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

OPERATING PROCEDURE

Title: Field Sampling and Measurement Procedures and Procedure Validation

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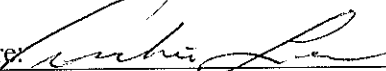
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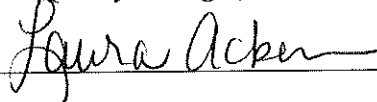
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Revision History

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-012-R2, <i>Field Sampling and Measurement Procedures and Procedure Validation</i>, replaces SESDPROC-012-R1</p> <p>General: Corrected typographical errors.</p> <p>Title Page: Changed 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>	December 18, 2009
<p>SESDPROC-012-R1, <i>Field Sampling and Measurement Procedures and Procedure Validation</i>, replaces SESDPROC-012-R0</p> <p>Revision History: Changed title for Antonio Quinones from Environmental Investigation Branch to Enforcement and Investigations Branch.</p>	November 1, 2007
<p>SESDPROC-012-R0, Procedure Development, Revision and Validation, Original Issue</p>	October 10, 2007

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1 General Information

1.1 Purpose

SESD field branches operating procedures are reviewed periodically, 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:

- Development and validation of new SESD procedures; and
- Development, review/validation and approval process to be followed when adopting or revising standard or non-standard procedures.

All SESD sampling and measurement procedures in use as of February 5, 2007 are considered standard procedures and do not require validation.

1.2 Scope/Application

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

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 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

The following definitions apply to this operating procedure.

1.4.1 Standard Procedure

This term applies to an established environmental sampling or measurement procedure used and accepted within the environmental industry.

1.4.2 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.

1.4.3 SESD-Developed Procedure

A new sampling or measurement procedure developed by the SESD field branches for internal use.

1.5 References

SESD Operating Procedure for Document Control (SESDPROC-001, most recent version)

2 Field Sampling and Measurement Procedures

2.1 Standard Procedures

SESD field investigators use standard procedures in the course of conducting field investigations. SESD procedures are subject to periodic review and where necessary, may be revised to ensure continuing suitability and conformance with applicable industry standards and requirements. SESD procedures undergoing periodic review that are updated with minor modifications are not subject to the validation process described in Section 3 of this procedure.

New standard procedures may be adopted for use by SESD 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 SESD to develop and publish new operating procedures for field measurement and sampling activities.

New standard procedures adopted for use by the field branches will not be subject to an extensive validation as described in Section 3 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.

Documentation supporting the use and acceptance of standard procedures adopted after February 5, 2007 will be maintained by the Field Quality Manager.

2.2 Non-standard Procedures

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

1. Inform the customer in writing (email or memo) that a non-standard procedure will be used;
2. Document that the customer is in agreement with the use of a non-standard procedure; and
3. 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).

Non-standard procedures will be fully validated according to Section 3 of this procedure. If the non-standard procedure is not adopted into the scope of the field branches 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.

If the field branches choose to include the non-standard procedure in the scope of their quality system, this will be done in accordance with the SESD Operating Procedure for Document Control (SESDPROC-001).

2.3 SESD-Developed Procedures

When it is necessary for the field branches 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:

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

3 Validation

3.1 General

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. SESD will validate 1) non-standard procedures; 2) SESD 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.

3.2 Validation Team

SESD field branches 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 field branches, 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.

3.3 Field Testing or Evaluation

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.

3.4 Assessment

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.

3.5 Acceptance/Rejection of Operating Procedure

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.

3.6 Records

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

1. Validation plan
2. Relevant literature
3. Draft and final operating procedures
4. Results of field tests/evaluations
5. Results of the assessment

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 Field Quality Manager.