Region 4 U.S. Environmental Protection Agency Laboratory Services and Applied Science Division Athens, Georgia	
Operating Procedure	
Title: Project Planning	**ID: LSASDPROC-016-R6**
Issuing Authority: FSB Branch Chief	
Effective Date: November 23, 2021	**Next Review Date: November 23, 2025**
Method Reference: NA	**Author: Chris McHugh**

Purpose

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

Scope/Application

This procedure addresses projects conducted by LSASD field investigators. This SOP is specific to the Laboratory Services and Applied Science Division to maintain conformance to technical and quality system requirements. While this SOP may be informative for other organizations, it is not intended for and may not be directly applicable to operations in other laboratories. Mention of brand names or vendors does not constitute an endorsement of products or services by the EPA.

Note: LSASD is currently migrating to a paperless organization. As a result, this SOP will allow for the use of electronic logbooks, checklists, and report forms as they are developed, which will also be housed in the LIMS and traceable to each project. LSASD is committed to maintaining its quality system by continued traceability of original observations in the final report as migration to an electronic system occurs.

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General Information

1. Documentation/Verification

1.1. This procedure was prepared by persons deemed technically competent by LSASD management, based on their knowledge, skills, and abilities. The official copy of this procedure resides on the LSASD 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.

2. Definitions

2.1. Project Leader - is a field investigator designated by management to coordinate the technical support requested by LSASD 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.

2.2. Project Manager - Region 4 program office contact or the requestor for a project.

2.3. Quality Assurance Project Plan (QAPP) - is a document that records the project scope, objective(s), schedule, and quality goals. FSB has adopted an overarching QAPP with project specifics detailed in a Sampling and Analysis Plan (SAP).

2.4. S.E.I.S. - LSASD's Environmental Information System for electronic storage of analytical data and field measurements.

2.5. Project Log (R4LIMS) - a graphical user interface that interacts with the Region 4 laboratory information management system. Region 4 laboratory information management system (R4LIMS) is the database system used to generate and manage project identification #s and analytical project numbers.

3. Methodology

3.1. Project Acceptance

3.1.1. Each fiscal year the LSASD Field Branch hold an annual in-depth meeting with their respective Region 4 program offices to discuss potential field requests. Each Region 4 program outlines 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) LSASD 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 meeting the planned projects are subject to change based on reassessments of project priorities by the Region 4 program offices. Requests for projects will be entered into

LSASD project request system by the Program Branch Chief or his/her designee. Section Chiefs will be responsible for maintaining a record of any changes which affect their section.

3.2. Project Leader Assignment

3.2.1. Once LSASD 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. Study team members are assigned by the appropriate FSB Section Chief to address project needs, staff developmental/training needs, and other staff considerations. When projects require in-house analytical support, LSB Management will assign a lab staff member to the project planning team to advise on technical issues.

3.2.1.1. Project Planning - Following are basic project planning components that project leaders must address:

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

3.2.1.2. Quality Assurance Project Plans

3.2.1.2.1. 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. For most field projects, FSB utilizes an overarching QAPP with project-specific Sampling and Analysis Plans.

3.2.1.2.2. Project Leaders will design a study and prepare a QAPP/SAP based on the project request. If LSASD 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.

3.2.1.2.3. 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 most projects, the LSASD SAP Template will be used. For larger scale projects or as requested by the Programs, stand-alone QAPPs may be developed.

3.2.1.2.4. 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:

3.3. Group A: Project Management

3.3.1. 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.

3.4. Group B: Data Generation and Acquisition

3.4.1. 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.

3.5. 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.

3.6. Group D: Data Validation and Usability

3.6.1. 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/SAP.

3.7. Quality Assurance Project Plan Format

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

- project title;
- signature page (Section Chief, Project Leader, applicable reviewers);
- the name and address of LSASD and the location where the field investigation will be conducted;
- unique identification of the QAPP (e.g., by project identification from R4LIMS) 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; and,
- identification of field sampling and/or field measurement procedures that will be used during the project.

3.8. Quality Assurance Project Plan Review and Approval

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

- A technical review of QAPPs will be conducted by qualified LSASD 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.
- 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.
- 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 LSASD generated QAPPs.

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

3.8.1.2. 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.

3.8.1.3. If circumstances require any significant deviations from the QAPP during the field investigation that affect the overall data quality objective, the Project Leader will inform the Project Manager and a record of the communication will be made and placed in the LSASD 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 LSASD field investigations meets the objectives of the project.

3.9. Transmission of Quality Assurance Project Plans

3.9.1. 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 LSASD 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. It is Project Leader's responsibility to ensure that the QAPP is available at the study location, but the method of availability is left to the Project Leader's discretion (e.g. hard copy, electronic copy, etc.).

3.9.2. If appropriate or deemed necessary, draft QAPPs that have completed the initial LSASD internal review process may 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 LSASD project file that the draft QAPP was transmitted electronically and show the person(s) to whom the QAPP was transmitted. Additionally, if a draft QAPP was

transmitted, 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 LSASD project file.

3.10. Safety Plans

3.10.1. A site safety plan is required for all field investigations conducted by LSASD field investigators of the Hazardous Waste Section sites and for all Water Quality Section projects that involve data collection. The Field Branch Safety Officer 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 LSASD Safety, Health and Environmental Management Program (SHEMP) Manual, Most Recent Version. A copy of the Safety Plan will be included in the LSASD Project File.

3.10.2. 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.

3.11. Float Plans

3.11.1. 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 LSASD Safety, Health and Environmental Management Program (SHEMP) Manual, Most Recent Version. A copy of the Float Plan should be included in the LSASD Project File.

3.12. Dive Plans

3.12.1. 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 LSASD Project File.

3.13. Sample Scheduling and Laboratory Analysis Requests

3.13.1. Projects requiring chemical analyses are routinely scheduled into Project log - a graphical user interface that interacts with the Region 4 laboratory information management system (R4LIMS) by project leaders. Each time samples are scheduled; a project number is assigned automatically by Project Log (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.

3.13.2. 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 LSASD Laboratory 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.

3.13.3. 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~~ FSB manager to address the issue.

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.

LSASD Internal ISO 17025 QAPP Review Checklist (LSASDFORM-017, most recent version)

LSASD Internal QA/R5 QAPP Review Checklist (LSASDFORM-025, most recent version)

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

Table 1: LSASD Project Categories

CATEGORIES	ATTRIBUTES	EXAMPLES	ELEMENTS	DQOs	PEER REVIEW
Category 1 Projects in this category include the most complex, multi-media studies	- complex sampling design - complex data quality objectives - long term studies - extended aerial coverage - multiple media - special QC concerns - complex analytical requirements - methods development studies	- Everglades Study - West Louisville Air Toxics Study - Larger Remedial Investigations - Larger Water Quality Studies	All QA/R-5 elements must be closely reviewed and addressed	Fully addressed including uncertainty analysis and decision error, use of statistical study designs should be considered	Typically External & Independent
Category 2 Projects in this category include environmental studies of moderate complexity	- moderately complex study design - limited coverage area - limited time frame - routine analytical requirements - routine QC concerns	- RCRA CDIEs and Criminal Investigations - NPDES Diagnostic Evaluations - Superfund field investigations - Drinking water studies - Air monitoring studies - Water quality studies	QA/R-5 Elements should be evaluated; some may be addressed using summary statements. QAPP template is appropriate.	Addressed with an emphasis on the sampling design and other appropriate inputs, level of uncertainty and decision error typically not defined	Typically Internal
Category 3 Projects in this category are of limited scope and complexity	- limited scope sampling design - single media - limited analytical requirements - no special QC concerns	- NPDES CSIs - Limited scale RCRA CDIEs and Superfund investigations - Limited scope water quality studies - Limited scope air studies	Limited review of QA/R-5, several elements may be addressed in a summary statement. QAPP template is appropriate.	DQOs often established by program or permit, but may be adjusted as needed	Internal Review

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 Category

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

Revision History

History	Effective Date
LSASDPROC-016-R6, Project Planning, replaces SESDPROC-016-R5 **General:** Corrected any typographical, grammatical, and/or editorial errors. Throughout the document certain terms were replaced with their appropriate acronyms. Replaced SESD with the new organization name LSASD. Discussed the use of the Project Log interface with R4LIMS	July 12, 2021
SESDPROC-016-R5, Project Planning, replaces SESDPROC-016-R4 **General:** Corrected any typographical, grammatical, and/or editorial errors. Throughout the document certain terms were replaced with their appropriate acronyms. **Section 2.3.5:** Language was revised to reflect SESD current practice of distributing the draft QAPP to the customer for review if it is appropriate or deemed necessary.	March 31, 2016
SESDPROC-016-R4, Project Planning, replaces SESDPROC-016-R3	July 2, 2015
SESDPROC-016-R3, Project Planning, replaces SESDPROC-016-R2	October 23, 2014
SESDPROC-016-R2, *Project Planning*, replaces SESDPROC-016-R1	September 8, 2010
SESDPROC-016-R1, *Project Planning*, replaces SESDPROC-016-R0	November 1, 2007
SESDPROC-016-R0, Project Planning, Original Issue	September 24, 2007