

Quality Management Plan For

EPA Region 4 Science and Ecosystem Support Division

980 College Station Road Athens, Georgia 30605

April, 2011

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LIST OF ACRONYMS

ASB - Analytical Support Branch
CERCLA - Comprehensive
Environmental Response,
Compensation and Liability Act
CWA - Clean Water Act
DQO - Data Quality Objectives
EAB - Ecological Assessment Branch
EIB – Enforcement and Investigations
Branch
ESAT - Environmental Services
Assistance Team
NPDES - National Pollutant Discharge
Elimination SystemOTOP – Office of
Technology Operations and Planning
QAS - Quality Assurance Section

PO - Project Officer **QA** - Quality Assurance **QMP** - Quality Management Plan **QAPP** - Quality Assurance Project Plan **QC** - Quality Control **RCRA** - Resource Conservation and Recovery Act **RQAM** - Regional Quality Assurance Manager **RA** - Regional Administrator **SDWA** - Safe Drinking Water Act **SESD** - Science and Ecosystem Support Division **SOP** - Standard Operating Procedure **START** - Superfund Technical Assistance and Response Team

Science and Ecosystem Support Division Quality Management Plan Revision 3 April, 2011

1.0 QUALITY MANAGEMENT PLAN IDENTIFICATION FORM

Document Title Quality Management Plan

Organization Title EPA Region 4 Science and Ecosystem Support Division

Address 980 College Station Road, Athens, Georgia 30605

Plan Coverage: <u>This quality management plan (QMP) documents the quality system of the EPA Region 4 Science and Ecosystem Support Division. This management plan serves as a supplement to the Region 4 Quality Management Plan and is intended to meet the requirements of Section 6.1 of that document that each division have a QMP. This plan covers quality assurance policies, roles and responsibilities for environmental data collection activities within the division. The SESD QMP will be reviewed annually and updated whenever elements of the quality system change.</u>

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2.0 QUALITY ASSURANCE POLICY and DEFINITIONS

This management plan serves as a supplement to the Region 4 Quality Management Plan and is intended to meet the requirements of Section 6.1 of that document that each division have a QMP. This QMP does not supersede the Region 4 QMP, but complements it by describing quality assurance policies and procedures which are specific for the USEPA Region 4 Science and Ecosystem Support Division (SESD). SESD's quality assurance policy is that environmental data used to support Agency decisions are of suitable quality and are usable for their intended purpose. It is also divisional policy that the quality system and operations of SESD are in conformance to EPA Order CIO 2105.0 (formerly 5360.1 A2), "Policy and Program Requirements for the Mandatory Agency-Wide Quality System".

This Quality Management Plan (QMP) describes the quality systems of SESD. A quality system is defined in Section 2.1 below. This document is intended for use by SESD managers and staff. The document provides a link between the Agency's quality assurance (QA) policy as defined in EPA Order CIO 2105.0, and the implementation of this Agency Directive in SESD.

The following definitions are essential to understanding the roles, responsibilities, policies, and procedures outlined in this document.

- 2.1 Quality System A structured and documented management system describing the quality assurance policies and procedures for (1) ensuring that environmental data are of known and documented quality; and, (2) that environmental technology is designed, constructed and operated in a manner to produce the desired environmental results.
- 2.2 Environmental Data Information collected directly from measurements, produced from models, or compiled from other sources such as data bases or literature, which are used for decision making purposes.
- 2.3 Quality Assurance (QA) An integrated system of activities including planning, implementation and assessment to ensure that environmental data are of known and documented quality, and that environmental technology produces the desired results.
- 2.4 Quality Control (QC) The overall system of technical activities that measure the performance of a process or item against defined standards to ensure that the process or item meets the pre-defined standards of the

customer.

- 2.5 Quality Assurance Project Plan (QAPP) A critical planning document for a project or task, describing how data collection activities are planned, implemented and assessed.
- 2.6 Data Quality Objectives (DQOs) A systematic planning system designed to produce qualitative and quantitative statements that clarify project objectives, define the appropriate type of environmental data, and specify tolerable levels of decision error.
- 2.7 Graded Approach The process of selecting the elements needed in a project-level planning document based on the degree of confidence needed in the environmental data and the intended use of the results.

3.0 MANAGEMENT and ORGANIZATION

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

SESD is strongly committed to sound science and QA practices which will produce environmental data of appropriate quality to be used for decision making. The commitment is achieved by ensuring that adequate and acceptable planning, implementation, and assessment procedures are utilized through all phases of projects/tasks which require the generation or use of environmental data.

Divisional managers and staff assure that there are sufficient QA activities to provide reasonable confidence that all environmental data generated are scientifically valid, of adequate statistical quantity, of known precision and bias when required, of acceptable completeness, representativeness, and comparability, legally defensible. SESD consists of four branches, the Analytical Support Branch (ASB), the Ecological Assessment Branch (EAB), the Enforcement and Investigations Branch (EIB), and the Management and Technical Services Branch (MTSB). SESD's organizational chart is shown in Appendix A.

Within SESD, the Branches have the following major responsibilities:

<u>Analytical Support Branch</u> - Provides environmental chemistry data for decision making in EPA's media programs. This is achieved by maintaining a fully equipped environmental laboratory and a technically skilled, properly trained and dedicated staff that produces physical and chemical data of a known and defensible quality. ASB provides environmental data at the request of data users within the Agency, no data are reported to outside clients. This Branch is accredited under the National Environmental Laboratory Accreditation Program. ASB's quality system is detailed in the <u>Analytical Support Branch Laboratory</u> <u>Operations and Quality Assurance Manual</u>

<u>Ecological Assessment Branch</u> - Provides a wide range of biological and engineering sciences to provide a multidisciplinary approach to ecosystem assessment and management. The Branch is accredited under ISO 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories. The branch's quality system is detailed in the SESD Field Branches Quality Management Plan. Branch services include:

- Surface water quality studies which include nutrient loading, algal toxicity and eutrophication.
- Benthic macroinvertebrate and sediment quality characterization in inland, estuarine, and marine systems.
- Wetlands characterization including functional assessments, jurisdictional delineations, and soils biogeochemistry.
- Oxygen dynamics (sediment oxygen demand, reaeration, and community oxygen metabolism) and wasteload allocation studies.
- > Algal assay and chlorophyll a testing.
- Criminal Investigations including specialized water quality studies.
- QA and technical reviews of environmental study plans (QAPPs) and reports.

<u>Enforcement and Investigations Branch</u> - Conducts environmental field studies pertaining to all media including air, water, wastewater, groundwater, soil, sediment, and waste. The Branch is accredited under ISO 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories. The branch's quality system is detailed in the SESD Field Branches Quality Management Plan. Branch services include:

- Site Characterizations and Criminal Investigations which include Superfund, RCRA, Water and Air Studies.
- > Technical Assistance and Training.
- > Review of environmental study plans and investigative reports.
- > Overviews of State and private consulting environmental activities.
- Air Technical System Audits, Air Performance Audits, QA Reviews, Data Validation.

<u>Management and Technical Services Branch</u> - Provides quality service in a variety of support functions. The Branch is comprised of the Program Support Section and the Quality Assurance Section.

- The Branch Chief serves as the Region 4 Quality Assurance Manager. Additional details on the RQAM roles and responsibilities can be found in Section 4.2.2 of the Region 4 Quality Management Plan.
- The Program Support Section provides administrative support including: personnel, payroll, property, budget (travel, training, and procurement), information management and computer support, fleet management, and management of the Field Equipment Center (equipment and supplies for field investigations).
- The Quality Assurance Section provides support to various regional programs including Safe Drinking Water and Clean Water Acts, Superfund, RCRA, and Criminal Investigations. The goal of the office is to assure environmental data of acceptable quality which can be used to make sound environmental decisions. The Quality Assurance Section includes a diverse group of chemists, microbiologists, and environmental scientists who assist Agency, state, tribal, and private organizations in planning, implementing and assessing data collection activities. The section provides the following services:
 - o Laboratory Evaluations and Investigations
 - o Data Validation
 - o Quality Assurance Management and Project Plan Reviews
 - o Manage the Regional Quality Assurance Program
 - Manage Analytical Services/Support Contracts

4.0 QUALITY SYSTEM and DESCRIPTION

The Division falls under the overall umbrella of the Region 4 QMP. This document does not duplicate details of the regional quality system found in the regional QMP, but only those quality system components which are unique to SESD. 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 EPA management. The primary function of SESD's data collection activities is to provide technical support to the Region 4 Program Offices through sample collection and measurement, 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, 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.

Within SESD, three of the four branches' primary mission is the generation of environmental data through sample collection and analysis; these branches are ASB, EAB, and EIB. Both the laboratory (ASB) and field (EAB and EIB) quality systems are structured to complement the Region 4 QMP. All SESD quality systems are designed to conform to EPA Order CIO 2105.0, the EPA Quality Manual, and the specific accreditation standard under which the laboratory and field branches operate. SESD's branches have procedures for reviewing each quality system to evaluate its continuing suitability and effectiveness and to introduce necessary changes and improvements. Details of these procedures are found in the specific quality documents of the laboratory and field branches:

ASB's quality system is detailed in the <u>Analytical Support Branch</u> <u>Laboratory Operations and Quality Assurance Manual</u> (http://www.epa.gov/region4/sesd/asbsop/asbsop.html). As a NELAP- accredited laboratory, ASB's quality system conforms to the requirements of the National Environmental Laboratory Accreditation Conference (NELAC) 2003 standard (http://www.nelacinstitute.org/docs/2003nelacstandard.pdf).

The EAB and EIB quality system is detailed in the <u>SESD Field Branches</u> <u>Quality Management Plan:</u>

(http://www.epa.gov/region4/sesd/fbqstp/index.html).

These branches are accredited under ISO 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories. The quality system is structured to be compliant with the Region 4 Quality Management Plan (most recent version), 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).

5.0 PERSONNEL QUALIFICATIONS and TRAINING

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 Agency's Human Resources staff verifies that the applicant meets the OPM education and experience requirements for the appropriate series and grade. After the verification process is complete, SESD managers are allowed to hire an applicant who meets the OPM requirements from a certificate of eligible candidates.

EPA staff is assisted by an on-site contract staff (Environmental Services Assistance Team or ESAT). 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 EPA. EPA will evaluate all new hires and communicate concurrence or non-concurrence.

When EPA proposes new areas of support or requests additional contract personnel, EPA will provide detailed task descriptions to the ETM. 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 EPA and submit the candidate's complete resume. EPA will evaluate all new hires and communicate concurrence or non-concurrence. In all contractors hiring, the ETM will offer the candidate the position only after the EPA Contract Officer has modified the contract to include the new ESAT employee.

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 Quality Managers maintain records of professional development and quality system training received for personnel within the data generating 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 Quality Managers, Section Chiefs, and Project Leaders will ensure that such personnel work within the parameters of the SESD Quality System. Details of specific training requirements are found in the laboratory and field quality system documents referenced in Section 3.

ESAT contractor management is responsible for ensuring contract personnel are properly trained and qualified to perform technical operations for the SESD's technical operations. 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 SESD's designated schedule.

6.0 PROCUREMENT of ITEMS and SERVICES

SESD has established procedures for purchasing services and supplies as documented by the respective branches. 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 field and laboratory 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. If inspection or subsequent quality control checks indicate that purchased items are unsuitable for their intended use, the purchasing official will be notified. The purchasing official will then contact the vendor to return the item and obtain replacement supplies. The laboratory and field managers keep records of unsuitable supplies to track trends and determine if vendors should be avoided because of quality reasons.

7.0 DOCUMENTS and RECORDS

The field and laboratory branches have implemented and documented a process to control documents and information that relate to their respective quality systems. 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.

The field and laboratory branches have 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.

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.

8.0 COMPUTER HARDWARE and SOFTWARE

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. When 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 or during development. 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 OTOP. Regional PC site coordinators and/or system administrators are responsible for evaluating software to determine its performance capabilities and documentation requirements.

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 employees PCs and laptops. Employees must request and receive branch chief approval to have any non-standard software installed on Agency computers by the specialists in MTSB.

Files stored of 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 SESD SOP "SESDPROC-011-R3, Field Sampling Quality Control", Section 4.4, and in <u>Analytical Support Branch Laboratory Operations and Quality Assurance Manual, Section 5.5.</u>

9.0 PLANNING

Planning, implementation and assessment processes are necessary to effectively conduct environmental data collection operations. SESD's quality system includes activities in the planning, implementation and assessment phases. The two field branches, EAB and EIB, conduct all project planning activities for the division. The planning process is documented in a QAPP, the implementation phase is performed and overseen by the project manager/leader, and the assessment phase is conducted as specified in the applicable project planning document. SESD uses the graded approach in project planning. Specific details on project planning procedures are found in the SESD Field Branches Quality Management Plan. The quality system components described below are used for the collection of environmental data by SESD personnel.

Data Quality Objectives

The data quality objectives (DQOs) process is a systematic planning process 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 <u>Guidance on Systematic Planning using the Data Quality Objectives Process</u> QA/G-4, EPA/240/B-06/001(February 2006) ; and <u>Data Quality Assessment: A Reviewer's Guide</u>

QA/G-9R, EPA/240/B-06/002 (February 2006). The Agency's DQO process is the preferred method of developing objectives for those projects requiring the collection of environmental data or the use of environmental technology. However, any systematic planning process may be used 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 decision maker (i.e., Branch Chief, Section Chief, Project Manager, etc.) is responsible for initiating the DQO development process. During the early planning phase of the investigation, the data user must clearly establish the intended use of the data, time and resource constraints, and in general terms, the quality of data needed. The project manager (this position may also be referred to as 'Project Leader' within SESD) 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 manager, 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. The application of the data quality objectives process is explained in SESD Operating Procedure for Project Planning, SESDPROC-016, most recent version.

Note: Many data collection activities mandated by EPA already have project objectives and data quality indicators (such as precision, accuracy and comparability) specified in the applicable regulations or in the methodology required by the regulations. In these instances it may not be necessary to proceed through all phases of formal DQO development.

Quality Assurance Project Plans

SESD relies on QAPPs (also still commonly referred to as a Study Plan within SESD) coupled with detailed SOP's to define specific project QA/QC requirements. In preparing a QAPP, the project manager 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, Final, March 2001, 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, Final, December 2002, provides a detailed look at the process of developing a QAPP. Within the region, different organizations may refer to the project-level planning document using terms such as "sampling and analysis plan" or "study plan."

elements specified in EPA QA/R-5, while at the same time considering the application of the graded approach to the planning document. The application of the graded approach is explained in the SESD Operating Procedure for Project Planning. QAPP approval is performed by the RQAM or an approved designated approving official (DAO) acting on behalf of the RQAM.

Standard Operating Procedures

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

SOPs are prepared by the SESD branch which has determined that a certain task, procedure, or job function must be performed in a uniform, consistent manner often by multiple personnel. It is necessary that SOPs be prepared by staff who are most knowledgeable in a specific task or procedure. The SOPs are reviewed by appropriate staff in the branch, and at times by technical specialists in other organizations. The SOPs are prepared in document control format by the user and are to be maintained on permanent file. The EPA document entitled "Guidance for the Preparation of Standard Operating Procedures" (EPA QA/G-6), Final, March 2001, should be consulted for an example of a typical document control format. The second level supervisor (Branch Chief or equivalent) approves the SOP for use. SOPs are dynamic documents that are revised as needed. SOP revisions may be the result of changes in regulations, procedures, instruments and equipment, or by inadequacies noted during implementation and/or audits. Revisions are reviewed and approved as described above.

10.0 IMPLEMENTATION of WORK PROCESSES

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.

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.

All samples collected in the field are subject to procedures outlined in the SESD Quality Management Plans and all associated SOPs. 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 protocol(s) used and any deviations from written procedures become part of project records.

Laboratory analysts use a variety of published or written materials to aid them in selecting or developing measurement methodologies. Various EPA programs, including RCRA, CERCLA, NPDES, Drinking Water, and Air Toxics, require or recommend the use of specific analytical methods associated with these programs. For the purpose of generating valid defensible environmental data, the laboratory will use the standard, published, validated methods referenced in the laboratory quality manual whenever possible.

It is extremely rare that new measurement techniques are developed by the laboratory. If a new measurement method is required, its development will be governed by the policies and procedures specified in the <u>Analytical Support</u> <u>Branch Laboratory Operations and Quality Assurance Manual</u> and supporting SOPs. Standardized methods are selected by the analysts in consultation with the appropriate laboratory group leader and/or section chief based on DQOs and other information contained in the QAPP or provided when the samples are scheduled into the lab. Laboratory supervisors or group leaders select the appropriate preparation and determinative methods based on matrix type, required quantitation limit, and known or suspected interferences. The laboratory maintains written standard operating procedures for all analytical methods used in the laboratory to determine the precision and bias associated with the data which is produced. Details of laboratory quality control procedures are found in the Analytical Support Branch Laboratory Operations and Quality Assurance Manual.

11.0 ASSESSMENT and RESPONSE

The Field and Laboratory Quality Managers (QM) are 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 QMs and managers within the field and laboratory 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. Review of Nonconforming Work
- 9. Corrective Action

As a condition of the laboratory's continuing accreditation under the National Environmental Laboratory Accreditation Program (NELAP) and the field accreditation under ISO 17025, on-site external assessments by the accrediting bodies (AB) are required. An on-site external assessment is required once every two years under both accreditations. In addition, EPA's Office of Groundwater and Drinking Water conducts an on-site assessment of the Region 4 Drinking Water Laboratory Certification Program every three years. The accredited organizations are required to respond in writing to the AB for all findings and corrective actions initiated. These documents are maintained as part of the official divisional records.

It is the responsibility of the Field and Laboratory Quality Managers 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. Additional details for quality assessment and response are found in the <u>Field Branches Quality Management Plan</u> and the <u>Analytical Support</u> <u>Branch Laboratory Operations and Quality Assurance Manual</u> and supporting SOPs.

12.0 TRAINING

Each divisional manager ensures that all personnel performing duties which require the use of environmental data or technology will have the needed education, experience, and training. Formal education and experience are prerequisites of each federal job series. Personnel who may require QA training include, but are not limited to, laboratory technicians, analysts, supervisors, project officers, project managers, field project leaders, and regional QA staff. QA training needs will be identified by supervisors during annual performance evaluations and through career development plans. Supervisors should contact the RQAM to determine if the identified training needs can be met through regional training provided by the RQAM/staff, or if other sources are needed for the training. The RQAM will assist the supervisor in locating the most appropriate QA training to meet the need which has been identified.

Appendix A

SESD ORGANIZATIONAL CHART

