

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

Operating Procedure

Title: Document Control

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Purpose

This Operating Procedure is specific to the Region 4 Laboratory Services and Applied Science Division (LSASD) to maintain conformance to technical and quality system requirements. This procedure defines the process for identifying, storing, maintaining, and controlling Quality System documents that form the LSASD Quality Management System (QMS).

Scope/Application

The requirements of this procedure apply to all personnel who perform work under the LSASD QMS. This Standard Operating Procedure (SOP) applies to all technical and administrative SOPs, forms, and Quality System documents used in LSASD's QMS; however, this procedure does not apply to Records Management. Refer to the LSASD Operating Procedure for Control of Records (LSASDPROC-1001) for records requirements. While this Standard Operating Procedure (SOP) may be informative, it is not intended for and may not be directly applicable to operations in other organizations. Mention of trade names or commercial products in this operating procedure does not constitute endorsement or recommendation for use.

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1. Procedural Section

1.1. Development and Revisions to Quality System Documents

Newly developed documents and documents requiring revisions include, but are not limited to, management plans, policies, manuals, operating procedures (technical and administrative), forms and guidance. Once the need for a new document or a revision to a document has been identified, the Quality Assurance Coordinator (QAC), in consultation with the appropriate Section Supervisor or Branch Manager, assigns an author and designates a technical reviewer. Typically, the author or technical reviewer of the document is a subject matter expert (Field Branch and Quality Assurance Section) or primary analyst (Lab). Once an author has been assigned as the responsible person to a specific SOP/document, that responsibility stays with that individual unless the SOP has been reassigned. Forms and guidance documents follow the same revision process but do not require a technical review.

1.2. Document Review

1.2.1. Document Review Frequency

Quality System documents are subject to periodic review, and where necessary, are revised to ensure continuing suitability and conformance with applicable requirements. Divisional, Laboratory, Field, and Quality & Services SOP documents will be reviewed every 4 years, excluding technical procedures for drinking water methods, which must be reviewed annually. Forms and guidance documents are reviewed every five years for relevancy and revised as needed, due to a process change, new instrumentation, and/or errors, or to make them fillable electronically. This review process, when a revision is not made, is documented by updating the review date in the inventory spreadsheet controlled by the QAC.

1.2.2. The QAC will develop and maintain a document review schedule for all Quality System documents. The schedule will include the effective date of the most recent version of the document and the next review start date. The QAC will update the review schedule as additional reviews are conducted and as new documents are developed. Documents may be reviewed prior to the next scheduled review date if changes are deemed necessary. If an unscheduled review is completed, it will follow the regular LSASD review process as described below. LSASD's document control system does allow for the temporary amendment of quality system documents, on a limited basis, as detailed in Section 2 below.

1.2.3. The following procedure is used to develop, review, authorize, control, and distribute Quality System documents related to the LSASD QMS:

1.2.3.1. New Documents

Once an assignment has been made, the QAC, in consultation with the Section Supervisor or Branch Manager, will notify the document author. The QAC will provide the author with an appropriate document template, including the document's assigned Document Control Number, and the LSASD Document Review Form (LSASDFORM-1006). The Section Supervisor will identify a technical reviewer for completing the process. It is the Section Supervisor's responsibility to monitor the document development.

1.2.3.2. The author will prepare a first draft and submit it to a technical reviewer. The author will document the review on the appropriate LSASD Document Review Form (LSASDFORM-1006).

1.2.3.3. Existing Documents

The QAC or designee maintains an inventory file of all existing SOPs, Forms, and Guidance. The QAC or designee monitors the due dates of each SOP over the year and within 120 days of expiration, sends an email notification to the author of the SOP for its review. The QAC will provide the author with an editable Microsoft Word document from the last revision. The QAC will remove any markup and comments from the Word version prior to sending it to the author for revision. The redline strike out version will then be archived. The QAC will also include the LSASD Document Review Form (LSASDFORM-1006), with the increased revision number. It is the Section Supervisor's responsibility to monitor the document review by the due date. Section Supervisors and reviewers will be included in this notification, so the review team is aware of the assignment and associated deadlines.

Note: The 120-day review period includes the final administrative review and posting of the document to the LAN. Reviewers must be cognizant of these additional process steps when undertaking a review.

1.2.3.4. For existing documents, the assigned author will review and make edits to the document using the "Track Changes" feature in Microsoft Word so that the technical reviewer and QAC can verify edits and modifications to the document. The author will document the review on the appropriate LSASD Document Review Form (LSASDFORM-1006).

1.2.3.5. If it is necessary to extend the review time, the reviewer shall contact the Section Supervisor and the QAC via email specifying that an extension is needed and provide an alternative review due date. The new date cannot exceed 60 days past the original due date, unless approved by the Branch Manager.

1.2.3.6. If a new author is necessary, the QAC, in consultation with the Section Supervisor, will assign the review to a new author.

1.2.3.7. If procedural changes are not required, the author will notify the Section Supervisor, providing them with the appropriately filled out LSASD Document

Review Form (LSASDFORM-1006). The Section Supervisor will then provide all documentation to the QAC, who will revise the document review date and route the document for approval and authorization.

1.2.3.8. If procedural changes are needed, the author will update the procedure and provide the first draft to the technical reviewer(s), who have been selected by management in consultation with the QAC within 30 days of the assigned review. The reviewers will provide comments to the author within 30 days of receipt of the edited document. These steps are repeated until all comments are addressed. The entirety of the process, including management review and posting, should not exceed 120 days from the initial assignment date. The review process will be documented on the LSASD Document Review Form (LSASDFORM- 1006).

1.2.3.9. As part of the review process, the author shall update the revision history table to reflect the changes made to the document. As part of the technical review, the reviewer should verify that the Revision History table has been completed appropriately.

1.2.4. Administrative Review

Once the development and appropriate reviews are complete, the author or Section Supervisor or Branch Manager will submit the document to the QAC for an administrative review. The QAC will ensure that all documentation is filled out and updated (i.e., revision history, table of contents, Document Review Form, etc.) and that the document is in the proper format. Once the administrative review is complete the QAC will verify that the revision number on the document has been increased to the next revision and assign the effective date of the new revision as the date the document will be posted to the LAN. The document and the LSASD Document Review Form (LSASDFORM- 1006) will then be electronically routed to the author and appropriate management for final approval and authorization using electronic signatures. This review shall not exceed 10 days from the receipt of the final document.

1.2.5. The electronically signed document review form and approved SOP will be posted to the Local Area network (LAN) by the QAC. The previous version of the SOP, Form, or Guidance will be watermarked with “Archived” and moved to the appropriate archive folder on the LAN. An email notification will be sent to all appropriate staff and management notifying them of the new revision of a SOP, Form, or Guidance document each time one is posted.

1.3. Document Format and Requirements

1.3.1. All Quality System documents, regardless of format, must contain the following required elements: document control number, effective date, revision number, issuing authority, and revision history. The LSASD Operating Procedure for Preparation of Standard Operating Procedures (LSASDPROC-1014) provides the specific requirements for establishing a uniform procedure for developing, revising,

and approving procedures followed within LSASD. These procedures (i.e., SOPs) are intended to assist in ensuring compliance and consistency with analytical methods, field procedures, ISO/IEC 17025:2017 requirements, federal regulations, and EPA policies and procedures.

2. Interim Changes that Impact Data Quality

- 2.1. In the rare occurrence that significant changes to a document need to be made immediately, changes that if not made would call into question data quality, the following process shall be followed:
 - 2.1.1. LSASD staff that identified the need for a significant change, in consultation with the author of the procedure, will make an electronic change using electronic stamps to indicate the need for the change. The author will then initial and date the change(s) using electronic stamps and immediately provide the document to the appropriate Section Supervisor.
 - 2.1.2. The Section Supervisor will review the change and determine its acceptability. The Section Supervisor will then initial and date the change on the document using an electronic data stamp.
 - 2.1.3. The Section Supervisor is required to provide the edited document to every staff member that is affected by the change, explain the revision, and request an electronic initial and date from those staff members on the last page of the document, along with the electronic signature of the QAC.
 - 2.1.4. The QAC will edit the electronic document with a new effective date, update the revision number, and then upload the document to the appropriate LAN locations. The QAC will send an email notification to all Divisional staff members that they should begin using the new version of the document.
 - 2.1.5. Following the interim posting, the author must document and complete the interim changes on the LSASD Document Review Form (LSASDFORM- 1006), update the revision history, and send to the QAC for administrative review.
 - 2.1.6. For documents where an immediate change is needed and has been approved, the complete document review form must be finalized within 120 days of the effective date of the document. No extensions will be allowed in these instances.

3. Document Control

- 3.1. The official copies of all LSASD Quality System documentation reside on the LAN/SharePoint and are accessible to all staff. All other electronic or printed copies are unofficial. A watermark of “Uncontrolled When Printed” will be added to all LSASD SOPs.

- 3.2. For posting, each SOP and guidance document is converted to a .pdf file. Each SOP and guidance document is password protected to allow staff to review and print, but not edit the document. Forms that are saved as fillable files are not protected; however, access is controlled through the LAN and SharePoint and are the official version of the document.
- 3.3. In addition to the LAN and SharePoint, copies of select Quality System documents reside on the LSASD internet website. These copies are available to agencies and individuals outside of Region 4 who conduct environmental investigations and may be required to use these procedures. By allowing other agencies or individuals access to LSASD operating procedures, no inference is made that the work is covered under the scope of LSASD’s accreditation. Documents posted to the R4 Internet Website is done by the Program Services Section at the request of the QAC.
- 3.4. A master list identifying the current revision status of Quality System documents is available on the LSASD LAN or SharePoint. The list is maintained by the QAC or designee.
- 3.5. A unique control number is assigned to each LSASD management system document. using the following alpha-numeric scheme:

Organization Acronym (i.e., LSB, FSB, QSB) Document Type-Sequential #-Revision #
 Example: LSBPROC-001-R0

3.5.1. Document Types:

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

Table 1: Number Ranges for SOPs and Guidance Documents

Operating Procedure Category	Number Range
Field Services Branch Quality System (FSB)	001-099
Field Measurement (FSB)	100-199
General Field Sampling (FSB)	200-299
Hazardous Waste Section (FSB)	300-399
Laboratory Services Branch Quality System (LSB)	100-199
Water Quality Section (FSB)	500-599
Inorganic Chemistry Section (LSB)	600-699*

Field Services Branch Laboratory (FSB)	700-799
Organic Chemistry Section (LSB)	800-899*
Facilities (QSB)	900-999
Divisional Management System Documents (LSASD)	1000-1099
Quality Assurance Section (QSB)	1100-1199

Notes:

*Laboratory Technical Procedures will be assigned a document control number as listed above; however, the reference method ID number will also be utilized where applicable.

The original issuance of an LSASD document will be Revision 0. When a document is reviewed (including handwritten changes), the revision number of the document will increase one whole number (e.g. Revision 0 to Revision 1).

Equipment and software manuals maintained only for general reference purposes are not subject to document control requirements. In this context, "general reference purposes" means that personnel are not required to follow specific procedures or instructions contained in the equipment or software manuals.

Table 2: Series Numbers for Forms

Group	Department	Form Series
Inorganic Chemistry Section	Classicals	100
	Microbiologicals	200
	Metals	300
	Nutrients	400
	Algal	500
Organic Chemistry Section	Air	600
	Extractions	700
	Monitored Natural Attenuation	800
	PFAS/Pesticides	900
	Semi-Volatiles	1000
	Volatiles	1100
LSB	Branch Forms	1200
LSASD	Divisional Forms	1300
FSB	Branch Forms	1400
Water Quality	Section Forms	1600
Hazardous Waste	Section Forms	1800
QSB	Branch Forms	2000

4. Authorization and Approval

- 4.1. Authorization of documents generated by LSASD will be documented using the Document Review Form (LSASDFORM-1006). Depending upon the document, multiple reviewing officials might be needed. These officials range from technical experts to management representatives and will be assigned based on the document content. LSASD Documents are subject to authorization by the following issuing authorities:

Table 3: Approval Authority

Document Type	Issuing Authority
Divisional Documents	Deputy Division Director
Branch Documents	Branch Chief
Section Specific Documents	Branch Chief
Forms	Section Chief/QAC

5. Distribution

- 5.1. The QAC is responsible for ensuring that all internally issued documents that form the LSASD Quality System are readily available. The official copy of all Quality System documents resides on the LSASD LAN. The QAC will notify all personnel via email of document updates. It is the responsibility of the employee to ensure that all hard and/or electronic copies of documents in their possession are the most recent version.
- 5.2. When documents are revised or archived, the QAC will move obsolete copies to the restricted access “Archived” folder of the LSASD LAN. The QAC will add the “ARCHIVED” watermark to each document. In addition, “ARCHIVED” will be added to the file name for each archive document. Via email, the QAC will advise all affected personnel, including ESAT, based on the branch or divisional level, to discontinue use of the archived document (See Table 1 for Guidance).

6. External Documents

- 6.1. Documents of external origin referenced in the implementation of the LSASD management system may include national and international standards, EPA manuals and directives, manufacturer’s manuals, equipment software, and other associated types of information. External documents will be reviewed for context to determine their applicability before being added to the LAN, if appropriate. This review will be conducted by the author of the management system document in which the external document will be referenced. Copyrighted documents will not be scanned and posted to the LAN; only a hardcopy will be maintained in the appropriate lab.
- 6.2. When applicable, national and international standards, and EPA manuals and directives will be controlled by documenting the title, document number, most recent and/or approved revision/edition number, and year of publication. Equipment software is controlled in accordance with the LSASD Operating Procedure for Equipment Inventory and Management (LSASDPROC-1009). All other documents will be assigned document control numbers. The QAC will maintain a list of all controlled external documents. The QAC will review the list annually and consult with personnel to determine if updates are needed. If the QAC updates the list, each obsolete copy will be removed from service and the updated version will be labeled with the next revision of the document. On a case-by-case basis, the QAC, in consultation with affected

personnel, will determine if it is necessary to maintain a copy of the previous version.

7. Definitions

- 7.1. Document Control: The act of ensuring that documents are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly, and controlled to ensure use of the correct version.
- 7.2. Subject Matter Expert: For the purposes of this procedure, the subject matter experts (SMEs) are personnel deemed competent, experienced, and knowledgeable by LSASD management in the topic of the procedure, guidance or other subject matter for which the document is intended.
- 7.3. Author: The personnel that prepares the draft version of the document.
- 7.4. Reviewer: The personnel, assigned by management, responsible for reviewing the technical content of the document for accuracy.
- 7.5. Procedural Changes: Changes to the LSASD process described in the operating procedure. This does not include administrative changes such as revision number or date.
- 7.6. See the most recent version of the Laboratory Operations and Quality Assurance Manual for additional definitions.

References

LSASD Equipment Inventory and Management, LSASDPROC- 1009, Current Version

LSASD Document Review Form, LSASDFORM-1006, Current Version

LSASD Control of Records, LSASDPROC-100, Current Version

LSASD Preparation of Standard Operating Procedures, LSASDPROC-1014, Current Version

Revision History

History	Effective Date
SESDPROC-1000-R0, Field Quality System Document Control, Original Issue	October 1, 2017
<p>LSASDPROC-1000-R1, Document Control</p> <p>Revised to update Division and Branch nomenclature post-realignment. Removed references to the Document Control Coordinator and replaced with the Quality Assurance Coordinator. Also replaced references to the appropriate system manager with Quality Assurance Coordinator. Added milestones for the review process to Section 1.1.3. Modified language in Section 1.1.3 to allow for handwritten changes as detailed within Section 1.1.4.</p>	January 15, 2020
<p>LSASDPROC-1000-R2, Document Control</p> <p>Revised to update Division and Branch nomenclature post-reorganization in 2021. Removed references to the Quality Assurance Coordinator and replaced with the Quality Assurance Manager. Add Table 2, series control numbers for forms. Modified language throughout the document for clarification.</p>	September, 2021
<p>LSASDPROC-1000-R3, Document Control</p> <p>Updated throughout with electronic records guidance. Added number ranges for SOPs, Guidance Documents and Forms. Add procedural information for guidance documents and forms.</p>	January 5, 2024