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OPERATING PROCEDURE

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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>SESDPROC-016-R2, <i>Project Planning</i>, replaces SESDPROC-016-R1</p> <p>Title Page: Changed the following: Author and Field Quality Manager from Laura Ackerman to Liza Montalvo; and Enforcement and Investigations Branch Chief from Antonio Quinones to Archie Lee.</p> <p>Revision History: Changed Field Quality Manager to Document Control Coordinator.</p> <p>Section 1.3: Omitted reference to the H: drive. Changed the Field Quality Manager to the Document Control Coordinator.</p> <p>Section 2.3.2: Omitted reference to the H: drive.</p> <p>Section 2.3.4: Added that the amended QAPP will be reviewed.</p> <p>Section 2.3.5: Added last sentence in first paragraph stating that the QAPP will be available where the study is taking place. Added statement in second paragraph regarding transmittal of the draft QAPP to the customer for review.</p> <p>Section 2.3.6: Replaced “must” and “should” with “will”.</p> <p>Section 2.4: Added section on sample scheduling.</p> <p>Table 1: Added examples for Cat. 2 and 3.</p>	<p>September 8, 2010</p>
<p>SESDPROC-016-R1, <i>Project Planning</i>, replaces SESDPROC-016-R0</p> <p>Title Page Changed title for Antonio Quinones from Environmental Investigation Branch to Enforcement and Investigations Branch.</p> <p>Section 2.3.6 Changed first sentence to reflect that site safety plans are required for hazardous waste site investigations and for Ecological Assessment Branch projects involving data collection.</p>	<p>November 1, 2007</p>
<p>SESDPROC-016-R0, <i>Project Planning</i>, Original Issue</p>	<p>September 24, 2007</p>

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1 General Information

1.1 Purpose

The purpose of this procedure is to describe the processes of project planning and quality assurance project plan preparation for projects conducted by SESD field investigators.

1.2 Scope/Application

This procedure addresses projects conducted by SESD field investigators.

1.3 Documentation/Verification

This procedure was prepared by persons deemed technically competent by SESD management, based on their knowledge, skills and abilities. The official copy of this procedure resides on the SESD Local Area Network (LAN). The Document Control Coordinator (DCC) is responsible for ensuring the most recent version of the procedure is placed on the LAN and for maintaining records of review conducted prior to its issuance.

1.4 Definitions

1.4.1 Project Leader

The Project Leader is a field investigator designated by management to coordinate the technical support requested by SESD customers. The Project Leader has the primary responsibility for developing quality assurance project plans (QAPPs). During the planning of the project, the Project Leader and Project Manager are responsible for developing data quality goals appropriate for the data collection request. 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.

1.4.2 Project Manager

U.S. EPA Region 4 program office contact or the requestor for a project.

1.4.3 Quality Assurance Project Plan

The quality assurance project plan is a document that records the project scope, objective(s), schedule, and quality goals.

1.4.4 D.A.R.T.

SESD's Data Archival and ReTrieval software system for electronic storage of analytical data and field measurements.

1.5 References

EPA Dive Safety Manual, Most Recent Version

EPA Guidance for Quality Assurance Project Plans (EPA QA/G-5), EPA/240/R-02/009.

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

EPA Quality Manual for Environmental Programs, 5360 A1, May 5, 2000.

EPA Science Policy Council Peer Review Handbook, EPA 100-B-98-001, January 1998.

SESD Internal ISO 17025 QAPP Review Checklist (SESDFORM-017, most recent version)

SESD Internal QA/R5 QAPP Review Checklist (SESDFORM-025, most recent version)

SESD Safety, Health and Environmental Management Program (SHEMP) Manual, Most Recent Version.

2 Methodology

2.1 Project Acceptance

Each fiscal year both SESD Field Branches develop Memorandums of Agreement (MOA) with their respective Region 4 program offices based on in-depth discussions of potential field requests. The MOAs outline the field and technical support work that is planned for the fiscal year. Prior to undertaking new projects in existing environmental data collection areas, or commencing new services, managers and staff from the field branches review the projects to ensure that: 1) the requirements, including the methods 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 program requirements. In each MOA the planned projects are subject to change based on reassessments of project priorities by the Region 4 program offices. Section Chiefs will be responsible for maintaining a record of any changes to the MOAs which affect their section.

2.2 Project Leader Assignment

Once SESD agrees to undertake a project, a Project Leader is selected by the appropriate Section Chief and a study team is formed to define and address project objectives. Project Leaders are selected by management based on their knowledge, skill, and experience relative to the objectives of the project.

2.3 Project Planning

2.3.1 General

Following are basic project planning components that project leaders must address:

1. Quality assurance project plan preparation
2. Safety Plan/Float Plan/Dive Plan preparation, as applicable
3. Project team member assignment (in conjunction with Section Chief)
4. Sample booking with laboratory
5. Vehicle reservations
6. Travel authorization preparation
7. Equipment preparation and loadout.

2.3.2 Quality Assurance Project Plans

EPA policy requires that all work performed by or on behalf of EPA involving the collection of environmental data shall be implemented in accordance with an Agency-approved Quality Assurance Project Plan (QAPP). The QAPP provides the mechanism for documenting the results of the planning process. No environmental data collection work should be started until the QAPP has been approved and distributed to project personnel except under circumstances requiring immediate action to protect human health

and the environment. This policy is defined in EPA Order 5360.1 A2 (EPA 2000), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, for EPA organizations.

Project Leaders will design a study and prepare a QAPP based on the project request. If SESD is not able to design a study as specified in the request, the Project Leader and Project Manager will resolve the differences prior to preparation of the QAPP. Project Leaders are responsible for communicating and coordinating project requirements and information with the various participants in the investigation.

The content and level of detail in each QAPP may vary according to the nature of the work being performed and the intended use of the data. The QAPP should provide sufficient detail to demonstrate that:

- the project objectives are identified
- the intended measurements or data acquisition methods are appropriate for achieving project objectives
- assessment procedures are sufficient for confirming that data of the type and quality are obtained, and
- any limitations on the use of the data can be identified and documented.

Depending on the complexity of the project, a systematic planning tool such as EPA's Data Quality Objectives Process may be used for planning. EPA guidance notes that a graded approach to project planning is acceptable based on the complexity of the data collection activity. The graded approach helps ensure that the level of detail in planning is commensurate with the intended use of the work and available resources. For the purposes of project planning, SESD has identified three categories of projects, with varying degrees of complexity.

- Category 1 projects are highly complex environmental studies (multiple media, complex study design and/or DQOs, etc.) which require the most stringent quality assurance approach. The data quality objectives should be fully addressed and include uncertainty analysis and decision error.
- Category 2 projects are environmental studies of moderate complexity. Data quality objectives should be addressed with an emphasis on sampling design and other appropriate inputs. The majority of the studies conducted by SESD will be Category 2 projects.
- Category 3 projects are environmental studies of limited scope and complexity. Data quality objectives are often established by environmental regulations or permits.

Table 1, located at the end of this procedure, contains additional information which describes the attributes of each project category. The Section Chief in consultation with the Project Leader will determine which category individual projects fall within and the level of detail needed in the QAPP.

The EPA Region 4 Quality Management Plan requires that project-level planning documents (i.e., QAPPs) contain the necessary elements specified in the document “EPA Requirements for Quality Assurance Project Plans,” EPA QA/R-5, while at the same time considering the application of the graded approach. QA/R-5 requires the use of standardized, recognizable elements which cover the entire project from planning, through implementation, to assessment. The elements are organized into four groups. Their intent is summarized below:

Group A: Project Management

The elements in this group address the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.

Group B: Data Generation and Acquisition

The elements in this group address all aspects of project design and implementation. Implementation of these elements ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and are properly documented.

Group C: Assessment and Oversight

The elements in this group address the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities during the project. The purpose of assessment is to ensure that the QA Project Plan is implemented as prescribed. The level of assessment varies with the complexity of the project.

- Category 1: A Category 1 project may have external peer reviewers and a Quality Assurance Officer who is responsible for conducting on-site assessments and ensuring the project is being implemented according to the QAPP.
- Category 2: For Category 2 projects, the Project Leader is responsible for all field quality control and quality assurance activities and also for ensuring the project is being implemented according to the QAPP.
- Category 3: For Category 3 projects, the Project Leader is also responsible for all field quality control and quality assurance activities and for ensuring the project is being implemented according to the QAPP, however, assessment activities are commensurate with the scope of the study.

Group D: Data Validation and Usability

The elements in this group address the QA activities that occur after the data collection or generation phase of the project is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving the project objectives.

All applicable groups must be addressed in the QAPP. In general, the level of detail required for the categories of SESD QAPPs is:

Category 1: All applicable QAPP elements should be addressed in detail.

Category 2: All applicable QAPP elements should be addressed with the level of detail commensurate with the complexity of the project. Some elements can be addressed using summary statements.

Category 3: All applicable QAPP elements should be addressed but with considerably less detail. Many elements may be addressed using summary statements.

Table 2, located at the end of this procedure, identifies the elements that are typically required for each project category and those covered by summary statements for Category 2 and 3 studies. SESD has developed QAPP templates for category 2 and 3 projects. The templates are located on the SESD LAN.

2.3.3 Quality Assurance Project Plan Format

In addition to the requirements of EPA QA/R-5, the following information must be included in all SESD QAPPs:

- project title
- signature page (Section Chief, Project Leader, applicable reviewers)
- the name and address of SESD and the location where the field investigation will be conducted;
- unique identification of the QAPP (e.g., by project identification from DART) on each page;
- the page number and the total number of pages (i.e., page x of y) on each page;
- the name and address of the requestor;
- identification of field sampling and/or field measurement procedures that will be used during the project.

2.3.4 *Quality Assurance Project Plan Review and Approval*

The following **internal** reviews will be conducted for each SESD generated QAPP prior to issuing the final version.

1. A technical review of QAPPs will be conducted by qualified SESD staff. Section Chiefs in consultation with the Project Leader will assign a technical reviewer who is familiar with the type of measurements and/or sampling procedures covered in the QAPP.
2. An administrative review will be conducted to ensure there are no grammatical, spelling, punctuation or formatting errors. The administrative review will be conducted in conjunction with the technical review.
3. As required by the Region 4 Quality Management Plan, QAPPs must be reviewed by a designated approving official (DAO) who has been delegated authority to approve QAPPs by the Regional Quality Assurance Officer. All Section Chiefs in the field branches and several field investigators are authorized as DAOs, following DAO training. The Section Chiefs or their designees will serve as the DAOs for SESD generated QAPPs.

The technical and administrative reviews will be documented using the SESD Internal ISO 17025 QAPP Review Checklist (SESDFORM-017). The DAO review will be documented using the SESD Internal QA/R5 QAPP Review Checklist (SESDFORM-025). The forms will be included in the SESD project file.

The results of the reviews will be provided to the Project Leader. If deficiencies are noted during the reviews, the Project Leader will address the deficiencies and re-submit the QAPP to the reviewers, if necessary. Upon completion of the reviews, the Project Leader will submit the QAPP to their Section Chief for approval. The field branches Section Chiefs are responsible for ensuring all three reviews are completed for a project and approving and authorizing distribution of finalized QAPPs. In accordance with EPA policy, all QAPPs will be approved prior to any data collection activities except under circumstances requiring immediate action to protect human health and/or the environment. External Peer Review may be scheduled depending on the nature and complexity of the study. External peer review should be conducted in accordance with the *EPA Peer Review Handbook*, EPA 100-B-98-001.

If circumstances require any significant deviations from the QAPP during the field investigation, the Project Leader will inform the Project Manager and a record of the communication will be made and placed in the SESD project file. If the QAPP must be amended during a field investigation, the Project Leader will inform the Project Manager and the appropriate Section Chief. The Section Chief will ensure that the QAPP is amended, reviewed, and redistributed to all individuals on the QAPP distribution list as soon as possible. Ultimately the Project Leader is responsible for ensuring that data generated during SESD field investigations meets the objectives of the project.

2.3.5 Transmission of Quality Assurance Project Plans

The official QAPP will be a hard copy version transmitted by official correspondence (typically a memo). Final QAPPs may be transmitted electronically to customers at any time after the QAPP has completed the SESD review process and been authorized for distribution by the Section Chief. The Project Leader must document in the project file that the QAPP was transmitted electronically and must show the QAPP recipient(s). The QAPP will be available at the location where the study is taking place.

Draft QAPPs that have completed the initial SESD internal review process will be transmitted to the customer for review. Transmittal may be accomplished via hard copy, FAX, or electronic transmission. The field investigator's immediate supervisor will be copied on all external electronic transmissions. Electronic copies must clearly identify the QAPP as a draft. The Project Leader must document in the SESD project file that the draft QAPP was transmitted electronically and show the person(s) to whom the QAPP was transmitted. Additionally, the Project Leader must inform the receiving parties that all electronic and hard copies of the draft QAPP are no longer valid once they receive the final QAPP. This will also be documented in the SESD project file.

2.3.6 Safety Plans

A site safety plan is required for all field investigations conducted by SESD field investigators at hazardous waste sites and for all Ecological Assessment Branch projects that involve data collection. The Field Branch Safety Officers and Section Chiefs will review and approve project safety plans prior to the project. Safety plans will 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 Safety Plan will be included in the SESD Project File.

When a safety plan is not required for a field investigation, field investigators will adhere to safety protocols described in the SHEMP Manual, Most Recent Version.

2.3.7 Float Plans

A float plan is required whenever field investigators will be using boats as part of the field investigation. 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 should be included in the SESD Project File.

2.3.8 Dive Plans

A dive plan is required for all field operations that involve EPA divers. The dive plan should be prepared by the Dive Master and approved by the Unit Dive Officer prior to the field investigation. Additional information regarding the preparation of dive plans can be

found in the U.S. Environmental Protection Agency Diving Safety Manual, Most Recent Version. A copy of the Dive Plan should be included in the SESD Project File.

2.4 Sample Scheduling and Laboratory Analysis Requests

Projects requiring chemical analyses are routinely scheduled into the Region 4 laboratory information management system (R4LIMS) by project leaders. Each time samples are scheduled, a project number is assigned automatically by R4LIMS. The R4LIMS project number is “passed through” to ELEMENT®, a commercial LIMS for the management and reporting of analytical data, and is used in conjunction with the ELEMENT® work order number for tracking of the analyses.

The project’s chain-of-custody record also serves as a sample logging mechanism for the laboratory sample custodian and it is the final authority used by the SESD Analytical Services Branch for the analytical work performed. Therefore, it is important that the project leader or designee clearly and accurately indicate in the chain-of-custody form the analyses requested for each sample, the number of bottles per sample, preservatives used when applicable, and other pertinent information.

Once the samples are logged into ELEMENT® by the laboratory sample custodian, the laboratory sample custodian will provide a copy of the project’s chain-of-custody record and a copy of the computer print-out (Work Order) from ELEMENT® to the project leader. The project leader will review the work order against the R4LIMS project request and the chain-of-custody record to ensure that the requested analyses are accurate and that the sampling station identification information is correct. If there are any discrepancies, the project leader will contact the laboratory sample custodian or the appropriate ASB manager to address the issue.

Table 1: SESD Project Categories

CATEGORIES	ATTRIBUTES	EXAMPLES	ELEMENTS	DQOs	PEER REVIEW
<p><u>Category 1</u> Projects in this category include the most complex, multi-media studies</p>	<ul style="list-style-type: none"> - complex sampling design - complex data quality objectives - long term studies - extended aerial coverage - multiple media - special QC concerns - complex analytical requirements - methods development studies 	<ul style="list-style-type: none"> - Everglades Study - West Louisville Air Toxics Study - Larger Remedial Investigations - Larger Water Quality Studies 	<p>All QA/R-5 elements must be closely reviewed and addressed</p>	<p>Fully addressed including uncertainty analysis and decision error, use of statistical study designs should be considered</p>	<p>Typically External & Independent</p>
<p><u>Category 2</u> Projects in this category include environmental studies of moderate complexity</p>	<ul style="list-style-type: none"> - moderately complex study design - limited coverage area - limited time frame - routine analytical requirements - routine QC concerns 	<ul style="list-style-type: none"> - RCRA CDIEs and Criminal Investigations - NPDES Diagnostic Evaluations - Superfund field investigations - Drinking water studies - Air monitoring studies - Water quality studies 	<p>QA/R-5 Elements should be evaluated; some may be addressed using summary statements. QAPP template is appropriate.</p>	<p>Addressed with an emphasis on the sampling design and other appropriate inputs, level of uncertainty and decision error typically not defined</p>	<p>Typically Internal</p>
<p><u>Category 3</u> Projects in this category are of limited scope and complexity</p>	<ul style="list-style-type: none"> - limited scope sampling design - single media - limited analytical requirements - no special QC concerns 	<ul style="list-style-type: none"> - NPDES CSIs - Limited scale RCRA CDIEs and Superfund investigations - Limited scope water quality studies - Limited scope air studies 	<p>Limited review of QA/R-5, several elements may be addressed in a summary statement. QAPP template is appropriate.</p>	<p>DQOs often established by program or permit, but may be adjusted as needed</p>	<p>Internal Review</p>

Note: The Section Chief in consultation with the Project Leader will determine which category individual projects fall within and the level of detail needed in the QAPP.

Table 2: QAPP Elements for Project Categories

QAPP Element		Project Category Applicability		
		1	2	3
Project Management				
A1	Title and Approval Sheet	√	√	√
A2	Table of Contents	√	#	#
A3	Distribution List	√	√	√
A4	Project/Task Organization	√	√	√
A5	Problem Definition/Background	√	√	√
A6	Project/Task Description	√	√	√
A7	Quality Objectives and Criteria	√	√	*
A8	Special Training/Certification	√	#	#
A9	Documentation and Records	√	*	*
Data Generation and Acquisition				
B1	Sampling Design	√	√	√
B2	Sampling Methods	√	√	√
B3	Sample Handling and Custody Requirements	√	*	*
B4	Analytical Methods	√	√	√
B5	Quality Control	√	√	*
B6	Instrument/Equipment Testing, Inspection, and Maintenance	√	√	*
B7	Instrument/Equipment Calibration and Frequency	√	√	*
B8	Inspection/Acceptance Requirements for Supplies	√	*	*
B9	Non-Direct Measurements	√	#	#
B10	Data Management	√	*	*
Assessment and Oversight				
C1	Assessments and Response Actions	√	*	*
C2	Reports to Management	√	*	*
Data Validation and Usability				
D1	Data Review, Validation and Verification	√	*	*
D2	Verification and Validation methods	√	*	*
D3	Reconciliation with User Requirements	√	*	*

- √ - Unique for each project and addressed individually
- * - May be addressed using summary statements from QAPP templates
- # - May not be applicable depending on complexity of study