

Region 4
U.S. Environmental Protection Agency
Science and Ecosystem Support Division
Athens, Georgia

OPERATING PROCEDURE


Title: Document Control

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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 Document Control Coordinator.

| History | Effective Date |
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| <p>SESDPROC-001-R3, <i>Document Control</i>, replaces SESDPROC-001-R2</p> <p>This revision reflects the following changes:</p> <p>History Corrected that SESDPROC-001-R2, Document Control, replaces SESDPROC-001-R1.</p> <p>General This revision incorporates the responsibilities of the Document Control Coordinator (DCC). Some of the duties that were previously carried on by the FQM have been tasked to the DCC. These changes are reflected in sections 1.3, 2.1, 2.5, 2.7, 2.8, and 3.</p> <p>Section 1.4 Added definition for document control coordinator.</p> <p>Section 2.8 Added the development of a document review schedule.</p> | <p>February 11, 2008</p> |
| <p>SESDPROC-001-R2, <i>Document Control</i>, replaces SESDPROC-001-R1</p> <p>This revision reflects the following changes:</p> <p>General Corrected any typographical, grammatical, and/or editorial errors.</p> <p>Updated referenced procedures to reflect most recent version.</p> <p>Title Page: Changed title for Antonio Quinones from Environmental Investigation Branch to Enforcement and Investigations Branch.</p> <p>Section 1.5 Alphabetized.</p> | <p>November 1, 2007</p> |

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| <p>SESDPROC-001-R1, <i>Document Control</i>, Replaces SESDPROC-001-R0</p> <p>This revision reflects the following changes:</p> <p>General Changed name from Field Quality System Document Control to Document Control. Deleted all references to the SOSA. Due to extensive revisions made by Laura Ackerman, author was changed to Laura Ackerman.</p> <p>Section 1.2 Deleted reference to Project File Management operating procedure in third paragraph. Project File Management operating procedure was retired.</p> <p>Section 1.4 Changed name from “Document Approval and Issue” to “Definitions” and incorporated original information into Sections 2.3 and 2.5. Added definition for subject matter expert.</p> <p>Section 1.5 Deleted references to SESD Operational Standard for Accreditation, SESD Operating Procedure for Project File Management, and SESD Document Control Task Request Form. Added reference to Document Review Form (SESDFORM-003, most recent version).</p> <p>Section 2.1 Deleted Table A and second sentence of first paragraph. Added second and third paragraphs.</p> <p>Section 2.3 Changed name from “Initial Review” to “Document Approval”. Added all current text. Moved previous text to current Section 2.4, Review.</p> <p>Section 2.4 Changed title from “Control” to “Review”. Current text was previously in Section 2.3. Updated reference at end of second sentence from Section 2.7 to Section 2.8. Moved all previous text to Section 2.5, Control.</p> <p>Section 2.5 Changed name from “Authorization” to “Control”. Incorporated information from former Section 2.4. Moved previous text to Section 2.6. Changed first</p> | <p>October 1, 2007</p> |

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| <p>paragraph to reflect that official copy of all Quality System documents resides on SESD LAN. Deleted “controlled number assignment” from first sentence in third paragraph. Reworded second sentence of third paragraph to reflect that FQM will ensure electronic copies on LAN and website are updated. Deleted third sentence of third paragraph.</p> <p>Section 2.6 Changed name from “Distribution” to “Authorization”. Incorporated information from former Section 2.5. Moved previous text to 2.7. Deleted Table B. Incorporated information from Table B into Steps 2 and 3. Added Step 1.</p> <p>Section 2.7 Changed name from “Periodic Review and Revision (Document Changes)” to “Distribution”. Incorporated information from former Section 2.6. Moved previous text to Section 2.8. First paragraph, deleted part of first sentence beginning at “...to all personnel...”and ending at end of sentence. Deleted second sentence. Added last two sentences. Reworded second paragraph to incorporate retired documents, to clarify how staff would be notified and to state that FQM will maintain a copy of the email notification. Deleted third paragraph.</p> <p>Section 2.8 Created this section. Incorporated information from previous Section 2.7. Deleted “(Document Changes)” from title. Changed review period from five to two years in second sentence. Deleted third and fourth sentences. Revised last sentence to be more specific about reviews and how FQM will track review status. Deleted second paragraph. Added numbered procedure.</p> <p>Section 3 Deleted last sentence of first paragraph. Added second paragraph.</p> | |
| <p>SESDPROC-001-R0, Field Quality System Document Control, Original Issue</p> | <p>February 05, 2007</p> |

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Contents

1 General Information

1.1 Purpose

The documents that form the SESD Field Branches Quality System (either internally generated or from external sources) are managed as controlled documents and information. This procedure describes the process for development, review, authorization, control, and distribution of controlled documents.

1.2 Scope/Application

SESD's field branches quality management documents include internally generated documents which provide information regarding how to conduct business and blank documents which provide a format for recording information. Quality management documents also include those of external origin used in the implementation of the quality system such as standards, regulations and manufacturers' manuals.

This procedure does not apply to materials obtained from other organizations during investigations. These items should be handled as project-related documents or evidence according to the SESD Operating Procedure for Sample and Evidence Management (SESDPROC-005).

1.3 Documentation/Verification

This procedure was prepared by persons deemed technically competent by SESD management, based on their knowledge, skills and abilities and has been tested in practice and reviewed in print by a subject matter expert. The official copy of this procedure resides on the H: drive of the SESD local area network. The Document Control Coordinator is responsible for ensuring the most recent version of the procedure is placed on the H: drive and for maintaining records of review conducted prior to its issuance.

1.4 Definitions

1.4.1 Document Control Coordinator

The Document Control Coordinator (DCC) is a quality management position appointed by management to maintain documents that form the SESD field branches quality system.

1.4.2 Subject Matter Expert

For the purposes of this procedure, subject matter experts (SMEs) are persons deemed competent, experienced, and knowledgeable by SESD management in the topic of the procedure, standard, guidance or other subject matter for which the document is intended.

1.5 References

Document Review Form, SESDFORM-003, Most Recent Version

SESD Operating Procedure for Sample and Evidence Management, SESDPROC-005, Most Recent Version

USEPA Region 4 Environmental Investigations Standard Operating Procedures and Quality Assurance Manual (EISOPQAM), November 2001

2 Internal Documents

2.1 Document Development

Internally issued SESD Field Quality System documents include standards, management plans, policies, manuals, operating procedures, test methods and guidance.

Once the need for a new document has been identified, management in consultation with the FQM assigns an author and designates reviewers. A subject matter expert is usually assigned as either the author or a reviewer. Once these assignments have been made, the FQM notifies the DCC via email and the Section Chiefs notify the author and reviewers either in person or via email. The DCC will provide the author with the document control number and a date for completion of the document.

The following steps are used to develop, review, authorize, control and distribute internal documents related to the SESD Field Quality System:

1. Author will prepare the first draft and submit it to the reviewers using the Document Review Form (SESDFORM-003).
2. Reviewers will provide comments to author.
3. Author will address comments and submit second draft to reviewers.
4. Reviewers will provide comments to author.
5. Steps 2-3 are repeated until all comments are addressed.
6. Once all comments have been addressed, the document will be submitted to the DCC for a format check and effective date assignment. The author will provide the Document Review Form to the DCC as a record of the reviews. The DCC will maintain a copy of the form.
7. The document will then be submitted to management and the FQM for final review and signatures.

2.2 Format

Flexible formatting is permitted for plans, manuals and methods, depending on the applicable program. All internally issued documents, regardless of format, must contain the following elements:

- Document number
- Effective date
- Revision number
- Page numbering indicating total number of pages
- Authorizing signatures
- Revision history

2.3 Document Approval

All documents generated by SESD, which form part of the field quality management system, will be reviewed and approved for use by the management within the field branches and the Field Quality Manager (FQM) prior to issuance.

2.4 Review

Document review is the process through which persons with subject matter knowledge contribute to the development of internal documents. Documents are periodically reviewed (see Section 2.8) and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements. Document review includes grammatical, editorial and technical assessment.

2.5 Control

The official copy of all SESD field branches Quality System documentation resides on the SESD LAN system at H:/Field Accreditation SOPs. All other electronic or printed copies are unofficial. Additionally, a copy of the field sampling and measurement procedures reside on the SESD internet. These copies are available to agencies and individuals outside of SESD who conduct environmental investigations and may be required to use these procedures by EPA Region 4. By allowing other agencies or individuals to follow SESD operating procedures, no inference is made that the work is covered under the scope of SESD's accreditation.

A master list identifying the current revision status of field quality system documents is available on the H: drive of the SESD LAN. The list is maintained by the DCC.

When internal documents have completed final review, they are forwarded to the DCC for a final format check, authorization and distribution, and placement in electronic form (read-only) on the SESD LAN system. The DCC will ensure that the all procedures on the SESD LAN and the public access location of the SESD web site are updated.

Document control numbers are assigned to SESD quality system documents using the following alpha-numeric scheme:

SESDDocument type-sequential #- revision #
Example: SESDSTND-001-R0

Document Types:

| | | |
|-----------------|------------------|-------------|
| GUID = guidance | PLCY = policy | PLAN = plan |
| MANL = manual | PROC = procedure | FORM = form |
| METH = method | STND = standard | |

2.6 Authorization

SESD quality system documents are subject to approval by the following authorities before issue:

1. Over-Arching Quality Documents: Division Director, Deputy Division Director, Branch Chiefs, Field Quality Manager, Author(s)
2. Multi-Branch Documents: Branch Chiefs, Field Quality Manager, Author(s)
3. Branch-Specific Documents: Branch Chief, Field Quality Manager, Author(s)

2.7 Distribution

The Document Control Coordinator is responsible for ensuring that all internally issued documents that form the SESD Field Quality System are readily available. The official copy of all field branches quality system documents resides on the H: drive of the SESD LAN. The DCC will notify all personnel within the field branches via email of document updates and will maintain a copy of the notification. It is the responsibility of the individual to ensure that all hard and/or electronic copies of documents in their possession are the most recent version.

When documents are revised or retired, the DCC will move obsolete copies to the “Archived and Retired Procedures” folder on the H: drive of the SESD LAN. The DCC will mark the documents with either an “ARCHIVED” or “RETIRED” watermark or the date of the action and the name of the procedure it was replaced with. Via email, the DCC will advise all affected personnel to dispose of electronic and hard copies of the superseded documents to preclude unintended use. The DCC will maintain a copy of the notification.

2.8 Periodic Review and Revision

Internal documents are subject to periodic review, and where necessary, revised to ensure continuing suitability and conformance with applicable requirements. Internal documents will be reviewed at least once every two years. In January of each year, the DCC will develop and maintain a document review schedule for the upcoming review period. The schedule will include the effective date of the most recent version of the document and the review date. The DCC will update the review schedule as additional reviews are conducted or new documents are developed. The following procedure will be followed:

1. The DCC will notify the author via email of the need for the review. The DCC will consult the FQM and management if there is a need to assign a new author based on staff changes.
2. The author will review the procedure to determine if updates are needed. If so, the author will notify the DCC via email and proceed to step 3 below. If no updates are needed, the author will notify the DCC via email. The DCC will maintain a copy of the email.
3. The DCC will consult with the FQM and management to assign reviewers and will notify the author of the reviewers using the Document Review Form (SESDFORM-003). The Section Chiefs will notify their staff when they are tasked to conduct reviews.
4. The author will update the procedure and provide the first draft to the reviewers.
5. The reviewers will provide comments to the author.
6. Steps 4-5 are repeated until all comments are addressed.
7. Once all comments have been addressed, the document will be submitted to the DCC for a format check and effective date assignment. The author will provide the Document Review Form to the DCC as a record of the reviews. The DCC will maintain a copy of the form.
8. The document will then be submitted to management and the FQM for final review and signatures.

Where practicable, changes to field quality system documents will be clearly indicated in the document, in an attachment, or in an update record. SESD's document control system does not allow for the temporary amendment of field quality system documents by hand.

3 External Documents

Documents of external origin referenced in the implementation of the SESD Field Quality System may include national and international standards, EPA manuals and directives, manufacturer's manuals, and other associated types of information.

These documents will be assigned document control numbers as described in Section 2.5 of this procedure. The DCC will maintain a list of all controlled external documents. The DCC will review the list each January and consult with personnel to determine if updates are available. If they are, the obsolete copy will be removed from service and the updated version will be labeled with the next revision of the document control number. On a case by case basis, the DCC in consultation with affected personnel will determine if it is necessary to maintain a copy of the previous version.