Director will appoint an Agency Records Officer to act on his/her behalf and will notify the State Archives of their appointment. DHEC program areas are required to designate Records Coordinators to work with the DHEC Records Officer to establish and maintain an active and efficient record management program. Agency forms must be approved by the DHEC Forms Manager and assigned a retention schedule by the Records Officer prior to use. As required by the S.C. Family Privacy Protection Act, DHEC must limit the collection of personal information to that which is necessary to fulfill a legitimate public purpose.

The management of the department's documents and records is described in the DHEC Records and Forms Management Procedures Manual. All retention schedules must be approved by the DHEC Records Officer and the S.C. Department of Archives and History to ensure compliance with all applicable statutory, regulatory, and EPA requirements. Records concerning environmental data and information must comply with applicable EPA regulations as well. Files, records, and information shall not be destroyed except in accordance with DHEC or State Record Retention Control Schedules and Procedures.

The division directors and/or QAM are responsible for identifying quality related documents and records in their area of EA. These documents can range from the QMP, guidance documents, SOPs, QAPPs, chain-of-custody forms, calibration and analysis records, and actual raw data.

Quality system documents are controlled through various means such as:

- Use of revision numbers, date of revision, and a revision history. The revision history will document what was changed and when it was changed.
- Designation of form custodians.
- Use of password protection of quality system documents.
- Use of multiple formats for document storage, such as a hardcopy and PDF.
- Use of watermarks on quality documents to designate controlled versus uncontrolled.
- Use of computer files organization to control access.

Specifics on how quality documents are prepared, reviewed, approved, and maintained are listed in Table 1.

Having complete documentation of a process is critical to ensure that the work is complete and accurate. This applies to field and/or laboratory work, writing permits, performing inspections, or performing any routine process in the Department. This is especially true when documentation is required by state and federal statutes and regulations. For many work

processes, training must be conducted to ensure that staff understand how to correctly perform the work and how to properly complete the required records and/or forms to document that the work was performed correctly. Checks are performed on records (chain-of-custody forms, field logbooks, calibration and analysis records, bench sheets, etc.) by management to ensure that staff records and documents accurately reflect the completed work. The checks include anything from the manager verifying an analytical result to a formal audit of the records.
SOPs and quality related guidance documents are generated by knowledgeable staff in the lab or office in which they are used. The QAM or designee also reviews the SOPs, QAPPs and some, but not all, technical guidance documents. The QAM or designee's review includes a check to ensure that the method cited in the SOP conforms to state/federal regulations and that the SOP is in conformance with the cited method. When a new version of a document has been approved, the new version is provided to all appropriate staff with the revisions and changes communicated. If the new version includes significant changes, training will be performed to communicate and explain the changes. This training is documented in the staff's training file. The manager will ensure that the employees have the newest version of the SOP, and that staff are instructed to recycle any printed copies of the older versions of the document. Obsolete SOPs are physically removed from the staff; however, they are retained for historical reference.

The laboratory SOPs are reviewed annually. Field operations SOPs are revised to incorporate changes to requirements, procedures and equipment. When reviewed, the SOP signature page is re-signed to indicate that a review has been performed. Revisions are indicated by the revision number, revision date, and entries in the revision history. Generally, laboratory SOPs are only distributed to the staff that will use them. When a new version of an SOP has been approved, the new version is provided to all appropriate staff with the revisions and changes communicated. If the new version includes significant changes, training will be performed to communicate and explain the required changes. This training is documented in the staff's training file. The laboratory director will ensure that all older versions of the SOP are no longer available electronically and that staff are instructed to recycle printed copies of the older versions of the document.

Technical guidance documents and quality-related guidance documents are distributed outside of the Department, electronically, or by mail. Guidance documents from the QAM or designee (including the QAPP Guide) are available on the Department's website. When these documents are updated or changed, the new document is replaced on the website and the availability of the revision is communicated to the Department.

QAPPs are authored by the project manager or designee. Signatures of approval must include a signature from the lab(s) of record and the QAM or designee. EPA Region 4 must approve QAPPs when EPA funding is used. The signature from the lab(s) indicates that the lab(s) has been consulted during the development process and that they agree with what is specified in the QAPP regarding the affected methods, QC requirements, and sample handling.

In the case of a criminal investigation, a study plan is required unless the investigation is considered to be an emergency. Following completion of the field activities, the project leader or designee must account for all field documentation, such as field logbooks and chain-of-custody records, and verify that they are complete. When requested by the criminal investigator, all final analytical data from the lab must be documented in a memorandum stamped "CONFIDENTIAL" and transmitted to the project leader, technical support team, and criminal investigator.

Each bureau has organized record keeping responsibilities in accordance with its functions, operations and duties. These responsibilities include the creation and maintenance of records and documentation as well as the security and integrity of the records (whether hardcopy or electronic) from their creation to their final disposal. The manner in which information is documented is supported by the requirement that staff use approved DHEC forms when possible. Each official DHEC form is reviewed by the DHEC form's manager and when the form is approved, it is assigned a unique number. Only then can the form be reproduced and used. These official forms are used in sample collection, field activity documentation, analysis request forms, laboratory analysis, and chain-of-custody. The use of approved forms standardizes the documentation and helps ensure that documents are accurate, complete, and legally defensible. Furthermore, managers are routinely required to review records and documentation produced by their staff to ensure that they are completed properly and completely.

Although retention schedules can vary in EA depending on applicable regulations, the records and information created, received, maintained, or acted upon shall be maintained in compliance with State Record Retention Schedules as approved by the DHEC Records Office and the S.C. Department of Archives and History to ensure compliance with all applicable statutory, regulatory, and EPA requirements. Records concerning environmental data and information comply with applicable EPA regulations.

Quality documents are not managed separately but are included in retention schedules in many bureaus. For special projects, the Project Managers shall be held responsible for ensuring that any project for which they are responsible (external or internal) adheres to their bureau's recordkeeping practices. DHEC employees leaving the Department must return all records to their manager prior to their severance from the Department.

Policy A-304, Discovery of Electronic and Other Documents, addresses compliance with federal and state requirements for the preservation and collection of documents required to be produced for litigation. The policy applies to both traditional paper discovery and electronic discovery. Documents that must be preserved for litigation include e-mails with all attachments, letters, memoranda, hand written notes, and recordings, as well as files and records maintained on matters of official agency business. Text messages and voice mails may also be included in discovery.

The DHEC Confidentiality of Information policy protects confidential information and the privacy of its employees, its clients, and members of the public to the fullest extent practicable and allowed by law. DHEC employees and agents will not disclose confidential information without written authorization from affected persons or parties, except as required by law or as required to perform agency responsibilities, and will keep confidential information secure at all times in order to prevent improper disclosure. DHEC program areas that maintain confidential information must limit access to this information to those employees and other individuals who are allowed by law and required to access this information to perform their jobs. In addition, employees must follow established procedures to ensure that confidential information is maintained and transmitted in the most secure manner. DHEC employees and agents will direct questions concerning proper handling of confidential information, and requests from outside the Department for confidential information, to the employee's supervisor, DHEC Privacy Officer, and DHEC Office of General Counsel, as appropriate.

Table 1: Quality Document Procedures

Quality Document	Activity	Responsible Position	Document Control
Quality Management Plan	Preparation	QAM and/or designee	Controlled Document
	Review and Approval	QAM EA Director Bureau Chiefs QA Liaisons EPA Region 4 QA Manager (as required)	Review and approval are documented by signature on the document approval page.
	Maintenance and Update	QAM and/or designee	Proposed update is changed using tracked changes. Management reviews and approves.
Project Specific and Programmatic QAPPs	Preparation	Project Manager or contractor	Controlled by the author of the document.
	Review	QAM and/or designee, QA Liaisons, EPA if applicable	Controlled by the reviewer.
	Approval	QAM or designee, EPA if applicable	Approval indicated by signed approval page. Signatures include the QAM or designee, project manager, bureau representative, and laboratory director. EPA as applicable. The document is now controlled by the project manager, usually in electronic PDF format.
	Maintenance	Project Manager	If a change is needed in the QAPP, the project manager must re-write the appropriate sections and obtain approval.
Standard Operating Procedures (SOPs)	Preparation	Management	Controlled Document
	Review	Management, QAM and/or designee	Controlled Document

Quality Document	Activity	Responsible Position	Document Control
	Approval	Management, QAM and/or designee Note: Air SOPs are approved by EPA Region 4.	Controlled document. Approval indicated by signed approval page by all approving parties. Once signed, the document is put in PDF form or restricted access so that only authorized personnel can update or make changes.
	Maintenance	Management	Prior to use of new equipment and/or procedures, the manager is responsible for updating the SOP. Inactive SOPs are removed from staff accessibility and archived according to the retention schedule.
Guidance Documents	Preparation	QAM or designee or applicable program area	Controlled document
	Approval	QAM or applicable program area	Disseminated via email or the web in a PDF format.
	Maintenance	QAM, Bureau Chief or designee or applicable program area	As new procedures are put into place, the documents are updated as needed and disseminated via email or the web.

9.0 Computer Hardware and Software

The Department is committed to following federal/state mandates regarding protection of data and associated software/hardware requirements.

The Bureau of Information Technology's (BIT) Chief Information Officer (CIO) manages the process of identifying management information technology (IT) needs and developing cost-effective management information systems and services to satisfy those needs. The CIO, the Director of Enterprise Applications, the Director of Business Systems Applications, and the Chief Information Security Officer (CISO) are responsible for the implementation of standard operating procedures and the identification and prioritization of IT needs. Together they also evaluate proposed changes that may have the potential for cross-program impact.

The CIO, the CISO, and the directors coordinate their efforts with the appropriate BIT section managers to identify and prioritize the Department's needs. The BIT coordinates with the Department's Bureau of Business Management (BBM) in procurements of software, hardware, and/or services for IT projects. Depending on the cost of the project (if greater than $50,000), the Department of Administration, IT Governance, and the IT planning Section will be involved in the approval process. The State IT approval process is completed by agency program staff and BIT management and submits formal documentation of the background of the request,

system/service requirements of the solution requested, options considered, risks and estimated cost of the solution, and an estimated timeframe to complete the scope of the work.

All hardware and software solutions are evaluated prior to purchase and/or renewal using industry best practices, experience from other states, and demonstrated performance. The Department adheres to all mandatory state procurement guidance to ensure the best price via appropriate market competition for the selected product or service.

The Department consolidated all IT support staff into a single bureau in 2013. Within the BIT is the Environmental Application Development Section, which includes all application development staff who previously worked within their primary environmental bureaus. Within the Environmental Application Development Section, a staff member has the designated role of coordinating efforts across the bureaus to improve data quality within EA. This staff member works with EA staff to ensure effectiveness and quality assurance of the information produced from or collected by the Environmental Facility Information System (EFIS). This effort will continue as the department migrates data from EFIS to the new replacement solution (ePermitting), with assistance from the Department's Project Management Office (PMO). EA also works closely with the EPA to ensure complete and accurate data is submitted through the Exchange Network via OpenNode2. The ePermitting project is expected to improve cross program access to data, data extraction results, and public access to departmental information.

In the BIT, assigned staff are responsible for maintaining the integrity of the computer databases and information systems for the department. They ensure that the records are backed up routinely and that transfers from one area to another of electronic records are performed accurately following industry best practices to meet Recovery Time Objective (RTO) and Recovery Point Objective (RPO) requirements. Staff also ensure that virus protection software is kept up-to-date on each computer in the department.

Prior to data being input to computer databases, the laboratory data is checked by the analyst and their supervisor. This review includes verification of calculations using the raw data. A percentage of data is checked by a third data verifier. Program areas accept the responsibility for data integrity when data is transferred to them from the laboratory. An example would be data is transferred from the EA Laboratory to BOW for entry into the Storage and Retrieval (STORET) database.

10.0 Systematic Planning

Systematic planning is a process designed to ensure that the level of detail in planning is commensurate with the importance and intended use of the work and the availability of the resources to accomplish project goals. The ultimate goal of systematic planning is to ensure collection of the appropriate type, quantity, and quality of data to support decisions with acceptable confidence. The collection, use, and dissemination of environmental data and information of known and appropriate quality are integral to the Department's mission. The systematic planning process generally involves the following elements:

- Identification and involvement of data generators and users.
- Identification of project schedule, milestones, resources, and any applicable requirements.
- Description of the project goals and objectives.
- Identification of the type, quantity and quality of data needed.

- Specification of acceptable performance criteria for ensuring the data collected meets the needs of the project.
- Description of how, when, and where the data will be obtained, and identification of any constraints on data collection.
- Specification of QA and QC activities needed to assess quality performance criteria.
- Description of how acquired data will be analyzed (i.e., field and/or laboratory), evaluated, and assessed against performance criteria.

The Department uses the EPA's Data Quality Objectives (DQO) Process for systematic planning when data are to be used to support a decision or estimation. The DQO process is discussed in detail in the *Guidance on Systematic Planning Using the Data Quality Objectives Process*, *EPA QA/G-4*. This systematic planning process will ensure that all organizations and/or parties who contribute to the quality of the environmental program or use the results are identified and that they participate in this process. The process includes the identification and involvement of the project manager and stakeholders: sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, suppliers, etc. The planning process also provides for direct communication between the data users and the generators to ensure that there is a clear understanding by all participants of the needs and expectations of the data user and the product/results to be provided by the activity.

The results of planning for environmental data operations will be documented in QAPPs, Waste Analysis Plans (WAPs), or Sampling and Analysis Plans (SAPs). Refer to Section 5.6.1 for the process for developing, reviewing, approving, implementing, and revising QAPPs. Also refer to *EPA Requirements for Quality Assurance Project Plans (QA/R-5)* and *EPA Guidance for Quality Assurance Project Plans (QA/G-5)*.

11.0 Implementation of Work Processes

The implementation of work processes must follow the plans detailed in QAPPs, Waste Analysis Plans (WAPs), and Sampling and Analysis Plans (SAPs) that have been established to ensure that data or information collected are of needed and expected quality for their desired use. EA has processes in place to determine how these plans are developed, distributed, and implemented.

Routine, repetitive work in the laboratory or field is a process requiring an SOP. Occasionally, office work such as use of specific software applications may also require an SOP. Some special studies which do not require sample collection may require only a work plan and/or graded QAPP. Special studies involving environmental data generation through field and laboratory analysis not only require QAPPs, but SOPs and/or a work plan. Once SOPs, work plans, or QAPPs are approved, the work may begin.

As discussed in the QAPP guidance document, the QAPP writer must distribute the approved QAPP to everyone in the distribution list (Section A3). This list is reviewed during the QAPP approval process for completeness to ensure that all involved parties such as stakeholders, lab staff, sampling staff, end data users, and EPA are included. If revisions are necessary, then the revisions must first be approved by the QAM or designee and then the revisions provided to those on the distribution list. If the revision incorporates major changes, then the entire QAPP must be redistributed. If only minor changes are made, the pages that have changed must be distributed or the changes are given as an addendum.

Inactive QAPPs are archived by the project manager. Project participants may archive their own copy for reference purposes. The project manager is responsible for ensuring everyone involved in the project has the most current version of the QAPP.

To ensure staff have a proper understanding of what is required by a QAPP or SOP, each person involved must have access to a copy of the appropriate quality document. Within EA, personnel routinely sign forms stating that they have read the SOP and agree to adhere to it. In addition, project managers and some designated bureau staff members will routinely review documentation and records as well as schedule visits of work sites. The Environmental Laboratory Certification Program periodically reviews records and documentation of regional laboratories and field staff (see Section 12 also). This helps to ensure that the work is being performed according to the governing quality documents.

SOPs used by DHEC staff for collecting and analyzing environmental samples are routinely reviewed. The analyst is responsible for ensuring they have a copy of the most recent published revision of the SOP. SOPs are reviewed by the immediate supervisor. The manager is expected to ensure that the employee has implemented any changes dictated by an approved change in a SOP and that older versions have been destroyed. Obsolete SOPs are physically removed from the staff; however, they are retained for historical reference.

Both field and laboratory SOPs are internal. There are circumstances in which the SOPs (typically for field operations) must be released outside of DHEC due to a QAPP or other requirement. This is allowed if the QAM has approved the release of the information or in response to a Freedom of Information request. The portions of the Quality System document provided must include a disclaimer stating that the document is subject to "change without notice." The document will include a watermark as an uncontrolled manuscript.

SOPs are archived according to either the QAPP defined procedure or the retention schedule for the laboratory that had generated the SOP.

The decision of when a SOP must be withdrawn is made by management with input from directors, section managers, and analysts. Withdrawal of procedures must include archiving the withdrawn SOPs and finished work plans.

12.0 Assessment and Response

The Department uses multiple tools to determine the suitability and effectiveness of the quality system and the quality performance of the environmental programs to which the quality system applies. Some of these tools include:

- Assessing the adequacy of the quality system through the annual review of time and effort expended in QA throughout EA.
- Internal assessments including informal reviews performed by assigned staff.
- Laboratory assessments including formal Laboratory Certification evaluations.
- Annual Proficiency Testing Studies for each parameter a laboratory performs.
- Assessments of facilities that provide data to the Department. These assessments are performed by regional staff and the staff of the Office of Environmental Laboratory Certification.

- Data Quality Assessments performed on data received by the Department for permit applications, permit compliance, environmental studies, and site contamination assessments.

For the quality system to be effective, personnel within the system must adhere to procedures and criteria contained in quality documents such as QAPPs, SOPs, work plans, and technical guidance. Assessments are the principal means to determine compliance with the established SOPs and QAPPs. Assessments are also essential to monitor the effectiveness and the efficiency of the QMP. Assessors must have extensive training and experience in the type of work being assessed. An assessor must not have a conflict of interest, direct involvement, or responsibility for any work being assessed. This however, does not preclude informal assessments by immediate supervisors and project managers who may assess personnel or projects to determine compliance with a QAPP or SOP.

Whether the assessment is internal or external, the assessment accomplishes the following:

- Defines and/or indicates necessary revisions to quality systems;
- Verifies compliance with SOPs and the QAPP during the term of the project;
- Identifies, prevents or remedies quality assurance problems;
- Monitors the policies and procedures involved in data gathering, generation, review, and use;
- Reviews the effectiveness of staff training;
- Determines program compliance with the quality system requirements;
- Recommends activities to improve the overall effectiveness of departmental programs and;
- Ensures that consistent policies are administered across organizational boundaries.

DHEC's Office of Internal Audits (OIA) maintains a list of internal and external audits/assessments or reviews that occur throughout the Department. The list will include the entity requesting the review, the scope of the review, and the names of those conducting the review. Additionally, OIA will serve as the repository of audit/assessment documents and finding/responses for the Department and will be a central point of contact for audit/assessment related requests. The following information must be provided to the OIA:

- Requests for assessments from outside entities or internal assessments.
- Invitations to all entrance conferences.
- Invitation to all exit conferences.
- Correspondence or reports containing assessment findings.
- Management responses to assessment findings.
- Final assessment reports.
- Correspondence or reports addressing assessment recommendations.
- Notices, reports, or correspondence that mention potential or actual non-compliance with laws, regulations, rules, contracts, grants, or other requirements.
- Reports generated from internal reviews of programs (e.g., procurement cards, grantees).
- Correspondence or reports containing self-disclosures to and from entities.
- All assessment and monitoring reports from grantees.

- Notice of any significant organizational changes impacting grant responsibilities.
- Changes in subrecipient funding, especially with the long-term subrecipients, due to potential non-compliance with grant requirements.

Internal assessments are routinely performed by immediate supervisors in verifying work and provide general oversight of their section. In the event that corrective actions are needed, the corrective actions will be documented along with a determination of whether the corrective actions were effective or not.

Assessors performing internal assessments are senior level staff. For laboratory certification assessments performed on EA regional laboratories, the assessors must be recognized by EPA as Laboratory Certification Officers for the drinking water analyses for which they are assessing. Laboratory Certification Officers' responsibilities are documented in the EPA's Manual for the Certification of Drinking Water Laboratories, 5th Edition. Results of both internal and laboratory certification assessments are reported to the appropriate laboratory director, regional director, the QAM, and the Bureau Chief for the Bureau of Environmental Health Services (BEHS). Assessments are also performed by the Office of Environmental Certification on commercial laboratories and facility laboratories that provide data to DHEC. These assessments include the review of data for SDWA, CWA, and SHW parameters. The assessment reports are sent to the laboratory's director. Management ensures that assessment reports are completed in a timely manner and are reviewed and approved by appropriate staff. The assessment report documents the required corrective actions and time frame for providing documentation that the corrective action has been implemented. The documentation must confirm the implementation and effectiveness of any corrective action. It must include the identification of root causes, determination as to whether the problem is unique or has more generic implications, and recommendation of procedures to prevent reoccurrence.

Findings that identify deficiencies in the analytical, biological, radiological, or physical data generated within DHEC shall be communicated to the QAM and the program area. The program area is responsible for notifying the end data users.

12.1. Types of Assessments and their Scope

12.1.1. Proficiency Testing (PT)

PTs are quantitative assessments of the ability of an analytical system to obtain reliable data. These assessments involve the analysis of proficiency testing (PT) samples that are used to measure a laboratory's proficiency in performing a particular method for specified parameters/analytes. The PT samples are normally annual assessments that are part of national proficiency testing programs such as the Water Supply (WS) PT Study, the Water Pollution (WP) PT Study, and the EPA's Discharge Monitoring Report-QA (DMR-QA) Study. EA utilizes the approved PT providers recognized by TNI/NELAP. The results of the PT studies are graded by the PT provider then made available to study participants and to the government organizations that have the responsibility for administering programs supported by the studies. The Department's EA Laboratories and drinking water and wastewater field staff currently participate in annual WS and WP PT studies. PTs are also required to be analyzed annually with acceptable results for all laboratories certified by the Department's Office of Environmental Laboratory Certification.

When corrective action is required for failed PT sample(s), a formal letter from the applicable program is sent to the QAM and/or the Laboratory Certification Program. This corrective action letter details the root cause of the failure and the subsequent corrective action taken. The effectiveness of the corrective action is determined by the successful participation in a second PT study. Corrective actions are tracked by the laboratory and the Laboratory Certification Program. A successful PT result must be received by SCDHEC Office of Environmental Laboratory Certification by December 31 of the calendar year. If a successful PT is not received for a laboratory by this date, the laboratory will lose certification for the affected parameter(s).

12.1.2. Technical System Assessments (TSAs)

TSAs are internal and external on-site assessments of environmental data gathering activities. The assessments are qualitative assessments of personnel, equipment, facilities, training, procedures, record keeping, data validation, data management and analysis, and QA activities. The two main purposes of the TSA are to determine that project personnel and equipment are functioning and that all procedures are being implemented as prescribed in the QAPP and other planning documents.

Internal assessments of the ARESD or DAQA laboratories are performed as requested by the QAM or designee. External assessments of DHEC's environmental laboratories and field air monitoring are conducted at three year intervals by the EPA Region 4 staff. Assessments of the Department's regional laboratories are conducted by the Environmental Laboratory Certification Program at least every three years as well as periodically by the EPA Region 4 Quality Assurance Section. Assessments of external (non-DHEC) certified laboratories that provide data to the Department are conducted by Laboratory Certification Officers of the Office of Environmental Laboratory Certification at least every three years. All certification assessments shall be conducted according to the applicable SOPs and EPA approved methodology. The EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, 5th Edition, is used as the reference for performance of assessments of drinking water laboratories.

Corrective action for a TSA consists of the following steps:

STEP 1. The party being assessed responds to the TSA report with a plan of corrective action.

STEP 2. The assessor reviews the response.

STEP 3. If the response is deficient, the assessor communicates where the corrective action plan is deficient.

STEP 4. Corrective action is closed out by the acceptance of the response and sometimes by documentation of compliance.

12.1.3. Data Quality Assessments

These are quantitative assessments in which data are reviewed and evaluated to determine the quality and usability of the data. This type of assessment may be performed by the Environmental Laboratory Certification Program or the respective Project Manager or personnel designated by the Project Manager or QAM to perform this data review. The data must be of acceptable quality as outlined in the laboratory's QA manual and/or the DQOs of the QAPP. The assessment of the data will include the review of chain-of-custody, sample collection and preservation procedures, and sample analysis raw data. In many cases, the data quality assessments are performed as part of the Laboratory Certification assessment conducted at least every three years as part of the certification renewal process. Other data quality assessments are performed by the Laboratory Certification Program as requested by the bureaus or as part of a QAPP. The bureaus also perform data quality assessments periodically to verify laboratory results submitted for regulatory compliance data and permit applications.

A report documents any findings with the data quality assessment and identifies data that is unusable. Corrective action for data quality assessments consists of rejecting the unusable data for the applicable samples, and recollection and reanalysis of pertinent samples.

12.1.4. Readiness Reviews

Prior to the beginning of a project, the project manager may elect to perform a readiness review to assess whether procedures, personnel, equipment, and facilities are ready for the environmental data to be collected. This can be something as simple as a checklist of items that must be in place prior to the beginning of a project, or as complex as a full "shake-down" period, documented in the QAPP, where project staff perform the work associated with the project. If problems are found during this shake-down, then corrective actions are put into place. If the corrective actions require a change in a QAPP, then the QAPP must be revised as per the QAPP Guidance Document.

12.2. Assessment Reports, Response, and Corrective Actions

Results of these various assessments will be reported to the appropriate Bureau Chief, ABC, Director, Project Manager, etc., with recommendations for corrective action. Alternatively, management can access the reports generated by Environmental Laboratory Certification Program through EFIS. Tracking of corrective action will be conducted in a number of ways (e.g. a response to an assessment report, a mid-year review by the specific program area, or an annual review), and the results of this tracking reported to appropriate management. In any case, corrective actions should be made promptly. The Environmental Laboratory Certification Program typically gives thirty days for a response to a TSA. This response serves as documentation of the corrective actions taken and their effectiveness. The effectiveness of the corrective actions can also be assessed by scheduling of additional assessments if necessary, by analysis of a single blind QC sample, or by participation in additional PT studies.

12.3. Disputes

Where technical issues regarding QA/QC are in dispute, the resolution will be handled at the lowest administrative level possible. If the managers and staff cannot resolve a finding, the QAM will be consulted. In some situations, it may be necessary for the QAM to consult with EPA Region 4. In the case of program issues, the QAM will communicate with the appropriate program personnel. For QA issues, the EPA QA Section in Athens, Ga. will be contacted. The QAM is the final authority for resolving internal disputes resulting from assessments. Based on the outcome of the resolution, SOPs and/or QAPPs will be revised as needed.

13.0 Quality Improvement

One of DHEC's core values is pursuing excellence. To accomplish this, staff must constantly look at improving the quality of all processes involved with environmental measurements and decision making.

Quality Improvement is achieved by:

- Anticipating problems and moving to prevent them;
- Identifying problems quickly and determining the nature and extent of the problem;
- Correcting problems as soon as practicable, by implementing the appropriate corrective actions and actions to prevent further occurrences;
- Documenting all corrective action(s);
- Tracking corrective and preventative actions to closure;
- Promoting open communication among staff at all levels;
- Promoting excellent customer service by improving communication between staff and their customers (internal or external) so that the customer's needs are understood;
- Improving communication between the Department's suppliers in order to meet the needs of the Department for defensible data; identifying process improvement opportunities and offering solutions to problems.

13.1. Addressing Quality Problems

Identifying quality problems and improving performance are key components of our quality improvement efforts. Department procedures and staff help to ensure that conditions adverse to quality are either prevented or identified quickly. The QAM is responsible for responding to and resolving quality assurance problems and needs. The QAM and/or senior staff have oversight over improvement activities.

To ensure continuous quality system improvement, the Department:

- Conducts routine internal and external assessments of its program activities;
- Initiates corrective actions to mitigate adverse conditions that compromise quality;
- Promotes problem solving and process improvement activities and suggestions;
- Encourages input and feedback throughout the planning, implementation, and evaluation processes by all staff and customers;
- Promotes tracking and documentation of corrective actions.

13.2. Communication

Effective communication is essential to ensure the success of a quality system. DHEC is committed to maintaining open communication in all aspects of planning, implementing, and evaluating its environmental programs. This is accomplished by:

- Exchange of information;
- Scheduled meetings conducted by bureaus, program committees, teams, taskforces, and workgroups;
- Program training initiatives, workshops, meetings, telecommunication, and e-mail.

13.3. Tracking the Quality System

13.3.1. Quality Management Plan

The QMP shall be kept current and revised as necessary. The QMP is to be revised on a five-year schedule, at a minimum.

13.3.2. Annual Report/Work Plan

The QAM or designee shall report QA implementation problems and progress to management and the EPA. To obtain the information needed to produce the report, each environmental monitoring program shall submit a QA report to the QAM or designee. The QAM or designee shall submit the QA report to the EPA's quality assurance officer or project officer as part of the Data Competency document.

QA reports shall contain at a minimum the following information:

- Status of QA program;
- Status of standard operating procedures;
- Data quality assessments performed to include both internal and external assessments;
- QA program resources;
- Proficiency testing results for the EA Environmental Laboratories;
- Summary of QA related training received and provided;
- Summary of the significant QA related problems and the associated corrective actions, plan(s), and the progress of on-going corrective actions, if any;
- Recommendations.

13.4. Ensuring Quality

In order to ensure that conditions adverse to quality are prevented, identified promptly, and corrected as soon as possible the following processes/procedures are used:

- Review of data by a second analyst or the manager;
- Review of data by the data users - particularly if the data is external;

- Review of SOPs, procedures, and data by the QAM;
- Meetings with staff to determine the extent of the problem;
- Workgroups to find solutions to the problems;
- Discussions with technical experts to solve problems.

Constant review of the work and work processes help to quickly identify conditions that would cause decreased data quality. Workgroups, meetings, and the assistance of experts also may help identify the complete problem and provide solutions so that the problem is quickly and effectively handled.

14.0 Quality Assurance (QA) Competency

The EPA Agency Policy Directive Number FEM-2012-02 requires organizations generating or using environmental data under Agency-funded assistance agreements or interagency agreements (if applicable) to submit documentation of their competency prior to the award of the agreement. This includes organizations performing environmental sampling, field measurements, and/or laboratory analyses under Agency-funded agreements. The following documentation must be provided to EPA to demonstrate competency:

- Quality management plan (QMP) and/or other documentation that demonstrates conformance to EPA quality program requirements;
- Demonstrations of competency in the field(s) of expertise.

Quality Assurance competency is demonstrated by the following:

- Certification by EPA for the applicable regulatory drinking water parameters/methods. This includes assessments on a triennial basis.
- Certification of satellite laboratories by the DHEC Office of Environmental Laboratory Certification. This certification includes not only drinking water, but parameters under the CWA and Hazardous Waste.
- Participation in annual PT studies for both the SDWA and the CWA.
- All field analysts participate in the PT studies for SDWA and the CWA. Each satellite laboratory selects a single analyst to be the “reporter”. This person’s results are reported for the study. All other field analysts independently analyze the PT sample for a continuing demonstration of capability. These results are documented by the Lab Director. If an analyst fails this PT sample, corrective action is initiated, and a second PT/unknown will be analyzed to demonstrate competency.
- Staff review SOPs on an annual basis. SOPs are located on the BEHS Sharepoint site and are available to employees for review.
- Internal assessments performed by senior staff.

15.0 References

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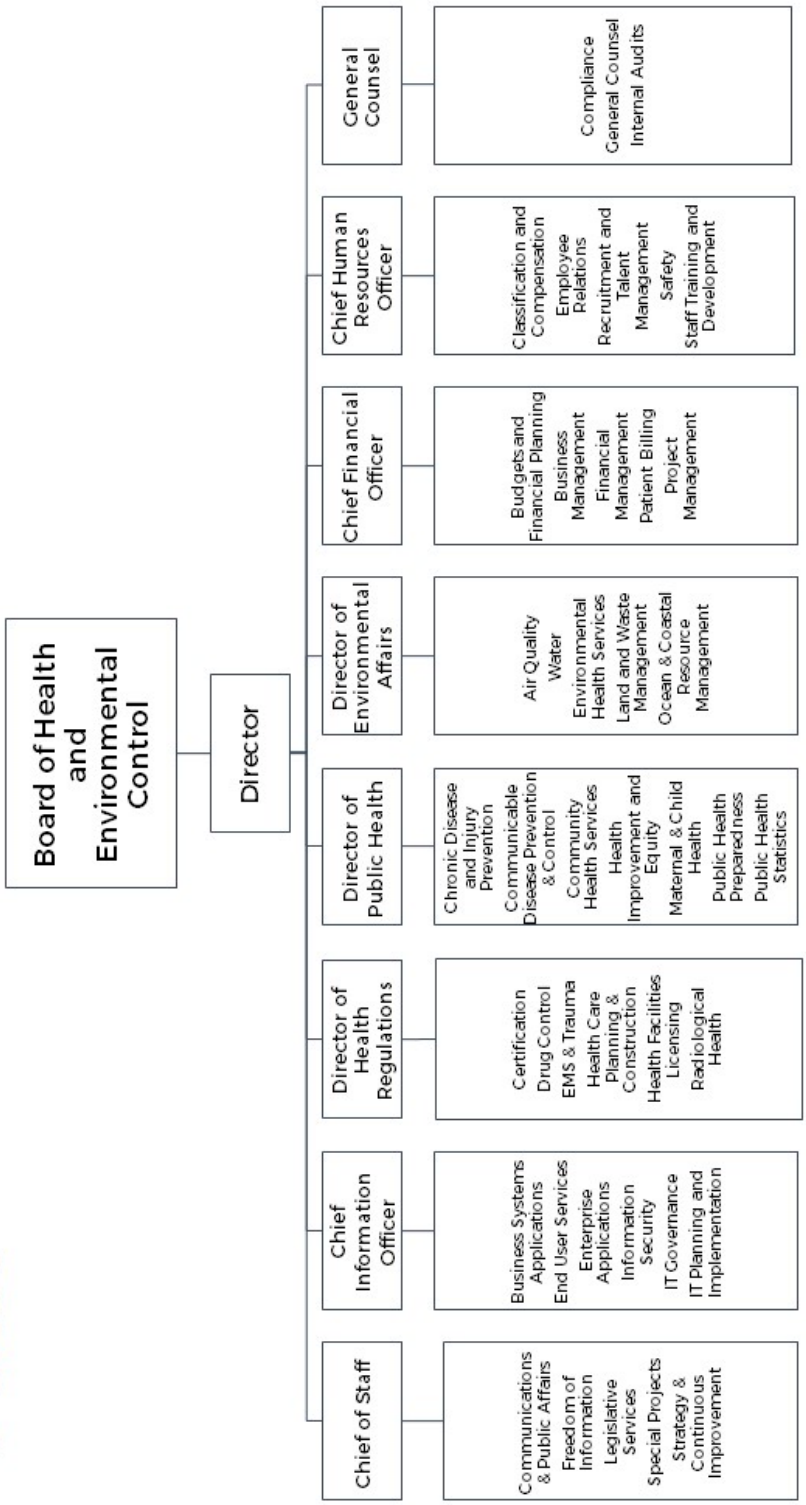
16.0 Revision History

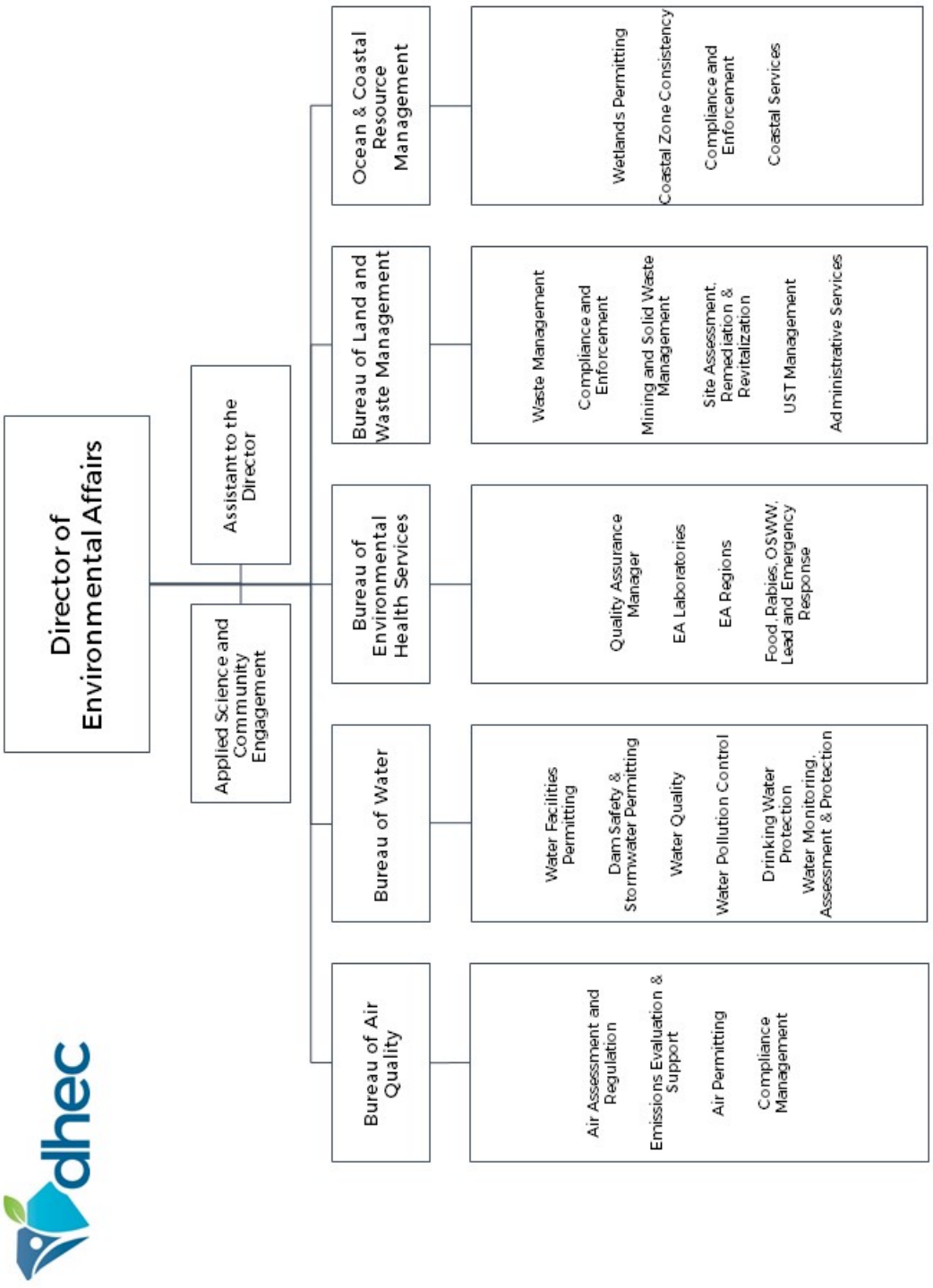
Revision #	Date	Section	Content Revised
0	2/2018	--	New Document

17.0 Appendices

17.1. Department of Health and Environmental Control Organization



17.2. Environmental Affairs Organization



17.3. Bureau of Environmental Health Services Organization