Region 4
U.S. Environmental Protection Agency
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QUALITY MANAGEMENT PLAN

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EPA Region 4 Quality Management Plan

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LIST OF ACRONYMS

ANSI-ASQ - American National Standards Institute-American Society of Quality
APTMD - Air, Pesticides and Toxics Management Division
CERCLA - Comprehensive Environmental Response, Compensation and Liability Act
CFR - Code of Federal Regulations
CLP - Contract Laboratory Program
CO - Contracting Officer
CSI - Compliance Sampling Inspection
CWA - Clean Water Act
DAO - Designated Approving Official
DMRQA - Discharge Monitoring Report Quality Assurance
DQA - Data Quality Act
DQO - Data Quality Objectives
ESAT - Environmental Services Assistance Team
FAR - Federal Acquisition Regulations
FOIA - Freedom of Information Act
GIS - Geographic Information System
IA - Interagency Agreement
IM - Information Management
IQGs - Information Quality Guidelines
NPL - National Priority List
NPDES - National Pollutant Discharge Elimination System
NTSD - National Technology Services Division
OEI - Office of Environmental Information
OPM - Office of Policy and Management (Region 4)
PAI - Performance Audit Inspection
PE - Performance Evaluation
PO - Project Officer
QA – Quality Assurance
QAS – Quality Assurance Section
QC - Quality Control
QAPP - Quality Assurance Project Plan
QAARWP – Quality Assurance Annual Report and Work Plan
QAFAP – Quality Assurance Field Activities Procedure
QMP - Quality Management Plan
RCRD - Resource Conservation and Restoration Division
RQAM - Regional Quality Assurance Manager
RA - Regional Administrator
SDWA - Safe Drinking Water Act
SESD - Science and Ecosystem Support Division
SOP - Standard Operating Procedure
START - Superfund Technical Assistance and Response Team
USACE - U.S. Army Corps of Engineers
USGS - United States Geological Survey
WPD - Water Protection Division

1.0 INTRODUCTION

This management plan documents the quality system used in EPA Region 4 as required by EPA CIO 2105.0, "Policy and Program Requirements for the Mandatory Agency-Wide Quality System" (Formerly EPA Order 5360.1 A2). CIO 2105.0 requires that each EPA Program and Regional Office develop and document a quality system to assure that environmental data used to support Agency decisions is of adequate quality and is usable for its intended purpose. This Quality Management Plan (QMP) describes Region 4's quality system. A quality system is a structured and documented management system which describes an organization's roles, responsibilities, policies, and procedures as they relate to the generation and use of environmental data and the implementation of environmental technology. The plan covers quality assurance policies, roles and responsibilities for environmental data collection activities. This includes the collection, evaluation, and use of environmental data produced by regional programs and data generated through extramural agreements. Extramural Agreements include:

- Acquisitions including: contracts, work assignments, task orders, technical directives
- Financial assistance including:
    - Cooperative agreements
    - Grants to state and local governments
    - Research grants
    - Grants to non-profit organizations
- Interagency agreements

In addition, the plan covers environmental technology which is funded by the Agency with a purpose to prevent pollutants from entering the environment or to remove pollutants from the environment.

This document is intended for use by EPA Region 4 managers and staff, as well as those organizations producing environmental data under an EPA extramural agreement. The document provides a link between quality assurance (QA) policy as defined in CIO 2105.0, and the implementation of this Agency Directive and associated procedure (EPA's Quality Assurance Field Activities Procedure (QAFAP), CIO 2105-P-02.0, 9/23/2014) in Region 4. It is important to note that this plan does not cover all Region 4 management systems, but only those which are related to the generation and use of environmental data and the use of environmental technology.

1.1 Importance of Environmental Data

Environmental data are a critical input to the Agency's decisions to protect human health and the environment. Most of the decisions which are made in the region concerning the management of the environment and reduction of risk ultimately require the use of environmental data which are generated by EPA, or by state, tribal, local government, and/or private sector organizations. Therefore, it is critically important that decision makers know the origin and quality of the environmental data used in these decisions. The quality of environmental data is known when all components associated with its derivation (precision, bias, completeness, comparability, sensitivity, representativeness, and usability) are documented.

1.2 Essential Definitions

1.2.1 Quality System - A structured and documented management system describing the quality assurance policies, practices, protocols, and procedures for ensuring that (1) environmental data are of known and documented quality; and, (2) environmental technology is designed, constructed and operated in a manner to produce the desired environmental results.

1.2.2 Environmental Data - Information collected directly from measurements, produced from models, or compiled from other sources such as databases or literature, which are used for decision making purposes. This data/information may include existing data.

1.2.3 Internal Data - Data generated by or for Region 4 programs where regional staff have primary responsibility for project or task decision making. Region 4's quality assurance system requirements apply to these data.

1.2.4 Extramural Data - Data generated by organizations other than Region 4 which are funded by EPA through extramural agreements.

1.2.5 Existing Data - any data or information available that was originally collected for a purpose different from the one for which they are intended to be used. This may be data or information:

- collected by the same project team previously for another purpose
- produced during other environmental investigations
- produced by the agency or a contractor to EPA
- produced outside EPA (extramurally),
- obtained from other document information systems
- obtained from studies

(See Chapter 3, Projects Using Existing Data, Guidance for Quality Assurance Project Plans, EPA/240/R-02/009, EPA QA/G-5, December 2002, for additional clarification.)

1.2.6 Environmental Technology - An all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and associated components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term applies to hardware-based systems; however, it also applies to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

1.2.7 Quality Assurance (QA) - An integrated system of activities including planning, implementation and assessment to ensure environmental data are of known and documented quality, and environmental technology produces the desired results.

1.2.8 Quality Control (QC) - The overall system of technical activities that measure the performance of a process or item against defined standards to ensure the process or item meets the pre-defined standards of the customer. Quality control measures also apply to engineering controls for construction and design activities.

1.2.9 Quality Assurance Project Plan (QAPP) - A critical planning document for a project, study or task, describing how data collection activities are planned, implemented, and assessed.

1.2.10 Data Quality Objectives (DQOs) - A systematic planning system designed to produce qualitative and quantitative statements that clarify project objectives, define the appropriate type of environmental data, delineate the decision rules, and specify tolerable levels of decision error.

1.2.11 Graded Approach - The process of selecting the elements needed in a project-level planning document based on the complexity of the project or study undertaken and the degree of confidence needed in the environmental data, and the intended use of the results.

2.0 REGIONAL QUALITY ASSURANCE POLICY and GOALS

2.1 Regional QA Policy

Region 4 is strongly committed to sound science and QA practices which will produce environmental data of appropriate quality to be used for decision making. This commitment is consistent with the goals of CIO 2105.0 and associated QAFAP. It is the policy of Region 4 that all decisions which are made to protect human health and safeguard the environment will be based on data of sufficient known quality to support the level of decision required. Regional policy also includes a commitment by management that the quality system supporting the generation of data of known quality and effective environmental technology will be implemented as described in this plan. The Region 4 policy is achieved by ensuring adequate and acceptable planning, implementation, and assessment procedures are utilized through all phases of projects/studies/tasks which require the generation of environmental data and/or the use of environmental technology.

Regional managers and staff will assure there are sufficient QA activities conducted by the environmental programs to provide reasonable confidence that all environmental data generated are scientifically valid; of adequate quality and quantity for the intended use; of known precision and bias; of acceptable completeness, representativeness, comparability, and usability; and where appropriate, legally defensible. Environmental data quality is the responsibility of all EPA Region 4 staff who are directly or indirectly involved in the collection, production, and use of data. Senior managers in each division will assure adequate

resources, including personnel, travel funds, and extramural funds, are available to implement the regional quality assurance system.

To effectively and efficiently utilize resources dedicated to quality assurance activities in Region 4, division and/or office staff are responsible for conducting a preliminary review of quality assurance project plans (QAPP) prior to submittal to the SESD, Quality Assurance Section (QAS) staff for review and Regional Quality Assurance Manager (RQAM) approval. However, Region 4 divisions may elect to use Designated Approving Officials (DAOs) to review and approve QAPPs. A division electing to use DAOs must clearly define protocols for their use in its divisional QMP, and ensure individuals selected to review and approve QAPPs complete DAO training.

The divisions will designate QA Coordinators. The duties and training requirements of the Quality Assurance Coordinator are outlined in Section 4.2.8 of this Plan. Their duties will be clearly defined in their respective Divisional QMP. The requirement for QA Coordinators must comply with all those defined in this QMP. Presently, QA Coordinators report directly to their first line supervisor unless otherwise stated in their respective QMPs, but receive guidance pertaining to Region 4 QA activities from the RQAM.

In addition, the divisions may designate Field Quality Coordinators (FQCs) responsible for implementation of the QAFAP. The duties of the FQCs vary by Division and are outlined in Section 4.2.9 and further defined in the Divisional QMP. The duties of the FQCs are outlined in Section 4.2.9 of this plan. Their duties will be clearly defined in their respective Divisional QMP. The requirement for FQCs must comply with all those defined in this QMP. Presently, FQCs report directly to their first line supervisor unless otherwise stated in their respective QMPs, but receive guidance pertaining to Region 4 QA activities from the RQAM.

2.2 Regional Objectives

The following are the regional objectives which serve to support the regional policy:

2.2.1 Regional QA System activities shall comply with, **ASQ/ANSI E4-2014, *"Quality Systems for Environmental Data and Technology Programs – Requirements with Guidance for Use"*** (ASQ/ANSI E4) with respect to planning, implementing and assessing quality assurance activities. It is EPA policy that all environmental programs performed by EPA or for EPA shall be supported by individual quality systems that comply fully with the ASQ/ANSI E4 specifications. In addition, all environmental technology constructed for pollution prevention, control, or waste remediation should be designed, constructed and operated according to pre-defined specifications. Specific guidance on environmental technology design, construction, and operation is found in EPA Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation, EPA QA/G-11.

2.2.2 The data quality objectives (DQO) process, or a similar systematic planning process, shall be used to plan project or study goals and objectives as related to

programmatic or regulatory requirements, and needed environmental data quality prior to the initiation of data collection activities. The Guidance on Systematic Planning Using the Data Quality Objectives Process (EPA QA/G-4), February 2006, provides a standard working tool to develop DQO for determining the type, quantity, and quality of data needed to reach defensible decisions or make credible estimates. DQOs, or similar outputs from a systematic planning process, shall be documented in a QAPP, or equivalent project-level planning document

2.2.3 QAPPs or equivalent planning documents shall be developed by those staff (either EPA or contractor) responsible for designing and implementing a project, study, or task which requires the collection or use of environmental data. QAPPs and equivalent planning documents shall meet the requirements specified in EPA's Requirement for QAPP, EPA/240/B-01/003, QA/R-5 (February 2006), and will incorporate project-specific DQOs. QAPPs will be developed using a graded approach consistent with the complexity of the project and the intended use of the data.

2.2.4 Extramural organizations which receive EPA extramural funding for environmental data collection activities, shall have an approved QMP with the requirements specified in EPA's Requirement for QMPs, EPA/240/B-01/002, QA/R-2 (March 2001) document. This document must illustrate that a quality system is in place to ensure all data collection activities are appropriately planned, implemented, and assessed. If it is determined by the divisions/programs or RQAM that a QAPP must be provided for a specific data collection activity. Then the document must comply with the requirements specified in EPA's Requirement for QAPPs, EPA/240/B-01/003, QA/R-5 (February 2006) document consistent with a graded approach. The Region has the authority to conduct oversight of organizations or their sub-organizations, and the authority to require corrective actions of both organizations in the event the Regional QA policies or objectives were not met.

2.2.5 Regional managers and staff shall receive QA training appropriate for their responsibilities related to data collection or environmental technology.

2.2.6 Communication on QA issues and activities shall be maintained between the RQAM, Regional Senior Management as appropriate, as well as with program managers, quality assurance coordinators, and staff.

2.2.7 Assessments shall be performed to determine the effectiveness of Regional and extramural quality systems.

2.2.8 QA processes shall be designed in the most resource-effective manner without compromising data quality. Continuous improvement in the quality management system shall be emphasized.

2.2.9 Projects using existing data will follow the guidance in EPA/240/R-02/009, EPA QA/G5.

3.0 REGIONAL ORGANIZATION and QA RESPONSIBILITIES

3.1 Regional Program Organization and Functions

Region 4's organizational structure is shown in Appendix A, pages 51 - 61. Major program elements and activities are shown in Appendix B, pages 62 - 65. The role of each regional program organizational unit covered by the QA requirements is briefly described below:

3.1.1 Science and Ecosystem Support Division (SESD)

The Division manages the regional quality system. The RQAM resides at SESD and is supported by SESD QATSB/QAS personnel.

This Division is one of the primary organizations within Region 4 that collects and produces environmental data. It conducts field investigations, inspections, projects, studies and assessments which often require sampling of environmental media. SESD also analyzes multi-media environmental samples; processes and evaluates multi-media environmental data; and prepares project or study reports which summarize results and/or provide conclusions and recommendations. All field and analytical activities are undertaken at the request of the regional program divisions under memoranda of agreement and work plans negotiated annually between SESD and the program divisions. Additional special projects may be requested by the Regional Administrator or other organizations. SESD performs specific QA assessments of selected external environmental monitoring projects as requested by the program divisions.

The SESD quality system encompasses all divisional QA related activities; field investigations, measurement and sampling; laboratory analyses; and management of the Regional QA Program. Within SESD, there are two (2) branches that generate environmental data and/or compliance monitoring data for the regional programs: Field Services Branch (FSB) and Analytical Services Branch (ASB). The Quality Assurance and Technical Services Branch (QATSB) personnel provides QA assistance to the regional programs including QMP and QAPP reviews, Contract Laboratory Program (CLP) data validations, etc. In addition, SESD maintains accreditation under ISO 17025, General Requirements for the Competence of Testing and Calibration Laboratories for both field and laboratory operations under one scope of accreditation.

The Agency's Science Policy Council's issued a directive on February 23, 2004, entitled "Assuring and Documenting the Competency of Agency Laboratories". The directive required all laboratories to maintain competency by documenting and maintaining a quality system which meets the requirements of CIO 2105.0, Policy and Program Requirements for the Mandatory Agency-Wide Quality System, May 2000. To demonstrate competency, the policy required EPA laboratories to (1) have periodic external assessments, (2) participate in an appropriate, recognized laboratory accreditation program when available, and, (3) participate in inter-laboratory comparison studies/programs. The SESD laboratory continues to meet the requirements of the Laboratory Competency Policy by maintaining its accreditation under ISO 17025.

The laboratory's quality system is documented in a QMP entitled "Analytical Support Branch Laboratory Operations and Quality Control Manual" dated April 24, 2017.

3.1.2 Air, Pesticides & Toxics Management Division (APTMD)

The Division manages the program for and implements the Clean Air Act (CAA); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); and the Toxic Substances Control Act (TSCA), except for TSCA Polychlorinated Biphenyls (PCB) managed by the Resource Conservation and Restoration Division (RCRD). APTMD also serves as the technical/program authority for all monitoring activities associated with these programs. It ensures that QA matters are reflected in budgets, program plans, and work/operating plans. The Division manages grants, contract funds, and cooperative agreements, and overviews external environmental monitoring programs which require the collection of environmental data. SESD provides the APTMD with technical assistance relevant to monitoring and data processing activities, including QA oversight.

3.1.3 Superfund Division

The Division manages the program for and implements the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) and the Oil Pollution Act (OPA) of 1990, including Emergency Response Programs. It manages federal grants and contract funds. The Division ensures QA matters are properly reflected in budgets, program plans, and work/operating plans. It serves as technical/program authority for all hazardous waste environmental monitoring activities within the geographical boundaries of Region 4. The data arising from these programs are the product of efforts both internal and external to the Region. The Division provides oversight for external environmental monitoring programs which require the collection of environmental data. SESD provides the Superfund Division with technical assistance relevant to the collection of environmental data, including QA oversight. This includes regional management of the CLP, data validation of CLP analytical data and regional contract laboratory data, management of the Environmental Services Assistance Team (ESAT) contract, systems audits of state field and laboratory activities, and overview of potentially responsible parties' remedial actions at CERCLA sites.

3.1.4 Resource Conservation and Restoration Division (RCRD)

The Division recommends goals, priorities, and objectives for the Resource Conservation and Recovery Act (RCRA), the Oil Pollution Act (OPA) of 1990, and the Small Business Liability Relief and Brownfields Revitalization Act programs to the Region 4 Regional Administrator, the Office of Land and Emergency Management (OLEM) and the Office of Enforcement and Compliance Assurance (OECA). Major program areas include RCRA Enforcement and Compliance, OPA Enforcement, RCRA Corrective Action, RCRA Permitting, Underground Storage Tanks, Brownfields, Solid Waste Management, Materials Management and the National

Environmental Policy Act (NEPA). It assists the States in developing comprehensive programs within delegated or related program areas including providing or arranging for technical assistance to state and local agencies in developing necessary plans, monitoring systems, instrumentation, data collection and analysis systems, and emergency response, including imminent hazards. The Division represents the Region in carrying out the implementation of programs for which it is responsible. The Division is comprised of three branches: Enforcement and Compliance; RCRA Cleanup and Brownfield; and Materials and Waste Management, and the NEPA Office.

SESD provides the RCRD with technical assistance for monitoring and data collection and interpretation activities, including QA oversight. Also, SESD conducts Comprehensive Groundwater Monitoring Evaluations and Compliance Enforcement Investigations at RCRA facilities, provides technical assistance and training to States/Indian Tribes/Region 4 RCRA program personnel and conducts system audits of state field and laboratory activities.

3.1.5 Water Protection Division (WPD)

This Division has the program and implementation responsibilities for the Safe Drinking Water Act (SDWA), Clean Water Act (CWA), ambient surface water and groundwater, underground injection control, estuarine waters, off-shore discharge, and domestic and industrial wastewater treatment programs. It is responsible for oversight of delegated permitting and compliance as well as the delegated enforcement for municipal and industrial wastewater treatment facilities. The Division manages federal grants and contract funds. It ensures QA matters are properly reflected in budgets, program plans, work/operating plans. WPD serves as the technical/program authority for all water-related environmental monitoring activities within the geographical boundaries of Region 4. The data arising from these programs are the product of efforts both internal and external to the Region. The Division provides oversight for external environmental monitoring programs which require the collection of environmental data. SESD provides the WPD with technical assistance relevant to monitoring and data collection and interpretation activities, including QA oversight. This includes oversight of State/Tribal/Local fixed, ambient water monitoring networks' special ambient water studies' performance audits on water and wastewater field monitoring and laboratory operations' National Pollutant Discharge Elimination System (NPDES) compliance inspections and oversight inspections; and systems audits of state field and laboratory activities.

3.1.6 Office of Enforcement Coordination (OEC)

This Office has the overall planning, accountability and coordinating responsibilities for enforcing the various environmental statutes which the Region implements. These responsibilities include: (1) integrating compliance assurance activities to facilitate multi-media projects at the Regional and State/Tribal/Local levels; (2) performing the planning and targeting necessary for the Region's compliance assurance plan; (3) assisting the media programs in developing strategies and tools for assisting the

regulated community in achieving compliance with Agency statutes; (4) supporting the environmental compliance activities on Tribal lands; and (5) coordinating with our State counterparts on environmental enforcement issues.

The activities of the OEC do not normally require monitoring or measurement activities which involve data collection.

3.1.7 Office of Policy and Management (OPM)

This Division administers human resources management, budget and finance, procurement and grants administration, information management, and planning and analysis.

Within OPM's Facilities, Grants & Acquisitions Management Branch (FGAMB), the Grants and Audit Management Section manages the business aspects of grants administration. This includes the award and administration of funded projects (from project initiation through final close-out).

Within the FGAMB, the Acquisitions Management Section contracts for goods and services. Implementation of quality standards for contracts is defined in CIO 2105.0, as well as the EPA Acquisition Guide.

OPM's Information Systems and Management Branch develops and implements policies and guidance to ensure information management (IM) resources are efficiently, economically and effectively utilized throughout the Region. The Branch reviews and approves requests for IM acquisitions and services to ensure conformity with policy directives and specifications. This organization also provides management and operational support for the integration of environmental data into Geographic Information Systems (GIS). GIS are software and hardware systems used by media programs and support organizations to more efficiently and accurately analyze and interpret environmental data. While the Environmental Information Services Branch does not generate environmental data, it cooperates with the appropriate media program to assure that the data used in GIS, computer models and databases are suitable for their intended use.

SESD provides OPM with technical assistance by reviewing QAPPs, QMPs, and contract Scopes of Work.

3.1.8 Gulf of Mexico Program

The Gulf of Mexico Program (GMP), initiated in 1988, is a non-regulatory program. Organizationally, the program falls within the Region 4 management structure. The program was developed because no single agency or level of government had either the necessary technical or financial resources or the legal mandate to address the spectrum of environmental and public health issues facing the Gulf. The Gulf Program is a collaborative effort including a consortium of stakeholders sharing significant interests in coastal and marine resources. The GMP's ecosystem-based approach brings the

appropriate science, together with the financial and technical resources, to help the Gulf States and coastal communities address their environmental problems within a broader regional and national context.

The GMP leads federal research, monitoring, scientific analysis, and financial resources supporting state and community actions that benefit the Gulf and its communities. The GMP engages in activities such as monitoring water quality in watersheds that flow into the Gulf. Staff are involved in managing grants and interagency agreements, providing technical/scientific support to stakeholders within the Gulf region, and coordinating/conducting scientific studies to achieve common goals. Environmental data are collected in partnership with Gulf communities to assess and solve environmental issues in the community.

SESD provides GMP with technical assistance, as appropriate, by reviewing QAPPs, QMPs, and contract Scopes of Work. GMP has certified DAOs to approve QAPPs and works with EPA Region 4, EPA Region 6, and other appropriate EPA locations to ensure required partner QA documents are approved. GMP's work with partners as a geographic great water body program naturally occurs in multiple EPA regions that make up the Gulf of Mexico watershed. GMP defers as much as possible to R6's QMP for consistency when working with entities in Louisiana and Texas (this helps GMP partners in those states have consistency in their QMP/QAPP development and expectations as they normally work through R6). GMP currently uses the R4 QMP as the GMP QMP. Because many of GMPs funded projects collect a minimal amount of environmental data, QAPPs and QMPs are developed using a graded approach consistent with the complexity of the project and the intended use of the data.

3.1.9 Office of Environmental Justice and Sustainability

The Office of Environmental Justice and Sustainability (OEJS) is located in the Office of the Regional Administrator. OEJS works collaboratively with the Headquarters, Office of Environmental Justice, internal and external stakeholders to address public health issues and concerns in minority, low-income, tribal and other vulnerable communities through the EPA Environmental Justice (EJ) Collaborative Problem-Solving Grants Program and the EJ Small Grants Program. Both programs provide financial assistance to assist communities develop and implement solutions to significantly address environmental and/or public health issues at the local level. Historically, resources from these programs consist of grant awards up to $120,000 through the EJ Collaborative Problem-Solving Grants Program and up to $30,000 through the EJ Small Grants Program. Additional resources include technical assistance, mapping tools and training materials.

3.2 Quality Assurance Responsibilities

Regional managers and staff have the following responsibilities for the quality system:

3.2.1 Regional Administrator (RA)

The RA has the overall responsibility for the development, implementation, and continued operation of the Regional QA Program. The authority for managing the day-to-day QA activities within the Region is delegated to the Regional Quality Assurance Manager.

3.2.2 Regional Quality Assurance Manager (RQAM) and SESD Quality Staff

The RQAM was delegated oversight of the Region 4 Quality System. The RQAM, administratively reports to SESD's QATSB Chief and is independent of any data generation activities within SESD or the Region. The RQAM serves the official Regional contact for all

QA matters within Region 4 by providing advice, guidance, assistance and training as needed or requested by regional managers and staff. Specifically, the RQAM:

- Facilitates development of the Region's QMP and prepares updates to the approved QMP;
- Represents the Region at national quality meetings, such as the RQAM monthly conference call, national QA conferences, etc. Also, serves as primary Regional Liaison with the Office of Environmental Information (OEI), Environmental Quality Management Division (OEI EQMD);
- Provides expert assistance to regional staff on QA/QC policies, requirements, and procedures applicable to technical activities/services;
- Provides, schedules and/or notifies Regional staff of required QA training;
- Advises staff on development of QAPPs for internal data. This may include explanation of and/or review of the data quality objective process. The RQAM will not review a QAPP in which he/she has assisted in its development, but will delegate the review to another staff member.
- Reviews and approves QAPPs for internal and external Regional data operations.
- Reviews and approves QMPs submitted by Region 4 Divisions and Offices and by holders of extramural agreements;
- Oversees Regions 4's field quality management system for compliance with EPA's QAFAP, CIO 2105-P-02.0, 9/23/2014;
- Performs periodic assessments of Regional organizations that conduct environmental data operations to determine the conformance of their mandatory quality systems to their approved QMPs and applicable standard operating procedures, and the effectiveness of their implementation;
- Coordinates and/or conducts system and performance audits of selected environmental monitoring programs.
- Coordinates and participates in the OEI EQMD review of the Region 4 quality system;
- Coordinates and submits the Annual QA Report and Workplan to Region 4 Senior Management and OEI EQMD;

- Distributes Agency QA guidance documents, policies, and procedures;
- Initiates and/or revises Regional QA policy & procedures; and
- Briefs senior staff on QA issues on an annual basis or more often as needed.

In addition to the RQAM, SESD QATSB/QAS personnel perform the following functions for the entire Region:

- Conduct assessments of State, Tribal and other external partner quality management systems.
- Review QMPs and QAPPs and recommend approval status of these plans to the RQAM.
- Perform laboratory assessments of state, commercial, tribal, and/or other government laboratories as required by SDWA, CWA, and CLP. The Region 4 CLP contracting officer representative (COR) is in SESD QATSB/QAS.
- Overview of the regional Drinking Water Certification program. The Certification Authority for the State Primacy Laboratories and Satellite labs is the responsibility of the Regional Administrator (RA) in the Region. The Region 4 RA has delegated this authority to the SESD Division Director. The Regional Drinking Water Certification Officers are in SESD QATSB/QAS.
- Perform assessments, including management system assessments, data quality audits, and performance audits.
- Manage and administer the regional ESAT Contract which includes overview of data review and validation and other QA activities conducted under this contract.
- Provide technical and quality assurance training to Region 4 staff and entities external to EPA.
- Provide technical assistance/support to the RQAM to meet the requirements addressed in this QMP.
- A designated SESD QATSB/QAS staff member serves as the regional Alternate Test Procedure (ATP) Coordinator for NPDES and Wastewater. Responsible for approving alternative testing procedures to those procedures required in EPA approved testing methods. Works in conjunction with the EPA Office of Water staff in this process.

Personnel from the SESD, Field Services Branch, perform QA assessment activities, including technical system assessments, data quality audits, performance audits, and technical/QA training for the Clean Air Act, CERCLA, RCRA, and the Clean Water Act.

The RQAM may require suspension of environmental data collection projects and request corrective action if data quality/environmental technology QA activities do not meet Agency QA policy or requirements. If the RQAM determines that any regional data collection activities (at the project or program level) do not meet Agency quality assurance policies or requirements, the RQAM shall make every effort to resolve disputes through discussion and negotiation. Disagreements will be resolved at the lowest administrative level possible. Should agreement not be reached at this level, the RQAM, after briefing the SESD Director, shall elevate the issue to Senior Management for resolution. The RQAM has the authority to directly and independently interact and communicate with the Deputy Regional Administrator (DRA) on all QA matters. This direct access to the DRA allows the RQAM to independently elevate critical quality-related issues at his/her discretion without challenge. The RQAM does not need

approval or pre-notification to initiate such communication. The RA/DRA shall have final dispute authority on all quality issues.

The RQAM utilizes the Regional QA staff including Quality Assurance Section, QA Coordinators and Field Quality Coordinators to assist in the day-to-day implementation of the Regional quality system. QA staff has access to appropriate levels of management to address all QA matters. They will use commonly accepted practices, such as starting with the lowest possible level of management and escalating to higher levels of management only as necessary, to resolve conflicts. The QA staff is expected to notify the RQAM whenever any level of management involvement is needed to resolve QA issues.

3.2.3 Regional Managers

Division/Office Directors ensure that internal and extramural data collection activities within their programs are conducted in accordance with Agency and Region 4 QA policy. QA management is the daily responsibility of the appropriate second or first level managers (i.e., Branch and Section Chiefs). Within their area, line managers establish procedures in their Divisional QMP to ensure the acceptability of data and the suitability of environmental technology. Managers will:

- Establish planning policies to ensure that appropriate QA procedures are reflected in budgets, program plans, and operating plans.
- Encourage the development of Data Quality Objectives (DQO's) for data collection activities.
- Require the development of QAPPs or an equivalent project-level planning document for projects involving data collection.
- Support regional quality system implementation and assessment.
- Take corrective action as required by QA assessments or reviews.
- Report data quality problems to the RQAM. Assure personnel receive appropriate QA training by working with the RQAM on the development of a training curriculum for staff. This training curriculum will be included in the Divisions/Offices QMP.
- Managers and supervisors will be expected to include staff QA training needs in employee Individual Development Plans. The Learning and Development Institute (LDI) maintains electronic records of all the training provided by the Institute and this information is available to both the employee and their manager/supervisor.
- Ensure that QA responsibilities of the RQAM are included in his/her performance appraisal system (PARS).
- Select, monitor and insure appropriate training is provided to Designated Approving Officials as defined by the RQAM.

3.2.4 Quality Assurance Coordinators (QA Coordinators)

Each Division director will appoint at least one manager or staff person to serve as the QA Coordinator for his/her Division. QA Coordinators are the central contact person for the division or office for all matters related to QA and serve as champions of QA activities within their respective Divisions. The RQAM and the QA Coordinators will work together

to ensure that an effective quality system will be consistent in all Region 4 Divisions. The QA Coordinators will:

- Serve as the official Division/Office contact for quality assurance matters pertinent to the data collection activities of that Division/Office.
- Attend the initial QAPP, QMP, DQO training classes, along with the workshop classes for the Region 4 QMP.
- Attend quarterly QA Coordinators' meetings convened by the RQAM to keep abreast of QA issues affecting the Region and Agency. Communicate QA issues to Division/Office personnel.
- Attend Regional QA training provided by the RQAM in the Region as appropriate.
- Respond to quality control issues and problems, and respond to requests for guidance or technical direction.
- Work with the Division's staff to develop and maintain an effective QA program.
- Responsible for the preparation and review of their Divisional/Program QMP.
- Advise the RQAM on changes needed to the Regional QMP.
- Coordinate Division/Program input for the Regional QA Annual Report and Work Plan (QAARWP) submitted by the RQAM to OEI EQMD Director. The report will be in the framework of QA Metrics measuring all QA inputs, activities, interim outcomes, and outcomes.
- Maintain an inventory of QAPPs for their Division/Office for tracking purposes, if the Designated Approval Authority has approved QAPPs in their division. The QA Coordinator will not be responsible for reviewing, or approving QAPPs and QMPs. If questions for review, inventory, oversight, etc. are involved concerning QAPPs or QMPs, the RQAM or designee should be contacted for assistance.
- Work with the RQAM or designee to maintain an accurate and up-to-date list of DAOs for their Division/Office.

3.2.5 Regional Project Managers

Project Managers, however named, are responsible for specific internal regional projects. Therefore, the Project Manager ensures that project objectives are met and that the data collected to support project decisions meet national and regional QA requirements. The Project Manager:

- Prepares or directs the preparation of a QAPP (or equivalent planning document) for each project and submit the QAPP to the RQAM or a Divisional DAO for review and approval.
- Prepares or approves Data Quality Objectives, technical and quality assurance specifications, and acceptance criteria for environmental data needed to support project decisions.
- Participates in conducting QA system/performance audits of projects as requested by the RQAM.
- Takes corrective action that may be required by audit findings.
- Reports data quality problems to the regional QA Coordinator located within the appropriate Organization/Program and the RQAM.

- Attends appropriate regional QA training provided in the region.
- Reviews QAPPs that are submitted to the Region as part of EPA's documentation requirements. The QAPP is to be reviewed using the appropriate QAPP Review Checklist. See Appendix C, pages 66 – 79, for QAPP Review Checklist.

3.2.6 Regional Project Officers/Contracting Officer Representatives

Project Officers (POs) are accountable for specific extramural assistance agreements while Contracting Office Representatives (CORs) are accountable for contracts. Therefore, while the POs/CORs are normally not directly involved in project activities, the POs/CORs ensure that all Agency QA requirements are met by the assistance agreement recipient or contractor. The POs/CORs:

- Require preparation of a QMP, QAPP, and/or equivalent document, as appropriate, for each assistance agreement or contract.
- Overview data quality generated from external projects funded through financial assistance agreements and/or contracts.
- Complete the required QA Review Form (QARF) in accordance with Chapter 46 of the EPA Acquisition Guidelines. (CORs only)
- Participate in conducting QA system and performance audits of projects as requested by the RQAM.
- Coordinate review of external QMP and/or QAPPs and submit to RQAM for review and approval.
- Take corrective action that may be required by audit findings.
- Report data quality problems to RQAM and the appropriate QA Coordinator.
- Attend appropriate regional QA training.
- Review QAPPs that are submitted to the Region as part of grant/assistance agreement and contract requirements.

3.2.7 Regional Program Technical Staff

Technical staff support the RQAM by providing technical assistance in their area of expertise if requested by the RQAM. This enhances the QA capability in Region 4. The specific duties assigned to the technical specialists are to:

- Assist the RQAM with technical aspects of QA as related to their expertise in air, water, toxic substances, hazardous waste, engineering, chemistry, biology, microbiology, field operations and data operations.
- As needed, review technical aspects of QAPPs that are submitted to the Region as part of grant/assistance agreement and contract requirements.
- Identify QA needs, resolve problems, and answer requests for guidance or assistance in area of expertise.
- Conduct and/or participate in on-site field and laboratory system and technical audits.

- Participate in technical assistance and training of State/Tribal/local, and private laboratory personnel in EPA methods, instrumental and QA requirements.

3.2.8 Designated Approving Officials

A Designated Approving Official (DAO) is a regional manager or staff person who has been delegated the authority by the RQAM to approve QAPPs The DAO is expected to review the QAPP to ensure that it is compliant with the requirements specified in EPA's QA/R-5 document, and follow prescribed procedures for reviewing, documenting, and approving QAPPs and must attend the DAO training course coordinated by the RQAM. Each division/office must include the protocols for DAOs in its QMP and such protocols must conform to those outlined in this QMP. Managers and supervisors are responsible for identifying prospective DAOs within their organizations.

To receive and maintain certification as a DAO, the individual must fully meet the following requirements:

Prospective DAO Education and Technical Knowledge

1. Should have at least a Bachelor's Degree in any of the physical or biological sciences, environmental engineering, or demonstrate an in-depth understanding of these disciplines based on hands-on job experience obtained internal or external to the agency.
2. Possess a clear understanding of the analytical methodologies or biological analyses/determinations usually employed for environmental investigations and must be familiar with sampling techniques and QA requirements. If biological parameters require collection and analysis/determination, the prospective DAO must either consult with the RQAM, or designated SESD QATSB/QAS staff on these issues or must be familiar with the requirements for collecting this information to approve the QAPP.
3. A firm knowledge of EPA program and regulatory requirements as appropriate to the program, is necessary.
4. Possess the necessary expertise in project management to review the QAPP.
5. The prospective DAO must have no direct conflict of interest. A project manager who writes a QAPP for a project under his/her direction cannot approve that same QAPP.
6. The QAPP review process must be documented using a checklist developed by SESD QATSB/QAS (See QAPP checklist in Appendix C), or similar program-specific checklist, and include specific comments addressing document deficiencies as needed.

Training Requirements and Certification Process

1. Satisfactorily complete an initial 4-hour training course provided by SESD QAS staff on QAPP requirements and review, Data Quality Objectives (DQO), and the QAPP Checklist.
2. After completion of the initial training, the prospective DAO must complete and submit the DAO Technical Competency Form to the RQAM documenting his/her educational and technical knowledge.
3. The RQAM reviews the form for completeness and competency.
4. Upon approval, the RQAM forwards the Technical Competency form to the designated SESD QATSB/QAS staff for filing and development of the DAO certificate. The DAO certificate will then be emailed to the DAO with a copy to the respective divisional QA Coordinator. The SESD QATSB/QAS staff will track the status of the DAOs.
5. To maintain continuing certification, the DAO must attend annual DAO refresher training available on-line via the EPA e-Learning or by webinar, as scheduled.
    a. Annual refresher training must be completed by the end of the following calendar year.
    b. If the annual refresher training is not completed by December 31st, the DAO certificate will expire and the DAO will not be allowed to approve QAPPs. To be re-instated as a DAO, the initial training must be re-taken and a new Technical Competency form submitted to the RQAM for approval.
6. DAO certification is not allowed to transfer into other programs. If the DAO moves to another program, he/she must be retrained and re-certified in that new area/program. If the DAO is current in his/her refresher training, he/she will not be required to re-take the initial DAO training, but must demonstrate the necessary technical competency in the new program area.

3.2.9 Field Quality Coordinators

The FQCs ensure the Region implements and maintains a quality management system in conformity with the QAFAP requirements. Duties may vary by division but include the following:

- Oversees all aspects of QAFAP implementation within their division/program.
- Works with subject matter experts to ensure development of applicable program-specific technical SOPs.
- Assists the RQAM with the coordination of internal/external audits and ensures corrective actions are initiated and completed.

  Communicates regularly with management concerning the status of the quality management system and make recommendations for improvements.

- Reports on the performance of the Management System to divisional QA Coordinator, Regional Senior Managers, and RQAM as needed.
- Provides input for the Annual QA Report and Work Plan.

4.0 REGIONAL QUALITY SYSTEM REQUIREMENTS – EXTERNAL ORGANIZATIONS

4.1 State, Local, and Tribal Grants

A substantial amount of environmental data required by EPA statutes and regulations are generated by state, local, and tribal organizations receiving one-time or continuing environmental grants. To qualify for financial assistance, state, local, and tribal organizations must meet the QA requirements in 2 CFR 1500.11.

4.1.1 To satisfy the QA requirements in 2 CFR 1500.11, the assistance agreement recipient must submit a QMP for review and approval (at a minimum of every 5 years) by the RQAM and the appropriate assistance agreement Project Officer (PO). If there are significant organizational changes, delegation authority modifications, etc., then a QMP will need to be updated to reflect those changes and submitted for approval prior to the five-year cycle. For a grantee's QMP to be approved, the grantee's quality system must meet the specifications of EPA Requirements for QMPs (EPA QA/R-2), March 2001 (or most recent edition). If grantees make sub-awards (either sub-grants or procurement) under an assistance agreement, they must ensure that the sub-awards meet the quality assurance requirements in EPA QA/R-2.

4.1.2 Clarifying language provided by EPA's Office of Grants and Debarment also requires the grant recipient to provide a QAPP in addition to the QMP. In addition, for continuing grants such as performance partnership grants (PPGs), where a single grant may cover several projects or studies and programs, each of these projects or studies will require a QAPP to meet the grant conditions. QAPPs will be developed using the graded approach depending on the complexity and intended use of the data being collected. Where grants are awarded to fund numerous, similar projects by the same organization, the preparation of a program-level QAPP in lieu of numerous individual project QAPPs may be appropriate. The management within the program will make the determination when a program-level QAPP is appropriate.

4.1.3 While state, tribal and local agencies are responsible for managing the QA programs under their grants, the Region retains overview responsibilities. The major overview functions are work plan reviews, program evaluations, and quality assurance assessments. QA input for these overview functions include QMP review/approval, QAPP implementation, and may include on-site QA audits of environmental programs, field activities, and laboratory operations. State program overview is the primary responsibility of the individual regional program division/office with extensive assistance from the RQAM and SESD personnel.

4.2 Academic, Hospital, and Non-Profit Grants and Cooperative Agreements

2 CFR 1500.11 contain QA requirements for grants and cooperative agreements with institutions of higher education, hospitals and other non-profit organizations. These grants are usually one-time assistance agreements as opposed to the continuing grants awarded to state, local and tribal organizations. The academic/non-profit QA requirement is satisfied by the grantee's submission of a QMP and QAPP, with subsequent approval of the QMP and QAPP.

The QMP and QAPP may be combined into a single document if the RQAM and Project Officer agree that the nature and extent of the environmental data collection effort warrants such action. QMPs and QAPPs will be approved by the RQAM and the appropriate Project Officer(s). It is recommended that QAPPs be approved prior to award. However, if the QAPP is not approved prior to award, then the assistance agreement will be conditioned to require an approved QAPP before data collection begins. If grantees make sub-awards (either sub-grants or procurement) under an assistance agreement, they must ensure that the sub-awards meet the quality assurance requirements specified in EPA's QA/R-2 document.

4.3 QA Operations for Interagency Agreements

For interagency agreements, before funding for environmental measurements or data collection activities is approved, EPA Region 4 and the other involved organizations must have agreed upon the QA requirements for the project. The organization receiving the funds is responsible for preparing the QMP or equivalent document. If the external organization's documented quality system meets the requirements found in the EPA Requirements for QMPs, EPA QA/R-2, March 2001 or the Intergovernmental Data Quality Task Force: Uniform Federal Policy for Implementing Environmental Quality Systems, EPA-505-F¬03-001, March 2005, its QMP, or equivalent document shall be acceptable. If comparable QA procedures do not exist, the QA procedures agreeable to both parties must be negotiated for the Interagency Agreements. Before any environmental data operations can be performed, the external organization must have an approved QMP and QAPP (or equivalent documents) or successfully negotiated and acceptable to both parties. These QA requirements are in accordance with the specifications provided in EPA Requirements for QAPPs, EPA QA/R-5, March 2001, or the Intergovernmental Data Quality Task Force: Uniform Federal Policy for QAPPs, EPA-505-B-04-900A, March 2005, as appropriate.

The QAPPs will be prepared post-award and will be reviewed and approved by either the RQAM or a Designated Approving Official. Upon completion of the monitoring activities, the Project Officer shall assess the data quality of the planned activity. If data quality issues arise with the collected data, these issues shall be communicated to the RQAM or designee for resolution.

4.4 Quality Management Plans for External Organizations

The following requirements must be met by those organizations submitting QMPs to Region 4 for grants, contracts, and cooperative agreements:

4.4.1 The QMP must satisfactorily address the main topic areas addressed in "EPA Requirements for Quality Management Plans," EPA QA/R-2, EPA240/B-01/002, March 2001, or most recent version.

4.4.2 QMPs must include a description of review and approval process for project or study-specific QAPPs covered by the assistance agreement. QMPs will be reviewed by the RQAM, SESD QATSB/QAS personnel and the appropriate assistance agreement project officer. The appropriate assistance agreement project officer will coordinate the review of the QMP for their specific extramural agreement. QMPs shall be approved for a period of no longer than five years.

4.4.3 The Facilities, Grants and Acquisitions Management Branch (FGAMB) within the Office of Policy and Management will review extramural agreements prior to award to ensure that all Agency quality requirements have been documented. The RQAM will provide GAMS staff and regional project officers with a listing of approved QMPs and the expiration dates for State and Tribal continuing assistance agreements.

4.4.4 Only the RQAM may approve an external organization's QMPs.

4.5 Quality Assurance Project Plans for External Organizations

The following requirements must be met by those organizations submitting QAPPs to Region 4 for grants, cooperative and interagency agreements:

4.5.1 The QAPP must satisfactorily address the topics specified in the document entitled "EPA Requirements for Quality Assurance Project Plans", EPA QA/R-5, Final, February 2006, or most recent version.

4.5.2 In reviewing QAPPs, the RQAM or Designated Approving Official will use the graded approach, where appropriate, recognizing that each data collection project or study is different. Simpler projects may require QAPPs which are not as detailed as those covering more complex projects.

4.5.3 The document entitled "EPA Guidance for Quality Assurance Project Plans" EPA QA/G-5, Final, December 2002, or most recent version, provides detailed information for preparing an EPA required QAPP document.

5.0 REGIONAL QUALITY SYSTEM - INTERNAL ORGANIZATIONS

This section describes the quality system requirements for environmental data generated within Region 4's programs/organizations (internal data). An overview of the quality system policies, procedures, roles, and responsibilities are described in this QMP. According to CIO 2105.0, "All Agency organizational units governed by CIO 2105.0, shall document their quality system in a QMP. The QMP is a policy statement describing how an EPA organization shall comply with the requirements of EPA CIO 2105.0. The QMP provides the blueprint for how an individual EPA

Program Office, Region, and National Laboratory or Center will plan, implement and assess its quality system for the environmental work to be performed as part of its mission."

5.1 Divisional Quality Management Plans (QMPs)

To ensure that Region 4 divisions and programs are adhering to the requirements and specifications outlined in the CIO Policy and the Regional Quality System/QMP, each division will develop and implement a QMP tailored to its management structure, QA policies, procedures and practices. Each QMP will provide:

5.1.1 The clearly delineated management structure of each division, and clearly defined roles (including DAOs and QACs) and responsibilities of division/program management, personnel and contractors.

5.1.2 An overview of data collection operations that are fully compliant with EPA's data quality objective process as outlined in EPA's QA/G-4 document.

5.1.3 The specific measurements undertaken by the division for determining the effectiveness of the divisional quality system in meeting regional goals and objectives as outlined by the RQAM or the RA. If deficiencies in the quality system are identified, the division must develop and implement a corrective action plan to mitigate deficiencies.

5.1.4 A detailed plan for overseeing, on an annual basis, the technical, programmatic and QA functions of State, Local and Tribes receiving EPA grant or assistance agreements.

5.1.5 The internal management, technical and QA assessments performed by divisional/program staff to identify any areas of vulnerability or non-compliance with divisional or regional requirements.

5.1.6 The system of documenting and communicating assessment findings to divisional/programmatic management. Assessment findings shall be reported to divisional management, senior management and the RQAM. Corrective measures in the form of recommendations and/or corrective actions will be implemented to mitigate vulnerabilities or non-compliance issues.

5.1.7 Delineate the process for overseeing State, Local and Tribes that have been delegated self- approval authority for QAPPs prepared within divisions/programs. The division QMP shall specify the number, type and frequency of QA oversight activities or assessments. The RQAM will ensure that the divisions and/or programs comply with Region 4 requirements for maintaining delegated self-approval authority.

Note: Currently, no State, Local or Tribal programs have received delegation for self-approval authority. However, before Region 4 would delegate this responsibility to the State, Local and Tribes, the RQAM would seek guidance from EPA OEI before implementation.

At the project level, the Region relies on project level quality documentation to describe project quality assurance and quality control procedures: the QAPP. It is generally recognized within the Region that other technical project level work plans, however named, must be equivalent to and compliant with the QAPP requirements specified in EPA's QA/R-5 document. For example, in the Superfund program, a Sampling and Analysis Plan may be used to document project level technical activities.

5.1.8 Divisional QA Coordinators are responsible for the preparation and review of its respective divisional QMPs. Draft QMPs must be submitted to SESD QATSB/QAS for review. Following review by the designated SESD QATSB/QAS personnel, the RQAM will review the draft divisional QMP. The RQAM approves all divisional QMPs.

5.2 Internal Data Operations

EPA Project Managers or their designees are responsible for preparing QAPPs when the projects involve the collection of environmental data or the use of environmental technology. The RQAM is available to assist in the development of QAPPs by discussing the Agency's requirements for QAPPs, but will not directly participate in writing the plan. The RQAM or his/her designee shall review and approve all QAPPs for internal data collection prior to the initiation of field operations.

5.3 QA Operations for Contracts

Since the mission of the regional programs is to protect human health and the environment rather than to produce a manufactured product, it is not anticipated that most regional divisions will procure manufactured items which impact the quality of data. Therefore, the inspection of routine procured items is not an element of the quality system for organizations other than SESD. Because one of SESD's primary missions is to produce data which support other divisional programs, SESD's standard operating procedures contain instructions on evaluating the suitability of manufactured items which are critical to data generation process (e.g. sampling equipment, laboratory instrumentation, reagents and supplies). The first line supervisors in SESD are responsible for including quality specifications in purchase requests and for inspecting or delegating the inspection of equipment and consumables to assure the items meet the quality specifications.

Many regional divisions use contractors for the collection of environmental data or utilizing environmental technology. During the contract pre-award phase, the originating program division shall notify the RQAM of all contracts involving the collection, generation, use, or reporting of environmental data, and/or the design, construction, and operation of environmental technologies. Normally the types of contracts which will require the generation of quality assurance documentation are those in which services are procured. Examples of these types of service contracts include contractor analytical operations, sampling/field measurements, data assessment, site investigations, etc.

The QA requirements in the Federal Acquisition Regulations (FAR) 46.202-4 and FAR 52.246-11 (*Higher-Level Contract Quality Requirement,* Dec. 2014) apply to regional

contracts involving the collection and use of environmental data. The appropriate Contracting Officer Representative (COR) is responsible for ensuring that all solicitations for work involving environmentally-related measurements meet the *Higher-Level Quality Requirements* specified in FAR 52.246-11. In addition, the COR shall ensure that a QA Review Form has been completed in accordance with the EPA Acquisition Guidelines. The COR is also responsible for including the RQAM as a technical evaluation panel member on those contracts that involve the collection, generation, use, or reporting of environmental data, and/or the design, construction, and operation of environmental technologies in the following situations:

- The potential value of the procurement exceeds $650,000; or
- The estimate of the percentage of costs or level-of-effort allocated to activities requiring quality requirements exceeds 15%; or
- Procedures defined in the Agency-approved QMP of the organization sponsoring the work apply.

The Acquisition Management Section within the Office of Policy and Management ensures that QA Review Forms, with appropriate signatures, are included in every solicitation package. The QA Review Form specifies if environmentally-related measurements are required under the contract's scope of work, and if so, which type of quality assurance documentation is required under the contract. The default submissions for contracts requiring the collection, generation, use, or reporting of environmental data, and/or the design, construction, and operation of environmental technologies are a QMP prior to award and a QAPP for each applicable project post-award. The QMP and QAPP may be combined into a single quality assurance document if agreed to before contract award by the contract COR and the RQAM. The Region 4 Acquisition Management Section will ensure that QMPs are reviewed and approved by the RQAM for those contracts requiring the collection, generation, use, or reporting of environmental data, and/or the design, construction, and operation of environmental technologies.

6.0 REGIONAL QUALITY SYSTEM COMPONENTS

Planning, implementation and assessment processes are necessary to effectively conduct environmental data collection operations and the use of environmental technology. The elements of the regional quality system include activities in the planning, implementation and assessment phases. The planning process is documented in the Divisional QMPs and QAPPs. The implementation phase is performed and overseen by the data user and/or project manager/leader, and the assessment phase is conducted as specified in the applicable project planning document. The components and procedures described below are used for the collection of environmental data by Region 4 personnel.

6.1 Data Quality Objectives

The data quality objectives (DQOs) process is EPA's systematic planning process which uses a step-wise system of developing the technical, programmatic and quality assurance requirements specific to a project or study. Detailed guidance for developing project or study-specific DQOs is provided in "Guidance on Systematic Planning Using the Data

Quality Objectives Process, EPA QA/G-4, EPA/240/B-06/001 (February 2006). The Agency's DQO process is the preferred method of developing objectives for those projects requiring the collection of environmental data or the use of environmental technology. However, any systematic planning process may be used if it results in the development of a QAPP that meets EPA requirements.

Having identified the need for an environmental data collection effort, the decision maker (i.e., Branch Chief, Section Chief, Project Manager, etc.) is responsible for initiating the DQO process. During the early planning phase of the investigation, the data user must clearly establish the intended use of the data, time and resource constraints, and the quality of data needed. The project manager is responsible for development of DQOs that will facilitate the generation of data that is of sufficient quality and quantity to support environmental decisions. The DQO process requires interaction between the project manager, field and laboratory technical staff, QA staff, and primary and existing data users as appropriate. The DQOs developed will be used for the detailed design of the investigation and preparation of the QAPP.

The RQAM will be the focal point for providing guidance and review of DQO development. The RQAM will consult with other Regional technical staff on DQO issues outside the technical expertise available within the SESD QATSB/QAS. A rigorous treatment of the statistical hypotheses and decision error types as outlined in Chapter 6 of the EPA QA/G-4 document may require consultation with a statistician.

6.2 Quality Assurance Project Plan Contents

Region 4 relies on QAPPs, coupled with detailed SOPs, to define project-specific quality assurance/quality control (QA/QC) requirements. In preparing a QAPP, the project manager must identify the project objectives, project management team, sampling design, critical measurements to be performed, and discuss the QA/QC activities to be conducted during the sampling, analytical, and data validation phases of the project. The document entitled "EPA Requirements for Quality Assurance Project Plans," (EPA QA/R-5), EPA/240/B-01/003 (March 2001) document provides basic instructions for preparing QAPPs. The content of Regional QAPPs shall adhere to the requirements of EPA QA/R-5, most recent version. The document entitled "EPA Guidance for Quality Assurance Project Plans" (EPA QA/G-5), EPA/240/R-02/009, (December 2002) provides detailed information for developing a QAPP. Within the region, different organizations may refer to the project-level planning document using terms such as "sampling and analysis plan" or "study plan." However named, the project- level planning document will contain the necessary elements specified in EPA QA/R- 5, while at the same time considering the application of the graded approach to the planning document.

All EPA regional projects requiring collection of environmental data or the use of environmental technology must have an approved QAPP. An exception to this requirement is for those projects where immediate danger to human health or the environment is present or suspected. Projects involving environmental technology shall follow the EPA "Guidance on Quality Assurance for Environmental Technology, Design, Construction and Operation"

(EPA QA/G-11), EPA/240/B- 05/001 (January 2005) document. The RQAM, or a designated approving official, shall review all QAPPs, provide input, recommend changes, and approve final plans. The RQAM may solicit assistance from regional technical staff when specialized expertise is needed to review certain QAPPs. Project QA activities are tracked by the appropriate Project Manager.

6.3 Standard Operating Procedures (SOP)

Standard Operating Procedures are documented protocols for performing certain routine repetitive tasks. These tasks frequently involve such operations as sample collection, chain of custody, analysis methods, instrument or method calibrations, preventive and corrective maintenance, quality control, and data reduction.

SOPs for field activities will be conducted in accordance with the QAFAP requirements. Region 4 has developed overarching SOPs that serve as the basis for implementation of the QAFAP. Region 4 divisions and/or programs may establish alternate standard operating procedures addressing the corresponding requirements and consistent with regional practice with the concurrence of the RQAM. When such alternate procedures have been established, these procedures form the basis for quality assurance evaluation of field activities in that division and/or program. Region 4 QAFAP procedures can be found on the EPA Region 4 Field Operations Intranet Site.

6.3.1 Preparation of SOPs

SOPs are prepared by the regional organization which has determined that a certain task, procedure, or job function must be performed in a uniform, consistent manner by multiple personnel. The purpose of an SOP is to minimize or reduce random error occurrences due to differences in performance of a task. It is advisable that SOPs be prepared by personnel who are most knowledgeable in a specific task or procedure. The SOPs are reviewed by appropriate staff in the user organization, and at times by technical specialists in other organizations. The SOPs are prepared in document control format by the user and are to be maintained on permanent file by the originating organization. In addition to the QAFAP requirements for document control, the EPA document entitled “Guidance for the Preparation of Standard Operating Procedures” (EPA QA/G-6), EPA/240/B-01/004 (March 2001), could be consulted for an example of the document control format. SOPs are dynamic documents that are revised as needed. SOP revisions may be the result of changes in regulations, procedures, instruments and equipment, or by inadequacies noted during implementation and/or audits.

6.3.2 Standard Operating Procedure Criteria

The following are considerations involved in the development and utilization of Standard Operating Procedures. SOPs should be:

6.3.2.1 Adequate to establish traceability of standards, instrumentation, samples, and environmental data.

6.3.2.2 Simple, so a user with basic education, experience and/or training can properly use them.

6.3.2.3 Complete enough so the user/reader follows the directions in a systematic manner through the sampling, analysis, and data-handling process.

6.3.2.4 Consistent with sound scientific/engineering principles.

6.3.2.5 Consistent with current EPA regulations and guidelines.

6.3.2.6 Consistent with the instrument manufacturers' specific instruction manuals.

6.3.2.7 At a minimum, a review of SOPs will occur every four years. However, the SESD laboratory and Field Services Branch will perform SOP reviews in accordance to ISO 17025 accreditation requirements.

6.3.3 Activities Requiring Standard Operating Procedures

The following protocols related to the collection of environmental data will be addressed in SOPs:

6.3.3.1 General sampling procedures.

6.3.3.2 Analytical methodology.

6.3.3.3 Sample collection devices, storage containers, and sample additives such as preservatives.

6.3.3.4 Instrumentation selection and use.

6.3.3.5 Instrumentation calibration and standardization.

6.3.3.6 Instrument preventative and remedial maintenance.

6.3.3.7 Duplicate, spiked, blank samples and analysis.

6.3.3.8 Field and laboratory quality control procedures.

6.3.3.9 Sample documentation, sample custody, transportation, and handling procedures.

6.3.3.10 Field and laboratory safety.

6.3.3.11 Data management and assessment procedures.

6.3.3.12 Document control.

6.3.3.13 Field personnel training and training records.

6.3.3.14 Field documentation

6.3.3.15 Records management

6.3.3.17 Planning field activities

6.3.3.18 Field report preparation.

6.4 Data Processing, Verification, and Validation

Data processing includes collection, reduction, transfer, verification, and storage. Precautions shall be taken each time the data are reduced, recorded, calculated, and transcribed to prevent the introduction of errors and the loss of information. Data processing requirements are as follows:

6.4.1 Collection: Each field and laboratory SOP, as appropriate, shall address the steps which must be used to avoid errors in the sample collection or sub- sampling process.

6.4.2 Verification: Data verification is the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual requirements. Data verification procedures will be specified in the applicable laboratory SOP, QA Manual, QAPP, or data review SOP.

6.4.3 Validation: Data validation is defined as an analyte and sample specific process that extends the evaluation of data beyond method, procedural, or contractual compliance (i.e., data verification) to determine the analytical quality of a specific data set. Criteria for data validation shall be specified in the applicable QAPP.

6.4.4 Storage: Each SOP, as appropriate, shall indicate how specific types of data will be stored.

6.4.5 Transfers: Each SOP, as appropriate, shall describe procedures which shall be used to ensure that data transfer is error-free, and that no information is lost in the transfer. Data transfer steps shall be kept to a minimum.

6.4.6 Reduction: Each SOP, as appropriate, shall contain procedures for ensuring the correctness of data reduction processes. Data reduction includes all processes which change either the form of expression or quantity of data items. It is distinct from data transfer in that it entails a reduction in size (or dimensionality) of the data set. It's also

the process of converting raw data from analytical instruments/measurements to final results. Each SOP, as appropriate, shall describe procedures for verifying the accuracy of the data reduction process.

6.5 Data Quality Assessment

Each QAPP shall include procedures for assessing the quality of all environmental data generated for accuracy, precision, completeness, comparability and representativeness. Detailed guidance for assessment may be found in EPA's "Data Quality Assessment: A Reviewer's Guide, (EPA QA/G-9R), February 2006 and Data Quality Assessment: Statistical Tools for Practitioners, (EPA QA/9S), February 2006 documents.

6.6 Corrective Action

Each QAPP shall include provisions for QA reporting or feedback to the responsible management to ensure that early and effective corrective action can be taken when data quality falls outside established data quality objectives, data acceptance criteria or quality assurance requirements. Each QAPP shall also include provisions to keep management informed when corrective actions are necessary. Corrective action shall relate to the overall QA management scheme: who is responsible for taking corrective actions when required, who follows-up to verify that corrective actions have been taken, and whether actions have produced the desired results. Corrective actions shall be documented and a formal system of communicating these actions to key project personnel, senior level management, and EPA personnel should be established by the data collection entity.

6.7 Information Management

EPA's Office of Environmental Information (OEI), Office of Information Technology Operations (OITO) is responsible for managing the hardware, software and communications components that form the foundation of the Agency's information technology. OEI/OITO has established the hardware and software standards with which the region must conform. Region 4 managers and staff will observe all hardware and software standards as detailed in the OITO Directives System at http://basin.rtpnc.epa.gov/ntsd/directives.nsf. This directives system is applicable to the personal computer platform, local area network and server platforms, open systems platforms, Agency electronic mail service and Supercomputer platform.

Specifically, Region 4's Information Systems Management Branch (ISMB) is responsible for assessing significant changes in the Agency's hardware and software policy to determine any impact on the Region. In the event changes are required, ISMB will work with regional management to plan and implement appropriate modifications. Region 4 will procure Agency-approved hardware and software that conforms with the Agency's enterprise information architecture and structure. This is projected in the development of an annual spend plan and strategic plan.

Hardware

It is very important to select good quality stable hardware to avoid program failure, since poor quality hardware can be costly to EPA. Region 4 currently purchases only Dell hardware for servers and workstations since it is recommended by the Agency.

Hardware evaluation comes in two distinct categories:

- to replace an existing server or workstation
- to acquire hardware for a new system

This process is reviewed on an annual cycle. Region 4 replaces critical systems hardware every 4 years. Determining factors for what equipment is replaced is based on the operating system, Agency software standards and cost of warranty versus replacement. Some non-critical systems can run on an older hardware platform beyond the warranty period provided by the system manufacturer.

Purchasing new hardware is determined by key factors that include: number of users, software, disk space, processing speed and applications. After these factors have been determined, the Region 4 process for installing new servers is as follows:

1. Install proper operating systems
2. Follow EPA guidelines for security settings
3. Install Symantec Antivirus
4. Install all CSIRC approved critical patches
5. Request IP address for server
6. Configure and install server according to application using EPA guidelines
7. Add server to appropriate network directory
8. Begin testing phase
9. Evaluate performance of network, application response and user connectivity
10. Correct any issues/problems identified during performance evaluation phase
11. Bring server online for production
12. Document and save server information after completion

Software

Region 4 complies with the Agency's System Life Cycle Management (SLCM) policy as a guide for all application/software development. The Region 4 Application Development Manager (ADM) reviews initial requirements to determine if an existing application will meet program needs. If a new application is needed, the ADM continues requirements discussions. Requirements are agreed to by both application program sponsor and application manager. Depending on the requirements, available EPA-approved software/platforms and programming expertise, decisions are made on what technology platform will be used to develop the application. Development then begins and is continued with ongoing discussions with the program.

Region 4 employs the Agile project management methodology to provide more rapid development of applications and demonstrate early success. The ADM is an ICAgile

(International Consortium for Agile) certified practitioner. Application testing plans are created and carried out in short 'sprints' and continuous activities with controlled audiences specific to the intended user base. Areas of consideration for identifying testing groups include (but are not limited to) hardware differences and user's IT experience. Test results are reviewed, and then changes/modifications are made as needed. Additional testing is completed if needed.

The ADM documents all requirements and creates maintenance, security and record plans. The application is then implemented. Follow-up meetings are scheduled and conducted as necessary. Application duplication is avoided by comparing all development and purchase requests to existing systems.

If a program has a need to purchase 'non-standard' application software that is not on Agency contract, the software will be evaluated prior to purchase. Software evaluation will be performed against written performance/ capability standards developed by the Application Administrator and/or System Administrator. Region 4 will evaluate system and software documentation to ensure that vendors comply with Agency standards, and to determine its performance capabilities and documentation requirements.

IT Support Services

After deployment of new hardware or software, Region 4 IT Technical Support Services receive 'service' calls for troubleshooting and/or repair of equipment or software via the Remedy Helpdesk ticketing system. These calls are captured and documented. Remedy can run online reports of categorized service calls that are evaluated to determine what corrections are needed.

Roles and Responsibilities

Region 4 System Administrators manage the entire network including hardware, software and user profiles. Responsibilities include ensuring server, switches, and computer images are properly configured according to EPA specifications and guidelines.

Region 4 Database and Application Administrators manage and maintain the Oracle and SQL server databases and applications on the server. Responsibilities include ensuring that databases and applications are accessible to users always and that maximum uptime is maintained.

Region 4 IT Technical Support Services manage desktop hardware and software. Responsibilities include repair, upgrading, and user training of equipment and Agency standard software.

R4 Information Security Officer is responsible for ensuring the network and all desktops follow the guidelines for security settings and policies of operation.
Region 4 uses 'Patchlink' reports to ensure that servers are following EPA information security requirements.

IT managers and supervisors are responsible for approving all activities of purchasing software and hardware. They are also responsible for day-to-day activities to ensure the network is functioning properly.

6.8 Data Quality Act/Information Quality Guidelines

The Data Quality Act/Information Quality Act [Section 515(a) of the Treasury and General Government Appropriations Act for FY 2001 (P.L. 106-554)] requires Federal agencies to develop guidelines for ensuring that quality information is disseminated to the public. The U.S. Office of Management and Budget (OMB) has oversight responsibility for implementation of the Act, and the Office of Environmental Information (OEI), Environmental Quality Management Division (OEI EQMD) has responsibility for implementation in the Agency.

Pursuant to these requirements, EPA issued the Information Quality Guidelines (IQG) officially titled "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency") in October 2002. The IQG contain policy and procedural guidance for ensuring "disseminated information" is accurate, reliable and unbiased, useful to the intended user, and secure from compromise.

The IQGs provide the opportunity for industry, private citizens, environmental organizations, or members of Congress to challenge the quality of information disseminated by any means by the Agency and to request corrections for EPA consideration. For purposes of IQG, Region 4 defines “information” as any communication on positions or policy, including facts or data adopted or endorsed by the Region. Information disseminated by the Region falls into the following six types of information:

a. Tools (data query, models, estimator tools, mapping/GIS-related)
b. Reports, journal articles, studies, trends analyses
c. Databases (searchable databases)
d. Guidance documents (training materials, user guides)
e. Outreach products (action plans, brochures, conference proceedings)
f. Information disseminated in support of regional decisions or policies (studies, assessments, and other supporting information)

Region 4 will, to the extent practicable, ensure that all information products subject to the Guidelines adhere to the quality principles of objectivity, utility, and accuracy. In addition, the Region will also ensure transparency and reproducibility of data as quality criteria for “Influential” information. For purposes of IQG, “disseminates” means when the Region initiates or sponsors the distribution of information to the public.

In 2006, EPA OEI developed Pre-Dissemination Review (PDR) Guidelines to serve as a template for Offices and Regions in reviewing information products subject to the IQG before they are "disseminated." Region 4 will focus on ensuring that the Region’s quality criteria discussed above build these principles into each step of the development of information, including its creation, collection, maintenance, and dissemination. All regional

Pre-Dissemination Review protocol and review procedures will incorporate these goals and policy as review criteria for disseminated information.

Region 4 Pre-dissemination Review procedures include programmatic and legal reviews, and QAPP and QMP reviews, as applicable, prior to dissemination. Peer Review will also be used, when appropriate, under OMB guidance. Branch Chiefs or designee will be responsible for developing and implementing PDR as appropriate in their areas of responsibility and will serve as the information product approver before such products are disseminated. The RQAM will be responsible for auditing division's implementation of IQG and PDR to be sure that IQG data quality criteria are incorporated into regional policy and decision making and that PDR procedures follow the PDR guidelines.

The RQAM will be the point of contact for OEI to direct them to the appropriate program that will be responsible for coordinating the review of any Requests for Correction or Requests for Reconsideration received on any Region 4 information product.

The RQAM will be responsible for bringing appropriate training to the Region for managers involved in pre-dissemination review and for staff who develop information products. The RQAM, in coordination with OEI, will provide regional guidance on IQG and PDR, as needed, and will get program input and management approval on needed guidance.

7.0 QUALITY SYSTEM ASSESSMENT

7.1 Assessment Management

An effective QA System requires periodic assessment to determine if the system is operating as designed and to establish a basis for corrective action. At the organizational level, each affected organization will be assessed against the appropriate divisional QMP. The RQAM or designee shall review and evaluate implementation of selected QMPs, including the Region 4 QMP and Region 4 State QMPs.

At the project level, all data collection activities will be assessed against an approved QAPP. The RQAM or designee shall review and evaluate the implementation of selected QAPPs during the operational phase of the monitoring activity. Selection of projects will depend on the following criteria: projects supporting litigation, high visibility projects, and requests from Project Managers. Upon completion of the project activity, the Project Manager shall assess the actual performance of the planned activities and subsequent results. The final project report shall contain the results of this assessment and state whether the data collected meet the objectives of the project.

The QAPP shall ensure that:

7.1.1 The DQO process or systematic planning process complies with the step-wise process outlined in EPA's QA/G-4 document.

7.1.2 The level of data quality required will be determined and stated in terms of precision, accuracy, completeness, comparability and representativeness, before the data collection effort begins.

7.1.3 All environmental data generated and processed will be of the quality, quantity and integrity established by each QAPP or by applicable EPA regulations as appropriate.

7.2 Types of Assessment

Oversight of the data generation activities in Region 4 will be tailored to the nature of the activity and the associated management and administrative system. Assessments are the principal means in Region 4's QA Program to determine compliance with established QA Management and Project Plans. Several types of assessments are used to verify that management and measurement systems are operating properly, to assess whether data quality is adequately documented, and to evaluate the management of QA programs. Detailed guidance for assessment may be found in Data Quality Assessment: A Reviewer's Guide, EPA QA/G9R, February 2006. The RQAM has the primary responsibility for conducting audits at the division and program levels.

Five specific types of assessments will be used at appropriate times by the Region 4 RQAM to determine whether the Divisional QMPs and Region 4's QMP have been implemented, to determine the status of measurement systems, the adequacy of the data collection systems, the completeness of documentation of data collection activities, and the abilities of program management to meet mandated data collection and data quality objectives. These five audit types are respectively, program audits, performance audits, technical system audits, data quality system audits, and management system reviews. These audits are assigned by managers/supervisors to staff who have the appropriate experience, training, knowledge and technical skills. It is the manager's/supervisor's responsibility to ensure auditors assigned for an assessment have the necessary training and experience to adequately perform the assessment assigned, that no conflict of interest exists and, whenever possible, they are independent of the activity to be audited. It is the responsibility of the auditor's supervisor/manager to review the audit findings to ensure appropriateness and consistency with EPA policy and guidance. The audit report will be reviewed by the appropriate supervisor/manager prior to distribution.

Each type of audit is described below:

7.2.1 Program audits are qualitative audits assessing the ability of the programs to oversee internal operations, and State, Local and Tribal environmental programs to ensure compliance with EPA regulatory or statutory requirements. Program audits of the Region 4 states are particularly important since many environmental programs have been delegated to these entities. Program audits should be conducted every three (3) years and the findings resulting from the audit, documented and communicated to EPA program staff, divisional management, and the RQAM. The RQAM and SESD QATSB/QAS staff will provide additional support to divisional/program staff conducting the on-site audit to ensure the necessary QA policies and procedures have

been properly implemented, and the federal, state or tribal regulatory/statutory requirements met. State and tribal obligations under on-going assistance agreements, cooperative agreements and other such grants, will also be evaluated during the program audit to ensure compliance with the terms and conditions of these documents.

7.2.2 Performance audits are quantitative audits of the ability of an analytical system to obtain reliable data. These audits involve submission of proficiency test (PT) samples as unknowns to laboratories or other analytical systems. For the most part, these are part of national program audits such as the Water Supply PT Studies, Water Pollution PT Studies, DMR QA Studies, Air Intercomparison Studies, etc. These audits are used as one indicator of the data produced by NPDES Permittees, certified drinking water laboratories, and Superfund contract laboratories (CLP). The Region 4 SESD laboratory routinely participates in these audits as appropriate. The Region routinely sends performance samples with each set of samples submitted to the CLP. Special performance samples are requested by a regional project manager to audit a laboratory producing data for a potentially responsible party remedial investigation of a Superfund site or at RCRA facilities.

7.2.3 Technical system audits are on-site environmental assessment activities. The audits are qualitative assessments of personnel, equipment, facilities, procedures, and QA activities. These audits are conducted at least biennially at state agencies and cover ambient air, water quality/water quality enforcement, drinking water, and hazardous wastes monitoring activities. For monitors used in evaluations of National Ambient Air Quality Standards, the frequency is specified in 40CFR Part 58 Appendix A as once every three years for each Primary Quality Assurance Organization (PQAO). Audits (known as Performance Audit Inspections (PAIs)) of NPDES permittees are conducted routinely in delegated states. PAI candidates are chosen by EPA and the states; performance in the DMR QA Studies is one of the criteria used. Other audits are conducted at RCRA facilities and CERCLA investigations at the request of the program division. The Region 4 SESD laboratory and field activities are audited every year by the ISO 17025 accrediting authority. Audits of randomly selected regional activities are conducted as resources permit, or an activity is audited if there is evidence of inadequate performance.

7.2.4 Data quality audits are quantitative audits in which data are reviewed and evaluated following collection to determine the quality and usability of the data. These audits are conducted by SESD QATSB/QAS staff on all CLP data for CERCLA and any programmatic analytical data which is contracted through SESD. Data quality audits are performed on data from other sources as requested by the appropriate project manager or leader.

7.2.5 A management system review (MSR) is an assessment of an organization's ability to implement and manage an effective QA program. A MSR of the regional quality system will be conducted every three years. This MSR may consist of a review of all organizations within the region, or if resources do not permit, of a selected organization within the region. MSRs also may be conducted of any regional contractor, or extramural organization which receives funding from the region.

7.2.6 Annually, the RQAM or designee will:

a. Randomly select QAPPs that have been reviewed by a one or more of the divisional DAOs to determine whether they have reviewed the document in accordance with EPA QA/R-5 requirements and have properly identified the deficiencies associated with this document. The RQAM may revoke DAO certification status if non-compliance with any of the above requirements is encountered or when random review of a DAO's work product warrants this action.
b. Conduct internal audits of the QAFAP in accordance with the Region 4 Standard Operating Procedure for Internal Audits and Corrective Actions, R4PROC-009.
c. Conduct an evaluation of the implementation of a divisional QMP.

7.3 Corrective Actions

Initially, assessment findings and appropriate corrective actions will be communicated to the organization's management and staff, as appropriate, during the exit briefing. In some cases, appropriate corrective actions may be implemented at the time of the exit briefing, especially if the findings relate to relatively simple issues. A timely report, outlining the findings of the audit, will be sent to the organization that was audited. The organization will have approximately 30 calendar days to request clarification of the findings or provide additional information which has an impact on the findings. After all challenges to the audit findings are received and reviewed, a final decision will be made by the RQAM and appropriate managers to resolve the issues identified in the report. If there is no resolution to the findings, then the assessment findings will be documented and communicated by the RQAM and provided to the appropriate organizational management official for resolution. If resolution cannot be reached at lower management levels, the Regional or Deputy Regional Administrator will be advised of the issues. The final decisions made by the Regional Administrator or Deputy Regional Administrator will be provided by the RQAM to all concerned parties. Once a final resolution on the finding is reached, the affected manager will have approximately 90 calendar days to develop a corrective action plan.

The corrective action plan includes the designation of a corrective action team that will assess the issues surrounding the nonconformance, determine the root cause of the problem, and identify feasible corrective actions. Corrective actions shall be commensurate with the magnitude and the risk of the finding, and depending on the risk associated with the finding, a corrective action team will be identified. The corrective action plan must be submitted to the RQAM or designee for review and approval prior to implementation of the selected corrective action. Corrective actions should be completed within 90 calendar days from approval. Additional time to implement the corrective action can be requested to the RQAM.

The need for follow-up assessments will be determined by the RQAM and if needed will be conducted within 6 months to determine if the corrective actions were appropriately addressed. A follow-up assessment to determine the effectiveness of the implemented action is especially important for MSR assessments. Corrective actions for Technical and

Management Assessments will follow the EPA QA/G7 “Guidance on Technical audits and related Assessments for Environmental Data Operations” Chapter 3, Section 3.5. Corrective actions and their effectiveness must be documented and the records maintained by the RQAM or designee.

8.0 DOCUMENTS and RECORDS

The Federal Records Act of 1950, as amended (44 U.S. C. 3101), requires that all Federal agencies make and preserve records containing adequate and proper documentation of the organization and its functions, policies, decisions, procedures, and essential transactions. These records are public property and must be managed according to applicable laws and regulations. In a Federal Agency, files and records serve as the official memory of the agency's activities. Records of the agency can be in many forms, formats and storage media. Because of legal statutes and regulations, all Federal agencies are required to create, maintain, and retain files, records and information as a valuable resource. All Federal records are subject to Federal requirements regarding creation, maintenance and retention. These standards, set by the National Archives and Records Administration (NARA), include guidelines on the information's ownership, value, and availability.

8.1 Region 4 Records Management System

Region 4 has issued standard operating procedures for managing records. Details of these procedures are described in documentation prepared by each Division and are based on identifying the EPA Records Schedule applicable to a document. The standard operating procedures are based on the following EPA requirements:

- Records Management Policy (CIO 2155.3) February 10, 2015
  This Policy establishes principles, responsibilities and requirements for managing EPA's records to ensure the Agency is in compliance with federal laws and regulations, EPA policies and best practices for managing records.
- Records Schedules
  EPA's official policies on how long to keep Agency records (retention) and what to do with them afterwards (disposition).
- Essential Records Procedures (EPA 2155.P-01.0) March 24, 2015
  These procedures prescribe the requirements and responsibilities for establishing and maintaining EPA's vital records program.

Quality- related records are not managed separately, but are included in the appropriate EPA Records Retention Schedule. The following general procedures for records management are in place in Region 4.

8.1.1 Each organizational element (Division or Office) is assigned record keeping responsibilities in accordance with its functional responsibilities and duties. Records and information created, received, maintained, or acted upon shall be maintained in accordance with EPA and NARA approved Records Retention Schedules.

8.1.2 Managers and supervisors will be held responsible for ensuring EPA personnel and contractor staff (working inside or outside EPA) are adhering to regional, EPA, and NARA record keeping procedures.

8.1.3 Mandatory Records Management training sessions will be provided for all EPA employees, managers, and contractor staff on record keeping procedures and FOIA requirements.

8.1.4 Files and agency records may not be checked out to EPA or contractor staff unless the required records management training courses have been completed.

8.1.5 Files and records may not be checked out for more than 90 days. File check-out procedures shall be followed by all records personnel. A monthly report shall be provided to the program management and Regional Records Management of all records and files removed for more than 90 days. A response will be required from the program manager for overdue records and files.

8.1.6 A flag in the records circulation system will indicate site files that have been checked out and not returned for six (6) months or more. This includes files sent to outside contractor staff. The user will be notified to return files to the records center. Manager approval is required for site files to be checked out longer than six (6) months.

8.1.7 A chain of custody form and receipt is required when files are checked out from the records centers, delivered to an employee and/or contractor staff, and returned to the record centers. User responsibility for checked out files is established by this procedure. The user is responsible to ensure the returned files and records are complete, in proper sequence or order and in the same condition in which received.

8.1.8 EPA employees leaving the agency must return all records to the Records Center including any records in their workstation that have never been placed in the Records Center. Supervisors and managers shall be responsible to ensure files and records are returned.

8.1.9 Files, records and information shall be created, maintained, and retained in accordance with EPA and the Region's CBI, Privacy, and Vital Record Protection program requirements.

8.1.10 To improve record reviews and responses to FOIA requests, the Region shall implement a records system which designates a document as the original or a copy, provides for a release determination to be made at the time of record creation, and negates the need for files to be repeatedly reviewed each time a FOIA request is made.

8.1.11 Electronic records and information held in an electronic format shall be maintained in accordance with approved and issued EPA and NARA guidelines and retained in accordance with approved Records Retention Schedules.

8.1.12 Files, records and information shall not be destroyed except in accordance with EPA and NARA guidelines, requirements and Records Retention Control Schedules. All destroyed records will have a Certificate of Destruction verifying destruction in accordance with such guidelines and requirements.

8.1.13 Divisional QMPs must clearly describe the record keeping policies and procedures for maintaining, archiving, storing, and retrieving documents prepared, reviewed, revised and approved by EPA.

The Divisional QMPs must also describe the process for:

- identifying quality related documents and records requiring control;
- handling documents and records to assure accessibility, protection from damage and deterioration, and means of retention, including discussion of the roles and responsibilities of management and staff for implementing the document control and maintenance policies of the Division;
- ensuring technical guidance documents are prepared, reviewed, approved, issued, used, and revised as required by regional QA policy;
- ensuring compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs are adequately preserved and maintained to support the Division's mission.

8.1.14 All QAPPs, QMPs and other QA documents reviewed by the RQAM and/or SESD QATSB/QAS are maintained in an electronic database in the Local Area Network (LAN). Included in the database are the date the document was received, who conducted the review, the date the memo/report was issued and whether the document was approved.

9.0 QA COMMUNICATION/REPORTING/WORK PLAN

The purpose of communication is to ensure staff in different programs can effectively develop and implement programs, perform activities, and resolve problems related to the generation of environmental data and the use of environmental technology. To effectively implement the regional quality system, communications must occur between the RQAM and regional managers and staff.

The Office of Environmental Information Enterprise, Quality Management Division (OEI EQMD) is the primary office for policy and guidance on the Agency's quality system. The RQAM or designee participates in monthly conference calls with the OEI EQMD and other regional QAMs to be aware of new or revised QA policies as well as implementation issues associated with the Agency-wide quality system. Regional requests for assistance, interpretation, and action will be forwarded by the RQAM to the appropriate OEI EQMD member. The RQAM will exchange QA information with Region 4 QA Coordinators, Program Managers and staff; EPA laboratories; headquarters' program offices; and other regions to implement the regional quality system.

9.1 Regional Communication

The RQAM shall exchange information with Division Directors, Regional Program Managers, Project Officers, QA Coordinators, Field Quality Coordinators, Technical Staff, and State/Tribal QA Officers.

9.1.1 A primary means of communication among regional staff is through the divisional QA Coordinators. The duties and responsibilities of the QA Coordinators are described in section 3.2.3 of this document.

9.1.2 A primary method of RQAM communication with the State/Tribal QA community is annual meetings of State/Tribal Laboratory and QA personnel sponsored by SESD. The State/Tribal QA Officers communicate with appropriate environmental monitoring personnel, the local Agency QA Officers, and industrial QA Officers.

9.2 QA Annual Report and Work Plan

Each year, the RQAM shall submit a QA Annual Report and Work Plan (QAARWP) to Region 4 Senior Management and the Director of OEI EQMD. This report shall reflect the implementation status of the Region 4 QA Program. The QA report will summarize the QA-related resources, training, accomplishments (i.e., innovative practices, technical assessments, QMP revisions, QA guidance, technical assistance, etc.) and quality system assessments/audits that have been conducted in the previous fiscal year. The Work Plan will also describe all planned QA activities for the fiscal year beginning in October and any other information required by OEI.

Each division or office that is a part of the Region's Quality System shall provide its information to be compiled into a Region-wide report. The QAARWP will be prepared according to Chapter 4 of the most current version of the CIO Procedure 2105-P-01.0 (formerly the EPA Quality Manual, 5360 A1) by the RQAM with cooperation from the QA Coordinators, Field Quality Coordinators, and SESD Quality Staff (Lab QA Manager, Field Quality Manager, and SESD QATSB/QAS). Prior to its distribution to the Director of the EPA OEI EQMD, the report shall be reviewed and approved by the Regional Administrator or designee.

9.3 National Meetings

In addition to the regular communication/reporting activities described above, the RQAM, or designee, will participate, at a minimum, in EPA's National QA Conference. The RQAM, or designee, will participate in other meetings and workgroups, which help to advance national and regional QA goals and to assist with implementation of the regional quality system.

9.4 Resources

National Program Managers (NPMs) set staffing levels for activities in each of the programs and regions. In Region 4, distribution of QA-related resources, including Full-Time

Equivalents (FTEs), are determined by the Regional Administrator and Division Directors. These senior managers must balance quality system resource needs with other program resource needs. The SESD Director, with input from the RQAM, will recommend staffing and resource needs for maintaining the regional quality system.

10.0 PEER REVIEW

Peer review is a documented critical review of specific EPA's major scientific and/or technical work products. Specifically, peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to the specific major scientific and/or technical work products and of the documentation that supports them. Peer review is conducted to ensure activities are technically adequate, competently performed, properly documented, and satisfy established quality requirements. Peer review of scientific and technical work products that support decision making actions is an important, fundamental step for ensuring the decision made or position taken by EPA, based on the work product, has a sound credible basis.

The U.S. Office of Management and Budget (OMB) issued its bulletin, *Final Information Quality Bulletin for Peer Review,* on December 16, 2004, as federal government-wide guidance to enhance the practice of peer review of government science documents. The bulletin provided guidance to federal agencies on what information is subject to peer review, selection of appropriate peer reviewers and opportunities for public participation. Further, the bulletin defined peer review processes to permit public and scientific societies to contribute to agency dialogue about which scientific reports merit especially rigorous peer review.

EPA's revised peer review policy *Peer Review and Peer Involvement at the U.S. Environmental Protection Agency,* approved by Administrator Stephen Johnson on January 31, 2006, encompasses scientifically and technically-based work products, including economic and social science products, that are intended to inform Agency decisions. The *U.S. EPA Science and Technology Policy Council (STPC) Peer Review Handbook, 4th edition* (October 2015) provides additional information and procedures for the implementation of EPA's peer review policy. An overview of EPA's peer review program including additional references and peer review history may be found at: http://www.epa.gov/peerreview/ . The Region 4 Science Liaison (RSL) is Region 4's Peer Review Coordinator and will coordinate all Peer Review activities in the Region with the Decision Makers (Office and Division Directors) and identified Peer Review Leaders in accordance with the Agency's most recent peer review policy and Peer Review Handbook.

11.0 TRAINING

The RQAM will develop, on an annual basis, a training plan providing the necessary courses to mitigate targeted deficiencies and vulnerabilities within the Region. Training will be conducted for QA staff on the basics of a quality system, including training to identify the types of projects that require a QMP and/or QAPP to meet agency requirements. Technical training in the form of hands-on sample collection techniques, analytical measurement requirements and data validation and review will also be offered to regional staff, upon request and depending on the needs. QA or technical training needs will be identified by supervisors during annual performance evaluations, career

individual development plans, annual management systems reviews performed by the RQAM or divisional/program staff, and by QA Coordinators. Supervisors should contact the RQAM to determine if the identified training needs can be met through regional training provided by the RQAM/staff, or if other sources are needed for training. The RQAM will assist the supervisor in locating the most appropriate QA or technical training to meet the need which has been identified. Results of the technical and QA training needs assessments will be documented and communicated to Division Directors, Program Managers, and if necessary, the Regional Administrator and the Deputy Regional Administrator.

11.1 Training Needs Assessments

The training needs of the RQAM and QA staff are not static, but change as the various environmental programs mature. Therefore, training needs of the RQAM and staff will be addressed in the Region's annual Quality Assurance Annual Report and Work Plan (QAARWP). The QAARWP shall be submitted annually to the OEI EQMD Director for review.

Annually, the RQAM, with assistance from the QAS staff and other SESD organizations, will present one or more of the following training courses:

- QA Orientation, Basics of the EPA Quality System
- Region 4 and Divisional QMP
- Introduction to the Data Quality Objectives Process,
- Preparation and Review of QMPs and QAPPs,
- Data Validation and Verification Procedures for Evaluating Environmental Data
- Designated Approving Official Training
- QA Tracking System
- QAPP development, requirements and checklists
- QAFAP Training
- Training for QAFAP auditors

The SESD QATSB/QAS staff typically schedules two training modules per QA course to facilitate attendance. Each QA course is offered via webinar or classroom setting at various times throughout the year. The RQAM is available to discuss specific training needs with supervisors or staff. Courses may be developed by the RQAM and SESD QATSB/QAS staff to meet specialized training needs. DAO refresher training is mandatory on an annual basis and documented in the QA Tracking System.

The RQAM must balance the resources needed to perform programmatic quality assurance support functions (data verification, performance audits, technical system audits, QAPP review, etc.) with the resources needed to perform QA training. Although the SESD QATSB/QAS has limited resources for QA training, the Section's staff continues to provide technical and QA training to regional personnel, state staff and tribal staff. Due to the lack of dedicated training resources, the Region currently does not provide QA training to private sector personnel.

11.2 Training Records

Each employee is required to maintain training records in accordance with program-specific requirements. All training records of field employees will be retained in accordance with the QAFAP and applicable regional and/or program-specific requirements. Training records shall be maintained in a training folder, in an Agency approved data system [e.g., Field Readiness Module (FRM), Federal Acquisition Institute Training Application System (FAITAS), etc.] or in a designated electronic system such as a SharePoint site, One Drive, etc. All QA training obtained external to the Region will be maintained by the employee, his/her supervisor, and when appropriate, provided to the RQAM. Training agendas and attendees of courses provided by the SESD QATSB/QAS and the RQAM will also be maintained by the RQAM.

12.0 QUALITY IMPROVEMENT

The RQAM implements and makes improvements to the Region 4 quality system when non-compliance or quality assurance issues are identified by management system reviews, technical systems reviews, performance evaluations, OEI audits, and communication from regional personnel. To facilitate improvements to the quality system, the RQAM will conduct meetings with the QA Coordinators to discuss non-compliance issues and to develop internal policies for communicating these issues to the appropriate Divisional Directors. The RQAM will also consult with OEI EQMD to develop strategies for updating the QMP as improvements are made to the regional quality system.

12.1 Divisional/Program QMPs

To ensure that the requirements specified in this QMP are consistently applied within the regional divisions and programs, the Divisional QMPs will: (1) specify the management process for identifying, planning, implementing and evaluating the effectiveness of quality assurance activities; (2) designate a staff member to coordinate quality improvement; and (3) require implementation of the corrective action program to ensure conditions adverse to quality are identified promptly and corrected within a specified time frame.

12.2 Management Systems Assessments/Review

Internal management system reviews will be instituted by the RQAM on an annual basis to verify the policies and procedures outlined in the Divisional and Regional QMPs have been implemented and that any corrective actions mandated by the RQAM or the QA Coordinators have been instituted to mitigate non-compliance with regional QA policies.

The Divisional QA Coordinator and the RQAM may assist in the QA oversight of the State/Tribal programs during mid-year or annual reviews performed by program staff. During the initial phase of these on-site QA assessments, grants, extramural agreements and interagency agreements will be targeted to determine whether the appropriate QA measures and requirements specified in the assistance agreement documents have been met.

12.3 Quality Assurance Training

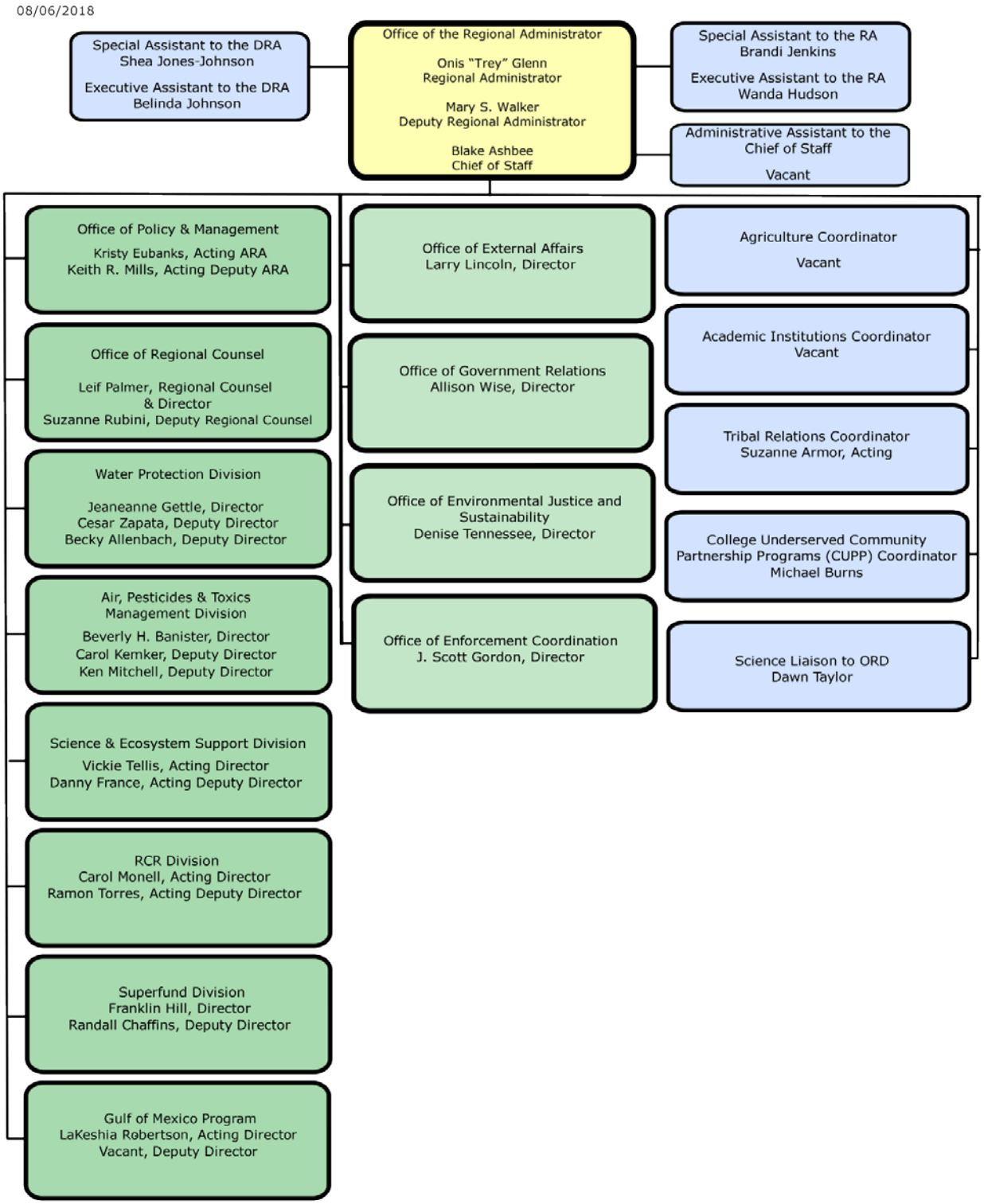
As part of the quality improvement process, the RQAM will conduct an internal QA training needs assessment annually to identify areas of vulnerability. QA training will focus on CIO 2105.0, the Region 4 QMP, Divisional QMPs, preparation of QMPs and QAPPs, development of DQOs, DAOs, and data quality assessments, and data validation. If the RQAM determines that the SESD QATSB/QAS personnel are not able to provide additional training, external training sources will be sought.

The RQAM will determine the effectiveness of the training provided to regional staff by conducting MSRs, by reviewing the quality of the work products, and by evaluating divisional work processes. When problems are noted by the RQAM through this exercise, a corrective action report identifying additional training needs will be developed in accordance with Section 7.3.

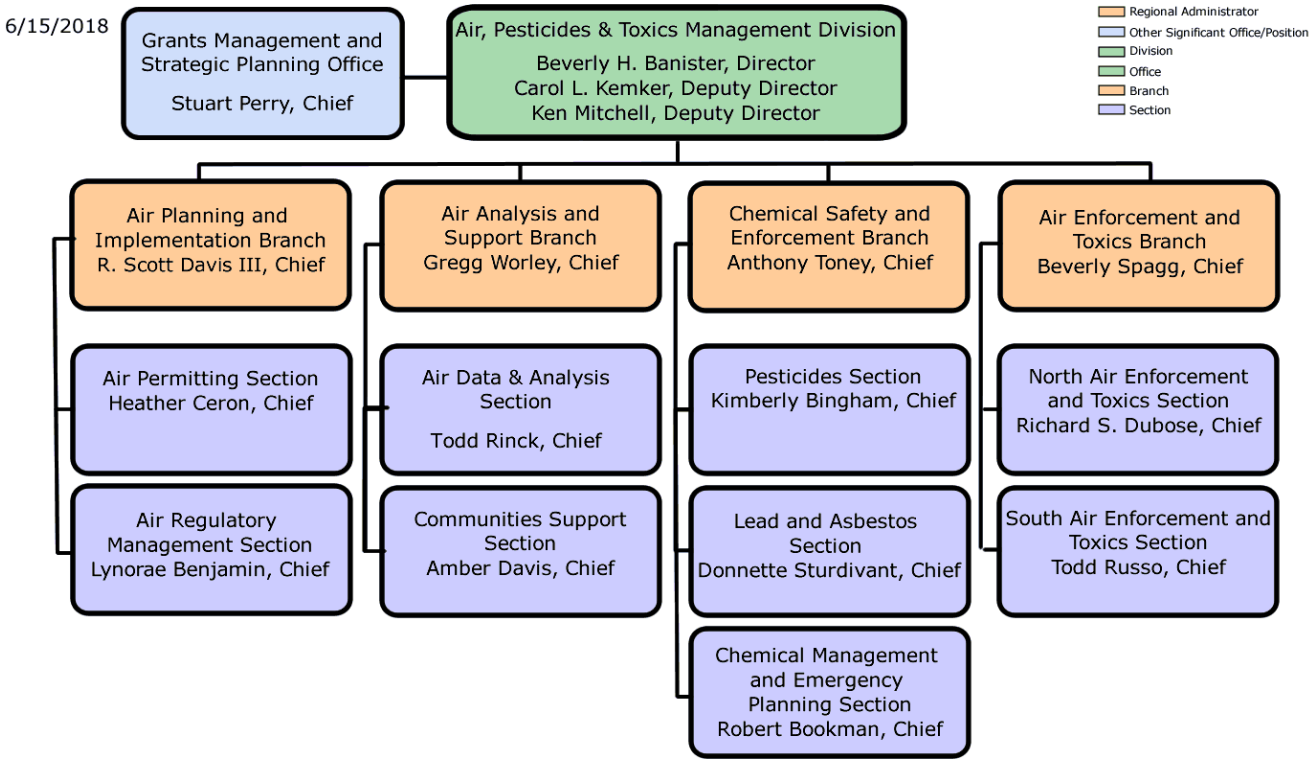
APPENDIX A

REGION 4 ORGANIZATIONAL CHARTS

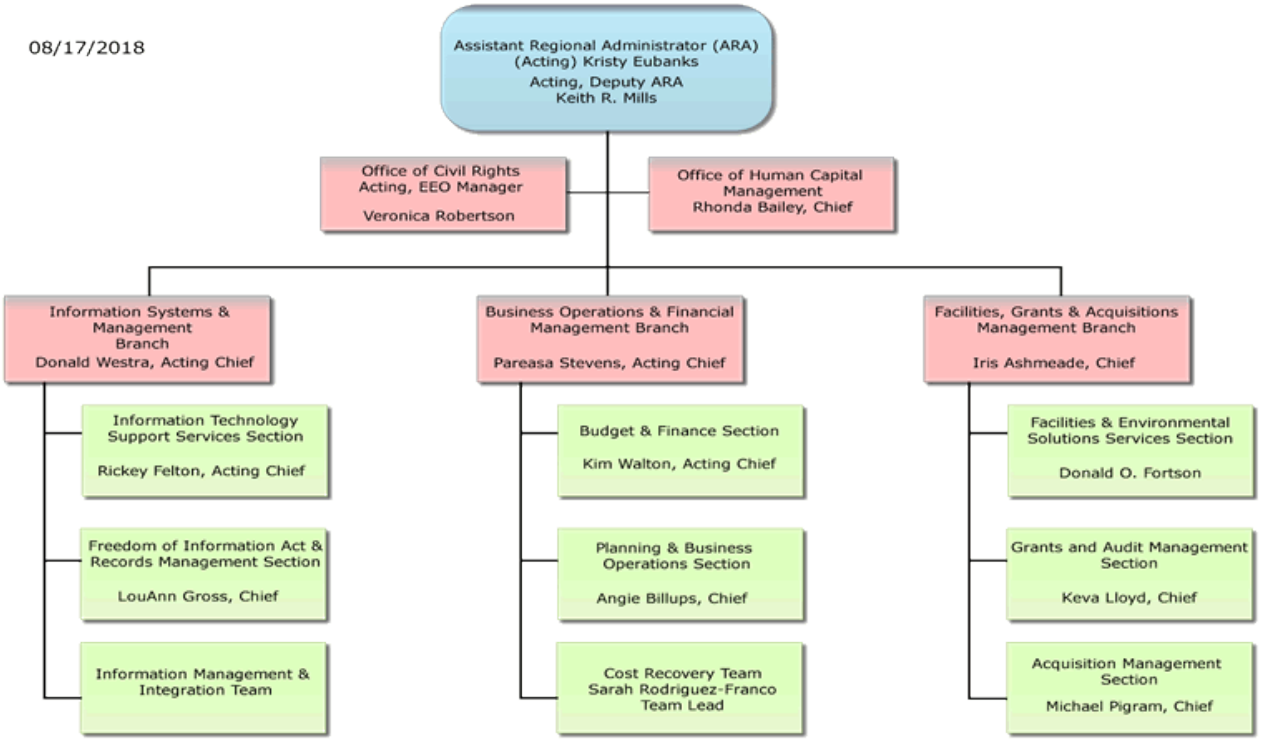
Region 4 Office of the Regional Administrator



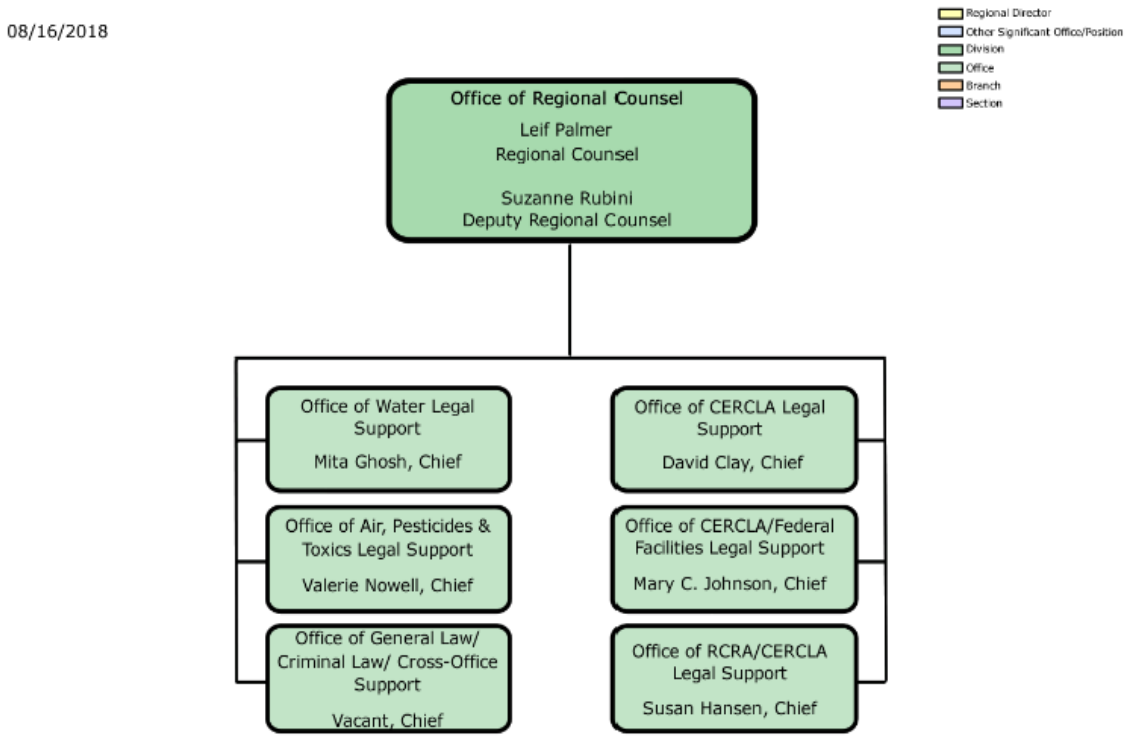
Region 4 Air, Pesticides and Toxics Management Division



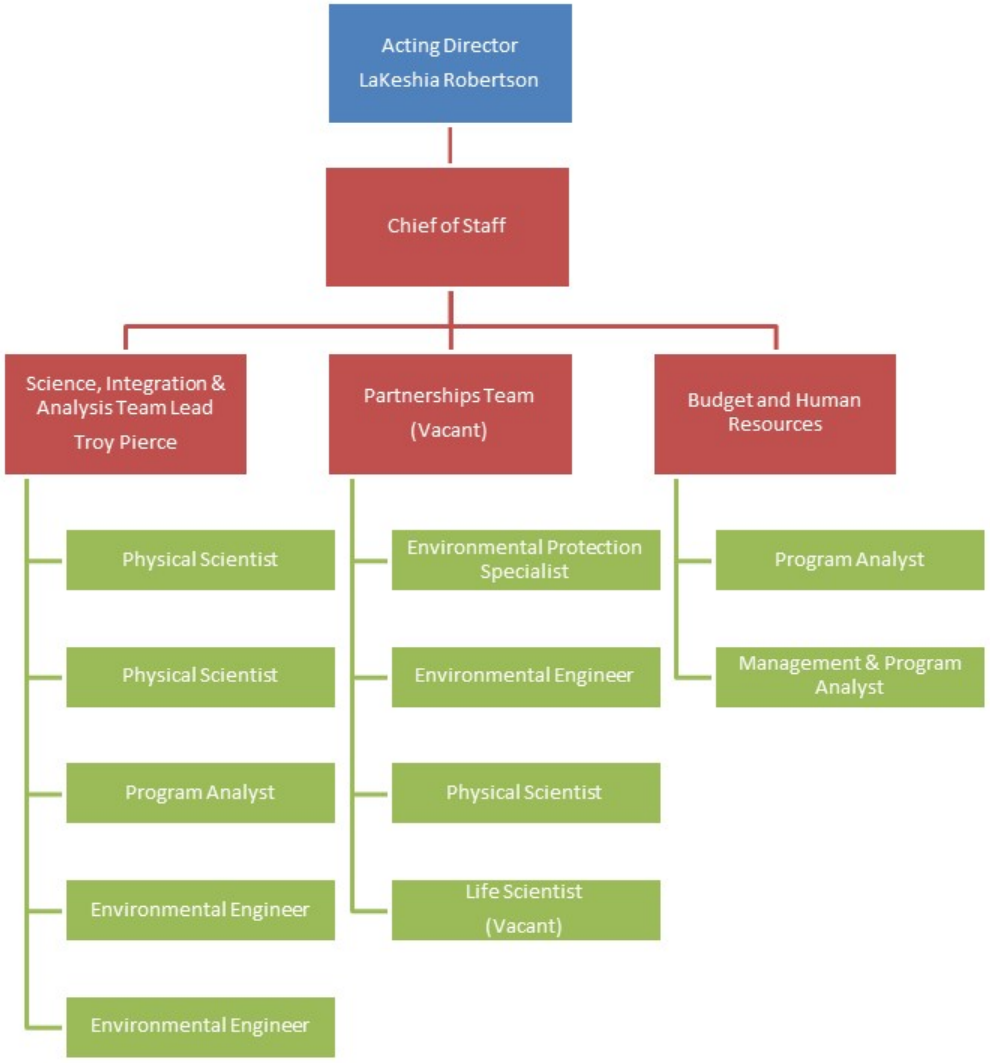
Region 4 Office of Policy and Management



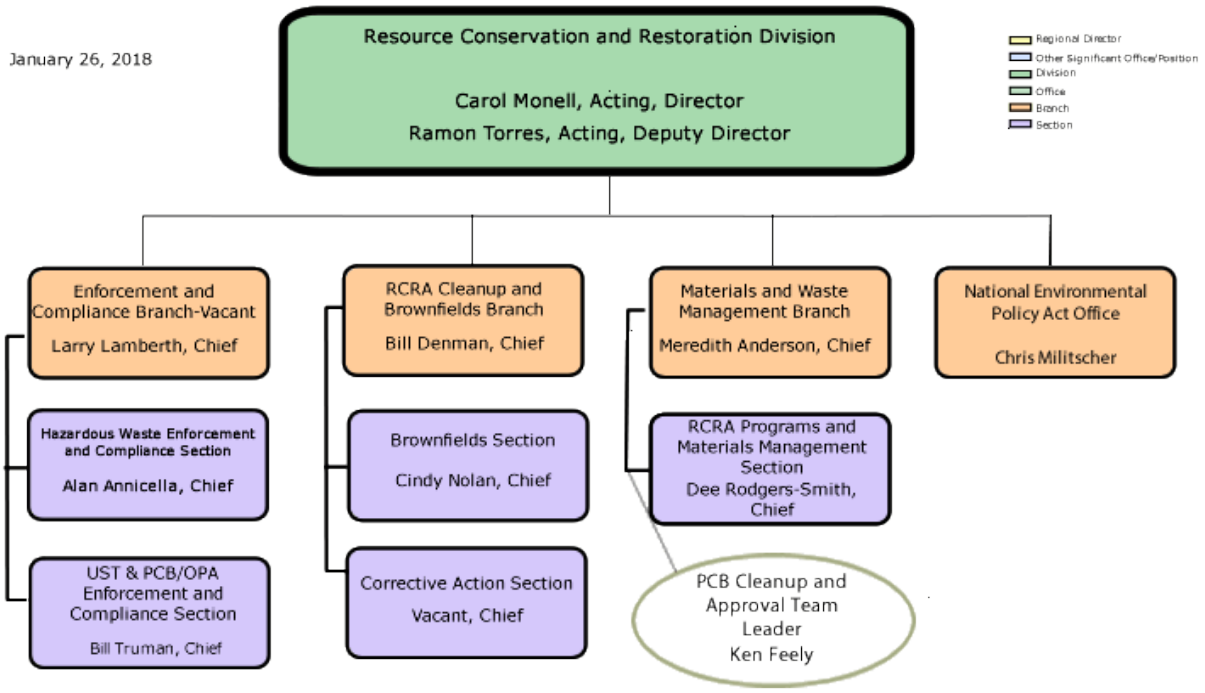
Region 4 Office of Regional Counsel



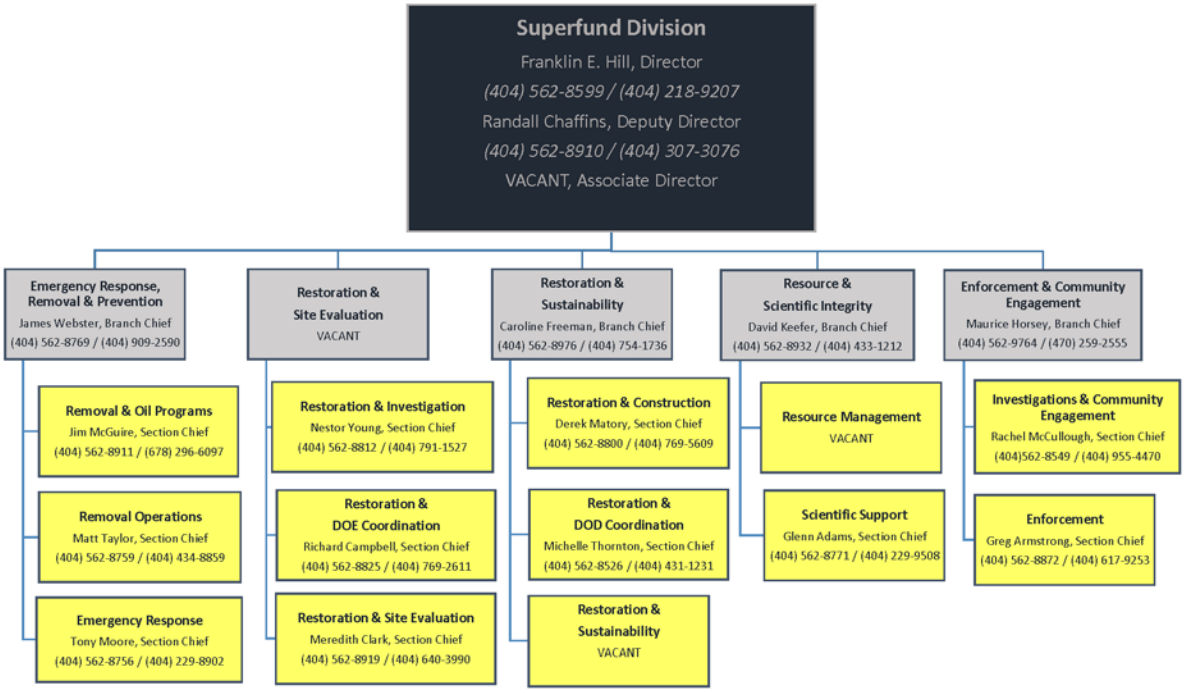
Gulf of Mexico Program



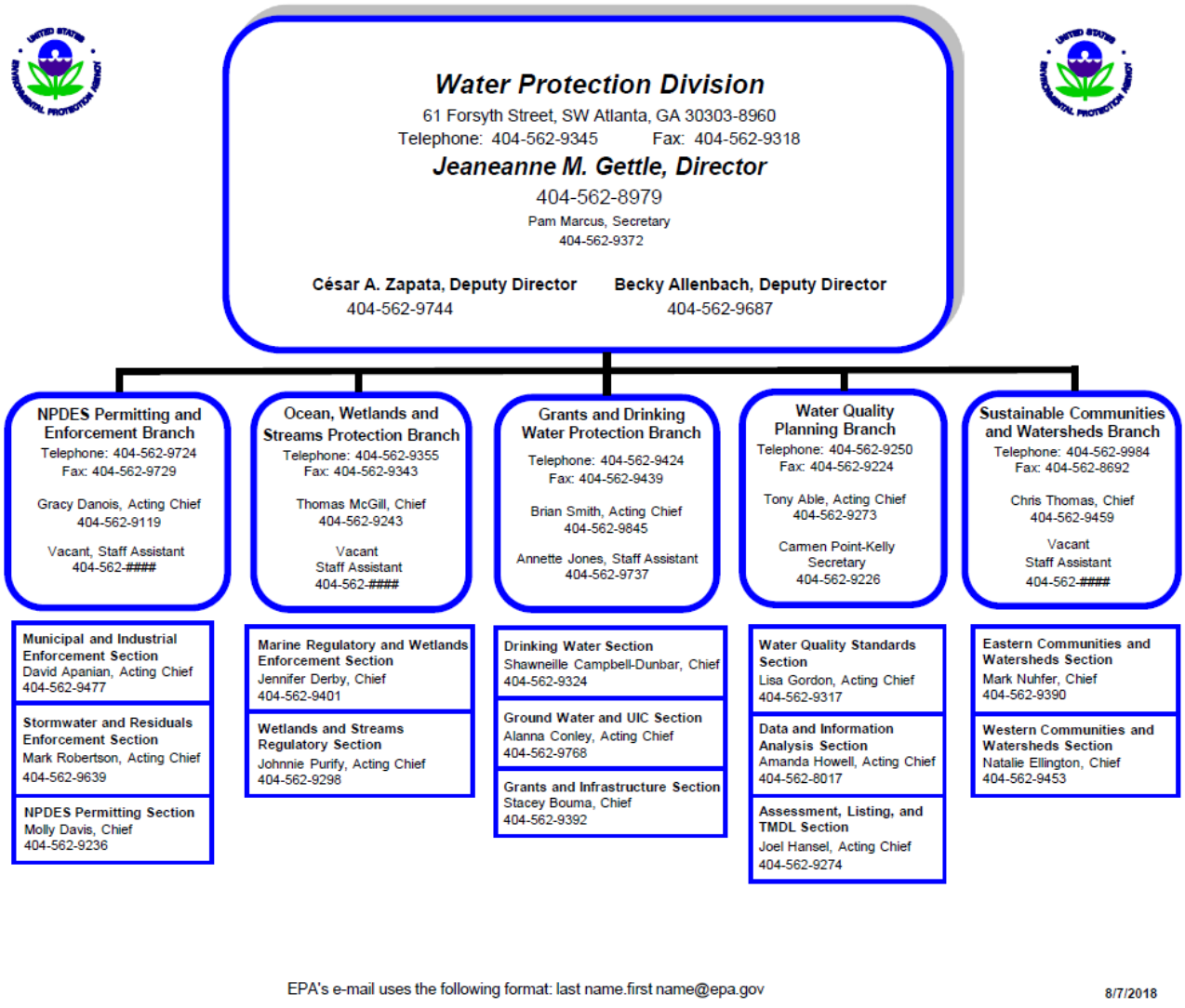
Region 4 Resource Conservation and Restoration Division



Superfund Division Organization

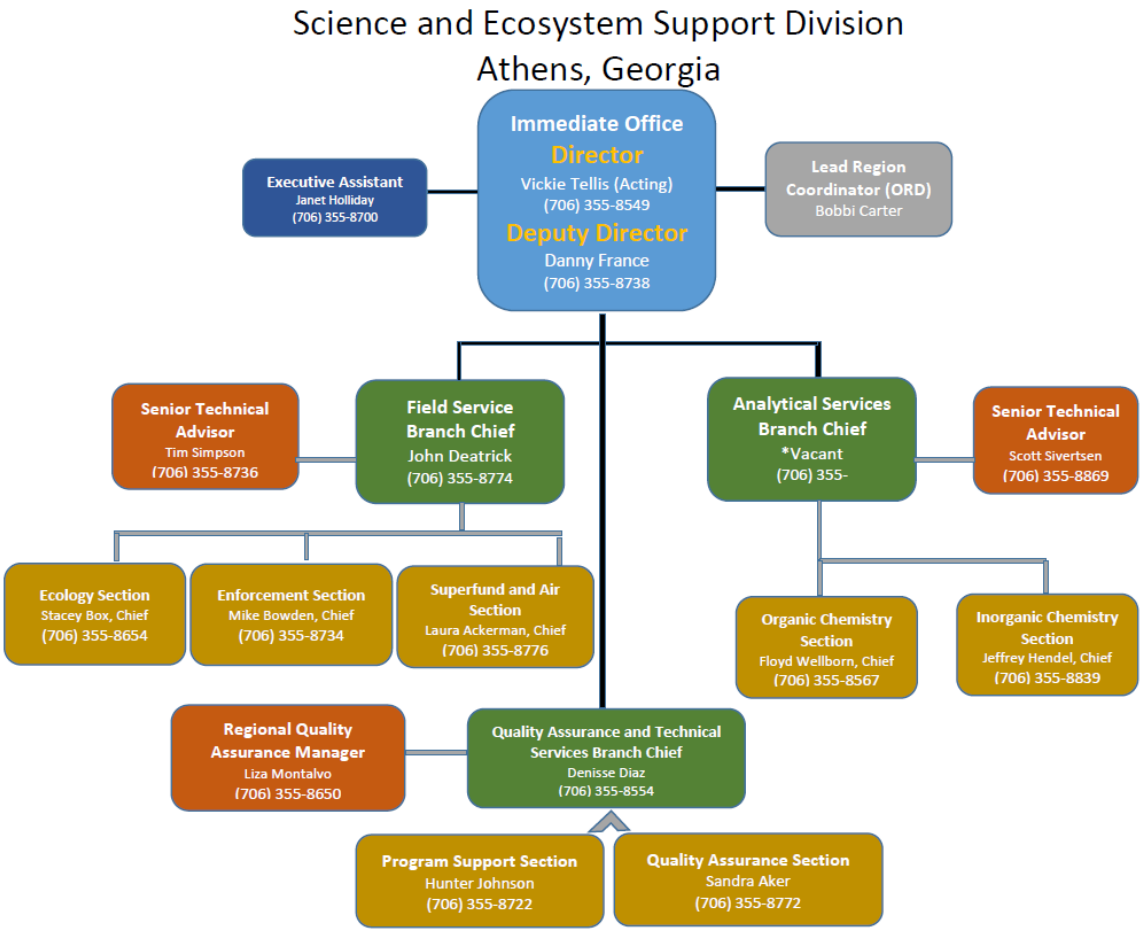


Region 4 Water Protection Division



EPA's e-mail uses the following format: last name.first name@epa.gov

8/7/2018


Science and Ecosystem Support Division
Athens, Georgia
Immediate Office
Director
Vickie Tellis (Acting)
(706) 355-8549
Deputy Director
Danny France
(706) 355-8738
Executive Assistant
Janet Holliday
(706) 355-8700
Lead Region Coordinator (ORD)
Bobbi Carter
Senior Technical Advisor
Tim Simpson
(706) 355-8736
Field Service Branch Chief
John Deatrick
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Analytical Services Branch Chief
*Vacant
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Senior Technical Advisor
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Ecology Section
Stacey Box, Chief
(706) 355-8654
Enforcement Section
Mike Bowden, Chief
(706) 355-8734
Superfund and Air Section
Laura Ackerman, Chief
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Organic Chemistry Section
Floyd Wellborn, Chief
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Inorganic Chemistry Section
Jeffrey Hendel, Chief
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Quality Assurance and Technical Services Branch Chief
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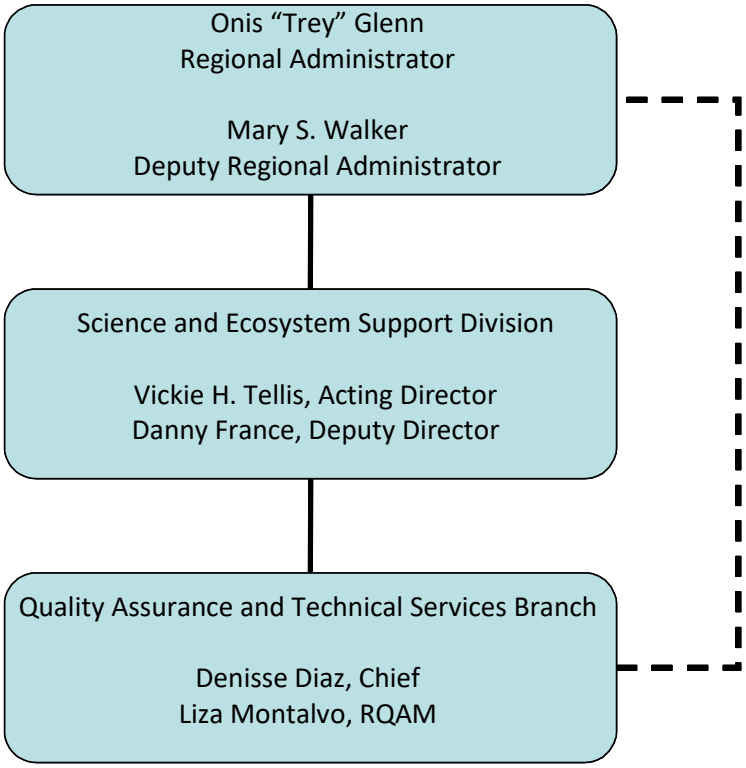
Program Support Section
Hunter Johnson
(706) 355-8722
Quality Assurance Section
Sandra Aker
(706) 355-8772

Region 4 Quality Assurance Management



APPENDIX B

REGION 4

MAJOR PROGRAM ELEMENTS

ACTIVITY	APPLICABLE LAW	RESPONSIBLE DIVISION	SESD BRANCH PROVIDING SUPPORT
Ambient Air Monitoring for Criteria Pollutants -- Delegated to the states. The Region has an overview/ technical assistance role. Special studies (i.e., Air Toxics) are conducted to support state programs.	CAA	APTMD	FSB, ASB
Stationary Source Enforcement -- Delegated to the states. The Region has an overview/technical assistance role.	CAA	APTMD	FSB, ASB
Mobile Source Inspections and Maintenance -- Delegated to the states. The Region has an overview/ technical assistance role.	CAA	APTMD	FSB, ASB
Pesticide Use/Misuses -- Delegated to the states. The Region has an overview/ technical assistance role. The states regulate and monitor the manufacture, sale, and use of pesticides.	FIFRA	APTMD	FSB, ASB, QATSB/QAS
PCB and Dioxin Inspections -- Inspections are conducted at transformer stations, substations, etc. Program inspectors conduct sampling; analyses are conducted by SESD and contract laboratories.	TSCA	APTMD	FSB, ASB

ACTIVITY	APPLICABLE LAW	RESPONSIBLE DIVISION	SESD BRANCH PROVIDING SUPPORT
Asbestos Inspections -- Overview of asbestos removal from schools and overview of renovation and demolition of buildings. Sampling and analyses are conducted by contractors.	TSCA	APTMD	QATSB/QAS
Water Quality Monitoring -- Most programs delegated to the states. Activities involve both fixed station networks and intensive studies. The Region has an overview/technical assistance role which includes special studies to support state programs.	CWA	WPD	FSB, QATSB/QAS
Water Quality Enforcement -- Delegated to all states. Several types of compliance inspections are conducted as overview for delegated states.	CWA	WPD	FSB, QATSB/QAS
Dredge and Fill – Investigations are conducted by SESD to support permitting decisions by the Region and for enforcement actions by the Department of Justice.	CWA	WPD	FSB, QATSB/QAS
RCRA Enforcement -- The program is delegated to the states. Several types of inspections are conducted by SESD and contractors. These include inspections of generators, transporters, and disposal facilities.	RCRA	RCRD	FSB, QATSB/QAS

ACTIVITY	APPLICABLE LAW	RESPONSIBLE DIVISION	SESD BRANCH PROVIDING SUPPORT
Investigations of Uncontrolled Hazardous Waste Site -- Several types of investigations are conducted to support listing of sites on the NPL and for remedial actions (immediate removal or clean-up activities). Investigations are conducted by contractors, states under cooperative agreements, potentially responsible parties under consent orders and SESD. The Region overviews all extramural investigations.	CERCLA	Superfund Division	FSB, QATSB/QAS
Monitoring of Public Water Supplies -- Program is delegated to the states. The Region has an overview/technical assistance role. SESD conducts special studies in support of state programs.	SDWA	WPD	FSB, QATSB/QAS
Underground Injection Control -- Program is delegated to the states. The Region has an overview/technical assistance role. SESD conducts special studies in support of the state programs.	SDWA	WPD	FSB
Investigations of Leaking Underground Storage Tanks -- The RCRA program (UST) is delegated to the states. The Region has primary responsibility for the UST program in Georgia and overviews the other seven state programs.	RCRA	RCRD	FSB

APPENDIX C

REGION 4

QUALITY MANAGEMENT PLAN CHECKLIST

QUALITY ASSURANCE PROJECT PLAN CHECKLIST

Region 4 Quality Management Plan Review Checklist – Revised March 2011

Title:
Organization:
QMP Date:
Received Date:
Review Date:
Reviewer:

Region 4 Quality Assurance Section
Quality Management Plan Checklist

Key: P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=Not Applicable

ELEMENT	COMMENTS
(1) Management and Organization	
1.1 Provides Title Page, Approval Page, Table of Contents, References- Approval Page includes signatures of senior management and the Quality Assurance Manager/Officer	
1.2 Summarizes the importance of QA and QC activities to the organization	
1.3 Describes the general goals and objectives of the quality system	
1.4 Summarizes the policy for resource allocation for the quality system	
1.5 Contains a reasonable organizational structure with respect to roles/responsibilities described in narrative & includes an organizational chart	
1.6 QA Manager is included in the organizational chart	
1.7 Demonstrates direct access from the QA Manager to senior organization manager – explains how the organization will ensure that QA personnel will have access to the appropriate levels of management to plan, assess and improve the organization's quality system	
1.8 Describes QA Manager's independence and authority with respect to decisions on data quality	
1.9 QA policy statement which demonstrates importance of environmental data in organizational decision-making	
1.10 Adequately describes the scope of the organization's environmental data collection programs which require quality management	
1.11 Discusses process for oversight of contractor activities (if data collection/analysis is contracted outside the agency)	

1.12 Provides a discussion of the technical activities or programs that are supported by the quality system	
1.13 Identifies the specific programs or activities that require quality management controls	
1.14 Identifies where oversight of delegated, contracted or other extramural programs is needed to assure data quality	
ELEMENT	**COMMENTS**
1.15 Where and how internal coordination of QA and QC activities among the group's organizational units needs to occur	
1.16 Describes how management will assure that applicable elements of the quality system are understood and implemented in all environmental programs	
1.17 Discusses the organization's process for resolving disputes regarding quality system requirements, QA and QC procedures, assessments, or corrective actions,	
(2) Quality System and Description	
2.1 Describes the main components of the quality system, including quality system documentation, planning, annual reviews, management assessments, training, systematic project planning, project-specific documentation, project and data assessments	
2.2 Discusses staff and management roles and responsibilities for quality assurance in environmental programs and for QA/QC in data collection	
2.3 Provides a list of tools for implementing each component of the quality system. Tools include Quality Management Plan, Quality System Audits, Training Plans (for technical and quality assurance training), Quality Assurance Project Plan, Data Verification and Validation	
2.4 Provides a list of the environmental programs that develop Quality Management Plans in support of the Quality System	
2.5 Describes the process for reviewing and approving internal Quality Management Plans within the organization	
2.6 Describes the process for implementing QA/QC activities within the organization	
2.7 Describes the roles and responsibilities of contractors or consultants in implementing the organization's quality system	
(3) Personnel Qualifications and Training	
3.1 Provides a policy statement regarding QA and technical training for staff and management	
3.2 Describes the process for assuring that personnel are qualified to perform the environmental data collection activities	

– identifies positions that require professional certifications, accreditation or other formal qualifications	
3.3 Describes the procedures for determining QA-related training needs; discusses how QA training is obtained; and describes how the effectiveness of the QA training obtained is measured	
3.4 Identifies the roles and responsibilities of management and authorities for obtaining QA training within the organization	

Key: P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=Not Applicable

ELEMENT	COMMENTS
(4) Procurement of Items and Services	
4.1 Describes the roles and responsibilities of management and staff for reviewing and approving procurement documents to ensure that they are accurate and complete	
4.2 Discusses the process for ensuring that procurement documents clearly describe the items and services needed; include the associated technical and quality requirements, identifies the quality system elements for which the supplier is responsible for adhering to; and discusses how the supplier's conformance to the customer's requirements are verified	
4.3 Describes the process for specifying QA and QC requirements in purchase orders, procurement documents, acquisitions and assistance agreements	
4.4 Identifies the individual(s) who are responsible for overseeing this process	
4.5 Describes the procedures for incorporating QA and QC requirements into contractor work assignments, technical directives, etc.	
(5) Documents and Records	
5.1 Describes the processes, including the roles and responsibilities, and authorities of management and staff for: identifying quality related documents and records (including hardcopy and electronic formats) requiring control	
5.2 Identifies the individual(s) who are responsible for preparing and reviewing documents for conformance to technical and quality system requirements	
5.3 Discusses the process for approving, issuing, using, authenticating, and revising documents and records	
5.4 Identifies the individual responsible for ensuring that records and documents accurately reflect completed work	
5.5 Describes the policies and procedures for maintaining documents and records including transmittal, distribution, retention (specifies retention time for documents and records),	

access, preservation (including protection from damage, loss and deterioration), traceability, retrieval, removal of obsolete documentation, and disposition.	
5.6 Identifies the individual and policies for ensuring that documents and records comply with all applicable regulatory, statutory, and EPA requirements	
5.7 Describes the procedures and identifies the individuals responsible for establishing and implementing appropriate chain-of-custody and confidentiality procedures for evidentiary records	

Key: P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=Not Applicable

ELEMENT	COMMENTS
(6) Computer Hardware and Software	
6.1 Describes the processes, including the roles, responsibilities and authorities of management and staff for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware and software used in environmental programs to ensure compliance with technical and quality system requirements	
6.2 Describes the procedures for assessing and documenting the impact of changes to user requirements	
6.3 Discusses the process for evaluating purchased hardware and software to ensure it meets user requirements and complies with applicable contractual requirements and standards	
6.4 Describes the process for ensuring that data and information produced from or collected by, computers meet applicable information resource management requirements and standards	
6.5 Describes the process for identifying and documenting the quality of environmental data in data bases and information systems – identifies the individual(s) responsible for certifying that data bases and information systems contain accurate information	
(7) Planning	
7.1 Describes the process for planning environmental data collection operations	
7.2 Identifies the roles and responsibilities of management and staff in the planning – discusses the involvement of project managers, sponsoring organization, project personnel, scientific experts, stakeholders and end data users	
7.3 Identifies how technical expertise in sampling, statistics, analytical services and QA/QC is provided	
7.4 Describes the use of a systematic planning process or data quality objectives process in planning environmental data collection operations	
7.5 Discussed the procedures for measuring the effectiveness of the planning process by management	
7.6 Describes the process for determining the type, quantity and quality of data to ensure that this information meets project objectives	
7.7 Describes the process for preparing, reviewing and approving QA project plans for environmental data collection operations performed by the organization	

7.8 Describes the process for preparing, reviewing and approving QA project plans for environmental data collection operations performed by contractors/consultants or assistance agreement holders	

Key: P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=Not Applicable

ELEMENT	COMMENTS
(8) Implementation of Work Processes	
8.1 Describes the process used for implementing QA Project Plans or other planning documentation for environmental data collection operations	
8.2 Discusses the system used to assure that such implementation is accomplished properly	
8.3 Describes how revisions to QA Project Plans and/or other planning documents are made, maintained and communicated to all parties involved (project personnel, stakeholders and end data users, etc.)	
(9) Assessment and Response	
9.1 Discusses how the adequacy of the quality system is assessed (audits, peer reviews, surveillance, readiness reviews, performance evaluations, etc.) annually and identifies the individual responsible for performing this assessment	
9.2 Describes the authority, competence, experience and training necessary to ensure that personnel conducting assessments or audits are technically knowledgeable, have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed	
9.3 Discusses the process for planning, conducting and reporting the results of assessment activities	
9.4 Discusses management's responsibility for reviewing and responding to assessment or audit findings	
9.5 Discusses how and when corrective actions will be implemented in response to audit/assessment findings	
9.6 Identifies the individual(s) who are responsible for addressing any disputes arising from audits/assessments	
(10) Quality Improvement	
10.1 Identifies who is responsible for identifying, planning, implementing and evaluating the effectiveness of quality improvement activities	
10.2 Describes the process for ensuring the continued improvement of the quality system	
10.3 Describes the process for ensuring that conditions adverse to quality are prevented, identified promptly and corrected as soon as possible	

10.4 Discusses how corrective actions are documented, tracked completed and verified	
References: Includes a reference section that identifies all of the documents used in QMP preparation and / or cited in the QMP.	

Final QMP Disposition:

____ Approved, no comments
____ Not Approved, ***Address Comments, Submit Revised QMP to EPA for Final Review and Approval***

References:

EPA Requirements for Quality Management Plans, EPA QA/R-2, EPA/240/B-01/002 (March 2001)

REGION 4 QAPP REVIEW CHECKLIST

P= Present & Acceptable; NP = Not Present; I = Incomplete; NA = Not Applicable

QAPP Title:
Project Location:
Originating Organization:
Receipt Date:
Review Date:
Reviewer:
Project Number:

USEPA
REGION 4 QUALITY ASSURANCE SECTION
QAPP REVIEW CHECKLIST

P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=Not Applicable

ELEMENT	COMMENTS
A1. Title and Approval Sheet	
Title	
Organization's Name	
Dated Signature of Project Manager	
Dated Signature of Quality Assurance Officer	
A2. Table of Contents	
A3. Distribution List	
A4. Project/Task Organization	
Identifies key project personnel, with their roles and	
Responsibilities well defined (includes end data users - project QA manager, subcontractors, etc).	
A5. Problem Definition/Background	
Clearly states problems or decision to be made	
Provides historical and background information	
A6. Project/Task Description	
Lists measurements to be made includes on-site field analysis and off-site fixed laboratory analysis	
Cites applicable technical, regulatory, or program-specific standards, criteria, or objectives	
Identifies types of personnel, equipment and instruments required to perform field sampling, field analysis and laboratory analysis	
Provides work schedule and data deliverable timelines	
Summarizes required project and QA records/reports	
A7. Objectives and Criteria for Measurement Data	
State project objectives - quantitatively and quantitatively	

Links measurement quality objectives to applicable action limits, criteria, etc.	

REGION 4 QAPP REVIEW CHECKLIST (Continued)

P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=Not Applicable

ELEMENT	COMMENTS
A8. Special Training Requirements/Certified Listed	
States how training is provided, documented and assured	
A9. Documentation and Records	
Lists information and records to be included in data report (e.g., raw data, field logs, results of QC checks, problems encountered	
Specifies the turnaround time for laboratory data deliverables	
Specifies the retention time and location for project records and reports	
B1. Sampling Process Design (Rational for Design)	
Specified the type, number and matrix of samples slated for collection	
Discusses the rationale for the proposed sampling design	
Specifies sample locations and frequency of sample collection at each location	
B2. Sampling Methods Requirements	
Describes sample collection procedures and methods	
Lists equipment needs	
Identifies support facilities	
Identifies individuals responsible for corrective actions in the field	
Describes the process for preparation and decontamination of sampling equipment	
Describes selection and preparation of sample containers – and specifies sample volumes	
Describes sample container, volume, preservation and holding time requirements per each chemical, physical or biological parameter	
B3. Sample Handling and Custody Requirements	
Summarizes sample handling requirements	
Summarizes chain-of-custody procedures	
B4. Analytical Methods Requirements	
Identifies the analytical methods to be followed (including method number – and sample preparation method such as digestion/extraction method where applicable)	
Provides validation information for non-standard methods	
Identifies individuals responsible for corrective action	
Specifies the laboratory turnaround time for analysis and data deliverables	

REGION 4 QAPP REVIEW CHECKLIST (Continued)

P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=Not Applicable

ELEMENT	COMMENTS
B5. Quality Control Requirements	
Identifies QC procedures and frequency for each sampling event, analysis, or measurement technique, as well as associated acceptance criteria and corrective actions	
References procedures and provides equations for calculating QC statistics including bias/accuracy, precision - specifies acceptance criteria for completeness, comparability and representativeness	
B6. Instrument/Equipment Testing, Inspection and Maintenance Requirements	
Identifies acceptance testing of sampling and measurement systems	
Describes equipment preventive and corrective maintenance	
Summarizes availability and location of spare parts	
B7. Instrument Calibration and Frequency	
Identifies equipment needing calibration and frequency for such calibration	
Summarizes required calibration standards, gases and/or equipment	
Cites calibration records and the manner traceable to equipment	
B8. Inspection/Acceptance Requirements for Supplies and Consumables	
Provides a list of the supplies and consumables including pH buffers, conductivity and turbidity standards, etc.	
States acceptance criteria for supplies and consumables	
Identifies the individuals responsible for inspecting supplies and consumables to ensure compliance with requirements	
B9. Data Acquisition Requirements for Non-Direct Measurements	
Identifies type of data needed from non-measurement sources (e.g., computer databases, literature searches, models, etc.) and provides the acceptance criteria for using this information	
Describes the limitations of this information and specifies when and when it cannot be used	
Documents the rationale for original collection of data and its relevance to the project	

REGION 4 QAPP REVIEW CHECKLIST (Continued)

P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=Not Applicable

ELEMENT	COMMENTS
B10. Data Management	
Describes record/data keeping, storage and retrieval policies/requirements for organization/project	
Provides attachments to the QAPP containing SOPs, Checklists, Analytical Methodologies, etc.	
Describes data handling equipment and procedures used to process, compile and analyze data (e.g., computer hardware and software) – identifies the type of software used such as Excel, Statistical, Data Validation, etc.	
Describes the process for assuring that applicable Office of Information Resource requirements are satisfied.	
C1. Assessments and Response Actions	
Lists the required number, frequency and type of assessments or audits complete with dates and names of auditors/personnel conducting these assessments (assessments can include management system reviews, technical systems reviews, peer reviews, surveillance, performance evaluation audits, laboratory audits, data quality audits, etc.)	
Describes the process for planning audits and assessments and identifies the individuals that participate in this planning	
Identifies those individuals responsible for performing audits and assessments	
Specifies the auditor's independence, authority and competence in performing audits/assessments	
Specifies how audit findings are documented, verified and communicated to project personnel, senior management and EPA	
Identifies individual(s) responsible for implementing corrective actions	
C2. Reports to Management	
Identifies the frequency and distribution of reports for:	
Project Status Reports	
Results of Performance Evaluations and Audits	
Results of periodic data quality assessments	
Results of quality assurance problems	
Identifies those individuals responsible for preparing reports and those that will receive these items	

REGION 4 QAPP REVIEW CHECKLIST (Continued)

P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=Not Applicable

ELEMENT	COMMENTS
D1. Data Review, Validation and Verification	
Specifies criteria for accepting, rejecting or qualifying data	
Provides a list of data qualifier flags and provides definition of each flag	
Provides project-specific statistics, calculations or algorithms	
D2. Validation and Verification Methods	
Describes or provides the data validation and verification process (can provide validation SOPs)	
Describe resolution procedures for data quality problems and identifies individuals responsible for resoling data quality issues	
Describes the procedures for documenting the results of data validation, review and verification	
Describes the process for communicating data validation results to project personnel	
D3. Reconciliation of Data to Project Objectives	
Describes the process for reconciling project results with the project-specific data quality objectives and identifies the limitations of the data	
Specifies the usability of the data and verifies that it meets project objectives	
Identifies the individuals who are responsible for reconciling the data to the project data quality objectives	
References: Includes a reference section that identifies all of the documents used in QMP preparation and / or cited in the QMP.	

Final QAPP Disposition:

____ *Approved, no comments*
____ *Not Approved,* ***Address Comments, Submit Revised QAPP to EPA PO***

References

1. EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5, EPA/240/B-01/002 (March 2001).

2. EPA Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4, EPA/240/B-06/001 (February 2006).

Both documents can be accessed at the following website: www.epa.gov/quality - Select guidance from the menu options to the left of the screen.