

Region 4 U.S. Environmental Protection Agency Laboratory Services and Applied Science Division Athens, Georgia	
Operating Procedure	
Title: Document Control	ID: LSASDDPROC-1000-R1
Issuing Authority: LSASD Deputy Division Director	
Effective Date: January 15, 2020	Review Due Date: January 15, 2024

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 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 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 Procedure

1.1 Internal Documents

1.1.1 Development

Internally issued documents include, but are not limited to, management plans, policies, manuals, operating procedures, forms and guidance. Once the need for a new document has been identified, the Quality Assurance Coordinator, in consultation with the appropriate Section/Branch Chief assigns an author and designates a reviewer. A subject matter expert or primary analyst is usually assigned as either the author or reviewer of the document. Once these assignments have been made, the QAC, in consultation with the Section Chief, will notify the Document author and reviewer of the assignment. The QAC will provide the author with the appropriate document template, including the document's assigned Document Control Number, and the LSASD Document Review Form (LSASDFORM-1006). It is the Section Chief's responsibility to monitor the document development.

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

- Author will prepare the first draft and submit it to the reviewer(s). The "Track Changes" feature in Microsoft Word will be utilized so the reviewer(s) can verify the changes being made are correct and applicable to the procedure. The author will document the review on the appropriate LSASD Document Review Form (LSASDFORM-1006).
- Reviewers will provide comments to author
- Author will address comments
- Author will provide revised draft to reviewers, if applicable
- Steps are repeated until all comments are addressed
- Once the development and appropriate reviews are complete the author 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 assign the effective date

- 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
- The signed document will be scanned and posted to the Local Area network (LAN) by the QAC. The previous version of the document will be watermarked with an archive date 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.

1.1.2 Format

Depending on the application, flexible formatting is permitted for plans, manuals, procedures and forms, unless otherwise indicated. All internally issued documents, regardless of format, must contain the following required elements:

- Document number
- Effective date
- Revision number
- Page numbering indicating total number of pages
- Issuing Authority
- Revision history (if practicable)

For consistency of LSASD Operating Procedures a template will be provided by the QAC. As current LSASD Operating Procedures come up for review, they will be converted to the new document format. At the time of this issuance, no additional effort will be made to update the LSASD document format outside of the scheduled review process.

1.1.3 Review

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 every 4 years, excluding technical procedures for drinking water methods, which will be reviewed annually.

The QAC will develop and maintain a document review schedule for internal 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 by hand on a limited basis as detailed in Section 1.1.4 below.

The author and reviewer will document the review process on the LSASD Document Review Form (LSASDFORM-1006).

The following procedure will be followed for document review:

- Approximately 120 days prior to expiration of the document (4 Years from the effective date of a document), the QAC will provide the appropriate document author with the Microsoft Word version of the document and the review due date. Section Chiefs 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 LSASD LAN. Reviewers must be cognizant of these additional process steps when undertaking a review.

- If it is necessary to extend the review time, the reviewer shall contact the Section Chief and the QAC via email that an extension is needed providing an alternative review due date, not to exceed 60 days past original due date, unless approved by the Branch Chief.
- If a new author is necessary, the QAC in consultation with the Section Chief will assign a new author.
- The author will review the procedure to determine if updates are needed.
- If procedural changes are not required, the author will notify the Section Chief providing them with the appropriately filled out LSASD Document Review Form (LSASDFORM-1006). The Section Chief will then provide all documentation to the QAC who will revise the document information and route the document for approval and authorization, as described below.
- 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 60 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 this process should not exceed 120 days from the initial assignment date. The review process will be documented on the LSASD Document Review Form (LSASDFORM-1006)
- Procedural changes to documents will be tracked in the revision history of the document, except for forms, which will be indicated in the Form Revision History section of the LSASD Document Review Form

(LSASDFORM-1006).

- Before document submission to the QAC, the document author will ensure that the document is properly formatted, the revision history is updated, and the table of contents is correct.
- Once the development and appropriate reviews are complete the author will submit the document to the QAC for final format and quality system review. The QAC or designee will ensure that all documentation is completely filled out and updated (i.e., revision history, table of contents, Document Review Form, etc.) and that the document is in the proper format. This review shall not exceed 10 days from the receipt of the document.
- Once the QAC review is complete the QAC will assign the effective date.
- The document and the LSASD Document Review Form (LSASDFORM-1006) will then be routed by the QAC to the author, and appropriate management for final approval and authorization. The approval process should be completed within 7 days of routing the document. Final posting of the document to the LAN and notification to staff of the new revision will be completed within 3 days of the final approval.

1.1.4 Handwritten Changes

In the rare occurrence that significant changes, changes that if not made would call into question data quality, to a document need to be made immediately the following process shall be followed:

- LSASD staff that identified the need for a significant change will make a handwritten change to the document, initial and date the change and immediately provide the document to the appropriate Section Chief.
- The Section Chief will review the change and determine its acceptability. The Section Chief will then initial and date the change on the document.
- The Section Chief is required to provide a copy to every staff member that might be affected by the change, explain the revision, and obtain an initial and date from those staff on the back page of the document along with the signature of the QAC.
- The QAC will hand write a temporary effective date, in the margin, update the revision number and then upload the document to the appropriate LAN locations.

- At the time that the QAC assigns the temporary effective date the formal document review process will be initiated, starting the 120-day review timeframe, as described in Section 1.1.3.
- For documents where an immediate change is needed, the complete review process must be finalized within 120 days of the temporary effective date of the document. No extensions will be allowed in these instances.

1.1.5 Control

The official copy of all LSASD quality management system documentation resides on the Local Area Network (LAN) and are assessable to all staff. All other electronic or printed copies are unofficial. A watermark of “Uncontrolled When Printed” will be added to all LSASD procedures.

Additionally, copies of quality management system and technical procedure documents associated with field activities, 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.

A master list identifying the current revision status of quality system documents is available on the LSASD LAN. The list is maintained by the QAC. When internal documents have completed final review, they are forwarded to the QAC for a final format check, authorization and distribution, and placement on the LSASD LAN system. The QAC will ensure that all procedures on the LSASD LAN and the public access location of the LSASD web site are the current version.

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

LSASD Document type-sequential #- revision #
Example: LSASDSTND-001-R0

Document Types:

GUID = guidance
MANL = manual
METH = method

PLCY = policy
PROC = procedure
STND = standard

PLAN = plan
FORM = form

Number Ranges:

Operating Procedure Category	Number Range
Applied Science Branch Quality System	001-099
Field Measurement	100-199
General Field Sampling	200-299
Superfund Section	300-399
Laboratory Services Branch Quality System	100-199
Environmental Sampling Section	500-599
Inorganic Chemistry Section	600-699*
Applied Science Branch Laboratory	700-799
Organic Chemistry Section	800-899*
Facilities	900-999
Management System Documents	1000-1099
Quality Assurance Section	1100-1199
Environmental Management System	1200-1299

* 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 hand written changes), no matter if changes are made or not, 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.

1.1.6 Authorization and Approval

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:

Document Type	Issuing Authority
Divisional Documents	Deputy Division Director
Branch Documents	Branch Chief(s)
Section Specific Documents	Section Chief
Forms	Section Chiefs, QAC

1.1.7 Distribution

The QAC is responsible for ensuring that all internally issued documents that form the LSASD quality management 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 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 QAC will move obsolete copies to the restricted access folder “Archived and Retired Procedures” folder of the LSASD LAN. The QAC will add the “ARCHIVED” or “RETIRED” watermark, as appropriate, and the archived or retired date to each document. Via email, the QAC will advise all affected personnel to discontinue use of the archived or retired document.

1.2 External Documents

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.

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, LSASADPROC-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, the 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.

2 Definitions

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.

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.

Author: The personnel that prepares the draft version of the document.

Reviewer: The personnel, assigned by management, responsible for reviewing the technical content of the document for accuracy.

Procedural Changes: Changes to the LSASD process described in the operating procedure. This does not include changes administrative in nature such as revision number or dates.

3 References

LSASD Operating Procedure for Equipment Inventory and Management, LSASDPROC-1009, Current Version

LSASD Document Review Form, LSASDFORM-1006, Current Version

LSASD Operating Procedure for Records Management (LSASDPROC-1002), Current Version

4 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 LSASD Quality Assurance Coordinator.

History	Effective Date
SESDPROC-1000-R0, Field Quality System Document Control, Original Issue	October 1, 2017
LSASDPROC-1000-R1, Document Control 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.	January 15, 2020