Region 4 U.S. Environmental Protection Agency Laboratory Services & Applied Science Division Athens, Georgia	
Operating Procedure	
Title: Control of Records	ID: LSASDPROC-1001-R2
Issuing Authority: Deputy Director, LSASD	
Effective Date: June 6, 2020	Review Due Date: June 6, 2024

Purpose

This Operating Procedure is specific to the Region 4 Laboratory Services & Applied Science Division (LSASD) to maintain conformance to technical and quality system requirements. This procedure defines the process used to identify, collect, index, access, file, store, maintain, protect, back-up and dispose of quality and technical records.

Scope/Application

This procedure applies to all quality and technical records generated by LSASD. The requirements of this procedure apply to all personnel who perform work under the LSASD Quality Management System (QMS). It is the responsibility of LSASD auditors, field investigators, and laboratory analysts to create records sufficient to document their business activities, and not to destroy or remove records except in accordance with approved Agency records schedules. This procedure does not apply to records obtained from other organizations during field investigations involving environmental data collection. Those records should be handled as evidence according to the LSASD Operating Procedure for Sample and Evidence Management (LSASDPROC-005). This procedure also does not apply to document control, which is described in the LSASD Operating Procedure for Document Control (LSASD PROC-1000).

While this 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 General

The Federal Records Act of 1950, as amended, requires all federal agencies to make and preserve records containing adequate and proper documentation of their organization, function, policies, decisions, procedures and essential transactions. These records are public property and must be managed according to applicable laws and regulations. The Federal Records Act also requires agencies to establish a records management program, defined as a planned, coordinated set of policies, procedures and activities needed to manage its recorded information.

Based on the Federal Records Act, EPA established the Records Management Policy requiring each regional office to establish and maintain a records management program. Within EPA, Region 4, each organizational element is assigned record keeping responsibility in accordance with its functional responsibilities and duties. Therefore, LSASD has established records management procedures that comply with federal, agency and regional requirements.

LSASD manages technical records in accordance with the LSASD Records Management Standard Operating Procedures, ISO 17025 requirements and Drinking Water Certification requirements. The LSASD Records Management Standard Operating Procedures do not address quality system records. Therefore, quality system records are managed in accordance with ISO 17025 and Drinking Water Certification requirements. Both quality records and technical records are included within the scope of the LSASD definition of records and will be managed in accordance with this procedure.

1.2 Creating Records

Records must be created to adequately document activities for which auditors, field and laboratory investigators are responsible. Records shall:

- Be in ink and legible, if handwritten
- Clearly and permanently identify the person making the record
- Include the date of creation

When mistakes occur in records, each mistake will be corrected by drawing a line through the error, **initialing and dating** the lined-through entry, and entering the correct value alongside. Under no circumstances should the mistake be erased, made illegible or obscured so that it cannot be read. The reason for the correction shall be documented if it was not due to transcription error.

2 Quality System Records

2.1 Identification

Quality records are identified with a descriptive title that clearly labels the record.

2.2 Collection

The individuals who are responsible for collecting quality records are identified in the specific operating procedures. In general, it is the user of the records, or the Division Quality Assurance Coordinator (QAC).

2.3 Indexing

Each record is assigned a unique name, number or alphanumeric identification to distinguish it from other records. Multi-paged administrative records which are bound together in some manner may be identified by the test record identifier one time. Refer to the LSASD Operating Procedure for Document Control (LSASDPROC-1000) for naming conventions applied to LSASD-generated quality records.

2.4 Access, Filing and Maintenance

For a specified period as discussed below, quality records are stored either at the LSASD laboratory facility or at the Field Equipment Center (FEC) and are readily accessible to individuals requiring information contained in the records. Following is a list of quality records and the individual responsible for their maintenance:

Table 1 Record Maintenance

Record	Responsible Individual
Training Records	QAC
Purchasing Records	Branch Equipment Managers, QAC, and Quality Assurance Section Chief
Quality System Plans, Procedures, and Guidance Documents	QAC, Branch Chiefs
Internal Audits	QAC
Corrective Actions	QAC
Quality Improvements/Preventive Actions	QAC
Competency Evaluations/Proficiency Tests	QAC
External Proficiency Tests	QAC
Supply Verification Results	QAC, Laboratory and Field Equipment Managers
Management Reviews	QAC
Measurement Uncertainty	QAC
Testimony Evaluations	QAC, Branch and Section Chiefs
Nonconforming Work	QAC
Complaints	QAC, Branch and Section Chiefs

Equipment	QAC and Field Equipment Managers
Validation of Methods/Techniques	QAC
Balance Calibration	QAC
Calibration Weight Certifications	QAC
Air Displacement Pipets and Autodiluter Calibration	QAC
Thermometer Certification	QAC
EMS	EMS Coordinator
SHMS	Safety and Occupational Health Manager

In the event that a hard copy record is converted to electronic format, the responsible party will ensure that the electronic record is complete prior to the proper disposal of the hard copy.

Electronic quality records are stored on the LSASD local area network (LAN). The LAN is backed up to magnetic tapes Monday through Saturday evenings using a redundant network backup system. One backup is conducted remotely from the EPA Office of Research and Development computer center in Athens, Georgia and another locally from the LSASD computer center. After successful backups, the tapes located at LSASD are placed in a fire-proof media safe and a copy of the Friday evening backup is rotated to the Atlanta EPA office for offsite storage.

2.5 Retention

Quality records are kept according to EPA record schedule 018 with a 30-year retention. Employee training records are transferred to the Central Records Center after separation and are maintained under EPA record schedule 571 for 5 years after separation.

2.6 Disposition

Records are disposed when the retention time has been exceeded. Disposition may be to discard or destroy the records or to put them in long-term storage. The responsible individual, as identified in Table 1, is responsible for disposition of quality records.

2.7 Storage

After the retention time, if long-term storage is required, quality records will be placed in the LSASD Central Records Room in a dedicated location that will be determined by the LSASD Records Information Manager responsible for the Records Room.

3 Technical Records

3.1 Project File Management

Project files are the mechanism used to document, control and manage technical records created or obtained during drinking water certification, ISO audits, and technical systems audits, CLP data validation, field investigations, and laboratory analyses. Project files will be originated upon the delivery of technical records to the LSASD Central Records Room by a Project File Specialist, Section Chief or their designee. Project file origination dates are assigned and stored in the LSASD Central Records Room project file database, maintained by the LSASD Records Information Manager.

3.2 Identification

Each project file is filed by the R4LIMS Project Log project identification number.

3.3 Collection

In general, project files should contain the records required to support reported results, conclusions and interpretations such that in the absence of the project participants, other personnel, as assigned by LSASD management, could evaluate what had been performed and interpret the data. All LSASD-generated records within the project file will include the following:

- a unique project identifier (project identification number) on each page,
- page numbers indicating the total number of pages (page x of y),
- clear identification of the project leader or lead analyst and any other responsible individuals, as appropriate, and
- all dates relevant to the project.
- all equipment, identified by unique ID number, utilized in the collection or analysis
- operating parameters for equipment utilized where appropriate

In addition, all technical records will contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty of measurements and to enable the measurement to be repeated under conditions as close as possible to the original. Test results or observations that are rejected must be accompanied by a documented reason for the rejection.

Non-LSASD-generated records in project files (e.g., background information) will be labeled with the project identification number as appropriate such that if the records are separated from the project file, they could be easily associated with the correct file.

For Field Investigations, once the final report has been issued for a project, the project leader or lead analyst must compile all of the applicable information listed on the Project File Checklist (LSASDFORM-016), sign and date the form and forward it to their Section Chief. The Section Chief will review the Project File Checklist to ensure the information is complete and sign and date the checklist form. The Section Chief or their designee will then deliver the information to the Project File Specialist who will inventory the project, complete a project file inventory form and merge the project file contents with the contents from the Laboratory Services Branch project files for the same project number. The project file specialist will transfer the final project file to the records room.

Laboratory Services Branch project files are assembled once the final data report has been issued. The Section Chief, or designee will compile all the data packages to be included in the project file. The compilation will be submitted to the designated project file specialist. The project file specialist will include the general project information documentation (Chain of Custody forms, Work Orders, Sample Receipt records, etc.) received from the sample custodian upon completion of sample log-in. The project file specialist will complete a Project File Inventory Form listing each component of the file along with the number of pages associated with each component and a total number of pages for each project file. The project file specialist will affix the Project File Inventory Form to the file, combine the project file contents with any applicable field project files, and deliver the entire file to the Central Records Room for storage.

The Quality Assurance Section project files are assembled when assessed drinking water labs have completed all corrective actions and are given certification letters. The QAS project files are mostly electronic and can be found at K\QA\State Audit Findings. This directory contains pre-audit information, assessment reports, electronic corrective actions received from states, and certification letters. Hard copy project files contain assessor's checklists and any hard copy materials received from states as objective evidence. When states are given drinking water certification, the hard copy project file is transferred to the Central Records Room for storage under record retention policy 1016C. Project file contents are inventoried using QASFORM-1100 and is included in the hard copy project file and the appropriate LAN directory at K\QA\State Audit Findings.

3.4 Indexing

Each project file is color-coded. The Field Services Branch project files will be maintained in yellow expandable file folders; the Analytical Services Branch project files in blue folders Quality Assurance Section project files in red folders, and combined laboratory and field projects are stored in green folders. Each folder will contain two outside labels which will state the EPA series number, project name, project identification number, city and state. Criminal investigation project files will be shelved the same as other project files within the Division.

3.5 Access, Filing and Maintenance

LSASD maintains its project files in the Central Records Room, B102, at the LSASD laboratory. The Central Records Room is staffed by a contractor, who serves as the LSASD Records Information Manager). The contract is managed by the Regional Records Manager, US-EPA, Region 4, Atlanta, Georgia. The Central Records Room, which is a controlled access area that provides centralized storage, management, retrieval and final disposition for project files by utilizing:

- Non-office space storage;
- Readily retrievable in a secure area to help prevent damage, deterioration or loss;
- Centralized, computerized tracking and circulation; and
- Uniform scheduling, destruction and archiving according to the U.S. EPA National Records Management Program and the Federal Records Act (44 U.S.C. 31).

The Central Records Room contract personnel are available to assist in locating project files and to see that the files are signed out appropriately. In the event the LSASD Records Information Manager is unavailable, the Central Records Room is locked. In the event that the Central Records Room is unattended, LSASD Branch Chiefs have a key to the Central Records Room and may escort individuals into the room. In this instance, the LSASD Branch Chief is required to stay with individuals while they obtain technical records. A sign-out sheet is maintained on the desk in the Central Records Room to log-out records in the absence of contract personnel. There is no public access to the Central Records Room. Files are made available to the public through the Freedom of Information Act.

For field measurement data collected and stored exclusively as electronic records, the original, raw data will be backed up to another media such as a laptop computer, jump-drive or CD prior to demobilization from the study. The location of the backup will be noted in the field logbook. Upon return to the laboratory, the original, raw data will be copied onto a non-rewritable CD or other appropriate dedicated data storage device, which will then be included in the LSASD project file. At a minimum, the dedicated data storage device should be labeled with the data identification, the project name, the project identification number and the date. Laboratory measurement data follows the same procedure of storing the original, raw data to another media such as a laptop computer, jump-drive or CD. Upon the completion of a project, any duplicate raw data or backup files can be kept as a convenience copy, as appropriate.

3.6 Retention

Technical records are retained according to the EPA records schedule dictated by each program's requirements. The most current EPA records schedules are available on the EPA website.

3.7 Disposition

Project files will be disposed of according to EPA records schedules. EPA records schedules identify records as either temporary or permanent, and provide specific, mandatory instructions for the disposition of the records when they are no longer needed for Agency business. Disposition schedules for the records generated by LSASD can be found on the EPA website.

3.8 Storage

Due to the limited capacity of the Central Records Room, selected project files may be transferred to the Federal Records Center in Atlanta, Georgia. LSASD maintains custody of the files stored at the Federal Records Center and access is strictly controlled. No individual may access LSASD records at the Federal Records Center without authorization from the LSASD Records Information Manager or their designee.

3.9 Confidential Business Information

Only individuals who have completed confidential business information (CBI) training are allowed to receive CBI material while in the field. If CBI is received while in the field, it should be secured until its return to LSASD, then submitted to contract personnel in the LSASD Central Records Room for labeling and processing. Authorization for access to this material is obtained by acknowledging, in writing, awareness of the agreement and the penalties for willful disclosure of CBI.

It is Region 4 policy that CBI will not be permanently maintained in LSASD files. CBI material, however, may be retained by LSASD field investigators for the duration of the project, but must be secured according to procedures outlined in the Region 4 guidance document Handling Confidential Business Information, Most Recent Version. Following completion of the project, CBI material will be maintained by the Region 4 EPA program office requesting the investigation.

4 Definitions

4.1 Records (EPA)

EPA defines records as all books, papers, maps, photographs, machine-readable materials or other documentary materials, regardless of physical form or characteristic, made or received by an agency of the U.S. Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, function, policies, decisions, procedure, operation, or other activities of the Government or because of the informational value of the data in them (44 U.S. C 3101, Definition of Records).

4.2 Records (LSASD)

For the requirements of ISO 17025, LSASD defines a record as objective evidence of actions taken or observations made while implementing the LSASD Quality Management System. This includes both hard-copy and electronic records.

4.3 Quality Records

For the requirements of ISO 17025, LSASD defines quality records as those including, but not limited to the following: audit reports, CLP data validation records, management reviews, corrective action requests, preventive action requests, quality improvements, equipment records and personnel records (including testimony evaluations, training records, and competency evaluations and proficiency tests).

4.4 Technical Records

ISO 17025 defines technical records as original observations, logbooks, calculations, derived data, calibration records, copies of test reports, as well as any ancillary information needed to establish an audit trail.

4.5 Records Management

The planning, controlling, directing, organizing, training, promoting and other managerial activities involved with respect to records creation, records maintenance and use, and records disposition in order to achieve adequate and proper documentation of the policies and transactions of the Federal Government and effective and economical management of agency operations.

4.6 Project File

For the purposes of ISO 17025 compliance, official project files are maintained in the LSASD Central Records Room. Project files include a variety of documents and records that support LSASD audits, CLP data validation, field investigations, laboratory analyses and document reviews.

4.7 Records Schedules

Documents that provide continuous authority to dispose of recurring series or systems of records, or to transfer them to Regional Records Centers. (See LSASD Records Management Standard Operating Procedures, Most Recent Version)

5 References

Analytical Support Branch Laboratory Operations and Quality Assurance Manual, Most Recent Version

Environmental Management System (EMS) Manual, USEPA Region IV Science and Ecosystem Support Division (LSASD), Athens, GA, Most Recent Version

EPA National Security Information Handbook, Most Recent Version

EPA Records Management Manual, Most Recent Version, www.epa.gov/records/policy/www.epa.gov/records/policy/

EPA Records Management Policy, Most Recent Version, www.epa.gov/records/list-epa-records-schedules-final-status

EPA Region 4 Guidance on Handling Confidential Business Information, Most Recent Version, http://r4intra.epa.gov/msd/records/pol-guide-proc/documents/R4GuidanceDoccbi.pdf

Project File Checklist, LSASDFORM-016, Most Recent Version

Safety and Health Management System Manual, Science and Ecosystem Support Division (LSASD), Athens, GA, Most Recent Version

LSASD Operating Procedure for Document Control, LSASDPROC-1000, Most Recent Version

LSASD Operating Procedure for Field Measurement Uncertainty, LSASDPROC-014, Most Recent Version

LSASD Operating Procedure for Sample and Evidence Management, LSASDPROC-005, Most Recent Version

LSASD Records Management Standard Operating Procedures, Most Recent Version

6 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 Document Control Coordinator.

History	Effective Date
SESDPROC-1001-R0, Control of Records, Original Issue	October 1, 2017
SESDPROC-1001-R1, Control of Records replaces SESDPROC-1001-R0, Control of Records, Original Issue. Added paragraph describing the Quality Assurance Sections project file collection and filing, Section 3.3. Added language describing Project File Specialist that will be combining FSB and ASB records, as appropriate.	December 3 2018
LSASDPROC-1001-R2, Control of Records replaces SESDPROC-1001-R1, Control of Records Updated names of the Division and Branches post re-alignment. Removed references to System Manager, Quality Manager, Laboratory and Field Quality Manager and replaced with Division Quality Assurance Coordinator. Added language to include The Quality Assurance Section activities (drinking water certification and technical assistance audits and CLP data validation) throughout.	June 6, 2020