

Region 4
U.S. Environmental Protection Agency
Laboratory Services and Applied Science Division
Athens, Georgia

Operating Procedure

**Title: Field Sampling and Measurement
Procedures and Procedure Validation**

ID: LSASDPROC-012-R6

Issuing Authority: LSASD Field Services Branch Chief

Review Issue Date: August 6, 2021

Next Review Date: August 6, 2025

Purpose

Laboratory Services and Applied Science Division (LSASD) Field Services Branch (FSB) operating procedures are reviewed at a frequency specified in LSASD Operating Procedure for Document Control (LSASDPROC-1000, most recent version), and where necessary, revised to ensure continuing suitability and conformance with applicable requirements and industry standards. Additionally, there may be the occasion where a new sampling or measurement procedure is developed internally or adapted from an existing standard or non-standard procedure. This document defines the different classes of procedures and describes the process for the development and validation of new LSASD procedures; and the development, review/validation, and approval process to be followed when adopting or revising standard or non-standard procedures.

Scope/Application

This document applies to all standard, non-standard, and LSASD-developed sampling and measurement procedures.

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 LSASD Local Area Network (LAN) 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.

Table of Contents

1. Documentation/Verification _____	3
2. Definitions _____	3
3. Field Sampling and Measurement Procedures _____	3
4. Validation _____	4
5. Procedure Implementation _____	6
References _____	6
Revision History _____	7

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 Quality Assurance Manager 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. Standard Procedure - This term applies to an established environmental sampling or measurement procedure used and accepted within the environmental industry.
- 2.2. Non-Standard Procedure - A non-standard procedure is an environmental sampling or measurement procedure that is not widely used or accepted within the environmental industry.
- 2.3. LSASD-Developed Procedure - A new sampling or measurement procedure developed by the LSASD field branches for internal use.

3. Field Sampling and Measurement Procedures

3.1. Standard Procedures

- 3.1.1. LSASD field investigators use standard procedures while conducting field investigations. LSASD procedures are subject to periodic review and where necessary, may be revised to ensure continuing suitability and conformance with applicable industry standards and requirements. LSASD procedures undergoing periodic review that are updated with minor modifications are not subject to the validation process described in Section 4 of this procedure.
- 3.1.2. New standard procedures may be adopted for use by LSASD field investigators. In addition, as state-of-the-art changes and new instruments, equipment, and procedures are developed and become available, it may be appropriate for LSASD to develop and publish new operating procedures for field measurement and sampling activities.
- 3.1.3. New standard procedures adopted for use by the FSB will not be subject to an extensive validation as described in Section 4 of this procedure. New standard procedures will be evaluated to the extent necessary to ensure the result provided is equivalent to a currently used procedure or consistent results are achieved.

3.2. Non-Standard Procedures

3.2.1. When it is necessary to use a non-standard sampling or measurement procedure, the project leader will:

- Inform the customer in writing (email or memo) that a non-standard procedure will be used;
- Document that the customer agrees with the use of a non-standard procedure; and,
- Document in the project file the customer's request and the need for using a non-standard procedure (i.e., description of the project request and why it required the use of a non-standard procedure).

3.2.2. Non-standard procedures will be fully validated according to Section 4 of this procedure. If the non-standard procedure is not adopted into the scope of the FSB quality system prior to use, any results generated by the procedure must be clearly identified as being outside the scope of the quality system in the field investigation report.

3.2.3. If FSB choose to include the non-standard procedure in the scope of their quality system, this will be done in accordance with the LSASD Operating Procedure for Document Control (LSASDPROC-1000, most recent version).

3.3. LSASD-Developed Procedures

3.3.1. When it is necessary for FSB to develop procedures for their own use, it will be a planned activity and management will designate qualified personnel to develop the procedure. Management will also ensure adequate resources (time, equipment, funding, personnel, etc.) are available to aid in the development process. If a team of staff members is tasked with the procedure development, management will designate an individual to serve as the team leader. This individual will be responsible for facilitating the development process. The development process will consist of:

- Review of relevant literature (manufacturers' documentation, scientific publications, etc.);
- Development of an operating procedure; and,
- Validation of the procedure.

4. Validation

4.1. General

4.1.1. Validation is the confirmation by examination and the provision of objective evidence that the requirements for a specific intended use are fulfilled. LSASD will validate 1) non-standard procedures; 2) LSASD developed procedures; 3) standard procedures used outside their intended scope; and 4) amplifications and modifications of standard procedures to confirm that the procedures are fit for the intended use. Validation will be as extensive as is necessary to meet the needs of the given application.

4.2. Validation Team

4.2.1. LSASD FSB management will designate members of the validation team and ensure adequate resources are available to complete the validation. Members may consist of subject matter experts (SMEs) and representatives from both FSB sections, as appropriate. Management will designate one team member as the team leader. The team leader will serve as the point of contact for the team and facilitate the validation process. The team will be responsible for developing a validation plan that should address, at a minimum, the objective of the validation, acceptance criteria, the level of testing necessary and peer review. The team will update the validation plan, as necessary, during the validation process.

4.3. Field Testing or Evaluation

4.3.1. The validation team will develop an appropriate field test or evaluation for the operating procedure. A member or members of the validation team will be present during the field test or evaluation to record information on the conditions, performance, and practicality of the proposed procedure.

4.4. Assessment

4.4.1. After completion of the field test or evaluation, the validation team will assess the results using the acceptance criteria established by the team in the validation plan.

4.5. Acceptance/Rejection of Operating Procedure

4.5.1. If the assessment indicates that the operating procedure meets the acceptance criteria, the validation team will finalize the operating procedure as written, or with modifications. If the acceptance criteria are not met, the team may continue the validation by returning to earlier steps in the validation process, as appropriate.

4.6. Records

4.6.1. The validation team will document all decisions and actions. The following records will be generated during the validation process:

- Validation plan
- Relevant literature
- Draft and final operating procedures
- Results of field tests and/or evaluations
- Results of the assessment

4.6.2. The validation team leader will be responsible for maintaining the records during the validation process. Upon completion of the validation, the records will be maintained by the Quality Assurance Manager.

5. Procedure Implementation

- 5.1. After a standard or nonstandard procedure has been assessed and accepted for use, the subject matter expert will provide training, to the appropriate staff, on how to correctly implement the operating procedure. Competency will be documented, in accordance with LSASD Operating Procedure for Training and Competency (LSASDPROC-1003, most recent version) for each staff member who will be assigned to implement the operating procedure.

References

LSASD Operating Procedure for Document Control (LSASDPROC-1000), most recent version.

LSASD's Training and Competency (LSASDPROC-1003), most recent version.

Revision History

History	Effective Date
<p>LSASDPROC-012-R6, <i>Field Sampling and Measurement Procedures and Procedure Validation</i>, replaces SESDPROC-012-R4</p> <p>General: Corrected any typographical, grammatical, and/or editorial errors. Throughout the document mention of quality system or SESD quality system was replaced with Laboratory Services and Applied Science Branch Quality System or LSASD. Changed field branches to Field Service Branch. SOP put into the new format. Updated SOP references.</p>	August 6, 2021
<p>SESDPROC-012-R4, <i>Field Sampling and Measurement Procedures and Procedure Validation</i>, replaces SESDPROC-012-R3</p> <p>General: Corrected any typographical, grammatical, and/or editorial errors. Throughout the document mention of quality system or SESD quality system was replaced with Field Branches Quality System or FBQS.</p> <p>Cover Page: Changed the Author from Bobby Lewis to Hunter Johnson. Updated cover page to represent SESD reorganization. John Deatrick was not listed as the Chief of the Field Services Branch.</p>	July 13, 2016
<p>SESDPROC-012-R3, <i>Field Sampling and Measurement Procedures and Procedure Validation</i>, replaces SESDPROC-012-R2</p>	August 30, 2012
<p>SESDPROC-012-R2, <i>Field Sampling and Measurement Procedures and Procedure Validation</i>, replaces SESDPROC-012-R1</p>	December 18, 2009
<p>SESDPROC-012-R1, <i>Field Sampling and Measurement Procedures and Procedure Validation</i>, replaces SESDPROC-012-R0</p>	November 1, 2007
<p>SESDPROC-012-R0, Procedure Development, Revision and Validation, Original Issue</p>	October 10, 2007