Quality Management Plan

for

EPA Region 4

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

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Prepared by Region 4
Quality Assurance Manager
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LIST OF ACRONYMS

APTMD - Air, Pesticides and Toxics Management Division
ARCS - Alternative Remedial Contracting Strategy
ASB - Analytical Support Branch
CERCLA - Comprehensive Environmental Response, Compensation and Liability Act
CFR - Code of Federal Regulations
CLP - Contract Laboratory Program
CID - Criminal Investigation Division
CO - Contracting Officer
COE - U.S. Army Corps of Engineers
CSI - Compliance Sampling Inspection
CWA - Clean Water Act
DAO - Designated Approving Official
DMRQA - Discharge Monitoring Report Quality Assurance
DQA - Data Quality Act
DQO - Data Quality Objectives
EAB - Ecological Assessment Branch
EIB - Environmental Investigations Branch
ESAT - Environmental Services Assistance Team
FAR - Federal Acquisition Regulations
FIFRA - Federal Insecticide, Fungicide and Rodenticide Act
FOIA - Freedom of Information Act
GIS - Geographic Information System
GMO - Grants Management Office
IAG - Interagency Agreement
IM - Information Management
IQGs - Information Quality Guidelines
NDPD - National Data Processing Division
NEPA - National Environmental Policy Act
NERL - National Environmental/Exposure Research Laboratory
NPL - National Priority List
NPDES - National Pollutant Discharge Elimination System
NTSD - National Technology Services Division
OEI - Office of Environmental Information
OPM - Office of Policy and Management (Region 4)
QAS - Quality Assurance Section
PAI - Performance Audit Inspection
PE - Performance Evaluation
PO - Project Officer
QA - Quality Assurance
QC - Quality Control
QACs - Quality Assurance Coordinators
QAPP - Quality Assurance Project Plan
QAARWP – Quality Assurance Annual Report and Work Plan
QMP - Quality Management Plan
RCRA - Resource Conservation and Recovery Act
RQAM - Regional Quality Assurance Manager
RA - Regional Administrator
SDWA - Safe Drinking Water Act
SESD - Science and Ecosystem Support Division
SOP - Standard Operating Procedure
START - Superfund Technical Assistance and Response Team
TSCA - Toxic Substances Control Act
TEP - Technical Evaluation Panel
TVA - Tennessee Valley Authority
USGS - United States Geological Survey
UST - Underground Storage Tank

1.0 QUALITY MANAGEMENT PLAN IDENTIFICATION FORM

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Organization Title EPA Region 4
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Plan Coverage: This management plan documents the quality system used in EPA Region 4 and is required by EPA Order CIO 2105.0, *"Policy and Program Requirements for the Mandatory Agency-Wide Quality System."* The plan covers quality assurance policies, roles and responsibilities for environmental data collection activities. This includes the collection, evaluation, and use of environmental data produced by regional programs and data generated through grants, contracts, interagency and cooperative agreements. In addition, the plan covers environmental technology which is funded by the Agency whose purpose is to prevent pollutants from entering the environment or to remove pollutants from the environment.

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2.0 INTRODUCTION

EPA Order CIO2105.0, Policy and Program Requirements for the Mandatory Agency-Wide Quality System, requires that each EPA Program and Regional Office develop and document a quality system to assure that environmental data used to support Agency decisions is of adequate quality and is usable for its intended purpose. This Quality Management Plan (QMP) describes Region 4's quality system. A quality system is a structured and documented management system which describes an organization's roles, responsibilities, policies, and procedures as they relate to the generation and use of environmental data and the implementation of environmental technology. This document is intended for use by EPA Region 4 managers and staff, as well as those organizations producing environmental data under an EPA extramural agreement, i.e., contract, grant, cooperative agreement, and interagency agreement. The document provides a link between quality assurance (QA) policy as defined in EPA Order CIO 2105.0, and the implementation of this Agency Directive in Region 4. It is important to note that this plan does not cover all Region 4 management systems, but only those which are related to the generation and use of environmental data and the use of environmental technology.

2.1 Importance of Environmental Data

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

2.2 Essential Definitions

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

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

2.2.2.1 Internal Data - Data generated by or for Region 4 programs where regional staff have primary responsibility for project or task decision making. Region 4's quality assurance system requirements apply to these data. Regional contracts which produce environmental data for regional programs (air, water or waste) also fall into this category.

2.2.2.2 Extramural Data - Data generated by organizations other than Region 4 which are funded by EPA through grants, cooperative agreements, contracts and/or interagency agreements. Overall EPA quality assurance requirements for financial assistance agreements, covered in 40 CFR 30.54 and 31.45, apply to these data. Extramural data is also referred to as external data.

2.2.3.2 Secondary Data - Historical data or information produced during previous environmental investigations or studies, etc. Secondary data includes internal data produced by the agency or a contractor to EPA, and extramural data produced outside EPA. This includes information or data that were collected for other purposes or obtained from other document information systems is considered secondary data/information. (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.)

2.2.3 Environmental Technology - Pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies which are used to remove contaminants from the environment or prevent contaminants from entering the environment.

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

2.2.5 Quality Control (QC) - The overall system of technical activities that measure the performance of a process or item against defined standards to ensure that 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.

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

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

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

3.0 REGIONAL QUALITY ASSURANCE POLICY and GOALS

3.1 Regional QA Policy

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

Regional managers and staff will assure that there are sufficient QA activities conducted by the environmental programs to provide reasonable confidence that all environmental data generated are scientifically valid, of adequate statistical quantity, of known precision and bias, of acceptable completeness, representativeness, comparability, 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 generation of data. Senior managers in each division are responsible for assuring that adequate resources, including personnel, travel funds, and extramural funds, are available to implement the regional quality assurance system.

To effectively and efficiently utilize resources dedicated to quality assurance activities in Region 4, Division and/or Office staff will be responsible for conducting a prescreening review of quality assurance project plans prior to submittal to the SESD, Quality Assurance Section (QAS) for review and RQAM approval. QAPPs received without a completed prescreening checklist (completed for the appropriate sections) attached to the document will be returned to the sender with a memorandum stating the Regional QAS's policy for QAPP review and approval. However, Region 4 Divisions/Offices may elect to utilize Designated Approving Officials (DAOs) to review and approve QAPPs. When Division/Offices elect to use DAOs, protocols for their use must be clearly defined as part of their Division/Office Quality Management Plan. QAS staff will conduct, at a minimum, an annual audit of those Divisions/Offices that elect to have DAOs to ensure that all activities delegated to them are being conducted in accordance with EPA requirements and this QMP. Designated Approving Official (DAO) training will be required for those individuals selected to review QAPPs as part of their Divisional duties. The region anticipates that 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 within the region.

The Divisions will be required to designate Quality Assurance Coordinators. The duties and training requirements of the Quality Assurance Coordinator are outlined in Appendix E and those presently designated as Quality Assurance Coordinators will be

included in the offices/Division QMP. Their duties will also be clearly defined in the Division/Office QMPs. The requirement for QACs must comply with all those defined in this QMP. Presently, all QACs report directly to their first line supervisor but receive guidance pertaining to Region 4 QA activities from the RQAM.

3.2 Regional QA Objectives

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

3.2.1 Regional QA System activities shall comply with, **ANSI/ASQ E4-2004, *Quality Systems for Environmental Data and Technology Programs – Requirements with Guidance for Use*."** 2004 with respect to planning, implementing and assessing quality assurance activities. It is EPA policy that all environmental programs performed by EPA or directly for EPA through EPA funded extramural agreements shall be supported by individual quality systems that comply fully with the ANSI/ASQC E-4 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 quality assurance implementation policy for environmental technology will be developed as guidance by the Office of Environmental Information/Quality Staff (OEI/QS).

3.2.2 The data quality objectives (DQO) process, or a similar systematic planning process, shall be used to plan project or study goals and objectives as they relate to programmatic or regulatory requirements, and needed environmental data quality prior to the initiation of data collection activities. DQOs, or similar outputs from a systematic planning process, shall be documented in a quality assurance project plan, or equivalent project-level planning document.

3.2.3 QA Project Plans (QAPPs) or equivalent planning documents, however named, shall be developed by those staff (either EPA or contractor) responsible for designing and implementing a project, study, or task which requires the collection or use of environmental data. QAPPs and equivalent planning documents shall meet EPA requirements and will incorporate project-specific DQOs. QAPPs will be developed using a graded approach consistent with the complexity of the project and the intended use of the data.

3.2.4 Extramural organizations which receive EPA extramural funding for environmental data collection activities, shall have in place an approved Quality Management Plan with the requirements specified in EPA's Requirement for Quality Management Plans, EPA/240/B-01/002, QA/R-2 (March 2001) document. This document must illustrate that a quality system is in place to insure that all data collection activities are appropriately planned, implemented, and assessed. If it is determined by the Divisions/Programs or R4QAM that a QAPP must be provided for a specific data collection activity then the document must comply with the requirements specified in EPA's Requirement for Quality

Assurance Project Plans, EPA/240/B-01/003, QA/R-5 (February 2006) document consistent with a graded approach. The Region has the authority to conduct oversight of organizations or their sub-organizations, and the authority to require corrective actions of both of these organizations in the event that the Regional QA policies or objectives were not met.

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

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

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

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

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

4.0 REGIONAL ORGANIZATION and QA RESPONSIBILITIES

4.1 Regional Program Organization and Function

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

4.1.1 Science and Ecosystem Support Division (SESD)

The Division has overall management responsibility for the regional quality system. This Division is one of the primary organizations within Region 4 responsible for collection of environmental data. The Division conducts field investigations, inspections, projects, and studies which often require sampling of environmental media. SESD also analyzes multi-media environmental samples; processes and evaluates multi-media environmental data; and prepares project or study reports which summarize results and/or provide conclusions and recommendations. All investigations and projects are done at the request of the regional program divisions under memoranda of agreement and work plans negotiated annually between SESD and the program divisions. SESD performs specific QA assessments of selected external environmental monitoring projects as requested by the program divisions.

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

As a collective group, the EPA Regional Laboratories chose to meet the requirements of the Agency's Laboratory Competency Policy by seeking accreditation under the National Environmental Laboratory Accreditation Conference (NELAC) Standards. The regional laboratories' approach of seeking NELAC accreditation to satisfy the policy directive was approved by EPA's Forum on Environmental Measurements (FEM) Laboratory Competency Action Team, in a memorandum dated January 20, 2005.

The SESD laboratory met the requirements of the Laboratory Competency Policy on June 13, 2005, when it received NELAC accreditation from the Oregon Environmental Laboratory Accreditation Program for chemistry. The laboratory was accredited in all five fields of testing offered by NELAC: air, potable water, non-potable water, solid and chemical waste, and tissue. The laboratory's quality system is documented in a quality management plan entitled "Analytical Support Branch Laboratory Operations and Quality Control Manual" dated January 11, 2007.

4.1.2 Air, Pesticides & Toxics Management Division (APTMD)

The Division has the program management and implementation responsibilities for the Clean Air Act (CAA), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). It serves as the technical/program authority for all monitoring activities associated with the CAA, FIFRA, and TSCA. It ensures that QA matters are reflected in budgets, program plans, and work/operating plans. The division manages grants, contract funds, and cooperative agreements, and overviews external environmental monitoring programs which require the collection of environmental data. SESD provides the APTMD with technical assistance relevant to monitoring and data processing activities, including QA oversight.

4.1.3 Superfund Division

The Division has the program management and implementation responsibilities for the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and Emergency Response Programs. It manages federal grants and contract funds. The Division ensures that QA matters are properly reflected

in budgets, program plans, and work/operating plans. It serves as technical/program authority for all hazardous waste environmental monitoring activities within the geographical boundaries of Region 4. The data arising from these programs are the product of efforts both internal and external to the Region. The division provides oversight for external environmental monitoring programs which require the collection of environmental data. SESD provides the Superfund Division with technical assistance relevant to the collection of environmental data, including QA oversight. This includes regional management of the Contract Laboratory Program (CLP), review of CLP and regional contract lab data, systems audits of state field and laboratory activities, and overview of potentially responsible parties' remedial actions at CERCLA sites.

4.1.4 RCRA Division

The RCRA Division function is to recommend goals, priorities, and objectives for the Resource Conservation and Recovery Act (RCRA), the Oil Pollution Act (OPA) of 1990, and the Small Business Liability Relief and Brownfields Revitalization Act programs to the Regional Administrator and other appropriate Regional management and to the Office of Solid Waste and Emergency Response (OSWER) and the Office of Enforcement and Compliance Assurance (OECA). Major program areas include RCRA Enforcement and Compliance, OPA Enforcement, RCRA Corrective Action, RCRA Permitting, Underground Storage Tanks, Brownfields, Solid Waste Management, and Materials Management. It assists the States in developing comprehensive programs within delegated or related program areas including providing or arranging for technical assistance to state and local agencies in developing necessary plans, monitoring systems, instrumentation, data collection and analysis systems, and emergency response, including imminent hazards. The Division represents the Region in carrying out the implementation of programs for which it is responsible. The RCRA Division is comprised of three branches: the RCRA and OPA Enforcement and Compliance Branch, the Restoration and Underground Storage Tank Branch, and the RCRA Programs and Materials Management Branch. SESD provides the RCRA Division with technical assistance relevant to monitoring and data collection and interpretation activities, including QA oversight. Also SESD conducts Comprehensive Groundwater Monitoring Evaluations and Compliance Enforcement Investigations at RCRA facilities, provides technical assistance and training to States/Indian Tribes/Region 4 RCRA program personnel and conducts system audits of state field and laboratory activities.

4.1.5 Water Management Division (WMD)

This Division has the program and implementation responsibilities for the Safe Drinking Water Act (SDWA), Clean Water Act (CWA), ambient surface water and groundwater, underground injection control, estuarine waters, off-shore discharge, and domestic and industrial wastewater treatment programs. It is

responsible for oversight of delegated permitting and compliance as well as the delegated enforcement for municipal and industrial wastewater treatment facilities. The division manages federal grants and contract funds. It ensures that QA matters are properly reflected in budgets, program plans, work/operating plans. WMD serves as the technical/program authority for all water-related environmental monitoring activities within the geographical boundaries of Region 4. The data arising from these programs are the product of efforts both internal and external to the Region. The division provides oversight for external environmental monitoring programs which require the collection of environmental data. SESD provides the WMD with technical assistance relevant to monitoring and data collection and interpretation activities, including QA oversight. This includes oversight of State/Tribal/Local fixed, ambient water monitoring networks, special ambient water studies, performance audits on water and wastewater field monitoring and laboratory operations, NPDES compliance inspections and oversight inspections (CSI's and PAI's) and systems audits of state field and laboratory activities.

4.1.6 Office of Environmental Accountability (OEA)

This Division has the overall planning and accountability responsibility for enforcing the various environmental statutes which the Region implements. These responsibilities include: (1) integrating compliance assurance activities to facilitate multi-media projects at the Regional and State/Tribal/Local levels; (2) performing the planning and targeting necessary for the Region's compliance assurance plan; (3) assisting the media programs in developing strategies and tools for assisting the regulated community in achieving compliance with Agency statutes; (4) supporting the environmental compliance activities carried out by Tribal governments; (5) providing legal support for enforcement actions relative to violations of Agency statutes and regulations; and (6) providing legal counsel to the Region's senior management and operating programs.

The legal and technical programs within OEA do not normally require monitoring or measurement activities which involve data collection.

4.1.7 Office of Policy and Management (OPM)

This office has the responsibility for human resources management, budget and finance, procurement and grants administration, information management, and planning and analysis.

Within OPM's Grants, Finance and Cost Recovery Branch, the Grants and Interagency Agreement Section (GIAGS) is responsible for the business management aspects associated with financial assistance agreements (grants and cooperative agreements). This includes the review and negotiation of applications, and the award and administration of funded projects (from project initiation through final close-out). GIAGS is also tasked with the administrative management responsibility of coordinating and controlling the Interagency

Agreement (IAG) process within the Region. GIAGS reviews the regional programs' decision memoranda for both assistance agreements and IAGs to confirm that QA has been addressed in accordance with 40 CFR 30.54 and 31.45 whenever the agreements involve environmental measurements or technology. If the scope of work involves environmental measurements or technology, and a QA Management and/or QAPP has not been approved by the RQAM, the grant or IAG is conditioned to require the appropriate plan before any environmental measurements or data collection may begin.

Within the Grants, Finance and Cost Recovery Branch, the Office of Acquisition Management has the responsibility for contracting for goods and services. The QA requirements in the Federal Acquisition Regulations (FAR) 46.202-4 and FAR 52.246-11 *(Higher-Level Contract Quality Requirement,* Feb 1999) apply to regional procurements involving environmental data. EPA has selected ANSI/ASQC E-4, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs,"2004, as the quality standard which contractors must meet. Implementation of this standard for contracts is further defined in CIO 2105.0, as well as EPA Directive 1900, the Agency's Contract Management Manual.

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

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

4.1.8 Gulf of Mexico Program Office

The Gulf of Mexico Program Office (GMPO) was initiated by the U.S. Environmental Protection Agency (EPA) in 1988 as a non-regulatory program. Organizationally, the program falls within the Region 4 management structure. The program was developed because no single agency or level of government had either the necessary technical or financial resources or the legal mandate to address the spectrum of environmental and public health issues facing the Gulf. The Gulf Program is today a collaborative effort that includes a consortium of

key stakeholders that share significant interests in coastal and marine resources. It is an ecosystem-based approach founded on the principles of bringing the appropriate science, together with the financial and technical resources, to help the Gulf States and coastal communities effectively address their environmental problems within a broader regional and national context.

Normally GMPO personnel do not directly perform environmental data collection. Staff is involved in managing grants and interagency agreements, providing technical/scientific support to stakeholders within the Gulf region, and coordinating scientific studies in order to achieve common goals.

SESD provides GMPO with technical assistance by reviewing QAPPs, Quality Management Plans, and contract Scopes of Work.

Appendix B further identifies Regional program roles and responsibilities by listing major mission elements (data gathering activities), the responsible Division/Branch, and the SESD Organizations that provide support.

4.2 Quality Assurance Responsibilities

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

4.2.1 Regional Administrator (RA)

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

4.2.2 Regional Quality Assurance Manager (RQAM)

The RQAM is the branch chief of the Management and Technical Services Branch, located within the SESD. The RQAM is independent of any data generation activities within SESD or the Region. The RQAM will provide briefings to senior staff on QA issues on approximately a semiannual basis or more often as needed.

The RQAM may require suspension of environmental data collection projects and request corrective action in the event that data quality/environmental technology QA activities do not meet Agency QA policy or requirements. In the event that the RQAM determines that any regional data collection activities (at the project or program level) do not meet Agency quality assurance policies or requirements, the RQAM shall make every effort to resolve disputes through discussion and negotiation. Disagreements will be resolved at the lowest administrative level possible. Should agreement not be reached at this level, the RQAM, after briefing the SESD Director, shall take the issue to Senior

Management for resolution. The RA/DRA shall have final dispute authority on all quality issues.

The RQAM has the prerogative to meet directly with the Regional Administrator or Deputy Regional Administrator (RA/DRA) to discuss QA issues.

In addition to the RQAM's responsibilities, SESD Quality Assurance Section (QAS) personnel perform the following functions:

1. Conduct assessments of State, Tribal and other external partner quality management systems.
2. Review QMPs and QAPPs and recommend approval status of these plans to the RQAM.
3. Perform laboratory assessments of state, commercial, tribal, and/or other government laboratories as required by SDWA, CWA, and CLP.
4. Perform assessments, including management system assessments, data quality audits, and performance audits.
5. Manage and administer the regional Environmental Services Assistance Team (ESAT) Contract which includes overview of data review and validation and other QA activities conducted under this contract.
6. Provide technical and quality assurance training to Region 4 staff and entities external to EPA.
7. Provide technical assistance/support to the RQAM to meet the requirements addressed in this QMP.

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

Additionally, the RQAM:

4.2.2.1 Serves as 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.

4.2.2.2 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.

4.2.2.3 Reviews, comments, and approves QAPPs for internal and external Regional data operations. Reviews implementation of selected QA plans and adequacy of the data generated from a quality perspective.

4.2.2.4 Serves on the Regional Peer Review Panel which has been established (Regional Order 2200.1) to review and approve study plans and reports for major special studies, and other technical documents for publication and distribution. This review process helps ensure that Agency QA requirements are incorporated in all major monitoring activities.

4.2.2.5 Assists Regional programs in integrating EPA QA Program requirements into the State/Tribal grants and into contract/IAG scopes of work.

4.2.2.6 Assists State/Tribes and other grantees in the development and implementation of QA Management and Project Plans.

4.2.2.7 Coordinates and/or conducts system and performance audits of selected environmental monitoring programs.

4.2.2.8 Submits annual QA Status Report and Work Plan to Regional management and EPA's Quality Staff Director.

4.2.2.9 Coordinates and participates in the OEI Quality Staff review of the Region 4 quality system.

4.2.2.10 Reviews the Region 4 QMP annually and when appropriate, updates and submits changes to OEI/QS for approval.

4.2.3 Regional Managers

Division/Office Directors are responsible for ensuring that internal and extramural data collection activities within their programs are conducted in accordance with Agency and Region 4 QA policy. Daily QA management is the responsibility of the appropriate second or first level managers (i.e., Branch and Section Chiefs). The line managers are responsible for procedures within their area of responsibility to ensure the acceptability of data and the suitability of environmental technology. Key responsibilities of managers are:

4.2.3.1 Establish planning policies to ensure that appropriate QA procedures are reflected in budgets, program plans, and operating plans.

4.2.3.2 Encourage the development of Data Quality Objectives (DQO's) for data collection activities.

4.2.3.3 Require the development of QAPPs or an equivalent project-level planning document for projects involving data collection.

4.2.3.4 Support regional quality system implementation and assessment.

4.2.3.5 Take corrective action as required by QA assessments or reviews.

4.2.3.6 Report data quality problems to RQAM.

4.2.3.7 Assure personnel receive appropriate QA training by working with the RQAM on the development of a training curriculum for their staff. This training curriculum will be included in the Divisions/Offices QMP.

Managers and supervisors will be expected to include their staffs QA training needs in their employees Individual Development Plan. The Learning and Development Institute (LDI) maintains electronic records of all the training provided by the Institute and this information is available to both the employee and their manager/supervisor.

4.2.3.8 Ensure that all staff that are assigned QA responsibilities have those responsibilities included in their position descriptions and in the performance appraisal system (PARS).

4.2.3.9 Select, monitor and insure appropriate training is provided to their Designated Approving Officials as defined by the RQAM. (See 4.2.3.7 above)

4.2.4 Quality Assurance Coordinators (QACs)

Each Division director will appoint at least one manager or staff person to service as the QAC for his/her Division. QAC's serve as 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. Details of the QAC role are more clearly defined in the QA Coordinators SOP, Appendix D. Key responsibilities of the QAC are:

4.2.4.1 Serve as the official Division/Office contact for quality assurance matters pertinent to the data collection activities of that Division/Office.

4.2.4.2 Attend meetings called by the RQAM to keep abreast of QA issues affecting the Region and Agency. Communicate QA issues to Division/Office personnel.

4.2.4.3 Advise the RQAM on changes needed to the Regional Quality Management Plan. Coordinate program input for the Regional QA Annual Report submitted by the RQAM to Quality Staff Director.

4.2.4.4 Respond to quality control issues and problems, and respond to requests for guidance or technical direction.

4.2.4.5 Work with the Division's staff to develop and maintain an effective QA program.

4.2.4.6 Attend Regional QA training provided by the RQAM in the Region as appropriate.

4.2.5 Regional Project Managers

Project Managers, however named, are responsible for specific internal regional projects. Therefore, the Project Manager has the principal responsibility for ensuring 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 Manager are:

4.2.5.1 Prepare or direct the preparation of a QAPP (or equivalent planning document) for each project and submit the QAPP to the RQAM or a Divisional DAO for review and approval.

4.2.5.2 Prepare or approve Data Quality Objectives, technical and quality assurance specifications, and acceptance criteria for environmental data needed to support project decisions.

4.2.5.3 Participate in conducting QA system/performance audits of projects as requested by the RQAM.

4.2.5.4 Take corrective action that may be required by audit findings.

4.2.5.5 Report data quality problems to the regional QA Coordinator located within the appropriate Organization/Program and the RQAM.

4.2.5.6 Attend appropriate regional QA training provided in the region.

4.2.5.7 Review QAPPs that are submitted to the Region as part of EPA's documentation requirements. The QAPP is to be reviewed using Region 4's Prescreening Checklist.

4.2.6 Regional Project Officers

Project Officers are accountable for specific extramural assistance agreements or contracts. Therefore, while the Project Officers are normally not directly involved in project activities, the Project Officer has the overall responsibility for ensuring that all Agency QA requirements are met by the assistance agreement recipient or contractor. Key responsibilities of the Project Officer are:

4.2.6.1 Require preparation of a Quality Management Plan, a QA Project Plan, and/or equivalent document, as appropriate, for each assistance agreement or contract.

4.2.6.2 Overview data quality generated from external projects funded through financial assistance agreements and/or contracts.

4.2.6.3 Participate in conducting QA system and performance audits of projects as requested by the RQAM.

4.2.6.4 Coordinate review of external QMP and/or QAPPs and submit to RQAM for review and approval.

4.2.6.5 Take corrective action that may be required by audit findings.

4.2.6.6 Report data quality problems to RQAM and the appropriate QA Coordinator.

4.2.6.7 Attend appropriate regional QA training.

4.2.6.8 Review QAPPs that are submitted to the Region as part of grant/assistance agreement requirements.

4.2.7 Regional Program Technical Staff

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

4.2.7.1 Assist RQAM with technical aspects of QA as related to their expertise in air, water, toxic substances, hazardous waste, engineering, chemistry, biology, microbiology, field operations and data operations.

4.2.7.2 Identify QA needs, resolve problems, and answer requests for guidance or assistance in area of expertise.

4.2.7.3 Conduct and/or participate in on-site field and laboratory system and technical audits.

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

4.2.7.5 Review QAPPs that are submitted to the Region as part of grant/assistance agreement requirements.

4.2.8 Designated Approving Officials

A designated approving official (DAO) is a regional manager or staff person who is only authorized to approve internal and external quality assurance project plans (QAPP) by the RQAM. The DAO will follow prescribed procedures for reviewing, documenting, and approving QAPPs and must attend the DAO training course coordinated by the RQAM. Each division/office must include the

protocols for their DAOs in their QMP and such protocols must be in line with those outlined in this QMP. The Divisions/Offices QMP must be approved by the RQAM. The DAO competencies are defined in the Technical competency Form, Appendix E.

5.0 REGIONAL QUALITY SYSTEM REQUIREMENTS - EXTERNAL ORGANIZATIONS

Within the Region, QA data generation activities fall into three broad categories:

a. External: data generated by organizations receiving grants, cooperative agreements, and interagency agreements.
b. Internal: data generation projects designed and conducted by Regional EPA staff and/or EPA contractors.
c. Secondary: data that were collected for other purposes or obtained from other sources including, literature, surveys, models, databases, and information systems. (See section 2.2.3.2)

5.1 State, Local, and Tribal Grants

A substantial amount of environmental data required by EPA statutes and regulations are generated by state, local, and tribal organizations receiving one-time or continuing environmental grants. To qualify for financial assistance, state, local, and tribal organizations must meet the QA specifications of 40 CFR Part 31.45, which require that the "grantee shall develop and implement quality assurance practices consisting of policies, procedures, specifications, standards and documentation sufficient to produce data of quality adequate to meet project objectives...".

5.1.1 In order to satisfy the QA requirements in 40 CFR Part 31.45, the assistance agreement recipient must submit a Quality Management Plan for review and approval (at a minimum of every 5 years) by the Region 4 QA Manager 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. Approval of the QMP is a joint responsibility of the RQAM and PO and requires approval by both parties. In order for a grantee's QMP to be approved, the grantee's quality system must meet the specifications of EPA Requirements for Quality Management Plans (EPA QA/R-2), March 2001 (or most recent edition). If grantees make sub-awards (either sub-grants or procurement) under an assistance agreement, they must ensure that the sub-awards meet the quality assurance requirements in EPA QA/R-2.

5.1.2 Clarifying language provided by EPA's Office of Grants and Debarment also requires the grant recipient to provide a QAPP in addition to the QMP. In addition, for continuing grants such as performance partnership grants (PPGs), where a single grant may cover several projects, 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 program level QAPP in lieu of numerous individual project QAPPS may be appropriate. The RQAM will make the determination when a program level QAPP is appropriate. Approval of the recipient's QMP by the EPA Project Officer and the TQAM may allow delegation of the authority to review and approve QAPPs to the recipient based on procedures documented in the QMP.

5.1.3 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 Quality Management Plan review/approval, QAPP implementation, and on-site QA audits of environmental programs, field activities, and laboratory operations. State program overview is the primary responsibility of the individual regional program division/office with extensive assistance from the RQAM and SESD personnel.

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

40 CFR Part 30.54 contains QA requirements for grants and cooperative agreements with institutions of higher education, hospitals and other non-profit organizations. Section 30.54 states: "If the Project Officer determines that the grantee's project involves environmentally related measurements or data generation, the grantee shall develop and implement quality assurance practices consisting of policies, procedures, specifications, standards and documentation sufficient to produce data of quality adequate to meet project objectives". These grants are usually one-time assistance agreements as opposed to the continuing grants awarded to state, local and tribal organizations. The academic/non-profit QA requirement is satisfied by the grantee's submission of a QMP and QAPP, with subsequent approval of the QMP and QAPP.

The QMP and QAPP may be combined into a single document if the RQAM and Project Officer agree that the nature and extent of the environmental data collection effort warrants such action. QMPs and QAPPs will be approved by the Region 4 QA Manager and the appropriate Project Officer(s). QMPs must be approved prior to award of the financial assistance. 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.

5.3 QA Operations for Interagency Agreements

For interagency agreements, before funding for environmental measurements or data collection activities is approved, EPA Region 4 and the other involved organizations

must have agreed upon the QA requirements for the project. The RQAM shall review and approve QA Management/Project Plans, as appropriate, prior to award of the inter-agency agreement. The Program Manager/Project Officer shall review and evaluate the use of these Plans. Upon completion of the monitoring activities, the Program Manager/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 for resolution.

5.4 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:

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

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

5.4.3 The Grants Management Office within the Office of Policy and Management will review extramural agreements prior to award to ensure that all Agency quality requirements have been documented. The RQAM will provide GMO staff and regional project officers with a listing of approved QMPs and their expiration dates for State and Tribal continuing assistance agreements.

5.4.4 Only the RQAM may approve external organization QMPs.

5.5 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:

5.5.1 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.

5.5.2 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.

5.5.3 The document entitled “EPA Guidance for Quality Assurance Project Plans” EPA QA/G-5, Final, December 2002, provides detailed information for preparing an EPA required QAPP document.

6.0 REGIONAL QUALITY SYSTEM - INTERNAL ORGANIZATIONS

As noted earlier, QA data generation activities fall into three broad categories: internal, external and secondary. This section describes the quality system requirements for environmental data generated within Region 4's programs/organizations (internal data). An overview of the quality system policies, procedures, roles, and responsibilities are described in this QMP. According to EPA Order CIO 2105.0 CHG 2, “All Agency organizational units governed by EPA Order CIO 2105.0 CHG2, shall document their quality system in a Quality Management Plan (QMP). The QMP is a policy statement describing how an EPA organization shall comply with the requirements of EPA Order CIO 2105.0 CHG2. 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.” Within the next 2 years, the RQAM, with assistance from the QA coordinators will prepare Divisional QMPs. To further this effort, the RQAM (with assistance from QAS) will develop a QMP template and outline that will comply with the information requirements specified in EPA’s QA/R-2 document.

6.1 Divisional Quality Management Plans (QMPs)

In order to ensure that Region 4 Divisions and Programs are adhering to the requirements and specifications outlined in the Agency Order and the Regional Quality System/QMP, each division will develop and implement a Quality Management Plan tailored to its management structure, QA policies, procedures and practices. Each QMP will provide:

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

6.1.2 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.

6.1.3 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.

6.1.4 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.

6.1.5 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.

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

6.1.7 Delineate the process for overseeing State, Local and Tribes that have been delegated self- approval authority for QAPPs prepared within their divisions/programs. The division/official QMP shall specify the number, type and frequency of QA oversight activities or assessments. (At this time no programs have asked for or received delegation for self approval authority. However, before Region 4 would delegate this responsibility to the State, Local and Tribes, the RQAM would seek guidance from OEI before implementation.) 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 quality assurance project plan (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, due to existing contract language and program precedents, a sampling and analysis plan coupled with a QAPP may be used to document project level technical activities.

6.2 Internal Data Operations

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

6.3 Designated Approving Officials

A designated approving official (DAO) is a regional manager or staff person outside of the Quality Assurance Section who has been delegated the authority by the RQAM to approve quality assurance project plans. The DAO is expected to review the QAPP to ensure that it is compliant with the requirements specified in EPA's QA/R-5 document. In order to receive approval authorization as a DAO, the individual must fully meet the following requirements:

6.3.1 Should have obtained at least a Bachelor's Degree in any of the physical or biological sciences, or demonstrates an in-depth understanding of these disciplines based on job experience obtained internal or external to the agency.

6.3.2 Must register with the RQAM or Divisions Quality Assurance Coordinator by filling out a technical competency form documenting the educational and technical background of the prospective DAO.

6.3.3 Satisfactorily complete a one day training course provided by the RQAM on QAPP requirements and review. Completion of this training module shall be documented by the RQAM with a certificate naming the individual as a DAO and shall be tracked by the division in which the DAO resides, and by the RQAM.

6.3.4 The DAO must also attend annual refresher QA courses provided by QAS to maintain continuing certification.

6.3.5 If the DAO moves to another program, they must be re-certified in that new area/program to insure technical competency in their new position.

6.3.6 Possess the necessary expertise in project management to review the QAPP.

6.3.7 The prospective DAO must have 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 on these issues or must be familiar with the requirements for collecting this information in order to approve the QAPP. A firm knowledge of EPA program and regulatory requirements is also necessary.

6.3.8 Have no direct conflict of interest. A project manager who writes a QAPP for a project under his/her direction cannot approve that same QAPP.

6.3.9 Document the QAPP review process using a checklist developed by QAS and prepares specific comments addressing document deficiencies.

Annually the RQAM will randomly select QAPPs that have been reviewed by a one or more of the divisions 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.

6.4 QA Operations for Contracts

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

Many regional divisions use contractors for the collection of environmental data or utilizing environmental technology. During the contract pre-award phase, the originating program division shall notify the RQAM of all contracts involving environmental data collection. 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,* Feb 1999) apply to regional contracts involving the collection and use of environmental data. The appropriate project and contracting officer (PO and CO) are 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 (Contracting Officer's Representative) shall ensure that a QA Review Form has been completed in accordance with EPA Order 1900, the Contracts Management Manual. The COR is also responsible for including the RQAM as a technical evaluation panel member on those contracts with a value of $500,000 or greater, if the contracts involve environmental measurements or technology.

It is the responsibility of the Office of Acquisition Management within the Office of Policy and Management to ensure that QA Review Forms, with appropriate signatures, are included in every solicitation package. The QA Review Form will specify 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 environmental measurements are a Quality Management Plan prior to award and a Quality Assurance Project Plan for each applicable project post - award. The Quality Management Plan (QMP) and Quality Assurance Project Plan may be combined into a single quality assurance document if agreed to before contract award by the contract PO and the RQAM. Prior to contract award, the Office of Acquisition Management will ensure that QMPs are reviewed and approved by the RQAM for those contracts requiring environmental measurements or technology.

7.0 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 Quality Management Plans (QMPs) for 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.

7.1 Data Quality Objectives

The data quality objectives (DQOs) process is EPA's systematic planning process which uses a step-wise system of developing the technical, programmatic and quality assurance requirements specific to a particular project or study. Detailed guidance for developing project or study-specific DQOs is provided in "Data Quality Assessment: A Reviewer's Guide", (EPA QA/G-9R), EPA/240/B-06/002 (February 2006) and; "Data Quality Assessment: Statistical Tools for Practitioners, (EPA QA/G-9S), EPA/240/B-06/003 (February 2006) documents. The Agency 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 as long as 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 in general terms, 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 secondary 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 Quality Assurance Section. 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.

7.2 Quality Assurance Project Plan Contents

Region 4 relies on QAPPs coupled with detailed SOP's to define project-specific 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) document provides detailed information for developing a QAPP. Within the region, different organizations may refer to the project-level planning document using terms such as "sampling and analysis plan" or "study plan." However named, the project-level planning document will contain the necessary elements specified in EPA QA/R-5, while at the same time considering the application of the graded approach to the planning document.

All EPA regional projects requiring collection of environmental data or the use of environmental technology must have an approved QAPP. An exception to this requirement is for those projects where immediate danger to human health or the environment is present or suspected. Projects involving environmental technology shall follow the EPA "Guidance on Quality Assurance for Environmental Technology, Design, Construction and Operation" (EPA QA/G-11), EPA/240/B-05/001 (January 2005) document. The RQAM, or a designated approving official, shall review all QAPPs, provide input, recommend changes, and approve final plans. The RQAM may solicit assistance from regional technical staff when specialized expertise is needed to review certain QAPPs. Project QA activities are tracked by the appropriate Project Manager.

7.3 Standard Operating Procedures (SOP)

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

7.3.1 Preparation of SOPs

SOPs are prepared by the regional organization which has determined that a certain task, procedure, or job function must be performed in a uniform, consistent manner by multiple personnel. The purpose of an SOP is to assure that random error produced as a result of differences in performance of the task, are minimized. It is advisable that SOPs be prepared by personnel who are most knowledgeable in a specific task or procedure. The SOPs are reviewed by appropriate staff in the user organization, and at times by technical specialists in other organizations. The SOPs are prepared in document control format by the

user and are to be maintained on permanent file by the originating organization. The EPA document entitled “Guidance for the Preparation of Standard Operating Procedures” (EPA QA/G-6), EPA/240/B-01/004 (March 2001), should be consulted for an example of the document control format. The second level supervisor (Branch Chief or equivalent) approves the SOP for use. 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. Revisions are reviewed and approved as described above.

7.3.2 Standard Operating Procedure Criteria

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

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

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

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

7.3.2.4 Consistent with sound scientific/engineering principles.

7.3.2.5 Consistent with current EPA regulations and guidelines.

7.3.2.6 Consistent with the instrument manufacturers' specific instruction manuals.

7.3.2.7 At a minimum, an annual review of SOPs will be required. However, the SESD laboratory will perform SOP reviews in accordance to NELAP accreditation requirements and the SESD field branches will review SOPs in accordance to ISO 17025 accreditation requirements.

7.3.3 Activities Requiring Standard Operating Procedures

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

7.3.2.1 General sampling procedures.

7.3.2.2 Analytical methodology.

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

7.3.2.4 Instrumentation selection and use.

7.3.2.5 Instrumentation calibration and standardization.

7.3.2.6 Instrument preventative and remedial maintenance.

7.3.2.7 Duplicate, spiked, blank samples and analysis.

7.3.2.8 Field and laboratory quality control procedures.

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

7.3.2.10 Field and laboratory safety.

7.3.2.11 Data management and assessment procedures.

7.3.2.12 Document control.

7.4 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:

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

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

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

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

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

7.4.6 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. Each SOP, as appropriate, shall describe procedures for verifying the accuracy of the data reduction process.

7.5 Data Quality Assessment

Each QAPP should 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.

7.6 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 corrective actions are required, and who follows-up to verify that corrective actions have been taken and that they have produced the desired results. Corrective actions should 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.

7.7 Information Management

EPA's Office of Environmental Information (OEI) and the National Technology Services Division (NTSD) are responsible for managing the hardware, software and communications components that form the foundation of the Agency's information technology. NTSD 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 NTSD Directives System at http://basin.rtpnc.epa.gov/ntsd/directives.nsf. This directive system is applicable to the personal computer (PC) platform, local area network and server platforms, open systems platforms, Agency electronic mail service, IBM Compatible Mainframe Platform and Supercomputer Platform.

Specifically, Region 4's Environmental Information Services Branch (EISB) will be 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, EISB will work with regional management to plan and implement appropriate modifications.

Region 4 uses the Agency's System Life Cycle Management (SLCM) policy as a guide for all application/software development. The R4 Application Development Manager (ADM) reviews initial requirements to determine if an existing application will meet the sponsor's needs. If a new application is needed, the ADM continues requirements discussions. Requirements are agreed to by both application sponsor and application manager. Depending on requirements, available EPA-approved software/platforms and programming expertise, decisions are made on what technology will be used to develop the application. Development then begins and is continued with ongoing discussions with the sponsor.

Application testing plans are created and carried out 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 any identified changes/modifications are made. Additional testing is completed if needed.

Implementation plans are developed and agreed to by both parties. The ADM creates maintenance, security, and record plans. The application is then implemented and follow up meetings are conducted. Applications that are created based on processes used by multiple regional programs or offices are presented to the regional Environmental Program Information Council (EPIC) for regional implementation consideration. Application duplication is avoided by comparing all development and purchase requests to existing systems.

Region 4 will procure Agency-approved hardware and software that conforms to the Agency-wide information management structure. Software purchases are considered using the same process, requirements, standard software compliance, controlled group testing, implementation, and follow-up.

In the event that a Regional organization has a need to purchase or develop application software that is not on Agency contract, the software will be evaluated prior to purchase or during development. Software evaluation will be performed against written performance/capability standards developed by the Application Administrator and/or System Administrator. R4 will evaluate system and software documentation to ensure that vendors comply with Agency standards and to determine its performance capabilities and documentation requirements.

It is very important to select stable hardware to avoid program failure since bad hardware can be costly to EPA. R4 currently purchases only DELL hardware for servers and workstations since it is recommended by the Agency and tested by the NIS group. Hardware evaluation comes in two different categories:

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

This process is reviewed on a yearly cycle. R4 replaces critical systems hardware every 3 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 R4 process for installing new servers is as follows:

1. Install proper operating systems
2. Follow EPA guidelines for security settings
3. Install Symantec Antivus
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

After new software or hardware deployment, the Region 4 Computer & Telecommunications Services (CATS) Helpdesk receives trouble calls via Footprints Helpdesk software. These calls are documented and stored in an Oracle database. Footprints is capable of running online reports of categorized trouble calls that are evaluated to determine what corrections are needed.

R4 uses Bindview and Patchlink reports to ensure that servers are in compliance with EPA requirements.

R4 System Administrators mange 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.

R4 Application Administrators maintain and manage applications on the server. Responsibilities include ensuring that the application is accessible to users at all times.

R4 Helpdesk Support manages desktop hardware and software. Responsibilities include repair, upgrading, and user training of equipment and Agency standard software.

R4 Information Security Officer (ISO) is responsible for ensuring that the network and all desktops follow the guidelines for security settings and policies of operation.

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

Region 4 is in the process of adopting a Regional System Life Cycle Policy which addresses this issue in section "V. Roles and Responsibilities" as follows:

The Regional Administrator, is responsible for:

1. Approving the SLCM Policy

The Assistant Regional Administrator is responsible for:

1. Ensuring compliance, within the organizations, with system life cycle management policies, procedures and standards

2. Leading the development and maintenance of regional compliance with the Agency's target Enterprise Architecture in conjunction with the SLCM Policy

3. Reviewing and approving waivers to the SLC for General Support Systems and Major Applications and Major Investments defined by the CPIC process (if so designated by the CPIC)

The Branch Chief of the Information Services Branch is responsible for:

1. Maintaining the System Life Cycle Management Policy (SLCMP)

2. Monitoring compliance with this Policy through the IT Investment Management security processes where applicable.

3. Defining, identifying, developing, approving and issuing and communicating procedures, Technical Operations and Standards (TOPS), and guidance in support of the Agency=s SLCMP

The Office of Budget and Acquisition Management is responsible for:

Ensuring the SLCMP is incorporated, as appropriate, in requests for proposals, contracts and assistance agreements

The Information Management Officers leading the development and maintenance of regional compliance with the Agency's target Enterprise Architecture in conjunction with the SLCM Policy are responsible for:

1. Ensuring the Quality and Information Council (QIC) is apprised of major SLC issues within their office

2. Ensuring compliance with SLC Policy for systems within their office

3. Reviewing and concurring on waivers to the SLCM Policy as applicable

4. Reviewing SMPs as appropriate

The Information Security Officer (ISO)is responsible for:

Ensuring that responsible program offices and individuals throughout the AA-ship or Regional Office are cognizant of security requirements and processes which must be considered throughout the system's life-cycle

(not certification and accreditation, not system security design, not enforcement of security policy)

The System Sponsors/Owners are responsible for:

1. Concurring on waivers from the SLC, as applicable

2. Authorizing, approving and ensuring adequate funding and resources during the system life cycle of an information system

3. Appointing System Manager and authorizing those individuals to initiate system development

The following is a list of Responsible Regional Personnel and their assigned System Responsibilities:

Project Manager

1. Managing the project through its life cycle

2. Monitoring compliance with the SLCMP

3. Ensuring compliance to Section 508 requirements during the SLC

4. Providing day-to-day management of the system life cycle process and products within their program(s)

5. Ensuring the system advances through the SLC phases and sub-phases

6. Managing the records related to a system's life cycle

7. Identifying and keeping management apprised of project issues and risks

System Manager

1. Coordinating SLC development activities with those of the Region 4 IT Investment Management processes

2. Identifying and keeping management apprised of project issues and risks

3. Recommending and preparing written justification for waivers and documenting them in the SMP

The Privacy Act Officer is responsible for:

Ensuring that adequate safeguards against disclosure of information protected under the Privacy Act are incorporated into the system

8.0 QUALITY SYSTEM ASSESSMENT

8.1 Assessment Management

An effective QA System requires periodic assessment to determine if the system is operating as designed and to establish a basis for corrective action. At the

organizational level, each affected organization will be assessed against the appropriate divisional QMP. The RQAM or designee shall review and evaluate implementation of selected QMPs, including the Region 4 QMP and Region 4 State QMPs every 5 years.

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

The QAPP shall ensure that:

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

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

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

8.2 Types of Assessment

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

Five specific types of assessments will be used at appropriate times by the Region 4 RQAM to determine whether the Divisional QMPs and Region 4's QMP have been implemented, to determine the status of measurement systems, the adequacy of the data collection systems, the completeness of documentation of data collection activities, and the abilities of program management to meet mandated data collection and data quality objectives. These five audit types are respectively, program audits,

performance audits, technical system audits, data quality system audits, and management system reviews. These audits are assigned by managers/supervisors to staff that have the appropriate experience, training, knowledge and technical skills. It is the manager's/supervisor's responsibility to ensure that auditors assigned for an assessment have the necessary training and experience to adequately perform the assessment assigned and that no conflict of interest exists. It is the responsibility of the auditor's supervisor/manager to review the audit findings to insure that they are appropriate and consistent with EPA policy and guidance. The audit report will be reviewed by the appropriate supervisor/manager prior to distribution.

Each type of audit is described below:

8.2.1 Program audits are qualitative audits assessing the ability of the programs to oversee internal operations, and State, Local and Tribal environmental programs to ensure compliance with EPA regulatory or statutory requirements. Program audits of the Region 4 states are particularly important since many environmental programs have been delegated to these entities. Program audits should be conducted annually and the findings resulting from the audit, documented and communicated to EPA program staff, divisional management, and the RQAM. The RQAM and QA staff will provide additional support in the form of technical and QA expertise, to divisional/program staff conducting the on-site audit to ensure that 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.

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

8.2.3 Technical system audits are on-site environmental assessment activities. The audits are qualitative assessments of personnel, equipment, facilities, procedures, and QA activities. These audits are conducted at least biennially at state agencies and cover ambient air, water quality/water quality enforcement, drinking water, and hazardous wastes monitoring activities. Audits (known as

Performance Audit Inspections (PAIs)) of NPDES permittees are conducted routinely in delegated states. PAI candidates are chosen by EPA and the states; performance in the DMR QA Studies is one of the criteria used. Other audits are conducted at RCRA facilities and CERCLA investigations at the request of the program division. The Region 4 SESD chemistry laboratory activities are audited every two years by a NELAC accrediting authority. Audits of randomly selected regional activities are conducted as resources permit, or a particular activity is audited if there is evidence of inadequate performance.

8.2.4 Data quality audits are quantitative audits in which data are reviewed and evaluated following collection to determine the quality and usability of the data. These audits are conducted by Quality Assurance Section (QAS) staff on all contract laboratory program (CLP) data for CERCLA and any programmatic analytical data which is contracted through SESD. Data quality audits are performed on data from other sources as requested by the appropriate project manager or leader.

8.2.5 A management system review (MSR) is an assessment of an organization's ability to implement and manage an effective QA program. A MSR of the regional quality system will be conducted annually. 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, for example, the Air, Pesticides and Toxics Management Division. MSRs also may be conducted of any regional contractor, or extramural organization which receives funding from the region.

8.3 Corrective Actions

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

9.0 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 their organization, 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 come in many forms, formats and storage media. Because of legal statutes and regulations, all Federal agencies are required to create, maintain, and retain their files, records and information as a valuable resource. All Federal records are subject to Federal requirements regarding their creation, maintenance and retention. These standards, set by the National Archives and Records Administration (NARA), include guidelines on he information's ownership, value, and availability.

9.1 Region 4 Records Management System

Region 4 has issued standard operating procedures for managing records within the region. Details of these procedures are described in documentation prepared by each Division and are based on identifying the EPA Records Schedule applicable to a particular document. The standard operating procedures are based on the requirements of EPA Information Resources Management Manual (Directive 2100) and the EPA Records Management Manual (Directive 2160), July 1984. Quality-related records are not managed separately, but are included in the appropriate EPA Records Retention Schedule based on Directives 2100 and 2160. The following general procedures for records management are in place in Region 4.

9.1.1 Each organizational element (Division or Office) is assigned record keeping responsibility 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.

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

9.1.3 Mandatory Records Management training sessions will be provided for all EPA employees, managers, and contractor staff on record keeping procedures and FOIA requirements. Such training classes shall be provided and attendance required once every three years or as changes in requirements warrant.

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

9.1.5 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 riles removed for more than 90 days. A response will be required from the program manager for overdue records and riles.

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

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

9.1.8 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 record center. Supervisors and managers shall be responsible to ensure that files and records are returned.

9.1.9 Files, records and information shall be created, maintained, and retained in accordance with EPA and the Regions CBI, Privacy, and Vital Record Protection program requirements.

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

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

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

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

The Divisional QMPs must also describe the process for:

- identifying quality related documents and records requiring control;
- handling documents and records to assure their accessibility, protection from damage and deterioration, and means of retention, including discussion of the roles and responsibilities of management and staff for implementing the document control and maintenance policies of the Division;
- ensuring that technical guidance documents are prepared, reviewed, approved, issued, used, and revised as required by regional QA policy;
- ensuring that 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.

9.1.14 All QAPPs, QMPs and other QA documents reviewed by the RQAM and/or QAS are maintained in and electronic data base. Included in the data base are the date the document was received, who conducted the review, the date the memo/report was issued and whether the document was approved.

10.0 QA COMMUNICATION/REPORTING/WORK PLAN

The purpose of communication is to ensure that 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. In order to effectively implement the regional quality system, communications must occur between the RQAM and regional managers and staff. The Office of Environmental Information Quality Staff (OEI/QS) is the focal point for policy and guidance on the Agency quality system. The RQAM or designee participates in monthly conference calls with the OEI/QS and other regional QAMs in order to be aware of new or revised QA policies as well as implementation issues associated with the Agency-wide quality system. Regional requests for assistance, interpretation, and action will be forwarded by the RQAM to the appropriate OEI/QS member. The RQAM will exchange QA information with the Regional QA Coordinators, Regional Program Managers, Regional Staff, EPA Laboratories, Headquarters Program Offices, and other Regions as needed to accomplish the implementation of the regional quality system.

10.1 Regional Communication

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

10.1.1 A primary means of communication among Regional staff is through the QA Coordinators. The duties and responsibilities of the Coordinators are described in section 4.2.4 of this document and Appendix D.

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

10.2 Annual Report and Work Plan

In December of each year, the RQAM shall submit a QA Annual Report and Work Plan (QARWP) to Regional Management and to the Director of OEI/QS. This report shall reflect the implementation status of the Region 4 QA Program. The Work Plan will describe all planned QA activities for the fiscal year beginning in October.

The QA Report shall contain as a minimum the following types of information:

10.2.1 Implementation Status of Regional QA Program.

10.2.2 Revisions to Regional Quality Management Plan.

10.2.3 Significant QA-related needs i.e., new policies, changes to existing policies, guidance documents, audit protocols, resources, etc.

10.2.4 Data Quality Objectives.

10.2.5 Status of QA Program/Projects and Standard Operating Procedures.

10.2.6. Assessments conducted

10.2.7 QA Program resources

10.2.8 QA training received and provided

10.3 Quality Assurance Report and Work Plan (QARWP)

The QA Work Plan shall contain as a minimum the following types of information:

10.3.1 Total proposed EPA full time employees (FTE) for supporting QA management activities in Region 4.

10.3.2 Total proposed EPA FTEs for QA/QC support activities.

10.3.3 Total dollar amounts proposed for QA travel for oversight and audits.
10.3.4 Total dollar amounts proposed for QA training.

10.3.5 Brief description of major QA/QC activities.

10.4 National Meetings

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

10.5 Resources

National Program Managers (NPMs) set staffing levels for activities in each of the programs and regions. At present, no FTEs are specifically designated by the NPMs for the implementation of the mandatory Agency-wide quality system. In Region 4, distribution of QA-related resources, including FTEs, are determined by the Regional Administrator and Division Directors. These senior managers must balance quality system resource needs with other program resource needs. The SESD Director, with input from the RQAM, will recommend staffing and resource needs for maintaining the regional quality system.

11.0 PEER REVIEW

Two Peer Review protocols exist within the Region. The first, Region 4 Order 2200.1, entitled Review and Clearance of Materials for Public Distribution was issued April 15, 1982. The second protocol, entitled Region 4 Standard Operating Procedures for Peer Review, October 1, 1995 - September 30, 1996, was established in response to the EPA Administrator's June 7, 1994, Peer Review Policy Statement.

11.1 Internal Peer Review

Regional Order 2200.1 establishes a protocol for peer review of technical reports, study plans, and documents intended for public release. The purpose of this protocol is to ensure that such materials are based on sound scientific, technical, legal, and policy principals. Division and Office Directors are responsible for initiation of review and clearance of applicable documents generated within their respective areas. This peer review process is an internal Region 4 review conducted by a Peer Review Panel composed of the following members:

Deputy Regional Administrator, Chairman
Director, Science and Ecosystem Support Division
Assistant Regional Administrator for Policy & Management
Director, Office of Environmental Accountability
Director, Office of Congressional and External Affairs
Director, Air, Pesticides and Toxics Management Division
Director, Waste Management Division

Director, Water Management Division
Regional Quality Assurance Manager

11.2 External Peer Review

Region 4 Standard Operating Procedures for Peer Review, October 1, 1995 - September 30, 1996, provides for an objective, critical review of a specific Agency major scientific and/or technical work product by independent peer reviewer(s). An independent peer reviewer is an expert not associated with the generation of the specific work product, either directly by the substantial contribution to its development, or indirectly by consultation during the development of the specific product. The purpose of an independent peer review is to disclose any technical problems or unresolved issues in a preliminary work product in order to revise the work product. The peer review process will allow the final work product to reflect sound scientific and/or technical information. Each Division/Office Director has the responsibility for selecting major work products subject to independent peer review. A Regional Peer Review Coordinator responsible for leading the peer review activities is appointed each year by the Regional Administrator. Specific roles and responsibilities are detailed in the Peer Review SOP.

12.0 TRAINING

Based on Region 4 MSR assessments identifying technical and QA training needs within the divisions and programs, 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 project and technical officers 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. QA or technical training needs will be identified by supervisors during annual performance evaluations, through career individual development plans, through management systems reviews performed by the RQAM or by divisional/program staff annually, and by the QACs. 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 (RA) and the Deputy Regional Administrator DRA). The RQAM will meet with the senior management of each office/division yearly to discuss QA training needs and other Regional QA issues.

12.1 Training Needs Assessments

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

Annually, the RQAM, with assistance from the Quality Assurance Section and other SESD organizations, will present one of the following training courses:

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

The QAS typically schedules two training modules per QA course to facilitate attendance. Each QA course is offered at two separate locations at various times throughout the year. One course is held at the Sam Nunn Atlanta Federal Center and the other at SESD in Athens, Georgia. The RQAM is available to discuss specific training needs with supervisors or staff. Courses may be developed by the RQAM and staff to meet specialized training needs. The DQO training will be mandatory for all project officers, regional project managers and technical project officers. In essence, this training is mandatory for any individual overseeing projects/studies conducted within the region or is responsible for acquiring work products from state/tribal cooperative agreement recipients. Refresher training for Designated Approving Officials (DAOs) 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 systems audits, QAPP review, etc.) with the resources needed to perform QA training. Although the QAS has limited resources for QA training, the Section 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 at this time does not provide QA training to private sector personnel.

12.2 Training Records

Training that is obtained by the Region 4 Learning Develop Institute (LDI) will be available to the staff and their supervisors electronically by a system that is maintained by the LDI. All training obtained external to the Region will be maintained by the employee, their supervisor and when appropriate, provided to the

RQAM. Training agendas and attendees of courses provided by QAS/RQAM will also be maintained by the RQAM.

13.0 QUALITY IMPROVEMENT

The RQAM is responsible for implementing and making improvements to the Region 4 quality system when non-compliance or quality assurance issues are identified by management system reviews, technical systems reviews, performance evaluations, OEI audits, and by communication from regional personnel. To facilitate improvements to the quality system, the RQAM will conduct seminars with the QACs to discuss non-compliance issues and to develop internal policies for communicating these issues to the appropriate divisional directors and will consult with OEI/Quality Staff to develop strategies for updating the QMP as improvements are made to the regional quality system.

13.1 Divisional/Program QMPs

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

Corrective actions shall include the identification of deficiencies, whether the problem is unique, isolated, systemic, etc., and a recommendation of corrective and a recommendation of procedures to prevent reoccurrence.

13.2 Management Systems Assessments/Review

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

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

13.3 Quality Assurance Training

As part of the quality improvement process, the RQAM will conduct an internal QA training needs assessment on an annual basis to identify areas of vulnerability. QA training will focus on the Agency Order CIO 2105.0, the Region 4 QMP, Divisional

QMPs, preparation of QMPs and QAPPs, development of DQOs, DAOs, and data quality assessments, and data validation. If the RQAM determines that the QAS personnel are not able to provide additional training, external training sources will be sought.

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

13.4 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. OMB has oversight responsibility for implementation of the Act, and the Office of Environmental Information, Data Quality Division 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 that "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. Region 4 has received one Request for Correction to date and worked with OEI to respond appropriately to that request.

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, OEI developed Pre-Dissemination Review (PDR) Guidelines to serve as a template for Offices and Regions in reviewing information products subject to the IQG before they are "disseminated." Region 4 is just beginning to that regional PDR processes follow the PDR Guidelines. The IQG Officer will work with programs to upgrade their current procedures for pre-dissemination review, most of which are currently not fully documented. Through these efforts, the Region 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 will contain a process for the approval of information to be disseminated at the branch chief level or above management prior to dissemination. Peer Review will also be used, when appropriate, under OMB guidance. The Region’s PDR protocol will require the use of clear disclaimer language when data has not undergone regional quality review in compliance with the IQG and PDR.

13.4.1 Roles and Responsibilities

The Assistant Regional Administrator will be responsible for ensuring that IQG and PDR are implemented. Division Directors are responsible for ensuring that information quality complies with IQG criteria and that programs have adequate PDR procedures in place. Branch Chiefs 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 IQG Officer 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 IQG Officer will also be responsible for coordinating the review of any Requests for Correction or Requests for Reconsideration received on any Region 4 information product.

13.4.2 Region 4 IQG/PDR Implementation Plan

13.4.2.1 The IQG Officer is located in the Planning and Environmental Accountability Branch in the Office of Policy and Management, and works closely with the Quality Assurance staff in the Science and Ecosystem Support Division to implement IQG and PDR.

13.4.2.2 In 2006, in preparation for the distribution of the Pre-Dissemination Review (PDR) guidance, the IQG Officer began an effort to inform regional managers about their IQG responsibilities and the need for documented PDR procedures. The IQG Officer distributed a fact sheet (attached to this document) to division directors and set up a regional IQG team.

13.4.2.3 The IQG Officer is working with the regional team to identify the types of information disseminated in each division and to ensure that pre-dissemination clearance processes are in place in each responsible organization and that the process includes checks for ensuring the quality, objectivity, usefulness, and integrity of the information to be disseminated.

13.4.2.4 The IQG Officer will share all information on IQG and PDR implementation with these contacts and seek input from them to provide to the Office of Environmental Information Data Quality staff on IQG issues. The IQG Officer will be responsible for training or bringing appropriate training to the Region for managers involved in pre-dissemination review and for staff who develop information products. The IQG Officer will work with the Region's Quality Assurance staff on such training.

13.4.2.5 The IQG Officer will provide periodic updates to managers on IQG management responsibilities, issues and/or changes and perform periodic reviews of the programs' pre-dissemination review process.

13.4.2.6 The IQG Officer will provide regional guidance on IQG and PDR, as needed, and will get program input and management approval on needed guidance.

13.5 Quality Policy

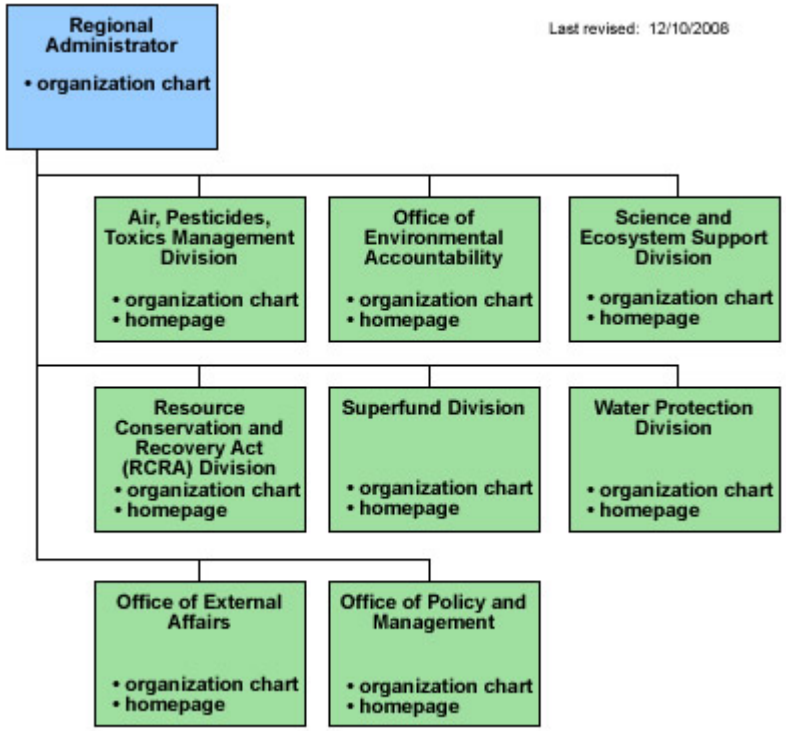
The purpose of this policy is to ensure that all products and services provided by EPA, or for EPA through extramural agreements or voluntary submissions, are of adequate quality for their intended uses. This policy is intended to harmonize EPA's existing quality related policies, guidance, and procedures into a coordinated Quality Management System to assure the reliability or, transparency, completeness, validity, and credibility of products and services that support EPA's mission to protect human health and the environment. Implementation of the QMS is anticipated to occur over the course of several years. For additional information on the Quality Policy and Implementation Plan, refer to the EPA Office of Environmental Information website; Policy for Agency-wide Quality System.
http://www.epa.gov/quality/qa_docs.html

APPENDIX A

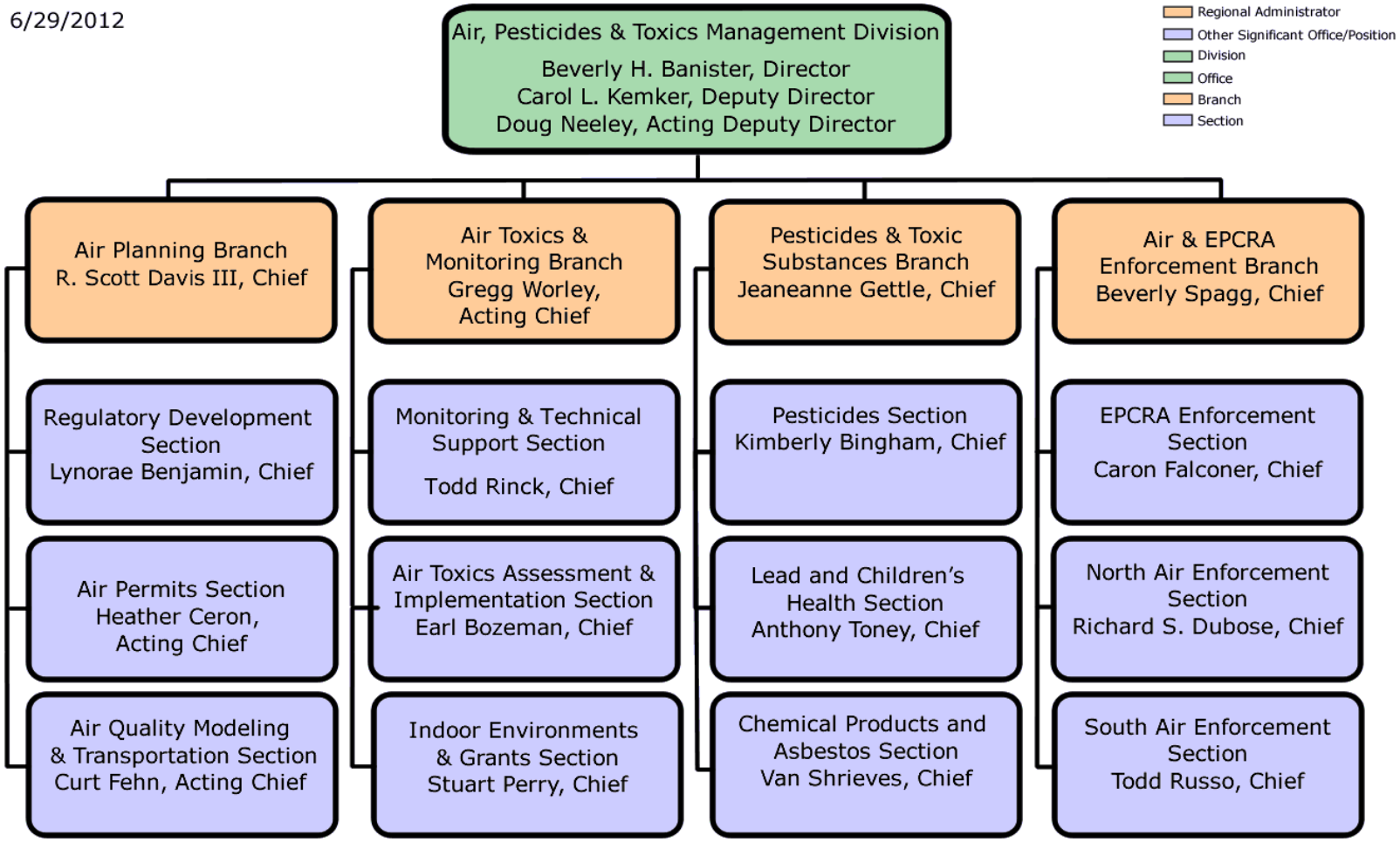
REGION 4 ORGANIZATIONAL CHARTS

Region 4 Office of the Regional Administrator

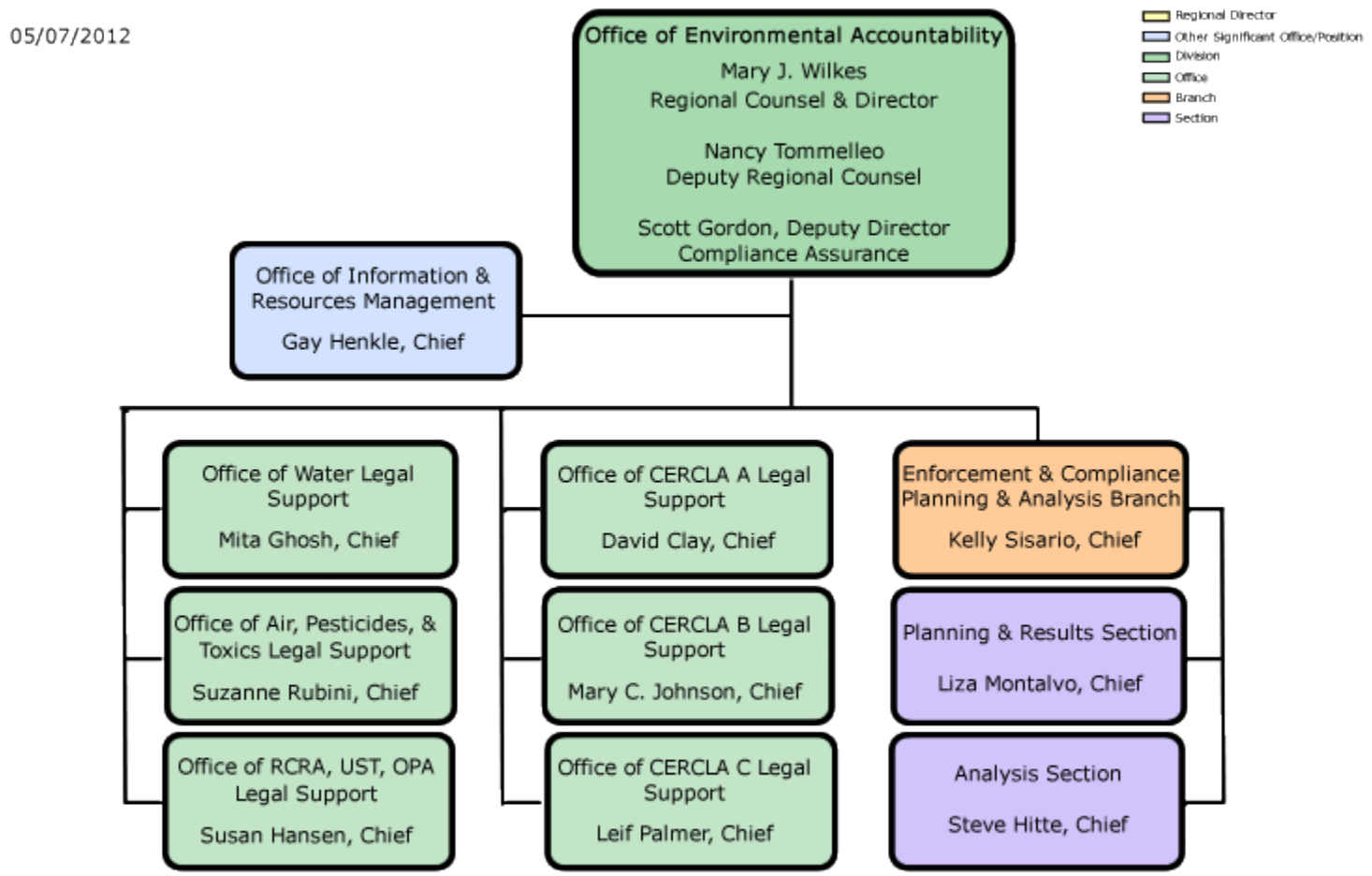
Regional Administrator: Gwendolyn Keyes Fleming
Deputy Regional Administrator: A. Stanley Meiburg
Chief of Staff: Javoyne Hicks White



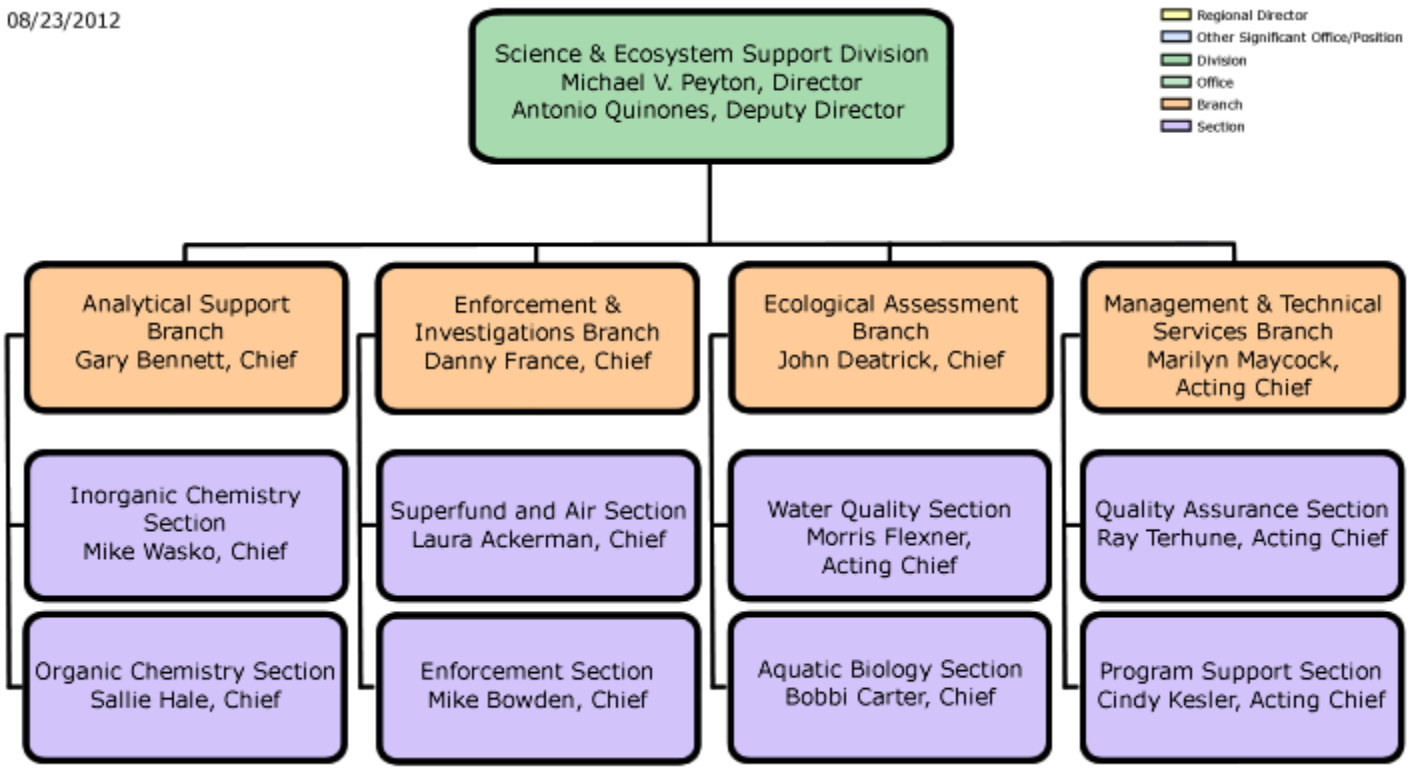
The diagram ABOVE illustrates the offices and divisions of EPA Region 4



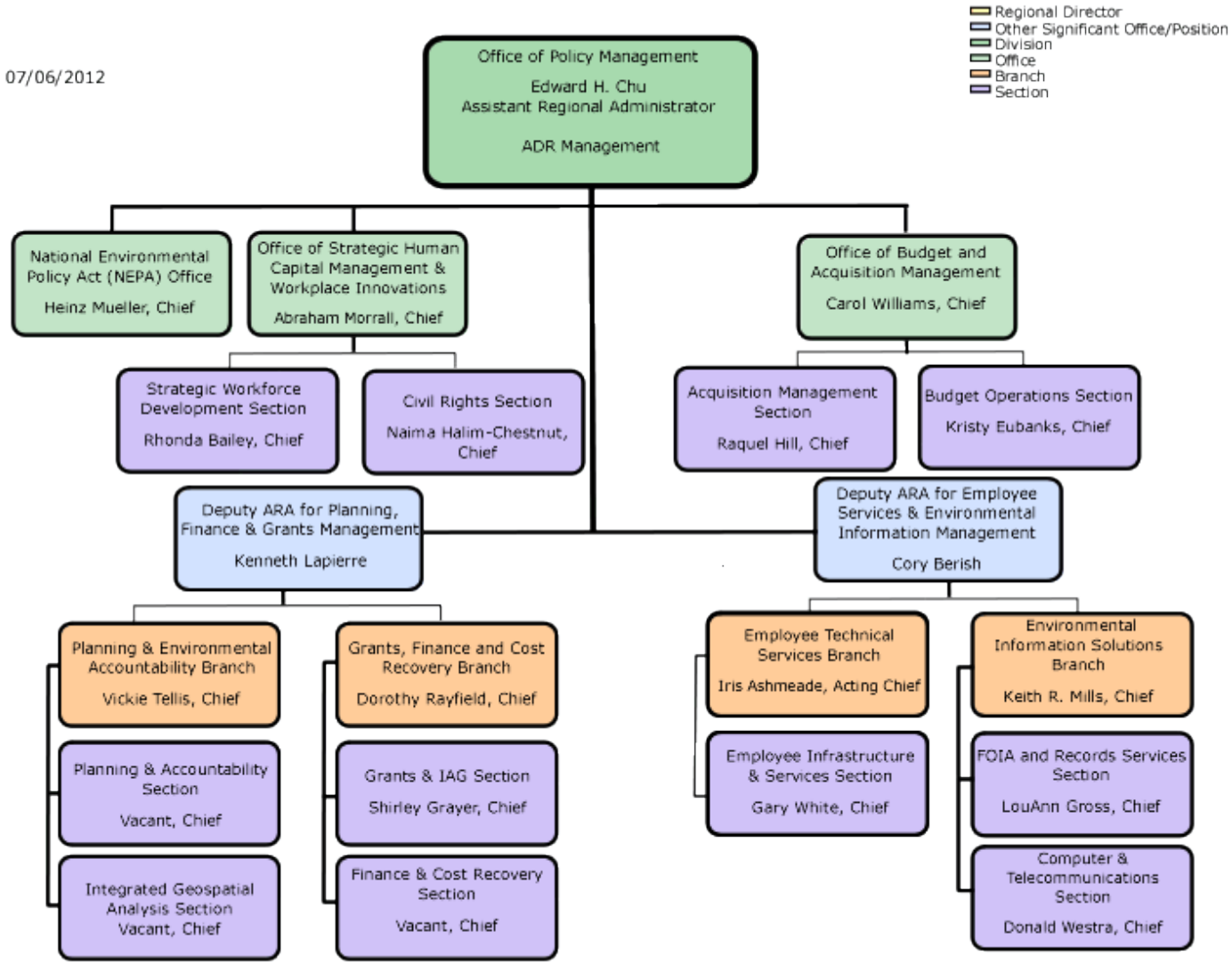
Region 4 Air, Pesticides and Toxics Management Division



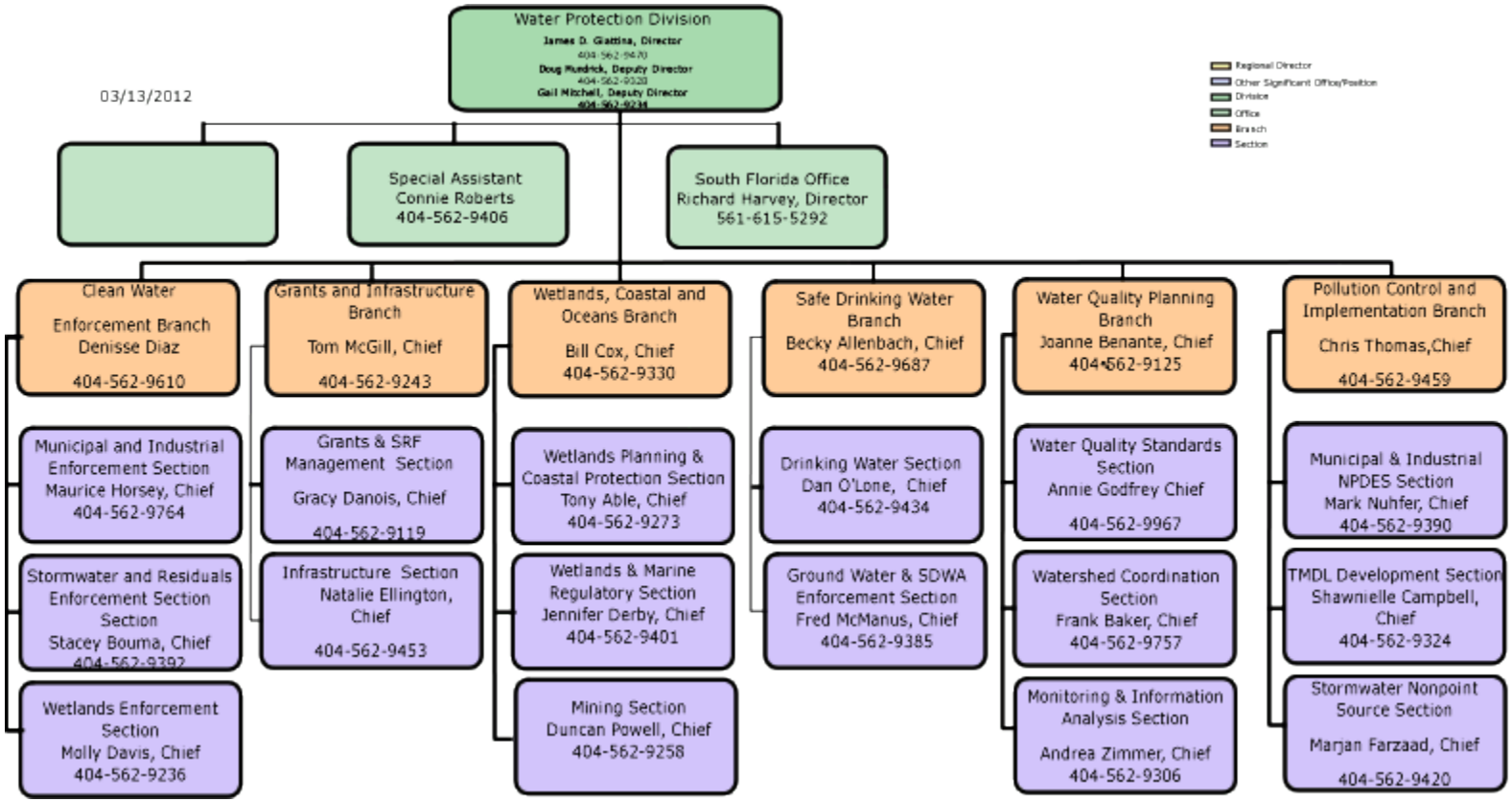
Region 4 Office of Environmental Accountability



Region 4 Science and Ecosystems Support Division

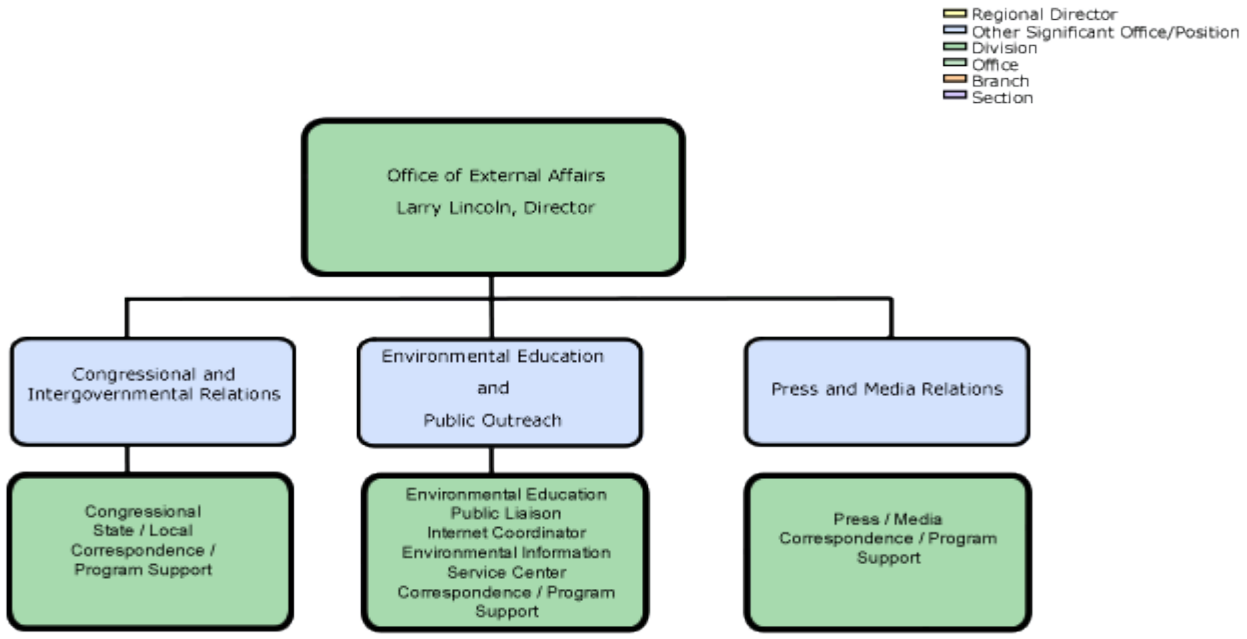


Region 4 Office of Policy and Management



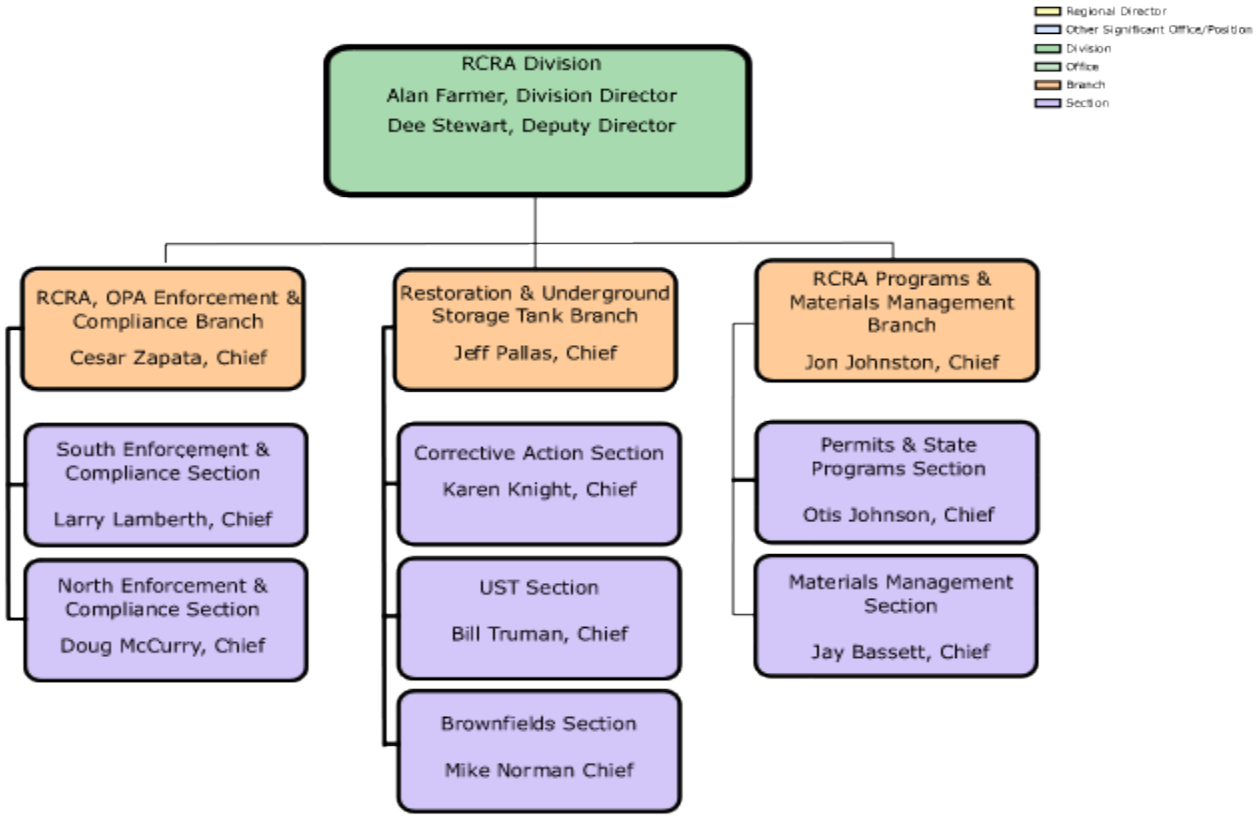
Region 4 Water Management Division
6-A

02/09/2012

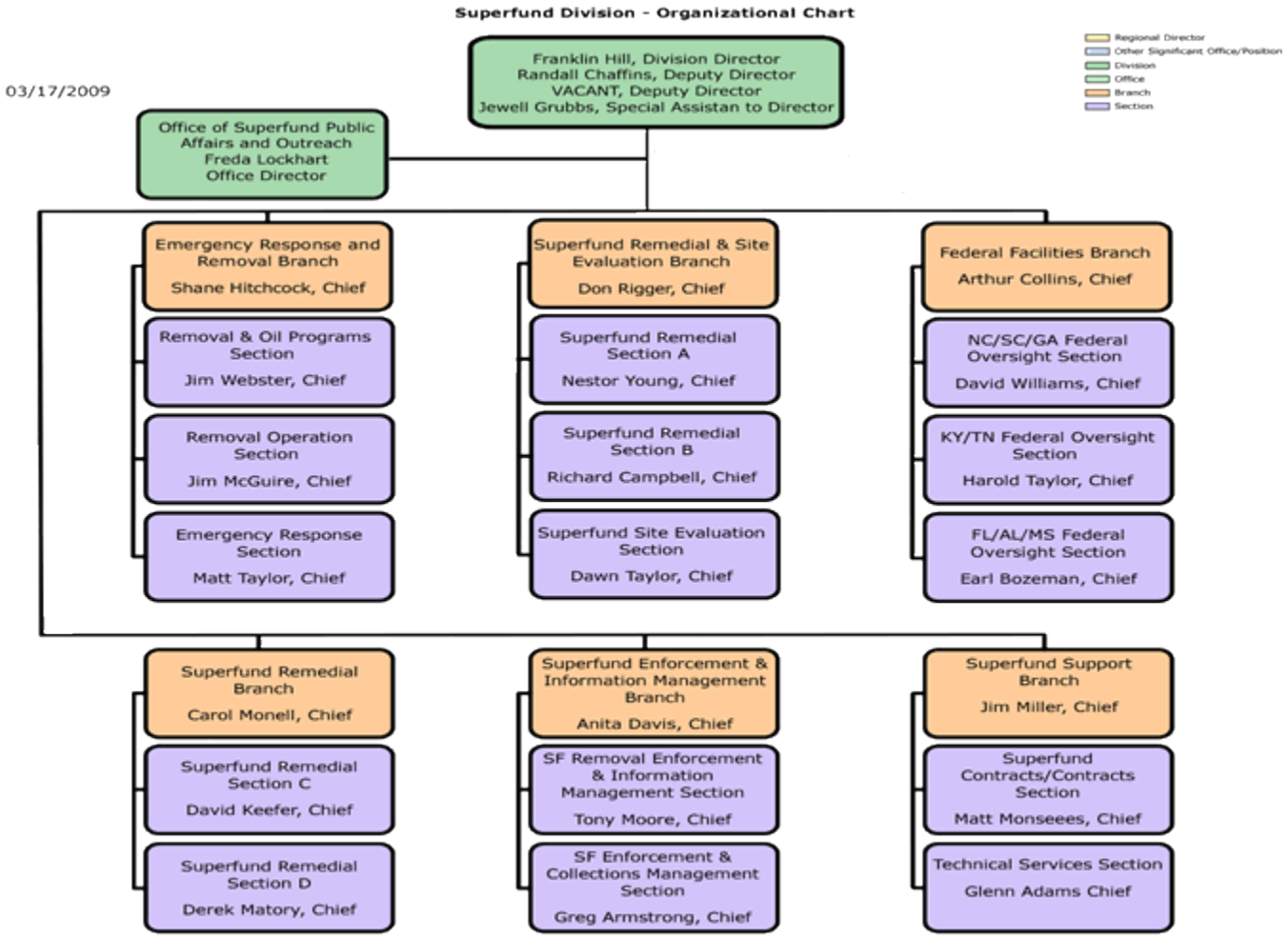


Region 4 Office of Public Affairs

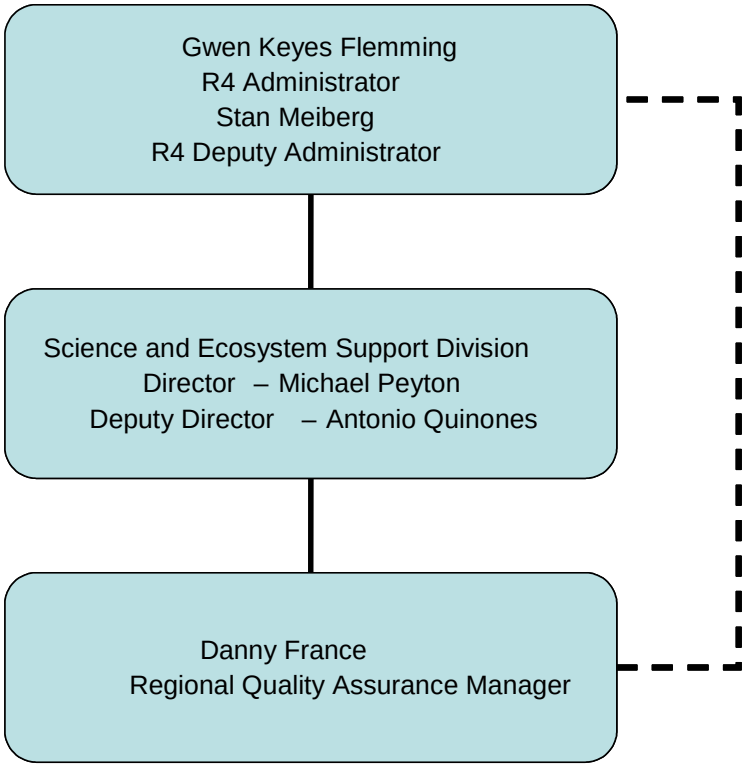
2/29/2012



Region 4 Office of Resource Conservation and Recovery Act Division



Region 4 Office of Superfund Division



Region 4 Quality Assurance Manager

APPENDIX B

REGION 4

MAJOR PROGRAM ELEMENTS

Appendix B **MAJOR PROGRAM ELEMENTS**

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

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

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

APPENDIX C

REGION 4

QUALITY MANAGEMENT PLAN CHECKLIST
QUALITY ASSURANCE PROJECT PLAN
PRE-SCREENING CHECKLISTS

Region 4 Quality (Assurance) Management Plan Checklist
Rev.4
05-16-2002

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

Region 4 Quality Assurance Section
Quality (Assurance) Management Plan Checklist

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

ELEMENT	COMMENT(S)
(1) Management and Organization	
1.1 Reasonable organizational structure with respect to roles and responsibilities described in narrative.	
1.2 QA Manager shown in the organization structure.	
1.3 Demonstrates direct access from QA Manager to senior organization manager.	
1.4 Describes QA Manager's independence and authority with respect to decisions on data quality.	
1.5 QA policy statement which demonstrates importance of environmental data in organizational decision-making.	
1.6 Adequately describe the scope of the organization's environmental data collection programs which require quality management.	
1.7 Discusses process for oversight of the contractor's activities discussed (if data collection is contracted).	
(2) Quality System and Description	
2.1 Describes the main components of quality process (e.g., planning, annual reviews, training, project-specific quality documentation).	
2.2 Discusses staff and management roles and responsibilities for QA/QC in data collection.	
2.3 Describes implementation of QA/QC activities.	
2.4 Describes roles of contractors or other organizations in implementing the quality system.	
(3) Personnel Qualifications and Training	

3.1 Describes process for assuring that personnel are qualified to perform the environmental data collection activities.	
3.2 Discusses procedures for determining QA-related training needs, providing the training, and measuring its effectiveness.	
3.3 Identifies roles, responsibilities and authorities for QA training.	
(4) Extramural Agreements and Procurement of Items and Services *(NOTE: Only as related to collection and use of environmental data).*	
4.1 Describes process for specifying QA and QC requirements in purchase orders, procurement documents, acquisitions, assistance agreements.	
4.2 Identifies person(s) responsible for this process.	
4.3 Discusses procedures for incorporating QA/QC requirements into contractor work assignments, technical directives, etc.	
(5) Documents and Records	
5.1 Describes process for records management to support decisions based on environmental data collection activities.	
5.2 Defines personnel responsibilities in records management.	
5.3 Discusses records storage and archival.	
6) Computer Hardware and Software	
6.1 Describes process for assuring that computer hardware and software configurations perform as required when used to support environmental data operations *(NOTE: Item is more critical when organization develops customized software for managing or using data).*	
6.2 Describes process for identifying and documenting the quality of environmental data in data bases and information systems.	
(7) Planning	
7.1 Describes process for planning environmental data operations.	
7.2 Identifies roles and responsibilities of management and staff in planning.	
7.3 Identifies how technical expertise in sampling, statistics, analytical services, and QA/QC is provided.	
7.4 Describes use of data quality objectives process or similar systematic planning process in planning environmental data operations.	
7.5 Discussed procedures for measuring the effectiveness of the planning process by management.	
7.6 Describes process for preparing, reviewing, and approving QA Project Plans for environmental data collection performed by the organization.	

7.7 Describes process for preparing, reviewing, and approving QA Project Plans for environmental data collection performed by contractors or assistance agreement holders.	
(8) Implementation of Work Processes	
8.1 Describes process used for implementing QAPPs or other planning documentation for environmental data operations	
8.2 Discusses system used to assure that such implementation is accomplished properly.	
8.3 Describes how revisions to QAPPs (and other planning documents) are made, maintained, and communicated to parties involved.	
(9) Assessment and Response	
9.1 Describes assessment methods (such as audits, peer reviews, surveillance, readiness reviews, performance evaluations, etc.) used to examine the effectiveness of the technical activities in a project.	
9.2 Discusses the process for planning, conducting, and reporting the results of assessment activities.	
9.3 Identifies personnel roles and responsibilities for conducting assessments.	
(10) Quality Improvement	
10.1 Discusses process for corrective actions in the organization.	
10.2 Describes roles and responsibilities for corrective actions?	

Final QMP disposition:
___ *Approved, no comments*
___ *Approved with comments, Submit revised QMP to EPA PO*
___ *Conditionally Approved, Address Comments, Submit revised QMP to EPA for Final Approval*
___ *Not approved, Address Comments, Submit Revised QMP to EPA for Final Approval*

References

EPA Requirements for Quality Management Plans, EPA QA/R-2, EPA240/B-01/002, March 2001

(Available from EPA's Website: http://www.epa.gov/quality)

USEPA
REGION 4 QUALITY ASSURANCE SECTION
QAPP PRE-SCREENING CHECKLIST WASTE MANAGEMENT DIVISION

QAPP Title:
Project Location:
Originating Organization:
QAPP Date:
Receipt Date:
Review Date:
Reviewer:
EPA Regional Project Manager:
EPA Project Officer:

Purpose: The purpose of this pre-screening checklist is to determine whether the grantee, or consultants/contractors have addressed the required topics or elements in sufficient detail to meet EPA's requirements for QAPPs. The Elements you are responsible for reviewing are those defined in the attached SOP - these must be covered in sufficient detail in order to receive EPA approval.

Topic covered in accordance with requirements: Yes No

Yes - Indicates that the topic/element was covered in sufficient detail to meet EPA's requirements as specified in this checklist.

No - Indicates that the topic/element covered in the QAPP does not provide sufficient detail to meet EPA's requirements or the topic is entirely missing from the document.

Element	Meets Topic Requirements Yes No
A-1. Title and Approval Page	Yes No
Title of QAPP	Yes No
Organization's Name: Both the name of the organization preparing the QAPP and the organization conducting the project or the grantee's name.	Yes No
Dated Signature of Project Manager: Both the originating organization's PM and EPA's corresponding PM and/or PO.	Yes No

Date and Signature of Quality Assurance Manager's approval for the originating entity and for EPA.	Yes No
Other Signatures as Needed:	Yes No
A-2. Table of Contents: Including Tables, Figures and Appendices	Yes No
A-3. Distribution List: Including Addresses of all entities or agencies requiring copies of the QAPP	Yes No
A-4. Project - Task Organization	
Identifies key project personnel, specifies technical disciplines, details their roles/responsibilities and details the chain of command.	Yes No
Organization chart provided: Depicts lines of authority, independence (of QA manager), and reporting responsibilities. Org- chart also contains entries for all agencies, contractors and individuals responsible for performing QAPP preparation, sample collection, laboratory analysis, data verification, review and validation, data quality assessment; and project oversight responsibilities.	Yes No
A-5. Problem Definition/Background.	
Clearly states the particular environmental problem to be solved, decision to be made, or outcome to be achieved. Include sufficient background information to provide a historical, scientific, and regulatory perspective for this particular project.	Yes No
Provides historical and background information concerning prior environmental investigations or assessments performed at the site. Discusses the data collected from these prior investigations and identifies any additional information that may be contained in computer databases (secondary data), etc.	Yes No
A-6 Project/Task Description	

Provides a summary of all work to be performed, products to be produced, and the schedule for implementation. Lists the actual measurements to be made: Including in-situ field measurements, fixed laboratory measurements, or any other type of information collected as part of the project.	Yes No
Cites applicable regulatory standards or criteria such as action limits, ARARs, PRGs, MCLs, risk assessment screening levels, etc. Must provide the actual numerical criteria for the above items.	Yes No
Identifies all instruments/equipment needed to conduct project and identifies all key study personnel (field technicians, chemists, risk assessors, engineers, project managers, quality assurance managers, etc.)	Yes No
Provides work schedule for all tasks including report preparation, response to comments, etc.	Yes No
Identifies all required reports, records, data reports, quality assurance reports/documents	Yes No
A-7. Data and Field Quality Objectives and Criteria for All On-Site and Off-Site Measurement Data	
Provides the Data Quality Objectives in accordance and compliance with EPA's Data Quality Objective Process (EPA-QA/G-4) document. Lists the seven steps of the DQO process and provides the project-specific information pertaining to each of these steps.	Yes No
Applies the DQO process to the project study undertaken. Provides the qualitative and quantitative data quality objectives for all aspects of the project. Must provide clearly delineated project objectives such as determining the presence/absence of potential contaminants, nature and extent of contamination, determining whether human health is affected. Must provide a list of decisions and alternative actions (remediation, removal, further assessments, no further action, etc.).	Yes No

Provides all regulatory standards/criteria as part of DQO process (action limits, ARARs, PRGs, MCLs, etc.) on an analyte by analyte basis. Provides a list of all the critical contaminants/analytes along with their respective detection limit requirements (for chemical parameters) and QA/QC requirements.	Yes No Yes No
A-8. Special Training Requirements and Special Certifications	
Identifies how training needs are determined and lists all training requirements for the project. Specifies whether certain professionals require a license or certification to perform duties as required by federal or state laws.	Yes No
Identifies where training records will be maintained	Yes No
Identifies how any new training requirements are communicated to program/upper management. Discusses the importance of QA training and discusses how this training is provided.	Yes No Yes No
A-9. Documentation and Records	Yes No
Provides a comprehensive list of the documents and records required for this project (including raw data, field logs, audit reports, QA reports, progress or status reports, analytical data reports, data validation reports/data quality assessments reports.)	Yes No
Specifies the turnaround time for laboratory data deliverables (both hardcopy and electronic formats). Provides hardcopy data package content requirements and electronic data requirements.	Yes No
Provides the retention time and location of study records, reports and formal documents.	Yes No
B-1. Sampling Process Design	

Provides a table with type and number of samples required for collection such as surface, subsurface, or groundwater.	Yes No
Provides design of the sampling/collection network.	Yes No
Provides maps or diagrams with sample locations/collection locations and provides table with frequency of sampling events.	Yes No
Provides the sample matrices slated for collection in the sample table (surface soil, subsurface soil, sediment, surface water, groundwater samples, etc).	Yes No
Provides an extensive discussion regarding the rationale for the sampling design. (This also includes a discussion regarding the rationale and relevance of the analytical program).	Yes No
Provides a table identifying the chemical parameters/analytes of interest for each collected sample along with the required detection limits, regulatory standards/criteria, QA/QC criteria, analytical method number, sample container requirements, sample preservation requirements, sample volume requirements and holding time criteria.	Yes No
B-2. Sampling Method Requirements	
Provides the required field sample collection procedures, protocols and methods.	Yes No
Provides a list of sampling/collection equipment (including make and model of equipment).	Yes No
Identifies on-site support facilities that are available to field staff.	Yes No
Identifies key study personnel in charge of or overseeing sampling/collection activities.	Yes No
Describes equipment decontamination procedures and requirements. Discusses whether sampling equipment is dedicated or non-dedicated.	Yes No
Provides table listing sample container requirements and preparation requirements for these containers (if provided by laboratory, clearly states such).	Yes No

Provides table listing sample preservation requirements (for chemical parameters) and holding time criteria (where applicable).	Yes No
B-3. Sample Handling and Custody Requirements	
Provides a detail description of the procedures for post sample handling (once the sample has been collected).	Yes No
Provides a detailed description of the chain-of-custody procedures.	Yes No
B-4. Analytical Method Requirements	
Clearly identifies the extraction, digestion, analytical methodologies (provides the actual method numbers) to be followed (includes all relevant options or modifications required), identifies the required instrumentation. Provides laboratory SOPs or QAM.	Yes No
Provides validation criteria for non-standard or unpublished methodologies proposed for use for a given study.	Yes No
Identifies individual(s) responsible for overseeing the success of the analysis and for implementing corrective actions if deemed necessary.	Yes No
Specifies the turnaround time for hardcopy and electronic laboratory data deliverables.	Yes No
B-5. Quality Control Requirements	
Identifies the type, number and frequency of procedures and frequency of QA/QC sample collection along with the required QC statistically derived limits for each analyte (for spike samples, internal standards, surrogate spikes).	Yes No
Provides the statistical equations for accuracy, precision, and comparability. Specifies the acceptance criteria for these measurements.	Yes No
B-6. Instrument or Equipment Testing and Inspection Requirements	Yes No
Provides a list of all in-situ testing instruments and field equipment.	Yes No
Provides the technical criteria by which the field instruments or sampling equipment is checked for acceptable performance.	Yes No

Provides a comprehensive list of the supplies required for the project.	Yes No
Identifies the individual(s) responsible for checking and inspecting consumables and supplies.	Yes No
Provides the acceptance criteria consumable item, instrument and equipment.	Yes No
Describes equipment and corrective maintenance practices to ensure that on-site equipment or instruments are performing within the required specifications.	Yes No
Identifies the availability and location of spare parts	Yes No
B-7. Instrument Calibration and Frequency	
Identifies all equipment requiring calibration and discusses the frequency of calibration.	Yes No
Identifies the calibration requirements for each instrument requiring calibration. (For fixed laboratory this may be in the SOPs or QA manual).	Yes No
Provides the calibration requirements and calibration acceptance criteria for each type of equipment or instrument. (Again for the off-site laboratory this information will reside in the method-specific SOPs and the QA manual).	Yes No
Identifies the type of documentation required for calibrations and instrument checks and discusses how calibrations are traced back to specific instruments for each analytical parameter. (Once again for the off-site laboratory this information will reside in the method-specific SOPs and the QA manual).	Yes No
B-8 Inspection/Acceptance Criteria and Requirements for Supplies and Consumables	Yes No
Provides a comprehensive list of the consumables such as, solvents, reagents, buffer solutions and other consumables or supplies required for the project.	Yes No
Provides the acceptance criteria for each of these items.	Yes No

Identifies those individual(s) responsible for checking/inspecting supplies and consumables.	Yes No
B-9. Data Acquisition Requirements for Non-Direct Measurements	
Identifies the type and frequency of non-direct measurement techniques for the project (for computer databases, literature searches, etc.).	Yes No
Clearly identified and describes the limitations of such data.	Yes No
Discusses the rationale for using this data and explains its relevance to the project.	Yes No
Specifies how limitations in this data will be communicated to all end data users and stakeholders.	Yes No
B-10. Data Management	
Describes the record-keeping, archival and retrieval requirements for hard-copy and electronic information produced during the course of the project.	Yes No
Provides audit checklists or other standardized forms in an appendix to the QAPP.	Yes No
Describes data handling equipment and procedures used to process, compile and analyze data (provides a complete list of computer hardware and software needs) - Specifies whether computer databases will have restricted access or will be password protected Discusses how the accuracy of computer databases is assured.	Yes No
Describes process for assuring that applicable Office of Information Resource Management requirements are satisfied (mainly this is required if the data will be entered into an EPA or other Federal Database).	Yes No
C-1. Assessments, Audits and Corrective Actions	
Lists the required number, frequency and type of assessments with approximate dates and names of individual(s) responsible for performing these assessments.	Yes No

Discusses one or more of the following types of assessments: peer reviews, technical audits, surveillance, management system reviews, readiness reviews, quality system audits, performance evaluations, data quality assessments.	Yes No
Identifies the individual(s) performing these assessments and discusses the authority and independence of these individual(s) in relation to those being assessed.	Yes No
Provides a description of the types of corrective actions that may be instituted to resolve any issues raised during the audit.	Yes No
Discusses where audit findings will be documented and how the audit findings will be communicated to all key project staff, state and EPA personnel responsible for the study oversight.	Yes No
C-2. Reports to Management: Identifies the frequency and distribution of the following types of reports:	
Project Status Reports	Yes No
Results of Assessments or Audits	Yes No
Results of periodic Data Quality Assessments	Yes No
QA Audit Reports	Yes No
Identifies the individual(s) responsible for preparing, reviewing and receiving these reports - discusses the retention time for maintaining such reports.	Yes No
D-1 & D-2. Data Review, Verification and Validation	
Identifies the guidance documents or SOPs governing the data review, verification and validation processes.	Yes No
Clearly discusses the criteria by which data will be accepted or rejected and provides a comprehensive list of the data flags or qualifiers that will be assigned to non-compliant data points (including the definitions for each of these flags).	Yes No

Describes the process, and provides the criteria by which the data will be assessed for its overall usability and intended purpose.	Yes No
Identifies the individual(s) responsible for validating the data and identifies the company or consultant for whom they work (Note: EPA recommends using an independent second or third party validator or at least a person that is unaffiliated with the laboratory performing the analyses on site samples).	Yes No
Identifies how problems associated with the laboratory will be documented and communicated to all end data users and stakeholders (where will the results of the data validation process be documented).	Yes No
D-3. Reconciliation of the Data to the Project-Specific DQOs	
Describes the process by which the on-site and off-site analytical data will be reconciled to the project-specific DQOs (especially if the data is non-compliant).	Yes No
Discusses how limitations in the final data set will be documented and communicated to all end data users and stakeholders.	Yes No
Describes the circumstances under which data would be rejected and removed from the final data set.	Yes No
Identifies the individual(s) responsible for reconciling the data to the project-specific DQOs.	Yes No
Identifies the SOP or guidance document outlining the DQO reconciliation process.	Yes No

Note: EPA's guidance and requirements documents for the DQO process, QAPP preparation, Data Validation and Data Quality Assessments, are located at www.epa.gov/quality. These documents include:

Guidance for the Data Quality Objectives Process, EPA/600/R-96/055 QA/G-4 (August 2000)

Requirements for Quality Assurance Project Plans, EPA/240/B-01/003, QA/R-5 (March 2001)

Guidance for Environmental Data Verification and Data Validation, EPA/240/R-02/004, QA/G-8 (November 2002)

Guidance on Data Quality Assessment: Practical Methods for Data Analysis, EPA/600/R-96/084 (July 2000)

Waste Management Division Reviewer - Approved/Not Approved:

_____ QAPP Not Approved for Sections A5, A6, A7, B1 and B2 - QAPP forwarded to Athens for full review.

_____ QAPP Approved for Sections A5, A6, A7, B1 and B2 - QAPP forwarded to Athens for full review.

Comments:

USEPA - REGION 4
QUALITY ASSURANCE SECTION
QAPP PRE-SCREENING CHECKLIST WATER MANAGEMENT DIVISION

QAPP Title:
Project Location:
Originating Organization:
QAPP Date:
Receipt Date:
Review Date:
Reviewer:
EPA Technical Officer:
EPA Project Officer:

Purpose: The purpose of this pre-screening checklist is to determine whether the grantee, or others have addressed the required topics or elements in sufficient detail to meet EPA's requirements for QAPPs. Your contribution will be to determine whether elements A5, A6, A7, B1, and B2 were covered in sufficient detail to warrant approval.

Topic covered in accordance with requirements: Yes No

Yes - Indicates that the topic was covered in sufficient detail to meet EPA's requirements as specified in this checklist.

No - Indicates that the topic covered in the QAPP does not provide sufficient detail to meet EPA's requirements or the topic is entirely missing from the document.

Element	Meets Topic Requirements Yes No
A-1. Title and Approval Page	Yes No
Title of QAPP	Yes No
Organization's Name: Both the name of the organization preparing the QAPP and the organization conducting the project or the grantee's name.	Yes No
Dated Signature of Project/Study Manager: Both the originating organization's PM and EPA's corresponding PM or PO.	Yes No
Date Signature of Quality Assurance Manager: All QA Managers - grantees, consultants/contractors and state (where applicable), etc.	Yes No

Other Signatures as Needed - Senior Management: grantees, consultants/contractors, etc.:	Yes No
A-2. Table of Contents: Including Tables, Figures and Appendices	Yes No
A-3. Distribution List: Including addresses, phone numbers, email addresses of all entities or agencies requiring copies of the QAPP	Yes No
A-4. Project - Task Organization	
Identifies key project personnel, specifies technical disciplines, details their roles/responsibilities and details the chain of command	Yes No
Organization chart provided: Depict lines of authority, independence of QA functions, and reporting responsibilities. Org- chart also contains entries for all agencies, contractors and individuals responsible for performing sampling/monitoring, math modeling design, statistical analysis, and oversight of study.	Yes No
A-5. Problem Definition/Background.	
Clearly states the particular environmental problem or study issues associated with the watershed/water quality studies specific of study area or site including industrial contamination issues (NPDES), nutrient loadings, etc. - clearly identifies the type of decisions to be made from this information.	Yes No
Provides historical and background information concerning prior environmental/water quality studies performed specified watershed and any additional information contained in electronic databases, etc.	Yes No
A-6 Project/Task Description	
Lists measurements/data to be collected: Including in-situ/field measurements, meteorological conditions, laboratory analyses/measurements. Biological collection: benthic, algae, fish, other. Surface water/sediment. Physical/habitat characteristics.	Yes No

Cites applicable water quality standards, human health or ecological risk screening levels and/or other state/federal regulatory standards/criteria. Must specify/cite the applicable statutory or regulatory program.	Yes No
Identifies all instruments/equipment needed to conduct study. Identifies all key study personnel (biologists, aquatic scientists, ecologists, laboratory personnel, project/study managers, quality assurance managers/officers, etc.).	Yes No
Provides work schedule for all tasks including report preparation, response to comments, etc., to completion of grant.	Yes No
Identifies all required reports, records, data reports, quality assurance reports/documents	Yes No
A-7. Data and Field Quality Objectives and Criteria for All On-Site and Off-Site Measurement Data	
Provides the Data Quality Objectives in accordance with EPA's Data Quality Objective Process (EPA-QA/G-4) document. Provides the study-specific information for each of the 7 steps of the DQO process.	Yes No
Provides the qualitative and quantitative data quality objectives for all data collection activities. Includes in-situ/field measurements, laboratory analytical measurements, sample handling requirements, modeling requirements, and any other data collection activity as part of the seven step DQO process. Also specifies storage requirements for STORET EDAS or other publicly accessible databases.	Yes No

Provides all regulatory criteria as part of DQO process (water quality standards, human health and/or ecological risk screening levels, etc.) on an analyte by analyte basis. Provides a list of all the critical analytes or biological specimens intended for collection. Specifies the respective detection limit requirements (for chemical parameters) and QA/QC requirements. For biological collections, specifies identification requirements and QA/QC protocols for proper identification.	Yes No Yes No
A-8. Special Training Requirements and Special Certifications	
Identifies how training needs are determined and lists all staff training requirements for study. Specifies whether certain professionals require a license or certification to perform duties as required by federal or state laws.	Yes No
Identifies where training records will be maintained	Yes No
Identifies how any new training requirements are communicated to program/upper management.	Yes No
A-9. Documentation and Records	Yes No
Provides a comprehensive list of the documents and records required for this project (including raw data, field logs, audit reports, QA reports, progress or status reports, analytical data reports).	Yes No
Specifies the turnaround time for laboratory data deliverables (both hardcopy and electronic formats). Provides hardcopy data package content requirements and electronic data requirements	Yes No
Provides the retention time and location of study records, reports and formal documents.	Yes No
B-1. Sampling Process Design	
Provides a table with type and number of samples or identifies biota to be collected per sampling location.	Yes No

Provides design of the sampling/collection network	Yes No
Provides maps or diagrams with sample locations/collection locations. Provides table with frequency of sampling events	Yes No
Provides an extensive discussion regarding the rationale for the monitoring or study design/approach	Yes No
Provides a table identifying the chemical parameters/analytes of interest for each sample collected along with the required detection limits, QC criteria, analytical method number, sample container requirements, sample preservation requirements, sample volume requirements and holding time criteria. Identifies biological and physical/habitat sampling locations.	Yes No
B-2. Sampling Method Requirements	
Provides the SOPs or protocols for field sample/biota collection.	Yes No
Provides a list of sampling/collection equipment (including make and model of equipment).	Yes No
Identifies on-site support facilities.	Yes No
Identifies key study personnel in charge of or overseeing sampling/collection activities.	Yes No
Describes equipment decontamination procedures and requirements (where applicable).	Yes No
Provides table listing sample container requirements and preparation requirements for these containers (if provided by laboratory, clearly states such) - identifies biota collection containers, bags, etc.	Yes No
Provides table listing sample preservation requirements (for chemical parameters) and holding time criteria (where applicable).	Yes No
B-3. Sample Handling and Custody Requirements	
Provides a detail description of the procedures for post sample handling (once the sample has been collected).	Yes No

Provides a detailed description of the chain-of-custody procedures (if water, sediment and biota samples are collection).	Yes No
B-4. Analytical Method Requirements	
Clearly identifies the extraction, digestion, analytical methodologies (provides the actual method numbers) to be followed (includes all relevant options or modifications required), identifies the required instrumentation. For biota or other biological collection - must provide the identification procedures (can supply SOPs).	Yes No
Provides validation criteria for non-standard or unpublished methodologies proposed for use for a given study.	Yes No
Identifies individual(s) responsible for overseeing the success of the analysis and for implementing corrective actions if deemed necessary.	Yes No
Specifies the turnaround time for hardcopy and electronic data deliverables (for laboratory data deliverables).	Yes No
B-5. Quality Control Requirements	
Identifies the type, number and frequency of procedures and frequency of QA/QC sample collection along with the required QC statistically derived limits for each analyte.	Yes No
Provides the statistical equations for accuracy, precision, and comparability (for chemical parameters and where applicable for biological).	Yes No
B-6. Instrument or Equipment Testing and Inspection Requirements	Yes No
Provides a list of all in-situ testing instruments and field equipment, where applicable.	Yes No
Provides the technical criteria by which the field instruments or sampling equipment is checked for acceptable performance.	Yes No
Provides a comprehensive list of the solvents, reagents, buffer solutions and other consumables or supplies required for the project.	Yes No

Identifies the individual(s) responsible for checking and inspecting consumables and supplies.	Yes No
Provides the acceptance criteria consumable item, instrument and equipment.	Yes No
Describes equipment and corrective maintenance practices to ensure that on-site equipment or instruments are performing within the required specifications.	Yes No
Identifies the availability and location of spare parts.	Yes No
B-7. Instrument Calibration and Frequency	
Identifies all equipment requiring calibration and discusses the frequency of calibration.	Yes No
Identifies the calibration requirements for each instrument requiring calibration.	Yes No
Provides the calibration requirements and calibration acceptance criteria for each type of equipment or instrument.	Yes No
Identifies the type of documentation required for calibrations and instrument checks. Discusses how calibrations are traced back to specific instruments for each analytical parameter.	Yes No
B-8 Inspection/Acceptance Criteria and Requirements for Supplies and Consumables	Yes No
Provides a comprehensive list of the solvents, reagents, buffer solutions and other consumables or supplies required for the study	Yes No
Provides the acceptance criteria for each item (supplies and consumables)	Yes No
Provides a list of individual(s) responsible for checking/inspecting supplies and consumables	Yes No
B-9. Data Acquisition Requirements for Non-Direct Measurements	
Identifies the type and frequency of non-direct measurement techniques for the study (for computer databases, literature searches, etc.)	Yes No
Clearly identified and describes the limitations of such data.	Yes No

Discusses the rationale for using non-measurement (secondary data) and explains its relevance to the study.	Yes No
Specifies how limitations in this data will be communicated to all end data users/stakeholders.	Yes No
B-10. Data Management	
Describes the record-keeping, archival and retrieval requirements for hard-copy and electronic information produced during the course of the study.	Yes No
Provides copies of audit checklists or other standardized forms in an appendix to the QAPP.	Yes No
Describes data handling equipment and procedures used to process, compile and analyze data (provides a complete list of computer hardware and software needs) - Specifies whether computer databases will have restricted access or will be password protected.	Yes No
Describes process for assuring that applicable Office of Information Resource Management requirements are satisfied (mainly this is required if the data will be entered into an EPA or other Federal Database such as STORET/EDAS, etc.).	Yes No
C-1. Assessments, Audits and Corrective Actions	
Lists the required number, frequency and type of assessment with approximate dates and names of individual(s) responsible for performing these assessments.	Yes No
Types of assessments include but are not limited to: peer reviews, technical audits, surveillance, management system reviews, readiness reviews, quality system audits, performance evaluations, data quality assessments, etc. Discusses these types of assessments.	Yes No
Identifies the individual(s) performing these assessments and discusses the authority and independence of these individual(s) in relation to the entities being assessed.	Yes No

Provides a description of the types of corrective actions that may be instituted to resolve any issues raised during the audit.	Yes No
Discusses where audit findings will be documented and how the audit findings will be communicated to all key project personnel or associated agencies responsible for the study oversight.	Yes No
C-2. Reports to Management: Identifies the frequency and distribution of the following types of reports:	
Study Status	Yes No
Results of assessments or audits	Yes No
Results of periodic data quality assessments	Yes No
QA audit reports	Yes No
Identifies the individual(s) responsible for preparing, reviewing and receiving these reports - discusses the retention time for these reports	Yes No
D-1 & D-2. Data Review, Verification and Validation	
Identifies the guidance document or SOP governing the data review, verification and validation process.	Yes No
Clearly discusses the criteria by which data will be accepted or rejected. Provides a comprehensive list of the data flags or data qualifiers that will be assigned to non-compliant data (including the definitions for each of these flags).	Yes No
Describes the process and provides the criteria by which the data will be assessed for its overall usability.	Yes No
Identifies the individual(s) responsible for validating the data and identifies the company or consultant for whom they work (Note: EPA recommends using an independent third party validator or at least a person that is un-affiliated with the laboratory performing the analyses on site samples).	Yes No

Identifies how problems associated with the laboratory will be documented and communicated to all end data users (where will the results of the data validation process be documented).	Yes No
D-3. Reconciliation of the Data to the Project-Specific DQOs	
Describes the process by which the in-situ/field data and laboratory analytical data will be reconciled to the project-specific DQOs (especially if the data is non-compliant)	Yes No
Discusses how limitations in the final data set will be documented and communicated to all end data user/stakeholders.	Yes No
Describes the circumstances under which data would be rejected and removed from the final data set.	Yes No
Identifies the individual(s) responsible for reconciling the data to the project-specific DQOs	Yes No
Identifies the SOP or guidance document outlining this process.	Yes No

Note: EPA's guidance and requirements documents for the DQO process, QAPP preparation, Data Validation and Data Quality Assessment, are located at www.epa.gov/quality. These documents include:

Guidance for the Data Quality Objectives Process, EPA/600/R-96/055, QA/G-4 (August 2000)

Requirements for Quality Assurance Project Plans, EPA/240/240B/B-01/003, QA/R-5 (March 2001)

Guidance on Environmental Data Verification and Data Validation, EPA/240/R-02/0004, QA/G-8 (November 2002)

Guidance on Data Quality Assessment: Practical Methods for Data Analysis, EPA/600/R-96/084 (**July 2000**)

Water Management Division Reviewer - Approved/Not Approved:

_____ QAPP Not Approved for Sections A5, A6, A7, B1, and B2 - QAPP forward to QAS-Athens for full review.

_____ QAPP Approved for Sections A5, A6. A7, B1, and B2 - QAPP forwarded to QAS-Athens for full review.

Comments:

APPENDIX D

Quality Assurance Coordinator SOP

USEPA REGION 4
Science and Ecosystem Support Division
Quality Assurance Section
980 College Station Road
Athens, Georgia 30605

Standard Operating Procedure # 004

Quality Assurance Coordinator
Roles and Responsibilities

Prepared by_____ Date_____

Reviewed by_____ Date_____

Approved by_____ Date_____

Periodic QC Review:

Signature	Title	Date
_____	_____	
_____	_____	
_____	_____	

Table of Contents

1.0 Purpose

Region 4 is strongly committed to sound science and quality assurance (QA) practices which will produce environmental data of appropriate quality to be used for decision making. This commitment is consistent with the goals of CIO 2105.0. It is the policy of Region 4 that all decisions which are made to safeguard the environment and protect human health will include a consideration of the quality of environmental data and/or environmental technology which supports the decision.

Regional managers and staff will assure that there are sufficient QA activities conducted by the environmental programs to provide reasonable confidence that all environmental data generated are scientifically valid, of adequate statistical quantity, of known precision and bias, of acceptable completeness, representativeness, and comparability, 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 generation of data. Senior managers in each division are responsible for assuring that adequate resources, including personnel, travel funds, and extramural funds, are available to implement the regional quality assurance system.

2.0 Applicability

Regional QA System activities shall comply with ANSI/ASQC E-4, ASpecifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs@, 2004, with respect to planning, implementing and assessing quality assurance activities. Communication on QA issues and activities shall be maintained among the Regional Quality Assurance Manager, program managers, staff and QA Coordinators. QA processes shall be designed in the most cost-effective manner without compromising data quality. Continuous improvement in the quality management system shall be emphasized.

3.0 Summary

CIO 2105.0, Policy and Program Requirements For the Mandatory Agency-wide Quality System, requires that each EPA Program and Regional Office develop and document a quality system to assure that environmental data used to support Agency

decisions is of adequate quality and are usable for their intended purpose. A quality system is a structured and documented management system which describes an organization=s roles, responsibilities, policies, and procedures as they relate to the generation and use of environmental data and the implementation of environmental technology. The Regional Quality Assurance Manager (RQAM) and the QA Coordinators will work together to ensure that an effective quality system will be consistent in all Region 4 Divisions. The QA Coordinators serve as the QA contact for their Division, Office and/or Program. The function of the QA Coordinator is to serve as a conduit for communication on quality issues within the region. Each Division/Office will appoint at least one QA Coordinator to represent their Division / Office. The key responsibilities of the QA Coordinators are referenced in Section 4.

4.0 Roles and Responsibilities

The QA Coordinator shall:

4.1 Serve as the official Division/Office contact for quality assurance matters pertinent to data collection activities of that Division/Office/Program. (Assigned duties and responsibilities be included in the individual's performance description.)

4.2 Attend the initial QAPP, QMP, DQO training classes, along with the workshop classes for the EPA Agency Order 5360.1, A2 and the Region 4 QMP. Designated annual refresher training will be mandatory. The QA Coordinators will receive a certificate upon completing all QA coordinator requirements. The certificate will be valid for 1 year.

4.3 Attend the quarterly QA Coordinator meetings to keep abreast of QA issues affecting the Region and Agency. Communicate QA issues to Division/Office and RQAM.

4.4 Keep an inventory of QAPPs for their Division/Office for tracking purposes, if the Designated Approval Authority (DAOs) has approved QAPPs in their division. RQAM will receive copies of the approved QAPPs and tracking reports. The QA Coordinator will not be responsible for reviewing, or approving QAPPs and QMPs. If questions for review, inventory, oversight, etc. are involved concerning QAPPs or QMPs, the RQAM should be contacted for assistance.

4.5 Respond to quality control issues and problems, and respond to requests for guidance or technical direction.

4.6 Work with their Division=s staff, and the RQAM to develop and maintain an effective QA program.

4.7 The Regional QA Annual Report submitted by the RQAM to the Quality Staff Director is due annually in December. The Annual QA report will be in the framework of QA Metrics measuring all QA inputs, activities, interim outcomes, and outcomes. The QA Coordinator will serve as the liaison from their Division/Program in providing input for QA parameters involved with the QA Annual Report and Work Plan (QAARWP).

5.0 Records Management

All information obtained from the QA Coordinators, and the information obtained from the on-site evaluations of Divisions /Program offices will be kept in the files of the Quality Assurance Section (QAS). Some copies of the QA Division/Program files will also be kept in the Record File Room of the Science and Ecosystem Support Division (SESD) building.

6.0 Quality Control

This SOP will be reviewed annually, and will be updated at any time in response to recommendations, complaints, changes in mandates, etc. The Regional Quality Assurance Officer shall be responsible for the maintenance of this SOP. The goal of this SOP is to ensure continuous quality improvement in the Region 4 Quality System.

7.0 References

US Environmental Protection Agency, March 2001. *EPA Guidance for Preparing Standard Operating Procedures (SOPs)*. EPA QA/G-6. Washington D.C.

ANSI/ASQC E-4, A*Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs,@2004*

CIO 2105.0, *APolicy and Program Requirements for the Mandatory Agency-Wide Quality System.@*

APPENDIX E

Designate Approving Official, Technical Competency Form

Designated Approval Officials
Technical Competency Form
March 2007

Name:

Position:

Section:

Branch:

Section Chief Name:

Branch Chief Name:

1. Specify the college/university degree you have obtained. Include the name of the college/university you have attended.

2. What is your official position with EPA?

3. Specify how long you have served in this position.

4. What other positions have you served in at EPA?

5. What is your area of technical knowledge or expertise?

6. Have you attended Quality Assurance Project Plan and Data Quality Objectives training at EPA?

7. When did you attend these training courses (Month/Year)?

8. Are you required to prepare Quality Assurance Project Plans (QAPPs) as part of your position description?

9. If you prepare QAPPs as part of your duties, who reviews these documents within you section and branch?

10. Are your required to review QAPPs as part of your position description?

11. How do you document your QAPP reviews?

Terms and Conditions for Acquiring
and
Maintaining DAO Status

1. Should have obtained at least a Bachelor's Degree in any of the physical or biological sciences, or demonstrates an in-depth understanding of these disciplines based on hands-on job experience obtained internal or external to the agency.

2. Must register with the RQAM by filling out a technical competency form documenting the educational and technical background of the prospective Designated Approval Official (DAO).

3. Satisfactorily complete a day training course provided by the RQAM on QAPP requirements and review, and attend a training course on the QAPP Checklist. Completion of these training modules shall be documented by the RQAM with a certificate naming the individual as a DAO and shall be tracked by the division in which the DAO resides, and by the RQAM.

4. The DAO must also attend annual refresher QAPP and QAPP Checklist courses provided by QAS to maintain continuing certification.

5. If the DAO moves to another program, they must be retrained and re-certified in that new area/program.

6. Possess the necessary expertise in project management to review the QAPP.

7. The prospective DAO must have 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 on these issues or must be familiar with the requirements for collecting this information in order to approve the QAPP. A firm knowledge of EPA program and regulatory requirements is also necessary.

8. Have no direct conflict of interest. A project manager who writes a QAPP for a project under his/her direction cannot approve that same QAPP.

   Document the QAPP review process using a checklist developed by QAS and prepare specific comments
   addressing document deficiencies.

9. The Regional Quality Assurance Manager will review your work products to determine whether you are performing document reviews in accordance with the requirements stated above and to verify your continued competency as a DAO.

Prospective DAO Signature: _____

Section Chief Signature: _____

Branch Chief Signature: _____

By signing this document you, your immediate supervisor and your branch chief agree to adhere to the DAO requirements specified in the Terms and Conditions (Requirements 3 through 8) stated above. Your section chief and branch chief signatory approvals serve to confirm that you meet the minimum requirements outlined above, that you possess the appropriate knowledgeable and skills mix to serve as a DAO, and are capable of reviewing and approving QAPPs submitted to your section/branch/program.