

**Region 4
U.S. Environmental Protection Agency
Science and Ecosystem Support Division
Athens, Georgia**

PLAN

Title: Field Branches Quality Management Plan

Effective Date: January 19, 2012

Number: SESDPLAN-001-R4

Authors

Name: Bobby Lewis

Title: Field Quality Manager, Science and Ecosystem Support Division

Signature:  **Date:** 1/18/2012

Approvals

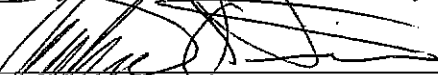
Name: Michael V. Peyton

Title: Director, Science and Ecosystem Support Division

Signature:  **Date:** 1/17/2012

Name: Antonio Quiñones

Title: Deputy Director, Science and Ecosystem Support Division

Signature:  **Date:** 1/18/2012


Name: Danny France

Title: Regional Quality Assurance Manager

Signature:  **Date:** 1/18/2012

Name: Danny France

Title: Chief, Enforcement and Investigations Branch

Signature:  **Date:** 1/18/2012

Name: Bill Cosgrove

Title: Chief, Ecological Assessment Branch

Signature:  **Date:** 1/18/2012

Revision History

This table shows changes to this controlled document over time. The most recent version is presented in the top row of the table. Previous versions of the document are maintained by the SESD Document Control Coordinator.

History	Effective Date
<p>SESDPLAN-001-R4, <i>Field Branches Quality Management Plan</i>, replaces SESDPLAN-001-R3</p> <p>Figures 1 and 2 (pages 46 and 47): The effective date was added to the footer.</p>	<p>January 19, 2012</p>
<p>SESDPLAN-001-R3, <i>Field Branches Quality Management Plan</i>, replaces SESDPLAN-001-R2</p> <p>Title Page: Changed the Field Quality Manager from Liza Montalvo to Bobby Lewis. Changed the Enforcement and Investigations Branch Chief from Archie Lee to Danny France.</p> <p>Section 2.4: Added a statement (3rd sentence on the 4th paragraph) regarding the review of draft QAPPs by the customer.</p> <p>Section 2.5.8: Revised first sentence to allow management flexibility in the organizational placement of the FQM position.</p> <p>Section 3.6: On the 8th paragraph, modified the 2nd sentence by adding the following italicized/underlined language: “An exception to this requirement is projects where immediate danger to human health or the environment is present or suspected <u>and emergency response staff is immediately deployed.</u>”</p> <p>Section 7: Revised to conform to the SESD Quality Management Plan. On the 1st sentence and throughout the Section, replaced EPA’s OEI and NTSD with EPA’s OTOP.</p> <p>On the 5th paragraph, 4th sentence, replaced “SESD personnel” with “Computer specialists.” Added the 5th sentence on branch-chief approval for non-standard software installation.</p> <p>Added the last paragraph.</p> <p>Section 8.3: On the 4th sentence, replaced “preliminary plans” with “plans.”</p> <p>Section 10.4: Removed the last sentence of the third paragraph. (“<i>Failure of a proficiency test will result in a corrective action and documentation of action taken.</i>”)</p> <p>Section 10.9: Added language on the first sentence to clarify when nonconforming work will result in a corrective action.</p> <p>Figure 2: Revised to conform to the organizational placement of the FQM.</p>	<p>January 13, 2012</p>

History	Effective Date
<p>SESDPLAN-001-R2, <i>Field Branches Quality Management Plan</i>, replaces SESDPLAN-001-R1</p> <p>General Made editorial changes.</p> <p>Title Page Changed Deputy Director to Antonio Quinones. Changed Regional Quality Assurance Manager to Danny France. Changed EIB Branch Chief to Archie Lee.</p> <p>Section 1.2 Added “data assessment” to first sentence in first paragraph. Removed specific reference to EAB analytical procedures in last sentence in first paragraph.</p> <p>Section 2.1 Added sentence that addresses requests for special projects.</p> <p>Section 2.4 Added more detail about the Memorandums of Agreement with the program offices for clarity. Deleted last two sentences of third paragraph regarding modifications to the scope of work.</p> <p>Added detail describing QAPPs to paragraph 4 and that for the purposes of ISO 17025, the QAPP serves as our written agreement with the customer.</p> <p>Paragraph 5, modified requirements for addressing the changes to the QAPP once a project has begun.</p> <p>Section 2.5.6 Added last sentence that states ESAT field investigators may be tasked with primary responsibility for the implementation of field sampling and measurement activities.</p> <p>Section 2.5.9 Added descriptions of QAO responsibilities regarding quality control checks of supplies and quality control reports.</p> <p>Section 2.5.11 Added entire section.</p> <p>Section 4.1 Added clarifying language to the second and third paragraphs regarding the duties of the ESAT Contract Officer and the Project Officer.</p> <p>Section 4.2.2 Third paragraph, the job descriptions will be updated under the contractor’s Quality Management Plan rather than in accordance with the contract Statement of Work.</p> <p>Fourth paragraph, added first sentence. Remove statement that FQM will periodically audit ESAT training records.</p>	<p>May 8, 2009</p>

History	Effective Date
<p>Section 7 Added fourth paragraph.</p> <p>Section 8.2 Added second paragraph.</p> <p>Section 9.2.1 Changed title to “Field Sampling/Measurement”. Added “if requested by the customer” to fourth paragraph. Added fifth paragraph.</p> <p>Section 9.2.2 Deleted first sentence of fifth paragraph.</p> <p>Section 10.6.1 Second paragraph, clarified requirement for customer feedback. Feedback will be sought for a minimum of 10% of Category 2 and 3 projects from each branch. Fourth paragraph, eliminated requirement for Section Chiefs to send summary report to the FQM each year. Instead, the Section Chiefs will forward feedback forms to the FQM.</p> <p>Section 10.6.2 Removed “EAB” from section title and first paragraph. Change “Bioassessment and Toxics Evaluation Section Chief” to “Aquatic Biology Section Chief”.</p> <p>Section 10.7 Revised definition of nonconforming work in first sentence of first paragraph. Added policy that FQM will work with management and staff to ensure nonconformances are resolved. Deleted last paragraph.</p> <p>Figure 1 Changed Water Management Division to Water Protection Division.</p>	
<p>SESDPLAN-001-R1, <i>Field Branches Quality Management Plan</i>, replaces SESDPLAN-001-R0</p> <p>Revision History Changed Field Quality Manager to Document Control Coordinator.</p> <p>Section 1.2 Added “International Laboratory Accreditation Cooperation Guide 19” to first sentence of second paragraph.</p> <p>Section 2.1 Added first paragraph regarding creation of EPA.</p> <p>Section 2.5.4 Deleted Project Manager and all text associated with the title from this section. Moved Project Leader and all text associated with the title from Section 2.5.5. All subsequent sections were renumbered. Added “In the event a Project Leader is unable to perform his/her duties, the responsible Section Chief will appoint someone to act on their behalf.”</p>	<p>February 11, 2008</p>

History	Effective Date
<p>Section 2.5.7 Added “In the event the RQAM is not able to perform his/her duties, the Chief of the Quality Assurance Section will act on their behalf.”</p> <p>Section 2.5.8 Added clarifying language in first paragraph regarding reporting responsibilities of Field Quality manager.</p> <p>Section 2.5.8, Item #1 Added “the forensic amplification of the International Standard as offered by Forensic Quality Services-International”.</p> <p>Section 2.5.10 Added all language about Document Control Coordinator and the Document Control Coordinator’s duties.</p> <p>Section 3.2.3 Deleted “Departures are communicated to and discussed with the Project Leader prior to being exercised, and they must be fully documented in the project logbook.” Added clarifying language in last paragraph regarding departures from SESD operating procedures.</p> <p>Section 10.3 Added “Regional Quality Assurance Manager” to first sentence.</p> <p>Section 10.7 Revised section that that information is consistent with revision to the SESD Operating Procedure for Control of Nonconforming Work (SESDPROC-019). When nonconforming work is identified, its significance is evaluated by the Field Quality Manager and management rather than “personnel designated by management”. In addition to the Field Quality Manager having the authority to stop work, project leaders, laboratory analysts, and management may stop work. The Field Quality Manager and management will determine when it is appropriate for work to resume.</p> <p>Figure 2 Added dashed line between the Field Quality Manager and the Enforcement and Investigations Branch Chief and the Regional Quality Assurance Manager.</p>	
<p>SESDPLAN-001-R0, <i>Field Branches Quality Management Plan</i>, Original Issue</p>	<p>October 30, 2007</p>

Table of Contents

1	Introduction.....	8
1.1	SESD Mission.....	8
1.2	SESD Field Branches Quality Management Plan	8
2	Management and Organization.....	10
2.1	Organizational Structure.....	10
2.2	Ethics	11
2.3	Quality Policy	11
2.4	Team Approach to Project Management.....	11
2.5	Quality System Organizational Structure.....	12
2.5.1	<i>Director</i>	13
2.5.2	<i>Branch Chiefs</i>	13
2.5.3	<i>Section Chiefs</i>	13
2.5.4	<i>Project Leader</i>	14
2.5.5	<i>Technical Project Staff</i>	14
2.5.6	<i>Environmental Services Assistant Team Support</i>	14
2.5.7	<i>Regional Quality Assurance Manager</i>	15
2.5.8	<i>Field Quality Manager</i>	15
2.5.9	<i>Branch Quality Assurance Officer</i>	16
2.5.10	<i>Document Control Coordinator</i>	16
2.5.11	<i>Branch Field Equipment Manager</i>	17
3	Quality System Components.....	18
3.1	General.....	18
3.2	Quality System Documentation.....	18
3.2.1	<i>The SESD Field Branches Quality Management Plan</i>	19
3.2.2	<i>SESD Policies</i>	19
3.2.3	<i>SESD Operating Procedures</i>	19
3.3	Annual Reviews and Planning	20
3.4	Management Assessment.....	21
3.5	Training.....	21
3.6	Project Planning	21
3.7	Quality Assessment	23
4	Personnel Qualifications and Training	24
4.1	Personnel Qualifications	24
4.2	Training.....	24
5	Procurement of Services and Supplies.....	27
5.1	General Procurement.....	27
5.2	Contracting of Analytical Services	27

6	Document Control and Records Management	28
6.1	Document Control.....	28
6.2	Records Management	28
7	Computer Software and Hardware	29
8	Project Planning	31
8.1	Initial Contact with Customer	31
8.2	Project Acceptance.....	31
8.3	Quality Assurance Project Plan Development.....	31
8.4	Safety Plans, Float Plans and Dive Plans	32
9	Implementation of Technical Work Processes	33
9.1	Management Level	33
9.2	Project Level	33
9.2.1	Field Sampling/Measurement	33
9.2.2	Analysis.....	34
9.2.3	Data Interpretation/Review.....	35
9.2.4	Report Development.....	35
9.3	Equipment Maintenance and Calibration	35
10	Quality Assessment and Response	37
10.1	Internal Review.....	37
10.2	Administrative and Technical Review	37
10.3	Internal and External Audits	38
10.4	Competency Evaluation and Proficiency Testing Program	38
10.5	Management Review	39
10.6	Customer Feedback.....	39
10.6.1	Field Investigations	39
10.6.2	Analytical Services	40
10.7	Nonconforming Work	40
10.8	Complaints	41
10.9	Corrective Action.....	41
11	Quality Improvement	42
12	Safety, Facilities, and Security	43
12.1	Safety and Health	43
12.2	Facilities.....	44
12.3	Security	44

Figures

Figure 1: EPA Region 4 Organization Chart	46
Figure 2: SESD Organization Chart	47

1 Introduction

1.1 SESD Mission

The mission of the Science and Ecosystem Support Division (SESD) is to provide quality science support for congressional mandates and initiatives, and partnerships with academia, state and local governments, and tribal nations.

SESD supports the Region 4 program offices through expertise in field and laboratory activities. These activities include engineering evaluations of water and wastewater treatment systems, technical audits at industrial and municipal facilities, surface water studies which include both engineering and ecological assessments, studies at Resource Conservation and Recovery Act (RCRA) regulated facilities, Superfund site investigations, air monitoring studies, and technical training. This support can cover any aspect of the environmental enforcement continuum from civil to criminal. With regard to environmental measurements, SESD may participate in all phases of the process including planning, sampling, analysis, and data interpretation. SESD is sometimes required to present facts, as well as, expert witness testimony in court. SESD customers include the Region 4 programs, EPA headquarters, the Criminal Investigation Division of the Office of Criminal Enforcement, other federal agencies, and tribal, state, and local organizations that have environmental enforcement and monitoring responsibilities.

1.2 SESD Field Branches Quality Management Plan

This quality management plan describes those elements of the SESD Field Branches Quality System applicable to environmental data collection, sample analysis, and data assessment. For the purposes of this plan, environmental data collection includes field sampling and field measurements. Sample analysis includes analytical procedures conducted within the field branches laboratories.

The SESD Field Branches Quality System and Quality Management Plan (QMP) are structured to be compliant with the Region 4 Quality Management Plan (most recent version), International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, International Laboratory Accreditation Cooperation (ILAC) Guide 19, *Guidelines for Forensic Science Laboratories* and the EPA Quality Manual (based on the American National Standard ANSI/ASQC E4-1994). ANSI/ASQC E4-1994 is the national standard adopted by the U.S. EPA for quality management of environmental data collection.

This QMP shows the SESD field branches blueprint for implementing its quality management process for environmental data collection and for assessing its effectiveness.

The following quality system elements are addressed in this Quality Management Plan:

1. Management and Organization
2. Quality System Components
3. Personnel Qualifications and Training
4. Procurement of Services and Supplies

5. Document Control and Records Management
6. Computer Software and Hardware
7. Project Planning
8. Implementation of Technical Work Processes
9. Quality Assessment and Response
10. Quality Improvement
11. Safety, Facilities, and Security

This Quality Management Plan references or describes procedures developed solely to provide internal guidance to employees within the SESD field branches.

2 Management and Organization

2.1 Organizational Structure

The United States Environmental Protection Agency (EPA) was created through an Executive reorganization plan (Reorganization Plan #3 of 1970) designed to consolidate a number of federal environmental activities into a single agency. EPA was formally established as an independent agency in the Executive Branch on December 2, 1970. The United States Congress authorized EPA to enforce environmental laws and to create environmental regulations. EPA's headquarters are located in Washington, DC. The Agency is comprised of ten regions and more than a dozen laboratories. EPA is led by an Administrator who is appointed by the President of the United States.

The Science and Ecosystem Support Division (SESD) is a division of the U.S. EPA, Region 4 Office (Figures 1 and 2). SESD is led by a Director and Deputy Director, with Branch and Section Chiefs designated to supervise allocated resources. SESD has an Immediate Office for the Director and four Branches: Analytical Support, Enforcement and Investigations, Ecological Assessment, and Management and Technical Services.

The Analytical Support Branch (ASB) is accredited under the National Environmental Laboratory Accreditation Conference (NELAC) standards. ASB's quality system is documented in a quality management plan titled *Analytical Support Branch Laboratory Operations and Quality Assurance Manual*.

The quality system for the two field branches, the Enforcement and Investigations Branch (EIB) and the Ecological Assessment Branch (EAB), are documented within this quality management plan and its associated policies, plans and procedures. The Division Director, Deputy Division Director, and management and staff within EIB and EAB are subject to the provisions of ISO 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories*. Work conducted by the two field branches is performed within the scope of their quality system at the laboratory and during field operations, however, if necessary, work which is not covered within the scope of the quality system may be conducted as long as this is clearly indicated when the results are presented.

SESD has overall management responsibility for the regional quality system. The regional quality assurance manager (RQAM) is organizationally located within the Management and Technical Services Branch in SESD.

SESD is one of the primary organizations within Region 4 responsible for the collection and analysis of environmental samples. 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. Investigations and projects are typically done at the request of the regional program divisions under memoranda of agreement and work plans negotiated annually between SESD and the program divisions. Additional special projects may be requested by the Regional

Administrator or other organizations. SESD performs specific quality assurance assessments of selected external environmental monitoring projects as requested by the program divisions.

2.2 Ethics

As public servants, federal employees must place loyalty to high ethical standards above private gain. It is the policy of the SESD field branches to conduct all business with integrity and in an ethical manner. Each staff member and manager is held to the highest ethical standard of professional conduct in the performance of all duties.

Standards of ethical conduct are described in the *Standards of Ethical Conduct for Employees of the Executive Branch*, October 2002 and the *Environmental Protection Agency Ethics Resource Guide*, 2006.

2.3 Quality Policy

The SESD field branches' quality policy provides for operating within a quality system that supports the mission and goals of the organization. The quality system provides a framework of policies, procedures, and management plans for planning, implementing, and assessing work performed by SESD. The quality policy states management commitment to support staff efforts in meeting customer expectations of quality, including providing resources.

2.4 Team Approach to Project Management

SESD customers include federal, state, tribal, and local government personnel. Typically, customers request field and laboratory support from SESD through the Region 4 program office. Projects may include extensive field work to address environmental problems or may be limited to technical document reviews. SESD projects may involve laboratory analyses, in-depth technical and regulatory compliance investigations, hazardous waste investigations, groundwater studies, water quality studies, or air studies.

Each fiscal year SESD develops Memorandums of Agreement (MOAs) with the Region 4 program offices based on discussions of potential work requests. The MOAs describe the responsibilities and expectations of SESD and the Program Office and provide an outline of the technical support work that is planned for the fiscal year. The MOAs establish the process for project identification and prioritization, therefore assisting SESD management with resource allocation and planning. In each MOA the planned projects are subject to change based on reassessments of project priorities by the Region 4 program offices.

Prior to undertaking new projects in existing environmental data collection and measurement areas, or commencing new services, managers and staff from EIB and EAB must review the projects to ensure that: 1) the requirements, including the procedures to be used, are adequately defined, documented and understood, 2) SESD has the capability and resources to meet the customers' requirements, and 3) the appropriate sampling and/or measurement procedures are available and are capable of meeting the project requirements. Within SESD a team approach is used to manage projects. A Project Leader is selected by the appropriate Section Chief to define

and address project objectives. Project Leaders are selected by management based on their knowledge, skills, and experience relative to the objectives of the investigation. They are responsible for communicating and coordinating project requirements and information with the various participants in the investigation. The Project Leader interacts with the customer and key SESD staff (including the Analytical Support Branch) to plan and coordinate the pending study. Project objectives are identified during the planning process which typically uses EPA's Data Quality Objectives (DQO) process.

Based on the DQOs, the Project Leader prepares a Quality Assurance Project Plan (QAPP) which for the purposes of ISO 17025 serves as a written agreement with the customer with regard to project objectives and specific data collection activities. An internal technical review of the QAPP is conducted by other field investigators familiar with the study tasks. Draft QAPPs that have completed the initial SESD internal review process are transmitted to the customer for review. The Project Leader is responsible for ensuring that data generated during SESD field studies meets the objectives of the project. If the customer requests deviations, additions, or exclusions from standard SESD operating procedures, the Project Leader will indicate this in the QAPP and final report. Prior to transmittal to the customer, QAPPs must be reviewed by a designated approving official (DAO) who has been delegated authority to approve QAPPs by the Regional Quality Assurance Manager. All SESD Section Chiefs are authorized as DAOs and are ultimately responsible for ensuring the content of the QAPPs is in accordance with the requirements of the SESD Field Branches Quality System and approving the QAPP for distribution. External Peer Review may be scheduled depending on the nature and complexity of the study.

Any differences between the project request and the QAPP will be resolved before the work commences. If circumstances in the field require any significant deviations from the QAPP such as changes in the objectives of the project or changes in resources required for the project, the customer will be notified by either the Project Leader or SESD management. If the QAPP has to be amended after the study has begun, the Project Leader will seek approval from SESD management.

A safety plan is prepared for field sampling and measurement activities. Safety plans are approved by the respective Branch Safety Officer and Section Chief prior to initiation of field activities. Float Plans and Dive Plans are also prepared when applicable.

2.5 Quality System Organizational Structure

The SESD field branches quality system is applicable to sampling and measurement activities conducted by the Enforcement and Investigations Branch and the Ecological Assessment Branch and is led by the Director and overseen by the Branch and Section Chiefs. It includes both administrative and technical functions. Authorized signatories for SESD work products (including reports) are identified in relevant procedures, and management plans. The signatories can include one or more of those listed in this QMP as having quality management responsibilities. The following sections outline quality system responsibilities.

2.5.1 Director

The Director provides policy definition, leadership, and oversight for the field branches quality system and serves as the overall authority for directing SESD activities in accordance with EPA policy. The Director's responsibilities, with regard to quality, include serving as the final authority for resolving quality related issues, ensuring that the proper training is provided, that resources are available to support the SESD quality approach, that managers and SESD technical staff have quality system management responsibilities incorporated into their performance standards, and that an adequate Field Branch Quality Management Plan is in place. The Deputy Director, Branch Chiefs, and Section Chiefs assist in that effort.

2.5.2 Branch Chiefs

Branch Chiefs report to the Director and are responsible for supervising and providing training opportunities to branch staff, managing resources, and evaluating work products within a branch. The Branch Chief is the technical manager who has overall responsibility for Branch technical operations and for ensuring that work assigned to his/her Branch is carried out in a timely manner and meets the needs of the customers. A Branch Chief's duties, with regard to quality, are deliberately redundant with some of the responsibilities of the Section Chief. Branch Chiefs are responsible for insuring that the Section Chiefs identify the resource needs for their branches; identify and provide opportunities for specific technical, quality, and safety training for the staff; assure that standard procedures are available to the staff and are understood by staff involved in sampling and measurement activities; and identify and implement SESD's Field Branches Quality System and project management improvements. Branch and Section Chiefs authorize individual staff to perform work independently based on the satisfactory completion of competency evaluations. In the event a Branch Chief is not available to perform their duties, he/she will designate an Acting Branch Chief.

2.5.3 Section Chiefs

Section Chiefs report to their respective Branch Chief and are responsible for direct oversight and supervision of their sections which includes providing training opportunities to branch staff, managing resources, and evaluating work products within a their section. The Section Chief is the technical manager who, with the Branch Chief, has overall responsibility for Branch technical operations and for ensuring that work assigned to his/her Section is carried out in a timely manner and meets the needs of the customers. A Section Chief's duties, with regard to implementation of the quality system, are deliberately redundant with some of the responsibilities of the Project Leader. Section Chiefs work with their respective Branch Chief to identify the resource needs for their section; identify and provide opportunities for specific technical, quality, and safety training for the staff; assure that standard procedures are available to the staff and are understood by staff involved in measurement activities; and identify and implement the SESD Field Branches Quality System and project management improvements. Branch and Section Chiefs authorize individual staff to perform work independently based on the

satisfactory completion of competency evaluation. Section Chiefs are responsible for approving Quality Assurance Project Plans (QAPPs) for distribution. In the event a Section Chief is not available to perform their duties, he/she will designate an Acting Section Chief.

2.5.4 Project Leader

The Project Leader is designated by management to coordinate the technical support requested by SESD customers. The Project Leader has the primary responsibility for planning and conducting field investigations and evaluating the results and completing a report for the customer. During the planning of the project, the Project Leader and customer are responsible for developing data quality goals appropriate for the regulations involved. These data quality goals will be noted in the QAPP and will be used to define data quality requirements appropriate for the sampling/measurement methods selected. Throughout the project, they are responsible for ensuring that the quality of the information generated meets the data quality requirements of the project. This responsibility is fulfilled in consultation with assigned project team members, and, if needed, with the appropriate Section Chief.

In the event a Project Leader is unable to perform his/her duties, the responsible Section Chief will appoint someone to act on their behalf.

2.5.5 Technical Project Staff

Technical project staff consists of field investigators and lab analysts. Field investigators provide specific knowledge, skills, and expertise to field studies. Field investigators may assist Project Leaders in defining project objectives and data quality requirements, developing QAPPs, conducting measurements, collecting samples, reviewing data, and developing and assessing standard procedures. Lab analysts analyze samples, review data, develop and implement standard operating procedures, maintain lab instrumentation, and ensure lab quality control practices meet applicable requirements.

2.5.6 Environmental Services Assistant Team Support

Field and laboratory support are often obtained through the Environmental Services Assistant Team (ESAT) contract. Work is assigned by EPA Work Assignment Managers to ESAT staff through technical direction documents and work unit documents following all contractual rules and regulations. ESAT personnel are subject to all provisions of and are expected to be familiar with the SESD Field Branches Quality System and to follow SESD Field Branches policies and practices. ESAT personnel serve as analysts in the EAB laboratories and serve as field investigators during SESD field investigations. ESAT field investigators may be tasked with primary responsibility for implementation of field sampling and measurement activities for a project, however, do not serve as project leaders.

2.5.7 Regional Quality Assurance Manager

The Regional Quality Assurance Manager (RQAM) serves as 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 and/or the Director of SESD provide briefings to senior staff regarding quality assurance issues on approximately a quarterly 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 quality assurance activities do not meet Agency quality assurance policy or requirements. In the event the RQAM determines 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, then the RQAM and the SESD Director will take the issue to Senior Management for resolution. The Regional Administrator/Deputy Regional Administrator (RA/DRA) shall have final dispute authority on all quality issues.

The RQAM has the prerogative to meet with the RA/DRA to discuss quality assurance issues. A meeting between the RQAM and Regional Administrator (or Deputy Regional Administrator) will be coordinated through the SESD Director/Deputy.

In the event the RQAM is not able to perform his/her duties, the Chief of the Quality Assurance Section will act on their behalf.

2.5.8 Field Quality Manager

Organizationally, the Field Quality Manager (FQM) reports to either the EIB or the EAB branch chief as agreed upon by management, however, functionally, the FQM reports to both branch chiefs. When the field branches quality system is subject to management system reviews conducted by the Regional Quality Assurance Manager, the FQM is responsible for addressing any findings. The FQM has the overall responsibility for ensuring the scientific validity and procedural quality for all SESD field and EAB laboratory activities. The FQM or his/her designee:

1. Ensures the SESD field branches implement the Field Branches Quality Management criteria in order to maintain compliance with International Organization for Standardizations (ISO) 17025 requirements and the forensic amplification of the International Standard as offered by Forensic Quality Services-International
2. Ensures the development and implementation of Field Branches Quality System training for SESD staff
3. Manages the internal audit program

4. Coordinates and manages external audits
5. Coordinates accreditation activities
6. Maintains and distributes all quality system documents for the field branches
7. Maintains a master list of current versions of quality documentation
8. Trains personnel on Quality Management System activities
9. Monitors the Quality Management System
10. Reports on the performance of the Quality Management System to management for review and as a basis for improvement of the Quality Management System
11. Oversees the internal competency evaluations and proficiency testing program.

In the event the Field Quality Manager is not available to perform his/her duties, the Document Control Coordinator will act on his/her behalf.

2.5.9 Branch Quality Assurance Officer

Branch quality assurance officers (QAOs) are designated by and report to the Section Chiefs in their respective branches. The QAOs assist the Field Quality Manager in disseminating, reviewing, and implementing the quality policy and other quality system documents. The EIB QAO is responsible for quality control checks of supplies at the SESD Field Equipment Center and preparation of a quarterly report that summarizes the results of the quality control checks and quality control results of samples collected during EIB field investigations. The EAB QAO is responsible for quality control checks for supplies ordered by EAB and preparation of an annual report that summarizes the results of the quality control samples collected during EAB field investigations.

2.5.10 Document Control Coordinator

The Document Control Coordinator (DCC) is a quality system position within the field branches. The DCC is appointed by management to maintain documents that form the SESD field branches quality system. Responsibilities of the DCC include:

1. communicating with the FQM, management and staff regarding document development, control, distribution, review and revision;
2. maintaining a master list of field branches quality system documents;
3. ensuring the most recent versions of field branches quality system documents are on the SESD LAN and internet;

4. assigning effective dates for quality system documents;
5. assigning document control numbers;
6. archiving obsolete and retired documents;
7. tracking the review status of documents and notifying the FQM, management and staff of document requiring review and/or revision;
8. maintaining records associated with the quality system document control requirements.

The DCC serves as the acting FQM if the FQM is unavailable to perform his/her duties. If the DCC is unavailable to perform his/her duties, management will appoint someone to act on their behalf.

2.5.11 Branch Field Equipment Manager

Branch Field Equipment Managers are staff members, designated by management, who are responsible for ensuring that the procedures for Equipment Inventory and Management are followed. At least one Branch Field Equipment Manager (BFEM) will be designated for the Enforcement and Investigations Branch (EIB) and one for the Ecological Assessment Branch (EAB). The EIB BFEM is responsible for the procurement of supplies and equipment for EIB and the Field Equipment Center. The EAB BFEM is responsible for procurement of supplies and equipment for EAB.

3 Quality System Components

3.1 General

The SESD Field Branches Quality System is a structured and documented system describing policies, procedures, guidance, management plans, and manuals; and organizational authority and responsibilities for building quality into SESD work processes, products, and services. The quality system provides a framework for planning, implementing, recording, and assessing work conducted by the SESD Field Branches. The Quality System is structured to reflect the requirements and guidance of EPA's Quality System and ISO 17025.

The quality system has the following components:

1. Quality System Documentation
2. Annual Reviews and Planning
3. Management Assessments
4. Training
5. Project Planning
6. Quality Assessment.

3.2 Quality System Documentation

At the core of the quality system is the quality policy. Its purpose is to define the intentions of the system. The SESD Quality Policy reflects management's philosophy on quality and stands as a guiding principle for SESD sampling and measurement activities. The quality policy requires all personnel to be familiar with the aspects of the quality system that relate to their work and responsibilities. SESD personnel in each field branch are responsible, as individuals, for the quality of their work products and for continuous improvement of processes. They are expected to deliver information using scientific methods and data appropriate for agency activities. The Quality Policy states management's commitment to support staff efforts in meeting customer expectations of quality. The Quality Policy is part of the controlled documents of the organization and can be accessed by all personnel through the SESD local area network.

The quality system documentation described below provides the information needed to produce work products and services for environmental sampling and measurement activities. These are:

1. SESD Field Branches Quality Management Plan (QMP)
2. EPA/SESD Policies
3. SESD Field Branches Operating Procedures

A comprehensive list of SESD standards, plans, policies and procedures is maintained on the SESD local area network. This documentation is reviewed periodically to address changes in the quality system. Suggestions for changes come from staff proposals for improvements, experience gained from SESD involvement in environmental studies, internal audits and administrative reviews.

EPA or SESD policies, procedures, guidance, and management plans are not intended to supersede sound professional judgment. SESD personnel are encouraged to use their knowledge, skills, and abilities when providing support to environmental field investigations. If that support includes variance from current quality system documentation, then SESD personnel should record the variance in the project records, with a brief description that is dated and signed.

3.2.1 The SESD Field Branches Quality Management Plan

The SESD Field Branches QMP is an essential component of the quality system. It describes and documents the system, and is the plan that is used to implement the quality policy. It identifies what SESD does in quality management and gives a rationale for why it is done. The QMP provides the basis for discussing changes and improvements to the quality system.

The QMP is used by both SESD management and staff as a general reference document. All SESD Field Branch employees are required to read and be familiar with this basic document as it relates to their work. SESD management uses the QMP as a tool to gauge whether the quality system is being successfully implemented.

3.2.2 SESD Policies

The SESD Director, along with contributions from the management team, provides documented directives in the form of policies that reflect a philosophy, guiding principle, or desired course of action or behavior on a given subject that provide the backbone for the quality system.

3.2.3 SESD Operating Procedures

Operating procedures are developed to provide consistency in activities performed in support of field investigations and laboratory analysis and are the foundation for competency evaluations, proficiency tests, and some training. All are part of the controlled documents of the organization and can be accessed through the SESD local area network.

SESD has a process for developing new and/or modifying existing written controlled documents. Processes that are candidates for standardization are identified by SESD management, the quality staff, or technical staff. The documents are written by persons who are deemed technically competent by management, based on their knowledge, skills, and abilities. The documents are reviewed and evaluated or tested by staff prior to approval by SESD management. Staff is expected to follow applicable procedures while

conducting technical operations. Procedures are modified or new ones are developed when existing procedures are inadequate or inappropriate to meet the needs of the organization. The information used to develop procedures or modify existing written procedures must be documented. Personnel can depart from existing written procedures on a project-specific basis. Planned departures are acceptable if needed to meet project objectives and/or data quality objectives. Planned departures will be described in the project specific quality assurance project plan. Planned departures are not considered nonconformances within the SESD field branches quality system. Unplanned departures that may occur during field or laboratory operations will be communicated to and discussed with the Project Leader prior to being exercised and they must be fully documented in the appropriate logbook. Unplanned departures will be reported as nonconformances as soon as practicable and will be handled in accordance with the SESD Operating Procedure for Control of Nonconforming Work (SESDPROC-019).

3.3 Annual Reviews and Planning

The SESD field branches have a procedure for reviewing the SESD Field Branches Quality System to evaluate its continuing suitability and effectiveness and to introduce necessary changes and improvements. The review is conducted at least annually by the Director, Deputy Director, the EIB and EAB Branch and Section Chiefs and the FQM.

The review will consider but not be limited to the following:

1. Suitability of policies and procedures
2. Annual audit plan and recent internal audits
3. External Audits
4. Proficiency tests
5. Corrective and/or preventive actions
6. Quality improvements
7. Complaints
8. Customer feedback
9. Quality Management Plan
10. Quality Assurance Annual Report
11. Accreditation activities/issues
12. Reports, records and other documentation
13. Facilities, security, and resources
14. Safety, health, and environmental management
15. Changes to the volume and/or type of work undertaken
16. Staff training
17. Operating Plan.

3.4 Management Assessment

The SESD Director provides policy definition, leadership, and oversight for the quality system. The SESD field branches management is responsible for allocating resources, so that the quality policy can be implemented. Management supports the staff quality effort by promoting teamwork, facilitating exchange of information from both inside and outside the organization, providing training opportunities, and providing the resources necessary to meet customers' expectations of quality. SESD senior managers shall insure that the integrity of the management system is maintained when changes are planned and implemented.

3.5 Training

The SESD field branches have a procedure that describes the process of identifying the training needs of SESD employees, providing training opportunities to them, and evaluating and documenting the training received. The purpose of the training program is to plan for retention and enhancement of employee knowledge, skills, and abilities in performing work and providing services. The Branch and Section Chiefs are responsible for ensuring staff is adequately trained with regards to technical, quality, and safety issues.

ESAT personnel are subject to the same quality system training requirements as personnel within the SESD field branches. ESAT contract management is responsible for ensuring their staff is properly trained and in compliance with EPA requirements.

3.6 Project Planning

Systematic planning and quality assessment enable SESD to conduct project-specific planning, verify and document the integrity and accuracy of work products, evaluate the effectiveness of the quality system, and report on that effectiveness to SESD and EPA management.

The primary function of the SESD field branches is to provide technical support to the Region 4 Program Offices through sample and measurement collection, data assessment, and sample analysis. This support is usually provided on a project-specific basis.

The protocol for evaluating project requests, assigning teams, collecting environmental data if necessary, managing evidence, analyzing samples, reviewing data, and developing reports on the project investigative results are addressed in a series of documented processes available to the staff as part of the controlled documents of SESD.

Planning, implementation and assessment processes are necessary to effectively conduct environmental data collection operations and the use of environmental technology. The elements of the SESD quality system include activities in the planning, implementation and assessment phases. The planning process is documented in QAPPs, the implementation phase is performed and overseen by the data user and/or project 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.

Data Quality Objectives (DQO) Process

The data quality objectives (DQOs) process is a systematic planning tool which is used to delineate project-level elements. During the DQO process, the elements which are developed include project management, data generation and acquisition, project assessment and oversight, and data validation/usability. Detailed guidance for developing DQOs is provided in “Guidance for the DQO Process”, EPA QA/G-4, Final, August 2000; and “Guidance for Data Quality Assessment - Practical Methods for Data Analysis,” EPA QA/G-9, Final, July 2000. The Agency’s DQO process is the preferred method of developing objectives for those projects requiring the collection of environmental data or the use of environmental technology. However, any systematic planning process may be used as long as it leads to the generation of a QAPP which meets EPA’s requirements.

Having identified the need for an environmental data collection effort, the project leader and the decision maker (i.e., Branch Chief, Section Chief, customer, etc.) are responsible for initiating the DQO development process. During the early planning phase of the investigation, the customer must clearly establish the intended use of the data, time and resource constraints, and in general terms, the quality of data needed. The Project Leader is responsible for development of DQOs that will facilitate the generation of sufficient data of the quality needed by the ultimate data user/decision maker. The DQO process requires interaction between the Project Leader, customer, field and laboratory technical staff, QA staff, and secondary data users as appropriate. The DQOs developed will be used for the detailed design of the investigation and preparation of the QAPP.

Quality Assurance Project Plans (QAPPs)

Region 4 relies on QAPPs coupled with detailed operating procedures to define specific project QA/QC requirements. In preparing a QAPP, the Project Leader must identify the project objectives, sampling design, critical measurements to be performed, and discuss the QC activities to be conducted during the sampling, analytical, and validation phases of the project. The document entitled “EPA Requirements for Quality Assurance Project Plans,” EPA QA/R-5, 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 provides a detailed look at the process of developing a QAPP.

All regional projects requiring collection of environmental data or the use of environmental technology must have an approved QAPP prior to data collection. An exception to this requirement is projects where immediate danger to human health or the environment is present or suspected and emergency response staff is immediately deployed. The Regional Quality Assurance Manager (RQAM), or a designated approving official (DAO), shall review all QAPPs, provide input, recommend changes, and approve final plans. The SESD field branches have a procedure for reviewing and approving all internally generated QAPPs. For SESD projects, the Section Chiefs serve as the DAOs.

SESD utilizes the Region 4 Laboratory Information Management System (R4LIMS) for tracking all projects and any associated QAPPS.

3.7 Quality Assessment

The SESD field branches conduct quality assessments to determine if the organization is clearly stating its program goals, following its guidance and procedures, and that what is being done is adequate, appropriate, and effective. For measurement and sampling activities, SESD conducts assessments to verify and document the integrity and accuracy of information generated during laboratory and field studies and to identify opportunities for improving the measurement and sampling process. Quality assessment can include internal/external audits, observations, internal reviews, quality control checks, performance evaluations, and/or management reviews.

4 Personnel Qualifications and Training

For SESD to maintain an expert staff and sophisticated technical capabilities, priority is placed on defining personnel qualifications and identifying training needs.

4.1 Personnel Qualifications

EPA operates its' hiring procedures under the federal government's Office of Personnel Management (OPM) regulations. The OPM qualification and classification standards describe the educational and experience requirements which a potential employee must meet to satisfy the OPM requirements for a specific job series and grade. Before an employee is hired, the Region 4 EPA Human Capital Management Branch verifies that the applicant meets the OPM education and experience requirements for the appropriate series and grade. After the verification process is complete, SESD field branch managers are allowed to hire an applicant who meets the OPM requirements from a certificate of eligible candidates.

In the event of ESAT contract employee replacement due to resignation or otherwise, the ESAT Team Manager (ETM) will advertise the position, propose the best available candidate and submit the candidate's complete resume to the ESAT Contract Officer (CO) and or Project Officer (PO) to ensure the replacement has comparable qualifications as to the person being replaced. The PO will evaluate all new hires and communicate concurrence or non-concurrence to the CO.

When EPA proposes new areas of support or requests additional contract personnel, the CO/PO will provide detailed task descriptions to the ESAT contractor. The ETM will establish minimum qualifications, prepare job position descriptions, advertise the position, and evaluate available candidates. The ETM will propose the best available candidate to the CO/PO and submit the candidate's complete resume. The PO will review all new hires' resumes against the qualifications and communicate concurrence or non-concurrence to the CO. In all cases of hire, the ETM will offer the candidate the position only after the ESAT Contract Officer has modified the contract to include the new ESAT employee.

4.2 Training

4.2.1 EPA Personnel

SESD management maintains a commitment to personnel development and training. SESD encourages supervisors and employees to identify training needs and opportunities. Supervisory support is the cornerstone of the technical program. The Field Quality Manager maintains records of all professional development and quality system training received for personnel within the field branches.

SESD will use personnel who are permanently employed to conduct sampling, measurement, and analytical activities whenever possible. Where other than permanent employees (e.g., contract personnel, grantees, students, interns, etc.) are used and the work products of those personnel are reported by SESD, the Field Quality Manager,

Section Chiefs, and Project Leaders will ensure that such personnel work within the parameters of the SESD Quality System.

The SESD Safety, Health and Environmental Management Program (SHEMP) Coordinator identifies mandatory safety and health training and certifications and notifies employees and managers of requirements. Supervisors are advised of the training and certification status of their staff in this area and are responsible for their staff taking advantage of training opportunities. The respective Field Branch Safety Officers and Section Chiefs review and approve the Safety Plans developed for field activities prior to deployment. The Safety Officers and Section Chiefs also verify that the training, certifications, and medical monitoring for employees involved in field activities are current.

Project Leaders identify field investigators needed for the successful completion of field studies from a group of qualified individuals. The Section Chiefs are responsible for insuring that the qualifications that are required for effective participation in a specific study are met by the project staff. This process can include the use of competency evaluations and proficiency testing. Also, supervisors, in consultation with their staff, determine what program-specific training is required by EPA.

Required and general interest training courses are made available to EIB and EAB field and lab personnel. Training courses offered can include scientific/engineering courses, ethics, safety and environmental management, quality management, basic statistics, sampling and analytical methodology, project management, and courtroom training. Quality management training includes keeping EIB and EAB personnel, and ESAT contract personnel apprized of the elements of the EPA and SESD Field Branches Quality Systems that relate to their duties and responsibilities. SESD provides ethics training for EPA personnel that includes a review of the SESD Ethics Policy and discussing EPA ethics requirements. Individual on-the-job training by peers is also widely practiced.

For personnel within the field branches, education level, training, work experience and records of individual competency and proficiency evaluations are documented in personal qualification files maintained by the Field Quality Manager. Personnel files containing transcripts of college courses, verification of college degrees received, and records of many training activities are maintained in accordance with Agency procedures.

4.2.2 ESAT Personnel

ESAT contractor management is responsible for ensuring contract personnel are properly trained and qualified to perform technical operations for the SESD field branches. ESAT employee training will be provided by qualified ESAT personnel.

In cases where specialized training can only be provided by EPA personnel, a Technical Direction Form (TDF) will be submitted to and approved by the EPA ESAT Project Officer, or other contract representative. All ESAT employees subject to the field

branches quality system will demonstrate periodic proficiency based on EPA's designated schedule.

All ESAT employee training development plans are consistent with contract Statement of Work (SOW) requirements and in accordance with EPA authorized and ESAT management approved tasks. All ESAT field investigators shall receive annual performance evaluations and establish specific and achievable goals which are consistent with their position responsibilities under the contract. Job descriptions are updated at least annually under the contractor's Quality Management Plan.

Upon the request of the PO or other contract representative, ESAT shall provide documentation of all required training. The EPA FQM will evaluate ESAT employee skills, and may recommend additional training through the EPA ESAT Project Officer, or other contract representative. The FQM maintains records of evaluation of proficiency testing results, internal audits, and external assessments as a means of measuring the effectiveness of the training that was given to ESAT field branch personnel. These recommendations will be based on based on areas of non-conformance or through proficiency testing.

Education level, training, work experience and records of individual competency and proficiency evaluations for ESAT contractors will be documented in personal qualification files maintained by the Field Quality Manager. All ESAT contract personnel files will be maintained by the ESAT contract holder.

5 Procurement of Services and Supplies

5.1 General Procurement

SESD has documented procedures for purchasing services and supplies in the operating procedure for Purchasing Services and Supplies. Materials and general supplies used in environmental measurement activities must be of known quality and meet the technical requirements of the activity for which they are to be used. Procurement is the coordinated responsibility of the EIB and EAB field and lab personnel and management.

The individual initiating the purchase is required to: 1) obtain management's approval to commit funds, 2) establish specifications for the item to be purchased including quality criteria, 3) establish acceptance criteria and procedures for use in verifying/evaluating the purchased item upon receipt or prior to use, and 4) provide procurement source recommendation(s).

The purchase of services and supplies can be initiated with a procurement request (PR) or bankcard order. Once the PR or bankcard order has been prepared, management must then review the documentation to ensure the information is accurate and complete and contains a clear description of the services or supplies needed. Management will then authorize and sign the PR or bankcard order prior to forwarding to the purchasing official. The purchasing official will have the experience, training and certification necessary to ensure that all purchases of services are conducted in accordance with the Federal Acquisition Regulations, Office of Federal Procurement Policy, and the EPA Contracts Management Manual [EPA Order 1900 (EPA 1998)]. Upon receipt of the item(s) the individual initiating the purchase will inspect the item(s) to insure agreement with the PR or bankcard order and the packing slip.

5.2 Contracting of Analytical Services

In the event the SESD field branches find it necessary to establish a contract for analytical services, the individual initiating the purchase will work in conjunction with a member of the Quality Assurance Section, who is familiar with contracting of analytical services, to ensure all relevant information particularly with regard to the quality of the data required is included in the PR or bankcard order. All purchasing will be conducted as described in Section 5.1 above.

6 Document Control and Records Management

The SESD Field Branches Quality System documentation consists of documents used to produce work products and services and records providing objective evidence of actions taken. The SESD Field Quality Manager develops, implements, and assesses document control and records management components of the SESD Field Branches Quality System. The Field Quality Manager also provides guidance to SESD management and staff in this area. The processes used in this area are documented in the SESD operating procedures for Document Control and Control of Records.

6.1 Document Control

SESD has implemented and documented a process to control documents and information that relate to the quality system.

SESD has a systematic process for generating, indexing, disseminating, and retiring the policies, procedures, guidance, management plans, and information that make up the quality system documentation.

SESD has a process for identifying the current version of quality system documents, for distributing those documents to personnel, and for precluding the use of obsolete documents. When obsolete documents must be retained for legal and/or institutional knowledge purposes the documents are archived and identified as retired documents.

Controlled documents and a master list of plans, policies, procedures and forms are readily available to all personnel via the SESD local area network.

6.2 Records Management

At SESD a record provides objective evidence of actions taken or observations made while implementing the quality system. SESD has a systematic and documented process for generating, identifying, controlling, storing, and accessing records. The records management system provides a secure environment to prevent damage, deterioration, or loss and promote customer confidentiality. Records retention and disposal schedules are consistent with the EPA Records Management Policy.

7 Computer Software and Hardware

EPA's Office of Technology Operations and Planning (OTOP) is responsible for managing the hardware, software and communications components which form the foundation of the Agency's information technology. OTOP has established the hardware and software standards with which the Region must conform. Region 4 managers and staff including SESD will observe all hardware and software standards as detailed in the OTOP 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.

SESD will procure Agency-approved hardware and software that conforms to Agency-wide information management structure. Region 4's Environmental Information Solutions Branch (EISB) will assess significant changes in the Agency's hardware and software policy to determine the effect on the Region. In the event changes are required, EISB managers will work with regional managers to plan and implement appropriate modifications.

In the event that SESD has a need to purchase or develop application software which is not on Agency contract, the software will be evaluated prior to purchase. Software evaluation will be performed against written performance/capability standards developed by the PC site coordinators and/or system administrators. Vendors must comply with the Agency standards provided by NTSD. Regional PC site coordinators and/or system administrators are responsible for evaluating software to determine its performance capabilities and documentation requirements.

Specialized software developed by the SESD Field Branches will be documented within the software itself. Validation (testing) will be done by the developer. The developer will maintain records of the testing results including details of problems and suggestions for improvement.

SESD has computer specialists within the Management and Technical Services Branch who are responsible for system applications development, installation and maintenance of computers. In the event of a hardware or software failure on a PC or laptop, SESD personnel contact a computer specialist for support. The computer specialists are responsible for network application software upgrades and hardware upgrades for PCs. Computer specialists are responsible for upgrades of any specialized commercial software installed on their PCs and laptops and also for backing up files stored on their PCs and laptops. Employees are required to request and receive branch chief approval to have any non-standard software installed on Agency computers by the specialists in MTSB. Files stored on the SESD local area network (LAN) are backed up to magnetic tapes Monday through Saturday evenings using a redundant network backup system. One backup is conducted remotely from the Office of Research and Development computer center and another locally from the SESD computer center. After successful backups, the daily tapes located at SESD are placed in a fire-proof media safe and a copy of the Friday evening backup is rotated to the Atlanta EPA office for offsite storage. Detailed backup procedures can be found in the 'ADP Disaster Recovery Plan for Region 4' dated June 10, 2004 (and any future updates). The custodian of the document is the Region 4 Information Security Officer in the

Atlanta office. An electronic copy is available from the Athens LAN administrator, and a hard copy is located in the safe in room B107.

SESD generates field and laboratory data from sampling and measurement activities. These data are stored and managed in SESD databases such as the Element Laboratory Information Management System and the Data Archival/Retrieval System. The processes for ensuring the accuracy of these data are described in the SESD Operating Procedure for Field Sampling Quality Control (SESDPROC-011) and in the Analytical Support Branch Laboratory Operations and Quality Assurance Manual.

8 Project Planning

SESD has a systematic project planning process detailed in the operating procedure for Project Planning. This section summarizes how and by whom environmental data collection activities are planned. At SESD, project planning can include initial contact with the customer in the Region 4 Program Office, project acceptance, project plan development, and health and safety planning.

8.1 Initial Contact with Customer

Measurement and sampling activities, requested as a part of a field study, are initiated primarily by a Region 4 supervisor (usually a Section Chief) contacting an SESD Section Chief.

8.2 Project Acceptance

Requests for field support are reviewed for acceptance by the appropriate SESD Section Chief. When SESD accepts an investigation, a Project Leader is selected by management. This selection is based on knowledge, skill, and experience relative to the objectives defined for the investigation. Project Leaders typically select field investigators for the project based on their qualifications to meet the objectives of the investigation. Project participants are always subject to review and change by the respective Section Chief.

Requests for laboratory support are also reviewed for acceptance by the appropriate SESD Section Chief. Acceptance of samples for laboratory analysis is based on availability of laboratory resources including qualified analysts, appropriate instrumentation, available operating procedures and laboratory capacity.

8.3 Quality Assurance Project Plan Development

The information that is known about the project prior to its onset and that is related to scope, objectives, and data quality goals is used to develop a quality assurance project plan (QAPP). The Project Leader communicates with the customer to identify technical procedures suitable to meet the project objectives. Depending on the complexity of the project, a systematic planning tool such as EPA's Data Quality Objectives Process may be used for planning. The Project Leader then works with the SESD technical staff and Analytical Support Branch to develop a plan for accomplishing project technical and quality goals, a time line for the project, and to determine acceptance criteria for the results of the sampling or measurement activities. Project planning guidance documents developed by EPA are available online at www.epa.gov/quality/qa_docs.html. The documents cover topics such as developing data quality objectives for a study and requirements for quality assurance project plans. Project plans will vary in their level of complexity based on the nature of the work being performed, the available resources and the intended use of the data. Project plans are reviewed and approved by the respective Section Chiefs prior to implementation.

8.4 Safety Plans, Float Plans and Dive Plans

The SESD SHEMP Coordinator and Field Branch Safety Officers evaluate technical activities and advise the Management Team and staff of potential safety issues. The Field Branch Safety Officers and Section Chiefs review and approve project safety plans developed for field activities.

The Branch Safety Officers work with the SHEMP Coordinator to insure that all staff training, certifications, and medical monitoring are current.

When boats are used during field operations, a float plan is prepared. Float plans should be prepared in accordance with the procedures provided in the SESD Safety, Health and Environmental Management Program (SHEMP) Manual, Most Recent Version. A copy of the float plan is left with an individual who can contact the individuals indicated on the plan if field investigators have not returned at the specified time.

A dive plan is prepared anytime dive operations are used during field investigations. The dive plan is prepared in accordance with the U.S. Environmental Protection Agency Diving Safety Manual, Most Recent Version. The dive plan is prepared by the Dive Master and approved by the Unit Dive Officer. The plan contains information related to safety regarding dive operations.

9 Implementation of Technical Work Processes

9.1 Management Level

The basic provisions for project management are found in the SESD operating procedure for Project Planning. SESD management has developed a process for participation in every phase of a project from the preliminary discussions through request, implementation, reporting, and field study support.

Once a project is initiated and appropriate planning completed, progress is tracked by the Section Chiefs and Project Leader. As unanticipated events conflict with scheduled activities, management intervenes to set new priorities, reassign staff, or otherwise influence the pace of project implementation. Changes in time lines and resource needs are discussed and reconciled with the customer, and they are notified as to the impact of decisions on prior commitments, in either scope or timeliness.

9.2 Project Level

9.2.1 Field Sampling/Measurement

Upon completion of the QAPP, the Project Leader ensures copies are distributed to the requestor and all involved parties. A distribution list is included in the QAPP.

Once the field study is underway the specific strategy and sampling plan are often modified on-site as additional information is gained by the Project Leader. Activities in the field are documented as they occur and become part of project records.

All samples and measurements collected in the field are subject to procedures outlined in the SESD Field Branch Quality Management Plan and all associated Operating Procedures. Chain-of-custody records and an in-house tracking system are used to track samples from collection through analysis to disposal. There are sampling and sub-sampling procedures available to the project team. A record of the sampling and/or measurement protocol(s) used and any deviations from written procedures become part of project records.

Departures from existing written sampling procedures are allowed if given the latitude by the applicable regulations, if warranted by the sampling situation, if requested by the customer or if safety concerns dictate a change or variance. Departures are communicated to and discussed with the Project Leader and documented in the field logbook.

Personnel may also modify or develop new procedures for sample collection or field measurements. Procedures are modified or new ones are developed when existing procedures are inadequate or inappropriate to meet the needs of the investigation effort or when new procedures may result in improved resource efficiency. The information used to develop, validate, or establish uncertainty of the procedure must be documented, as well as the steps followed in implementing the procedure. There is a review and approval

process for developing or modifying existing written procedures. Obsolete or retired versions of procedures and guidance are archived by the Document Control Coordinator.

The Project Leader is typically responsible for all field quality control and quality assurance activities and also for ensuring the project is being implemented according to the QAPP. For large scale projects, a Quality Assurance Officer, who is responsible for conducting on-site assessments and ensuring the project is being implemented according to the QAPP, may be appointed. If changes to the QAPP are implemented during a field investigation, it is the responsibility of either the Project Leader or the Quality Assurance Officer to communicate the changes to affected participants.

Field measurement and sampling activities are focused toward meeting the regulatory and technical requirements defined during planning. Sampling activities require:

- Coordinating field activities with laboratory activities
- Maintaining the sample integrity
- Focusing on regulatory and SESD defined data quality requirements.

9.2.2 Analysis

Analysis involves the determination of the chemical, physical, and/or biological characteristics of samples and results in raw data generated from instrumental examination, chemical laboratory analysis, biological identification, or physical testing. The analytical methods used should be specific and sensitive enough to answer the study question and meet the data quality goals objectives associated with the study.

Analysts may use a variety of published or written materials to aid them in selecting or developing measurement methodologies. These materials include required regulatory analytical procedures found or referenced in the applicable volumes of the Code of Federal Regulations (CFR); instrument manufacturer manuals; general procedures of analysis compiled by EPA, ASTM, and Standard Methods; methods found in the scientific literature; and in-house procedures, practices, or reports developed to archive EPA institutional knowledge. EPA procedures and guidance are available to EPA personnel on the SESD local area network site.

If given the latitude by the regulations and if warranted by the situation, personnel can modify procedures or develop new ones. Procedures are modified or new ones developed when existing procedures are inadequate or inappropriate to meet the needs of the investigation effort or when new procedures may result in improved resource efficiency. The information used to develop, validate, or establish uncertainty of the procedure must be documented, as well as the steps followed in implementing the procedure. There is a review and approval process for developing or modifying existing written procedures. Obsolete or retired versions of procedures and guidance are archived by the Field Quality Manager.

Departures from existing written analytical procedures or test methods are allowed if given the latitude by the applicable regulations and if warranted by the sample matrices. Departures are communicated to and discussed with the Project Leader and/or Analyst, with concurrence from the Section Chief, the quality assurance officer, or program coordinator, as appropriate.

Quality control indicators and professional knowledge should be used to identify instances when general analytical procedures are inappropriate based on scientific applicability, interferences, or other problems. Analysts should ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any environmental measurement activity. Particular care should be taken when sampling and tests are performed at sites other than a permanent facility.

9.2.3 Data Interpretation/Review

SESD sampling and measurement data must be evaluated to determine if the results of sampling and measurement activities are adequate to satisfy their intended purpose and are properly documented. The requirements and responsibilities for sampling and measurement data review are discussed in field and laboratory operating procedures. The Project Leader, with input from technical staff, will review the field notes, field measurement data and analytical results in the context of the study objectives. The EPA guidance document *Data Quality Assessment: A Reviewer's Guide (QA/G9-R)* may be used as a data assessment tool.

9.2.4 Report Development

The results of environmental sampling and measurement shall be reported accurately, clearly, and objectively in accordance with SESD operating procedures. Authorized signatories for SESD reports are identified in relevant quality system documents and can include one or more of those listed in this QMP as having quality management responsibilities.

9.3 Equipment Maintenance and Calibration

The SESD field branches have established and implemented an approach for maintaining and calibrating equipment that is adequate for the type and range of environmental data collection and measurement activities that it conducts. Records will be maintained of each item of equipment and all reference materials significant to the environmental data collection performed.

Equipment used for sampling and analysis will be maintained so that it is capable of achieving the accuracy required and conform to the specifications relevant to the measurement activities of concern. Prior to use, equipment will be calibrated or otherwise checked to establish that it meets equipment specifications and relevant procedure requirements. Calibration status of equipment will be noted on the instrument, where appropriate. Calibrations will use standards traceable to national or international standards, where possible.

Any equipment that is defective, suspected to be in error, mishandled, etc., will be taken out of service and clearly identified until repairs, calibration, or verification of that equipment has been performed. Equipment used at SESD for environmental measurements will be handled, transported, shipped, stored, and used in a manner that prevents damage, contamination, and deterioration. Equipment will be handled in accordance with safety precautions and guidelines. Equipment that has been used or has been outside SESD's permanent control, transported, or otherwise moved, will be calibrated or otherwise checked to establish that it meets the equipment specification requirements and relative procedure requirements prior to use. Personnel using equipment for measurement activities will be trained and authorized by supervisors to do so.

10 Quality Assessment and Response

The goal of the field branches is to generate scientifically sound and legally defensible information. Assessments are used to evaluate work products for integrity and quality and to define the usability of the information generated. SESD also uses the assessments to identify opportunities for improving our quality system.

The Field Quality Manager (FQM) is responsible for coordinating quality assessments and ensuring the findings are communicated to management. All findings will be addressed at the lowest administrative level possible. If the FQM and managers within the field branches are unable to resolve a finding, the Regional Quality Assurance Manager will be consulted. The SESD Director is the final authority for resolving any disputes resulting from these assessments. Management is responsible for ensuring the integrity of the information generated. Quality assessments can include:

1. Internal Review
2. Administrative Review
3. Internal and External Audits
4. Competency Evaluation and Proficiency Testing Program
5. Management Review
6. Customer Feedback
7. Complaints
8. Nonconforming Work
9. Corrective Action.

It is the responsibility of the Field Quality Manager and the Section Chiefs to ensure all findings from quality assessments are communicated to the staff. This may be accomplished through emails, training, or direct communication.

10.1 Internal Review

Internal review includes reviews conducted during project acceptance/planning, sampling and measurement activities, report development/review, and project assessment. Guidelines for conducting and documenting these reviews are discussed in relevant procedures and guidance. The Section Chiefs are responsible for confirming that applicable internal reviews have been completed and documented prior to transmitting results outside SESD.

Internal reviews for measurement activities include evaluating data/information for accuracy, completeness, and appropriateness to meet data quality requirements for the study objective(s).

10.2 Administrative and Technical Review

Administrative and technical reviews are conducted for quality assurance project plans and reports. Administrative review of quality assurance project plans and reports can include identifying and correcting typographical errors, determining if report pages are numbered; determining if project records show project numbers, the name of the sampler, and dates

associated with performance of the measurement activities. Administrative reviews are also conducted for project files. The review includes a check that the records are complete and accurate and that appropriate records are present.

Technical review of quality assurance project plans and reports consists of verifying that the information included in the report is complete and accurate and that interpretations of data and other technical findings are correct.

10.3 Internal and External Audits

Internal and external audits are an integral part of SESD quality assessment. SESD schedules internal audits of the quality system annually and submits to external audits from accrediting bodies and the Regional Quality Assurance Manager. SESD receives written audit reports from both internal and external audits and responds with documented corrective action, as appropriate and as required.

10.4 Competency Evaluation and Proficiency Testing Program

Managers within the field branches are responsible for determining the areas of competency for their employees. Management designates at least one Subject Matter Expert (SME) for each field measurement, field sampling, and analytical procedure. This individual is an experienced staff member with extensive knowledge of the procedure under consideration. They are responsible for conducting competency evaluations under the quality system.

A competency evaluation is designed to evaluate personnel to determine if they have acquired the required skills and knowledge to independently conduct measurement, sampling, or analytical procedures. New staff members or staff acquiring new skills must have satisfactorily completed training and been deemed competent by the SME for the measurement, sampling, or analytical procedure under consideration before being authorized to work independently. The competency evaluation may use real or simulated sampling, measurement, or analytical activities.

EIB and EAB staff are required to complete an internal proficiency test for all accredited measurement, sampling, and analytical procedures, for which they work independently, every four years. This test may be conducted by an SME or any other staff member that is currently proficient for the field or laboratory procedure under consideration. Proficiency tests can be performed using real or simulated activities and can include on-the-job evaluation by experienced personnel. Each staff member authorized to work independently must have successfully completed a competency evaluation and be currently proficient prior to independently conducting a field or laboratory procedure.

Additionally, each year, one staff member will participate in an externally administered proficiency test for one field measurement procedure. The Field Quality Manager will be responsible for coordinating the Competency Evaluation and Proficiency Testing program and all related documentation.

10.5 Management Review

Annually, the Director, Deputy Director and the managers from the field branches in conjunction with the Field Quality Manager conduct a review of the SESD Field Branches Quality System to gauge whether the quality system is being successfully implemented and to identify opportunities for improvement. Patterns or issues that can affect project commitments or performance quality are identified using audit findings, corrective actions, external complaints, customer feedback, briefings, progress reports, and other internal assessments. This review also fosters effective two-way communication to promote an environment in which properly trained personnel can perform their jobs. The Field Quality Manager evaluates project efforts and work products which may be used for refining acceptance criteria for projects. Furthermore, SESD management supports the Field Quality Manager in his/her efforts to assess situations, identify any problems/issues, and recommend appropriate solutions.

As problems that need attention are identified through the various assessments, management will facilitate a corrective action process to determine satisfactory solutions, while recognizing that those who actually do the work are best suited to focus on the issues and recommend the most effective solutions.

10.6 Customer Feedback

The Branch and Section Chiefs work closely with their counterparts in the Regional office to adjust the priorities of the field branches to ensure the data provided meets each program's needs. Management also seeks feedback from customers to monitor the performance of the field branches in relation to the work performed.

10.6.1 Field Investigations

Managers within the field branches will seek feedback from customers to assess the quality of their work products. Although the managers and technical staff typically receive customer feedback as a regular part of their interaction with their customers, a formal evaluation of customer satisfaction will be sought either using customer feedback surveys or during meetings with customers.

For projects with interaction between SESD Project Leaders and the customer, customer satisfaction will typically be evaluated using surveys. At the completion of projects, a Customer Feedback Form 1 (SESDFORM-019, most recent version) will be transmitted to the customer for all SESD Category 1 projects and for a minimum of 10% of Category 2 and 3 projects for each field branch (See SESD Procedure for Project Planning for a description of project categories). The actual percentage for each category will be determined by the FQM on an annual basis.

Some projects such as Compliance Evaluation Inspections, Performance Audit Inspections and Compliance Sampling Inspections are governed by EPA regulations and require limited customer/project leader interaction. Customer satisfaction will be sought for these types of projects at least annually during meetings with SESD managers and the

customers requesting the projects. When feedback is sought during meetings, the Customer Feedback Form 2 (SESDFORM-022, most recent version) will be completed by SESD management.

The Section Chiefs will forward the original copies of the feedback forms to the FQM. Feedback will be evaluated by the FQM to identify opportunities for improvement with the Field Branches Quality System. The results will be evaluated by management and the Field Quality Manager during the annual Management Review.

10.6.2 Analytical Services

Most customers receiving analytical services from the field branches laboratories are in-house Project Leaders, although some services are conducted directly for other external Federal and State Agencies. For internal analytical services, a request for customer feedback is automatically included with every electronic report that is generated. The cover page of the report also includes a quicklink to a Customer Survey Form which can be used to provide feedback to the laboratories. Surveys of customer service are conducted for 10% of external customers by the Aquatic Biology Section Chief. The results are documented on the Customer Feedback Form 2 (SESDFORM-022, most recent version).

The original forms will be maintained by the Field Quality Manager for each fiscal year. The results will be evaluated by management and the Field Quality Manager during the annual Management Review to identify potential areas of improvement in the SESD Field Branches quality system, analytical services, and customer service.

10.7 Nonconforming Work

Nonconforming work includes any field sampling, measurement, or other work performed by personnel under the scope of the Field Branches Quality System that does not follow the requirements of the Quality Management Plan or the SESD Field Branches Operating Procedures. Anytime there is a nonconformance within the Field Branches Quality System that impacts the work or results of the work conducted, management, the FQM and staff will work together to ensure the nonconformance is resolved. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations, record reviews and internal or external audits. When a nonconformance has been confirmed, an evaluation of the significance and acceptability of the nonconforming work will be made by the Field Quality Manager in consultation with management. Actions to correct the nonconformance will be taken immediately, if appropriate. When nonconforming work occurs, project leaders, laboratory analysts, management and the Field Quality Manager have the authority and responsibility to stop work if appropriate. If work is stopped, the Field Quality Manager or management will determine when it is appropriate for work to resume. The customer will be notified of the nonconforming work and actions taken as soon as possible, depending on the nature of the nonconformity.

10.8 Complaints

All complaints will be evaluated by management and resolved in a timely manner. The Section Chief will contact the source of the complaint to discuss the substance and details of the relevant issue. If the issue is associated with the field branches quality system, the Section Chief will consult the Field Quality Manager to determine if the complaint is a nonconformance that warrants a corrective action.

10.9 Corrective Action

Corrective actions will be taken when nonconforming work or departures from the policies and procedures in the field branches quality system or technical operations are identified that may create the potential for the nonconformance to recur or cause an adverse impact on the quality of the work generated. Management in conjunction with the FQM will designate personnel to conduct an evaluation to determine the root cause of the problem. The designated personnel will formulate a recommendation for addressing the issue. The recommendation will be commensurate with the magnitude and risk of the problem. Management will approve the recommendation and ensure the action(s) are implemented. The Field Quality Manager will monitor the results of the corrective action to ensure the action(s) taken are effective. Records of the corrective action will be maintained by the Field Quality Manager.

11 Quality Improvement

Management actively supports quality improvement by encouraging staff to:

1. Continually evaluate the adequacy, implementation, and effectiveness of current policies, procedures, and practices through preventive actions and internal auditing of the quality system.
2. Apply innovative approaches while maintaining integrity and accuracy.
3. Respond to corrective action requests and search for the root cause.
4. Take appropriate actions by planning, documenting and implementing responses to findings in a timely manner.

SESD personnel use the assessment process to identify opportunities for continually improving sampling and measurement procedures. Improvement can take the form of preventing quality problems from occurring by adjusting current work processes.

SESD personnel are encouraged to continually search for improved ways to conduct field sampling and measurement activities. SESD personnel actively participate in discussions defining project objectives and data quality requirements and in developing and assessing standard procedures. SESD personnel are involved in establishing specifications for suppliers of goods and services. These efforts can lead to introduction of new quality management tools and requests for on-site training or individual off-site training.

12 Safety, Facilities, and Security

SESD management is responsible for insuring that all personnel have the opportunity to take the safety training required to minimize the risk of accidents or exposure during field and laboratory operations. Equipment and facilities will be provided to insure that all work is completed in as safe a manner as possible.

12.1 Safety and Health

Safety and health are an integral part of the SESD Quality System, because SESD management philosophy is that a safe workplace is essential for the long term success of the quality system. The SESD Safety, Health and Environmental Management Plan (SHEMP):

1. assists management in developing policies and procedures focused toward a safe working environment,
2. develops and directs a program that is adequate to protect the safety and health of SESD management and staff,
3. implements applicable EPA and OSHA regulations, and
4. conducts specialized training programs to meet the safety needs of SESD measurement activities.

The SESD SHEMP is the mechanism that ensures that appropriate issues are considered prior to the initiation of measurement activities. The program includes the following key elements.

1. Policies, Plans, Programs, and Procedures - Address requirements of federal, state, and local laws and regulations, as well as the Agency Occupational Health and Safety Manual 1440, Agency Orders, Directives, and Guidelines. This function includes preparing and updating documents that describe the SESD program.
2. Occupational Health and Safety Committee (OHSC) - Meet to address health, safety, and environmental compliance issues. The committees are composed of representatives from each SESD Branch, a management representative, and the SESD SHEMP Coordinator.
3. Training - Includes field and laboratory safety, first aid and CPR, driving safety, supervisory safety training, office safety, hazardous waste training, radiation safety, and other pertinent training.
4. Audits, Inspections, Investigations, and Hazard Control - Includes planning reviews and associated reporting and record keeping to identify, prevent, and/or abate health and safety problems.

5. Occupational Medical Monitoring - For staff who may be exposed to chemical, biological, radiological or other agents, or who may experience physical stress during their work.

12.2 Facilities

SESD management is committed to providing adequate work space(s) and measurement facilities that:

1. Provide facilities for the monitoring, control, and recording of environmental condition(s) where they can influence the quality of results.

Note: In addition to work conducted at the SESD laboratory and Field Equipment Center, many measurements are conducted in the field where environmental conditions cannot be controlled. Every effort will be made by field investigators to minimize the impact of environmental conditions on measurement and sample results. Field measurement and sampling will be halted when environmental conditions jeopardize the quality of the data. Whenever environmental conditions affect results, it will be noted in the field logbook and if relevant, discussed in the final report.

2. Provide effective separation between neighboring areas when the activities there are incompatible.
3. Provide adequate and appropriate space for records, reference publications, and other necessary documents.
4. Provide adequate housekeeping/cleanliness and order to facilitate efficiency, protect integrity of samples, and protect the health and safety of personnel.
5. Provide safety features such as fume hoods; fire detection, alarm and fire suppression systems; eyewash and safety showers, and first aid and spill kits, as required.
6. Provide for safe, secure storage of project samples and analytical chemicals in environmentally controlled storage areas, as appropriate.
7. Provide for appropriate working and walking surfaces, means of egress, lighting, ventilation, and electrical service.

12.3 Security

SESD follows the Region 4 security policy, a security operating procedure, and an evidence management procedure that details measures that provide for security of personnel, equipment, facilities and work product. Defined in the policy and procedures are:

1. Building and laboratory security provisions including key cards and hard key issuance and control, as well as visitor security requirements.

2. Restriction of operational areas of SESD to authorized personnel.
3. Provisions for the secure handling of evidentiary materials for both civil and criminal enforcement cases.
4. Provisions for confidential information.
5. Provisions for safe storage and preservation of evidentiary documents, work product documents and records.
6. Telecommunication and computer hardware and software protection and security.

Access to the SESD laboratory is limited by the use of keycards. EPA employees and ESAT contractors are issued keycards for use at all main entrances of the building. Visitors are required to enter through the main entrance at the front of the building and sign a visitor's log. Security personnel then issue them a visitor's badge. All visitors are required to have an escort while in the laboratory.

When samples are returned to the SESD laboratory for analysis, they are placed in the custody room. The custody room is controlled with keycard access. The entry is monitored by computer and each time the card is used the name of the individual assigned to the card, the date, and the time of the entry is stored electronically. Authorized entry is coordinated with the Facilities Manager by each Branch Chief submitting a memo listing all staff authorized for entry. This list will be updated whenever there is a change of personnel. It is the responsibility of the Facilities Manager to ensure that the authorized names are properly entered into the computer.

Figure 1: EPA Region 4 Organization Chart

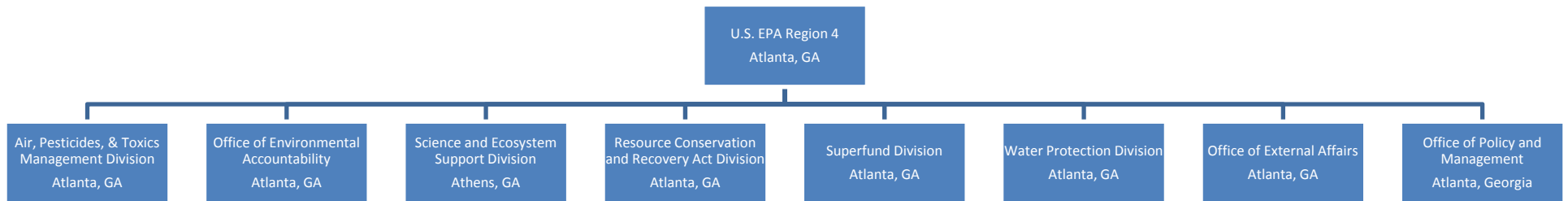


Figure 2: SESD Organization Chart

