Region 4 U.S. Environmental Protection Agency 61 Forsyth Street, SW Atlanta, Georgia 30303

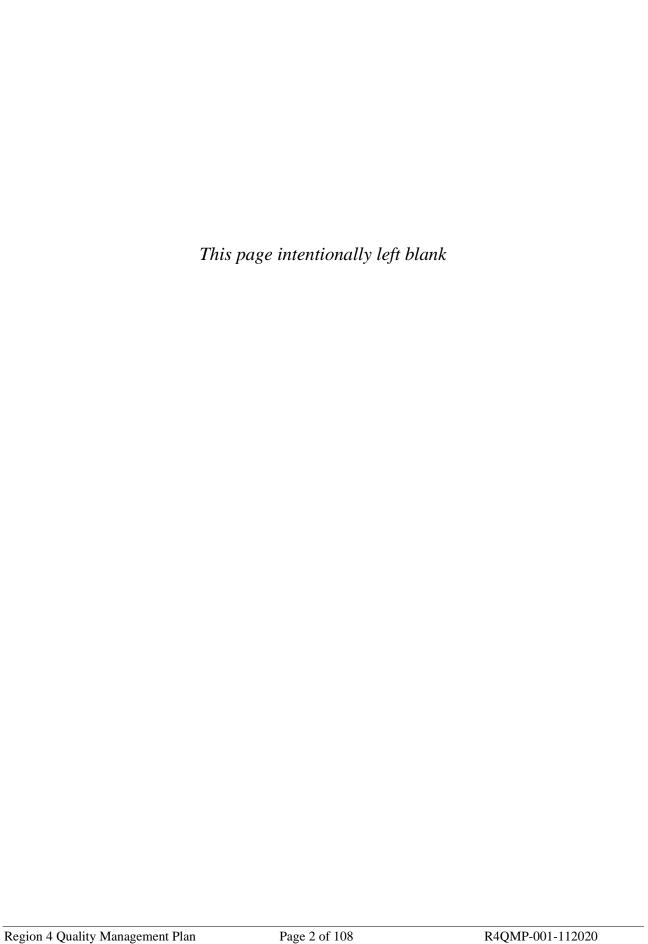


QUALITY MANAGEMENT PLAN

November 2020

Prepared by:

Liza I. Montalvo Region 4 Quality Assurance Manager



EPA Region 4 Quality Management Plan

APPROVAL FOR AGENCY

Name: Fitle:	Vaughn Noga Chief Information Officer & Deputy Assistant Administrator for Environmental Information, Office of Mission Support, U.S. EPA
Signature	
APPROVAL	S FOR REGION 4
	Liza I. Montalvo Region 4 Quality Assurance Manager
Signature	
Title:	Danny France Acting Director, Laboratory Services and Applied Science Division
Signature	
Name: Title:	Caroline Freeman Director, Air and Radiation Division
Signature	
Name: Fitle:	Marc Wyatt Director, Gulf of Mexico Division
Signature	

	Cesar Zapata Director, Land, Chemicals and Redevelopment Division
Signature	
	Carol J. Monell Director, Superfund & Emergency Management Division
Signature	
	Jeaneanne Gettle Director, Water Division
Signature	
Name: Title:	Kristy Eubanks Acting Director, Mission Support Division
Signature	
Name: Title:	Leif Palmer Director, Office of Regional Counsel
Signature	
Name: Title:	Mary S. Walker Regional Administrator
Signature	

Table of Contents

1.0	INTRODUCTION	8
1.1	IMPORTANCE OF ENVIRONMENTAL INFORMATION	8
1.2		
2.0	REGIONAL QUALITY ASSURANCE POLICY AND GOALS	10
	·	
2.1		
2.2	REGIONAL OBJECTIVES	12
3.0	REGIONAL ORGANIZATION AND QA RESPONSIBILITIES	14
3.1	REGIONAL PROGRAM ORGANIZATION AND FUNCTIONS	14
3.2	QUALITY ASSURANCE RESPONSIBILITIES	41
É	3.2.1 Regional Administrator (RA)	41
3	3.2.2 Regional Quality Assurance Manager (RQAM)	41
Ė	3.2.3 Regional Managers	
3	3.2.4 Quality Assurance Coordinators (QA Coordinators)	44
3	3.2.5 Designated Approving Officials	
	3.2.6 Divisional Project Managers	
	3.2.7 Divisional Project Officers/Contracting Officer Representatives	
Ĵ	3.2.8 Divisional Technical Officers	47
4.0	REGIONAL QUALITY SYSTEM REQUIREMENTS – EXTERNAL ORGANIZATIONS	48
4.1	STATE, LOCAL, AND TRIBAL GRANTS	48
4.2		
4.3		
4.4	QUALITY MANAGEMENT PLANS FOR EXTERNAL ORGANIZATIONS	50
4.5	QUALITY ASSURANCE PROJECT PLANS FOR EXTERNAL ORGANIZATIONS	51
4.6	DEMONSTRATION OF COMPETENCY FOR EXTRAMURAL ORGANIZATIONS	51
5.0	REGIONAL QUALITY SYSTEM - INTERNAL ORGANIZATIONS	52
5.1	DIVISIONAL QUALITY MANAGEMENT PLANS (QMPs)	52
5.2		
5.3	QA OPERATIONS FOR CONTRACTS	54
6.0	REGIONAL QUALITY SYSTEM COMPONENTS	55
6.1		
6.2 6.3		
	6.3.1 Preparation of SOPs	
	6.3.2 Standard Operating Procedure Criteria	
6.4	•	
6.5	·	
6.6	·	
6.7		
6.8		
7.0	QUALITY SYSTEM ASSESSMENT	
7.1		
7.2		
	7.2.1 Internal Assessments of EPA Activities	
73	7.2.2 External Assessments of State/Local/Tribal Activities	67 68
, ,	INTERNAL MODEL AND CONNECTIVE MODELS OF PROCESS	

8.0	DOCUMENTS AND RECORDS	70
8.1	REGION 4 RECORDS MANAGEMENT SYSTEM	70
9.0	QA COMMUNICATION/REPORTING/WORK PLAN	73
9.1	REGIONAL COMMUNICATION	73
9.2	QA Annual Report and Work Plan	
9.3	NATIONAL MEETINGS	74
9.4	Resources	74
10.0	PEER REVIEW	74
11.0	TRAINING	75
11.1	Training Needs Assessments	76
11.2	Training Records	76
12.0	QUALITY IMPROVEMENT	77
13.0	MANAGEMENT REVIEW	77
14.0	REFERENCES	78
APPEN	DIX A REGION 4 ORGANIZATIONAL CHARTS	79
	DIX B_REGION 4 MAJOR PROGRAM ELEMENTS	
APPEN	DIX C_REGION 4 QMP & QAPP CHECKLISTS	95
APPEN	DIX D REGION 4 DATA COMPETENCY CERTIFICATION FORM	107

LIST OF ACRONYMS

ARD - Air and Radiation Division

ASQ/ANSI - American Society of Quality/

American National Standards Institute

CERCLA - Comprehensive Environmental

Response, Compensation and Liability Act

CFR - Code of Federal Regulations

CIO – Chief Information Officer

CLP - Contract Laboratory Program

CO - Contracting Officer

CWA - Clean Water Act

DAO - Designated Approving Official **DMR** -

Discharge Monitoring Report

DQO - Data Quality Objectives

ECAD – Enforcement and Compliance

Assurance Division

EQMD – Enterprise Quality Management

Division

ESAT - Environmental Services Assistance

Team

FAR - Federal Acquisition Regulations

FOIA - Freedom of Information Act

GIS - Geographic Information System

GMD – Gulf of Mexico Division

IA - Interagency Agreement

IM - Information Management

IQGs - Information Quality Guidelines

LSASD – Laboratory Services and Applied

Science Division

NAAQS – National Ambient Air Quality

Standards

NESHAP – National Emission Standards for

Hazardous Air Pollutants

NPL - National Priorities List

NPDES - National Pollutant Discharge

Elimination System

NSPS - New Source Performance Standard

OMS – Office of Mission Support

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

RQAM - Regional Quality Assurance Manager

RA - Regional Administrator

SDWA - Safe Drinking Water Act

SEMD – Superfund and Emergency

Management Division

SOP - Standard Operating Procedure

WD - Water Division

1.0 INTRODUCTION

On April 28, 2019, EPA Region 4 implemented a new organizational structure to more closely align with EPA headquarters' structure. This resulted in significant changes to the quality management system. This Quality Management Plan (QMP) has been revised to ensure it conforms to the current organizational structure and the Agency's Quality Policy.

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) and ASQ/ANSI E4:2014, Quality management systems for environmental information and technology programs. CIO 2105.0 requires that each EPA Program and Regional Office develop and document a quality system to assure that environmental information used to support Agency decisions is of adequate quality and is usable for its intended purpose. ASQ/ANSI E4:2014 extends the Agency's requirements to all environmental information including data. 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 information and the implementation of environmental technology. The plan covers quality assurance policies, roles and responsibilities for environmental information collection activities. This includes the collection, evaluation, and use of environmental information produced by regional programs and generated through extramural agreements. Extramural Agreements include:

- Acquisitions including contracts, task orders, technical directives
- Financial assistance including:
 - o Cooperative agreements
 - Grants to state and local governments
 - Research grants
 - o 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. The document provides a link between the 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 information and the use of environmental technology.

1.1 Importance of Environmental Information

Environmental information is 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 information 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 information used in these decisions.

1.2 Essential Definitions

- 1.2.1 <u>Quality System</u> A structured and documented management system describing the quality assurance policies, practices, protocols, and procedures for ensuring that (1) environmental information is 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 <u>Environmental Information</u> Any data, measurement or calculations that describe environmental processes, location or conditions; ecological or health effects and consequences; or the performance of environmental technology. Environmental information includes data collected directly from measurements, produced from models and compiled from other resources such as databases or the literature. It also includes data derived from samples collected from the environment, the results of other analytical testing (e.g. geophysical, hydrological) of environmental conditions, and process data or physical parameters collected from the operation of environmental technology.
- 1.2.3 <u>Internal Information</u> Information 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 this information.
- 1.2.4 <u>Extramural Information</u> Data generated by organizations other than Region 4 which are funded by EPA through extramural agreements.
- 1.2.5 <u>Existing Information</u> 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 <u>Environmental Technology</u> - An all-inclusive term used to describe pollution monitoring, measurement and control devices and systems, waste

treatment processes and storage facilities, and site remediation processes and their components. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). It also includes 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 <u>Quality Assurance (QA)</u> An integrated system of activities including planning, implementation and assessment to ensure environmental information are of known and documented quality, and environmental technology produces the desired results.
- 1.2.8 <u>Quality Control (QC)</u> 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 <u>Quality Assurance Project Plan (QAPP)</u> A critical planning document for a project, study or task, describing how data collection activities are planned, implemented, and assessed.
- 1.2.10 <u>Data Quality Objectives (DQOs)</u> A systematic planning system designed to produce qualitative and quantitative statements that clarify project objectives, define the appropriate type of environmental information, delineate the decision rules, and specify tolerable levels of decision error.
- 1.2.11 <u>Graded Approach</u> 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 information, 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 information 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 known and documented 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 information 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 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, divisions are responsible for reviewing and approving Quality Assurance Project Plans (QAPPs) utilizing Designated Approving Officials (DAOs) in accordance with the requirements in Section 3.2.5 of this QMP. In some cases, QAPPs may be referred to qualified DAOs in other divisions for review, or states may be tasked to prescreen or comment on QAPPs. In addition, those QAPPs that are determined to require review or partial review by the Region Quality Assurance Manager (RQAM) (or designee) and/or scientists, chemists or environmental engineers at the Laboratory Services and Applied Science Division (LSASD) will be sent to the Chief of the Quality Assurance Section electronically outlining the anticipated areas or depth of review. In such cases, a prescreening QAPP review checklist prepared by the Project Manager may also accompany the document that has been sent to LSASD for partial review. This approach will greatly reduce the turnaround time for QAPP reviews, improve quality of the QAPP reviews, and will provide a more uniform work product. Checklists for DAO reviews are provided in Appendix C. Superfund program-specific DAO review checklists can be found in the QMP for the Superfund & Emergency Management Division (SEMD).

All Quality Management Plans (QMPs) whether generated by EPA Region 4 or extramural organizations, must be submitted to the RQAM for review and approval. QMPs must be submitted electronically to the RQAM via R4QMP@epa.gov, or hardcopy via mail.

The divisions will designate QA Coordinators. The minimum duties and training requirements of the QA Coordinator are outlined in Section 3.2.4 of this Plan. Presently, QA Coordinators report directly to their first line supervisor but receive guidance pertaining to Region 4 QA activities from the RQAM. QA Coordinators will have direct access to the Division Director and/or Deputy Division Director, as well as the RQAM, to resolve QA/QC issues in the Division.

In addition, the divisions may designate Field Quality Coordinators (FQCs) responsible for implementation of the QAFAP. When an FQC is not designated, the QA Coordinator is responsible for the implementation of the QAFAP in his/her division.

The duties of the FQCs may vary by Division but the minimum requirements are outlined in Section 3.2.9 of this QMP. Presently, FQCs report directly to their first line supervisor but receive guidance pertaining to Region 4 QA activities from the RQAM.

2.2 <u>Regional Objectives</u>

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 information 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 information 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 such as Sampling and Analysis Plans (SAPs) 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 information. 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), incorporate project-specific DQOs, approved by the DAO prior to project implementation. 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 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. QMPs will be developed using a graded approach according to the specific objectives and needs of the organization. If it is determined by the divisions/programs or RQAM that a QAPP or SAP 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 suborganizations, and the authority to require corrective actions of both organizations in the event the Regional QA policies or objectives were not met.

Region 4 supports the flexibilities provided by the Agency's Quality Policy for use of the graded approach by extramural organizations. For large organizations and/or complex projects, a QMP must be submitted in addition to the QAPP and any other QA documentation required under the Terms & Conditions of the assistance agreement demonstrating the organization's commitment to quality, describing their organizational roles and responsibilities, and their internal systematic planning process. The RQAM in consultation with the Project Officer or divisional QA Coordinator, may grant an exception or modification to the QMP requirement of organizations receiving financial assistance if they meet criteria which may include, but not be limited to, the following:

- small grants as defined by the EPA Small Grants Policy;
- one-time, short-term, and special projects or projects of limited scope;
 and
- organizations using or generating environmental information for public education purposes.

Organizations meeting these criteria or any other agreed upon by the RQAM may submit a combined QMP/QAPP in lieu of a separate QMP and a QAPP. QMP requirements to include in the combined QMP/QAPP must be clearly identified by the Project Officer either by providing a Region 4 EPA-approved QMP/QAPP template or providing a list of the QMP elements that must be included in the QAPP. The combined QMP/QAPP template must be approved by the RQAM or QAS designee.

2.2.5 Extramural organizations under agency-funded assistance agreements generating or using environmental information and expected to exceed a maximum value of \$200,000, must comply with the Agency Policy Directive Number FEM-

2012-02, Revision 1, Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements.

2.2.6 On September 23, 2014, the EPA Chief Information Officer issued the EPA QA Field Activities Procedure (QAFAP), CIO 2105-P-02.0, requiring all

EPA organizations that conduct field activities including Headquarters Offices, Program Offices, Regions, National Research Laboratories and Centers, and their sub-organizations, to implement a quality management system that incorporates all 10 elements of the Field Operations Group Operational Guidelines for Field Activities. These 10 elements are: (1) Personnel and Training; (2) Document Control; (3) Records Management; (4) Sampling and Environmental Data Management; (5) Field Documentation; (6) Field Equipment; (7) Field Inspections and Investigations; (8) Reports; (9) Internal Audits; (10) Corrective Action. Region 4 has incorporated these elements into the Regional quality management system and are addressed in this QMP.

- 2.2.7 The Region 4 Laboratory will maintain a documented quality system in accordance with applicable Agency policies and accreditation standards. In addition, the laboratory will demonstrate competency in accordance with the February 23, 2015 Agency Policy Directive for Assuring the Competency of Environmental Protection Agency Laboratories.
- 2.2.8 Regional managers and staff shall receive QA training appropriate for their responsibilities related to data collection or environmental technology.
- 2.2.9 Communication on QA issues and activities shall be maintained between the RQAM, Regional Senior Management as appropriate, as well as with program managers, QA Coordinators, Field Quality Coordinators, and QA staff including Project Officers.
- 2.2.10 Assessments shall be performed to determine the effectiveness of Regional and extramural quality systems.
- 2.2.11 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.
- 2.2.12 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 76-87. Major program elements and activities are shown in Appendix B, pages 88-91. The role of each regional program organizational unit covered by the QA requirements is described below:

3.1.1 <u>Laboratory Services and Applied Science Division (LSASD)</u>

The Division manages the regional quality system. The RQAM resides at LSASD and is supported by the Quality Assurance & Program Services Branch (QAPSB), Quality Assurance Section (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. LSASD 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 work plans negotiated annually between LSASD and the program divisions. Additional special projects may be requested by the Regional Administrator or other organizations. LSASD performs specific QA assessments of selected external environmental monitoring projects as requested by the program divisions.

The LSASD quality system is described in their QMP and encompasses all divisional QA related activities; field investigations, measurement and sampling; laboratory analyses; and management of the Regional QA Program. Within LSASD, there are three (3) branches that generate environmental information and/or compliance monitoring data for the regional programs: Applied Science Branch (ASB); Laboratory Services Branch (LSB); and, Quality Assurance and Program Services Branch (QAPSB). The ASB provides a wide range of sampling, and technical service activities to support Region 4's regulatory media programs. The LSB provides environmental chemistry data for decision making in EPA's multi- media programs for the protection of human health and the environment. The QAPSB personnel provides QA assistance to the regional programs including QMP and QAPP reviews, Contract Laboratory Program (CLP) data validations, and technical systems audits, among others. In addition, LSASD 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 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 interlaboratory comparison studies/programs. The LSASD 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 quality manual

entitled "Analytical Support Branch Laboratory Operations and Quality Control Manual" dated April 24, 2020.

3.1.2 Air and Radiation Division (ARD)

ARD implements the programmatic aspects of Clean Air Act (CAA) within the geographic boundaries of Region 4. Inspections and enforcement are principally managed by the Enforcement and Compliance Assurance Division. Under this statute and in accordance with implementing regulations and agency guidelines, the Division conducts activities to reduce emissions so that air pollution does not constitute a threat to public health, safety, well-being and the environment. To carry out its mission, the Division works with other federal agencies, state and local agencies, tribal governments, the public, and the private sector. The Division coordinates with the Office of Air and Radiation to ensure national consistency and strives to meet legal deadlines imposed by the CAA.

ARD consists of the Division Director's Immediate Office, the Grants Management and Strategic Planning Office, and two Branches that report directly to the Division Director. The two Branches are: Air Planning and Implementation Branch; and, Air Analysis and Support Branch. ARD has one Deputy Director who reports to and assists the Director with the management and direction of the organization's program and work.

Presently, ARD has a designated Division Quality Assurance Coordinator (QAC) located in the Air Analysis and Support Branch. The QAC reports directly to the Air Data and Analysis and Support Section (ADAS) Chief. However, this individual will have direct access to the Division Director and/or Deputy Division Director, as well as the RQAM, to resolve QA/QC issues in the Division.

QA requirements and responsibilities of each organizational unit in the Division are briefly described below.

3.1.2.1 Grants Management and Strategic Planning Office (GMSPO)

The GMSPO reports to the Division Director and manages the administrative aspects of ARD's grants programs for the CAA grants and special project grants. The Grants Team coordinates the administration of continuing environmental program grants, cooperative agreements and special purpose grants for the Division and coordinates with programmatic offices to provide oversight of state and tribal programs and other grant recipients and their use of financial support.

The GMSPO's Administrative Project officers (APOs) work with Technical Project Officers (TPO) throughout the Division to ensure that all funded projects are conducted under an approved QMP and QAPP. LSASD reviews and approves QMPs for all projects. For most projects, ARD DAOs review and approve the QAPPs. For air monitoring projects,

LSASD DAOs review and approve the QAPPs as described in the Memorandum of Understanding (MOU) between ARD and LSASD. The status of grant recipient QA activities is tracked using the Integrated Grants Management System (IGMS).

3.1.2.2 Air Planning and Implementation Branch (APIB)

APIB implements two key programs under the CAA – Air Quality Planning and air permitting. These programs provide for the development and approval of plans and regulatory programs for the attainment and maintenance of the National Ambient Air Quality Standards (NAAQS) and addressing visibility concerns in designated areas. APIB also manages the New Source Review/Prevention of Significant Deterioration (NSR/PSD) construction and Title V operating air permitting programs and provides policy and programmatic guidance to state and local agencies that issue such permits to sources. APIB also issues permits in areas not delegated to states (e.g., Outer Continental Shelf permits).

APIB will appoint a Branch Quality Assurance Coordinator. This Branch QAC will work with Branch management and appropriate staff to:

- Identify any staff activities involving the collection or use of environmental information that must be covered by QAPPs and/or SOPs, and assist in developing these documents
- Track these QAPPs and SOPs that cover Branch staff activities and ensure that they are revised and approved as necessary
- Maintain centralized copies of these approved QAPPs or SOPs in the Branch files and on the ARD SharePoint site (for non-field activities; APIB does not typically participate in field activities that are subject to the QAFAP)
- Facilitate Branch DAO training in coordination with the Division QAC
- Track Branch DAOs certification status and renewal dates
- Track and maintain centralized copies of Branch environmental data-related SOPs

As applicable, QA responsibilities for staff include: TPOs ensuring that QMPs/QAPPs covering Grants or Cooperative Agreements have been submitted and approved as required and ensuring that appropriate SOPs are in place.

Air Regulatory Management Section (ARMS)

ARMS serves as the Region 4 technical authority and resource for the states for overall attainment and maintenance of the NAAQS and compliance with the visibility and transportation conformity requirements. ARMS provides oversight and management of states' attainment and

maintenance of the NAAQS through technical analyses for designations, regulatory and non-regulatory air quality planning efforts, and through the implementation of general and transportation conformity requirements. ARMS evaluates the approvability of and acts on state implementation plans (SIPs) related to mobile and stationary sources, visibility, and conformity. ARMS also provides technical and other assistance to Agency stakeholders to support clean air activities, such as consultation on NEPA, enforcement and compliance assurance, and emergency preparedness and response issues.

Air Permits Section (APS)

APS provides technical consultation, program assistance, and ensures the consistency for state and local permitting activities for stationary sources of air pollution that are regulated under Title I (PSD and NSR), Federally Enforceable State Operating Permit programs, and Title V (Part 70 and Part 71 Operating Permit Programs) of the CAA, as well as provides training and assistance to builds technical and programmatic capacity in the states. APS evaluates and processes revisions to the state and local operating permit programs authorized under Title V of the CAA and issues federal PSD/NSR, OCS and DWP permits to applicable sources. Staff provides technical, policy and compliance assistance to the regulated community through communication and various tools, including training and outreach materials, presentations at workshops and conferences, technical and policy assistance via pre-submittal reviews, etc. APS provides technical and other assistance to Agency stakeholders to support clean air activities, such as consultation on NEPA, enforcement and compliance assurance, and emergency preparedness and response issues.

3.1.2.3 Air Analysis and Support Branch (AASB)

AASB administers the monitoring, modeling and emissions inventories programs. AASB develops programs for assessing and responding to geographic, community, and place-based- environmental problems and issues including the design or participation in initiatives to address criteria and toxic air pollution and providing outreach to various stakeholders that promote voluntary efforts to reduce human exposures to environmental risks and to support energy efficiency (i.e., CEH, Asthma, Indoor Air, and Energy Star). AASB also provides input on state program grants, including review of state work plans and conducting grant-related oversight for the monitoring, modeling, emissions inventories, stationary source programs, and voluntary air programs.

AASB will appoint a Branch Quality Assurance Coordinator. This Branch QAC will work with Branch management and appropriate staff to:

- Facilitate implementation of the QAFAP for field activities conducted in the branch.
- Facilitate Branch DAO training in coordination with the Division QAC
- Track Branch DAOs certification status and renewal dates
- Maintain copies of all AASB-approved SOPs or other QA documents for field work on the R4 Air Monitoring Team SharePoint site:

https://usepa.sharepoint.com/sites/R4/air-monitoring/SitePages/Home.aspx?e=1:cbb96bb6ac0247aeab9c6be2a595b892. Maintain centralized copies of AASB-approved QAPPs or SOPs for any non-field activities in the Branch files and on the ARD SharePoint site.

The Branch QA Coordinator also serves as the Document Control Coordinator (DCC) and Field Equipment Manager. The AASB Coordinator will work with the AASB managers and QA coordinator to ensure that field activities within the branch follow the EPA QAFAP requirements, including records management, document control, sampling and environmental information management, field documentation, field equipment, reports, internal audits, and corrective actions.

The Branch QA Coordinator should inform the ARD QA Coordinator of any ongoing QA activities/issues including results of internal and external QAFAP audits. Branch TPOs should also inform the Branch QAC of any ongoing QA activities/issues related to QMPs/QAPPs developed and implemented as required for any Branch grant/cooperative agreement. The Branch QA Coordinator should raise important QA issues to the appropriate Section Chief or if necessary, to the Branch Chief, and to the division QA Coordinator.

As applicable, QA responsibilities for staff include: TPOs ensuring that QMPs/QAPPs covering Grants or Cooperative Agreements have been submitted and approved as required and ensuring that appropriate SOPs are in place.

Communities and Air Toxics Section (CATS)

CATS provides the expertise within the Regional Office for various management and implementation activities involving radon and indoor air. The Section provides technical assistance to states, municipalities, and the public concerning indoor radon measurement and mitigation including various demonstration activities. CATS implements an indoor air outreach program advising interested parties of the potential problems and solutions to indoor air problems, and assists state and local agencies to develop indoor air programs. Furthermore, CATS works with various school districts to develop and implement programs to mitigate indoor

contaminants within school buildings and increase the educational awareness of school officials and students regarding maintenance of indoor air.

CATS serves as the primary contact for the design, coordination, and implementation of geographic and community based initiatives involving air issues. CATS conducts various compliance assistance activities by implementing the Community Based Environmental Program Framework and to support targeting of priority places within each state for EPA and other federal support.

CATS provides authoritative policy, technical guidance, and expertise on mobile source air quality modeling necessary for the attainment and maintenance of the NAAQS. CATS provides guidance and assistance to the state and local agencies developing the mobile source and transportation components of strategies for the attainment and maintenance of standards, including interpretation of regulations and policies.

CATS manages and promotes the Energy Star and other voluntary pollution prevention programs that reduce atmospheric emissions, help to integrate pollution prevention into state and local programs, and provide pollution prevention and other voluntary program information.

CATS also conducts investigations, compliance inspections, and evaluations concerning the effect or potential effect of nuclear activities on the environment. CATS staff operates a RadNET monitoring station at the Atlanta Federal Center under the direction of the National Analytical Radiation Environmental Laboratory (NAREL) in Montgomery, Alabama.

CATS conducts activities that are developed to further reduce risks to human health from air emissions of priority persistent, bioaccumulative, and toxic (PBT) pollutants.

CATS implements CAA source-specific emissions guidelines under 111(d), and combustion-related emission guidelines under Section 129. CATS reviews the level and quality of effort by state and local air agencies to ensure that delegated programs are being implemented consistent with the delegation agreements. CATS also provides training and technical assistance to staff within state and local air agencies.

CATS implements an authoritative technical consultation and assistance program for state and local agency delegated activities for stationary air pollution sources that are regulated under Title I and Title III of the CAA. CATS provides guidance and technical support to state and local agencies, and to other Region 4 programs, for the implementation of the New Source Performance Standards (NSPS) and Section 111(d)/Section 129 plans. CATS provides technical assistance to state and local agencies for determining the applicability of NSPS and Section 111(d)/Section 129

requirements. CATS implements NSPS in jurisdictions where delegation to state and local agencies has not occurred or initiates federal plans in absence of approved state and local Section 111(d)/Section 129 plans. CATS provides authoritative guidance and technical support to state and local agencies for the implementation of the National Emission Standards for Hazardous Air Pollutants/Maximum Achievable Control Technology (NESHAP/MACT) regulations and standards.

CATS also provides authoritative technical expertise on stationary source emission testing and continuous emission monitoring. This includes providing assistance to clients (state and local air agencies, industry, and other EPA programs) on the implementation of current sampling methodology and analysis of alternative method proposals.

Air Data and Analysis Section (ADAS)

ADAS implements the monitoring, modeling and emissions inventories programs and provides technical assistance to all the Division's programs.

Staff conduct and review air quality modeling activities, including the development of emissions inventories, necessary to evaluate the effectiveness of programs implemented by the Division.

Staff provide modeling, and emissions inventory guidance and assistance to the state and local agencies as they develop SIP strategies for attainment of the NAAQS, NSR/PSD and Air Toxics programs.

Staff provide guidance and assistance to state and local agencies in developing and implementing air monitoring programs in coordination with the LSASD; review state and local monitoring networks for compliance with air monitoring regulations including the approval/disapproval of proposed revisions to monitoring networks. ADAS conducts special research projects to evaluate emerging air monitoring technology.

Staff provide technical and other assistance to Agency stakeholders to support clean air activities, such as consultation on NEPA, enforcement and compliance assurance, and emergency preparedness and response issues.

ADAS conducts and reviews air quality modeling activities necessary to evaluate the effectiveness of programs implemented by the Division. ADAS also provides modeling guidance and assistance to the state and local programs as they develop SIP strategies for attainment of the NAAQS, NSR/PSD and Air Toxics programs, and general guidance and oversight.

3.1.3 Superfund and Emergency Management Division (SEMD)

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. The quality system for the SEMD is described in their QMP.

The SEMD 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. LSASD provides the SEMD with technical assistance relevant to the collection of environmental data, including QA oversight. This includes regional coordination with 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 <u>Land Chemicals and Redevelopment Division (LCRD)</u>

The Division is under the supervision of a Director and is assisted by one program Deputy Director. The Deputy Director, in the absence of the Director, is responsible for the management, coordination, and implementation of the Division's programs. In addition, the Deputy has programmatic duties dealing with regional and national positions supporting RCRA, TSCA, and FIFRA programs, site specific issues, state and tribal relations, budgetary functions and legislative liaison matters for the eight southeastern states. The Deputy reports to the Division Director who has the overall responsibility for the program elements and organizational units.

The Division performs the following functions:

- Implements the Resource Conservation and Recovery Act (RCRA), as amended by the 1984 Hazardous and Solid Waste Amendments (HSWA), which includes the RCRA Subtitle C (Hazardous Waste), Subtitle D (Solid Waste), and Subtitle I (Underground Storage Tank-UST) programs; the Small Business Liability Relief and Brownfields Revitalization Act (Brownfields Law); the Toxic Substances and Control Act (TSCA), which includes Polychlorinated Biphenyls (PCBs), Lead-based Paint, and Asbestos Hazard Emergency Response Act (AHERA); and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).
- Strategically develops goals and priorities supporting the Division's responsibilities under these Statutes and that are also aligned with the goals

- and priorities of the Regional Administrator, the Office of Chemical Safety and Pollution Prevention (OCSPP), the Office of Land and Emergency Management (OLEM), and the Office of Enforcement and Compliance Assurance (OECA).
- Assists the states in developing comprehensive programs within delegated 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.
- Manages grant programs and works with grantees to ensure that work plans support national and regional goals; provides oversight of grant programs as a requirement of federal grant management.
- Represents the Region in carrying out the direct implementation of programs for which it is responsible, including compliance and enforcement, permitting, grants management, and corrective action activities.
- Conducts community engagement and outreach consistent with Agency priorities.

The Laboratory Services and Applied Sciences Division (LSASD) supports LCRD with technical assistance relevant to monitoring and data collection and interpretation activities, including Quality Management Plan (QMP) and Quality Assurance Project Plan (QAPP) reviews and overall QA oversight. LSASD also conducts Comprehensive Groundwater Monitoring Evaluations and Compliance Enforcement Investigations at RCRA facilities; provides technical assistance and training to States, Indian Tribes, and RCRA program personnel; and conducts system audits of State and grantee field and laboratory activities.

The responsibilities of each organizational unit in the Division are briefly described below.

3.1.4.1 Redevelopment and Chemicals Branch

The Redevelopment and Chemicals Branch (RCB) is comprised of three sections, the Brownfields and Redevelopment Section, the Chemical Safety Section, and the PCB and Sustainability Section. The Branch Chief reports directly to the Director of the LCRD Division. The three Section Chiefs report directly to the Branch Chief.

The Redevelopment and Chemical Branch has appointed a Branch Quality Assurance Coordinator. This Branch QAC will work with Branch management and appropriate staff to:

- Identify any staff activities involving the collection or use of environmental information that must be covered by QAPPs and/or SOPs and assist in developing these documents.
- Track these QAPPs and SOPs that cover Branch staff activities and ensure that they are revised and approved as necessary.

- Maintain copies of all approved SOPs or other QA documents for field work on the R4 QAFAP intranet site.
- Maintain centralized copies of these approved QAPPs or SOPs for any non-field activities in the Branch files and on the RCB SharePoint site.
- Facilitate Branch DAO training in coordination with the Division OAC.
- Track Branch DAOs certification status and renewal dates.
- Track and maintain centralized copies of Branch environmental data related SOPs

As applicable, QA responsibilities for staff include: TPOs ensuring that QMPs/QAPPs covering Grants or Cooperative Agreements have been submitted and approved as required and ensuring that appropriate SOPs are in place.

Division-wide functions supported by the branch and the duties, responsibilities, and activities of each section are described below.

- Leads the Division's efforts on Land Revitalization.
- Co-leads the Division's activities for Quality Assurance.
- Implements the Division's Environmental Justice (EJ), Community Engagement (CE), and Children's Health (CH) efforts.

Brownfields and Redevelopment Section

The Brownfields and Redevelopment Section performs the following functions:

- Implements the Region 4 Brownfields program.
- Administers and manages grants for Brownfields projects to facilitate Brownfields Assessments, Cleanups, Job Training and Reuse/Revitalization efforts.
- Administers and manages State/Tribal Response Program grants issued pursuant to CERCLA Section 128(a), working with Region 4 States and Tribes to ensure appropriate and effective use of funds.
- Oversees projects where select communities will restore to productive use, idled, or under-used industrial and commercial properties where redevelopment is complicated by real or perceived environmental contamination.
- Administers and manages the Targeted Brownfields Assessment (TBA) program.
- Works with Brownfields grantees, the Division's Land Revitalization and Community Outreach Team, and other EPA Regional programs to promote and facilitate cleanup and redevelopment of Brownfields sites and create jobs.

The Brownfields and Redevelopment Section performs the following QA described below:

- For the Brownsfield Program, QAPPs are prepared by CERCLA §104(k) and §128(a) grantees for Brownfields assessments and cleanups and by EPA contractors for Targeted Brownfields Assessments.
- For review and approval of QAPPs, the Brownfields Section will maintain approximately ten (10) Designated Approving Officials (DAO) with one (1) serving as the section's lead DAO providing quarterly reporting to the Division QA Coordinator and maintaining an up to date record of QAPPs in the LSASD QA Tracking System.
- Quality Assurance documents, including Generic and Site-Specific Addendum QAPPs, are maintained by the Project Officer or Work Assignment Manager in the project files.
- Active files are maintained in the Records Center and inactive files will be maintained according to the appropriate records retention schedule. For CERCLA 104(k) grants, the QMP elements are addressed in the generic QAPP. Therefore, a separate QMP is not required for these grants.
- Details on tracking, review, and record keeping procedures for Brownfields program QAPPs are outlined in the Brownfields Section QAPP Review SOP (December 2008 or most recent version).

Chemical Safety Section (CSS)

The Chemical Safety Section (CSS) performs the following the functions:

- Coordinates with the Office of Chemical Safety and Pollution Prevention and the Office of Enforcement and Compliance Assurance to implement programs supporting FIFRA (pesticides) and TSCA (Lead-based paint and AHERA asbestos).
- Implements of the Lead-Based Paint Program under TSCA, including the Renovation, Repair and Painting (RRP), Lead Abatement, and the Training Provider Accreditation programs.
- Coordinates with authorized State Lead Agencies on the implementation of FIFRA pesticides programs including the Worker Protection Standard, Pesticide Applicator Certification and Training, Integrated Pest Management, Bed Bugs, and Mosquito Control.
- Develops and implements federal programs responsive Title X requirements for states who do not elect to or cannot receive program authorization for all or a portion of lead-based paint programs.

• Provides administrative oversight of the grants and cooperative agreements in the CSS programs.

CSS performs the following QA functions described below.

- FIFRA/TSCA R4 State and Tribal grantees prepare QMPs and QAPPs for environmental data collection activities associated with compliance monitoring inspections in the FIFRA and TSCA Leadbased paint programs.
- All QAPPs are prepared with the assistance of a CSS TPO.
- LSASD will review and approve all QMPs and assist CSS on the review and approval of all QAPPs as needed.

PCBs and Sustainability Section

The PCBs and Sustainability Section performs the following functions:

- Approve cleanups and write permits for PCB sites
- Implement the Sustainable Materials Management program to promote recycling, food waste prevention, technical assistance
- Support disaster recovery and pollution prevention programs

3.1.4.2 RCRA Programs and Cleanup Branch

The RCRA Programs and Cleanup Branch (RPCB) is comprised of three sections, the RCRA Programs and Permitting Section, the RCRA Corrective Action Section and the UST and Data Management Section. Duties, responsibilities, and activities are described below. The Chief of the RCRA Programs and Cleanup Branch reports directly to the Director of the LCR Division.

The Branch has several DAOs on its staff and one DAO serving as the Branch lead DAO, providing quarterly reporting to the Division Quality Assurance Coordinator (DQAC) and maintaining an up to date record of QAPPs in the LSASD QA Tracking System.

The RCRA Programs and Cleanup Branch performs the following functions:

 Provides leadership, program development and project implementation supporting the full range of the Agency's RCRA programs, ranging from support for state hazardous and solid waste regulatory/management programs to the ongoing development and implementation of a sustainable materials management (SMM) program.

- Coordinates with other Branches and Programs in the Division to provide consistency in EPA's oversight of delegated state RCRA Subtitle C and I Programs, including community engagement and environmental justice.
- Provides leadership for the Landfill Team.
- Provides technical support required for State delegation assistance under RCRA Subtitles C and D.
- Manages review and approval for RCRA Subtitle C Program delegation/authorization and processing program applications.
- Provides State program overview, including managing review and approval for RCRA Subtitle C Program delegation/authorization
- Administers RCRA Subtitle C grants; Tribal Cooperative Assistance; and Interagency Agreements.
- Manages financial assistance awarded to States/Tribes through Cooperative Assistance Agreements and Interagency Agreements.
- Manages and coordinates all activities related to Subtitle D.

RCRA Corrective Action Section

The RCRA Corrective Action Section performs the following functions:

- Implements the Region's Corrective Action Program under HSWA as it relates to RCRA Sections 3004(u) and (v) and manages RCRA corrective action orders/consent decrees issued pursuant to Sections 3008(a), 3008(h), 3013, and 7003 of RCRA.
- Issues HSWA permits in unauthorized States, including the modification/renewal of HSWA permits. This includes reviewing and processing corrective action RCRA/HSWA permit applications as well as arranging public hearings/meetings and working with the Land Revitalization and Community Outreach Team on Community Engagement efforts associated with those permits and approvals.
- Leads and manages the Division's contract services available under the RCRA Enforcement and Permitting Assistance (REPA) contract.
- Tracks each State's progress towards achieving the RCRA Corrective Action and permitting goals identified in their respective Grant Work Plans.

The Section's QA responsibilities include ensuring that HSWA permits and administrative orders issued to facilities in Mississippi require the preparation, submittal, approval, and implementation of QAPPs, or equivalent project-level planning documents, for all activities involving the collection of environmental data. All Corrective Action Project Managers in the Section are expected to maintain Designated Approving Official (DAO) certification. One Project Manager will serve as the section's lead DAO and Division's Quality Assurance Coordinator, maintaining an up to

date record of QAPP reviews in the LSASD QA Tracking System. The Corrective Action QAPP Management SOP (February 25, 2010 or most recent version) establishes uniform procedures for the review, approval, and tracking of QAPPs, or equivalent project-level planning documents, that are prepared and submitted by RCRA facility owners/operators pursuant to EPA-issued permits and enforcement orders.

RCRA Programs and Permitting Section

The RCRA Programs and Permitting Section performs the following functions:

- Manages all aspects of RCRA Subtitle C program authorization, reviewing program revision applications and coordinating these reviews.
- Plans, awards and grants management as well as post award monitoring of state RCRA/HSWA Subtitle C/D.
- Issues RCRA permits in unauthorized States, including the modification/renewal of RCRA permits. This includes reviewing and processing non-corrective action RCRA/HSWA permit applications as well as arranging public hearings/meetings and working with the Land Revitalization and Community Outreach Team on Community Engagement efforts associated with those permits and approvals.
- Negotiates with the States to resolve interpretation differences and needed changes in legislation, regulations and application documents, as well as coordinating post delegation activities such as changes in federal law and regulations which require corresponding state changes and determining the acceptability of state changes.
- Manages Cooperative Assistance Agreements and Interagency Agreements with Tribes pursuant to Subtitle D to meet national goals and objectives presented in the EPA's strategic plan, the national program managers' guidance, and the Budget Formulation System.
- Provides leadership, program development and project implementation supporting the full range of the Agency's RCRA programs, including support for state hazardous and solid waste regulatory/management programs.
- Tracks each State's progress towards achieving the RCRA Permitting goals identified in their respective Grant Work Plans.

Underground Storage Tank and Data Management Section

The Underground Storage Tank and Data Management Section performs the following functions:

- Manages the Regions UST program under RCRA Subtitle I as it relates to USTs and Leaking Underground Storage Tanks (LUST), as well as ensuring greater compliance with environmental laws as it relates to RCRA-Subtitle I, TSCA (PCBs), and OPA.
- Conducts Compliance and Enforcement activities pursuant to the RCRA Subtitle I UST program in Indian Country and for States that have not been delegated and/or authorized for the RCRA Subtitle I UST program (or portions thereof) or where EPA is requested to take the lead by the State, including but not limited to, conducting lead inspections and investigations, the issuance and management of administrative enforcement actions, the referral of civil judicial litigation packages to the Department of Justice, compliance assistance, and compliance monitoring.
- Conducts oversight inspections, reviews state compliance and enforcement actions, and takes independent action where state delegated UST programs do not meet agreed upon criteria.
- Implements the UST program primarily through state delegated programs and provides financial support through grant awards, technical support, advice, and recommendations to the states to assure that statutory mandates are implemented.
- Administers and manages Leaking UST Cleanup and Prevention Grants/Cooperative Agreements, and tracks and ensures that each State meets goals identified in their respective grant/cooperative agreement work plans.
- Ensures that each State meets and maintains compliance with the provisions of the Energy Policy Act and provides oversight of the Region 4 States in the administration of the Leaking Underground Storage Tank Trust Fund.
- Works with the Division's Brownfields Section to implement the Petroleum Brownfields program as it relates to cleaning up and revitalizing abandoned gas stations along selected corridors.
- Works with EPA regional and state program managers and staff, contractors, members of the regulated community, neighborhood associations, elected officials, grantees and other EPA programs and federal and state/local agencies, to promote the cleanup and reuse of properties contaminated by petroleum.
- Assists the Brownfields Section in managing Brownfield grants and Targeted Brownfields Assessments at sites involving petroleum contamination.
- Performs information management for RCRA as it relates to the RCRAInfo database, biennial reporting, PCBs and management of hazardous and non-hazardous solid waste.

3.1.5 Water Division (WPD)

WD has the program and implementation responsibilities for the Safe Drinking Water Act, Clean Water Act, ambient surface water and

groundwater, underground injection control, estuarine waters, off-shore discharge, and domestic and industrial wastewater treatment programs. The Division is responsible for oversight of delegated permitting. The division manages federal grants and contract funds. It ensures that QA matters are properly reflected in budgets, program plans, and work plans. WD 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. LSASD provides the WD with technical assistance relevant to monitoring and data collection and interpretation activities, including QA oversight. This includes oversight of State/Tribal/Local ambient water monitoring networks, special ambient water studies, performance audits on water and wastewater field monitoring and laboratory operations.

3.1.5.1 Ocean & Estuarine Management Section

The National Estuary Programs (NEPs) prepare QA documentation at the time of award, but before sample collection, generation or use commences. NEPs then awards funds to subawardees and/or contractors. The subawardees or contractors produce the QMP, QAPP and data competency certification. The RQAM has authorized the production of a combined QMP/QAPP for programs like the NEPs Wetlands and South Florida based on a graded approach according to the specific objectives and needs of the organization. The technical aspect of the QAPP is approved by the R4 DAO. The NEP director approves and signs the QMP/QAPP and certifies the subawardee or contractor has satisfied the requirements of the updated Agency's Policy to Assure the Competency of Organizations Generating Environmental Measurement Data Under Agency-Funded Assistance Agreements.

3.1.6 Enforcement and Compliance Assurance Division (ECAD)

The ECAD is responsible for developing and implementing Regions 4 enforcement and compliance assurance programs and statutes EPA administers in Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina and Tennessee. The Enforcement and Compliance Assurance Division works closely with the other Region 4 divisions, Office of Regional Counsel (ORC), Criminal Investigations Division (CID), and Department of Justice (DOJ) to deliver a comprehensive enforcement and compliance assurance program utilizing the entire spectrum of compliance assurance tools available to the region. This includes strategic planning for enforcement, compliance monitoring and compliance assistance activities, conducting inspections, developing enforcement cases, preparing and issuing administrative actions, assessing penalties, developing judicial enforcement actions, negotiating settlements, measuring and reporting

results of the Region's enforcement efforts. The Division ensures QA matters are properly reflected in budgets, program plans, and work/operating plans.

The Division works with federal, state and tribal partners in ensuring environmental compliance. The Division coordinates and collaborates with States on enforcement planning and implementation for delegated programs. The Division maintains responsibility for planning and implementation of enforcement and compliance assurance in direct implementation programs.

The Division works with ORC and the National Program Manager (NPM) - Office of Enforcement and Compliance Assurance (OECA) to implement EPA statutes, enforcement policies and regulatory requirements, and provides guidance and advice on compliance and enforcement matters.

The Enforcement and Compliance Assurance Division enforces a broad spectrum of Federal environmental laws, including the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), Resource Conservation and Recovery Act (RCRA), Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Toxics Substance Control Act (TSCA), Emergency Planning and Community Right-To-Know Act (EPCRA), Marine protection, Research, and Sanctuaries Act (MPRSA), and other Federal Statutes.

Program Functions includes planning, managing, and implementing the Region's enforcement, compliance monitoring, and compliance assurance activities in the following programmatic areas:

- Clean Air Act (CAA)
- Clean Air Act (CAA) 112(r)
- Clean Water Act (CWA) National Pollutant Discharge Elimination System (NPDES)
- Clean Water Act (CWA) Wetlands (404)
- Clean Water Act (CWA) Oil Pollution Act (311)
- Safe Drinking Water Act (SDWA) Underground Injection Control
- Safe Drinking Water Act (SDWA) Public Water Systems
- Resource Conservation and Recovery Act (RCRA) (with exception of Corrective Action)
- Resource Conservation and Recovery Act (RCRA) Underground Storage Tank (UST) (with exception of Corrective Action)
- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
- Toxics Substance Control Act (TSCA) Core (includes Asbestos Hazard Emergency Response Act – AHERA)
- Toxics Substance Control Act (TSCA) Lead Paint
- Toxics Substance Control Act (TSCA) Polychlorinated Biphenyl (PCBs)
- Emergency Planning and Community Right-To-Know Act (EPCRA) 313
- Emergency Planning and Community Right-To-Know Act (EPCRA) Non-313 (EPCRA 311/312) / Comprehensive Environmental Response Compensation and Liability Act (CERCLA) 103

- Comprehensive Environmental Response Compensation and Liability Act (CERCLA) 121(d)(3) (CERCLA Offsite Rule)
- Marine protection, Research, and Sanctuaries Act (MPRSA)
- Non-CERCLA Federal Facilities Enforcement

Support Functions manage, coordinate, and direct a comprehensive suite of functions supporting the Region's enforcement program, including:

- Inspection and compliance monitoring program: targeting, on and off-site compliance monitoring activities, inspections, inspector credentialing, inspection reports
- Data System Support (managing enforcement data for systems such as ICIS, ICIS- NPDES, RCRA info, etc.)
- Data analytics, reporting, and results measurement
- Coordination on external communications
- Planning with State and Tribal compliance assurance and enforcement programs
- State Review Framework Implementation and state oversight of delegated programs
- Administrative processes including coordination with other Divisions on enforcement- related grant conditions and implementation and fiscal responsibility for compliance assurance and enforcement funding
- Tips and Complaints (when related to enforcement) tracking and resolution
- Monitoring and implementation of consent decrees and orders
- Provide technical and program support to CID, as appropriate

ECAD consists of the Division Director's Immediate Office, the Policy, Oversight and Liaison Office, the Targeting, Data and Measures Office, and four Branches that report directly to the Division Director. The four Branches are the Compliance Assistance Branch, Air Enforcement Branch, Chemical Safety and Land Enforcement Branch and the Water Enforcement Branch. ECAD has two Deputy Directors who report to and assist the Director with the management and direction of the organization's program and work.

Presently, EACD has a designated Division Quality Assurance Coordinator (QAC) located in the Compliance Assistance Branch. The QAC reports directly to the Industrial Compliance Assistance Section (ICAS) Section Chief However, this individual will have direct access to the Division Director and/or Deputy Division Director, as well as the RQAM, to resolve QA/QC issues in the Division. The QAC, working with management and staff, will ensure all QA requirements described in this document are followed and documented, as appropriate.

3.1.6.1 <u>Targeting</u>, <u>Data & Measures Office</u>

The Targeting, Data & Measures Office is responsible for strategic planning for enforcement and reporting results of the Region's

enforcement efforts. The Compliance Policy and Strategy Branch works with federal and state partners on enforcement planning for delegated programs and maintains responsibility for planning enforcement and compliance assurance activities in direct implementation programs.

The Targeting, Data & Measures Office manages, coordinates, and directs a comprehensive suite of functions supporting the Region's enforcement program, including:

- Inspector credentialing
- Data System Support (managing enforcement data for systems such as ICIS, ICIS- NPDES, Case Pipeline tracking systems, RCRA info. etc.)
- Data analytics, reporting, and results measurement
- Inspection targeting
- Strategic planning

3.1.6.2 Chief, Policy, Oversight & Liaison Office

The Policy, Oversight & Liaison Office works with the National Program Manager (NPM) - Office of Enforcement and Compliance Assurance (OECA) to interpret and create EPA enforcement policies and regulatory requirements and provides guidance and advice on compliance and enforcement matters.

The Policy, Oversight & Liaison Office manages, coordinates, and directs a comprehensive suite of functions supporting the Region's enforcement program, including:

- Coordination on external communications
- Planning with State and Tribal enforcement programs
- State Review Framework Implementation and state oversight of delegated programs
- Administrative processes including coordination with other Divisions on enforcement- related grant conditions and implementation, implementation of regional Human Capital Strategies, and fiscal responsibility for enforcement funding
- Tips and Complaints tracking and resolution
- Providing technical and program support to CID, as needed
- Coordination on federal facility enforcement and other compliance assurance activities
- Coordination with sampling and laboratory services

3.1.6.3 Compliance Assistance Branch

The Compliance Assistance Branch is responsible for developing and implementing Region 4's compliance assistance activities. The

Compliance Assistance Branch coordinates and collaborates with federal, state and tribal partners on compliance assistance activities for delegated and direct implementation programs.

The Compliance Assistance Branch provides leadership to two Sections that comprise the Branch - the Municipal Compliance Assistance Section and Industrial Compliance Assistance Section.

Municipal Compliance Assistance Section

The Municipal Compliance Assistance Section is responsible for developing and implementing Region 4's compliance assistance activities for municipalities in Region 4. The Municipal Compliance Assistance Section provides technical assistance to states and municipalities to help municipalities comply with applicable environmental statutory and regulatory requirements and build capacity to ensure their success and effectiveness in achieving compliance. This includes collaborating with EPA's Water Infrastructure and Resiliency Finance Center to assist in leveraging funding availability. Technical assistance may also include providing diagnostic evaluations and efficiency tools to optimize such things as water and power use. The Municipal Compliance Assistance Section provides such assistance by responding to requests for technical assistance and through outreach activities such public workshops and trainings. The Municipal Compliance Assistance Section is also responsible for promoting EPA's incentives policies to return to compliance. The Municipal Compliance Assistance Section develops strategies to improve the performance of the regulated communities by integrating regulatory and voluntary programs and developing and utilizing a range of assistance tools (e.g. web sites, on-site assistance, and training).

Industrial Compliance Assistance Section

The Industrial Assistance Section is responsible for developing and implementing Region 4's compliance assistance activities for industrial (non-municipal) sectors of the regulated community in Region 4. The Industrial Compliance Assistance Section provides technical assistance to states and industrial (non-municipal) sectors to help facilities comply with applicable environmental statutory and regulatory requirements and build capacity to ensure their success and effectiveness in achieving compliance. The Industrial Compliance Assistance Section provides such assistance by responding to requests for technical assistance and through outreach activities such as public workshops and trainings to trade groups or associations. The Industrial Compliance Assistance Section is also responsible for promoting EPA's incentives policies to return to compliance. The Industrial Compliance Assistance Section develops strategies to improve the performance of the regulated communities by

integrating regulatory and voluntary programs and developing and utilizing a range of assistance tools (*e.g.* web sites, on- site assistance, and training).

3.1.6.4 Air Enforcement Branch

The Air Enforcement Branch (AEB) is comprised of two Sections, Air Section 1 and Air Section 2. The Branch implements compliance assurance and enforcement activities under the CAA primarily in the following areas: NSPS, NESHAP, MACT, PSD/NSR, Title V Operating Permits, State Implementation Plans, CAA source specific emissions guidelines under Section 111(d), and combustion related emission guidelines under Section 129 of the CAA. Compliance assurance in these areas encompasses regulatory determinations and compliance monitoring including reviews of permit conditions and settlement agreements, inspections, full compliance evaluations, investigations, self-disclosures, citizen complaints, data management, and whether threats to human health or the environment exist. The Sections pursue enforcement through administrative penalty actions, administrative complaints, and civil referrals to the Department of Justice. The Sections also support and assist the Criminal Investigation Division. The Sections participate in national, regional and multi-regional priorities that will yield the greatest environmental benefit and are not duplicative of efforts by delegated agencies. The priorities generally focus on specific industrial sectors and environmental justice communities. The Sections review the level and quality of effort by states and local air agencies to ensure that delegated programs are being implemented consistent with the delegation agreements. The two Air Sections also provide training and technical assistance to staff within state and local air agencies. AEB works to implement programs in all Region 4 States.

The Air Enforcement Branch Sections performs the following functions:

- Implements enforcement under the CAA: Stationary Source Enforcement: inspections and enforcement response at sources of emissions of volatile organic compounds (VOCs), nitrogen oxides (NOx), sulfur dioxide (SO2), and hazardous air pollutants.
- Mobile Source Enforcement: inspections and delegated enforcement response at sources who manufacture, sale, and install aftermarket defeat devices for vehicles and engines; and who import noncompliant vehicles and engines.
- Implements inspections and enforcement response at facilities regulated under the CAA, Section 112(r) (RMP). The goal is to reduce the risk to human health and the environment by decreasing the likelihood of chemical accidents.
- Implements enforcement under the Emergency Planning and Community Right-to-Know Act (EPCRA) Sections 302-313 and Section 103 of CERCLA.

Air Section 1 and 2 conduct inspections, develops enforcement cases, prepares and issues administrative actions, assesses penalties, develops judicial enforcement actions, and negotiates settlements in conjunction with the Office of Regional Counsel, Office of Enforcement and Compliance Assurance, and the Department of Justice. Investigates and responds to citizen suit notices.

3.1.6.5 Chemical Safety and Land Enforcement Branch

The Land and Chemical Enforcement Branch implements enforcement under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA) which includes the core program, Polychlorinated Biphenyls (PCBs), the Residential Lead-Based Paint Hazard Reduction Act, and the Asbestos Hazard Emergency Response Act (AHERA). Implements enforcement activities pursuant to RCRA Subtitle C (with the exception of Corrective Action) and RCRA Subtitle I (UST) (with the exception of Corrective Action). Implements the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Offsite Rule and works with the Superfund Division to resolve CERCLA Offsite Rule as well as CERCLA deferral policy issues, including CERCLA off-site determinations and issuing Initial Determination Letters of Acceptability and Unacceptability.

The Chemical Safety and Land Enforcement Branch provides leadership to two Sections that comprise the Branch - the Chemical Safety Section and the Land, Asbestos and Lead Section. The sections conducts inspections, develops enforcement cases, prepares and issues administrative actions, assesses penalties, develops judicial enforcement actions, and negotiates settlements in conjunction with the Office of Regional Counsel, Office of Enforcement and Compliance Assurance and the Department of Justice. Investigates and responds to citizen suit notices.

Chemical Safety Section

The Chemical Section performs the following functions:

- Implements enforcement under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) at pesticide producing facilities for compliance with registration, labeling, production, and purity requirements.
- Implements enforcement under the Toxic Substances Control Act (TSCA) which includes:
 - TSCA Core: inspections and enforcement response at chemical manufacturers and importers
 - Polychlorinated Biphenyls (PCBs): inspections and enforcement response sources of PCBs in electrical equipment

- Oversees and administers the Confidential Business Information provisions of TSCA and FIFRA.
- Conducts inspections, develops enforcement cases, prepares and issues administrative actions, assesses penalties, develops judicial enforcement actions, and negotiates settlements in conjunction with the Office of Regional Counsel, Office of Enforcement and Compliance Assurance and the Department of Justice.

Land, Asbestos and Lead Section

The Land, Asbestos and Lead Section performs the following functions:

- Implements enforcement under the RCRA Subtitle C hazardous waste program (with the exception of Corrective Action) for compliance with the requirements governing the handling, treatment and/or disposal of hazardous waste.
- Implements the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Offsite Rule and works with the Superfund Division to resolve CERCLA Offsite Rule as well as CERCLA deferral policy issues, including CERCLA off-site determinations and issuing Initial Determination Letters of Acceptability and Unacceptability.
- Implements enforcement under the Toxic Substances Control Act (TSCA) which includes:
 - The Residential Lead-Based Paint Hazard Reduction Act: inspections and enforcement at housing complexes, realtors, and property management firms
 - The Asbestos Hazard Emergency Response Act (AHERA): inspections and enforcement for compliance with asbestos in schools
- Conducts inspections, develops enforcement cases, prepares and issues administrative actions, assesses penalties, develops judicial enforcement actions, and negotiates settlements in conjunction with the Office of Regional Counsel, Office of Enforcement and Compliance Assurance and the Department of Justice.

3.1.6.6 Water Enforcement Branch

The Water Enforcement Branch implements enforcement actions under (a) the Safe Drinking Water Act's Underground Injection Control (UIC) and Public Water Systems (PWS) programs, (b) Sections 311 (Oil Pollution Act or OPA), (c) Section 402 (NPDES) of the Clean Water Act, (d) Section 404 (Wetlands) of the Clean Water Act (CWA), and (e) the Marine Protection, Research and Sanctuaries Act (MPRSA).

The Water Enforcement Branch provides leadership to two Sections that comprise the Branch - the Surface Water/GW Section and the Drinking

Water/Wastewater Section. The sections conduct inspections, develops enforcement cases, prepares and issues administrative actions, assesses penalties, develops judicial enforcement actions, and negotiates settlements in conjunction with the Office of Regional Counsel, Office of Enforcement and Compliance Assurance and the Department of Justice. Investigates and responds to citizen suit notices.

Surface Water/Groundwater Section

The Surface Water/GW Section performs the following functions:

- Responsible for initiating enforcement actions for NPDES
 discharges (excluding wastewater discharges): stormwater
 (industrial, construction and Municipal Separate Stormwater
 System (MS4) dischargers; Confined Animal Feeding Operations
 (CAFOs) discharges; mineral extraction discharges; dredge and
 fill discharges under Section 404 (Wetlands); and ocean
 discharges under the Marine Protection, Research and Sanctuaries
 Act (MPRSA).
- Responsible for initiating enforcement actions for the Safe Drinking Water Act's Underground Injection Control (UIC).
- Conducts inspections, develops enforcement cases, prepares and issues administrative actions, assesses penalties, develops judicial enforcement actions, and negotiates settlements in conjunction with the Office of Regional Counsel, Office of Enforcement and Compliance Assurance and the Department of Justice.

Drinking Water/Wastewater Section

The Drinking Water/Wastewater Section performs the following functions:

- Responsible for initiating enforcement actions for the Safe Drinking Water Act's Public Water Systems (PWS) programs.
- Responsible for initiating enforcement actions for wastewater NPDES discharges including industrial wastewater discharges and wastewater collection system sanitary sewer overflows and combined sewer overflows, and Pretreatment standards and requirements.
- Responsible for initiating enforcement actions for vessel general permit (VSP) discharges.
- Responsible for initiating enforcement actions for discharges under Section 311 (OPA) and the Spill Prevention, Control, and Countermeasures (SPCC) plan regulations for prevention of hazardous substances spills.
- Conducts inspections, develops enforcement cases, prepares and issues administrative actions, assesses penalties, develops judicial enforcement actions, and negotiates settlements in conjunction

with the Office of Regional Counsel, Office of Enforcement and Compliance Assurance and the Department of Justice.

3.1.7 <u>Mission Support Division (MSD)</u>

Formerly the Office of Policy and Management, this Division administers human resources management, budget and finance, procurement and grants administration, information management, and planning and analysis.

Within MSD'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). The Acquisition 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.

The Planning & Business Operations Section within the Budget Operations & Financial Management Branch manages the Region 4 State's Performance Partnership Agreements (PPAs) and Performance Partnership Grants (PPGs). This includes soliciting data competency packages from the states in accordance with requirements of the Agency Policy Directive Number FEM-2012-02, Revision 1, Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements. The competency packages are then forwarded to the respective divisional program contact for review and acceptance. The RQAM and LSASD QA Section staff are available to assist with the review of the data competency packages, upon request.

MSD's Information Systems Management Branch (ISMB) 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 ISMB 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.

LSASD provides MSD with technical assistance by reviewing QAPPs, QMPs, and contract Scopes of Work.

3.1.8 Gulf of Mexico Division

The GMD is a non-regulatory program founded to facilitate collaborative actions to protect, maintain, and restore the health and productivity of the Gulf of Mexico

in ways consistent with the economic well-being of the region. The GMD provides federal research, monitoring, scientific analysis, and financial resources to support state and community actions that benefit the Gulf and its communities. The GMD engages in activities such as monitoring water quality in watersheds that flow into the Gulf. This includes the collection, evaluation, and use of environmental data produced by regional programs and generated through extramural agreements. 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 which are generated by the GMD, or by state, tribal, local government, and/or private sector organizations are rarely used to support agency decision making. The GMD data collection activities include studies that support Gulf states and/or communities and the funding of assistance agreements which are not principally for the direct benefit or use of the federal government. Although these activities do not support agency decisions, it is important that environmental data generated with federal funds is of known origin and quality. The GMD will support a graded approach to the quality system of assistance agreements which bases the level of managerial controls applied to an item or work commensurate with the intended use of the results and the degree of confidence needed for the results. The quality system for the GMD is described in their QMP.

LSASD provides GMD with technical assistance, as appropriate, by reviewing QAPPs, QMPs, and contract Scopes of Work. GMD has certified DAOs to approve QAPPs and works with EPA Regions to ensure required partner QA documents are approved. GMD's work with partners as a geographic great water body program naturally occurs in multiple EPA regions and internationally in order to cover the Gulf of Mexico watershed. Concerning QMP/QAPP development for partnering organizations, the GMD defers as much as possible to the region where work is occurring. This helps GMD partners to have consistency in their QMP/QAPP development and expectations. Many of GMD's projects are one-time, short-term, or special projects that collect a minimal amount of environmental data that is not typically used in agency decision making. 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 the Regional Administrator

The Environmental Justice and Children Health Section (EJCH) is located in the Office of the Regional Administrator. The Section works collaboratively with the EPA Headquarters (i.e., the OPM-based Office of Environmental Justice), internal and external stakeholders to address public health issues and concerns in minority, low-income, tribal and other vulnerable communities. The Environmental Justice program manages several grants, which includes: the EPA Environmental Justice (EJ) Collaborative Problem-Solving Grants Program; the EJ Small Grants Program; and the State Environmental Justice Cooperative Agreement Program

(recent new grant offering, as of mid-2020). All three programs provide financial assistance to assist communities to 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, up to \$30,000 through the EJ Small Grants Program, and up to \$200,000 through the State Environmental Justice Cooperative Agreement Program. Additional resources include technical assistance, mapping tools and training materials.

Additionally, the EJCH Section works collaboratively with the EPA Headquarters (i.e., the Office of Administrator-based Office of Children's Health Protection, OCHP), as well as internal and external stakeholders to address children's environmental health issues. This includes efforts to: reduce negative environmental impacts on children through involvement in EPA rulemaking, policy, enforcement actions, research and applications of science that focuses on prenatal and childhood vulnerabilities; promote safe chemicals management; and coordinate community-based programs to eliminate threats to children's health where they live, learn and play. On an annual basis, Region 4 receives between \$25,000 and \$40,000 from OCHP grant funding to award to external parties to support children's environmental health. These monies are traditionally not used for data collection or research, so therefore there are no triggers for Quality Assurance Project Plans (QAPPs).

The Regional Indian Program Coordinator (RIC) is located in the Office of the Regional Administrator. The RIC is the direct liaison between EPA Region 4 and the six federally-recognized Tribes of the southeastern US. The RIC is also the Project Officer for the Indian General Assistance Program grants, many of which are within the Performance Partnership Grants for the Region 4 Tribes.

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)

The RQAM was delegated oversight of the Region 4 Quality System. The RQAM, administratively reports to the LSASD Deputy Director and is independent of any data generation activities within LSASD 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 EPA Office of Mission Support (OMS), Environmental Information (EI), Office of Enterprise Information Programs (OEIP), Enterprise Quality Management Division (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 conformance with approved quality systems, and the effectiveness of the implemented quality system;
- Coordinates assessments of selected environmental monitoring programs.
- Coordinates and participates in the EQMD review of the Region 4 quality system;
- Coordinates and submits the Annual QA Report and Workplan to Region 4 Senior Management and EQMD;
- Distributes Agency QA guidance documents, policies, and procedures;
- Initiates and/or revises Regional QA policy & procedures; and
- Briefs senior leaders on QA issues on an annual basis or more often as needed.

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 LSASD 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 the LSASD 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 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 to ensure the acceptability of data and the suitability of environmental technology. Key responsibilities of the Division Directors are 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.
- Assure that personnel receive appropriate QA training by working with the QA Coordinator and RQAM on the development of a training curriculum for their staff. Include staff QA training needs in employee Individual Development Plans.
- Ensure that all staff that are assigned QA responsibilities have those responsibilities included in their position descriptions and in their Performance Appraisal and Recognition System (PARS) agreements.
- Select, monitor and ensure appropriate training is provided to Designated Approving Officials as defined by Section 3.2.8 of this QMP.

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. Key responsibilities of the QA Coordinators are to:

- Serve as the official Division contact for quality assurance matters pertinent to the data collection activities of that Division/Office.
- Attend the initial QAPP and DQO training classes, as needed, and any other pertinent training provided by the RQAM.
- Attend quarterly QA Coordinators' meetings convened by the RQAM to keep abreast of QA issues affecting the Region and Agency.
- Report any data quality issues to the appropriate manager or Division Director, and to the RQAM, as appropriate.
- Communicate QA issues to Division personnel.
- Respond to quality control issues and problems, and 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, when applicable.
- Advise the RQAM on changes needed to the Regional QMP.
- Coordinate Division input for the Regional QA Annual Report and Work Plan (QAARWP) submitted by the RQAM to the EQMD Director.
- Maintain an inventory of QAPPs for their Division 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 OAPPs.
- Work with the RQAM or designee to maintain an accurate and up-to-date list of DAOs for their Division/Office.

3.2.5 <u>Designated Approving Officials</u>

A Designated Approving Official (DAO) is a regional manager or staff person who has been delegated the authority by the RQAM to approve internal and extramural QAPPs. The DAO is expected to review the QAPP to ensure it is compliant with the requirements specified in EPA's QA/R-5 document, and follow prescribed procedures for reviewing, documenting, and approving QAPPs. If the QAPP is complex or otherwise beyond the scope of the DAO's expertise, the DAO may elect to forward the QAPP to the LSASD QAPSB Quality Assurance Section Chief (indicate on the request if RQAM approval is also needed) for review and/or approval.

Managers and supervisors are responsible for identifying prospective DAOs within their organizations. Each Division must conform to the following requirements. Additional duties may be included in Division QMPs. 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 indepth 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 LSASD QAPSB/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 shall not approve that same QAPP.
- 6. The QAPP review process must be documented using a checklist developed by LSASD QAPSB/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 LSASD QAS staff on QAPP requirements and review, Data Quality Objectives (DQO), and the QAPP Checklist.
- After completion of the initial training, the prospective DAO must complete and submit the DAO Technical Competency Form (TCF) 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 TCF to the designated LSASD QAPSB/QAS staff for filing and development of the initial DAO certificate. The DAO certificate will then be emailed to the

- 5. Division QA Coordinator for distribution. The LSASD QAPSB/QAS staff and the RQAM will track the status of the DAOs.
- 6. To maintain continuing certification, the DAO must attend annual DAO refresher training available on-line via the Region 4 QA Program SharePoint site or by webinar, as scheduled.
 - a. Annual refresher training must be completed by December 31 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.
- 7. DAO certification is not allowed to transfer into other programs. If the DAO moves to another program, he/she must be retrained and recertified 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.

3.2.6 <u>Divisional Project Managers</u>

Project Managers 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. Key responsibilities of the Project Managers are to:

- Prepare or approve DQOs, technical and quality assurance specifications, and acceptance criteria for environmental data needed to support project decisions.
- Prepare or direct the preparation of a QAPP (or equivalent planning document) for each project and submit the QAPP to the QAC for review/approval prior to data collection activities.
- Ensure that QAPPs are approved prior to the initiation of data collection or generation activities.
- Participate in conducting QA system/performance audits of projects as requested by the QAC and the RQAM.
- Take corrective action that may be required by audit findings.
- Report data quality problems to the QAC and the RQAM.
- Attend appropriate QA training.
- Review QAPPs that are submitted to the Region using the appropriate QAPP Review Checklist. See Appendix C, pages 66 – 79, for QAPP Review Checklist.

3.2.7 <u>Divisional Project Officers/Contracting Officer Representatives</u>

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 as described by the Terms and Conditions by the assistance agreement recipient or contractor. Key responsibilities of the POs/CORs are to:

- Ensure QMPs, QAPPs and data competency certifications for each assistance agreement, if required, are added to the Terms and Conditions of the assistance agreement.
- Ensure QMPs, QAPPs and data competency certifications are submitted to the appropriate divisional QA staff for review and approval, in accordance with divisional program-specific procedures. The POs will maintain the QMP, QAPP and data competency certification within the official grant file.
- 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 QA system and performance audits of projects as requested by the RQAM.
- Coordinate review of extramural QMPs and/or QAPPs. QMPs are submitted to the RQAM via R4QMP@epa.gov for review and approval. QAPPs are submitted to the QA Coordinator or appropriate DAO for review and approval, in accordance with program-specific procedures.
- Assist in completing corrective actions that may be required by audit findings.
- Report data quality problems to the Divisional QAC and the RQAM, as needed.
- Attend appropriate regional QA training.

3.2.8 <u>Divisional Technical Officers</u>

Technical Officers (TOs) will support the QAC by providing technical assistance in their area of expertise. Key responsibilities of the TOs are:

- Some TOs function as DAOs and perform QAPP reviews, as required.
- Assist DAOs by reviewing QAPPs for programmatic concerns as required.
- Answer requests for guidance or assistance in area of expertise.
- Report data quality problems to the QAC. Appropriate actions may include QA system and/or performance audits of data collection and/or generation activities. Prepare appropriate documentation for project file. RQAM and/or QA Section assistance may be requested as necessary by the QAC.

- Participate in conducting QA system and performance audits of projects as requested by the QAC and the RQAM.
- Attend appropriate and required QA training, as needed.
- Coordinate with the QAC to ensure the review and approval of extramural QMPs, QAPPs and data competency certifications are completed prior to start of data collection.

4.0 REGIONAL QUALITY SYSTEM REQUIREMENTS – EXTERNAL ORGANIZATIONS

4.1 State, Local, and Tribal Grants

A substantial amount of environmental information 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). QMPs will be developed using a graded approach according to the specific objectives and needs of the organization.

The production of quality documentation will be added to the terms and conditions of the grant agreement to ensure the grantee obtains prior approval of the documents 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. The sub-award recipients must have approved QA documentation prior to the start of data collection. The grantee is responsible for reviewing and approving the sub-awardee's

associated QA documents (QAPPs, QMPs, and data competency certification packages).

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. EPA QA/R-2, "EPA Requirements for Quality Management Plans," provides that, in some cases, QAPPs and QMPs may be combined into a single document that contains both organizational and project-specific elements. The RQAM or designee will determine when a single document is applicable and will define the content requirements for such a document. 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 divisional or branch QA Coordinator within the program will make the determination when a programlevel QAPP is appropriate. Awardees approving sub-awardee QAPPs shall have an approved QMP describing the QA measures that are in place or will be implemented to assure their internal QA system effectively manage sub-awardee OAPPs including document review, oversight and/or assessment activities that will be conducted to verify adequacy of these measures. If a grantee's QMP is already approved but does not sufficiently describe the process, the grantee may submit a QMP addendum to EPA for review and approval until the next revision of their QMP.

The RQAM in consultation with the divisional QA Coordinator will review the documentation provided to determine if the QA measures, oversight and assessment are adequate for the approval of sub-awardee QA documents. Final approval will be provided by the RQAM.

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 review, approval and 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 assistance from the RQAM and LSASD personnel. For field activities conducted by external organizations (e.g. state environmental agencies) LSASD may be tasked to perform field audits to verify adherence to a QAPP and to report on the adequacy of field procedures such as sample collection, chain of custody, and preservation of samples.

4.2 Academics, 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 will be developed using a graded approach consistent with the complexity of the project and the intended use of the data.

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, the applicable Region 4 division 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 Quality Management Plans, 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) acceptable to both parties. The QAPP requirements are in accordance with the specifications provided in EPA Requirements for Quality Assurance Project Plans, 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 by the divisional QA Coordinator 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 of the "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 extramural agreement. The appropriate assistance agreement project officer or COR will coordinate the review of the QMP for their specific extramural agreement. QMPs will be

reviewed by the RQAM or designee, and the appropriate assistance agreement project officer or COR. 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 Mission Support Division will review extramural agreements prior to award to ensure that all Agency quality requirements have been documented. Upon request the RQAM will provide GAMS staff and divisional 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 approves 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.

4.6 Demonstration of Competency for Extramural Organizations

In order to satisfy the QA requirements in Agency Policy Directive Number FEM-2012-02, the assistance agreement recipient may be required to submit documentation of their competency for review and acceptance by the appropriate assistance agreement PO. Any grantee that meets the requirements of the FEM-2012-02 will be notified of the requirement and will be required to submit a demonstration of competency certification and supporting documentation.

- 4.6.1 Organizations performing activities involving the use or generation of environmental information or environmental technology under covered assistance agreements shall provide the Agency with:
 - 4.6.1.1 Quality documentation such as a quality management plan (QMP), and/or other documentation that demonstrates conformance to U.S. EPA quality program requirements; and

- 4.6.1.2 Demonstration of competency in the field(s) of expertise. Demonstration of competency may include (but not be limited to):
 - Current participation in accreditation or certification programs that are applicable to the environmental data generated under the Agency-funded assistance;
 - Ongoing participation by the organization in proficiency testing (PT) or round robin programs conducted by external organizations;
 - Ongoing U.S. EPA accepted demonstrations and audits/assessments of proficiency; and
 - Other pertinent documentation that demonstrates competency (e.g., past performance to similar statement of work [SOW]).
- 4.6.2 The Demonstration of Competency certification and supporting documentation will be reviewed for completeness by the appropriate divisional staff (e.g. QA Coordinator, PPG Coordinator, PO, DAO, etc). After acceptance of the Demonstration of Competency, a copy of the documentation will be maintained in the assistance agreement files.
- 4.6.3 The RQAM or designee may assist with the review of the Demonstration of Competency certification package.
- 4.6.4 The Demonstration of Competency may be documented using the Region 4 Data Competency Certification Form in Appendix C. Grantees may also submit a demonstration of competency certification in another format, but it must address the same topics referenced in 4.6.1 and the Data Competency Certification Form.

5.0 REGIONAL QUALITY SYSTEM - INTERNAL ORGANIZATIONS

This section describes the quality system requirements for environmental data generated within Region 4's programs/organizations. 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)

Divisional QMPs are not required. However, if a Region 4 Division has program-specific QA and/or QC requirements not described in this QMP, a divisional QMP must be developed. Currently, GMD, LSASD and SEMD have divisional QMPs. The divisional QMP must also adhere to the requirements and specifications outlined in the CIO Policy and the Region 4 QMP, unless a justification for the deviation is provided and approved by the RQAM. Divisions QMPs will include:

- 5.1.1 A clearly delineated management structure of the division, and clearly defined roles (including DAOs and QA Coordinators) 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 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 authority. 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.

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 their respective divisional QMP, when applicable. Draft QMPs must be submitted to the RQAM via R4QMP@epa.gov for review and approval.

5.2 <u>Internal Data Operations</u>

EPA Project Managers or their designees are responsible for preparing QAPPs when the projects involve the collection of environmental information or the use of environmental technology. The RQAM and LSASD QAPSB/QAS staff 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 divisional DAOs shall review and approve all QAPPs for internal data collection prior to the initiation of field operations.

For circumstances requiring immediate action (emergency responses) but involving environmental information or environmental technology, QA documentation may be prepared during or after the event. This documentation describes the event that occurred and contains the type of information that would have been included in an approved planning document. The QA documentation must contain a statement that is was developed after the fact and follow the established review and approval process.

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 LSASD. LSASD'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 LSASD 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, generation, use or reporting of environmental data, and the design, construction, and operation of environmental technologies. 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 (QARF) has been completed in accordance with the EPA Acquisition Guide (EPAAG). The COR is also responsible for including the RQAM or designee 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.

It is the responsibility of the Acquisition Management Section within the Mission Support Division to ensure QARFs, with appropriate signatures, are included in every solicitation package. The QARF 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 or designee 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 stepwise 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 LSASD QAPSB/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." 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 information 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. For circumstances requiring immediate action (emergency responses) but involving environmental information or environmental technology, QA documentation may be prepared during or after the event. This documentation describes the event that occurred and contains the type of information that would have been included in an approved planning document. The QA

documentation must contain a statement that is was developed after the fact and follow the established review and approval process. 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 QA Coordinator or appropriate Project Manager in accordance with divisional program-specific procedures

6.3 <u>Standard Operating Procedures (SOP)</u>

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. Several Region 4 divisions and/or programs have established alternate standard operating procedures addressing the corresponding requirements and are consistent with regional practice. 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 <u>Preparation of SOPs</u>

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 field activities SOPs are prepared in accordance with the QAFAP requirements and Region 4 Operating Procedure for Document Control, R4PROC-001, 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. Region 4 SOPs are reviewed every four (4) years or more often as needed.

6.3.2 <u>Standard Operating Procedure Criteria</u>

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 LSASD LSB and ASB will perform SOP reviews in accordance to ISO 17025 accreditation requirements.

6.3.3 <u>Activities Requiring Standard Operating Procedures</u>

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 <u>Collection</u>: 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 <u>Verification</u>: 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 <u>Validation</u>: 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. Details on this process are provided in EPA Guidance on Environmental Data Verification and Data Validation (EPA QA/G-8) (EPA/240/B-02/004, November 2002).

- 6.4.4 <u>Storage</u>: Each SOP, as appropriate, shall indicate how specific types of data will be stored.
- 6.4.5 <u>Transfers</u>: 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. For example, if during an environmental data collection project, staff identifies that the data quality acceptance criteria have not been met, the projectspecific QAPP will define the appropriate corrective action. In this case, this would likely involve reporting the data quality issue to the project leader or to an immediate supervisor, who would then work with the appropriate managers and QA Coordinator to address the data quality issue.

6.7 Information Management

EPA's Office of Mission Support (OMS), 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.

OMS/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. 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 spending 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 Mission Support (OMS), Environmental Information (EI), Office of Enterprise Information Programs (OEIP), Enterprise Quality Management Division (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 OMS 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 EQMD 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 EQMD, 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. Assessments are the

principal means in Region 4's QA Program to determine compliance with established QA Management and Project Plans. 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. The RQAM has the primary responsibility for conducting audits at the division and program levels.

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, selected 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. Project Officers will be responsible for reviewing and evaluating 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 met the objectives of the project. If any particular issues or deficiencies were noted in these project QAPP assessments, the divisional QA Coordinator and RQAM must be notified to determine if corrective actions and/or follow-up actions are warranted.

The QAPP shall ensure that:

- Data collected for the characterization of environmental processes and conditions are of the appropriate type and quality for their intended use.
- The DQO process or systematic planning process complies with the step- wise process outlined in EPA's QA/G-4 document.
- 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.
- 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.

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.

7.1.1 Air and Radiation Division (ARD)

ARD conducts an annual visit with each state to discuss issues and updates in the air programs, including a discussion on quality assurance. For the states with local air programs, the local agencies may participate in these annual visits. The Division Director or Deputy Division Director is briefed on major issues and conducts the exit briefing for these reviews. Grants to State and local governments and non-profit entities have quarterly or semi-annual progress reporting requirements as well as annual baseline monitoring and post-award review of grants performed by program grants staff. On-site technical systems audits of state and local ambient air monitoring organizations are planned and prioritized annually in MOA negotiations between ARD and LSASD. Reviews conducted as part of grants requirements are written and placed in the grantee's files and entered into the Air Planning Agreement database or IGMS database. As required by the EPA Policy To Assure The Competency Of Organizations Generating Environmental Measurement Data Under Agency-Funded Assistance Agreements (FEM-2012-02, March 13, 2013), the grant project officer reviews and approves a demonstration QA competency submitted by each organization that receives a new assistance agreement expected to exceed a total maximum value of \$200,000 (in federal funding) that will involve the generation or use of environmental data. Grant awards that are subject to the FEM QA competency policy are also reviewed annually to ensure that the grantees are in compliance. The on-site visits and reviews are incorporated into the post award monitoring reports which are forwarded to the grantee for review and comment before finalization and entered into the Integrated Grants Management System (IGMS). Findings are presented to senior divisional managers during staff meetings including what, if any, corrective action is required. Schedule for corrective action will be dependent upon the nature and severity of area of non-compliance. Significant non-compliance issues related to National or Regional Quality Assurance Guidance will be forwarded to the Regional Quality Assurance Manager for consultation of issue(s).

7.2 <u>Types of Assessment</u>

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.

These audits are assigned by managers/supervisors to staff who have the appropriate experience, training, knowledge and technical skills.

7.2.1 Internal Assessments of EPA Activities

7.2.1.1 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.

7.2.1.2 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 LSASD 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.

7.2.2 External Assessments of State/Local/Tribal Activities

7.2.2.1 Program audits are qualitative audits assessing the ability of the programs to oversee 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. When oversight audits are required by the program, they should be conducted every three (3) years or at the frequency required by the program or assistance agreement and the findings resulting from the audit, documented and communicated to EPA program staff, divisional management, and the RQAM. The RQAM and LSASD QAPSB/QAS staff will provide additional support to divisional/program staff conducting the 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.

7.2.2.2 Technical Systems Audits (TSAs) 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). The air monitoring agencies in the Region that operate National Air Toxics Trends sites receive Technical Systems Audits conducted by a contractor managed by EPA OAQPS. Region 4 staff assist in these TSAs as resources allow.

7.2.2.2 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 LSASD QAPSB/QAS staff on all CLP data for CERCLA and any programmatic analytical data which is contracted through LSASD. Region 4 programs may also ask LSASD to conduct performance audits at laboratories for state or local agencies to verify the integrity of data from these labs. The frequency and scheduling of such audits will be determined during annual negotiations of the Memorandum of Agreement (MOA).

7.2.2.3 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.

7.2.2.4 Other audits are conducted at RCRA facilities and CERCLA investigations at the request of the program division. Audits of randomly selected regional activities are conducted as resources permit, or a particular activity is audited if there is evidence of inadequate performance.

7.3 Internal Audit and Corrective Action Process

QA Internal Audits and Corrective Actions will be conducted in accordance with the Region 4 Standard Operating Procedure for Internal Audits and Corrective Actions, R4PROC-009. Internal audits will be conducted by the RQAM to assess the implementation of the quality system for conformity with the applicable QMP. The RQAM or designee will prepare the annual schedule and coordinate the internal audits. The schedule of audits will be kept as a record and updated as required during the year as appropriate.

Annually, the RQAM or designee will conduct any of the following assessments:

a. Randomly select QAPPs that have been reviewed by 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. Internal MSRs will be conducted by the RQAM on an annual basis to verify the policies and procedures outlined in the Divisional and/or 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 MSRs will be conducted on a three-year cycle.
- c. In addition, the Divisional QA Coordinator and the RQAM, as needed, may assist in the QA oversight of the State/Tribal programs during mid-year or annual reviews performed by program staff, as requested by the program. During the initial phase of these on-site QA assessments, grants, extramural agreements and interagency agreements may be targeted to determine whether the appropriate QA measures and requirements specified in the assistance agreement documents have been met.

Initially, assessment findings 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 draft report, outlining the findings of the audit, will be sent to the audited organization within 14 calendar days from the closing meeting. The organization will have approximately 30 calendar days to request clarification of the findings or provide additional information 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 LSASD Director or Deputy Director (DD) will be advised of the issues. The LSASD Director or DD may communicate with the program's Division or DD to discuss the matter and reach a final a resolution. If a resolution is not reached, the final decision will be made by the LSASD Director or DD. The RQAM will notify the final resolution 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 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.

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.
- <u>Records Schedules</u>
 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:

- a. identifying quality related documents and records requiring control;
- b. 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;
- c. ensuring technical guidance documents are prepared, reviewed, approved, issued, used, and revised as required by regional QA policy;
- d. 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 and approved by the RQAM and LSASD/QAS are tracked and maintained in an electronic database. The electronic database tracks the current status of the document including date received by EPA, reviewer name, date comments submitted to requestor, revision dates, and approval date, among other tracking data. In addition, a copy of the final signed and approved document is maintained within the system. Divisional QA Coordinators or other designated staff must also track the current status of the QAPPs approved by their DAOs. The tracking tool must include date received by EPA, reviewer name, date comments submitted to requestor, revision dates, and approval date, among other tracking data.

8.2 Field Documentation

In addition, SOPs for the management of field-related records have been developed by the Region and, when applicable, supplemented by the divisions in accordance with the QAFAP requirements for Records Management. As required by the QAFAP, divisions must maintain updated copies of QA documents such as Agency memos, Region 4 SOPs, program-specific SOPs, and other pertinent information.

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, DAOs, regional managers and staff.

The Office of Mission Support, Environmental Information (EI), Office of Enterprise Information Programs (OEIP), Enterprise Quality Management Division (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 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 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. In accordance with the communications memorandum Enhancing Communications between EPA and Grantees regarding Quality Assurance Project Plans (QAPPs), dated July 9, 2019, to ensure the "timely, transparent, and consistent communications" regarding Quality Assurance Project Plans (QAPPs), QAS staff should be able to communicate directly with the grantee about the development/revision(s) and review/approval of QAPPs, and maintain the Project Officer informed of all communications with grantee. This could be accomplished by copying the Project Officer on all correspondence to the grantee and/or inviting the Project Officers to participate in conference calls.
- 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 LSASD and the Regional Tribal Coordinator. 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 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.),quality system assessments/audits or any other quality information requested by EQMD 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 required information.

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 by the RQAM with cooperation from the QA Coordinators according to the format specified by EQMD. Prior to its distribution to EQMD, the report shall be reviewed and approved by the Regional Administrator or designee but not signed. Signatures will be obtained upon receiving Conditional Approval from EQMD.

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, when available. 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 LSASD 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, <u>Final Information</u> <u>Quality Bulletin for Peer Review</u>, on December 1, 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 <u>Peer Review and Peer Involvement at the U.S. Environmental Protection Agency</u>, 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>U.S. EPA Science and Technology Policy Council (STPC) Peer Review Handbook, 4th edition (October 2015)</u> provides additional information and procedures for the implementation of EPA's peer review policy. 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.

Personnel responsible for field activities will have appropriate qualifications, education, training, experience and a satisfactory knowledge of the requirements of the activities to be carried out. Field groups have a documented system through the QAFAP to ensure that up-to-date records of training are maintained for field personnel. These records include external and/or internal courses attended and relevant training received, including on-the-job training.

Training will initially be provided for project and technical officers so that they may function as DAOs. Future QA training for other Division personnel may be provided 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.

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. 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, data quality assessments, and data validation. If the RQAM determines that the LSASD QAPSB/QAS personnel are not able to provide additional training, external training sources may be sought.

Annually, the RQAM, with assistance from the QAS staff and other LSASD 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 LSASD QAPSB/QAS staff typically schedules two training modules per QA course to facilitate attendance. Each QA course is offered via webinar 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 LSASD QAPSB/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 LSASD QAPSB/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 <u>Training Records</u>

Each employee is required to maintain training records in accordance with programspecific 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 either in a training folder, in an Agency approved data system [e.g., Field Readiness Module (FRM), Federal Acquisition Institute Training Application System (FAITAS), etc.] in a designated electronic system such as a SharePoint site, One Drive, etc., or a combination thereof. QA training agendas and attendees of courses provided by the LSASD QAPSB/QAS and the RQAM will also be maintained by the RQAM or designee.

Training that is obtained through the Region 4 Learning Development Institute (LDI) will be available to the staff and their supervisors electronically by a system maintained by the LDI. All QA training obtained external to the Division or Region will be maintained by the employee, their supervisor and when appropriate, provided to the Division QA Coordinator or 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, Office of Mission Support assessments, 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 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.

13.0 MANAGEMENT REVIEW

Annually, the LSASD Director and Deputy Director, in conjunction with the RQAM, will conduct a Management Review of the Region 4 Quality System to evaluate the effectiveness of the implemented quality system, its adherence to the Regional and Agency's policies and procedures, adequacy of resources, and identify opportunities for improvement. The Management Review will consider but not be limited to the following:

- Status of action items from past management reviews
- Suitability of policies and procedures
- Changes to volume and/or type of work
- Internal audits conducted, nonconformities and corrective actions
- Results of QSAs conducted by EQMD
- Quality improvements
- Recommendations for improvements

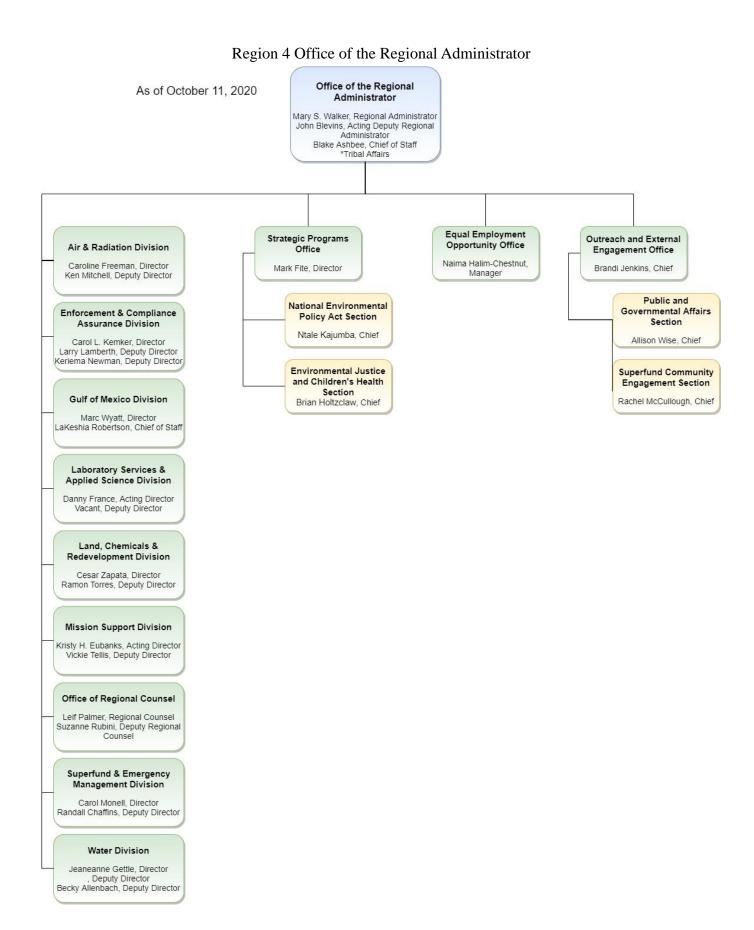
The Management Review documentation including the agenda and action items resulting from the Management Review will be maintained by the RQAM. If the management review results in changes to the quality system, the Region 4 QMP will be revised accordingly.

14.0 REFERENCES

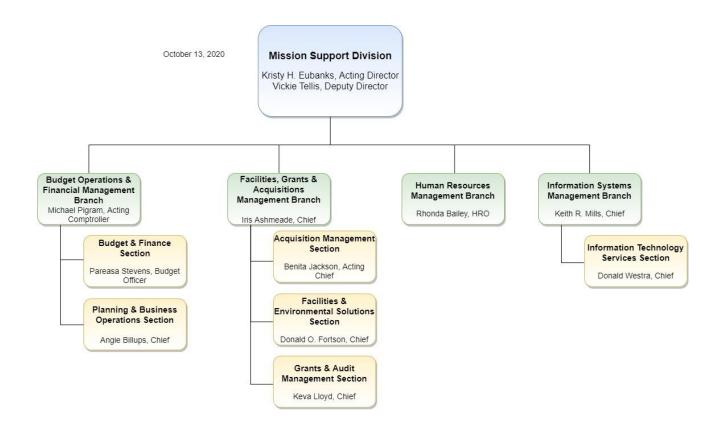
- 1. EPA Region 4 Quality Management Plan (QMP), September 2012
- 2. EPA 2105.0, Policy and Program Requirements for the Mandatory Agency-wide Quality System (CIO 2105.0, May 2000)
- 3. EPA 2105-P-01.0, EPA Quality Manual for Environmental Programs (CIO 2105-P-01.0, May 2000)
- 4. EPA 2105-P-02.0, EPA QA Field Activities Procedure (CIO 2105-P-02.0, September 2014)
- 5. ANSI/ASQ E4-2014, Quality Systems for Environmental Data and Technology Programs Requirements with Guidance for Use
- 6. EPA Requirements for Quality Management Plans (EPA/240/B-01/002, QA/R-2, March 2001)
- 7. EPA Requirements for Quality Assurance Project Plans (EPA/240/B-01/003, QA/R-5, March 2001)
- 8. *Guidance for Quality Assurance Project Plans* (EPA/240/R-02/009, EPA QA/G-5, December 2002)
- 9. Guidance on Systematic Planning Using the Data Quality Objectives Process (EPA QA/G-4, EPA/240/B-06/001, February 2006)
- 10. Environmental Protection Agency Acquisition Guide (EPAAG), Chapter 46
- 11. Agency Policy Directive Number FEM-2012-02, Revision 1, *Policy to Assure Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements*
- 12. EPA Interim Records Management Policy (EPA Information Policy CIO-2155.2, June 2013)
- 13. EPA Records Management Manual (February 2007 and subsequent revisions)
- 14. *Peer Review Handbook* (EPA/100/B-06/002, Third Edition, 2006 and addendum) or subsequent revisions
- 15. Federal Acquisition Regulations at 48 CFR Part 52.246-12

APPENDIX A

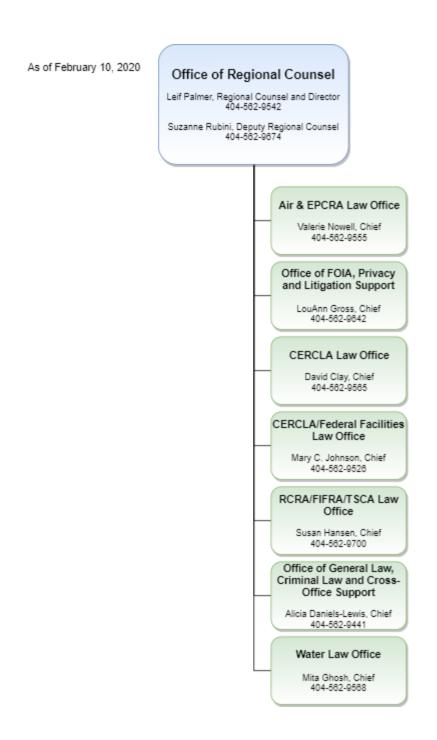
REGION 4 ORGANIZATIONAL CHARTS



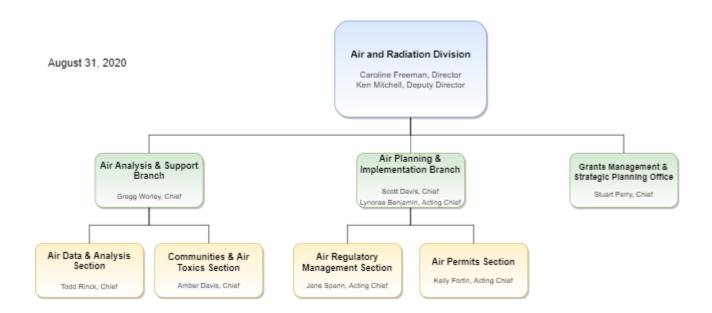
Region 4 Mission Support Division



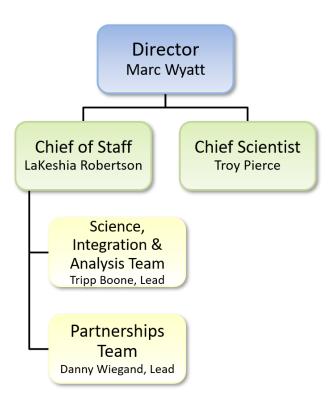
Region 4 Office of Regional Counsel



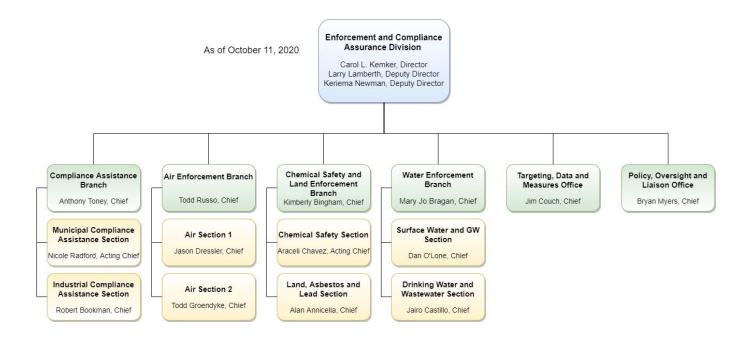
Region 4 Air and Radiation Division



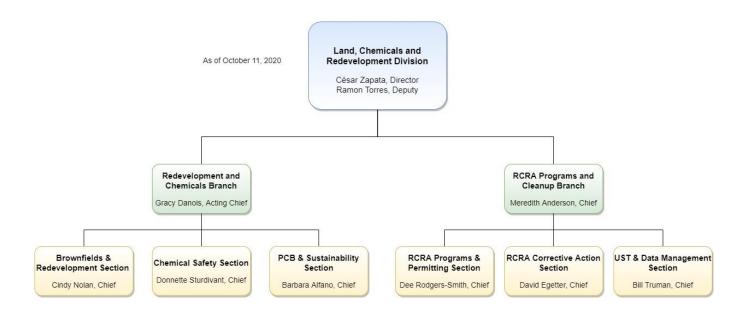
Region 4 Gulf of Mexico Division



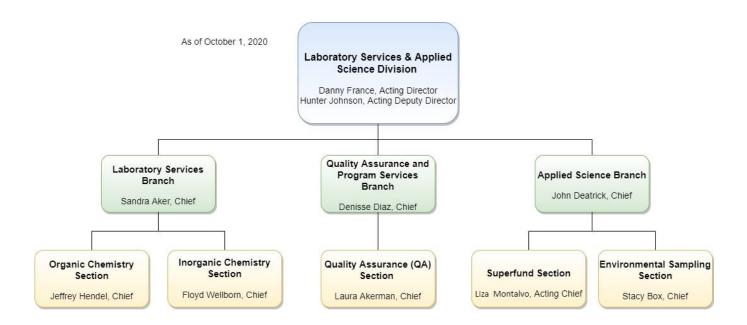
Region 4 Enforcement and Compliance Assurance Division



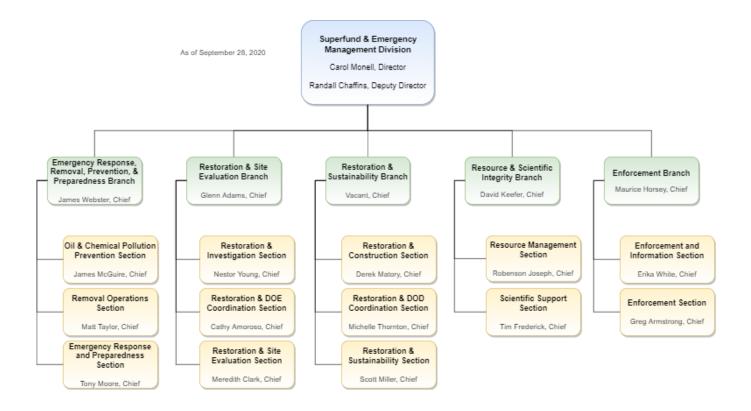
Region 4 Land, Chemicals and Redevelopment Division



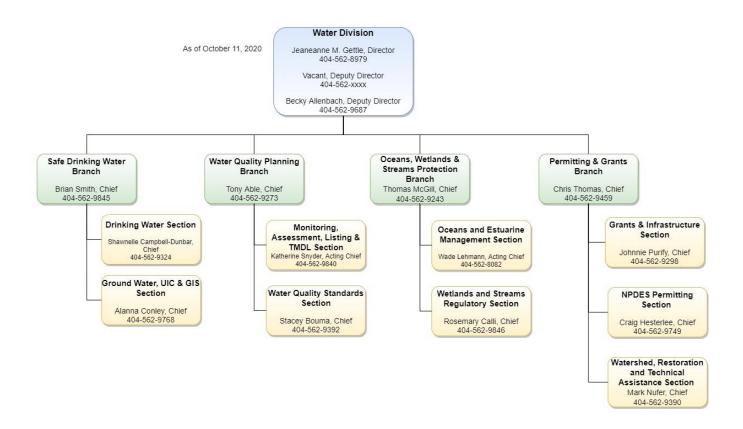
Region 4 Laboratory Services and Applied Science Division



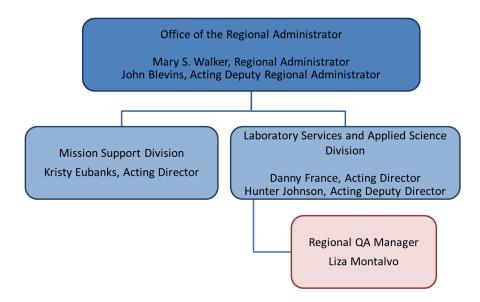
Region 4 Superfund and Emergency Management Division



Region 4 Water Division



Region 4 Quality Assurance Management



APPENDIX B

REGION 4 MAJOR PROGRAM ELEMENTS

ACTIVITY	APPLICABLE LAW	RESPONSIBLE DIVISION	LSASD 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	ARD	ASB
Stationary Source Program Implementation – primarily delegated to the states. The Region primarily has an overview/technical assistance role.	CAA	ARD	ASB
Mobile Source Enforcement Direct Implementation	CAA	ARD	
Mobile Source Inspections and Maintenance Delegated to the states. The Region has an overview/ technical assistance role.	CAA	ARD	
Protect, maintain, and restore the Gulf of Mexico – Make assistance agreements to State water pollution control agencies, interstate agencies, other public or nonprofit private agencies, institutions, organizations, and individuals to conduct and promote the coordination and acceleration of, research, investigations, experiments, training, demonstrations, surveys, and studies relating to the causes, effects, extent, prevention, reduction, and elimination of pollution in the Gulf of Mexico Watershed.	CWA	GMD	
Stationary Source Enforcement Delegated to the states. The Region has an overview/technical assistance role.	CAA	ECAD	
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	ECAD	LSB, ASB, QAPSB/QAS
PCB and Dioxin Inspections Inspections are conducted at transformer stations, substations, etc. Program inspectors conduct sampling; analyses are conducted by LSASD and contract laboratories.	TSCA	ECAD	LSB, ASB

Asbestos Enforcement – Delegated to the states. The Region has an overview/technical assistance role in all Region 4 states except Georgia.	TSCA/CAA	ECAD	QAPSB/QAS
RCRA Enforcement The program is delegated to the states. Several types of inspections are conducted by LSASD and contractors. These include inspections of generators, transporters, and disposal facilities.	RCRA	ECAD	ASB, QAPSB/QAS
Water Quality Enforcement Delegated to all states. Several types of compliance inspections are conducted as overview for delegated states.	CWA	ECAD	ASB, QAPSB/QAS
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	LCRD	ASB
RCRA Corrective Action – The RCRA corrective action program is delegated to the states except in Mississippi. The Region has primary responsibility for the corrective action program in Mississippi and overviews the other seven state programs.	RCRA	LCRD	
Investigations of Uncontrolled Hazardous Waste Sites Several types of investigations are conducted to support removal and remedial response actions and/or listing of sites on the NPL actions. Investigations are conducted by contractors, states under cooperative agreements, potentially responsible parties under consent orders and LSASD. The Region overviews all extramural investigations.	CERCLA as amended by SARA, Section 311 of CWA, OPA	SEMD	LSB, ASB, QAPSB
Removal and Remedial Response Actions at Uncontrolled Hazardous Waste Sites	CERCLA as amended by SARA, Section 311 of CWA, OPA	SEMD	LSB, ASB, QAPSB

Emergency Management Provide response capability, and implement emergency planning, preparedness and prevention activities. Co-chair the standing Regional Response Team (RRT) with the U.S. Coast Guard and coordinate the Emergency Support Function #10 (ESF-10) under the Federal Emergency Management Agency (FEMA) Department of Homeland Security's National Response Framework.	CERCLA as amended by SARA, Section 311 of CWA, OPA, EPCRA, Robert T. Stafford Disaster Relief and Emergency Assistance Act	SEMD	LSB, ASB, QAPSB
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	WD	ASB, QAPSB/QAS
Dredge and Fill – Investigations are conducted by LSASD to support permitting decisions by the Region and for enforcement actions by the Department of Justice.	CWA	WD	ASB, QAPSB/QAS
Monitoring of Public Water Supplies Program is delegated to the states. The Region has an overview/technical assistance role. LSASD conducts special studies in support of state programs.	SDWA	WD	ASB, QAPSB/QAS
Underground Injection Control Program is delegated to the states. The Region has an overview/technical assistance role. LSASD conducts special studies in support of the state programs.	SDWA	WD	ASB

APPENDIX C



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

Region 4 Quality Assurance Section Quality Management Plan Checklist

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	COMMINICATION
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; ELEMENT	COMMENTS
(6) Computer Hardware and Software	COMMENTS
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; 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 and Approval	Review
References:	
EPA Requirements for Quality Management Plans, EPA QA/R-2, EPA/240/B-01/002 (2001)	March

REGION 4 QAPP REVIEW CHECKLIST

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

USEPA REGION 4 QUALITY ASSURANCE SECTION QAPP REVIEW CHECKLIST

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

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	

ELEMENT	COMMENTS
B5. Quality Control Requirements	COMMENTS
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	

P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=N ELEMENT	COMMENTS
B10. Data Management	001/11/1201
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	

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

P=Present & Acceptable; NP=Not Present; I=Incomplete; NA=Not 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	
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 <u>Guidance on Systematic Planning Using the Data Quality Objectives Process</u>, 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.

APPENDIX D

REGION 4 DATA COMPETENCY CERTIFICATION FORM

Revised Jan 17, 2020

U.S. Environmental Protection Agency Region 4 **Data Competency Certification Form**

The Competency Policy (FEM-2012-02), requires organizations generating or using environmental data under Agency-funded assistance agreements (greater than \$200K) to submit documentation of their

the	mpetency prior to award of the agreement or if not practicable, prior to beginning any work involving generation, or use of environmental data. This includes organizations performing environmental mpling, field measurements, and/or laboratory analyses.
	Quality system documentation such as a Quality Management Plan (QMP), Quality Assurance Project Plan (QAPP) and/or other documentation that demonstrates conformance to U.S. EPA quality program requirements. If already submitted, provide the document(s) title and expiration date.
	monstration of Competency may include the following: (Check one or more of the appropriate blocks
tha	t supports your "Data Competency" certification).
	Participation in Accreditation or Certification Programs e.g., National Environmental Laboratory Accreditation Program (NELAP), Internation Organization of Standardization (ISO). The accreditation or certification program must be applicable to the environmental data generated under the Agency-funded assistance. <i>Provide accreditations or certifications</i> .
	Participation in an external Proficiency Testing (PT) Program (independent of external programmatic certifications (e.g. laboratory)). <i>Provide a list of proficiency testing programs and dates</i> .
	Standard Operating Procedures (SOPs) Provide a list of SOPs pertinent to activities of generating, collecting, or using environmental data within the Scope of Work (SOW). Include the date of last review of the SOPs.
	Demonstrations and Audits/Assessments of Proficiency <i>Provide the date of the audit and a summary of the findings.</i>
	Contract Laboratories <i>Provide current/up-to-date certificates for accreditations and certifications held by contract laboratories used in data analysis.</i>
	Other Pertinent Documentation that Demonstrates Competency (e.g. training records, past performance of similar SOW) <i>Provide a list of other activities not mentioned that is considered part of your Quality Assurance (QA) program.</i>
	ease return the completed and signed form, with supporting documentation, to your Project ficer (PO).
co gra	rantee Data Competency Certification: I acknowledge the terms and conditions listed in the grant operative agreement, which address Quality Assurance and Data Competency requirements for the unt. The signature attests to the best of my knowledge that the above information is accurate and mplete.
Gr	antee's Authorized Official (print):Title:
	gnature of Authorized Official: